Bridging the gap between the distinct regulatory frameworks of international trade law and UN human rights law: Access to medicines

VOLUME I of II

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Abstract

This research is focused on the complexity of two distinct legal frameworks, the World Trade Organization and the United Nations human rights systems, which converge on the issue of enhancing effective access to medicines for all. This research explores the intellectual property rules specifically in relation to patents, set out in the Agreement on Trade-Related Aspects of Intellectual Property Rights, administered by the World Trade Organization, for the purpose of understanding how these legal norms impact upon securing access to medicines. Measures intended to enhance access to medicines within this framework will also be explored in order to evaluate their effectiveness.

This research also explores whether the issue of access to medicines can be considered within the context of a human right, through an examination of the UN human right systems, specifically in relation to the right to the highest attainable standard of physical and mental health under Article 12 of the International Covenant on Economic, Social and Cultural Rights. An analysis of the interpretation of this right will be undertaken, and an examination of the work of the UN human rights bodies to advance access to medicines will also be explored, in order to further understanding on the status of access to medicines within this framework.

The purpose of this research is to highlight factors which may impede access to medicines and also potential factors for consideration when proposing solutions to this global concern. In order to further understanding of specific issues that impact on patients, two country case studies are also undertaken, to examine whether key themes emanating from earlier chapters are evident, and to provide insights into the challenges experienced at national level, as well as good practices that could help to inform policy at international level, for the purpose of enhancing access to medicines for all.

DECLARATION

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

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STATEMENT 1

This thesis is the result of my own investigations, except where otherwise stated.

Other sources are acknowledged by footnotes giving explicit references. A bibliography is appended.

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Table of Abbreviations

APRODEH	Asociación Pro Derechos Humanos (Association for Human Rights)
ALAFARPE	Asociación Nacional de Laboratorios Farmacéuticos (National Association of Pharmaceutical Laboratories)
BERD	Business enterprise expenditure on research and development
CAFTA	Central American Free Trade Agreement
CAMR	Canada's Access to Medicines Regime
CEDAL	Centro de Asesoria Laboral del Peru (Center for Rights and Development)
CESCR	Committee on Economic, Social and Cultural Rights
CETA	Comprehensive Economic and Trade Agreement
CGPA	Canadian Generic Pharmaceutical Association
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
CPTPP	Comprehensive and Progressive Agreement for Trans-Pacific Partnership
DIGEMID	Dirección General de Medicamentos, Insumos y Drogas (Directorate General of Medicines, Supplies and Drugs)
DfID	Department for International Development
DSB	Dispute Settlement Body
EC	European Community
ECHR	European Convention on Human Rights
EU	European Union
FNHA	First Nations Health Authority
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICSID	International Centre for Settlement of Investment Disputes
IP	Intellectual Property
IPC	Intellectual Property Committee
IPR	Intellectual Property Rights
MeTA	Medicines Transparency Alliance
NAFTA	North American Free Trade Agreement
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Cooperation and Development

OHCHR	Office of the High Commissioner for Human Rights
pCPA	pan-Canadian Pharmaceutical Alliance
PCT	Patent Cooperation Treaty
PMPI	Patented Medicines Price Index
PMPRB	Patented Medicine Prices Review Board
PNCS	Plan Nacional de Salud Coordinado (Coordinated National Health Plan)
R&D	Research and development
SME	Small and Medium-sized Enterprise
TMB	Treaty Monitoring Bodies
TPP	Trans-Pacific Partnership
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration on Human Rights
UK	United Kingdom of Great Britain and Northern Ireland
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS Secretariat
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organisation
UPR	Universal Periodic Review
US	United States of America
USD	United States Dollars
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Chapter 1: Introduction

Securing effective access to medicines for all is a global public health concern. The World Health Organization estimates that nearly two billion people do not have access to basic medicines[1]. Two related considerations operate to limit sufficient access. First, the intellectual property rights protection, particularly in the form of patents, afforded to pharmaceutical companies. These rights can lead to a monopoly in the market, resulting in less competition and higher prices of medicines, putting them out of reach for many people. Secondly, the physical accessibility of medicines stemming from the lack of research and development of medicines to treat diseases that are prevalent in developing countries, or so-called 'neglected' diseases. Justifications for the monopoly rights are that pharmaceutical companies need to recoup the substantial research and development costs involved in creating new medicines, so patent protection acts as an incentive to investment and innovation in developing new medicines. However this creates an incentive to invest in research and development in commercially valuable medicines rather than medicines necessary to treat diseases predominantly in developing countries. These issues negatively impact on patients' access to medicines and create tensions with international human rights law, which protects the human right to the highest attainable standard of physical and mental health[2].

This issue is examined in the context of international trade and intellectual property (IP) law and United Nations (UN) human rights law. The growth of technology and emergence of new industries has increased the demand for intellectual property protection[3] and seen the incorporation of intellectual property law into the World Trade Organization framework through the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights[4] (TRIPS) as part of the Agreement Establishing the World Trade Organization[5] (WTO). This has had important consequences, changing

[1] World Health Organization, 'Ten Years in Public Health 2007-2017: Report by Dr Margaret Chan, Director-General, World Health Organization' (World Health Organization 2017), P.14, <https://www.who.int/publications/10-year-review/medicines/en/> (accessed 27/04/2020)

[2] See Article 12, International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) UNGA res 2200A (XXI). The link between access to medicines and the Article 12 right to the highest attainable standard of health is discussed in Chapter 3.

[3] L Helfer and G Austin, *Human Rights and Intellectual Property: Mapping the Global Interface,* (Cambridge University Press, Cambridge 2011), P.2

[4] Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) LT/UR/A-1C/IP/1 [hereinafter the TRIPS Agreement]

[5] Agreement Establishing the World Trade Organization (15 April 1994) LT/UR/A/2

the way in which IP rights are protected and enforced. As the first multilateral treaty on IP rights, TRIPS requires WTO Members to implement a minimum standard of IP rights protection into national law, which requires all WTO Members to implement patent laws which protect IP rights in pharmaceuticals. Tensions exist where the cost of medicines resulting from the monopoly rights afforded through IP rights becomes prohibitive, and this negatively impacts upon the health of patients who cannot afford the medicines they need.

The UN human rights system has also expanded in recent decades, with near-universal ratification of the International Covenant on Economic, Social and Cultural Rights[6] (ICESCR). This has led to increased recognition of economic and social rights including the right to health, as well as the work of the UN human rights bodies[7] on elaborating and clarifying the content of such rights and the obligations of states under international human rights law. Globalisation has contributed to the expansion of trade regulation into the area of IP and leading to intersections between trade and human rights that had not previously been contemplated.[8] Examples of these intersections include the impact of farming subsidies on the right to food, addressing environmental concerns such as pollution and sustainable energy, as well as public health concerns have received increasing attention in academic literature.[9] Despite the robust nature of the TRIPS rules

[6] International Covenant on Economic, Social and Cultural Rights (n 2); See also UN Office of the High Commissioner for Human Rights, 'Status of Ratifications' <http://indicators.ohchr.org/> (accessed 27/04/2020).

[7] The UN Human Rights law framework comprises UN Human Rights Charter-based Bodies and the relevant UN Human Rights Treaty Monitoring Bodies. The UN Human Rights Charter bodies include the Special Procedures mechanism and the Universal Periodic Review. The Special Procedures mechanism allows the Human Rights Council to address specific issues in a particular State or to address thematic issues globally, involving experts acting in a personal capacity as either an individual Special Rapporteur, or as a Working Group. The UPR is a State-driven process of review of the human rights records of all UN Member States. Under the UN Human Rights Treaty Monitoring system there are ten human rights treaty bodies that monitor implementation of the core international human rights treaties. The UN Human Rights Treaty Monitoring body relevant to this thesis is the Committee on Economic Social and Cultural Rights, which monitors the implementation of the ICESCR. See also United Nations Office of the High Commissioner for Human Rights, 'Human Rights Bodies' <http://www.ohchr.org/EN/HRBodies/Pages/HumanRightsBodies.aspx> (accessed 27/04/2020)

[8] T Cottier, J Pauwelyn and E Bürgi, 'Linking Trade Regulation and Human Rights in International Law: An Overview' in T Cottier, J Pauwelyn and E Bürgi (eds), *Human Rights and International Trade,* (Oxford University Press, Oxford, 2005), 2

[9] See examples: O De Schutter and KY Cordes (eds), *Accounting for Hunger: The Right to Food in the Era of Globalisation*, (Hart Publishing, Oregon 2011); Helfer and Austin (n 3); P Menell and S Tran (eds), *Intellectual Property, Innovation and the Environment,* (Edward Elgar 2014); W Benedek, K De Feyter and F Marrella (eds), *Economic Globalisation and Human Rights,* (Cambridge University Press, New York 2007); P Yu, 'Intellectual Property and Human Rights 2.0' (2019) 53(4) University of Richmond Law Review 1375

and the near-universal ratification of UN core instruments, there are still problems for states to adopt domestic patent rules which do not act as a barrier to access to medicines, while also appropriately protecting the interests of pharmaceutical manufacturers. This can have negative human rights consequences as a lack of access to medicines can raise issues in relation to states' international human rights obligations in relation to public health. This thesis explores the challenges raised by the applicability of the TRIPS and the UN human rights framework, as distinct legal systems, to the issue of access to medicines, as well as responses to these challenges.

a) Access to medicines against the backdrop of public international law

The issue of access to medicines is an example of the interaction between international intellectual property law, international trade law and international human rights law, in the context of patent protection for medicines and the right to health. Therefore it is pertinent for this issue to be considered against the backdrop of international law. International law does not have a central law-making body, with the main sources of international law being treaties, customary international law and general principles of law, as outlined in Article 38(1) Statute of the International Court of Justice (ICJ).[10] As international law is decentralised, specialised regimes have evolved, such as World Trade Law, Human Rights Law, Environmental Law, within the international legal order. These specialised regimes have developed independently of one another as each regime has its own distinct law-making process, which has facilitated the evolution of norms within the regimes[11]. The diversification of these regimes is highlighted by some regimes having developed adjudicative bodies which contribute to the development of the legal norms and the regulation of the regimes[12], such as the WTO dispute resolution mechanism. Despite the differing histories of the evolution of WTO trade law and UN human rights law, the TRIPS Agreement and the ICESCR are treaties that exist as part of a larger body of public international law. This is of relevance to this thesis as it presents the issue of

[10] Statute of the International Court of Justice, annexed to the Charter of the United Nations, 24 October 1945, 1 UNTS XVI [hereinafter ICJ Statute]

[11] T Cottier 'Trade and Human Rights: A Relationship to Discover' (2002) 5(1) JIEL 111, 119; PM Dupuy, 'The Danger of Fragmentation or Unification of the International Legal System and the International Court of Justice' (1999) 31 International Law and Politics 791, 791-2; M Koskenniemi and P Leino 'Fragmentation of International Law? Postmodern Anxieties' (2002) 15 LJIL 553, 557

[12] J Pauwelyn, *Conflict of Norms In Public International Law: How WTO Law Relates to other Rules of International Law* (Cambridge University Press, Cambridge 2003), 16

whether there is a tension between the World Trade and UN human rights regimes, when the obligations under these regimes intersect in relation to access to medicines.

International law scholars have paid increasing attention to the 'fragmentation' of international law[13], including the impact of the rules emanating from the specialised regimes in international law, given that they pursue diverse objectives and may develop differing interpretations of the law[14]. The issue of fragmentation was given prominence by the International Law Commission (ILC) report on the Fragmentation of International Law[15]. The ILC report highlighted that the growth in multilateral treaties in the last fifty years has made it increasingly probable that multiple rules of international law will apply in a particular circumstance[16], so determining the relationship between them is increasingly important, due to the complications which may arise where more than one international law rule applies to a particular situation. It is recognised that specialised regimes are not fully self-contained[17] and therefore there is scope for some overlap as the distinct regimes have expanded. This can lead to some fragmentation as the principles of general international law evolve. Further, that there being no hierarchy between these distinct laws presents the problem of conflicting jurisdictions and uncertainty over interpretation of international legal norms[18], with concerns that the specialised regimes could lead to the breaking up of the international legal order, affecting the unity of

[13] See examples PM Dupuy, 'The Danger of Fragmentation or Unification of the International Legal System and the International Court of Justice' (n 11); A Fischer-Lescano and G Teubner 'Regime Collisions: The Vain Search for Legal Unity in the Fragmentation of Global Law' (2004) 25 Michigan Journal of International Law 999; E Benvenisti and G Downs, 'The Empire's New Clothes: Political Economy and the Fragmentation of International Law' (2007) 60 Stan. L. Rev. 595; G Hafner 'Pros and Cons Ensuing from Fragmentation of International Law' (2004) 25 Mich. J. Int'l L. 849

[14] Pauwelyn (n 12*)* 12, 16; Koskenniemi and Leino (n 11); G Abi-Saab, 'Fragmentation or Unification: Some Concluding Remarks' (1999) 31 N.Y.U. J.Int'l L. & Pol. 919

[15] International Law Commission, 'Fragmentation of International Law: Difficulties arising from the diversification and expansion of international law', Report of the Study Group of the International Law Commission. Finalized by Martti Koskenniemi (13 April 2006) UN Doc A/CN.4/L.682

[16] ibid para 7

[17] See ILC Fragmentation Report (ibid) which refers to examples from WTO and Human rights as examples in support of this theme. See also Pauwelyn (n 12) 460; A Peters, 'The refinement of international law: From fragmentation to regime interaction and politicization' (2017) 15 (3) Int J Constitutional Law 671, 696; PM Dupuy 'A Doctrinal Debate in the Globalization Era: On the Fragmentation of International Law'(2007) 1 Eur. J. Legal Stud. 25, 26

[18] See I Brownlie 'The Rights of Peoples in Modern International Law' in Crawford J (ed), *The Rights of Peoples* (Clarendon Press Oxford 1988), 15; W Jenks, 'Conflict of Law-Making Treaties' (1953) 30 British Yearbook of International Law 401, 405; Abi-Saab (n 14) 926; Benvenisti and Downs (n 13); Peters (n 17); Dupuy (n 11) 792

international law[19], and ultimately undermining its legitimacy[20]. Positive aspects of fragmentation have also been debated in the literature, including that fragmentation creates more diversity in international law, and that the widening of the context of international law can lead to a more sophisticated body of law.[21] Other academics consider that fragmentation is beyond legal conflicts but about political differences, and fragmentation is inevitable because it is an expression of political diversity internationally.[22] Instead, the focus should be on finding compatibility between fragments[23]. These are compelling arguments as although sophisticated specialised regimes have developed and continue to evolve in international law, there has not been a collapse of the public international law system. Instead the depth and complexities of the evolving international legal order can be seen as a natural consequence of the expansion of the specialised regimes, and not unlike the specialisms in national law. With growing specialisations and advancement of experts in policy and law making within the specialised regimes, States may perceive that their individual position is better respected and therefore could be more likely to comply with the rules of the regime[24]. By placing the focus on finding coherence within the international legal order, and to ensure continued coherence among specialised regimes, work of the distinct specialised regimes which a specific situation may fall within should be understood and respected. This has been described as 'convergence' instead of fragmentation[25], to reflect how states and adjudicative bodies find ways to interact coherently. This is of particular relevance to this thesis. Although the focus of this research is not on fragmentation and convergence in international law, this thesis will address the challenges which arise when international trade law rules and UN human rights law converge in relation to access to medicines.

[19] G Guillaume, 'The Future of International Judicial Institutions'(1995) 44 Int'l & Comp. L.Q. 848, 862; Hafner (n 13) 854

[20] Peters (n 17); Abi-Saab (n 14); Benvenisti and Downs (n 13)

[21] R Higgins, 'A Babel of Judicial Voices? Ruminations from the Bench', (2006) 55 Int'l & Comp. L. Q. 791; B Simma, 'Universality of International Law from the Perspective of a Practitioner' (2009) 20 (2) Eur J Int Law 265; J Crawford, 'Chance, Order, Change: The Course of International Law, General Course on Public International Law', 365 (2013) Hague Academy Int'l L. 228, 394

[22] Koskenniemi and Leino (n 11); Fischer-Lescano and Teubner (n 13)

[23] Koskenniemi and Leino (n 11); Fischer-Lescano and Teubner (n 13)

[24] Hafner (n 13) 859

[25] P Webb, 'Factors influencing fragmentation and convergence in international courts' in M Andenas & E Bjorge (eds), *A Farewell to Fragmentation: Reassertion and Convergence in International Law* (Cambridge University Press, 2015), 146; Dupuy (n 17) 30-31 ; C Greenwood 'Unity and Diversity in International Law' in in M Andenas & E Bjorge (eds), *A Farewell to Fragmentation: Reassertion and Convergence in International Law* (Cambridge University Press, 2015)

This thesis will also address how states are to resolve situations where their obligations under international trade law rules come into conflict with their human rights obligations.

This thesis focuses on the relationship between the patent provisions in the TRIPS Agreement and the provisions of the ICESCR protecting access to medicines and will consider if a conflict exists between the respective treaties. In considering whether a conflict exists between international trade law and international human rights law, it is important to consider the question of what is a conflict. The ILC report recognised that conflict can be interpreted narrowly and broadly.[26] The narrow definition of conflict first articulated by Jenks is that a conflict only arises where a party to two treaties cannot comply with its obligations under both treaties simultaneously[27]. Under this definition it can be said that there is no conflict between TRIPS and the ICESCR as compliance with one of the treaties does not violate the other. There are flexibilities in TRIPS relating to the implementation of IP law which can be utilised for the protection of public health[28], so there is no direct incompatibility between them. However, Pauwelyn argues that this view ignores the complexities of the interactions between norms[29]. He gives a hypothetical example of a treaty between two states in which they grant each other permission to trade in slaves, highlighting that under Jenks' narrow definition of conflict, there would not be a conflict between this treaty and the *jus cogens* prohibition of slavery, as only if a treaty obliges trade in slaves would there be a conflict.[30] Instead, Pauwelyn outlines a broader definition, that a conflict will arise where one norm has led to, or may lead to the breach of another norm[31], equating a conflict with a breach of norm. Pauwelyn argues that an advantage of this approach is that "conflict becomes an 'objective' question, based on the rights and obligations set out in the norms in question, to be determined by normal rules on, for, example, treaty interpretation"[32], rather than the subjective intentions of the states involved[33].

[26] ILC Fragmentation Report (n 15) paras 21-26
[27] Jenks (n 18) 426. Pauwelyn discusses strict definitions of conflict in doctrinal writings, in Pauwelyn (n 12) 166
[28] For example Articles 7 and 8 of TRIPS as well as the Preamble which reflect the need to balance IP rights with public health objectives. This is discussed further in Chapter 2.
[29] Pauwelyn (n 12) 171
[30] ibid 174
[31] ibid 175-6
[32] ibid 176
[33] ibid

The ILC report also adopts a broad definition of conflict to include where two rules suggest different ways of dealing with a situation[34]. This position proposes that regimes cannot be truly isolated as completely autonomous regimes, and rather than a conflict, the interaction between international intellectual property law and international human rights law could be seen as a tension, where one treaty may encumber the objectives of another in relation to the issue of access to medicines. While it is noted above that there is no direct conflict between TRIPS and the ICESCR under the narrow definition of conflict, taking the broader definition of conflict there could be a tension between the treaties in terms of different approaches could be taken under both treaties to address access to medicines. This thesis adopts the broader definition of conflict. A key objective of this thesis is to explore how a potential conflict may be resolved in a manner that is consistent with States' obligations under the respective treaty regimes.

The ILC report has emphasised that the complexity of fragmentation has not undermined the coherence and systemic integrity of the international legal system, and considered how existing legal norms respond to conflicts between applicable norms[35]. The ILC report considered the *lex superior* rule, where a superior norm prevails over an inferior norm; *lex posterior*, where a later rule prevails over an earlier rule, and *lex specialis*, where a specialist norm prevails over a generalist norm[36]. However the ILC and academics have conceded that the principles are of limited utility in resolving conflict, as the *lex specialis* rule is not always helpful where the norms are within different specialised regimes[37] such as the WTO and UN human rights law frameworks, while it is difficult to argue that the norms within the respective frameworks are superior or inferior and the fragmented nature of international law means that the value of the *lex posterior* rule is reduced[38].

The ILC report also discusses particular norms that should be given effect in cases of conflict, despite the horizontal nature of international law and lack of a formal hierarchy of norms or treaties[39]. Specifically the report discusses Article 103 of the

[34] ILC Fragmentation Report (n 15) para 24
[35] ILC Fragmentation Report (n 15) Section C, P.30 and Section D, P.122
[36] ibid
[37] See ILC Fragmentation Report (n 15) para 488; HG Ruse-Khan, 'Conflict-of-laws approach to competing rationalities in international law: The case of plain packaging between intellectual property, trade, investment and health' (2013) 9(2) Journal of Private International Law 309, 320-321; R Harris and G Moon, 'GATT Article XX and human Rights: What Do We Know From the First 20 Years?' (2015) 15 Melbourne Journal of International Law, 14-15
[38] ILC Fragmentation Report (n 15) para 243; Ruse-Khan (n 37) 310; Pauwelyn (n 12) 97
[39] ILC Fragmentation Report (n 15) paras 324-327

United Nations Charter, the concepts of peremptory norms (*jus cogens*) and obligations *erga omnes*[40]. Although Article 103 UN Charter gives priority to obligations set out in the UN Charter, it does not give priority to human rights treaty obligations or non-binding resolutions of human rights bodies[41]. Despite criticism[42], it is accepted that *jus cogens* norms are peremptory norms which are accepted as such by the international community and cannot be derogated from[43], while obligations *erga omnes* are obligations owed by states to the international community as a whole[44]. Currently there is no evidence to suggest that the right to health or trade rules are universally recognised as *jus cogens* or obligations *erga omnes* within international law[45]. Therefore these rules also have limited utility in reconciling conflicts between international trade and international human rights law in relation to access to medicines, and will not be the focus of this thesis.

The limited applicability of the above principles led the ILC to conclude that harmonisation can be achieved between norms of specialised regimes through interpretative techniques, in light of the general principles of treaty interpretation set out in Article 31(3)(c) of the Vienna Convention on the Law of Treaties (VCLT).[46] Article 31(3)(c) states that any relevant rules of international law applicable in the relations between the parties shall be taken into account in the context of treaty interpretation.[47]. The report outlines that the VCLT provides the normative basis for dealing with fragmentation[48], as treaties are part of the international legal system and therefore should

[40] ibid para 327
[41] See H Charlesworth and C Chinkin 'The Gender of Jus Cogens' (1993) 15 Human Rights Quarterly 63, 63-64; P Weil, 'Towards Relative Normativity in International Law?' (1983) 77 American Journal of International Law 413; ILC Fragmentation Report (n 15) paras 331, 374-6.
[42] Weil (n 41)
[43] See B Simma and P Alston 'The Sources of Human Rights Law: Custom, Jus Cogens, and General Principles' (1988)12 Aust. YBIL 82; C Chinkin 'The Challenge of Soft Law: Development and Change in International Law' (1989) 38 Int'l & Comp. L.Q. 850, 856; J Pauwelyn 'The Role of Public International Law in the WTO: How Far Can We Go' (2001) 95 Am. J. Int'l L. 535, 537; R Higgins, *Problems and Process: International Law and How We Use It,* (Oxford University Press 1994), P.21, R Baker 'Customary international law in the 21st century: old challenges and new debates' (2010) 21(1) E.J.I.L. 173, 177
[44] See Baker (n 43) 177; H Thirlway 'Human rights in customary law: an attempt to define some of the issues' (2015) 28(3) L.J.I.L. 495, 499; A Cassimatis 'International Trade and Human Rights--Which Human Rights' (2001) 6 Int'l. Trade & Bus. L. Ann. 19, 48
[45] L Forman, 'An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Rights to Health in International Law' (2011) 14(2) JWIPO 155, 157; Cottier (n 11) 5(1) 114; Cassimatis (n 44) 46
[46] ILC Fragmentation Report (n 15) 410
[47] Vienna Convention on the Law of Treaties (23 May 1969) 1155 UNTS 331, entered into force 27 January 1980, Article 31
[48] ILC Fragmentation Report (n 15) 250

be interpreted in light of the general principles of international law[49]. The question of determining the most appropriate legal rule to be applied and to ensure greater coherence between the international regimes can be addressed through treaty interpretation, and therefore is a principal way of avoiding conflicts between treaties[50]. Of the various techniques discussed in the ILC report, this thesis will pay closest attention to Article 31 VCLT to determine whether a conflict between TRIPS and the ICESCR can be avoided by interpreting TRIPS in a manner conducive to promoting human rights, particularly the right to health and to enhance access to medicines.

b) International Trade and Human Rights Law

There is a considerable body of academic literature on the interaction of international trade and human rights law, including in relation to development, public health and environment[51]. This literature has explored the issue at a conceptual level, examining the legal foundations of the relationship between trade law and human rights law and has discussed the existence of a qualitative difference between trade and human rights norms[52], whether human rights are of a higher normative level than trade law[53] and therefore whether the regimes could interact successfully. The Preamble of the WTO agreement sets out the purposes of the WTO system being that trade should be conducted with a view to increasing standards of living, employment, expanding the production of and trade in goods and services, while stressing the importance of the objective of

[49] C McLachlan 'The Principle of Systemic Integration and Article 31(3)(c) of the Vienna Convention (2005) 54 International and Comparative Law Quarterly 279, 280

[50] ibid; Pauwelyn (n 12) 244; Peters (n 17) 693; Forman (n 45) 163

[51] Illustrative examples include T Cottier, J Pauwelyn, and E Bürgi (eds), *Human Rights and International Trade,* (Oxford University Press, Oxford 2005); F Abbott, C Breining-Kaufmann, T Cottier (eds),*International Trade and Human Rights: Foundations and Conceptual Issues,* (University of Michigan Press, Michigan, 2006); D Kinley, *Civilising Globalisation: Human Rights and the Global Economy*, (Cambridge University Press, Cambridge, 2009); EU Petersmann, 'The WTO Constitution and Human Rights' (2000) 3 JIEL 19; Benedek, De Feyter and Marrella (n 9); J Trachtman 'Legal Aspects of a Poverty Agenda at the WTO: Trade Law and 'Global Apartheid'' (2003) 6(1) JIEL 3; G Moon, 'Fair in form, but discriminatory in operation—WTO Law's discriminatory effects on human rights in developing countries' (2011) 14(3) JIEL 553

[52] D McRae, 'International Economic Law and Public International Law: The Past and The Future', (2014) 17 (3) Journal of International Economic Law 627, 633; Cottier (n 11); EU Petersmann, 'Human Rights and International Economic Law in the 21st Century—The Need to Clarify their Interrelationships' (2001) 4 (1) JIEL 3; C Breining-Kaufmann 'The Legal Matrix of Human Rights and Trade Law: State Obligations versus Private Rights and Obligations' in T Cottier, J Pauwelyn, and E Bürgi (eds), *Human Rights and International Trade,* (Oxford University Press, Oxford 2005); A Lang, 'Re-Thinking Trade and Human Rights' (2007) 15 Tul. J. Int'l & Comp. L.335

[53] United Nations Commission on Human Rights, 'The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights: Report of the High Commissioner' (27 June 2001) UN Doc. E/CN.4/Sub.2/2001/13, para 22

sustainable development, and of the integration of developing countries. The Preamble states that these objectives are to be achieved through the progressive reduction in barriers to trade and elimination of discrimination[54]. The objectives set out in the WTO Preamble are not contradictory to the obligations under the ICESCR outlined in Article 2, and Howse argues that the progressive fulfilment of economic and social rights can be achieved with the advancement of the goals stated in the WTO Preamble[55]. Article XX of the General Agreement on Tariffs and Trade (GATT) also provides that WTO Members may be exempted from trade rules where necessary for the protection of human health[56]. The lack of inherent conflict is also evidenced by the inclusion in WTO treaties of exceptions or limitations clauses which allow states to depart from trade rules for the realisation of fundamental norms, including the TRIPS agreement which includes exception clauses to be utilised for the benefit of public health[57]. The WTO Appellate Body in *EC - Asbestos*[58] suggested that WTO law must be interpreted and applied in light of the notion that the preservation of human life and health is a vital and important value[59], although it should be noted that the Appellate Body did not articulate this with reference to human rights context. However, academics have raised the question of whether more could be done to recognise the importance of the protection and promotion of human rights within the international trade system[60], with the interpretation of such provisions presenting challenges in consistent implementation of the rules to promote human rights[61]. This thesis will explore the challenges in interpreting the patent provisions in

[54] Agreement Establishing the World Trade Organization (n 5) Preamble

[55] R Howse and R Teitel 'Beyond the divide: the International Covenant on Economic, Social and Cultural Rights and the World Trade Organization' in S Joseph, D Kinley and J Waincymer (eds) *The World Trade Organization and Human Rights: Interdisciplinary Perspectives* (Edward Elgar, Cheltenham 2009), P.42-43

[56] General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT], Article XX

[57] Agreement on Trade-Related Aspects of Intellectual Property Rights (n 4) Articles 30 and 31. The Doha Declaration on TRIPS and Public Health also provides an authoritative legal interpretation of TRIPS, and is discussed below and in Chapter 2.

[58] European Communities – Measures Affecting Asbestos and Asbestos-Containing Products, WT/DS135/AB/R (5 April 2001), (EC – Asbestos)

[59] ibid 172

[60] Howse and Teitel (n 55); J Harrison, *The Human Rights Impact of the World Trade Organization* (Hart, Oxford 2007) P.36; J Harrison and A Goller, 'Trade and Human Rights: What Does Impact Assessment Have to Offer' (2008) 8 Hum Rts L Rev 587, 591; EU Petersmann, 'Human Rights and International Economic Law' (2012) 4 Trade L & Dev 283, 301; Lang (n 52); H Haugen, 'Human Rights and TRIPS Exclusion and Exception Provisions' (2008) 11 J World Intell Prop 345; EU Petersmann 'Human Rights and International Trade Law: Defining and Constructing the Two Fields' in T Cottier, J Pauwelyn and E Burgi, *Human Rights and International Trade* (Oxford University Press, Oxford 2005), 42

[61] C Kaufmann and L Meyer, 'Trade and Human Rights' (2007) 1 Hum Rts & Int'l Legal Discourse 61; P Cullet, 'Human Rights and Intellectual Property Protection in the TRIPS Era' (2007) 29 Hum Rts Q 403; W

TRIPS in the light of human rights, and the importance of taking full account of the right to health, including within the WTO legal order, to promote access to medicines. While not an inherent conflict, this thesis will explore interpretational challenges where the WTO and UN human rights regimes converge on the issue of access to medicines, and how such challenges could be resolved by giving full consideration of the right to health. The WTO is not a self-contained regime and has to take other international law into account, including human rights, although there are also limits to the WTO mandate in terms of the promotion and protection of human rights. This has been considered in academic literature which has discussed methodologies by which consistency between trade norms and human rights norms could be achieved.

Some academics have discussed the integration of human rights and WTO norms to resolve conflicts, most notably in the exchange between Petersmann and Alston[62], where Alston described Petersmann's theory of coordinating human rights and trade law under an international constitutional structure as hijacking international human rights law[63]. While these are important debates, this thesis focuses on reconciling tensions between treaties within the international human rights law regime and WTO law regime through treaty interpretation. Other academics have taken a more functional perspective, examining how human rights questions may be addressed in the WTO dispute settlement mechanism, with differing views as to how human rights norms can be brought in to the WTO mechanism. Pauwelyn proposed a rather expansive view that the jurisdiction of a WTO panel, and the applicable law before that panel, are distinct concepts[64]. While jurisdiction is limited to claims under the WTO covered agreements, the applicable law when assessing these claims comprises not only WTO law, but also the broader corpus of

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Benedek 'The World Trade Organization and Human Rights' in W Benedek, K de Feyter and F Marrella, *Economic Globalisation and Human Rights* (Cambridge University Press, New York 2010) 155; D Ovett, 'Making Trade Policies More Accountable and Human Rights-Consistent: A NGO Perspective of Using Human Rights Instruments in the case of Access to Medicines', in W Benedek, Koen De Feyter and F Marrella (eds), *Economic Globalisation and Human Rights* (Cambridge University Press, New York 2010)

[62] EU Petersmann, 'Time for a United Nations "Global Compact" for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration' (2002) 13(3) European Journal of International Law 621; P Alston, 'Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann' (2002) 13(4) European Journal of International Law 815; EU Petersmann, 'Taking Human Rights, Poverty and Empowerment of Individuals More Seriously: Rejoinder to Alston' (2002) 13 European Journal of International Law 845; R Howse 'Human Rights in the WTO: Whose Rights, What Humanity? Comment on Petersmann' (2002) 13 EJIL 651

[63] Alston (n 62) 816

[64] J Pauwelyn 'Human Rights in WTO Dispute Settlement' in T Cottier, J Pauwelyn, and E Bürgi (eds*) Human Rights and International Trade* (Oxford University Press, Oxford 2005) 215

public international law[65]. His main argument is that the WTO Dispute Settlement Understanding does not explicitly state that the applicable law is limited to WTO law[66]. This is a contentious point as it proposes that human rights norms could apply over WTO norms in dispute settlement within the WTO. Trachtman takes a narrower view, and does not accept that there is a distinction between the law on which a claim must be based, and the applicable law.[67] Other academics have also taken a more moderate view, outlining that trade and human rights law are separate principles, and that there is no normative foundation for the position that human rights law should outrank WTO law, but that they can be interpreted in the light of the general rules of treaty interpretation in Articles 31-32 VCLT[68]. This view is the most widely accepted and is convincing as it proposes that regimes cannot be truly isolated as completely autonomous regimes, and rather than a direct normative conflict, the interaction between international trade law and international human rights law could be seen as a tension, where one treaty may encumber the objectives of another. To mitigate the effects of the convergence of the distinct norms and avoid tensions between the state obligations in the respective treaties, this can be dealt with through treaty interpretation[69]. This view may also provide some assistance to States seeking to reconcile their obligations under the respective specialised regimes at national level. This speaks to an objective of this thesis which is to explore how might the potential conflicts be resolved in a manner that is consistent with States' obligations under the respective treaty regimes, in relation to the issue of access to medicines.

c) International Intellectual Property Law and Medicines

TRIPS requires all WTO Members to implement national laws which protect the IP rights of owners of IP. There has been some debate in the literature about the impact of IP law on medicines, specifically how patent law can impede access to medicines, particularly

[65] Pauwelyn (n 43) 577
[66] Pauwelyn (n 64) 215
[67] J Trachtman, 'Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law by Joost Pauwelyn, (Review)' (2004) 98 American Journal of International Law 855, 855-861
[68] See for example, Trachtman (n 67); G Marceau, 'WTO dispute settlement and human rights' (2002) 13(4) EJIL 753; L Bartels, 'Applicable Law in WTO Dispute Settlement Proceedings', (2001) 35 Journal of World Trade 499; A Cassimatis, *Human Rights Related Trade Measures Under International Law: The Legality of Trade Measures Imposed in Response to Violations of Human Rights Obligations under General International Law* (Brill/Nijhoff 2007)
[69] Marceau (n 68); Bartels (n 68)

in developing States[70]. The key issue discussed in this literature is how patent protection protects innovation, giving the owner an incentive and reward in the form of a monopoly right, leading to less competition in the market and therefore higher pricing of medicines, putting them out of reach for poorer patients[71]. A related concern is that patents create an incentive to innovate in commercially valuable medicines, leading to lack of physical accessibility to medicines for 'neglected' diseases[72]. There has also been some debate in the literature about how prohibitive costs of medicines might be addressed through competition law principles, including by addressing anti-competitive practices such as patent tying arrangements and pay-for-delay agreements between branded pharmaceutical companies and generic competitors[73]. While competition law undoubtedly is an important tool to combat anti-competitive pricing, this thesis focuses on how these challenges might be addressed in a human rights context, given the absence of a global competition law framework. Threats of sanctions for anti-competitive pricing may not be most effective for developing States as not all states have a national competition law framework[74]. There is a difference between a developed state imposing

[70] Examples include F Abbott, 'The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference' (2002) 5 J. World Intell. Prop. 15, 15-16; B Mercurio 'TRIPs, Patents, and Access To Life-Saving Drugs In The Developing World' (2004) 8 Intellectual Property L. Rev. 211, 211; F Abbott and J Reichman, 'The Doha Round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions' (2007) 10(4) JIEL 921, 928

[71] C Correa 'Public Health and Patent Legislation in Developing Countries' (2001) 3 Tul. J. Tech. & Intell. Prop. 1, 3; Forman (n 45) 156; Cullet (n 61) 416

[72] D Matthews 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) 7(1) JIEL 73, 74; A Chapman 'The Human Rights implications of Intellectual Property Protection' (2002) 5(4) JIEL 861, 877-878; H Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press Oxford 2007), 162. Neglected diseases are defined as 'Diseases for which there is a lack of sufficient medical innovation, resulting in inadequate, ineffective or non-existent means to prevent, diagnose and treat them. The lack of sufficient medical innovation is often rooted in an absence of market incentives owing to the low purchasing power of the populations disproportionately affected by such conditions' in United Nations Secretary-General's High-Level Panel on Access to Medicines, *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies*, September 2016, <http://www.unsgaccessmeds.org/final-report> (accessed 27/04/2020), P.5

[73] F Abbott 'The 'Rule of Reason' and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS' in T Cottier, J Pauwelyn, and E Bürgi (eds), *Human Rights and International Trade,* (Oxford University Press, Oxford 2005); S Musungu 'The Right to Health, Intellectual property and Competition Principles' in T Cottier, J Pauwelyn, and E Bürgi (eds), *Human Rights and International Trade,* (Oxford University Press, Oxford 2005); G Pitruzzella and L Arnaudo 'On vaccines, pharmaceutical markets, and a role for competition law in protecting (also) human rights' (2017) 38(8) E.C.L.R. 347; O Gurgula 'Anti-competitive patent acquisitions in the pharmaceutical industry' (2017) 38(1) E.C.L.R. 35

[74] R Anderson and H Wager 'Human Rights, Development, and the WTO: The Cases of Intellectual Property and Competition Policy (2006) 9 (3) J Int Economic Law 707, 734

a sanction, and a developing state imposing a sanction, on the basis that the sanctioned company must retain access to the developed country market but could relinquish access to the smaller developing country market.[75] Developing states often have a smaller number of competitors and therefore may be more vulnerable to anti-competitive practices[76]. Additionally, competition law may not be the most effective tool in addressing the challenge of incentivising innovation in neglected diseases[77], which is a key challenge in the access to medicines debate in terms of securing physical accessibility to medicines, in addition to economic accessibility in terms of affordable pricing. Addressing the challenge of enhancing access to medicines in a rights-based context means that the challenges can be addressed in the context of States' obligations to promote and protect the rights of individuals, regardless of the level of development of the State. Competition law will only go so far, in terms of its applicability to state actors. Given the absence of a universal competition law framework and the universal nature of human rights, this thesis will explore how states can effectively meet their obligations to secure effective access to medicines for patients in a human rights context.

There has also been some discussion in the literature of IP law and access to medicines in a rights-based context, particularly in relation to whether the patent provisions in TRIPS are in conflict with the realisation of economic and social rights or whether they are essentially compatible[78]. Specific focus has been on the rights within the ICESCR, and in particular the right of everyone to the enjoyment of the highest attainable standard of physical and mental health set out in Article 12. The debate on normative conflicts in international law[79] can facilitate a greater understanding of the interaction between TRIPS and the ICESCR, with the recognition that the obligations under TRIPS have to be interpreted in light of all other international law. As discussed above, Article 31(3)(c) VCLT has been significant in the discussion on the fragmentation of international law, forming the basis for arguments promoting harmonisation between

[75] U Aydin and T Buthe 'Competition Law and Policy in Developing Countries: Explaining Variations in Outcomes; Exploring Possibilities and Limits' (2016) 79 Law and Contemporary Problems 1, 24
[76] Abbott (n 73) 290
[77] D Matthews and O Gurgula 'Patent Strategies and Competition Law in the Pharmaceutical Sector: Implications for Access to Medicines' (2016) 38(11) E.I.P.R. 661, 666
[78] UN Sub-Commission on Human Rights Resolution 2000/7, 'Intellectual Property Rights and Human Rights' (17 August 2000) UN Doc. E/CN.4/Sub.2/Res/2000/7, Preamble; Hestermeyer (n 72) 169; L Helfer 'Human Rights and Intellectual Property: Conflict or Coexistence?' (2003) 5 Minn. Intell. Prop. Rev. 47, 54
[79] See discussion on fragmentation above.

specialised regimes.[80] Marceau, for example, argues that "a good faith interpretation of the relevant WTO and human rights provisions should lead to a reading of WTO law coherent with human rights law"[81], so that an interpretation of TRIPS consistent with international law will resolve tensions with UN human rights law under the ICESCR in relation to access to medicines. This principle has been applied by the WTO to treaty regimes other than UN human rights law, as the WTO Appellate Body referred to sources of environmental law from other international legal regimes in *US-Shrimp Turtle*[82] to assist its interpretation of terms in Article XX of GATT[83]. The WTO Appellate Body also confirmed in *US-Gasoline*[84] that WTO law should be interpreted according to customary rules of treaty interpretation being Article 31 and 32 VCLT[85]. Given that there is a presumption against conflict in international law[86], and that resolving normative conflicts can be achieved through interpretation[87], a key question is whether the patent law provisions under TRIPS can be interpreted so as to enhance access to medicines. The present thesis will consider whether potential tensions between TRIPS and the ICESCR can be resolved through interpretation of TRIPS in light of the right to health set out in Article 12 of the ICESCR, for the purpose of enhancing access to medicines.

States parties have obligations under TRIPS and the ICESCR respectively, which include interpreting and implementing their respective obligations at national level in order to comply with their international commitments. This poses the question of how States can resolve situations in which measures to protect intellectual property rights in medicines could conflict with obligations to protect human rights, specifically in relation to health, and how those situations can be resolved in a manner consistent with States parties obligations under TRIPS and the ICESCR. This research aims to fill gaps in the

[80] McLachlan (n 49); J Crawford, *Brownlie's Principles of Public International Law,* 8th ed (Oxford University Press, Oxford 2012)
[81] Marceau (n 68) 755
[82] *United States - Import Prohibition of certain Shrimp and Shrimp Products,* WT/DS58/AB/R, adopted 12 October 1998, 129-130
[83] General Agreement on Tariffs and Trade (n 56)
[84] *United States – Standard for Reformulated and Conventional Gasoline (US – Gasoline*), adopted 20 May 1996, WT/DS2/AB/R
[85] ibid 17. Article 3.2 of the Dispute Settlement Understanding requires interpretation "in accordance with customary rules of interpretation of public international law". See Art 3(2) Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 to Marrakesh Agreement establishing the World Trade Organization ("DSU'), in World Trade Organization, *The Legal Texts: the Results of the Uruguay Round of Multilateral Trade Negotiations* (Cambridge University Press, Cambridge 1999) 354, 355
[86] ILC Fragmentation Report (n 15) para 37
[87] ibid para 43

literature on how States might reconcile these competing obligations at national level, by exploring how States could implement their international commitments under TRIPS in light of wider societal interests such as public health and access to medicines, and how measures taken by States at national level may, or may not, address or resolve tensions. This thesis will address these questions by undertaking two country case studies, to explore how the issue of enhancing access to medicines can be addressed at national as well as international level. The case studies will be valuable in terms of offering insights into whether States appreciate the interaction between IP and human rights in relation to access to medicines at national level, and their ability to address possible tensions in order to meet their obligations simultaneously under TRIPS and ICESCR. The outcomes of the studies could also offer examples of good practice to other states on effectively meeting their obligations under the respective treaties so that the treaties can be implemented coherently at national level to enhance access to medicines globally. The studies will also explore how State practice at national level might inform understanding of key issues on reconciling obligations under TRIPS and the ICESCR and promoting access to medicines at international level.

Scope and objectives

a) Sources of Law

In exploring how TRIPS might be interpreted consistently with the right to health under the ICESCR, it is necessary to understand the content of the state obligations under the treaties. Therefore, it is important to consider the sources of law that will assist in interpreting the treaties. Article 38(1)(a)-(c) of the ICJ Statute provides that treaties, customary international law and general principles of international law are formal sources of international law. TRIPS, as an annex to the Agreement Establishing the World Trade Organization[88], which is the main source of WTO law, and the ICESCR, a core UN treaty on social and economic rights which contains the right to health, are treaties under Article 38(1)(a). These are the relevant treaties considered for the purpose of this research. The treaties are binding on all states which are parties to that treaty. Customary international law is binding on all states, and a norm will become a rule of customary international law

[88] Agreement Establishing the World Trade Organization (n 5)

if it reflects state practice and is accepted as law[89]. There is no hierarchy between these sources, except for *jus cogens* norms which have superior status[90]. Article 38(1)(d) ICJ Statute states that the Court can apply judicial decisions and doctrine as subsidiary means for the determination of rules of law, and the sources under Article 38(1)(d) can be used to understand the sources under Article 38(1)(a)-(c).

Reports of the WTO panels and the Appellate Body are also considered, as although they only bind the parties to the dispute, they have value in interpreting and clarifying WTO law[91]. The Doha Declaration on the TRIPS Agreement and Public Health[92] is also a non-binding WTO instrument but its significance is evident from the fact that the requisite number of WTO Members have agreed to amend TRIPS as a result of paragraph 6 of the Doha Declaration.[93] The amendment waives the requirement under Article 31(f) that production under a compulsory licence had to be predominantly for the domestic market, which limited states from importing cheaper generic medicines from states where medicines were patented[94]. The purpose of the waiver is to make it easier for states to import generic medicines, and the waiver took effect on 23 January 2017[95], so paragraph 6 of the Doha Declaration can now be said to have binding force. The WTO Panel in the *Plain Packaging*[96] case considered that the Doha Declaration amounted to a subsequent agreement of WTO Members within the meaning of Article 31(3)(a) VCLT.[97] The Panel stated that it confirms the manner in which each provision of TRIPS must be interpreted[98], underlining the importance of the Doha Declaration on the interpretation of the provisions within TRIPS, and also its significance to this research.

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[89] Higgins (n 43)
[90] Weil (n 41) 421
[91] Pauwelyn (n 12) 110
[92] Declaration on the TRIPS Agreement and Public Health (14 November 2001) WT/MIN(01)/DEC/2. (Herein referred to as the Doha Declaration)
[93] World Trade Organization, '2017 news items: WTO IP rules amended to ease poor countries' access to affordable medicines' 23 January 2017, <https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm> (accessed 27/04/2020)
[94] World Trade Organization 'Decision removes final patent obstacle to cheap drug imports' <https://www.wto.org/english/news_e/pres03_e/pr350_e.htm> (accessed 27/04/2020)
[95] World Trade Organization 'Amendment of the TRIPS Agreement' <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> (accessed 27/04/2020)
[96] *Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging* (28 June 2018) WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R
[97] ibid paras 7.2409-7.2410
[98] ibid

The UN, with near universal membership provides a clear central point for state practice[99], providing a good reason to look to UN practice for the direction of development of human rights in international law. Achieving access to affordable essential medicines for all is also one of the Sustainable Development Goals agreement by the Member States of the UN, highlighting the significance of the issue, and the commitments by states to address this.[100] The UN Charter[101] and Treaty Monitoring bodies[102] provide guidance to states on their obligations to protect human rights. The reports of the UN human rights bodies provide an authoritative interpretation of the content of the rights and the obligations they impose on States[103] and therefore provide valuable interpretative insights. Specifically the reports of UN human rights bodies in relation to the right to the highest attainable standard of health under Article 12 ICESCR, and the relationship between TRIPS and human rights in relation to access to medicines will be considered. The Committee on Economic, Social and Cultural Rights (CESCR), the treaty monitoring body of the ICESCR has issued General Comments providing guidance on the normative content of the ICESCR. The General Comments are non-binding but they are important for the setting of standards that States should meet in order to comply with their obligations under Article 12. For example, Chinkin notes that the ICJ has stated that the opinion of the Human Rights Committee, the treaty monitoring body of the International Covenant on Civil and Political Rights (ICCPR), should be given 'great weight', because it is an independent body established under a binding treaty with a specific remit as to its interpretation[104]. Similar considerations would apply in respect of the CESCR by the same reasoning of the Court. Further, the work of the treaty bodies and the responses of the States Party to it, generate subsequent practice within the

[99] Higgins (n 43) 23

[100] United Nations, 'Sustainable Development Goals', Goal 3.8 <https://sustainabledevelopment.un.org/?menu=1300> (accessed 27/04/2020)

[101] The UN Human Rights Charter system stems from the UN Charter and applies to all UN Member States. This is discussed further in Chapter 3. See also United Nations Office of the High Commissioner for Human Rights, 'Human Rights Bodies' (n 7)

[102] States have an obligation to report to the relevant Treaty Monitoring Body established under the UN human rights treaty to which the State is a party. This is discussed further in Chapter 3. See also United Nations Office of the High Commissioner for Human Rights, 'Human Rights Bodies' (n 7)

[103] L Sohn, 'The Human Rights Law of the Charter' (1977) 12 Tex Int'l L J 129, 135; R Lillich, 'The Growing Importance of Customary International Human Rights Law' (1995) 25 Ga J Int'l & Comp L 1, 19

[104] Chinkin refers to the case of *Ahmadou Sadio Diallo (Republic of Guinea v Democratic Republic of the Congo) [2010] ICJ Rep para 66,* in C Chinkin, 'Sources' in D Moeckli, S Shah, S Sivakumaran, *International Human Rights Law,* (Oxford University Press, Oxford 2014), 90

meaning of Article 31(3)(b) VCLT[105]. It demonstrates the significance of the work of these in terms of the interpretation of States' human rights obligations.

In addition to the UN Human Rights Treaty system, the UN Charter-based system[106] undertakes Universal Periodic Review of all UN Member States.[107] This applies regardless of whether they have ratified a UN human rights treaty and provides an important measure of accountability. Contributions to the UPR process also present examples of state practice[108], which must be taken into account under Article 31(3)(b) if it establishes the agreement of the parties regarding the interpretation of specific human rights[109]. Even if the state practice does not establish agreement under Article 31(3)(b), the state practice will still be relevant under Article 32 as a supplementary means of interpretation[110]. The reports of the Special Rapporteur on the right to the highest attainable standard of physical and mental health[111], who has a mandate to monitor the situation of the right to health globally and engage in discourse with States on alleged violations of the right[112] will also be considered. The Special Rapporteur is an

[105] K Mechlem 'Treaty Bodies and the Interpretation of Human Rights' (2009) 42 Vanderbilt Journal of Transitional Law 905, 919-920

[106] For a description of each of the UN human rights systems, see I Banktekas and L Oette, *International Human Rights Law and Practice*, 2nd ed, (Cambridge University Press 2016), Chapters 4 and 5.

[107] The documents on which the review is based are: the National Report, the Compilation of UN Information and the Summary of Stakeholders Information. The review involves interactive discussions between the State under review and other UN Member States in a Working Group of the UN Human Rights Council. Non-member States may also participate. States can make recommendations to the State under review. These recommendations can be accepted or rejected by the State under review. The Report of the Working Group on the Universal Periodic Review for the State concerned is then adopted at a plenary session of the Human Rights Council, during which the State under review can respond to recommendations or questions, and Member States and other stakeholders can make comments. The Universal Periodic Review is discussed further in Chapter 2. See also Office of the High Commissioner for Human rights, United Nations Human Rights Council, 'Basic facts about the UPR' <http://www.ohchr.org/EN/HRBodies/UPR/Pages/BasicFacts.aspx> (accessed 27/04/2020)

[108] Higgins (n 43) 18

[109] A Davies 'Investment Treaty Interpretation, Fair and Equitable Treatment and Legitimate Expectations' (2018) 15(3) MJIEL 314, 343-344

[110] ibid 344

[111] This is part of Special Procedures, for a description of this system, see Banktekas and Oette (n 106) 170. This system has traditionally been seen as the jewel in the crown of UN human rights mechanisms. See S Subedi, 'Protection of Human Rights through the Mechanism of UN Special Rapporteurs' (2011) 33 Hum Rts Q 201, 203; A Gallagher and J Ngozi Ezeilo, 'The UN Special Rapporteur on Trafficking: A Turbulent Decade in Review' (2015) 37 Hum Rts Q 913, 918; T Piccone, 'Human Rights Special Procedures: Determinants of Influence' (2014) 108 Am Soc'y Int'l L Proc 288, 288

[112] UNCESCR 'General Comment No. 14 (2000): The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights) 11 August 2000 UN Doc E/C.12/2000/4; UNCHR, 'The right of everyone to the enjoyment of the highest attainable standard of physical and mental health: Report of the Special Rapporteur, Paul Hunt: Addendum: Mission to the World Trade Organization' (1 March 2004) UN Doc. E/CN.4/2004/49/Add.1, para 11; UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover ' (31 March 2009) UN Doc. A/HRC/11/12; UNOHCHR, 'Special

independent expert so the reports provide a unique insight into the situation in relation to the right to health globally, and in specific states if a country visit is undertaken. The reports are not binding but are valuable to UN human rights bodies. For example, the reports of Special Rapporteurs can be used in review of the human rights situation of the State subject to UPR, and also provide authoritative guidance on interpretation of issues within its mandate.

In addition, the resolutions and declarations of the Human Rights Council and the General Assembly can have considerable effect on creating norms, particularly where a large majority has supported their adoption or where they have influenced the practice of states[113]. The resolutions can be standard setting, and can reflect the aspirations of the UN human rights regime for States. They can also impact on the formation of customary international law. An example of this is the role of the Universal Declaration of Human Rights adopted by General Assembly resolution which contributed to the formation of customary international law, inter alia, concerning the prohibition on torture.[114] The resolutions may also exert pressure on states to address human rights concerns, unanimous resolutions are highly persuasive and if subsequently endorsed can be evidence of state practice, and form the basis for binding norms.[115] Therefore although the resolutions of the General Assembly are considered to be soft law, they can influence State behaviour and can, in some instances, lead to the codification or progressive development of customary international law. These instruments can also have practical advantages as they may provide states with flexibility in implementation, and have also been achieved through a degree of consensus by states.[116]

Weil was critical of resolutions of international organisations being considered as part of international law as it was not straightforward to work out their normative force, and while they may be a stage in the development of new norms, they do not constitute a

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Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health: Introduction' <https://www.ohchr.org/en/issues/health/pages/srrighthealthindex.aspx> (accessed 27/04/2020)

[113] Higgins (n 43) 28

[114] ibid 22

[115] Chinkin (n 104) 90-91; A Cassese, *International* Law, 2nd ed, (Oxford University Press, Oxford 2005) 388-389; A Boyle 'Soft Law in International Law-Making' in M Evans (ed) *International Law,* 4th ed (Oxford University Press, Oxford 2014), 123; H Hillgenberg 'A Fresh Look at Soft Law' (1999) 10(3) EJIL 499, 501-502, 511

[116] M Peterson, *The UN General Assembly,* (Routledge London 2006), 3; L Sohn, 'Introduction: United Nations Decision-Making: Confrontation or Consensus' (1974) 15 Harv Int'l L J 438, 442; J Higashi, 'The Role of Resolutions of the United Nations General Assembly in the Formative Process of International Customary Law' (1982) 25 Japanese Ann Int'l L 11, 24

formal source of new norms[117]. In other words, if states wanted to be bound by these instruments they could have chosen to be so. However, scholars including Higgins argue that soft law can be considered a source of law, to have legal effect and not be binding[118], so while not being a substitute for legal custom, forms of soft law do have legal relevance in the creation of legal norms, as legal consequences can flow from non-binding acts[119]. Higgins also argues that the repeated practice of a UN human rights body in interpreting a human rights treaty may establish a practice that is of probative value as customary law[120]. Chinkin asserts that soft law provides the space for the shaping of values and the creation of expectations as to the limits States will accept on their actions, and that they will seek to impose on others[121], proposing that the consent of states to these instruments has a legitimising effect. Mendelson deftly articulates the controversy around the sources of international law as a failure to perceive the different observational standpoints, where persons performing different functions may adopt different attitudes to sources of law, and giving the example of a judge who has to apply the law impartially to the facts, contrasted with a government legal adviser who considers how a rule might develop and how they might assist this.[122] Mendelson argues that while it perhaps does not matter which standpoint is taken by legal commentators, it is important to appreciate that there is a spectrum and that different positions on it are possible[123]. So while forms of soft law are not directly enforceable, soft law does have a significant role in developing best practices and interpreting binding obligations of states under the UN human rights framework, with the *Nicaragua*[124] case a recognised example of a General Assembly resolution being utilised to interpret and apply the UN Charter[125]. Therefore, soft law is important for assisting with the interpretation of States obligations and the normative

[117] Weil (n 41) 416-417
[118] A Pellet, 'The Normative Dilemma: Will and Consent in International Law-Making' (1989) 12 Australian Year Book of International Law 22, 30-31; Higgins (n 43) 26-28
[119] Higgins (n 43) 24
[120] ibid 25
[121] Chinkin (n 43) 865
[122] See Appendix to the 1st Report of the Rapporteur (Mendelson), "Formation of International Law and the Observational Standpoint" (1986), Annex to the 1st Interim Report of the Committee, in Report of 63rd Conference (Warsaw 1988), 935, 941
[123] ibid
[124] Military and Paramilitary Activities in and against Nicaragua (Nicaragua v. United States of America), Merits, Judgment of 27 June 1986, paras 189, 191
[125] The resolution in question was the Declaration on Principles of International Law concerning Friendly Relations and Co-operation among States in accordance with the Charter of the United Nations (General Assembly resolution 2625 (XXV))

content of the right to health under the ICESCR. In undertaking country case studies, relevant national legislation, policy documents and related case law have been reviewed.

b) Definitions

For the purposes of this research, 'access to medicines' refers to 'access to essential medicines'. The term 'essential medicines' refers to the definition given by the World Health Organization, which defines essential medicines as "those that satisfy the priority health care needs of the population… [E]ssential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford."[126] The question of whether access to essential medicines forms part of the right to health under Article 12 ICESCR is discussed in Chapter 3. The earlier reports of the Special Rapporteur on the highest attainable standard of physical and mental health include the terminology 'access to essential medicines'[127] while the more recent reports refer to 'access to medicines'[128]. There is also evidence of both terms being used

[126] World Health Organization, 'Essential Medicines and Health Products' > 'Essential Medicines' <https://www.who.int/medicines/services/essmedicines_def/en/> (accessed 27/04/2020). The WHO has set out a Model List of Essential Medicines, which is "a guide for the development of national and institutional essential medicine lists. It was not designed as a global standard. However, for the past 30 years the Model List has led to a global acceptance of the concept of essential medicines as a powerful means to promote health equity. Most countries have national lists and some have provincial or state lists as well. National lists of essential medicines usually relate closely to national guidelines for clinical health care practice which are used for the training and supervision of health workers." The Model List can be viewed at <https://www.who.int/medicines/services/essmedicines_def/en/> (accessed 27/04/2020)

[127] See UN Commission on Human Rights 'The right of everyone to the enjoyment of the highest attainable standard of physical and mental health; Report of the Special Rapporteur, Paul Hunt: Addendum: Mission to the World Trade Organization' (1 March 2004) UN Doc E/CN.4/2004/49/Add.1; UNCHR 'Report submitted by the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Paul Hunt: Addendum: Mission to Romania' (21 February 2005) UN Doc E/CN.4/2005/51/Add.4; UNCHR 'Right of Everyone to Enjoyment of the Highest Attainable Standard of Physical and Mental Health; Report submitted by the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Paul Hunt; Addendum: Mission to Peru' (4 February 2005) UN Doc E/CN.4/2005/51/Add.3

[128] See UN Human Rights Council 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover: Addendum: Mission to Viet Nam' (4 June 2012) UN Doc A/HRC/20/15/Add.2; UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover: Addendum: Mission to Ghana' (10 April 2012) UN Doc A/HRC/20/15/Add.1; UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover: Addendum: Mission to Tajikistan (24 – 31 May 2012)' (2 May 2013) UN Doc A/HRC/23/41/Add.2; UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover: Addendum: Mission to Azerbaijan (16–23 May 2012)' (3 May 2013) UN Doc A/HRC/23/41/Add.1

in Reports of the Working Group on the Universal Periodic Review[129], as well as Concluding Observations of the CESCR[130], raising the question of whether there has been a shift in the discourse from whether access to essential medicines is part of the right to health, to whether access to non-essential medicines is also part of the right to health. However, it is evident that where the term 'access to medicines' is used, the medicines being referred to are predominantly to treat HIV/AIDS and tuberculosis, and are the same kinds of medicines as those commonly referred to as 'essential medicines'[131]. Therefore, this thesis would suggest that, this seems to indicate that 'access to essential medicines' is the intended meaning where the term 'access to medicines' is used. The issue of availability and accessibility of essential medicines encompasses a range of communicable and non-communicable diseases such as malaria, leukaemia, tuberculosis and other epidemics. Such concerns escalated during the HIV/AIDS pandemic across Africa during the late twentieth century. In 2016 it was estimated that 36.8 million adults and children were living with HIV, with approximately 25.6 million of those people living

[129] See examples from the first cycle of 'access to medicines' used in relation to HIV/AIDS in UN Human Rights Council 'Universal Periodic Review, Report of the Working Group on the Universal Periodic Review, South Africa' (23 May 2008) UN Doc A/HRC/8/32; UNHRC 'Universal Periodic Review, Report of the Working Group on the Universal Periodic Review, Brazil' (22 May 2008) UN Doc A/HRC/8/27; UNHRC 'Universal Periodic Review, Report of the Working Group on the Universal Periodic Review, Swaziland' (12 December 2011) UN Doc A/HRC/19/6; UN Doc A/HRC/8/32; UNHRC 'Universal Periodic Review, Report of the Working Group on the Universal Periodic Review, Uganda' (22 December 2011) UN Doc A/HRC/19/16; UNHRC 'Universal Periodic Review, Report of the Working Group on the Universal Periodic Review, Cameroon' (12 October 2009) UN Doc A/HRC/11/21. The UPR report for Cameroon also refers to 'access to medicines' in relation to tuberculosis. In the second cycle the reports of Zambia, Jamaica and Dominican Republic use the term 'access to medicines' in relation to HIV/AIDS, the report of Trinidad and Tobago uses the term 'essential medicines' in the context of HIV and the UPR report of Venezuela includes reference to 'access to essential medicines' and 'access to medicines' but no distinction between the terms is presented. UNHRC 'Universal Periodic Review, Report of the Working Group on the Universal Periodic Review, Zambia' (31 December 2012) UN Doc A/HRC/22/13; UNHRC 'Universal Periodic Review, Report of the Working Group on the Universal Periodic Review, Jamaica' (20 July 2015) UN Doc A/HRC/30/15; UNHRC 'Universal Periodic Review, Report of the Working Group on the Universal Periodic Review, Dominican Republic' (4 April 2014) UN Doc A/HRC/26/15; UNHRC 'Universal Periodic Review, Report of the Working Group on the Universal Periodic Review, Trinidad and Tobago' (15 July 2016) UN Doc A/HRC/33/15; UNHRC 'Universal Periodic Review, Report of the Working Group on the Universal Periodic Review, Bolivarian Republic of Venezuela' (27 December 2016) UN Doc A/HRC/34/6.

[130] Examples of the term 'essential medicines' in UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights; Republic of the Congo' (23 May 2000) UN Doc E/C.12/1/Add.45; UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Peru' (30 May 2012) UN Doc E/C.12/PER/CO/2-4. Examples of 'access to medicines' in the context of HIV/AIDS in UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights; Sudan' (1 September 2000) UN Doc E/C.12/1/Add.48; UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Jamaica' (6 December 2001) UN Doc E/C.12/1/Add.75

[131] Medicines to treat HIV/AIDS, tuberculosis and malaria all appear on the WHO Model List of Essential Medicines (n 126) 19, 16

in Africa[132]. There is presently no cure or vaccine for HIV/AIDS, with the current most effective treatment being a combination of antiretroviral drugs. While HIV/AIDS and tuberculosis are prominent concerns when discussing access to medicines, the issue of access to medicines is not limited to these diseases, and this is reflected in the WHO Model List of Essential Medicines, which also includes medicines for treatment of diseases including malaria, measles and others[133]. Therefore this thesis is not focused on exploring access to medicines to treat HIV/AIDS and tuberculosis specifically, but will include references to diseases such as HIV/AIDS as a specific example of challenges in relation to access to medicines.

The term 'pharmaceuticals' is referred to in this research where the academic literature under discussion uses this term[134]. The term is also used in cases relating to patent law in this thesis, for example by WTO panels and Appellate Body[135]. Where this term is used in the literature and a definition is not outlined, this thesis will take the term 'pharmaceuticals' to mean 'medicines' for definitional purposes in this research.[136]

The term 'right to health' used in this research is a shortened reference to the right of everyone to the enjoyment of the highest attainable standard of physical and mental health set out in Article 12 of the ICESCR. This is defined by the UN Committee on Economic, Social and Cultural Rights in General Comment 14 as "not confined to the right to health care. On the contrary, the drafting history and the express wording of article 12.2 acknowledge that the right to health embraces a wide range of socio economic factors that promote conditions in which people can lead a healthy life, and extends to the underlying determinants of health, such as food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment."[137] It is important to note that the "highest attainable" standard will vary

[132] World Health Organization, 'Global Health Observatory Map Gallery' <http://gamapserver.who.int/mapLibrary/app/searchResults.aspx> (accessed 27/04/2020)
[133] See the WHO Model List of Essential Medicines (n 126)
[134] See examples in J Reichman "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) 32(2) Journal of Law and Medicine Ethics 10; A Sykes 'TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution"' (2002) 3 CJIL 47; R Beall and R Kuhn 'Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis' (2012) 9 PLoS Med 1
[135] See examples in *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000; *Canada-Term of Patent Protection*, WT/DS170/AB/R, adopted 12 October 2000; *Canada-Term of Patent Protection,* WT/DS170/R, final report circulated 5 May 2000
[136] Pharmaceuticals are defined as a 'medicinal drug'. See Oxford English Dictionary, 'Pharmaceutical' <https://www.oed.com/view/Entry/142229?redirectedFrom=pharmaceutical#eid> (accessed 27/04/2020)
[137] General Comment No. 14 (n 112) 4

from state to state, as the highest attainable standard of health in a developed state will likely be higher than that of a developing state. Therefore the 'highest attainable standard' means the highest attainable standard within the state concerned.[138]

c) Towards improving access to medicines within states

One question addressed in this thesis is how states can interpret and apply their international IP and human rights obligations at national level in a manner that enhances effective access to medicines for patients. The interaction between patent protection afforded to pharmaceutical manufacturers and the right to health under the ICESCR is examined at international and national level, since TRIPS came into force in 1995. A key theme is whether TRIPS is more to the benefit of states which are creators of IP than states which are users of IP, presenting an asymmetry within TRIPS. Another key theme is whether IP protection can be seen, in one sense, as a trade impediment, but in another sense as facilitative of trade. The key tensions within TRIPS are traced, including extension of the term of patent protection. The success of measures aimed at promoting public health is also evaluated, including the only amendment to TRIPS following the Doha Declaration, which had the objective of making it easier for developing countries without manufacturing capacity to import medicines. Drawing on the object and purpose of the agreement, this thesis proposes that TRIPS is not fundamentally in conflict with UN human rights law. The work of the UN human rights bodies in clarifying the content of the right to health and the obligations of states parties to the ICESCR is also examined, to make the case that the right to health includes access to medicines. Therefore, states have obligations to implement measures into national law to protect and promote access to medicines, and that TRIPS can be interpreted in the context of the right to health to promote access to medicines.

The argument as to whether IP rights can amount to a human right under the ICESCR is also evaluated, to examine whether a conflict exists between state obligations towards creators of medicines and patients requiring medicines in international human rights law. Recent developments in the UN human rights framework are also analysed to evaluate their contribution to advancing access to medicines and how this discourse can assist states in meeting their concurrent obligations to protect the right to health and under IP law. The thesis then moves to undertaking two country case studies to provide insights

[138] ibid 12

into how the selected states have implemented TRIPS and to identify significant problems as well as possible solutions to key challenges in relation to complying concurrently with human rights law. The studies will draw upon illustrative examples from national law, policy and jurisprudence to examine the implications of the issue of access to medicines at national level, and assess whether states have found solutions which could be implemented in other states. In addition, how state practice could inform understanding of the key challenges at international level is also considered. The thesis concludes by proposing factors for consideration at national and international level for resolving tensions between the WTO and UN human rights frameworks in relation to access to medicines in a manner that promotes the rights of all to secure effective access to medicines.

Chapter 2 critically evaluates the rationale for intellectual property protection and the reasoning for the implementation of TRIPS as an international standard for intellectual property rights. This includes exploring the tensions with patent law and access to medicines, by analysing the terms on patents in TRIPS, the minimum standards for protection and how they have been interpreted, and challenges including the implementation of a higher standard of intellectual property protection by some WTO Members. Exceptions to patent rights under Article 30 and Article 31 of TRIPS will also be explored to analyse whether these exceptions are practicable. The difficulties in satisfying the compulsory licensing requirements under Article 31 has been addressed by Doha Declaration in November 2001, which led to an amendment of Article 31. The chapter does not provide a detailed historical analysis of IP rights, focusing instead on key developments in the law and providing context to the challenges in interpreting TRIPS in a manner that is consistent with securing access to medicines.

Chapter 3 undertakes a systematic review of the reports of the UN Human Rights Charter-based Bodies and the relevant UN Human Rights Treaty Monitoring body to explore the status of access to medicines in the context of international human rights law, and to explore the value of the interpretative guidance provided by these instruments. The purpose of this is to explore whether access to medicines can be considered as forming part of the human right to health in international human rights law, specifically under Article 12 of the ICESCR. The review of the Charter-based system involves a systematic analysis of the Universal Periodic Review (UPR) documentation with a view to ascertaining recommendations made to states in relation to medicines, to analyse state views on their human rights obligations and how improving access to medicines fits with

those obligations. A review of the reports of the Special Rapporteur on the highest attainable standard of physical and mental health to December 2019 is also undertaken, as the Special Rapporteur has a specific mandate to report on health matters and to provide guidance to states on their obligations under the right to health.

In relation to the UN Treaty Monitoring Bodies, the chapter also includes a systematic review of the reports on the concluding observations of the Committee on Economic, Social and Cultural Rights (CESCR) to December 2019, as the ICESCR includes the right to highest attainable standard of physical and mental health under Article 12, to understand the key concerns in relation to this right. The General Comments on the treaties are also informative and are considered as they provide guidance on the interpretation of the States parties' obligations. The purpose of this review is to explore how access to medicines is considered as part of the human right to health by the UN human rights bodies, identify concerns over barriers to access which prevent the fulfilment of the right to health. Also, how the UN human rights instruments can be instructive to states in interpreting and implementing their obligations under the ICESCR to enhance access to medicines while concurrently complying with their obligations under TRIPS.

Chapter 4 explores the question of whether IP rights could be considered as human rights also, specifically under Article 15 ICESCR. This includes a review of the content of Article 15 and the UN guidance on Article 15, including the relevant General Comments, to examine how IP rights fit into the UN human rights framework, to evaluate measures to advance this right within this framework, and the significance of this right internationally and domestically within states. The chapter then goes on to explore key recent developments in the UN that seek to enhance access to medicines in this rights-based context. Such developments include the expert consultation on access to medicines convened by the Office of the High Commissioner for Human Rights (OHCHR), and the UN Secretary-General's High-Level Panel on Access to Medicines[139], which outlined

[139] The Panel comprised fourteen members and two co-chairs from developed and developing countries, The co-chairs were Ruth Dreifuss, former Chairperson of the Commission on Intellectual Property Rights, Innovation, and Public Health, and Festus Gontebanye Mogae, former President of the Republic of Botswana and Chairman of Champions for a HIV Free Generation. The membership of the Panel included Andrew Witty, former CEO of GlaxoSmithKline; Stephen Lewis, the UN Secretary-General's Special Envoy for HIV/AIDS in Africa (2001-06);,Deputy Executive Director of UNICEF (1995 -1999), and he served as Canada's Ambassador to the UN (1984-1988); Malebona Precious Matsoso, former Director at the World Health Organisation (WHO) responsible for the implementation of the Global Strategy and Plan of Action; Michael Kirby, a retired Justice of the High Court of Australia, he served as the Special Representative of the United Nations Secretary-General for Human Rights in Cambodia between 1993

problems in terms of innovation and in terms of physical accessibility, and made a series of recommendations to address key challenges identified by the Panel. The chapter will evaluate the outcomes of these developments to assess the utility and efficacy of the recommendations made in helping states to interpret and implement their obligations under TRIPS and the ICESCR to enhance access to medicines. The chapter will also evaluate whether states parties can be bound to fulfil such recommendations, through monitoring and accountability mechanisms, and whether this would have a positive impact to enhance access to medicines and in influencing state behaviour.

Chapters 5 and 6 of this thesis will focus on country case studies, for the purpose of providing an examination of how the States are interpreting and implementing their TRIPS and ICESCR obligations in to national law, and to further understand how these issues impact upon patients within the States. Chapter 5 focuses on Canada as the first country case study and Chapter 6 focuses on Peru. The methodology of selecting these states is outlined in the introductory paragraphs of Chapters 5 and 6. The reasoning for selecting one developed state and one developing state is to analyse whether recommendations emanating from the international frameworks on how states should interpret their obligations under TRIPS and the ICESCR, are recognising the varied factors which can have an impact on states' abilities to comply with their international obligations on medicines. The purpose is to offer insights into the States' experience and to further understanding on how to develop the discourse on access to medicines at national and international level. National legislation on intellectual property will be explored in the studies, including national policy and available data in relation to the national pharmaceutical industry, as well as whether the studied State recognises access to medicines within their legislative system, and if so, the legal status and consequences.

The studies also outline illustrative examples of how the tensions identified between the states obligations within the international trade and human rights systems at international level, translate to domestic level, to highlight how such tension manifests at national level. Examples of good practice in the States is also highlighted, to evaluate whether such practices could be adopted in other states, and to further understanding on how to develop the discourse on access to medicines at national and international level.

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and 1996, From 2010 to 2012, he served as Commissioner on the Global Commission on HIV and the Law and co-chaired the Commission's Technical Advisory Group. In May 2013 he was appointed by the United Nations Human Rights Council to lead a Commission of Inquiry into human rights abuses in North Korea. United Nations Secretary-General's High-Level Panel on Access to Medicines, 'The Panel', <http://www.unsgaccessmeds.org/new-page/> (accessed 27/04/2020)

Important issues identified include physical accessibility of medicines, pricing and research and development (R&D) costs, data exclusivity and development of local generic medicines, and national constitutional measures impacting upon access to medicines. Specific challenges faced by the State's indigenous peoples are also explored, including how broader concerns such as access to culturally appropriate services, and the protection of traditional medicines, can impact on their access to medicines. This analysis fills gaps in understanding of how the complexities around enhancing access to medicines impact upon minority groups, the specific challenges that such groups face, which need to form part of the discourse on enhancing access to medicines for everyone.

The final chapter evaluates the outcomes of the research undertaken in each of the earlier chapters, for the purpose of raising questions relating to states' policy and measures on medicines and also to suggest possible actions to improve the position. The chapter will take a thematic approach to outline several factors for consideration for states to address the wide-ranging issues affecting access to medicines, and to comply with their international commitments. This chapter will outline the utility of the research not only at the national level but also to help inform initiatives at the intergovernmental or international level to promote effective access to medicines, for the benefit of patients across all states.

Chapter 2: Trade, Intellectual Property and the TRIPS Agreement

Introduction

The objective of this chapter is to provide an analysis of the terms in the TRIPS Agreement[140] that are relevant to medicines, to further understanding of where tension exists between compliance with TRIPS provisions and access to medicines. The chapter will critically examine the purpose of intellectual property law, and identify and analyse factors affecting access to medicines in the context of trade and intellectual property law. The TRIPS agreement, administered by the WTO, was the first multilateral trade agreement pertaining specifically to IP rights and sets minimum standards of IP protection which WTO Members are required to implement into national law. The chapter will provide an overview of how TRIPS came to be agreed by WTO Members, and the obligations the Agreement placed on Members. A key theme discussed in this chapter is whether TRIPS is more to the benefit of states which are creators of IP than states which are users of IP. Another key theme is whether IP protection can be seen, in one sense, as a trade impediment, but in another sense as facilitative of trade. The chapter will also consider the implementation of TRIPS specifically in relation to patents and access to medicines, and explore why some terms create challenges in securing access to essential medicines, to analyse where tensions exist between implementing patent law and promoting public health objectives.

A key question is whether potential tension between the WTO and UN human rights regimes can be resolved through interpretation, in particular whether TRIPS can be interpreted to serve public health interests such as enhancing access to medicines. An analysis of the exceptions to the patent rights afforded by TRIPS under Articles 30 and 31 and the effectiveness of their application in practice will be undertaken, as well as whether these provisions can be interpreted in a manner which promotes access to essential medicines. An evaluation of the current legal position will also be undertaken, including how the Doha Declaration was intended to address the public health concerns arising from TRIPS and whether this was successful. The chapter will also consider the effect of the implementation of IP provisions in bilateral trade agreements that are stricter than those set out in TRIPS. An evaluation of the literature surrounding this issue will

[140] TRIPS Agreement (n 4). The TRIPS Agreement came into force on 1 January 1995.

assist the discussion, and demonstrate how the issue of securing effective access to medicines is of key importance in a global context beyond the trade platform.

I. The evolution of IP in trade law

Since the TRIPS agreement came into force in 1995, as part of the agreement that established the WTO, the perspective on access to essential medicines has altered significantly. Prior to the implementation of TRIPS the absence of a standardised IP law resulted in varying types and standards of protection in different jurisdictions. The World Intellectual Property Organization (WIPO) administered various treaties[141] relating to IP rights which delivered a mechanism for protecting IP rights globally without the requirement for harmonisation.[142] However no cohesive system with a legitimate process for dispute resolution existed. TRIPS recognised the increasing relevance of trade in knowledge and creative ideas, with the outcome being that trade in intangible goods as well as tangible goods could be regulated within the same platform, harmonising IP law with trade law.

Prior to the creation of the WTO, the General Agreement on Tariffs and Trade (GATT) administered international trade in goods with the intention to reduce tariff duties between the contracting states. Although the general GATT provisions applied to IP[143], issues relating specifically to IP protection were left to the competency of contracting states, and territorial IP rights developed as a result.[144] As new Contracting Parties, including developing countries with more diverse interests joined the GATT system, dissatisfaction emerged as to the adequacy of the GATT system to address trade

[141] The Paris Convention (Industrial Property) and the Berne Convention (Literary and Artistic Works) referred to protection of IP rights, although IP rights were not included in GATT, the multilateral trade agreement which preceded TRIPS.

[142] P Drahos, 'Developing Countries and International Intellectual Property Standard-Setting' (2002) 5 J World Intell Prop 765, 768-769; M Blakeney 'Intellectual property in world trade: The Failure of the Ancien Régime of Intellectual Property Protection' (1995) 1(3) Int. T.L.R. 76, 76-77; M Elsmore, 'Comparing regulatory treatment of intellectual property at WTO and EU level' in S Gaines, B Olsen and K Sørensen (eds), *Liberalising Trade in the EU and the WTO* (Cambridge University Press, Cambridge 2014), 419; Helfer and Austin (n 3) 37-38

[143] D Gervais, *The TRIPS Agreement: Drafting Analysis and History* (4th ed Sweet and Maxwell, London 2012), [1.08]

[144] J Reichman, 'Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection' (1989) 22 Vand J Transnat'l L 747, 756-757; P Geller 'Intellectual Property in the Global Marketplace: Impact of TRIPS Dispute Settlements?' (1995) 29 Int'l Law 99, 106; Elsmore (n 13) 418; D Gervais 'The TRIPs Agreement: interpretation and implementation' (1999) 21(3) E.I.P.R. 156, 156

imbalances.[145] Therefore there was an inclination for reform of the international trading system.

The Uruguay Round of trade negotiations between the Contracting Parties began in 1986 and comprised new areas of trade regulation including trade in IP, with pressure to resolve the issue of trade in pirated and counterfeit goods.[146] The US in particular advocated the introduction of strict IP protection, and a Report to Selected Congressional Subcommittees by the US Accounting Office[147] outlined the US government efforts to combat counterfeiting and piracy by encouraging other states to implement stronger national IP rights.[148] Although the Uruguay Round began with concerns over counterfeit goods, the limited mandate evolved into a far-reaching agreement on IP protection.[149] During the negotiations it was evident that while the focus was on the protection and enforcement of IP rights, there was a lack of consensus on how these norms may be realised. For example, the US position was that the GATT articles on IP were inadequate to address distortions to trade and sought to establish enforcement mechanisms[150], while a Swiss proposal favoured the establishment of general normative principles including the avoidance of trade distortions caused by insufficient IP rights protection, to be enforced by the existing GATT procedures.[151]

Furthermore, submissions by several developing countries during the negotiations reflected a position in contrast to that of developed countries, and expressed concerns about a high level of IP protection obstructing technology transfer and affecting costs of

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[145] R Dreyfuss and A Lowenfeld, 'Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together' (1997) 37 Va J Int'l L 275, 277; P Gallagher, *The First Ten Years of the WTO: 1995-2005* (Cambridge University Press, Cambridge 2005), 3; Reichman (n 144) 765-766; C Wadlow '"Including trade in counterfeit goods": the origin of TRIPS as a GATT anti-counterfeiting code' (2007) 3 I.P.Q. 350, 350

[146] A Taubman, H Wager and J Watal (eds), *A Handbook on the WTO TRIPS Agreement* (Cambridge University Press, Cambridge 2012), 4; Wadlow (n 145) 351-352; Gervais (n 143) P.8-9

[147] US General Accounting Office, 'International Trade: Strengthening Worldwide Protection of Intellectual Property Rights', GAO/NSIAD-87-65 (1987) <http://archive.gao.gov/d2t4/132699.pdf> (accessed 27/04/2020)

[148] ibid 8

[149] C Arup, *The New World Trade Organization Agreements: Globalizing Law Through Services and Intellectual Property* (Cambridge University Press, Cambridge 2000), 64; S Joseph 'Democratic Deficit, participation and the WTO' in S Joseph, D Kinley and J Waincymer (eds) *The World Trade Organization and Human Rights* (Edward Elgar, Cheltenham 2009), P.317; Blakeney (n 142) 80-81; F Abbott, 'The WTO Trips Agreement and Global Economic Development' (1996) 72 Chi-Kent L Rev 385, 390

[150] Group of Negotiations on Goods (GATT) Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods , Statement by United States at Meeting of 25 March 1987, (3 April 1987) MTN.GNG/NG11/W/2, 4

[151] Group of Negotiations on Goods (GATT) Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods , Proposal by Switzerland, (21 June 1988) MTN.GNG/NG11/W/25, 3

medicines. In a statement to the Negotiating Group, Thailand highlighted developing countries' concerns over the scope of discussions, asserting that the objectives of some countries in proposing wider international standards of IP protection went beyond the intentions of the Round.[152] The State argued that enforcement procedures should further trade liberalisation and not lead to excessive protection which obstructed technology transfer.[153] It was also stated that the two fundamental aims pursued by governments when granting IP protection are the stimulation of intellectual creativity and appropriate protection of the public interest, and it "goes without saying that the former must not put undue burden on the latter."[154] These statements illustrated the competing interests of the developed and developing countries during the negotiations, with developing countries' concerns over how higher IP would limit the transfer of knowledge and development goals.

A statement from Peru also reiterated the balance between protecting creativity and furthering the development agenda[155] and stated that pharmaceutical products should be excluded from patentability, and provisions to ensure that patents further technology transfer should be included.[156] This underlined that the issue of access to essential medicines was a concern for a developing country before TRIPS was agreed, however through the negotiations the issue did not appear to have been adopted as a prominent concern. Submissions by Brazil noted that the discussions had been focussed on the IP owner, while there was a need to consider the IP user also, emphasising that the IP owner had not only rights but obligations, including to provide access to technological innovations.[157] The submissions by Brazil also demonstrated concerns of developing countries, emphasising that the mandate of the Negotiating Group was to discuss trade related aspects of IP rights in the broader context of promotion of growth and

[152] Group of Negotiations on Goods (GATT) Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Statement by Thailand at the meeting of 12-14 September 1988, (21 September 1988) MTN.GNG/NG11/W/27, 1
[153] ibid 2
[154] ibid 2
[155] Group of Negotiations on Goods (GATT) Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Guidelines for negotiations that strike a balance between intellectual property rights and development objectives – Communication from Peru, (27 October 1989) MTN.GNG/NG11/W/45, 1
[156] ibid 2
[157] Group of Negotiations on Goods (GATT) Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Submission from Brazil, (31 October 1988) MTN.GNG/NG11/W/30, 3

development[158], rather than in the context of enforcement of IP rights, including non-trade related rights.

Negotiating IP rights in WIPO was favoured by developing countries in order to consider the impact of IP rights on a wider scale outside of the trade forum[159], raising the question of why the developing countries participated in the discussions of IP right within the GATT given their fears over the impact of higher IP rights protection. However participation in the negotiations in GATT was perceived as beneficial due to potential gains in other areas of trade.[160] Developing countries had the opportunity to secure compromises on other trade matters such as textiles and agriculture, as part of the agreement that included IP rights, by having such discussions within the GATT mechanism rather than WIPO.[161] The development of a multilateral framework for enforcement and dispute resolution to address IP rights infringement was also preferable to "guarantee security against the power politics of aggressive unilateralism and bilateral bargaining" by developed countries.[162] Developing countries, including those with growing pharmaceutical industries, were granted greater access to developed markets for manufactured goods as well as assurances from developed countries to refrain from imposing unilateral sanctions for perceived inadequate IP protection.[163]

II. The TRIPS Agreement

An outcome of the Uruguay Round was the creation of a new trade organisation, the WTO, which would replace the GATT in administering trade relations between its

[158] ibid 1

[159] A Adede 'Origins and History of the TRIPS Negotiations' in C Bellman, G Dutfield and R Meléndez Ortiz (eds) *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (ICTSD, Earthscan London 2003), 30; C Thomas 'WTO and Labor Rights' WTO' in S Joseph, D Kinley and J Waincymer (eds) *The World Trade Organization and Human Rights* (Edward Elgar, Cheltenham 2009), P.279; Hestermeyer (n 72) P.44

[160] Drahos (n 142) 769-770; Adede (n 159) 30; Hestermeyer (n 72) P.46; F Abbott, 'Commentary: The International Intellectual Property Order Enters the 21st Century' (1996) 29 Vand J Transnat'l L 471, 472

[161] Abbott (n 149) 386-387; Adede (n 159) 24; T Cottier and M Foltea 'Global governance in intellectual property protection: does the decision-making forum matter?' (2012) 3(2) W.I.P.O.J. 139, 144; Abbott (n 160) 472

[162] C Arup, 'TRIPs: across the global field of intellectual property' (2004) 26(1) EIPR 7, 9

[163] L Helfer, 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking' (2004) 29 Yale Journal of International Law 1, 22; J Reichman, 'Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) 32(2) Journal of Law and Medicine Ethics 10–11, 247; S Sell, 'The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive, and Institutional Dimensions' (2004) 77 Temp L Rev 363, 371-372

Members. Against this background the obligations TRIPS imposes on WTO Members in relation to medicines will be considered. A key theme is whether TRIPS is more to the benefit of states which are creators of IP than states which are users of IP, presenting an asymmetry within TRIPS. Another key theme is whether IP protection can be seen, in one sense, as facilitative of trade, but in another sense as a trade impediment. A wealth of literature explores the scope of the international trade system and how it increasingly impacts upon other areas of law, and society[164]. There is recognition of the fact that decisions taken within the WTO legal framework have significant impacts on non-trade issues, including environmental concerns, labour standards, and health. Much of the academic literature discusses whether there is conflict between WTO trade law and other objectives where the distinct legal norms converge in international law, and has been framed in the context of promoting trade liberalisation against competing social values[165], providing an example of the problem of fragmentation in international law. However this assessment has been contested in academic literature which takes the view that trade liberalisation through the WTO has been shaped by its overarching purpose, including the contribution that trade makes to global welfare, and the problems that it was implemented to resolve[166]. Lang argues that the debate should be reframed, to instead analyse the norms and values that the trade regime is to pursue, and how the trade system contributes to broader social goals[167]. This view explores that the trade regime is complementary to the human rights regime as the trade regime protects economic

[164] See examples: J Trachtman, 'Institutional Linkage: Transcending Trade and' (2002) 96 Am J Int'l L 77; S Dillon, A Farewell to "Linkage": International Trade Law and Global Sustainability Indicators' (2002) 55 Rutgers L Rev 87; A Lang, 'Reflecting on Linkage: Cognitive and Institutional Change in the International Trading System' (2007) 70 Mod L Rev 523; J Alvarez 'How Not to Link: Institutional Conundrums of an Expanded Trade Regime' (2001) 7 Widener Law Symposium Journal 1; S Charnovitz, 'Free Trade, Fair Trade, Green Trade: Defogging the Debate' (1994) 27 Cornell Int'l L J 459; P Nichols, 'Trade Without Values' (1995-1996) 90 Nw U L Rev 658; R Wai, 'Countering, Branding, Dealing: Using Economic and Social Rights In and Around the International Trade Regime' (2003) 14 European Journal of International Law' 35

[165] Illustrative examples include: M Cohn, 'The World Trade Organization: Elevating Property Interests above Human Rights' (2001) 29 Ga J Int'l & Comp L 427, 432; D Esty, 'Linkages and Governance: NGOs at the World Trade Organization' (1998) 19 U Pa J Int'l Econ L 709, 713-714; L DiMatteo et al 'The Doha Declaration and Beyond: Giving a Voice to Non-Trade Concerns within the WTO Trade Regime' (2003) 36 Vand J Transnat'l L 95, 98; A Guzman, 'Global Governance and the WTO' (2004) 45 Harv Int'l LJ 303, 304

[166] See examples: A Lang, *World Trade Law after Neoliberalism: Reimagining the Global Economic Order* (Oxford University Press, Oxford 2011), P.187; J Ruggie 'International Regimes, Transactions, and Change: Embedded Liberalism in the Postwar Economic Order' (1982) 36(2) International Organization 379, 382; J Dunoff, 'Rethinking International Trade' (1998) 19 U Pa J Int'l Econ L 347, 350; J Gathii, 'Re-Characterizing the Social in the Constitutionalization of the WTO: A Preliminary Analysis' (2001) 7 Widener L Symp J 137, 173; S Cho, 'Linkage of Free Trade and Social Regulation: Moving beyond the Entropic Dilemma' (2005) 5 Chi J Int'l L 625, 640

[167] Lang (n 164) 530

freedoms and development, and is underpinned by the freedoms associated with human rights[168]. Article XX GATT provides foundation for the consideration of human rights law within the WTO framework, and TRIPS recognises the significance of public health under Article 8. The terminology within the WTO Preamble, as well as Article XX GATT, are not precise or unambiguous and are therefore open to interpretation. Therefore there is scope for the interpretation of TRIPS in light of human rights objectives, including the right to health. However the question is the extent to which this can be achieved. The WTO Preamble states the objectives of the WTO are the reduction of barriers and discrimination in trade to promote economic development and improve standards of living, in particular sustainable development and with regard to the needs of developing states[169]. Academic literature has considered the extent to which the WTO expanded the nature of the trading regime to development, economic and welfare gain[170]. While it is reasonable to propose that an aim of the WTO is to promote development through trade liberalisation[171], the Preamble does not outline specific goals for achieving this, and the wording does not indicate that there is an unlimited extent to which social considerations can be considered when seeking to reduce trade barriers. The Preamble does not outline the degree to which social and welfare considerations are to be taken into account, or given that there is not stated to be a hierarchy of objectives within the Preamble, whether the position is that these considerations are to be taken into account to the extent that they impact on trade.

As an instrument managed within the WTO, TRIPS has the objective of ensuring adequate protection of IP rights, while ensuring that enforcement of IP rights do not themselves create distortions and impediments to international trade[172]. IP rights are private rights which create positive obligations in the public international trade law system, and therefore a relevant issue is whether TRIPS is trade liberalising, facilitating

[168] See, for example, Article 1 ICCPR. Lang (n 166) 125
[169] Agreement Establishing the World Trade Organization (n 5)
[170] B Mercurio, 'WTO and Its Institutional Impediments' (2007) 8 Melb J Int'l L 198, 211; R Howse 'The World Trade Organization 20 years on: global governance by judiciary' (2016) 27(1) E.J.I.L. 9, 17-18; A Lang and J Scott 'The hidden world of WTO governance' (2009) 20(3) E.J.I.L. 575, 610; E Reid and J Steele, 'Free Trade: What is it Good For? Globalization, Deregulation, and 'Public Opinion'' (2009) 36 Journal of Law and Society 11, 19; S Charnovitz, 'A New WTO Paradigm for Trade and the Environment' (2007) 11 SYBIL 15, 19; F MacMillan 'If not this WTO, then what?' (2004) 10(3) Int. T.L.R. 41, 41
[171] Lang and Scott (n 170) 577; Charnovitz (n 170) 40; A Mattoo and A Subramanian 'The WTO and the poorest countries: the stark reality' (2004) 3(3) World T.R 385, 389; P Conconi and C Perroni 'Special and differential treatment of developing countries in the WTO' (2015) 14(1) World T.R. 67, 68
[172] TRIPS Agreement (n 4) Preamble

international trade through a common standard of rights. TRIPS requires WTO Members to provide regulation and enforcement procedures for IP in national law that allow foreign owners to establish and protect IP rights. For numerous states the effect is to require that their domestic industries pay to use the IP when previously their national laws permitted free and unrestricted use.[173] International IP standards may address disparities between international trading partners and promote trading relationships. The effect of reducing tariff barriers generally results in reciprocal benefits for trading partners. However, in dealing with this non-tariff trade issue, states, usually developing countries using IP to further development of national industries, now have to incur licensing fees for authorised use of IP. Therefore they do not receive a reciprocal benefit from this trade agreement.[174] This suggests a conflict between trade liberalisation and IP rights as the monopoly rights gained by the IP holders does not facilitate trade liberalisation for the benefit of all WTO Members, and states with little IP cannot achieve the gains that IP holders would benefit from. Therefore TRIPS may not be beneficial for states oriented to use of IP rather than creation of IP.

An argument in support of TRIPS as an instrument of trade liberalisation is that such protection provides a global benefit through encouraging innovation and creativity, by providing the inventor or holder of the idea to be entitled to an exclusive property right in the creation. This will in turn encourage investment in developing knowledge and ideas, which will then lead to the creation of new products to be introduced to the global market. However, the creation of new products only benefits the global economy if the new product is sought after.[175] It could be argued that IP does not promote creativity as this presumes that creators only create if they can profit from their creations, and therefore a more accurate assessment is that IP encourages commercially valuable research and development. This is particularly evident in the pharmaceuticals industry where the protection of such creations in the form of patents can impede trade in generic medicines,

[173] JM Finger, 'A diplomat's economics: reciprocity in the Uruguay Round negotiations' (2005) 4(1) WTR 27, 36

[174] Ibid; Cottier and Foltea (n 161) 156; G Dinwoodie and R Dreyfuss, 'Designing a Global Intellectual Property System Responsive to Change: The WTO, WIPO and Beyond' (2009) 46 Houston Law Review 1187, 1192; K Jones 'The WTO core agreement, non-trade issues and institutional integrity' (2002) 1(3) WTR 257, 267, G Moon, 'The WTO-Minus Strategy: Development and Human Rights under WTO Law' (2008) 2 Hum Rts & Int'l Legal Discourse 37, 53; S Frankel 'Some consequences of misinterpreting the TRIPs Agreement' (2009) 1(1) W.I.P.O.J. 35, 39

[175] C Wolf 'Patent fairness and international justice' (2015) 7(1) WIPOJ 62, 67; Cottier and Foltea (n 161) 148

as to authorise use of the creation would present unwanted generic competition in the market[176].

Where IP protection is strict and right holders can receive remuneration in exchange for authorised use of the protected idea or creation, this protects the value of the IP to the holder. This standard also furthers trade liberalisation because the information that is the subject of an IP right is traded and shared with both parties benefitting from the trading arrangement. The right holder receives payment in exchange for licensing the information for use and the licensee can use the information for the purpose of creating a valuable product. However, for this standard to continually occur, this could impact upon social and cultural interests, particularly the right to health articulated within Article 12 of the International Covenant on Economic, Social and Cultural Rights.[177] Article 12 provides that states which are parties to the Covenant are to take steps necessary to realise the right to health, including "creating conditions which would assure to all medical service and medical attention in the event of sickness."[178] However, if IP rights effectively cause the escalation of costs of essential medicines, and disincentivise research into treatments for diseases common to developing and least developed countries, then states may not be fully realising their obligations under Article 12 ICESCR. This point is raised only briefly here, with an analysis of the human rights implications of the effect of IP law, particularly in relation to patents, to be explored in more depth in subsequent chapters.

Since coming into effect in 1995 there has been debate over whether TRIPS may be too restrictive to meet the needs of developing countries in relation to access to medicines[179], and that TRIPS in effect creates a barrier to access to essential medicines for developing countries.

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[176] S Sell 'TRIPS-Plus Free Trade Agreements and Access to Medicines' (2007) 28 Liverpool Law Review 41, 43

[177] International Covenant on Economic, Social and Cultural Rights (n 2) Article 12

[178] ibid

[179] C Correa and D Matthews, United Nations Development Programme, Bureau for Development Policy 'Discussion Paper: The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Rights to Health' (United Nations Development Programme; Bureau for Development Policy; 20 December 2011) <http://www.undp.org/content/dam/undp/library/hivaids/Discussion_Paper_Doha_Declaration_Public_Health.pdf > (accessed 27/04/2020); Matthews (n 72) 74; S Sell, 'Trips and the Access to Medicines Campaign' (2001) 20 Wis Int'l LJ 481, 482; Abbott (n 70) 15; K Maskus, 'Ensuring Access to Essential Medicines: Some Economic Considerations' (2001) 20 Wis Int'l LJ 563, 564; Hestermeyer (n 72); Andrew Gowers, 'Gowers Review of Intellectual Property' (December 2006) (The Stationery Office, HM Treasury on behalf of HMSO), 61 at [4.64] <https://www.gov.uk/government/publications/gowers-review-of-intellectual-property> (accessed 27/04/2020)

Specific concerns include the cost of medicines, particularly as these are generally set by pharmaceutical companies, which are private entities and therefore are not bound by the same obligations under international law as states are under TRIPS and the ICESCR. Also, the availability of newer, more effective medicines to treat people in need and the cost of these new products is an additional concern. A particular problem is that although IP rights are considered to encourage the creation of new products, they can act as a barrier to existing medicines that are essential for sufferers of diseases which, without adequate treatment, can be life limiting or fatal. Therefore, securing physical access to new medicines and promoting innovation in developing new medicines to treat growing public health concerns is also a key challenge for states.

III. Patent law and essential medicines

Many factors can impede access to medicines for the poorest populations in developed and developing countries, including insufficient research in development of new medicines for new diseases, delays in obtaining regulatory approval and decreased production of unprofitable medicines.[180] A specific challenge resulting from TRIPS standards of protection has been the effect of the patent protection provisions set out in Section 5, Articles 27-34 on access to essential medicines including antiretroviral drugs. This challenge exists particularly in relation to pharmaceutical patents. IP rights reward the innovative process of the creation of new medicines by allowing the creator to control and restrict the use of the new creation, most commonly in the form of a patent.[181] Patented medicines are protected from being copied to produce generic copies for the duration of the patent. Generic manufacturers can copy existing medicines at much cheaper cost because they do not have to invest in research and development where a medicine is already in existence, merely needing to demonstrate the generic medicine's

[180] F Abbott and R van Puymbroeck, 'Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision', World Bank, Working Paper No.61 (2005), 1 <http://documents.worldbank.org/curated/en/173701468337882214/pdf/334260rev0pub.pdf> (accessed 27/04/2020); Maskus (n 179) 565-568; Sell (n 179) 496; C Correa, 'TRIPS Agreement and Access to Drugs in Developing Countries' (2005) 3 SUR - Int'l J on Hum Rts 25, 37; E 't Hoen, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha' (2002) 3 Chi J Int'l L 27, 28

[181] In order for a creation to be patented, it must be new, have an inventive step, and be capable of industrial application, as set out in Article 27 of TRIPS

'bioequivalence' to the patented medicine.[182] Therefore the IP rights given under the patent are extremely valuable to pharmaceutical companies so that the newly created medicines can be commercially exploited. The legal protection afforded by a patent can be an incentive to pharmaceutical companies to invest in the creation of new medicines, which can increase the availability of specific medicines needed during public health crises. Patents essentially create a monopoly right over the creation which protects the creator's investment and knowledge in the product, but the prices set by pharmaceutical companies which have the monopoly on trade in these medicines while they are under patent have been criticised[183] for creating a barrier to access.

Hestermeyer argues that although patents are territorial and the comprehensiveness of rights granted by national legislation varies, the lack of patent protection in a particular country does not necessarily mean that a company is suffering loss because of a lack of a licensing regime in that territory.[184] For example, the product may not be as successful in that particular market. The absence of patent protection in some developing markets is detrimental to pharmaceutical companies. Without patent protection, there is the potential for pharmaceutical manufacturers in that country, if such capacity exists, to reverse engineer the pharmaceutical products on the market in order to manufacture copies. There is a further risk that the copies could be exported to other markets in countries with weak or no IP regimes, and sold at a cheaper cost than the original. This would provide direct competition for the original manufacturer in various international markets. This would be objectionable to the original manufacturer because the copier is profiting from the original company's investment in the product by undercutting the cost of its own product. Lack of patent protection in a territory may also dissuade investment in research and development of medicines, as the return on such investment may be at risk due to the lack of security and legal protection over the invented product. The potential growth of the domestic pharmaceutical industry in a territory could therefore be detrimentally affected, which could have implications on social and economic development.

[182] M Silverman, 'The Case for Flexible Intellectual Property Protections in the Trans-Pacific Partnership' (2014) 27 J.L. & Health 215, 226

[183] See also J Odermatt, 'Investigating new models of pharmaceutical innovation to protect the human right to health' (2009) 40(2) IIC 173; D Schroeder & P Singer, 'Access to Life-Saving Medicines and Intellectual Property Rights: An Ethical Assessment' (2011) 20 Cambridge Quarterly of Healthcare Ethics 279; Sykes (n 134) 47

[184] Hestermeyer (n 72) 38

Reichman argues that pharmaceutical companies avoid differential pricing in least developed countries because those companies will maximise their profits by selling their products at a high cost to the most affluent members of society.[185] They can do so because their patents afford a monopoly right and the lack of market competition allows them to set high prices. However the effect is to price poor countries out of purchasing essential medicines for the members of society who are most in need, and presents a barrier to access to such medicines. Consequently the trade in essential medicines can result in access to such medicines being unobtainable, particularly for developing countries which cannot commit the necessary expenditure to purchase such medicines at the market value, while they lack sufficient manufacturing capacity to invest in the research and development of medicines that their populations need.

If IP rights effectively cause the escalation of costs of essential medicines, and disincentivise research into treatments for diseases common to developing and least developed countries, then states may not be fully realising their obligations under Article 12 ICESCR. This point is raised only briefly here, with an analysis of the human rights implications of the effect of IP law, particularly in relation to patents, to be explored in more depth in subsequent chapters. If states are not fully complying with their obligations under Article 12 ICESCR then this provides an example of the challenges for states where two international legal orders converge and also the question of how to resolve tensions between the regimes so that states can meet their obligations effectively under the respective regimes. Therefore the question is whether potential tension between these legal regimes can be resolved through interpretation. In particular, can TRIPS be interpreted to serve public health interests, specifically enhancing access to medicines.

IV. Interpreting the TRIPS provisions on patents

TRIPS provides a high level of patent protection under Article 28[186], providing exclusive rights of use by the patent holder and prohibiting unauthorised use and manufacture of the patented product. This protection is limited to a period of 20 years[187]. It is important to consider how these provisions have been implemented by WTO Members in national

[185] J Reichman, "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) 32(2) Journal of Law and Medicine Ethics 10–11, 252
[186] TRIPS Agreement (n 4) Article 28
[187] ibid Article 33

law, as this will demonstrate the effect of such protection on patent holders as well as those who wish to utilise the patented product.

The term of protection is an important provision because a greater term will provide stronger protection to the patent holder, as this will provide a longer period of market exclusivity for the patented product. This was highlighted in the decision of the WTO Appellate Body in *Canada-Term of Patent Protection*.[188] This case related to the implementation of TRIPS, and the issue in dispute was whether Canada was required to extend the term of protection for patents which were granted for a lesser term under the national law before TRIPS was implemented. Prior to TRIPS coming into effect, under Section 45 of Canada's Patent Act, patents were granted for a maximum term of 17 years.[189] Canada appealed the Panel's conclusion[190] that this provision violated Article 33 of TRIPS, arguing that Article 28 VCLT[191] which establishes a non-retroactivity principle in respect of treaties was applicable. The Appellate Body considered that the non-retroactivity rule under Article 28 only applied to any situation which ceased to exist before the date that a treaty entered into force.[192] The Appellate Body interpreted that this provision established that treaty obligations would apply to any situation which continued to exist when that treaty entered into force.[193] Therefore patents existing at the time that TRIPS entered into force were subject to the obligation under TRIPS. Canada also argued that as its national patent office regularly took approximately five years to grant a patent, this period should be added to the term of protection.[194] However the Appellate Body rejected this argument as the wording of Article 33 is clear, and to interpret it in the way in which Canada proposed would lead to inconsistencies with the implementation of the provision.[195]

This case demonstrates that where a patent exists at the date of entry into force of TRIPS, the patent obligations under TRIPS will apply to those patents[196]. This has important implications as the owners of patents that were granted in Canada prior to TRIPS being in force will benefit from the additional patent protection provided. The

[188] *Canada-Term of Patent Protection*, WT/DS170/AB/R, adopted 12 October 2000
[189] *Canada-Term of Patent Protection,* WT/DS170/R, final report circulated 5 May 2000, [2.1]
[190] ibid [6.88]
[191] VCLT (n 47) Article 28
[192] ibid
[193] *Canada-Term of Patent Protection*, WT/DS170/AB/R, adopted 12 October 2000 [72]
[194] ibid [88, 96]
[195] ibid [97]
[196] Given that TRIPS came into force in 1995, this case is of historical interest now.

decision also set a precedent for the term of patent protection to be incorporated in national legislation of other WTO Members. The patent holder will benefit from an extension of the monopoly rights provided by the patent even though this obligation was not in force when the patent was granted. Therefore a larger number of patents will be subject to the term of patent protection set out in TRIPS, which indicates that this decision favours the interests of the patent holders. However, extending the term of patent protection means that generic competitors are prevented from entering the market for a further period, which fails to promote access to essential medicines, and the furtherance of public health needs.

Although TRIPS provides extensive rights for patent holders in Section 5, two categories of permitted exceptions to the exclusive rights under Article 28 are found under Articles 30 and 31[197]. The exceptions to patent rights within TRIPS could potentially be significant provisions in securing improved access to essential medicines for all. It is important to evaluate the interpretation and application of these exceptions in order to determine whether they can be used effectively to promote access to medicines.

IV(i). Article 30

Article 30 of TRIPS states:

"Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of

[197] TRIPS Agreement (n 4) Article 30-31. Academics have referred to other flexibilities within TRIPS, including parallel importation and limits on data protection. This chapter is limited to exploring the flexibilities within the two permitted exceptions to patent protection under Articles 30 and 31 because these provisions are specific exceptions to patent rights already conferred, and have received significant attention in the academic literature in the context of enhancing access to medicines. For examples of discussion of TRIPS flexibilities, see D Matthews, 'TRIPS flexibilities and access to medicines in developing countries: the problem with technical assistance and free trade agreements' (2005) 27(11) EIPR 420, 420; HM Haugen 'Human Rights and TRIPS Exclusion and Exception Provisions' (2009) 11 JWIP 345, 351; S Musungu and C Oh, Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?' World Health Organization August 2005 CIPIH Study Paper 4C <http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf> (accessed 27/04/2020)

the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

Article 30 permits WTO Members to provide limited exceptions to patent rights. The broad drafting of the provision could be construed to permit exceptions to patent rights in the legitimate interest of improving global health, allowing the patented product to be used or manufactured without the authorisation of the patent holder. However, Article 30 has not been widely relied upon[198] by WTO Members. A WTO Panel has, as of March 2020, undertaken an analysis of Article 30 in only one case, *Canada – Patent Protection for Pharmaceutical Products*[199]. The Panel's interpretation of Article 30 has been criticised as failing to give full effect to Articles 7 and 8 when interpreting the exception[200], and therefore failing to fully take into account public health measures such as improving access to medicines as legitimate interests under Article 30.

The case concerned Canada's Patent Act, specifically Section 55.2(1) and 55.2(2)[201]. Section 55.2(1) permitted generic manufacturers of pharmaceutical products to conduct testing of patented pharmaceuticals and obtain marketing approval for generic copies of the product before the expiration of the patent, with the aim of marketing the generic drug immediately upon expiry of the patent.[202] Section 55.2(2) permitted generic producers to make generic medicines and to stockpile them six months prior to the expiration of the patent, so that they would have a supply of generic medicines which could be sold immediately upon expiration of the patent.[203]

The Panel found that the regulatory review provision under Section 55.2(1) of Canada's Patent Act was legitimate, confirming that generic copies could be tested while the patented drug was still under patent protection, for the purpose of preparing the

[198] S Joseph, *Blame it on the WTO? A Human Rights Critique* (OUP, Oxford 2013), 222; A McBeth, *International Economic Actors and Human Rights* (Routledge, Oxon 2010), 141
[199] *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000
[200] S Frankel 'The WTO'S Application of 'The Customary Rules of Interpretation of Public International Law' to Intellectual Property' (2014) 4 VUWLRP 2; A Slade, 'Articles 7 and 8 of the TRIPS Agreement: A Force for Convergence within the International IP System' (2011) 14 J World Intell Prop 413; P Yu, 'The Objectives and Principles of the Trips Agreement' (2009) 46 Hous L Rev 979; HG Ruse-Khan 'The (Non) Use of Treaty Object and Purpose in Intellectual Property Disputes in the WTO' (2011) Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 11-15; R Howse, "The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times" (2000) 3 J World Intell Prop 493
[201] *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000, [3.2]
[202] ibid [2.1]
[203] ibid [2.1]

generic medicines to be marketed as soon as the patent expired[204]. However, the Panel concluded that the stockpiling of generic medicines in anticipation of the expiration of the patent was not consistent with Article 30[205]. In the course of reaching its decision the Panel established that Article 30 had three requirements which must all be satisfied in order to qualify as a permitted exception; (1) the exception must be limited; (2) the exception must not unreasonably conflict with normal exploitation of the patent; (3) the exception must not unreasonably prejudice the legitimate interests of the patent holder, taking into account the legitimate interests of third parties.[206]

(i) *'Limited' exception*

The Panel found that the regulatory review exception was a 'limited exception' as it was "confined to conduct needed to comply with the requirements of the regulatory review process"[207] and would amount to a "narrow curtailment"[208] of the legal rights of the patent holder. The reasoning for the Panel's decision was that to prohibit all manufacturing and use of the patented product would amount to an extension of the period of the patent holders' exclusivity beyond the 20 year period to the time after the patent expired that competitors could place their generic product on the market[209]. Conversely, although the stockpiling provision was only available to non-right holders who had also invoked the regulatory review provision, and was only permitted during the last six months of the patent term, the Panel concluded that this provision was not a 'limited exception'.[210] The reasoning for this decision was that the stockpiling provision did not set any limitations on the quantity of the product, and as a result this would significantly restrict the patent holder's benefit of extended market exclusivity after the patent had expired[211]. The Panel considered it unnecessary to determine whether the stockpiling provision satisfied the second and third requirements of Article 30 as it had failed to satisfy the first requirement.[212]

[204] ibid [7.84]
[205] ibid [7.36]
[206] ibid [7.20]
[207] ibid [7.45]
[208] ibid [7.44]
[209] ibid [7.59]
[210] ibid [7.34]-[7.35]
[211] ibid [7.34]-[7.35]
[212] ibid [7.38]

Hestermeyer reasons that the Panel adopted a narrow interpretation of the term 'limited' by finding that an exception is by characterisation narrow, and the inclusion of 'limited' further restricts the scope of the exception[213]. However, this narrow interpretation has been criticised as being too narrow as the Panel should have taken into account the objectives and principles of TRIPS documented in Articles 7 and 8[214]. The Panel confirmed that the WTO Dispute Settlement Body has to follow the customary rules of interpretation set out in Articles 31 and 32 VCLT when interpreting WTO agreements, including TRIPS, stating that "[T]he rules that govern the interpretation of WTO agreements are the rules of treaty interpretation stated in Articles 31 and 32 of the Vienna Convention".[215] Articles 7 and 8 of TRIPS are part of the context of Article 30 and also speak to the object and purpose of the agreement. Articles 7 and 8 recognise that a balancing of interests is required when interpreting TRIPS and that Members may adopt measures necessary to protect public health, so limited exceptions should be permitted if they pursue purposes set out in Articles 7 and 8[216]. Therefore, by failing to fully apply Articles 7 and 8 the Panel's approach fails to consider fully why an exception may be required under TRIPS, such as to ensure access to essential medicines, and so does not appropriately balance those competing interests as required under Article 7. The Panel's interpretation also contradicts the conclusion of the Appellate Body in *EC-Hormones*[217] that the characterisation of a provision as an exception does not by itself justify a stricter interpretation of that provision[218]. The Panel's approach reversed the burden of proof to requiring the respondent to demonstrate that the exception does fall within Article 30 instead of the claimant being required to demonstrate prima facie that the exception does not fall within Article 30[219]. This directly contradicts the Appellate Body's decision in *EC-Hormones*[220] which states that the general rule in dispute settlement proceedings that

[213] Hestermeyer (n 72) 235
[214] Under Article 7 objectives of TRIPS include the promotion of innovation and dissemination of technological knowledge to further social and economic welfare, and Article 8.1 states that WTO Members may within national law implement measures necessary to protect public health.
[215] *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000 [7.13]
[216] Howse (n 200) 494; M Trebilcock, R Howse, A Eliason, *The Regulation of International Trade* (4th ed Routledge, Oxon 2013), 536-538; Hestermeyer (n 72) 235-236; A Slade, 'Good Faith and the Trips Agreement: Putting Flesh on the Bones of the Trips Objectives' (2014) 63 Int'l & Comp LQ 353, 367
[217] *EC Measures Concerning Meat and Meat Products (Hormones),* WTO/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, (*EC-Hormones)*
[218] ibid [104]
[219] M Kennedy, "The "three-step test" and the burden of proof in disputes under the TRIPs Agreement" (2014) 45(2) IIC 161, 177
[220] *EC Measures Concerning Meat and Meat Products (Hormones),* WTO/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, (*EC-Hormones)*

the burden of proof lies with the claimant to establish a *prima facie* breach of a provision "is *not* avoided by simply describing that same provision as an "exception.""[221]

A further argument relating to the inconsistencies in the Panel's interpretation of Article 30 is that, in considering the patent holder's market exclusivity when finding that the stockpiling provision did not amount to a limited exception, the Panel did address the economic impact of the first requirement, even though it had in the course of its decision stated that this was not intended to be addressed by this requirement.[222] This further highlights a potential ambiguity as to the application and interpretation of the 'limited exception' requirement.

(ii) *Do not unreasonably conflict with normal exploitation of the patent*

The Panel defined the normal approach to exploitation by patent holders as having the right to "exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity."[223] The Panel also considered that the period of market exclusivity which existed after the patent had expired was 'normal'. This indicates the Panel's emphasis on protecting patent rights, by failing to balance this interest with the social interest of protecting public health by promoting better access to essential medicines. This position highlights that it is likely that the stockpiling provision would have been found to be inconsistent with this requirement of Article 30, as having an unlimited stockpile which could be marketed immediately upon expiry of the patent would inhibit the patent holder's market exclusivity. However, the Panel acknowledged that pharmaceuticals are subject to the government's regulatory review process, which can be a rigorous and lengthy process to ensure the safety and effectiveness of the product, and this form of regulatory review is not usually applicable to other types of patented products[224]. Therefore this extended period of market exclusivity for pharmaceuticals was considered to give "a greater than normal period of market exclusivity to the enforcement of certain patent rights"[225] and the

[221] *EC Measures Concerning Meat and Meat Products (Hormones),* WTO/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, (*EC-Hormones),* [104]
[222] *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000 [7.49]
[223] ibid [7.55]
[224] ibid [7.57]
[225] ibid

regulatory review provision did not unreasonably conflict with normal exploitation of the patent.

(iii) *Not unreasonably prejudice the legitimate interests of the patent holder, taking into account the legitimate interests of third parties*

The specific wording of this requirement implies a need to balance the interests of the patent holder with competing third party interests, with scope to present the argument that public health is a legitimate third party interest, with reference to Article 8(1)[226]. The Panel considered that the regulatory review provision did not unreasonably conflict with the patent holder's legitimate interests[227]. However the basis of its decision was that the "effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized that it could be regarded as a "legitimate interest" within the meaning of Article 30 of the TRIPS Agreement"[228]. This highlights that the Panel prioritised the patent holder's interests over any balancing with competing third party interests, despite the explicit language of Article 30.

The Panel's emphasis on the legitimate economic interests of the rights holders is evident in its statement that "the weight of legitimate third party interests cannot be fully appraised until the legitimacy and weight of the patent owner's legitimate interests, if any, are defined"[229]. Howse argues that by doing so "one can silence competing social and economic interests entirely by starting off with defining the rights holder's interests as so weighty or fundamental that other legitimate interests cannot possibly outweigh the prejudice to rights holder's interests."[230] This seems to suggest an imbalance, with the Panel's focus on the interests of the patent holder. In considering how else the Panel could balance this third stage of the test under Article 30, a comparison could be drawn with EU law, specifically the Court of Justice decision in *Schmidberger v Austria*[231]. The

[226] Article 8(1) states that 'Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.' TRIPS Agreement (n 4) Article 8
[227] The Panel also concluded that the regulatory review provision did not amount to discrimination against a "particular field of technology" (pharmaceuticals) as the provision did not only apply to pharmaceuticals.
[228] *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000 [7.82]
[229] ibid [7.60]
[230] Howse (n 200) 501
[231] *C-112/00, Eugen Schmidberger, Internationale Transporte und Planzüge v. Austria [2003] ECR I-5659*

Court decided that free movement of goods and the right to assembly under the ECHR were both legitimate interests, were not absolute, and were competing rights of equal weight to be weighed with regard to all circumstances to ensure a fair balancing[232]. Were the Panel to follow this approach, this would involve recognising the right to health under Article 12 ICESCR as a legitimate interest of third parties to be balanced with the legitimate interests of the patent holder under TRIPS, and applying the balancing test so as to consider not only the patent's holder's economic interests, but the right to health under Article 12 ICESCR. Therefore, applying the balancing test and giving equal weight to the competing interests.

However, a distinction may be drawn in that the *Schmidberger*[233] case outlines the recognition in EU law that the EU must respect fundamental rights as an integral part of the general principles of law and the significance the ECHR in this respect[234], so it is reasonable to propose that human rights norms of the ECHR are integrated in EU law. In comparing this position to WTO law, the Article 12 ICESCR right to health is an external norm, it is not as integrated into the WTO trade law system in contrast to the position in relation to ECHR norms in EU law, so it is difficult to argue that this level of engagement can apply in the context of WTO dispute settlement. The *Schmidberger*[235] case demonstrates engagement with a human rights norm as a general principle of law[236], and as Article 38(1) ICJ Statute outlines, 'general principles of law of civilized nations'[237] are sources of international law. Article 31(3)(c) VCLT states that any relevant rules of international law applicable in the relations between the parties shall be taken into account in treaty interpretation[238]. Article 31(3)(c) VCLT covers Article 38(1) ICJ Statute[239] so that, when interpreting a TRIPS provision, Article 12 can be taken into account *if* it has

[232] A Biondi 'Free Trade, a Mountain Road and the Right to Protest: European Economic Freedoms and Fundamental Individual Rights' (2004) E.H.R.L.R. 1; J Morijn 'Balancing Fundamental Rights and Common Market Freedoms in Union Law: Schmidberger and Omega in the Light of the European Constitution'(2006) 12(1) European Law Journal 15; C Brown, 'Case C-112/00, Eugen Schmidberger, Internationale Transporte und Planzüge v. Austria' (2003) 40(6) Common Market Law Review 1499

[233] *C-112/00, Eugen Schmidberger, Internationale Transporte und Planzüge v. Austria [2003] ECR I-5659*

[234] ibid [1071]

[235] ibid

[236] ibid [1071]

[237] ICJ Statute (n 10) Article 38(1)(c)

[238] VCLT (n 47) Article 31(3)(c)

[239] WTO Appellate Body has confirmed that the 'rules of international law' referred to in Article 31(3)(c) VCLT correspond to the sources of international law in Article 38(1) ICJ Statute including general principles of law in *United States – Anti-Dumping and Countervailing Duties (China)*, WT/DS379/AB/R, adopted 5 March 2011, [308]. So Article 31(3)(c) provides a route for the WTO DSB to apply general principles of law under Article 38(1) ICJ Statute. See Davies (n 109) 329

reached the threshold of a general principle of international law[240]. Article 12 ICESCR could be brought into the interpretative process even where it is not yet a general principle of international law, as a supplementary means of interpretation under Article 32 VCLT[241]. The rules of treaty interpretation can be utilised to allow external norms to be taken into account in the WTO framework to an extent, although perhaps not to the same extent as the level of integration of ECHR norms in EU law as outlined in *Schmidberger*[242].

The starting point for the Panel in *Canada – Patent Protection for Pharmaceutical Products* when interpreting TRIPS provisions is Article 31(1) VCLT which states: "A treaty is to be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."[243] The provisions of a treaty are to be given their ordinary meaning in their context, which is to be informed by the object and purpose of the treaty. These are not hierarchical tests, as confirmed by the ILC[244], and should be viewed as a rule of interpretation. Therefore TRIPS must be interpreted in good faith and in light of its ordinary meaning taking into account its objectives and purpose, which are embodied in Articles 7 and 8. Articles 7 and 8 are directly about interpreting TRIPS, and are therefore treaty interpretation provisions internal to TRIPS, which the Panel should have referred to in interpreting Article 30. The relevance of Articles 7 and 8 to the interpretation of TRIPS provisions was recognised in this case, with the Panel stating that they must be "borne in mind"[245] when interpreting Article 30. However this does not go far enough. Article 30 is a permitted exception to patent rules so is qualified, but its object and purpose and Articles 7 and 8 must be considered when interpreting the provision. This requires a balancing of these standards but it is questionable if the Panel got the balance right

[240] It is not argued in this thesis that Article 12 has reached the threshold of a general principle of international law.
[241] Article 32 VCLT states that "Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31: (a) leaves the meaning ambiguous or obscure; or (b) leads to a result which is manifestly absurd or unreasonable." See also See Davies (n 109) 329
[242] *C-112/00, Eugen Schmidberger, Internationale Transporte und Planzüge v. Austria [2003] ECR I-5659*
[243] VCLT (n 47) Article 31(1)
[244] The ILC stated that Article 31(1) 'when read as a whole, cannot properly be regarded as laying down a legal hierarchy of norms for the interpretation of treaties'. See Yearbook of the International Law Commission, The International Law Commission's Commentary on Articles 27 to 29 of its Final draft Articles on the Law of Treaties, 1966, Volume II (United Nations, New York 1967), 219-220
[245] *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000 [7.26]

because it did not provide an appropriate analysis of Articles 7 and 8. The Panel's position indicates a missed opportunity to adopt an interpretation of Article 30 in line with the objectives of TRIPS Articles 7 and 8, in order to set a precedent in dispute resolution proceedings that the protection of public health is a legitimate exception to patent protection. The narrow interpretation of this requirement and the focus on the potential economic losses of the patent holder failed to adequately identify when a legitimate interest of third parties can justify an exception to patent protection for pharmaceuticals under Article 30. The regulatory review and stockpiling measures have been described as "incidental measures"[246], which suggests that if these provisions are considered narrowly then other, more significant provisions introduced to reduce the price of patented medicines may be held to be inconsistent with TRIPS obligations.

Rights holders are likely to take the view that Article 30 as an exception should be interpreted narrowly. However, academics have expressed a lack of support for this view[247]. Academic literature has highlighted that the Panel appears to indicate that the individual provisions in TRIPS, such as Article 30, which set minimum standards of IP rights protection already reflect the intended balance outlined in the Preamble[248] and so Articles 7 and 8 need not be considered[249]. Frankel and Slade argue that this is not what Article 31 VCLT suggests is correct treaty interpretation as this would mean that Articles 7 and 8 have no meaning[250]. This does not seem to be the correct approach as it cannot be the intentions of the parties to TRIPS for Articles 7 and 8 to have no practical effect. Yu points out the importance of Articles 7 and 8 to developing countries in terms of establishing that IP rights are intended to benefit society as a whole[251]. Therefore it is important to give due weight to Articles 7 and 8 in accordance with general rules of treaty interpretation so that a proper balancing is carried out. Discussions in the literature have further proposed that Articles 7 and 8 could be used to define a maximum standard of IP protection[252], although this approach could go too far in having a limiting effect on the

[246] Joseph (n 198) 222
[247] Slade (n 200); HG Ruse-Khan, 'A Conflict-of-Laws Approach to Competing Rationalities in International Law: The Case of Plain Packaging between Intellectual Property, Trade, Investment and Health' (2013) 9 J Priv Int'l L 309; Frankel (n 200); Slade (n 216)
[248] TRIPS Agreement (n 4), Preamble
[249] Frankel (n 200) 22; Slade (n 200) 414; Ruse-Khan (n 200) 29
[250] Frankel (n 200) 22; Slade (n 216) 368
[251] Yu (n 200) 1004-1007
[252] A Kur and HG Ruse-Khan 'Enough is enough – the notion of binding ceilings in international intellectual property protection' (2009) Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series No. 09-01, 45; Yu (n 200) 1034

flexibilities within TRIPS and the flexibility of Members to implement the most appropriate IP standards in national law. While this view may be a little too expansive in terms of the intentions of the parties to the agreement, the Panel should consider the value of Articles 7 and 8 for interpretive purposes when interpreting Article 30.

When discussing the three-stage test, The Panel referred to legitimate interests as those that are justifiable in that they "are supported by relevant public policies or other social norms"[253]. Therefore interpreting a 'legitimate interest' to include wider social interests such as public health and the objectives in Articles 7 and 8 would indicate a more balanced test. The Panel should have broadened discussion of the interpretation of 'legitimate interest' with reference to Articles 7 and 8, and then the issue of access to medicines as balanced with the interests of the right holder[254]. By considering all of the relevant circumstances including not only the patent holder's economic interests, but the interests of the users of the patented medicines, and wider societal interests in relation to promoting public health, this could have led to a more even balancing under the three-stage test. However, the Panel primarily considered the potential economic loss to the right holder,[255] and in doing so interpreted the patent provisions of TRIPS from the perspective of the patent holder, failing to carry out an appropriate balancing provided for in the objectives and purpose of TRIPS in Articles 7 and 8, and failing to interpret TRIPS in light of the customary rules of treaty interpretation under Article 31 VCLT. Therefore the Panel decision did not adequately consider the issue of access to essential medicines as a serious public health concern, and reduced "considerably the range of regulatory diversity permitted under TRIPS"[256]. The failure to balance social interests and economic interests, despite this balancing of obligations being a stated purpose within TRIPS Articles 7 and 8 brings into question the efficacy of the scope of the Article 30 exception in improving access to cheaper generic medicines. Therefore reliance upon this provision by WTO Members is unlikely, and if the exception cannot be utilised then its purpose is undermined.

(iv) Implications resulting from the Panel decision

[253] *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000 [7.69]
[254] Ruse-Khan (n 200) 30; Haugen (n 197) 357; Frankel (n 200) 23
[255] *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000 [7.49]
[256] Howse (n 200) 494

Following this decision it is difficult to be optimistic as to whether the WTO Dispute Settlement Body (DSB) will take full account of the right to health under Article 12 ICESCR in its interpretation and implementation of Article 30 TRIPS, as the Panel in this case did not pay due attention to the provisions in TRIPS to assist in its interpretation. However, Frankel argues this is exactly the analysis that the object and purpose of the TRIPS Agreement requires a Panel to do, and the failure to apply Article 31 VCLT interpretation to its fullest extent and then having recourse to Article 32 leaves the Panel decision open to criticism[257]. This analysis suggests that, had the Panel fully applied the customary rules of interpretation in VCLT, and the internal interpretive provisions in Articles 7 and 8, the outcome in relation to the stockpiling provisions could have been decided differently, which would have been a positive outcome in relation to enhancing access to medicines.

Although the Panel did not pronounce on the interpretation of Articles 7 and 8 in relation to Article 30, a positive perspective is that the Appellate Body can do so in future cases. The Appellate Body did not pronounce on Articles 7 and 8 in *Canada – Term of Patent Protection*, stating that they still await appropriate interpretation[258], but in light of the criticism of the Panel decision in *Canada-Patent Protection for Pharmaceutical Products*[259] the Appellate Body might take the view of providing some clarification in future. Going forward, the Doha Declaration provides an authoritative interpretation of TRIPS, and gives more weight to the need for a proper balancing and consideration of Articles 7 and 8 for the purpose of public health. Paragraph 5 of the Doha Declaration confirms the need to interpret TRIPS provisions in light of its object and purpose outlined in Articles 7 and 8[260]. The Doha Declaration is a 'subsequent agreement' under Article 31(3)(a) VCLT[261], and therefore should be taken into account when interpreting TRIPS. The Doha Declaration also confirmed that TRIPS should be interpreted in a manner supportive of WTO Members' right to protect public health, in particular to promote

[257] Frankel (n 200) 23

[258] *Canada-Term of Patent Protection*, WT/DS170/AB/R, adopted 12 October 2000, [101]

[259] *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000

[260] Doha Declaration (n 92) Paragraph 5(a)

[261] F Abbott 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 JIEL 469; 491; JT Gathii 'The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties' (2002) 15 Harvard Journal of Law and Technology 291; D Shanker, 'The Vienna Convention on the Law of Treaties, the Dispute Settlement System of the WTO and the Doha Declaration on the TRIPs Agreement' (2002) 36(4) Journal of World Trade 721

access to medicines[262]. A further cause for optimism is the Panel decision in the recent *Plain Packaging*[263] case, where, in relation to the interpretation of an exception to trademark protection under Article 20, the Panel affirmed that TRIPS is to be interpreted in light of the provision in Article 8 that Members may adopt measures to protect public health[264]. The Panel also found that the Doha Declaration was a subsequent agreement under Article 31(3)(a) VCLT and TRIPS must therefore be interpreted in light of paragraph 5 of the Declaration[265]. Therefore, this decision could have an important impact in future cases relating to Article 30 TRIPS in terms of the appropriate interpretation of the exception to give due weight to Article 8 and Members' public health objectives, including to improve access to medicines.

IV(ii). Article 31

Article 31 details the circumstances where other use of a patented product can be permitted without the authorisation of the patent holder, provided that the conditions in Article 31(a)-(l) are satisfied. Article 31 states:

"Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of national emergency

[262] Doha Declaration (n 92) Paragraph 4
[263] *Australia - Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging (Plain Packaging*), WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R (adopted 27 August 2018)
[264] ibid [7.2408]
[265] ibid [7.2409]

or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

> *(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;*
>
> *(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and*
>
> *(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent."*

Although not explicitly stated, this provision applies to the practice of compulsory licensing.[266] Compulsory licensing under TRIPS has been utilised in relation to medicines where a WTO Member that has implemented TRIPS into national legislation, grants a licence to a generic manufacturer to produce a medicine that is under patent in that Member state at cheaper cost. This licence is granted without the patent holder's

[266] Taubman, Wager and Watal (eds) (n 146) 109

authorisation irrespective of the holder's exclusive rights over the patented medicine. Compulsory licences can be issued by governments and such licences are not restricted to the manufacturer which holds the patent, but can also be issued to other pharmaceutical manufacturers. Multiple manufacturers producing generic copies of the patented medicine can increase competition in the market leading to lower prices. Increased production of such medicine will also lead to an increased supply, with the aim of ensuring that essential medicines are available at an affordable cost during public health emergencies. The construction of Article 31 indicates that the provision does not explicitly set limitations on the grounds upon which compulsory licenses can be granted but merely states the conditions that WTO Members should observe, although all conditions are mandatory.[267] Therefore, WTO Members have flexibility as to how to utilise this provision, in theory assisting WTO Members in developing better access to essential medicines by allowing WTO Members to circumvent a patent in order to make available medicines to treat public health crises. If the WTO Members clearly outlined the circumstances in which compulsory licences may be requested, this could add an additional impediment for WTO Members aiming to use Article 31. While the WTO Members have the flexibility to implement compulsory licensing provisions to satisfy domestic requirements, the additional structural and legislative burden before a compulsory licence could be granted may result in less flexibility and deter some WTO Members from engaging in the process. This flexibility gives Members scope to use this provision for public health purposes, however Members, in particular developing countries have faced challenges is using this provision to enhance access to medicines.

Matthews argues that this challenge existed because the exception provision under Article 31 was too onerous for developing countries to use, due to the requirements within Article 31 (a)-(l) above, which must be respected before a compulsory licence could validly be issued[268]. Developing countries may lack the bargaining power by which to attempt to negotiate a voluntary licence in the first instance, as is required under Article

[267] K-J Ni, "Legal aspects (barriers) of granting compulsory licenses for clean technologies in light of WTO/TRIPS rules: promise or mirage?" (2015) 14(4) WTR 701, 710; S Ford, 'Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents' (2000) 5 AUILR 15 941, 961; T Cottier 'TRIPS, the Doha Declaration and Public Health' (2003) 6(2) Journal of World Intellectual Property 373, 386; F Abbott 'WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries' Commission on Intellectual Property Rights (UK) Study Paper 2a (2002) 13; P Champ and A Attaran 'Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute' (2002) 27 Yale Journal of International Law 365, 368

[268] Matthews (n 197) 420-421

31(b). It is also unclear as to what would amount to a 'reasonable' period of time in which to negotiate before it is permissible to pursue a compulsory licence. Article 31(h) does not explicitly state what amounts to 'adequate remuneration' which was to be paid to the patent holder whose patent was circumvented by the compulsory licence. If 'adequate' remuneration was required to be almost the present market value, then the issuing of the compulsory licence would be futile.

A particular problem with the provisions under Article 31 has related to Article 31(f), which required that the medicines for which a compulsory licence was issued had to be predominantly for the domestic use of the WTO Member which issued that licence. This was problematic for WTO Members, particularly developing and least developed states that do not have the requisite manufacturing capacity to produce the necessary medicines for domestic use, and therefore relied on imports [269]. There is a clearly held view in the academic literature that Article 31 has failed to assist least developed and developing countries, which need the most support as these countries have little or no manufacturing capacity and therefore could not rely on the compulsory licensing provision[270]. This provision also prevented developing countries from importing essential medicines from countries with the necessary manufacturing capacity. WHO observed that compulsory licensing "is useful for the small group of developing countries (such as Brazil, India, and South Africa) that have a high-quality generics sector with the know-how and capacity to produce for the home market"[271]. However this provision is of little use to those countries lacking the capacity to produce pharmaceuticals domestically and therefore must import medicines which are under patent. Developing and developed countries with manufacturing capacity could not export because of this requirement, demonstrating an impediment to access and availability because they could not meet the non-domestic demand for essential medicines. States with the manufacturing capacity risked litigation from the patent holders if they misinterpreted the TRIPS flexibilities and scope.

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[269] S Bartelt 'Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health' (2005) 6(2) Journal of World Intellectual Property 283, 288; G Curci and M Vittori, 'Improving Access to Life-Saving Patented Drugs: Between Compulsory Licensing and Differential Pricing' (2004) 7 J World Intell Prop 739, 744

[270] Matthews (n 72) 82; K Paas, 'Compulsory licensing under the TRIPs Agreement - a cruel taunt for developing countries?' (2009) 31(12) EIPR 609, 610; Matthews (n 197) 420; B Mercurio, 'Trips, Patents, and Access to Life-Saving Drugs in the Developing World' (2004) 8 Marq Intell Prop L Rev 211, 223

[271] World Health Organization Commission on Macroeconomics and Health, 'Investing in Health for Economic Development' (2001), P.90, <http://apps.who.int/iris/bitstream/10665/42435/1/924154550X.pdf > (accessed 27/04/2020)

A number of disputes relating to compulsory licensing brought the debate to the fore[272]. In 1998 thirty-nine pharmaceutical companies challenged the South African government in its constitutional court over its national legislation relating to compulsory licensing and parallel imports of medicines patented in South Africa. However the negative reaction to this action and subsequent bad publicity caused the action to be withdrawn.[273] In 2001 the US government took an action to the WTO against Brazil, which had issued compulsory licences for medicines owned by US pharmaceutical companies that were patented in, but had not been produced in Brazil. This action was also settled.[274] Also in 2001, following 9/11, USA and Canada were subject to anthrax threats, and used the threat of issuing a compulsory licence to negotiate a voluntary licence with the German pharmaceutical company Bayer for the production of its patented drug for the treatment of anthrax.[275] This action appeared as a double standard following the US approach to Brazil. Abbott argues that "no responsible government with a choice would place the public health of its citizens below the interests of a few patent holders"[276], but in reality it is difficult for developing countries to use the threat of issuing a compulsory licence as an inducement in negotiations for a voluntary licence, because of their generally weaker position in the global market. There is a risk for developing countries that in making such threats, they will bear consequences in future trade negotiations, and will lose any goodwill with the patent holder companies.[277] For example, in 2007 Thailand was subjected to international political pressure, as a result of issuing a compulsory licence for Kaletra, a medicine used to treat HIV owned by Abbott Laboratories in the US.[278] Such pressure came from US and EU despite that fact that the compulsory licence was legitimately issued. Following the issue of the compulsory

[272]Matthews (n 72) 78; Curci and Vittori (n 269) 745; H Sun, 'The road to Doha and beyond: some reflections on the TRIPS Agreement and public health' (2004) 15(1) European Journal of International Law 123; R Wolfe, 'First Diagnose, then treat: what ails the Doha Round?' (2015) 14(1) WTR 7; Trebilcock, Howse and Eliason (n 92) 546.

[273] Matthews (n 72) 78; Curci and Vittori (n 269) 745; Mercurio (n 270) 223; Sun ibid 131; Correa and Matthews (n 179) 6

[274] S Andemariam, 'The cleft-stick between antiretroviral drug patents and HIV/AIDS victims: an in-depth analysis of the WTO's TRIPs Article 31 bis amendment proposal of 6 December 2005' (2007) 4 IPQ 414, 446

[275] F Abbott, 'The Doha Declaration On The Trips Agreement And Public health: Lighting A Dark Corner At The WTO' (2002) 5(2) JIEL 469, 487-488

[276] ibid 488

[277] E Van Zimmeren, 'A Paper Tiger? Compulsory License Regimes for Public Health in Europe' (2011) 42(1) IIC 4, 23

[278] J Wakely, 'The impact of external factors on the effectiveness of compulsory licensing as a means of increasing access to medicines in developing countries' (2011) 33(12) EIPR 756, 766-767

licence, the patent holding company decided to withdraw applications for regulatory approval of several other medicines from Thailand. Although in this case the Thai government had not attempted to negotiate a voluntary licence on this occasion[279], the reaction of the patent holder company demonstrates that a compulsory licence can be a hostile device and may result in retaliatory measures. Therefore the threat of a compulsory licence may be ineffective as well as counterproductive for developing countries.

V. Doha Declaration

The Doha Declaration[280] sought to address the challenges of Members lacking manufacturing capacity to make use of the compulsory licensing provision under Article 31. The Declaration affirmed that "the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[281] The Declaration provided explicit clarification that TRIPS can and should be interpreted by WTO Members in such manner as necessary to promote public health and to combat public health crises, and is a significant statement on the interpretation of TRIPS. This also supports the objective set out in Article 8, adding further clarity to the existing interpretative framework of TRIPS. Paragraph 5 also confirms that Members have discretion as to the grounds and circumstances as to when a compulsory licence can be granted, confirming that Article 31 does not limit the grounds for the grant of a compulsory licence[282]. Paragraph 5 also provides clarity with regard to the discretion of Members to determine a 'national emergency', and recognises that public health crises can be a national emergency, justifying the grant of a compulsory licence without prior negotiation on a voluntary licence[283]. As discussed in Chapter 1, the Declaration amounts to a subsequent agreement under Article 31 VCLT and is therefore an important tool for the interpretation of TRIPS in light of public health objectives including access to medicines.

[279] The Thai government had previously unsuccessfully attempted to negotiate a voluntary licence with the patent holder company. See also Wakely ibid 767
[280] Doha Declaration (n 92)
[281] ibid [4]
[282] ibid [5(b)]
[283] ibid [5(c)]

The route to the Doha Declaration was driven by global health crises, primarily the HIV/AIDS pandemic. The access to medicines debate was placed on the agenda of the General Council meeting in 2001 by African nations[284], with the developing countries sending "a clear signal that they were determined to reverse the unbalanced outcome of the Uruguay Round in the future new round of multilateral trade negotiations"[285] by requesting clarification on the interpretation and application of the flexibilities within TRIPS, specifically in relation to access to medicines. The result was the adoption of the Doha Declaration by the WTO Ministerial Conference on 14 November 2001.

The Declaration included a clear statement in paragraph 6 that:

"[W]e recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."[286]

The Implementation Decision[287] of TRIPS Council on 30 August 2003, in satisfaction of paragraph 6 of the Doha Declaration, stated that:

"The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:"[288]

This amounted to a waiver of the obligation on exporting WTO Members under Article 31(f) to allow export of medicines to countries without sufficient manufacturing capacity. Also agreed was a waiver of the domestic use obligation under Article 31(h) for importing

[284] Gervais (n 143) 48
[285] Sun (n 272) 136
[286] Doha Declaration (n 92) [6]
[287] Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (30 August 2003) WT/L/540. (Herein referred to as the Implementation Decision)
[288] ibid [2]

countries to provide adequate remuneration where the exporting country has already paid the remuneration for the same product.[289] The reference to 'pharmaceutical products' also demonstrates that the Decision was not limited to medicines only, permitting a wider scope for the type of products which may be imported.

The Implementation Decision was a significant development from the Doha Declaration, as developing countries were permitted to import medicines under a compulsory licence with the General Council agreeing a temporary waiver of the domestic use requirement under Article 31(f),[290] referred to as the 'paragraph 6 waiver'. This meant that the exporting WTO Member was not required to produce the pharmaceuticals predominantly for domestic use, and could produce the quantity of necessary medicines to meet the demand of a developing WTO Member. This provision was intended to make the compulsory licensing provision in TRIPS more effective, as developing and least developed countries with the inability to manufacture the medicines domestically were unable to utilise this TRIPS provision. However discussion in the literature reflects the view that the Declaration and Implementation Decision did not eliminate all of the problems generated by TRIPS, and related concerns including that economic pressures would dissuade developing countries from utilising the waiver.[291] This raises the question of how effective the Implementation Decision has been in improving access to medicines.

As noted in Chapter 1, the General Council Ministerial Decision on 6 December 2005[292] provided for an amendment to TRIPS to insert Article 31(*bis*). This amendment incorporates the TRIPS Council Decision on the implementation of paragraph 6 of the Doha Declaration into TRIPS, ensuring that the waiver of the domestic use requirement under Article 31(f) becomes permanent. This is the only amendment to TRIPS, which it could be argued demonstrates that the agreement itself is working appropriately. The

[289] ibid [3]

[290] Compulsory licensing allows for the legitimate use of IP under a patent without the authorisation of the patent holder, in specific circumstances, as set out in Article 31 of TRIPS. The Implementation Decision provided for a waiver of Article 31(f) TRIPS Agreement under paragraph 6 of the Doha Declaration, to allow manufacturing of patented medicines to for export (not only for domestic use).

[291] Abbott (n 70) 24; P Vandoren and JC Van Eeckhaute, 'The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making it Work' (2003) 6(6) JWIP 779, 780; Sun (n 272) 125

[292] Decision on Amendment of the TRIPS Agreement (6 December 2005) WT/L/641

amendment was approved by the requisite number of WTO Members on 23 January 2017[293], eleven years after it was approved by the General Council.

VI. After Doha

An objective of the Implementation Decision was to ensure that newer medicines reached individuals in need more rapidly[294], by clarifying that WTO Members had the freedom to realise national public health objectives by using the harmonised IP provisions under TRIPS. However, the Implementation Decision was another compromise between the competing interests of the needs of developing and least developed countries seeking greater clarity on the flexibilities of TRIPS in respect of manufacturing patented medicines to treat health emergencies, and those WTO Members with large pharmaceutical manufacturing industries that wanted to preserve strict IP protection. An example of the compromise is evident in the requirements that must be satisfied in order to take advantage of the paragraph 6 waiver. In particular, the requirements that the exported product must be clearly labelled and distinguishable from the patented version in terms of shape, colour and packaging demonstrates a compromise between ensuring that compulsory licensing could be used effectively for the furtherance of global public health aims, and the developed Members' concerns over trade diversion of the exported product. A United Nations Development Programme (UNDP) Discussion Paper[295] reviewing the implications of the Doha Declaration over a ten year period noted that the Doha Declaration was a significant achievement as it recognised the severity of the public health problems in developing and least developed countries. It also acknowledged the issue of cost of medicines and the effect of TRIPS on medicine prices, and emphasised that governments have a duty to interpret TRIPS as necessary to achieve public health goals.

This Discussion Paper specifically addressed the tensions between the Doha Declaration and the right to health, noting the conflict, in certain contexts, between IP as an incentive to stimulate innovation and the international human right to health.[296] The

[293] World Trade Organization, '2017 news items: WTO IP rules amended to ease poor countries' access to affordable medicines' 23 January 2017, <https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm> (accessed 27/04/2020)
[294] Implementation Decision (n 287) Preamble
[295] Correa and Matthews (n 179)
[296] ibid 13

Paper also considered the extent to which the Doha Declaration has contributed to achieving its main objective, being confirmation of the right of any WTO Member to use the TRIPS flexibilities to promote access to medicines. It concluded that while the Doha Declaration "has had a clear impact on the international discourse relating to IPRs and access to medicines",[297] it "has not been sufficient to prevent TRIPS-plus demands, concession and commitments in FTAs and other bilateral agreements that may negatively affect access to medicines."[298] The Paper places the review of the Doha Declaration in a human rights context and emphasises the urgent need to find a solution to impediments to access and availability.[299] However the Paper's conclusion on the success of the Doha Declaration in achieving its objective demonstrates that while it succeeded in bringing to an international platform the debate on affordability and access to medicines, it has so far not been successful in achieving improvements to access to essential medicines for all.

Matthews argues that the ineffectiveness of the Doha Declaration is that the compulsory licensing process resulting from the Implementation Decision is burdensome and arduous to use[300]. Both the importing and exporting countries have to issue compulsory licences and the importing country has to demonstrate insufficient manufacturing capacity. The Decision does not prescribe a specific method of establishing insufficient manufacturing capacity,[301] which may cause uncertainty as to which countries may rely on this provision. Administrative requirements must also be complied with, including issuing notice to the WTO. The information required includes the quantities required by the importing country, and the use for the drug and requires detailed information from the importing country at the outset. Information on the specific labelling and marking of the drug is required to counteract the risk of parallel importation. This requirement can be costly for the exporting country, and as a result this may act as a disincentive to generic manufacturers to engage in exporting medicines to developing and least developed countries. Another issue is that the process "fails to take into account that flexibility and rapidity of response to ever-changing circumstances are vital"[302], highlighting that these onerous requirements must be satisfied before the compulsory licence can be issued. This also reflects that access to medicines in emergencies during

[297] ibid 23
[298] ibid 23
[299] ibid 12
[300] Matthews (n 197) 422
[301] Vandoren and Van Eeckhaute (n 291) 785; Mercurio (n 270) 240; Abbott and Reichman (n 70) 939
[302] Paas (n 270) 613

public health crises requires immediate action, which may be difficult to respond to under the current compulsory licensing requirements.

The paragraph 6 waiver resulting from the Implementation Decision amounted to an exception to the domestic use restriction under Article 31(f). This exception amounts to a waiver of the restriction on exports of pharmaceuticals, allowing any WTO member to export pharmaceutical products, produced under compulsory licensing, to countries with no manufacturing capacity in the pharmaceutical industry. Difficulties in the application of this mechanism can be evidenced by the fact that there has been only one case where this has been relied upon in over ten years since the waiver was agreed. In 2007 the Canadian and Rwandan governments issued compulsory licences for Canadian generic manufacturer Apotex to supply Rwanda with antiretroviral drug Apo-Triavir to treat HIV/AIDS. In accordance with the requirements of the Implementation Decision[303] Rwanda as the importing WTO Member had to notify the TRIPS Council of its need. Then it was required to specify the names and expected quantities of the product(s) needed; to confirm that it had insufficient or no manufacturing capacity in the pharmaceutical sector;[304] and to confirm that it had granted or intended to grant a compulsory licence in relation to the required product. Canada as the exporting Member had to issue a compulsory licence upon the conditions that only the quantity of pharmaceutical products necessary to meet Rwanda's needs was to be manufactured and exported, the pharmaceutical products produced under the licence were to be clearly distinguishable from the patented product. Prior to exporting the product manufactured under the licence, the information relating to the quantity and distinguishing features of the product was posted on the WTO website.

This transaction was only completed on one occasion, with a single supply of the required medicines being provided to the importing country. Apotex was critical of the process, arguing that the "fact that countries cannot place a simple order or extend a tender for a specific product but have to initiate what is perceived to be a 'political' or legal process is in itself intimidating."[305] This supports the assertion that the administrative requirements are demanding, particularly as the need is a public health need which should be managed expeditiously. The company also commented that the "process is, for the

[303] Implementation Decision (n 287) [2(a)]

[304] Under paragraph 2(a)(ii), least developed Members are not required to satisfy this condition.

[305] Apotex Inc., 'Submission to the Standing Committee on Industry, Science and Technology; Bill C-393, An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act' (October 26, 2010), 3 (See Annex III)

most part, invisible to most agencies in countries that would access it."[306] This suggests that developing WTO Members are not taking advantage of the paragraph 6 waiver because the relevant governments are unaware or uninformed of the availability of this process. It may be contended that greater support from developed WTO Members is needed for importing Members during the application process, instead of a focus on protection of the patent holder's product. Developed Members which have sufficient expertise could provide technical assistance which may help to make this mechanism more effective. This further indicates that support from developed WTO Members could be valuable in apprising developing Members of the process.

Apotex, as of March 2020 the only pharmaceutical manufacturer to have been through the complete process of using the paragraph 6 waiver to supply generic antiretroviral drugs, has not repeated the process. The company's experience highlights why developing countries are unlikely to rely on the paragraph 6 waiver to import generic medicines. If the manufacturing industries within developed WTO Member countries considered that it was difficult to satisfy the export requirements under the mechanism then it is unlikely that they would continue to use it. If developing WTO Members cannot engage a developed Member with sufficient manufacturing capacity with the process then the problem of providing an adequate supply of medicines to the population is not resolved.

Academics have proposed several reasons for the lack of use of the waiver, including that the cost of the medicines imported by Rwanda was still higher than the cost of comparable Indian generic medicines[307]. This suggests that in addition to the process being burdensome, it was also not cost-effective and does not achieve the purpose of promoting the use of compulsory licensing for pharmaceuticals to treat pandemics and life limiting diseases. A further issue is that the waiver fails to allow developing countries to take advantage of cheaper generic medicines through economies of scale.[308] This is problematic in terms of encouraging generic manufacturers to invest in producing medicines under the Canadian regime, as the limitations on the quantities of medicines

[306] ibid 4

[307] Beall and Kuhn (n 134) 4; G Tsai, 'Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes under the WTO Doha Declaration' (2009) 49 Va J Int'l L 1063, 1081; S Lee, 'Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6' (2013) 44 Geo J Int'l L 1387, 1404

[308] J Wakely, 'Compulsory licensing under TRIPs: an effective tool to increase access to medicines in developing and least developed countries?'(2011) 33(5) EIPR 299, 307; Lee (n 307) 1405

would make it difficult to recoup the development costs. It is a significant challenge as although the Canadian regime was implemented for the purpose of promoting access to medicines, it is the pharmaceutical companies which manufacture the generic medicines to be ordered under the regime, and as commercial enterprises they are unlikely to enter into a commercial arrangement where they stand to make a loss.

Another suggested reason is that the lack of dedication in supporting developing countries to take the opportunity to utilise the waiver demonstrates that developed WTO Members are not willing to share in the transfer of technology to developing countries, which could assist them in developing production capacity to meet the needs of their own population.[309] Under Article 67 of TRIPS, developed Members have an obligation to provide financial and technical cooperation to developing and least developed Members for the purpose of implementing TRIPS. This suggests that TRIPS has not supported developing countries in their development because they are still reliant upon developed Members for imports, and have not benefitted from transfer of technology in order to develop domestic production. It questions the effectiveness of the Implementation Decision. It is clear that the aim of the Implementation Decision in providing greater accessibility to essential medicines for developing countries has so far not been achieved, and may indicate that developed countries have focused on the protection of intellectual property afforded by TRIPS rather than the dissemination of knowledge and technology transfer to developing countries which the agreement can support.

In contrast, Sykes argues that the Doha Declaration could lead to the erosion of patent protection of pharmaceuticals in developing countries.[310] Specific concern related to the compulsory licensing provision in Article 31(f) which provided that a country could issue a compulsory licence in a national emergency without notice to or negotiation with the patent holder.[311] Sykes argues that strong patent rights for pharmaceuticals are necessary for international trade which in turn will benefit developing countries in the long term as the strong patent rights will encourage innovation, which will benefit

[309] R Amollo, 'Revisiting the TRIPS regime: Rwanda-Canadian ARV drug deal "tests" the WTO General Council decision' (2009) 17(2) AJICL 240, 269; M Mellino, 'The TRIPS Agreement: Helping or Hurting Least Developed Countries' Access to Essential Pharmaceuticals' (2010) 20 Fordham Intell Prop Media & Ent LJ 1349, 1379; R Elliott 'Delivery Past Due: Global Precedent set under Canada's Access to Medicines Regime' (2008) 13 (1) HIV/AIDS Policy & Law Review, 7; M Rimmer 'Race against Time: The Export of Essential Medicines to Rwanda' (2008) Public Health Ethics 89, 14

[310] Sykes (n 134) 56

[311] ibid

developing countries in the long term.[312] It is important to note that patent holders are entitled to challenge a compulsory licence on particular grounds, for example, non-compliance with the legal requirements,[313] which may undermine this argument. While innovation is necessary to advance medical technologies in order to improve treatment for those in need, this position does not address the issue that developing countries are still reliant on the exporting country to issue a compulsory licence under the waiver. This in turn demonstrates that the developing countries are dependent on other countries to provide the particular medicines needed. This position also does not support the development of developing and least developed countries in assisting them to establish the capabilities to increase and improve their own manufacturing capacities, to manufacture the medicines that are needed domestically.

VII. Implications for public health

The experience of the participants in the Canadian regime suggests that there are significant public health concerns resulting from the provisions in TRIPS, and these have not successfully been addressed by the Doha Declaration. The Doha Declaration, and subsequent Implementation Decision, was a positive development in terms of promoting public health as it was a response to addressing the immediate problem of access to medicines. However, the challenges experienced by the participants in the Canadian regime in utilising the waiver, coupled with the fact that no other states have attempted to utilise the waiver, shows that this mechanism has not been effective in achieving its aim of promoting access to medicines[314]. It is important to acknowledge that the issue of global access to essential medicines requires a response which is much broader than simply amending intellectual property protection. Inadequate domestic health care systems, lack of infrastructure to distribute medicines in developing and least developed countries, and procedural and legislative problems involved in issuing compulsory

[312] ibid 57

[313] E Beas Rodrigues Jr, *The General Exception Clauses of the TRIPS Agreement (*CUP, Cambridge 2012), 198

[314] R Elliott, 'Delivering on the Pledge: Global Access to Medicine, WTO Rules, and Reforming Canada's Law on Compulsory Licensing for Export' (2007) 3 McGill Int'l J Sust Dev L & Pol'y 23, 67; A Attaran, 'Why Canada's Access to Medicines Regime Can Never Succeed' (2010) 60 UNBLJ 150; Mellino (n 309) 1376; G O'Farrell, 'One small step or one giant leap towards access to medicines for all?' (2008) 30(6) European Intellectual Property Review 211, 212; O Owoeye, "International patents law and public health: revisiting the TRIPS compulsory licensing regime and the Doha Paragraph 6 System" (2015) 37(12) European Intellectual Property Review 782, 789; Tsai (n 307) 1097

licences are all contributing factors. While the Implementation Decision may have provided clarification on the flexibilities in TRIPS, and provides an important interpretative tool in the analysis of Article 31(f) of TRIPS, it alone cannot provide the answer to the problem of improving accessibility and availability of essential medicines. Abbott and Reichman also point out that the restrictive administrative requirements of Article 31(*bis*) suggested that the provision resulted as a compromise with the pharmaceutical industry, and that it would be difficult to foresee further negotiations on the issue within the WTO[315]. This would indicate a further series of compromises, as well as highlighting that pressure from the pharmaceutical industry on pricing is also a significant issue for states. However, as the paragraph 6 waiver is a measure which was specifically implemented to improve access to medicines and has not successfully achieved this, it is important to explore whether the waiver could be utilised more effectively in order to achieve its aim of securing access to medicines for developing states.

In 2015 the WTO produced a working paper[316] analysing the impact of the paragraph 6 waiver and the ways in which it has been implemented by WTO Members. The paper surveyed the methods of implementation, finding that as of July 2015, 51 WTO Members had adopted specific implementation provisions at varying levels of detail.[317] It suggests that the system may be a useful tool for encouraging generic manufacturers to participate in the provision of medicines to developing countries, which could stimulate competition between creator and generic companies. The paper also found that the system "has the potential to serve as a significant procurement tool for access to medicines by expanding the base of trade opportunities to meet demand for medicines"[318]. Such opportunities may include the manufacturing of generic medicines leading to increased competition in the market, and promoting favourable trading relationships between importing and exporting Members. However, little use has been made of this so far. The paper was also critical of the annual review mechanism of the paragraph 6 system included in the Implementation Decision, which confirmed that the implementation and

[315] Abbott and Reichman (n 70) 984

[316] R Kampf, World Trade Organization Economic Research and Statistics Division, 'Special Compulsory Licences for Export of Medicines: Key Features of WTO Members' Implementing Legislation' (Staff Working Paper) (31 July 2015) ERSD-2015-07 <https://www.wto.org/english/res_e/reser_e/ersd201507_e.pdf> (accessed 27/04/2020)

[317] ibid 6

[318] ibid 16

efficacy of the paragraph 6 system was to be reviewed on an annual basis by the TRIPS Council and reported on to the General Council.[319] The Paper found that the annual review mechanism was not a useful indication of whether the system was functioning properly, and that a substantive review was needed.

In evaluating the system, the paper proposed that there may be a need to simplify national measures, and also to encourage suppliers and industry to participate more actively by making the process more sustainable and cost effective.[320] This proposal could go some way to addressing the challenges experienced by the participants under the Canadian regime, however it does not fully address the argument in academic literature that the waiver itself is too burdensome to be effective[321]. The paper also suggested a need to review whether the TRIPS-plus provisions under bilateral trade agreements has affected prospective use of the system.[322] The paper also suggests that political pressures may explain the limited use of the system, and a definitive statement is needed to clarify that allowing compulsory licensing for the export of medicines under the paragraph 6 system is a positive advance.[323] The paper also aimed to promote discussion within the WTO with the aim of ensuring that the paragraph 6 waiver can be used as a "practical procurement tool"[324] which actively contributes to improving trade in essential medicines between exporting countries and importing countries in need. This evaluation indicates that there is a need for closer collaboration between Members and the pharmaceutical industry in order to make effective use of the paragraph 6 system, and also suggests that the cost of medicines is still a barrier to access. Further, although the system was intended to clarify that TRIPS was to be interpreted in a manner supportive of public health interests, the fact that clarification is still required on this point suggests that Members remain concerned about potential consequences if they were to issue compulsory licenses to export medicines. The system was also intended to extend the scope in which compulsory licenses could be granted, and the extremely limited use of the compulsory licensing provisions in the twelve years between the Implementation Decision and the

[319] Implementation Decision (n 287) [8]
[320] Kampf (n 316) 8
[321] Abbott and Reichman (n 70) 932; R Thapa 'Waiver Solution in Public Health and Pharmaceutical Domain under TRIPS Agreement' (2011) 16 JIPR 470, 472; W Guan ' IPRs, Public Health, and International Trade: An International Law Perspective on the TRIPS Amendment' (2016) 29 Leiden Journal of International Law 411, 438-439
[322] Kampf (n 316) 8
[323] ibid
[324] ibid 17

Paper highlights the ineffectiveness of the system in securing access to medicines for all. Therefore the paragraph 6 system cannot be considered to be successful in achieving its aim.

The paragraph 6 waiver does not add considerably beyond TRIPS in terms of actually implementing processes to improve access to medicines. It was noted that although the difficulties of least developed countries in accessing essential medicines was explicitly considered in paragraph 7 of the Doha Declaration, this did not actually provide a significant improvement, and further consideration of the issues specifically experienced by least developed countries would need to be addressed by the WTO[325]. Paragraph 7 confirmed the commitment of developed countries to assist least developed countries by promoting and encouraging technology transfer. However there is little evidence of such commitment being fulfilled in relation to the pharmaceutical industry, and particularly in the development of essential medicines needed to treat diseases which are prevalent in least developed countries[326]. While paragraph 7 emphasised the commitment of developed countries, it did not explicitly set out the ways in which developed Members should fulfil this commitment or a mechanism by which to monitor the steps taken to fulfil this commitment. This suggests that the Doha Declaration did not provide assistance to least developed countries, and that further focus on the needs of least developed countries by the WTO is needed is order to effectively address the accessibility of essential medicines for these countries. This point further highlights that the compromises encountered due to a single system for all WTO Members regardless of development may not have been efficacious.

VIII. TRIPS-plus provisions

[325] C Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health' (World Health Organization 2002), WHO/EDM/PAR/2002.3 <https://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf> (accessed 27/04/2020) at P.48-49

[326] S Moon 'Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs? An Analysis of Country Submissions to the TRIPS Council (1999-2007)' UNCTAD - ICTSD Project on IPRs and Sustainable Development, policy brief Number 2, December 2008 <https://unctad.org/en/Docs/iprs_pb20092_en.pdf> (accessed 27/04/2020); J Watal and L Caminero 'Least-developed countries, transfer of technology and the TRIPS Agreement' (2017) WTO Staff Working Papers ERSD-2018-01, World Trade Organization (WTO), Economic Research and Statistics Division; R Smith, C Correa, C Oh 'Trade, TRIPS, and pharmaceuticals' (2009) 373 The Lancet 684, 689; United Nations Secretary-General's High-Level Panel on Access to Medicines (n 72) 19; R Dreyfuss 'The Role of India, China, Brazil and Other Emerging Economies in Establishing Access Norms for Intellectual Property and Intellectual Property Lawmaking' IILJ Working Paper 2009/5, 30 July 2009 <http://ssrn.com/abstract=1442785> (accessed 27/04/2020)

Another key challenge to improving access to medicines is that WTO Members can increase the IP protection standards under TRIPS through free trade agreements (FTAs), known as 'TRIPS-plus' agreements. TRIPS-plus agreements may go beyond TRIPS minimum standards in the case of patenting of medicines in several ways, including effectively extending the term of patent protection and restricting the use of compulsory licensing.[327] Matthews argues that developing countries may be subject to pressure to agree to TRIPS-plus standards into national law, for fear of otherwise damaging trading relationships with developed WTO Members.[328] Therefore, such bilateral pressure could add to existing challenges for developing states to balance their obligations under TRIPS with their public health goals in relation to enhancing access to medicines.

Correa contends that the TRIPS-plus agreements formalised in FTAs have a negative impact on development, arguing that it should not be assumed that strict IP protection will always promote innovation, and that "the higher the level of protection, the better for all trade partners",[329] because the social and economic conditions will also have relevance. Social and economic conditions including public health do not always benefit from strict IP protection. There is comparably little research into vaccines and treatments for malaria, leprosy and other tropical parasitic diseases[330] most commonly affecting poorer countries, with the contention that poor countries only benefit from research and development when rich countries suffer from a particular disease.[331] This indicates that IP rights promote research which is commercially valuable and lucrative. It also suggests that a harmonised IP regime internationally does not best serve the developing countries, particularly in relation to pharmaceutical patents. Frankel argues that although the nature of IP rights is to restrict other parties from using the IP, this argument does not justify the restrictions that TRIPS-plus agreements place on

[327] A comprehensive review of TRIPS-plus agreements beyond the scope of this research. For examples of TRIPS-plus terms in FTAs, see J Sellin, *Access to Medicines: The interface between patents and human rights. Does one size fit all?,* (Intersentia Cambridge 2014), 282; Hestermeyer (n 72) 290

[328] Matthews (n 197) 425

[329] C Correa, 'High costs, negligible benefits from intellectual property provisions in FTAs (2013) 44(8) IIC 902, 903

[330] WHO, 'Neglected tropical diseases' <http://www.who.int/neglected_diseases/diseases/en/> (accessed 27/04/2020)

[331] JD Sachs (Chair), *Macroeconomics and Health: Investing in Health for Economic Development,* (World Health Organization 2001) <http://www1.worldbank.org/publicsector/pe/PEAMMarch2005/CMHReport.pdf> (accessed 27/04/2020)

developing countries, particularly those countries which depend on using foreign IP for development.[332] Where the effect of IP protection is to restrict and control innovation, then it is difficult to justify having an even higher standard of IP protection than TRIPS already affords, through the formation of FTAs.

The Doha Declaration and paragraph 6 waiver are important measures in the interpretation and implementation of TRIPS in light of public health objectives, however the measures have not resolved the difficulties experienced in relation to TRIPS-plus provisions being included in bilateral free trade agreements, particularly favoured by the US and other developed states[333]. A clearly held view in the academic literature is that such agreements further negate the efficacy of the Doha Declaration as they are trade-focused and reduce the capacity of states to secure access to medicines nationally[334]. Although there are advantages for developing countries to entering into such agreements in the form of increased access to the US market, it has been observed that negotiations on such agreements are usually confidential, which is inappropriate for taking into consideration the interests of all participating states.[335] Correa argues that these agreements produce only a minor benefit for pharmaceutical companies contrasted with the major potential detriment to the poorer countries, and such agreements "give priority to narrow commercial interests rather than to improving the lives of people and development prospects around the world."[336] This type of agreement could be seen to conflict with the principles of TRIPS and the Implementation Decision, as WTO Members have agreed that these instruments may be interpreted in a way which promotes public health. Therefore developing countries should not be deterred from granting compulsory licences because of a potential risk of consequences on trade relationships with developed countries. However, it was noted that the USA entered into FTAs with a

[332] S Frankel, 'Trade-offs and transparency'(2013) 44(8) IIC 913, 914

[333] P Li and P Lim, 'A precautionary approach to compulsory licensing of medicines: tempering data exclusivity as an obstacle to access' (2014) 3 IPQ 241, 247

[334] Matthews (n 197); C Correa 'Implications of Bilateral Free Trade Agreements on Access to Medicines' (2006) 84(5) Bulletin of the World Health Organization 399; F Abbott 'The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements' Quaker United Nations Office (Geneva) (QUNO), Occasional Paper No. 14, April 2004; Musungu and Oh (n 197); WTO, WIPO, WHO, 'Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade' (World Trade Organization, Geneva 2012) WTO ISBN 978-92-870-3839-5

[335] S Flynn, B Baker, M Kaminski and J Koo, 'The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement' (2012) 28 Am. U. Int'l L. Rev. 105, 114-115

[336] C Correa, 'Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines' (2004) 36 Case W. Res. J. Int'l. L. 79, 94

number of developing countries which amounted to "favourable trading deals in exchange for agreement not to issue compulsory licences"[337], and that this may be a potential reason for the lack of use of the paragraph 6 system under the Implementation Decision.

FTAs also allow developed countries to restrict the production of generic medicines through data exclusivity provisions. Data exclusivity has the effect of preventing the generic manufacturers from using the original data of the patented drug to obtain regulatory approval for the generic copy.[338] Therefore generic manufacturers have to produce their own data on the safety and effectiveness of the generic copy, making the production of generics more costly and time consuming, which will have the effect of increasing in the cost. TRIPS does not provide for data exclusivity under Article 39.3, and the academic literature outlines the view that the US in particular is using the negotiation of FTAs to implement TRIPS-plus provisions that it was unsuccessful in securing under TRIPS.[339]

The Trans-Pacific Partnership (TPP) was signed on 4 February 2016[340] with the objective of liberalising trade in the Asia-Pacific through tariff reduction.[341] The TPP was a free trade agreement originally between twelve states, Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, USA and Vietnam[342], and was renamed the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)[343] in 2018, following the withdrawal of the US on 30 January 2017[344]. The intellectual property chapter proved controversial because it intended to introduce intellectual property standards which went far beyond TRIPS[345], including "the most

[337] C Tuosto, 'The TRIPs Council decision of August 30, 2003 on the import of pharmaceuticals under compulsory licences' (2004) 26(12) European Intellectual Property Review 542, 547
[338] O'Farrell (n 314) 214
[339] R Lopert and D Gleeson, 'The High Price of "Free" Trade: U.S. Trade Agreements and Access to Medicines' (2013) 41 J.L. Med. & Ethics 199, 199; Li and Lim (n 333) 247; Matthews (n 197); Correa (n 334) 399; Abbott (n 334)
[340] BBC News, 'Trans Pacific Partnership trade deal signed in Auckland' (4 February 2016), <https://www.bbc.co.uk/news/business-35480600> (accessed 27/04/2020)
[341] R Patel, 'Public Health Imperative: The Need for Meaningful Change in the Trans-Pacific Partnership's Intellectual Property Chapter' (2015) 16 Minn. J.L. Sci. & Tech. 477, 481
[342] BBC News, 'TPP: What is it and why does it matter?' <http://www.bbc.co.uk/news/business-32498715> (accessed 27/04/2020)
[343] Center for Strategic and International Studies, 'From TPP to CPTPP' (8 March 2018), <https://www.csis.org/analysis/tpp-cptpp> (accessed 27/04/2020)
[344] Office of the United States Trade Representative, 'Press Release: The United States Officially Withdraws from the Trans-Pacific Partnership' (30 January 2017) <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2017/january/US-Withdraws-From-TPP> (accessed 27/04/2020)
[345] S Sell, 'TRIPs Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP' (2011) 18 J Intell Prop L 447; P Yu 'TPP and Trans-Pacific Perplexities' (2014) 37 Fordham Int'l LJ 1129; D Elms 'The Trans-Pacific Partnership Trade Negotiations: Some Outstanding Issues for the Final Stretch' (2013) 8 Asian J WTO and

aggressive pharmaceutical intellectual property provisions to date"[346], due to proposals to grant a mandatory extension of five years to the term of patent protection, to introduce patent linkages, as well as increased data exclusivity provisions[347]. Significantly, in November 2017 it was announced that several of the IP provisions in the agreement had been suspended[348], including the requirement to adjust the term of patent protection if there are unreasonable delays in the patent being issued[349], and the requirement for five years of protection for test or other data submitted to a regulatory authority for the purposes of obtaining regulatory approval to market a pharmaceutical product, or a biologic pharmaceutical product[350]. These provisions were considered to be too extensive and far-reaching because they could have had a detrimental effect on medicines prices[351] so the suspension of the provisions is a positive step. However, as they are merely suspended, and not withdrawn or redrafted, there remains the possibility that these provisions could be restored to the agreement. The agreement came into force on 30 December 2018[352]. The success or failure of TPP will have implications on future trade agreements, and could lead to a change in forum for discussion on issues including the achievement of global public health objectives.

An objective of TRIPS was the harmonising of IP law, introducing uniformity and continuity in the scope of rights available to IP owners. However, bilateral trade agreements contradict this intention by supporting the implementation of diverging

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Int'l Health L. & Pol'y 379; K Cox, 'The Intellectual Property Chapter of the Transpacific Partnership Agreement and Investment in Developing Nations' (2014) 35 U Pa J Int'l L 1045

[346] Patel (n 341) 479

[347] Silverman (n 182) 224

[348] Government of Canada, 'Trans-Pacific Partnership Ministerial Statement' <https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptpgp/statement-declaration.aspx?lang=eng> (accessed 27/04/2020)

[349] World Trade Organization 'Regional Trade Agreements Database' <http://rtais.wto.org/UI/PublicShowRTAIDCard.aspx?rtaid=640> (accessed 27/04/2020), Article 18.47

[350] World Trade Organization 'Regional Trade Agreements Database' <http://rtais.wto.org/UI/PublicShowRTAIDCard.aspx?rtaid=640> (accessed 27/04/2020), Articles 18.50 and 18.51

[351] P Pusceddu 'Assessing access to medicines in preferential trade agreements: from the Trans-Pacific Partnership to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership' (2018) 49(9) IIC 1048; P Yu 'Thinking About the Trans-Pacific Partnership (and a Mega-Regional Agreement on Life Support)' (2017) 20 SMU Sci. & Tech. L. Rev. 97; Cox (n 345); C Correa 'Intellectual property in the Trans-Pacific Partnership: increasing the barriers for the access to affordable medicines' (2017) South Centre, research paper 62R <https://www.southcentre.int/wp-content/uploads/2017/07/RP62R_IP-in-TPP-Increasing-the-Barriers-for-the-Access-to-Affordable-Medicines_rev_EN.pdf> (accessed 27/04/2020)

[352] World Trade Organization, 'Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)' <http://rtais.wto.org/UI/PublicShowMemberRTAIDCard.aspx?rtaid=640> (accessed 27/04/2020)

standards between the parties, contrasted with the international legislative standards set out in TRIPS. As these agreements are free trade agreements, it could be argued that public health issues are not given sufficient prominence, and therefore responses to global health emergencies cannot be adequately comprehended within FTAs. It could also be argued that in agreeing stricter IP provisions as part of FTAs, developing and least developed countries will not have an equal opportunity to further development and participate in global free trade. Such provisions also raise IP rights protection standards globally making international agreements on IP standards redundant.

IX. IP and public health

With the ineffectiveness of the Doha Declaration in significantly improving access to medicines for developing countries, as well as the implementation of stricter IP standards in FTAs, it may be pertinent to consider other approaches to addressing what is a critical global public health concern. This is highlighted by the actions of intergovernmental organisations[353] and stakeholders to promote global public health, and including multilateral cooperation between the WTO, WHO and WIPO. In 2010 the WTO, WHO and WIPO held the first of a series of joint technical symposia on access to medicines[354]. This collaborative approach also provides an opportunity for policy coherence across the organisations on how to promote access to medicines, which is reflected in efforts to build on the trilateral study through joint technical symposia including the 2018 symposium looking at how innovative technologies can help to achieve the UN Sustainable Development Goals related to health[355]. However, it is states that have agreed to be

[353] For example, WHO's Global Strategy and Plan of Action on public health, innovation and intellectual property. The Global Strategy aims to promote needs-driven research with regard to diseases which disproportionately affect developing countries, aiming to "promote new thinking on innovation and access to medicines". See also World Health Organization, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property,* (World Health Organization 2011), 4 <https://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf> (accessed 27/04/2020)

[354] An outcome of the symposia was a trilateral report which considered the issue of access to medicines and aimed to improve the flow of practical information to guide and support technical cooperation for policy makers. See also WTO, WIPO, WHO, 'Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade' (World Trade Organization, Geneva 2012) WTO ISBN 978-92-870-3839-5

[355] In particular SDG 3 to 'ensure healthy lives and promote well-being for all at all ages' and SCG 9 to 'build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation'. UN, 'Sustainable Development Goals'< https://sustainabledevelopment.un.org/?menu=1300> (accessed 27/04/2020). See World Health Organization 'WHO-WIPO-WTO Technical Symposium on Sustainable Development Goals: Innovative technologies to promote healthy lives and well-being', February 2018 <https://www.who.int/phi/sustainable_development_goals_February2018/en/> (accessed 27/04/2020)

subject to obligations under TRIPS, and states also have obligations in relation to promoting public health under UN human rights law.

The right to health is an international human right[356], while Article 12 of the ICESCR recognises the right of everyone to the enjoyment of the highest attainable standard of physical and mental health[357]. This right imposes obligations on states to uphold this right for the benefit of individuals. The monopoly rights derived from patent protection conflict with human rights "if the product is essential for the enjoyment of human rights yet it becomes inaccessible to poor people."[358] Patents conflict with this right if the cost of such medicines, based on the manufacturer's monopoly in the global market, makes them inaccessible. Therefore, taking full account of states obligations in relation to the right to health in Article 12 ICESCR could help in interpreting TRIPS in a manner conducive to public health goals including enhancing access to medicines. However it is also pertinent to highlight that the rights of creators are protected under Article 15 of the ICESCR[359], while patents form part of the human right to protection of property under the European Convention on Human Rights (ECHR)[360]. Therefore it is also important to consider the rights that patent holders have in their creations, and the legal obligations that such rights create in favour of the protection of the rights of creators in their creations, such as new medicines.

While it is important to ensure that essential medicines are made available to countries that do not have the capacity to produce them domestically, it is also important to support the distribution of medicines to the population of such countries. Other barriers to medicines exist in developing countries, including lack of adequate health care systems and health insurance provisions, lack of access to education, and weak infrastructure to reach the poorest populations who are most in need. While the arguments in support of patent protection include the stimulation of creativity and innovation, this is not always the case, as many new patented medicines are minor modifications to existing medicines which provide little additional benefit.[361] This highlights that an issue relating to access

[356] Universal Declaration of Human Rights (adopted 10 December 1948 UNGA Res 217 A(III)
[357] International Covenant on Economic, Social and Cultural Rights (n 2) Article 12
[358] Joseph (n 198) 214
[359] International Covenant on Economic, Social and Cultural Rights (n 2) Article 15. This is discussed later in the thesis.
[360] Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (ECHR), Article 1 of the First Protocol
[361] Silverman (n 182) 228; Lopert and Gleeson (n 339) 210; C Correa 'Ownership of knowledge: the role of patents in pharmaceutical R&D' (2004) 82 Bulletin of the World Health Organization 784, 784-785

to medicines is that treatments must exist in order to be accessible. It emphasises that accessibility does not just relate to the affordability of medicines, but also the availability of medicines so that they can be physically accessed, and also indicates the complex issues in addition to IP rules which impact upon access to medicines.

X. Conclusion

It is evident that IP is a valuable form of property for creators, and its protection in the form of legally enforceable rights for the owners is beneficial and potentially lucrative. IP rights protect investment in creativity which is important in order to further development. Developed and developing countries came into the TRIPS negotiations with diverging views on whether IP rights should be concentrated on protecting inventors or whether such rights should be balanced with advancing public interests. The TRIPS Preamble and Articles 7 and 8 provide its objectives to be a balance of rights and obligations including the promotion of technological innovation and dissemination of technology in a manner conducive to social and economic welfare, and reflect that IP rights protection is not an end in itself. However, TRIPS is a trade agreement and the promotion of access to medicines was not a main objective when the agreement was negotiated. Since TRIPS came into force there have been increasing concerns over access to medicines as TRIPS requires a minimum standard of IP rights protection to be implemented by Members, including in relation to medicines. Particular problems have arisen from the length and exclusivity of patent rights, and the interpretation and implementation of such protection effectively creating a barrier to access to medicines.

This chapter has explored ways in which TRIPS can be interpreted and implemented in light of the promotion of public health objectives. The Doha Declaration has provided additional interpretative guidance for the purpose of helping Members promote access to medicines, and TRIPS includes exception to patent protection to allow Members to adopt measures to enhance access to medicines, balanced with the interests of patent holders, at national level. These provisions alone have not had the effect of removing barriers to medicines created by IP law, specifically in relation to patents. A key finding is that public health concerns, specifically access to medicines, is not being given sufficient prominence in the interpretation and implementation of TRIPS patent standards, even where there is scope to do so under TRIPS. Members have experienced challenges in relying upon the exceptions to patent protection under Articles 30 and 31,

and although Members have agreed to a permanent amendment of Article 31 for the purpose of making it easier for states without manufacturing capacity improve access to medicines, there are limitations as to the effectiveness of the amendment. In *Canada – Patent Protection for Pharmaceutical Products*, the failure of the WTO Panel to provide an appropriate analysis of Articles 7 and 8 of TRIPS, in line with the rules of treaty interpretation under Articles 31 and 32 VCLT, also raises the question of whether the Panel struck an appropriate balance between Articles 7 and 8, and Article 30 TRIPS. The narrow interpretation of Article 30 failed to fully take into account public health measures such as improving access to medicines as legitimate interests, and had a negative impact on access to generic medicines in this case. The utility of the exceptions to patent protection in TRIPS in enhancing access to medicines will be determined by the manner in which they can be implemented by Members. Therefore it is important that they are interpreted and implemented more effectively, so that Members can improve access to medicines nationally while meeting their obligations towards patent holders under the agreement.

A further concern is the increase of FTAs incorporating stricter IP protection, as such agreements do not appear to give due consideration to public health issues, such as access medicines. Other, wider, factors also impact upon access to medicines, including the lack of adequate health care systems and poor infrastructure in developing countries. Access to medicines is a serious public health issue due to the cost of essential medicines, as the most effective medicines remain under patent and are therefore too costly to be obtainable for the poorest populations. The complexity of the issue of access to essential medicines is demonstrated by the human rights implications that arise from lack of access to life-saving or life-prolonging medicines. Therefore it is pertinent to consider whether a rights-based approach could assist states in developing new strategies for securing access to essential medicines for all.

Chapter 3: Status of access to medicines in International Human Rights Law

Introduction

Helfer and Austin argue that the twenty-first century has seen "increasingly high profile and contentious debates over legal and political issues that arise at the interface of human rights and intellectual property"[362]. Access to medicines has been a significant matter for such debate. Chapters 1 and 2 discussed the issue of access to essential medicines and the relevance of this issue within international trade platforms as medicines are a commercially valuable and tradable product. This chapter will explore how the issue of access to medicines has been addressed within an international human rights framework. This chapter will explore whether there is a human right to medicines, and the scope of such a right. The obligations of states with respect to the right will also be analysed, which will assist in assessing the nature and scope of any potential conflict with the obligations under TRIPS. The position of the UN bodies with regard to reconciling the State's obligations in relation the right of access to medicines and State obligations under TRIPS will also be examined. The purpose of this is to explore whether these bodies have provided guidance on ensuring effective enjoyment of the right to medicines and whether there is guidance on how States could meet their human rights obligations and their obligations under TRIPS.

This chapter will review the work of bodies under the UN Charter-based system and the UN Treaty Monitoring Bodies system. The UN Charter-based system emanates from the UN Charter which applies to all UN Member States.[363] Two core features of this system include the Human Rights Council and Special Procedures. The Human Rights Council is an intergovernmental body made up of representatives from UN Member States, and a key function is the Universal Periodic Review (UPR).[364] The UPR is a process which involves a review of the human rights records of all UN Member States. The Special Procedures are independent experts with a mandate to report on human rights in a thematic context, undertake country visits, receive communications on potential violations, and have an important role in clarifying the scope and implementation of

[362] Helfer and Austin (n 3) 2

[363] For an overview of this system, see I Bantekas and L Oette, *International Human Rights Law and Practice,* 2nd ed, (Cambridge University Press, Cambridge 2016), Chapter 4

[364] D Moeckli, S Shah, S Sivakumaran, *International Human Rights Law,* (Oxford University Press, Oxford 2014), P.71

human rights.[365] The significance of the work of these bodies will be discussed later in the chapter, but it is important to note that they provide authoritative interpretations on the scope of state obligations, and proposals for how states can meet their obligations.[366] The Treaty Monitoring Bodies (TMB) system has developed extemporaneously since the inception of the UN, and applies to States that have ratified one or more of the nine core international human rights treaties and therefore have agreed to engage with the monitoring system under that treaty.[367] The relevant treaty to this research is the International Covenant on Economic, Social and Cultural Rights (ICESCR), which is a legally binding treaty and includes the right to health under Article 12.[368] The TMB promote and monitor compliance with the respective treaty, and therefore can provide important insights into the nature and scope of obligations on access to medicines, and how states can best discharge their obligations.

This chapter will undertake a systematic analysis of a series of original documents. The UPR is an important source as the review is cyclical, and the reports are produced by Member States, UN bodies and relevant stakeholders.[369] All available documents of the first and second cycles are reviewed. The third cycle is currently

[365] United Nations Office of the High Commissioner for Human Rights, 'Special Procedures of the Human Rights Council' <http://www.ohchr.org/EN/HRBodies/SP/Pages/Welcomepage.aspx> (accessed 27/04/2020)

[366] Moeckli, Shah, Sivakumaran (n 364) 80

[367] United Nations Office of the High Commissioner for Human Rights, 'Human Rights Bodies' (n 7). Committee on the Elimination of Racial Discrimination (CERD) monitors implementation of the International Convention on the Elimination of All Forms of Racial Discrimination; Committee on Economic, Social and Cultural Rights (CESCR) monitors implementation of the International Covenant on Economic, Social and Cultural Rights; Human Rights Committee (CCPR) monitors implementation of the International Covenant on Civil and Political Rights and its optional protocols; Committee on the Elimination of Discrimination against Women (CEDAW) monitors implementation of the Convention on the Elimination of All Forms of Discrimination against Women (1979) and its optional protocol; Committee against Torture (CAT) monitors implementation of the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment; Committee on the Rights of the Child (CRC) monitors implementation of the Convention on the Rights of the Child and its optional protocols; Committee on Migrant Workers (CMW) monitors implementation of the International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families; Committee on the Rights of Persons with Disabilities (CRPD) monitors implementation of the International Convention on the Rights of Persons with Disabilities; Committee on Enforced Disappearances (CED) monitors implementation of the International Convention for the Protection of All Persons from Enforced Disappearance.

[368] The relevance of this treaty to this research is also discussed in Chapter 1 of this thesis.

[369] The review is based on three sets of documents; the National Report, the Compilation of UN Information and the Summary of Stakeholders Information. The review involves an interactive dialogue in a Working Group of the Council which comprises other Member States. Non-member States may also participate. States can make recommendations to the reviewed State which may be accepted or rejected. The Report of the Working Group on the Universal Periodic Review for the State concerned is then adopted by the Council. See also: <www.ohchr.org/EN/HRBodies/UPR/Pages/UPRMain.aspx> (accessed 27/04/2020)

ongoing and so all available documents up to December 2019 are reviewed. The system of Special Procedures is also reviewed, most notably the reports of the Special Rapporteur on the highest attainable standard of physical and mental health to December 2019, due to the direct relationship to the topic of this research. The relevant treaty monitoring body to the ICESCR is the Committee on Economic, Social and Cultural Rights (CESCR)[370], and the chapter also includes a systematic review of the reports on the concluding observations and General Comments of the CESCR, to December 2019.

This chapter will focus predominantly on original documents to analyse how these bodies are addressing the provisions. The chapter will also draw on relevant academic literature in the analysis of the findings from this research. The chapter will begin with discussion of the Human Rights Council, with focus on the UPR to explore whether an authoritative interpretation of the scope of state obligations with regards to access to medicines is identifiable, and whether any proposals are made for states to meet their obligations. The documents of the Special Procedures will be reviewed, specifically the Special Rapporteur on the highest attainable standard of physical and mental health, to analyse whether the Special Rapporteur provides clarification on whether medicines form part of the right to health. The chapter will then move to discussion of the TMB system, to analyse how the reports of the CESCR assist in interpreting the scope of the Article 12 right to health and the scope of State obligations in relation to this right. The chapter will conclude with the findings from this research, including whether there is a right to access to medicines, and if so, what medicines are covered by this right. Findings will also include the nature of obligations of States, in relation to those residing within and outside of their jurisdiction, as well as what the work of the UN bodies adds to the understanding of the relationship of the UN human rights framework and TRIPS in relation to enhancing access to medicines.

I. The United Nations Human Rights System: Some Preliminary Considerations

[370] Under the UN Treaty Monitoring Bodies system, when a state ratifies a core UN human rights treaty, that states agrees to engage with the monitoring system under that treaty. States submit a report to the relevant treaty monitoring body and the treaty body will offer concluding observations on the report. See: United Nations Office of the High Commissioner for Human Rights, 'Monitoring the Core International Human Rights Treaties' <http://www.ohchr.org/EN/HRBodies/Pages/WhatTBDo.aspx> (accessed 27/04/2020)

The UN human rights system is important to this research for several reasons. The work of the UN bodies is important in terms of clarifying the nature and scope of obligations under UN treaties. One question to be explored in this chapter is whether access to medicines forms part of the right to health under Article 12 ICESCR. Clarifying the scope of Article 12 is of key relevance to this research as it is a legally binding treaty obligation. The UN human rights bodies also provide authoritative interpretations on the content and scope of human rights obligations, even though their reports are not legally binding, and provide insights on the application of human rights norms.[371] Therefore, they are of importance in addressing the question of the State's obligations in relation to access to medicines.

Even though some of the work of the UN bodies is soft law, there is a value to this as it is not always the case that legal obligations effect changes in state behaviour.[372] For example, the UPR has encouraged some states, including Viet Nam, to submit overdue state reports to TMBs, highlighting that the UPR has led to states re-engaging with their legally binding treaty obligations.[373] There is also a body of academic literature which recognises that soft law can make a significant contribution to the development of international law.[374] Examples include monitoring mechanisms which document violations, and creating expectations as to future behaviour of states.[375] Although there may not be direct legal sanctions for non-compliance, states may be subject to incidental effects such as moral and political pressure, which in practice can be an important enforcement mechanism in international law. [376]

It is also important to distinguish between the existence of obligations and the monitoring of compliance with those obligations. Clearly, Article 12 imposes legally binding obligations. However, in terms of enforcement there is no international human

[371] H Quane 'Legal Pluralism and International Human Rights Law: Inherently Incompatible, Mutually Reinforcing or Something in Between?' (2013) 33 (4) Oxford J Legal Studies 675, 693

[372] K Roth 'Defending Economic, Social and Cultural Rights: Practical Issues Faced by and International Human Rights Organization' (2004) 26(1) Human Rights Quarterly, 63; D Etone 'African States: Themes Emerging from the Human Rights Council's Universal Periodic Review' (2018) 62 (2) Journal of African Law 201, 202-3

[373] H Quane 'The Significance of an Evolving Relationship: ASEAN States and the Global Human Rights Mechanisms' (2015) 15(2) HRLR 283, 288

[374] This literature is discussed in Chapter 1. Examples include: Chinkin (n 43) 866; D Shelton, 'Compliance with International Human Rights Soft Law' (1997) 29 Stud Transnat'l Legal Pol'y 119, 140-141; Higgins (n 43) 24; D Cassel, 'Does International Human Rights Law Make a Difference' (2001) 2 Chi J Int'l L 121; Boyle (n 115) 123

[375] Chinkin (n 43) 859 & 862

[376] H Hillgenberg 'A fresh look at soft law' (1999) 10 EJIL 3 499, 511

rights court, and this is not viable due to significant resistance from Member States.[377] In the absence of a court, the work of independent experts, who have a treaty-based mandate, provide authoritative interpretations and guidance through their reports. The TMB are bodies established by treaties to promote and monitor human rights, so their interpretations, in concluding observations and General Comments, are authoritative, even though they are not legally binding. Intergovernmental mechanisms also provide authoritative interpretations on from those to whom the norm is addressed. The Human Rights Council is an intergovernmental body[378]. The value of the UPR is that it is the states themselves that are clarifying how they are interpreting their legal obligations. The UPR reports also include whether the state under review accepts, or rejects a recommendation, and their reasons for doing so. Therefore, it is a useful source in relation to how states view their obligations, and in terms of how they interpret how they should implement these obligations.

The UN human rights system is also important in terms of the extent to which these fora provide subsequent practice in relation to the rules of treaty interpretation under the VCLT. When exploring the questions of whether there is a right to medicines and the obligations of states in relation to this right, the interpretation of the ICESCR is a key focus in this chapter. Article 31 VCLT provides that treaties are to be interpreted in light of several factors, being the ordinary meaning of the treaty, its context and purpose, subsequent agreement and practice[379]. A literal interpretation of Article 12 ICESCR would result in a finding that access to medicines does not form part of the right to health. The position is less clear in relation to a contextual interpretation by reference to the Preamble of the treaty[380]. However, the treaty can be interpreted in light of subsequent practice of states[381], so the importance of the Human Rights Council as an intergovernmental body is relevant in terms of the important insights it provides in

[377] P Alston 'Against a World Court for Human Rights' (2014) 28(2) Ethics & International Affairs 197; S Trechsel 'A World Court for Human Rights?' (2003) 1 Northwestern University Journal of International Human Rights 3, 15; A Cassese 'A Plea for a Global Community Grounded in a Core of Human Rights' in A Cassese (ed) *Realizing Utopia: The Future of International Law* (Oxford University Press, Oxford 2012), 136, 141. This is symptomatic of international human rights law generally, as it is only the ECHR which is exclusively judicial.

[378] For further discussion of the Human Rights Council, see Bantekas and Oette (n 363) Chapter 4

[379] VCLT (n 47) Article 31

[380] J Tobin, 'Seeking to Persuade: A Constructive Approach to Human Rights Treaty Interpretation' (2010) 23 Harv Hum Rts J 1, 18; International Covenant on Economic, Social and Cultural Rights (n 2) Preamble

[381] Hillgenberg (n 376) 513

subsequent interpretation of the treaty obligations. Therefore, while non-binding the work of this body is valuable in relation to interpretation of the ICESCR.[382]

II. Human Rights Council

The Human Rights Council set up in 2006 to replace the Commission on Human Rights, is an intergovernmental body comprised of representatives of 47 elected Member States which serve three year terms[383]. It has an extensive human rights mandate including setting human rights standards and issuing resolutions on any human rights concern.[384] The resolutions passed may confirm human rights principles or censure the human rights performance of a particular state[385], and are persuasive in promoting compliance by those states. The Human Rights Council also submits annual reports to the UN General Assembly[386], which are instructive in the policy-making of the UN General Assembly, and also reaffirm the rights of individuals where there is concern that such rights are not being upheld.

The 2010 annual report referenced the Human Rights Council's resolution on the protection of human rights in the context of HIV/AIDS[387]. It highlights that access to medicines is a fundamental element in achieving the full realisation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, and that it is the responsibility of States to ensure access to medicines for all. The

[382] Mechlem (n 105) 919-920
[383] Bantekas and Oette (n 363) Chapter 4
[384] ibid
[385] ibid
[386] In the annual report to the UN General Assembly, the Human Rights Council can make recommendations, make requests of the UN Security Council and other bodies, and highlight issues that it believes need urgent consideration and action. See United Nations Office of the High Commissioner for Human Rights, 'United Nations Human Rights Council' <http://www.ohchr.org/EN/HRBodies/HRC/Pages/AboutCouncil.aspx> (accessed 27/04/2020)
[387] United Nations Human Rights Council Resolution 12/27 'The protection of human rights in the context of human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS)' (22 October 2009) UN Doc. A/HRC/RES/12/27. See also United Nations General Assembly, *Report of the Human Rights Council* (United Nations New York 2010) UN Doc A/65/53, 100

draft resolution was introduced by Brazil[388] and was adopted without a vote[389]. Significantly, the resolution reaffirms the responsibility of States to make full use of the TRIPS flexibilities to promote access to medicines for all. The issue of access to medicines is an important thematic issue for the Human Rights Council, which it reports upon to the General Assembly. The 2013 annual report refers to the Human Rights Council's resolution on access to medicines, in which it invited the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health to continue to focus on the issue of access to medicines.[390]

Universal Periodic Review

UPR has a significant role to play in assisting the promotion and protection of human rights, and in clarifying the content of human rights norms.[391] The UPR involves a review of the human rights records of each Member State, following which a report is issued including recommendations on the satisfaction of their obligations[392]. It is a cooperative process of peer review which every UN Member State must undergo every four and a half years. The review is driven by Member States and entails interactive dialogue among Member States on all human rights.[393] The utility of the UPR has been questioned by

[388] The draft resolution A/HRC/12/L.24 was introduced by Brazil at the thirty-second meeting on 2 October 2009 sponsored by Brazil and co-sponsored by Argentina, Bolivia (Plurinational State of), Bosnia and Herzegovina, Chile, Colombia, Guatemala, Mexico, Mozambique, Nicaragua, Panama, Paraguay, Peru, South Africa, Uruguay and Venezuela (Bolivarian Republic of). Subsequently, Angola, Armenia, Congo, Cuba, El Salvador, Guatemala, Montenegro, Senegal, Serbia and Thailand joined the sponsors. (UNHRC 'Report of the Human Rights Council on its twelfth session' (25 February 2010), UN Doc A/HRC/12/50, 172)

[389] At the thirty-second meeting the representative of Brazil orally revised the draft resolution, the representative of France made general comments and representatives of Egypt and Indonesia made statements. The draft resolution, as orally revised, was adopted without a vote. (UNHRC 'Report of the Human Rights Council on its twelfth session' (25 February 2010), UN Doc A/HRC/12/50, 173-174)

[390] United Nations Human Rights Council Resolution 23/14 'Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (24 June 2013) UN Doc A/HRC/RES/23/14, See Also United Nations General Assembly, *Report of the Human Rights Council* UN Doc A/68/53 (United Nations New York 2013), 164

[391] Quane (n 373) 294; L Richardson 'Economic, Social and Cultural Rights (and Beyond) in the UN Human Rights Council' (2015) 15(3) HRLR 409, 427; E Domınguez Redondo 'The Universal Periodic Review of the UN Human Rights Council: An Assessment of the First Session' (2008) 7(3) Chinese JIL 721, 733

[392] United Nations Office of the High Commissioner for Human Rights, 'Universal Periodic Review' <http://www.ohchr.org/EN/HRBodies/UPR/Pages/UPRMain.aspx> (accessed 27/04/2020)

[393] M e Silva, 'The United Nations Human Rights Council: Six Years On' (2013) 18 SUR - Int'l J on Hum Rts 97, 106; J Duggan-Larkin, 'Can an Intergovernmental Mechanism Increase the Protection of Human Rights? The Potential of Universal Periodic Review in Relation to the Realisation of Economic, Social and Cultural Rights' (2010) 28 Neth Q Hum Rts 548, 549; A Abebe, 'Of Shaming and Bargaining: African States

some academics due to the non-binding nature of the process.[394] The States are free to accept or reject the recommendations generated through this non-confrontational interactive dialogue. In practice, it appears that states are generally receptive to the recommendations, as during the first cycle 74 percent of the recommendations had been accepted.[395] This reflects the general acceptance of states obligations to engage with the process and highlights the utility of cooperative monitoring mechanisms[396], particularly in light of the unfeasibility of a UN human rights court. The cyclical nature of the review also allows scrutiny of the measures taken to meet recommendations of previous cycles and to evaluate progress towards full realisation of human rights.[397] Further, the UPR is also valuable in terms of influencing State behaviour, such as enhancing implementation of human rights at national level, promoting international cooperation and assistance among states and leading to increases in the ratification of core human rights treaties.[398] Therefore, UPR is important to this research in terms of providing valuable guidance to States on the interpretation of human rights norms in relation to medicines, as well as on the implementation of these norms.

It is pertinent to undertake a systematic evaluation of the available UPR reports of the first[399], second[400] and third[401] cycles. The review will explore whether states are making recommendations in relation to enhancing access to medicines, the types of

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and the Universal Periodic Review of the United Nations Human Rights Council' (2009) 9 Hum Rts L Rev 1, 11

[394] O de Frouville 'Building a Universal System for the Protection of Human Rights' in M.Cherif Bassouni and William A Schabas (eds), *New Challenges for the UN Human Rights Machinery: What Future for the UN Treaty Body System and the Human Rights Council Procedures*? (Intersentia, 2011) at 253-266; H Charlesworth and Emma Larking (eds) *Human Rights and the Universal Periodic Review: Rituals and Ritualism* (Cambridge University Press, Cambridge 2015); Etone (n 372) 202

[395] Bantekas and Oette (n 363) 167

[396] Etone (n 372) 202; T Opsahl 'Instruments of Implementation of Human Rights' (1989) 10(2) Human Rights Law Journal 13, 31-32; Roth (n 372) 63; C Careniero and Dominique Elden, 'Economic Sanctions, Leadership survival and human rights' (2009) 30(3) University of Pennsylvania Journal of International Law, 969; Abebe (n 393) 8

[397] Duggan-Larkin (n 393) 557; Quane (n 373) 299 & 303

[398] N Pillay ' Strengthening the United Nations human rights treaty body system A report by the United Nations High Commissioner for Human Rights' (June 2012), 17 <https://www2.ohchr.org/english/bodies/HRTD/docs/HCReportTBStrengthening.pdf> (accessed 27/04/2020)

[399] The documents of the first cycle of UPR which were reviewed are found in Annex I, part A) of the thesis.

[400] The documents of the second cycle of UPR which were reviewed are found in Annex I, part B) of the thesis.

[401] The documents of the third cycle of UPR which were reviewed are found in Annex I, part C) of the thesis. As the third cycle has not yet been completed, the documents were reviewed up to December 2019.

medicines being discussed and whether states are accepting the recommendations. The purpose of this review is to analyse the role of the UPR in clarifying the scope of state obligations with regards to access to medicines, and whether any proposals are made for states concerning the implementation of their obligations.

(a) Review of the reports

Of the 192 states reviewed in the first cycle, 11.5 percent of the national reports made reference to provisions for medicines domestically[402]. 4.2 percent of the national reports referred to access to medicines as of right in terms of forming part of the right to health. Only one of these national reports was that of a developed state[403]. Of the 193 states reviewed during the second cycle, 18.1 percent of the national reports made reference to provision of medicines, with only one of the states being a developed state[404]. 1 percent of national reports reporting on access to medicines as forming part of the right to health, with all being developing states which were net importers of pharmaceuticals[405]. This may suggest that more states had implemented provisions to increase access to medicines since the first cycle, although fewer were discussing medicines in terms of a right. However, none of the national reports indicated any objections to referencing medicines in the form of a right, so perhaps the lack of reference to medicines as a right may be because the states had generally accepted the Article 12 right included access to medicines.

8.9 percent of the reports of the Working Group from the first cycle, and 7.3 percent from the second cycle did include reference to medicines in some form, such as through recommendations on improving access to medicines in a particular state, or by recognising the measures taken by the state to improve access[406]. This demonstrates a lower scale of reporting on medicines compared to the national reports, and it is particularly interesting to note that only four of the reports of the Working Group

[402] 22 out of the 192 States included in Annex I, part A), comprising 21 developing States and 1 developed State.
[403] As at 2014. Classification of developed and developing countries taken from United Nations, *World Economic Situation and Prospects 2014*, (United Nations, New York 2014), ISBN 978-92-1-109168-7, Statistical Annex, Country Classification, P.145 <http://unctad.org/en/PublicationsLibrary/wesp2014_en.pdf> (accessed 27/04/2020).
[404] 35 out of the 193 States included in Annex I, part B), comprising 34 developing States and 1 developed State.
[405] The two States were Eritrea and Georgia. See also Annex I, part B) (n 400)
[406] Reports of the Working Group for 17 States in the first cycle and 14 States in the second cycle. See also Annex I, part A) (n 399) and Annex I, part B) (n 400)

contained reference to cost as hindering access to medicines across the first and second cycles and those reports were on developing states that were net importers of pharmaceuticals. It is encouraging to note that there was an increase, from 5.7 percent during the first cycle to 12.4 percent during the second cycle, in the number of states reporting on steps taken by their governments to address enhancing access to medicines domestically[407]. However, just one of the states which reported on this point was a developed state, further highlighting that the UPR has shown that improving access to medicines was predominantly a concern for developing states.

(b) Recommendations on enhancing access to medicines

Of the 192 states reviewed in the first cycle, 2.6 percent of the reports of the Working Group from the first cycle included recommendations relating to enhancing access to medicines. Five recommendations were made by four states; Azerbaijan, Switzerland, the Holy See and Egypt[408]. The recommendations by Azerbaijan to Mauritius, and by Switzerland to Mozambique related to improving access to medicines generally.[409] The recommendations by the Holy See to Swaziland and Uganda were to improve access to HIV/AIDS medicines.[410] The recommendation by Egypt to Malawi was to seek international assistance to address HIV/AIDS, in particular to ensure supply of HIV/AIDS medicines.[411] All states except Mozambique accepted the recommendations. Only Mozambique rejected its recommendation, on the basis that its Ministry of Health had a large budget deficit[412].

[407] An increase from 11 States during the first cycle to 24 States during the second cycle. See also Annex I, part A) (n 330) and Annex I, part B) (n 400)

[408] See recommendations in the following reports: UNHRC 'Report of the Working Group on the Universal Periodic Review: Mauritius' (3 March 2009) UN Doc A/HRC/11/28; UNHRC 'Report of the Working Group on the Universal Periodic Review: Mozambique' (28 March 2011) UN Doc A/HRC/17/16; UNHRC 'Report of the Working Group on the Universal Periodic Review: Malawi' (4 January 2011) UN Doc A/HRC/16/4, 102.63; UNHRC 'Report of the Working Group on the Universal Periodic Review: Swaziland' (12 December 2011) UN Doc A/HRC/19/6, 76.55;

[409] UNHRC 'Report of the Working Group on the Universal Periodic Review: Mauritius' (3 March 2009) UN Doc A/HRC/11/28, 56; UNHRC 'Report of the Working Group on the Universal Periodic Review: Mozambique' (28 March 2011) UN Doc A/HRC/17/16, 91.10

[410] UNHRC 'Report of the Working Group on the Universal Periodic Review: Swaziland' (12 December 2011) UN Doc A/HRC/19/6, 76.55; UNHRC 'Report of the Working Group on the Universal Periodic Review: Uganda' (22 December 2011) UN Doc A/HRC/19/16, 111.87

[411] UNHRC 'Report of the Working Group on the Universal Periodic Review: Malawi' (4 January 2011) UN Doc A/HRC/16/4, 102.63

[412] UNHRC 'Report of the Working Group on the Universal Periodic Review: Mozambique: Addendum' (31 May 2011) UN Doc A/HRC/17/16/Add.1, 45

Of the 193 states reviewed during the second cycle, 3.6 percent of the reports of the Working Group included recommendations relating to enhancing access to medicines, a slight increase from the first cycle. Seven states made recommendations relating to enhancing access to medicines; Ukraine, Pakistan, Sierra Leone, Belarus, El Salvador, Canada and Colombia.[413] The third cycle of review is currently ongoing and will be completed in 2021. Of the 84 states reviewed up to December 2019, 9.5 percent of the reports of the Working Group include recommendations relating to enhancing access to medicines. The cycle is not yet complete, and so this figure should be treated with caution when drawing comparisons with earlier cycles. However, it is notable that already the number of recommendations has exceeded the first and second cycles. Eight recommendations have been made, states that have made the recommendations are: Equatorial Guinea, Syrian Arab Republic, Saudi Arabia, Serbia, Algeria, Indonesia, Australia and Iran.[414]

A qualitative change in the recommendations made during the second and third cycles compared with the first cycle is that two recommendations explicitly referred to access to medicines as part of the right to health. During the second cycle, Colombia recommended that Trinidad and Tobago ensure the right to health of persons living with HIV through the establishment of programmes to make available essential medicines.[415] During the third cycle, Indonesia recommended that Uruguay strengthen efforts to provide affordable access to all medicines to ensure the right to health.[416] Both of these recommendations were accepted by the reviewed states.

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[413] See the recommendations in the following reports: UNHRC 'Report of the Working Group on the Universal Periodic Review: Trinidad and Tobago' (15 July 2016) UN Doc A/HRC/33/15, 106.57; UNHRC 'Report of the Working Group on the Universal Periodic Review: Bolivarian Republic of Venezuela' (27 December 2016) UN Doc A/HRC/34/6, 133.238 & 133.240; UNHRC 'Report of the Working Group on the Universal Periodic Review: Democratic People's Republic of Korea' (2 July 2014) UN Doc A/HRC/27/10, 124.164; UNHRC 'Report of the Working Group on the Universal Periodic Review: Cuba' (8 July 2013) UN Doc A/HRC/24/16, 170.254; UNHRC 'Report of the Working Group on the Universal Periodic Review: Malaysia' (4 December 2013) UN Doc A/HRC/25/10, 146.180

[414] See the recommendations in the following reports: UNHRC 'Report of the Working Group on the Universal Periodic Review: Uruguay' (18 April 2019) UN Doc A/HRC/41/8; UNHRC 'Report of the Working Group on the Universal Periodic Review: Turkmenistan' (6 July 2018) UN Doc A/HRC/39/3, 114.62; UNHRC 'Report of the Working Group on the Universal Periodic Review: Pakistan' (29 December 2017) UN Doc A/HRC/37/13, 152.213; UNHRC 'Report of the Working Group on the Universal Periodic Review: Yemen' (17 April 2019) UN Doc A/HRC/41/9, 123.83, 124.65

[415] UNHRC 'Report of the Working Group on the Universal Periodic Review: Trinidad and Tobago' (15 July 2016) UN Doc A/HRC/33/15, 106.57

[416] UNHRC 'Report of the Working Group on the Universal Periodic Review: Uruguay' (18 April 2019) UN Doc A/HRC/41/8, 118.06

During the second cycle, two recommendations related to seeking international assistance. Canada recommended that Venezuela ensure immediate and urgent provision of essential medicines, including by deploying necessary resources and accepting international assistance and cooperation.[417] El Salvador also recommended that Venezuela continue developing relevant international cooperation agreements to ensure universal access to medicines.[418] These recommendations were accepted. Other recommendations made during the second and third cycles related to ensuring the affordability and availability of medicines. Belarus made a recommendation that the Democratic Peoples' Republic of Korea consider further spending on health services, including access to essential medicines.[419] Saudi Arabia recommended that Turkmenistan implement a strategy for development of production of medicines.[420] Ukraine made a recommendation to Cuba to develop programmes to further expand availability of medicines to the elderly.[421] Syrian Arab Republic recommended that Pakistan ensure availability of good quality medicines at an appropriate price, especially for the disadvantaged.[422] Several of the recommendations relating to access to medicines were of a general nature, and did not elaborate on how states might implement the recommendations. Pakistan's recommendation to Malaysia and Equatorial Guinea's recommendation to Djibouti were to ensure that medicines were affordable.[423] Algeria made a general recommendation that the Central African Republic take steps to ensure the availability of medicines, and Serbia recommended that Turkmenistan address the lack of medicines in the state.[424] These recommendations were accepted.

The UPR recommendations are only useful if they are translated into practice by states. Of the 17 recommendations that were accepted, only three states have followed up

[417] UNHRC 'Report of the Working Group on the Universal Periodic Review: Bolivarian Republic of Venezuela' (27 December 2016) UN Doc A/HRC/34/6, 133.238
[418] UNHRC 'Report of the Working Group on the Universal Periodic Review: Bolivarian Republic of Venezuela' (27 December 2016) UN Doc A/HRC/34/6, 133.240
[419] UNHRC 'Report of the Working Group on the Universal Periodic Review: Democratic People's Republic of Korea' (2 July 2014) UN Doc A/HRC/27/10, 124.164
[420] UNHRC 'Report of the Working Group on the Universal Periodic Review: Turkmenistan' (6 July 2018) UN Doc A/HRC/39/3, 114.62
[421] UNHRC 'Report of the Working Group on the Universal Periodic Review: Cuba' (8 July 2013) UN Doc A/HRC/24/16, 170.254
[422] UNHRC 'Report of the Working Group on the Universal Periodic Review: Pakistan' (29 December 2017) UN Doc A/HRC/37/13, 152.213
[423] UNHRC 'Report of the Working Group on the Universal Periodic Review: Malaysia' (4 December 2013) UN Doc A/HRC/25/10, 146.180
[424] UNHRC 'Report of the Working Group on the Universal Periodic Review: Turkmenistan' (6 July 2018) UN Doc A/HRC/39/3, 114.63

on the extent to which they had implemented the recommendations. It is important to highlight that as the third cycle is ongoing, states that received recommendations could still follow-up on their implementation, either in interim reports or during the next UPR cycle. Swaziland outlined that it had improved the provision of free antiretroviral medicines in an interim report.[425] Uganda and the Democratic Republic of Korea reported on measures taken to improve access to medicines in their national reports in the subsequent UPR cycles.[426] The lack of effective follow-up on these recommendations is a weakness in the UPR system, which is a criticism of the UPR in the academic literature.[427]

Two recommendations made during the second and third cycles were rejected. In the second cycle, Sierra Leone made a recommendation that Malaysia consider the comments of the Special Rapporteur on the right to health of the negative impact of the Trans-Pacific Partnership on access to medicines, which was rejected because TPP negotiations were still ongoing at the time.[428] During the third cycle, Yemen received recommendations from Australia and Iran to facilitate the delivery of medicines to all Yemenis, in light of the conflict in the reviewed state.[429] Yemen rejected Iran's recommendation without explanation, but accepted Australia's recommendation.[430] Although these recommendations were rejected, it is notable that they were not rejected on the basis that states did not accept that access to medicines forms part of a human rights norm.

Given the very low number of recommendations which have been made in relation to access to medicines, it is not possible to draw definitive conclusions. This is perhaps understandable as the UPR has a broad scope and covers a range of human rights[431]. However, the UPR process provides some tentative insights. First, where access to

[425] UNHRC 'First Cycle Mid-Term Report: Swaziland' (April-May 2016)
[426] UNHRC 'National report submitted in accordance with paragraph 5 of the annex to Human Rights Council resolution 16/21: Uganda' (3 October 2016) UN Doc A/HRC/WG.6/26/UGA/1, 50; UNHRC 'National report submitted in accordance with paragraph 5 of the annex to Human Rights Council resolution 16/21: Democratic People's Republic of Korea' (20 February 2019) UN Doc A/HRC/WG.6/33/PRK/1, 39
[427] Etone (n 372) 220; e Silva (n 393) 107
[428] UNHRC 'Report of the Working Group on the Universal Periodic Review: Malaysia' (4 December 2013) UN Doc A/HRC/25/10, 146.174; UNHRC 'Report of the Working Group on the Universal Periodic Review: Malaysia: Addendum' (4 March 2014) UN Doc A/HRC/25/10/Add.1, 6
[429] UNHRC 'Report of the Working Group on the Universal Periodic Review: Yemen' (17 April 2019) UN Doc A/HRC/41/9, 123.83, 124.65
[430] ibid
[431] Duggan-Larkin (n 393) 549; e Silva (n 393) 106

medicines has been discussed in the context of a right, the focus has been on the right to health rather than, for example, the right to life. Second, there is a lack of precision as to the definition of the types of 'medicines' being referred to. Any conclusions on what states consider to be the definition of 'medicines' should be treated with caution because of the limited data, which is open to interpretation. It appears that as a minimum, HIV/AIDS medicines could be considered as essential medicines. However, this is a tentative conclusion and reflects the challenge in clarifying the definition of 'medicines' discussed in Chapter 1. Third, there is some recognition that trade agreements can raise issues in relation to human rights and specifically access to medicines.

Special Procedures

The Special Procedures mechanism involves experts acting in an independent capacity, as either an individual Special Rapporteur or as a Working Group, to carry out country missions, address communications to States and then prepare reports to the Human Rights Council[432]. Academics have taken the view that the reports and recommendations provide valuable information for UN bodies in developing strategies to address human rights concerns, as well as placing public pressure on governments.[433] In addition to providing information, Special Procedures promote human rights through the recommendations to address human rights issues within states. Subedi argues that the Special Procedures not only have a monitoring function, but have also influenced the interpretation and implementation of human rights norms.[434] This is because the process seeks collaboration and engagement with national governments, and this constructive dialogue is key to the promotion and protection of human rights under the UN human rights framework. A criticism of the Special Procedures is the lack of follow-up on the recommendations, so they cannot be enforced, while states cannot be obliged to cooperate with the process.[435] Freedman argues that as the reports are made public, States' weaknesses in complying

[432] N Rodley, 'United Nations Human Rights Treaty Bodies and Special Procedures of the Commission on Human Rights – Complementary or Competition?' (2003) 25(4) HRQ 882, 883
[433] M Kirby, 'UN Special Procedures - Reflections on the Office of UN Special Representative for Human Rights in Cambodia' (2010) 11 Melb J Int'l L 491, 505; Subedi (n 111) 223-224; Ovett (n 61) 202
[434] Subedi (n 111) 223-224
[435] PS Pinheiro 'Being a special rapporteur: a delicate balancing act' (2011) 15(2) IJHR 162, 169; Subedi (n 111) 223-224; J Gutter 'Special Procedures and the Human Rights Council: Achievements and Challenges Ahead' (2007) 7(1) HRLR 93, 105

with human rights are publicly exposed.[436] The reports are important to the implementation of human rights norms, as publicised criticism of a State practice following a State visit may be politically embarrassing. Therefore, the work of the Special Procedures has the potential to make an important contribution to the clarification of the scope of the right to health and access to medicines, and to the implementation of the right. There are a number of Special Procedures which have an impact on advancing access to medicines[437], and the most pertinent are discussed below.

a) Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health

In 2002, the first Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health was appointed with the mandate to report annually on the status of the right to health globally and to make recommendations on the promotion and protection of the right[438]. Therefore, given the significance of the right to health to this research, the reports of the Special Rapporteur on the right to health[439] will be examined, to evaluate their contribution to clarifying the scope of the right to health in relation to access to medicines, and how the recommendations of the Special Rapporteur further the implementation of the right[440].

[436] R Freedman and J Mchangama 'Expanding or Diluting Human Rights?: The Proliferation of United Nations Special Procedures Mandates' 38(1) HRQ 164, 169

[437] Examples include The Convention on the Rights of the Child; The International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families; The Convention on the Rights of Persons with Disabilities and The United Nations Declaration on the Rights of Indigenous Peoples

[438] United Nations Commission on Human Rights Resolution 2002/31 (22 April 2002) UN Doc. E/CN.4/RES/2002/31, 4

[439] It is pertinent to note that there have been three different Special Rapporteurs on health (Dainius Pūras since August 2014; Anand Grover, August 2008-July 2014; and Paul Hunt, August 2002-July 2008) and as such there is potential for each to take different approaches to key challenges relating to health. See also United Nations Office of the High Commission for Human Rights, 'Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' <https://www.ohchr.org/EN/Issues/Health/Pages/SRRightHealthIndex.aspx> (accessed 27/04/2020)

[440] It is pertinent to undertake a systematic review of the following annual reports of the Special Rapporteur, as well as reports generated as a result of country visits, up to July 2019; Annual Reports: Dainius Pūras (2014-present): (2019) A/74/174, A/HRC/41/34; (2018) A/73/216, A/HRC/38/36; (2017) A/72/137, A/HRC/35/21; (2016) A/71/304, A/HRC/32/32, A/HRC/32/33; (2015) A/70/213, A/HRC/29/33. Anand Grover (2008-2014): (2014) A/69/299, A/HRC/26/31; (2013) A/68/297, A/HRC/23/41, A/HRC/23/42, A/HRC/23/51; (2012) A/67/302, A/HRC/20/15; (2011) A/66/254, A/HRC/18/37, A/HRC/17/43, A/HRC/17/25, A/HRC/17/25/Add.1; (2010) A/65/255, A/HRC/14/20, A/HRC/14/20/Add 1/Corr.1; (2009) A/64/272, A/HRC/11/12, A/HRC/11/12/Add.1. Paul Hunt (2002-2008): (2008) A/63/263, A/HRC/7/11, A/HRC/7/11/Add.1, (2007) A/HRC/4/28, A/HRC/4/28/Add.1, A/62/214; (2006)

The 2004 report of the Special Rapporteur Paul Hunt specifically outlined that the right to health was made up of elements including access to essential medicines[441]. The 2006 report[442] highlighted that although the right to health is a right which is subject to progressive realisation, Member States have immediate obligations with regard to elements of the right[443]. A Member State has a core obligation of immediate effect to make essential medicines available and accessible throughout its jurisdiction.[444] This interpretation of the right to health is in line with the interpretation of the CESCR[445] and provides important clarification of the scope of the right to health. The Special Rapporteur Anand Grover's 2009 report to the Human Rights Council also clarified that access to essential medicines is a key element of the right to health,[446] He also explicitly

E/CN.4/2006/48, E/CN.4/2006/48/Add.1, A/61/338; (2005) E/CN.4/2005/51, E/CN.4/2005/51/Add.1, A/60/348; (2004) E/CN.4/2004/49, A/59/422; (2003) E/CN.4/2003/58, A/58/427. Country visits: Dainius Pūras (2014-present): Visit to Canada (5 to 16 November 2018) A/HRC/41/34/Add.2, Visit to Kyrgyzstan (22 to 31 May 2018) A/HRC/41/34/Add.1, Visit to Armenia (25 September to 5 October 2017) A/HRC/38/36/Add.2, Visit to Indonesia, (22 March to 3 April 2017) A/HRC/38/36/Add.1, Visit to Algeria (28 April-10 May 2016) A/HRC/35/21/Add.1, Visit to Croatia, (28 November to 6 December 2016) A/HRC/35/21/Add.2, Joint visit to Nigeria, (18-22 January 2016) A/HRC/32/32/Add.2, Visit to Paraguay (23 September-3 October 2015) A/HRC/32/32/Add.1, Visit to Malaysia (19 November-2 December 2014) A/HRC/29/33/Add.1. Anand Grover (2008-2014): Visit to Azerbaijan (16–23 May 2012) A/HRC/23/41/Add.1, Visit to Tajikistan (24–31 May 2012) A/HRC/23/41/Add.2, Visit to Japan (15-26 November 2012) A/HRC/23/41/Add.3, Visit to Ghana (May 2011)A/HRC/20/15/Add.1, Visit to Viet Nam (November-December 2011) A/HRC/20/15/Add.2, 2011 Visit to Guatemala (May 2010) A/HRC/17/25/Add.2, Visit to the Syrian Arab Republic (November 2010) A/HRC/17/25/Add.3,Visit to Australia (November 2009) A/HRC/14/20/Add.4, Visit to Poland (May 2009) A/HRC/14/20/Add.3, Visit to India (November 2007) A/HRC/14/20/Add.2, Visit to Glaxo Smith Kline (June 2008) A/HRC/11/12/Add.2. Paul Hunt (2002-2008): India (November-December 2007)Preliminary notes A/HRC/7/11/Add.4, Ecuador (May 2007) and Colombia (September 2007) Preliminary notes A/HRC/7/11/Add.3, Uganda (joint report with visit to the World Bank and the International Monetary Fund) (February 2007) A/HRC/7/11/Add.2, The World Bank, the International Monetary Fund (joint report with visit to Uganda) (October 2006) A/HRC/7/11/Add.2, Sweden (January 2006) A/HRC/4/28/Add.2, Lebanon and Israel (September 2006) Joint visit with the Special Rapporteur on extrajudicial, summary or arbitrary executions; the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; the Representative of the Secretary-General on human rights of internally displaced persons and the and the Special Rapporteur on adequate housing as a component of the right to an adequate standard of living, Miloon Kothari. A/HRC/2/7, Uganda (March 2005) E/CN.4/2006/48/Add.2,Mozambique (December 2003) E/CN.4/2005/51/Add.2, Peru (June 2004) E/CN.4/2005/51/Add.3, Romania (August 2004) E/CN.4/2005/51/Add.4, World Trade Organization (16 to 23 July 2003 and 27 to 28 August 2003) E/CN.4/2004/49/Add.1.

[441] UNGA 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (8 October 2004) UN Doc A/59/422, 16

[442] UNGA 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (13 September 2006) UN Doc A/61/338

[443] ibid 56

[444] ibid 58

[445] General Comment No. 14 (n 112)

[446] UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (31 March 2009) UN Doc A/HRC/11/12, 94

stated that access to essential medicines is a core obligation of the right to health[447]. This interpretation is consistent with the previous Special Rapporteur's analysis of the right, providing consensus on the scope of the right. The Human Rights Council noted the content of Special Rapporteur Anand Grover's 2011 report, and stated that access to medicines is one of the fundamental elements in progressively achieving the right to health[448], highlighting the agreement of the Human Rights Council, and hence States, on the scope of the right.

Special Rapporteur Paul Hunt also addressed the issue of neglected diseases and concluded that access to medicines to treat neglected diseases fell within the scope of the right. During the 2005 visit to Uganda, the Special Rapporteur had the opportunity to examine the national circumstances on research and development, noting that the international community should give a higher priority to health research and development[449], in particular for neglected diseases prevalent in the State. The Special Rapporteur stated that IP regimes should not constrain access to essential medicines and suggested the development of new IP frameworks in order to encourage research and development into medicines to treat neglected diseases as well as essential medicines.[450] However, the report did not elaborate on the type of frameworks that the State may need to implement, or give an indication of the substantive content of such frameworks. The Special Rapporteurs have also made recommendations on how states can meet their obligations under this right, which provide guidance on how states can implement this right. Trends in the recommendations relate to promoting compulsory licensing, concern over the impact of TRIPS-plus provisions on access to medicines, and states obligations in relation to the actions of pharmaceutical companies.

(i) Promoting use of compulsory licensing

[447] UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, Addendum, Mission to Guatemala' (16 March 2011) UN Doc A/HRC/17/25/Add.2, 76

[448] UNHRC 'Report of the Human Rights Council on its seventeenth session' (24 May 2012) UN Doc A/HRC/17/2, 38-39

[449] UNCHR 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Paul Hunt, Addendum, Mission to Uganda' (19 January 2006) E/CN.4/2006/48/Add.2, 83

[450] ibid

Special Rapporteur Paul Hunt visited the WTO in 2003 and his subsequent report[451] discussed in detail access to medicines as an element of the human right to health[452]. The report provided advice to Member States in promoting access to affordable medicines in compliance with their trade obligations by utilising the TRIPS flexibilities, including compulsory licensing, and also recommending that Member States place such provisions within national legislation in order to safeguard access to medicines[453]. It recognised that the WTO had taken positive steps to address the issue within the trade forum with the Doha Declaration.

The outcomes of the visit to the WTO included a number of recommendations aimed at numerous stakeholders. Recommendations to the Commission on Human Rights, predecessor of the Human Rights Council, included requesting a report on the relationship between trade, poverty and human rights and requesting the preparation of guidelines to assist treaty bodies to raise trade issues[454]. It was also recommended that special rapporteurs and treaty bodies consider the impact of trade policies and rules when carrying out their responsibilities[455]. Recommendations for the WTO Member States included promoting access to affordable medicines by incorporating the TRIPS flexibilities into national legislation[456]. This highlights the importance of addressing the barriers to using the TRIPS flexibilities addressed elsewhere in the thesis. Recommendations also included establishing mechanisms to enhance policy coherence between trade, human rights and health[457] and promoting intellectual property legislation that is consistent with their human rights obligations[458]. International organisations including the WTO, WIPO and WHO were also encouraged to promote the use of TRIPS flexibilities through technical assistance[459] and all stakeholders were recommended to identify measures to address the human rights concern of neglected diseases[460]. These recommendations highlight that there is no zero-sum conflict between trade law and the

[451] UNCHR 'The right of everyone to the enjoyment of the highest attainable standard of physical and mental health Report of the Special Rapporteur, Paul Hunt, Addendum, Mission to the World Trade Organization' (1 March 2004) E/CN.4/2004/49/Add.1
[452] ibid 43
[453] ibid 81
[454] ibid 72-76
[455] ibid 77-78
[456] ibid 81
[457] ibid 79
[458] ibid 82
[459] ibid 88
[460] ibid 89

right to health. Ovett argues that the Special Rapporteur's decision to visit the WTO for his first mission was evidence of the importance of cooperation with the WTO.[461] The visit opened a dialogue with the WTO and other stakeholders, and did result in recommendations that invited constructive and collaborative engagement with the WTO and states.

(ii) TRIPS-plus provisions

Numerous reports of the Special Rapporteur have identified concerns over the agreeing of TRIPS-plus provisions in FTAs. Following visits to Peru in 2004[462] Special Rapporteur Paul Hunt expressed concern that some of the terms of the bilateral trade agreement being negotiated with the United States were inconsistent with the Member State's human rights obligations, and would "significantly impede access to affordable medicines for some individuals and groups"[463]. The report recommended that Peru assessed the likely impact on access to medicines prior to finalising the agreement, and also impressed upon the United States that as part of its human rights responsibilities it should not exert pressure on Peru to agree to TRIPS-plus terms that would be inconsistent with its human rights obligations.[464] This highlights that all Member States must consider the human rights impact of FTAs in the negotiating state also, outlining an extraterritorial obligation on Member States.

The 2009 report also elucidated that TRIPS and FTAs can have an adverse impact on access[465], highlighting that although there was not considered to be a fundamental conflict between TRIPS and access to medicines, the use of FTAs to increase the minimum standards of IP protection set out in TRIPS was a significant risk to securing access. There was criticism of the implementation of paragraph 6 of the Doha Declaration and a call for a simpler mechanism to be devised[466], indicating the challenges posed by the current provisions. The report also found that States need to take advantage of the

[461] Ovett (n 61) 200
[462] United Nations Commission on Human Rights 'Report submitted by the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Paul Hunt, Addendum Mission to Peru' (4 February 2005) UN Doc E/CN.4/2005/51/Add.3
[463] ibid 48
[464] ibid 50-51
[465] UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (31 March 2009) UN Doc A/HRC/11/12
[466] ibid 102

flexibilities inherent in TRIPS, and also to ensure that national patent law standards were flexible to allow exceptions to further promote compulsory licensing and access to medicines.[467]

In the 2009 report following his visit to Guatemala[468], Special Rapporteur Anand Grover stated that major government policies combined with the IP provisions of the Central America-Dominican Republic-United States Free Trade Agreement had negatively impacted on access to medicines.[469] Furthermore, he recommended the elimination of barriers to procurement of generic medicines as well as utilising the TRIPS flexibilities and not entering into FTAs with TRIPS-plus provisions[470]. Special Rapporteur Anand Grover also expressed concern regarding Viet Nam's decision-making as part of the TPP negotiations, and its failure to involve stakeholders as part of the process[471], suggesting that there was a risk of TRIPS-plus provisions being agreed which would be detrimental to the accessibility of medicines in the Member State. The Special Rapporteurs' analysis of the right to health in these reports is significant as agreeing of TRIPS-plus standards in FTAs could amount to an infringement of the right, and failure by states to discharge their obligations under the right.

(iii) State obligations in relation to the actions of pharmaceutical companies

Special Rapporteur Paul Hunt's 2006 report noted that the business sector, including pharmaceutical companies, have some human rights responsibilities[472]. However, it must be emphasised that the business sector, including the pharmaceutical industry, is not currently bound by the UN human rights system, so it is difficult to enforce such responsibilities[473]. The report does note that 'naming and shaming' of businesses that fail to uphold human rights, as well as bringing them before the national courts, is an

[467] Ibid 102-104
[468] UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, Addendum, Mission to Guatemala' (16 March 2011) UN Doc A/HRC/17/25/Add.2
[469] ibid 74
[470] ibid 90
[471] UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, Addendum, Mission to Viet Nam' (4 June 2012) UN Doc A/HRC/20/15/Add.2, 39
[472] UNGA 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (13 September 2006) UN Doc A/61/338 92
[473] However, this position may change due to the work of the Working Group on the issue of human rights and transnational corporations and other business enterprises, discussed below.

important role in realising the rights to health, in particular access to medicines.[474] This suggests that despite a lack of enforcement mechanism within the UN system, States and private actors can face negative consequences for failing to uphold human rights.

In his last thematic report, Special Rapporteur Paul Hunt observed that he had frequently engaged with states regarding their responsibilities in relation to access to medicines, which he described as a "vital component of the right to the highest attainable standard of health"[475]. However, he noted that a common argument made by States was that the policies and practices of some pharmaceutical companies created obstacles with regard to their implementation of the right.[476] In response, the Special Rapporteur drafted guidelines for pharmaceutical companies[477], annexed to his 2008 report, to encourage collective responsibility for the enhancement of access to medicines for all. These guidelines include provisions that pharmaceutical companies should arrange differential pricing[478], issue voluntary licences with a view to increasing access to medicines[479], adopt anti-corruption policies and anti-counterfeiting measures[480], and should establish independent monitoring and accountability mechanisms to assess the impact of the company's activities on access to medicines[481].

This report encourages various states and non-state actors to appreciate that there is a collective responsibility to promote access to medicines globally, and some pharmaceutical companies do have corporate responsibility policies which indicate a commitment to promoting access to adequate health care including medicines[482]. However, the non-binding nature of the guidelines means that the lack of enforceability may be detrimental to their effectiveness. Grover et al acknowledged that the guidelines marked a first attempt to articulate responsibilities for pharmaceutical companies, but argued that they did not go far enough in creating direct legal obligations on

[474] UNGA 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (13 September 2006) UN Doc A/61/338, 96
[475] UNGA 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (11 August 2008) A/63/263, 20
[476] ibid 23
[477] ibid Annex
[478] ibid Annex 33
[479] ibid Annex 30
[480] ibid Annex 15-16
[481] ibid Annex 14
[482] See Novartis 'Our Corporate Responsibility Strategy' <https://www.novartis.com/about-us/corporate-responsibility/novartis-access-healthcare> (accessed 27/04/2020)

pharmaceutical companies under the right to health.[483] Grover et al commented that the guidelines were not mandatory, did not provide for a real accountability mechanism and did not provide an effective remedy to those individuals whose rights had been infringed by the behaviour of pharmaceutical companies.[484] Grover et al also asserted that it is evident that the international intellectual property regime "must be modified and that reasonable constraints be placed on the behaviour of pharmaceutical companies in order to allow for adequate levels of industry competition."[485] Although this demonstrates the influence of pharmaceutical companies on securing access to medicines, it also highlights that private businesses and companies are not directly bound by the conclusions of the human rights regime, which is increasingly problematic in terms of making progress to secure improved access to essential medicines worldwide.

The visit to GlaxoSmithKline undertaken by Special Rapporteur Paul Hunt in 2009[486] demonstrated his view that there is a need for an independent mechanism to monitor compliance of pharmaceutical companies with their corporate social responsibilities[487]. His reasoning for pharmaceutical companies having such responsibilities is that "[h]aving developed a life-saving medicine, the company has a human rights responsibility to take all reasonable steps to make the medicine as accessible as possible, as soon as possible, to all those in need"[488]. This suggests that if those companies undertake the responsibility of manufacturing essential medicines, there is an attached responsibility, shared with Member States, to ensure that the essential medicines are used for the purpose for which they were developed. This aligns with the UN Guiding Principles on Business and Human Rights[489], which sets out the responsibility of businesses to mitigate adverse human right impacts of their activities. Through the implementation of monitoring mechanisms, States could impose legal obligations on pharmaceutical companies at national level to comply with corporate social responsibility goals.

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[483] A Grover, B Citro, M Mankad and F Lander, 'Pharmaceutical Companies and Global Lack of Access to Medicines: Strengthening Accountability under the Right to Health' (2012) 40 Journal of Law, Medicine & Ethics 234, 242

[484] ibid 243

[485] ibid 236

[486] UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of health, Paul Hunt, Annex, Mission to GlaxoSmithKline' (5 May 2009) UN Doc A/HRC/11/12/Add.2

[487] ibid 32

[488] ibid 37

[489] UN Guiding Principles on Business and Human Rights will be discussed later in this chapter.

The 2013 report[490] of Special Rapporteur Anand Grover focused specifically on access to medicines and examined various factors, including those linked to production and pricing. To promote affordability, the report also recommended encouragement of local production of medicines, the establishment of an essential medicines list which is based on national need and irrespective of cost, and a recommendation that States adopt competition laws and policies to prevent pharmaceutical companies from indulging in anti-competitive practices and promote competitive pricing of medicines together with strong enforcement.[491] This recommendation demonstrates that the Special Rapporteur is pursuing devices to indirectly enforce responsibilities upon pharmaceutical companies by placing responsibility upon the State Members, which do have obligations under UN treaties to promote the right to health, to try to regulate the pricing of medicines set by pharmaceutical companies to promote access for all. States also have positive obligations to protect the right to health. However, it is problematic that the reports are not binding, and therefore enforcing state compliance with such recommendations is difficult. The Special Rapporteur noted that there was a gap between the formulation and implementation of health policies, which had a negative effect on a number of the elements of the right to health, including medicines[492]. Therefore, states have obligations to ensure the effective implementation of policies to enhance access to medicines as part of the right to health.

b) Working Group on the issue of human rights and transnational corporations and other business enterprises

The Working Group on the issue of human rights and transnational corporations and other business enterprises also has a thematic mandate under the Special Procedures. The Working Group examines the developing standards relating to the responsibilities of business enterprises with respect to human rights and, like the Special Rapporteur on the right to health, reports to the Human Rights Council.[493] One of the main functions of the

[490] UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines' (1 May 2013) UN Doc A/HRC/23/42
[491] ibid 71
[492] Ibid 49-51
[493] OHCHR ' Working Group on the issue of human rights and transnational corporations and other business enterprises'

Working Group is to promote the dissemination and implementation of the UN Guiding Principles on Business and Human Rights[494]. The Guiding Principles were developed by the Special Representative of the Secretary-General on human rights and transnational corporations and other business enterprises[495], John Ruggie, appointed in 2005. The Guiding Principles provide a framework for addressing the issue of human rights harms caused by business enterprises which is based on three central pillars. The first pillar is the State duty to protect against human rights abuses by third parties, including business enterprises. The second is the corporate responsibility to respect human rights. The third is effective access to remedies. The Guiding Principles were adopted unanimously[496], which is significant as it reflects the states' consensus on their utility. A key challenge in relation to enhancing access to medicines is the high pricing of medicines by pharmaceutical companies which make them unaffordable to many patients. Business enterprises do not have obligations under international human rights law, and the Guiding

<https://www.ohchr.org/EN/Issues/Business/Pages/WGHRandtransnationalcorporationsandotherbusiness.aspx> (accessed 27/04/2020)

[494] United Nations Office of the High Commissioner for Human Rights, *Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework,* (United Nations, New York and Geneva 2011) UN Doc HR/PUB/11/04 <https://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf> (accessed 27/04/2020). Due to the significance of the work of the Working Group in relation to access to medicines, a systematic review of the reports of the Working Group has been undertaken: Working Group reports to the Human Rights Council: A/HRC/41/43, A/HRC/41/43/Add.1, A/HRC/41/43/Add.2, A/HRC/38/48, A/HRC/38/48/Add.1, A/HRC/38/48/Add.2, A/HRC/35/32, A/HRC/35/32/Add.1, A/HRC/35/32/Add.2, A/HRC/32/45, A/HRC/32/45/Add.1, A/HRC/32/45/Add.2, A/HRC/32/45/Add.3, A/HRC/32/46, A/HRC/29/28, A/HRC/29/28/Add.1, A/HRC/29/28/Add.2, A/HRC/29/28/Add.3, A/HRC/29/28/Add.4, A/HRC/26/25, A/HRC/26/25/Add.1, A/HRC/26/25/Add.2, A/HRC/26/25/Add.3, A/HRC/26/25/Add.4, A/HRC/26/25/Add.5, A/HRC/23/32, A/HRC/23/32/Add.1, A/HRC/23/32/Add.2, A/HRC/20/29. Working Group reports to the General Assembly: A/74/198, A/73/163, A/72/162, A/71/291, A/70/216, A/69/263, A/68/279, A/67/285. Working Group country visit reports: A/HRC/29/28/Add.1, A/HRC/26/25/Add.4, A/HRC/26/25/Add.5, A/HRC/23/32/Add.1. Reports from the Working Group's sessions: A/HRC/WG.12/18/1, A/HRC/WG.12/17/1, A/HRC/WG.12/16/1, A/HRC/WG.12/15/1, A/HRC/WG.12/14/1, A/HRC/WG.12/13/1, A/HRC/WG.12/12/1, A/HRC/WG.12/11/1, A/HRC/WG.12/10/1, A/HRC/WG.12/9/1, A/HRC/WG.12/8/1, A/HRC/WG.12/7/1, A/HRC/WG.12/6/1, A/HRC/WG.12/5/1, A/HRC/WG.12/4/1, A/HRC/WG.12/3/1, A/HRC/WG.12/2/1. Annual Forum on Business and Human Rights: A/HRC/41/49, A/HRC/38/49, A/HRC/FBHR/2016/2, A/HRC/35/34, A/HRC/FBHR/2015/2, A/HRC/FBHR/2014/3, A/HRC/29/29, A/HRC/FBHR/2013/4, A/HRC/26/26, A/HRC/FBHR/2012/4, A/HRC/23/33. Reports of the Secretary-General and the High Commissioner: A/HRC/26/20, A/HRC/26/20/Add.1, A/HRC/21/21, A/HRC/21/21/Corr.1, A/HRC/14/29, A/HRC/14/29/Add.1, A/63/270, A/HRC/4/99, E/CN.4/2006/92, E/CN.4/2005/91. Reports of the Special Representative of the Secretary-General on human rights and transnational corporations and other business enterprises: A/HRC/17/32, A/HRC/17/31, A/HRC/17/31/Add.1, A/HRC/17/31/Add.2, A/HRC/17/31/Add.3, A/65/310, A/HRC/14/27, A/64/216, A/HRC/11/13, A/HRC/11/13/Add.1, A/HRC/8/16, A/HRC/8/5, A/HRC/8/5/Add.1, A/HRC/8/5/Add.2, A/HRC/4/35, A/HRC/4/35/Add. 1, A/HRC/4/35/Add. 2, A/HRC/4/35/Add. 3, A/HRC/4/35/Add. 4, A/HRC/4/74, E/CN.4/2006/97.

[495] UNCHR Res 2005/69 (20 April 2005) UN Doc E/CN.4/RES/2005/69

[496] UNGA Res 60/251 (3 April 2006) UN Doc A/RES/60/251

Principles were developed to address the adverse impacts that can be caused by businesses. Therefore, Guiding Principles and the work of the Working Group is important to this research in terms of the potential for delivering legally binding obligations for pharmaceutical companies in relation to the right to health and access to medicines.

A criticism of the Guiding Principles is that while the Guiding Principles have received a high level of endorsement by a range of stakeholders, including from the Human Rights Council and the UN Global Compact, the focus on 'responsibilities' rather than obligations and the absence of an effective remedy for failing to comply, means that the Guiding Principles do not go far enough to address business conduct which is harmful to human rights.[497] However, an alternative view is that the Guiding Principles were not intended to create legal obligations or to be a regulatory regime in itself, but a platform of guidelines by which stakeholders including states may define their own regulatory regimes, to promote policy coherence between states' human rights obligations and their actions in relation to business and commercial entities.[498] The fact that the Guiding Principles are non-binding could present challenges in persuading States and private enterprises of the need for enforceable norms to implement regulatory regimes for businesses where human rights concerns arise. However, the level of endorsement of the Guiding Principles reflects that there is a desire at the international level for guidance on how to address actions of corporations that harm human rights. The flexibility for States to develop their own national regulatory regimes could also encourage enhanced compliance with human rights norms. A challenge for States will be how to effectively address situations where business enterprises do not cooperate with the implementation of the Guiding Principles, although strategies could include 'naming and shaming' of infringing companies, withdrawal of government funding, should the company benefit from such funding, or imposition of sanctions.[499]

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[497] R Blitt, 'Beyond Ruggie's Guiding Principles on Business and Human Rights: Charting an Embracive Approach to Corporate Human Rights Compliance' (2012) 48 Tex Int'l L J 33, 51-53; N Jagers, 'UN Guiding Principles on Business and Human Rights: Making Headway towards Real Corporate Accountability' (2011) 29 Neth Q Hum Rts 159, 163; R Davis, 'The UN Guiding Principles on Business and Human Rights and conflict-affected areas: state obligations and business responsibilities' (2012) 94 Int'l Rev Red Cross 961, 978

[498] M Addo, 'The Reality of the United Nations Guiding Principles on Business and Human Rights' (2014) 14 Hum Rts L Rev 133, 146; Davis (n 497) 963; M Fasciglione, 'The Enforcement of Corporate Human Rights Due Diligence: From the UN Guiding Principles on Business and Human Rights to the Legal Systems of EU Countries' (2016) 10 Hum Rts & Int'l Legal Discourse 94, 116

[499] Davis (n 497) 968

The work of the Working Group provides an important source of information on experiences and lessons learned by states.[500] The Working Group encourages States to produce National Action Plans on business and human rights as part of their responsibility to implement of the Guiding Principles and has produced guidance in order to help States to do so[501]. The Guiding Principles have gained support from States and the private sector[502], and Member States including the UK, Spain and Colombia[503] have adopted National Action Plans as part of the State responsibility to implement the UN Guiding Principles nationally[504]. This illustrates that action is being taken by governments at national level to implement the Guiding Principles and operationalise the framework.

The Working Group created by the Human Rights Council in its resolution 17/4[505] in 2011 was originally established for a period of three years. In 2014 the Human Rights Council decided to establish an open-ended intergovernmental Working Group with a mandate to establish a legally binding instrument on human rights, transnational corporations and other business enterprises[506]. The instrument is currently in the drafting stage, with emphasis on building upon the Guiding Principles.[507] If the instrument does come into force, it could have significant implications for businesses, as it is likely that they will be held accountable for failing to respect human rights, through the introduction of stricter regulatory mechanisms by States bound by the proposed instrument.

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[500] Addo (n 498) 138

[501] UN Working Group on Business and Human Rights, *Guidance on National Action Plans on Business and Human Rights*, Version 1.0, December 2014, <http://www.ohchr.org/Documents/Issues/Business/UNWG_%20NAPGuidance.pdf> (accessed 27/04/2020)

[502]UN Working Group on Business and Human Rights, *Guidance on National Action Plans on Business and Human Rights: UN Working Group on Business and Human Rights,* Version 2.0, (United Nations, Geneva 2015), 1 <https://www.business-humanrights.org/sites/default/files/documents/UNWG_NAPGuidance_Version2%200_final_print_09112015.pdf> (accessed 27/04/2020)

[503]United Nations Office of the High Commissioner for Human Rights, 'State national action plans on business and Human Rights' <http://www.ohchr.org/EN/Issues/Business/Pages/NationalActionPlans.aspx> (accessed 27/04/2020)

[504] UN Working Group on Business and Human Rights, *Guidance on National Action Plans on Business and Human Rights: UN Working Group on Business and Human Rights,* Version 2.0 (n 502) 3

[505] UNHRC Res 17/4 'Human rights and transnational corporations and other business enterprises' (6 July 2011) UN Doc A/HRC/RES/17/4

[506] UNGA Res 26/9 (14 July 2014) UN Doc A/HRC/RES/26/9, 2. See also UNHRC 'Report on the first session of the open-ended intergovernmental working group on transnational corporations and other business enterprises with respect to human rights, with the mandate of elaborating an international legally binding instrument (5 February 2016) UN Doc A/HRC/31/50

[507] UNHRC 'Report on the fourth session of the open-ended intergovernmental working group on transnational
corporations and other business enterprises with respect to human rights' (2 January 2019) UN Doc A/HRC/40/48, 11-13

Following the development of the Guiding Principles, the CESCR issued its General Comment 24[508] in 2017 to clarify the obligations of States parties to the ICESCR with a view to addressing adverse effects of business activities on human rights. General Comment 24 highlights that States parties have a responsibility to regulate transnational corporations as part of their human rights obligations under the ICESCR.[509] General Comment 24 also highlights that States parties have extraterritorial obligations founded in Article 2 ICESCR[510] to take steps to prevent and remedy infringements of ICESCR rights that occur outside their territories due to the activities of business entities over which they can exercise control.[511] This guidance is significant in terms of clarifying the scope of States' parties obligations in relation to access to medicines and the right to health under Article 12 ICESCR, as it illustrates that States parties have obligations under the ICESCR to regulate pharmaceutical companies under their control, where the price of medicines could infringe the right to health. This obligation extends to the extraterritorial actions of those companies, such as setting high prices for medicines in other territories which could infringe the right to health of patients.

UN High Commissioner for Human Rights

In 2001, the UN High Commissioner for Human Rights also produced a report examining the links between human rights and TRIPS, with a focus on the right to health.[512] The report declared that when considering the operation of IP systems with regard to access to medicines the starting point is that access to essential medicines is a human right.[513] This is a significant statement from the UN High Commissioner that access to essential medicines forms part of the rights in the UN system. However, there is no clear guidance on where the issue of access to essential medicines fits in to the system, and on whether access to essential medicines should form a distinct human right, or whether it is an aspect of an existing human right. Article 31(1) VCLT provides the general rule of interpretation

[508] UNCESCR 'General comment No. 24 (2017) on State obligations under the International Covenant on Economic, Social and Cultural Rights in the context of business activities' (10 August 2017) UN Doc E/C.12/GC/24
[509] ibid 16
[510] ibid 36
[511] ibid 30
[512] UNCHR 'The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights: Report of the High Commissioner' (27 June 2001) UN Doc E/CN.4/Sub.2/2001/13
[513] ibid 42

being that a treaty is interpreted in good faith in accordance with its ordinary meaning in light of its object and purpose[514]. Furthermore, Article 38 of the ICJ Statute[515] provides that when deciding disputes in accordance with international law, the ICJ shall apply international conventions establishing rules expressly recognised by the contesting States, international customs and general principles of law, and does not expressly state that human rights principles must be given prominence.

The report also specifically addressed the impact of IP systems on access to medicines, observing that while protecting IP rights can enhance technology transfer to developing countries, such protection can also lead to higher pricing which can restrict access to medicines for the poor.[516] The report noted the potential links between human rights and the objective of promoting social and economic welfare under Article 7 TRIPS[517], but that "recognizing the links between the standards in the TRIPS Agreement and the promotion and protection of human rights is not the same as saying that the TRIPS Agreement takes a human rights approach to intellectual property protection."[518] The guidance from the High Commissioner's report included that states should prevent abuses of IP rights that lead to violations of the right to health, such as restrictive licensing practices or the setting of high prices for essential medicines.[519] The report encouraged states to implement the compulsory licensing provisions under Article 31 TRIPS in national legislation as safeguards to protect access to essential medicines as a component of the right to health.[520] The report also recommended that developing countries be cautious about enacting 'TRIPS-plus' legislation without first understanding the impact of such legislation on the protection of human rights[521].

The report provides useful guidance on the scope of the right to health includes access to essential medicines. The report also outlines the scope of states obligations, including that states should implement TRIPS in light of their obligations under the right to health and should utilise compulsory licensing to promote affordable access to medicines. While the statements in the UN High Commissioner's report are non-binding,

[514] VCLT (n 47) Article 31, 339
[515] ICJ Statute (n 10) Article 38
[516] UNCHR 'The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights: Report of the High Commissioner' (27 June 2001) UN Doc E/CN.4/Sub.2/2001/13, 42
[517] ibid 16
[518] ibid 21
[519] ibid 64
[520] ibid 66
[521] ibid 69

the report has been considered as a useful contribution to the discourse on the impact of economic globalisation on the enjoyment of human rights, because it outlines that the international trade system can work for the promotion and protection of human rights, and discusses how states can balance their obligations.[522] The guidance in the report considers how states could address potential tensions between their human rights obligations and their obligations under TRIPS, illustrating that the High Commissioner did not find that TRIPS was inherently compatible with human rights. However, the report did outline that the implementation of TRIPS-plus standards of IP rights protection could be inconsistent with states' human rights obligations.

III. United Nations Human Rights Treaty Monitoring Bodies

In addition to the Charter-based bodies, the bodies within the Treaty Monitoring system also have a remit with regard to the advancement of the right to health. Although the decisions of the Treaty Monitoring Bodies system are not legally binding they are considered to be authoritative[523]. The main role of the treaty bodies is to receive State parties' reports on the implementation of the rights within the specific treaty and to adopt concluding observations, which are valuable as an interpretative tool for the treaties.[524] Therefore, the work of the treaty bodies have significant interpretative value for this research in relation to the normative content of the right to health.

The findings of the treaty bodies are also relevant to domestic courts, with the International Law Association stating that national courts have recognised that the treaty bodies' interpretations deserve to be given considerable weight in determining the meaning of a relevant right and the existence of a violation.[525] This is significant in relation to the monitoring and accountability of state obligations at national level, as it demonstrates how domestic courts utilise the treaty bodies' reports to inform their interpretation of statutory or constitutional human rights provisions.[526] This suggests that

[522] Lang (n 52) 337; Chapman (n 72) 878; Helfer (n 78) 49
[523] Helfer and Austin (n 3) 113
[524] M O'Flaherty, 'The Concluding Observations of United Nations Human Rights Treaty Bodies' (2006) 6 HRLR 27, 51
[525] International Law Association, Committee on International Human Rights Law and Practice (1997-2008), 'Final Report on the Impact of Findings of the United Nations Human Rights Treaty Bodies', Conference Report, Berlin Conference 2004, <https://www.ila-hq.org/index.php/committees> (accessed 27/04/2020)
[526] R Higgins 'The United Nations at 70 years: the impact upon international law' (2016) 65(1) I.C.L.Q. 1, 8-9; D Desierto and C Gillespie 'A modern integrated paradigm for international responsibility arising

the treaty bodies have an influential role in terms of guidance to State parties on how they should meet their obligations under the treaties, rather than a mandate of enforcement.

The Treaty Monitoring Body system does face some challenges, including the non-binding nature of recommendations, the issue of effective follow-up action and non-submission of state reports.[527] The formulation of concluding observations is intended to be a process of interactive dialogue with the state, not a process of adjudication as in the case of court proceedings[528], but following up on the implementation of the recommendations made during the process could add to the utility of the concluding observations. Alston argues that although there are problems, difficulties in changing the system include reluctance from states as well as decreasing UN resources.[529] Various proposals for reform have been advanced, most notably the 2012 report of the then High Commissioner for Human Rights, Navi Pillay, which outlined proposals on simplifying reporting procedures and strengthening the expertise of treaty body members.[530] As yet, these have not been taken forward.

There are currently nine core international human rights treaties, with individual monitoring bodies in the form of Committees to promote and monitor state compliance with their obligations in the treaties.[531] The Committee on Economic, Social and Cultural Rights (CESCR) monitors the ICESCR. For the purposes of this chapter, the ICESCR is particularly significant due to the nature of the social and cultural rights contained in this treaty, including the right to the highest attainable standard of health under Article 12.[532] As at 31 March 2020, 170 states are states parties to the ICESCR, including Canada, Peru and EU Member States.[533] The US is one of four states that is a signatory but has not ratified the ICESCR.[534] The Committees overseeing the respective treaties may also publish General Comments on thematic issues, which provide authoritative interpretative

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from violations of economic, social, and cultural rights' (2014) 3(2) C.J.I.C.L. 556, 585; M Kanetake 'UN human rights treaty monitoring bodies before domestic courts' (2018) 67(1) I.C.L.Q. 201, 230

[527] N Rodley, 'Duplication and Divergence in the Work of the United Nations Human Rights Treaty Bodies: A Perspective from a Treaty Body Member' (2011) 105 Am Soc'y Int'l L Proc 512, 517

[528] Mechlem (n 105) 923; V Pandmanabhan, 'The Human Rights Justification for Consent' (2013) 35 U Pa J Int'l L 1, 20; O'Flaherty (n 524) 34

[529] P Alston, 'Ships Passing in the Night: The Current State of the Human Rights and Development Debate Seen through the Lens of the Millennium Development Goals' (2005) 27 Hum Rts Q 755, 825

[530] Pillay (n 398) 47, 60

[531] United Nations Office of the High Commissioner for Human Rights, 'Human Rights Bodies' (n 7)

[532] International Covenant on Economic, Social and Cultural Rights (n 2)

[533] United Nations Office of the High Commissioner for Human Rights, 'Status of Ratification' <https://indicators.ohchr.org/> (accessed 27/04/2020)

[534] ibid

guidance on the obligations of the State parties under the relevant treaty.[535] General Comments can also provide guidance in formulating concluding observations.

Article 2 of the ICESCR outlines States parties' obligations under the Covenant in general, stating that States are obligated to take steps to progressively realise the rights in the Covenant. This suggests that the States parties have a wide discretion in terms of the period of time in which to realise their responsibilities, although there are also immediate obligations such as non-discrimination. The CESCR issued General Comment 3[536], which clarifies that Article 2 recognises that some States will not be able to achieve full realisation of all of the Covenant rights in a short period of time, although they are required to immediately take steps to begin the full realisation of the rights.[537] Therefore the States must actively demonstrate that they have implemented processes in order to achieve full realisation of the rights in the Covenant.

(a) ICESCR Article 12

The ICESCR is the most significant treaty with regard to health rights, originally provided for in Article 25 of the Universal Declaration on Human rights (UDHR) as part of an adequate standard of living[538], and since enshrined in Article 12 of the ICESCR[539] which states:

"1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

[535] A Müller, 'Limitations to and Derogations from Economic, Social and Cultural Rights' (2009) 9 HRLR 557, 557-558

[536] Committee on Economic, Social and Cultural Rights, 'General Comment No. 3: The Nature of States Parties' Obligations (Art 2, Para 1 of the Covenant)' (14 December 1990) UN Doc E/1991/23

[537] ibid 9

[538] Article 25 of the UDHR states: "Article 25. (1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control. (2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection." Universal Declaration of Human Rights (n 356)

[539] The ICESCR has been ratified by 164 states. States may state any reservation or interpretive declarations in relation to particular articles. None have been made in relation to Article 12 or access to medicines. See also United Nations Office of the High Commissioner for Human Rights, 'Status of Ratification Interactive Dashboard' <http://indicators.ohchr.org/> (accessed 27/04/2020)

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness."

The obligations of the States parties in Article 12 are widely drafted, as the term "all steps necessary" is open to be interpreted differently by different State parties. While this flexibility may be an advantage to countries which do not have the resources to make the same provisions to realise the right as more developed countries, there is potential for uncertainty as to the limits of the States parties' obligations.

(b) National obligations of States parties under the ICESCR

There is no reference to medicines in the drafting history of the ICESCR[540], so it is important to consider the content and interpretation of the right in order to understand whether the right has been interpreted to include access to medicines. In 2000 the CESCR issued its General Comment 14 in order to provide guidance on interpreting Article 12.[541] General Comment 14 clarifies that Article 12 affords the right to equality of opportunity to enjoy the highest attainable standard of health[542]. General Comment 14 also clarifies that the essential elements of the right include availability of essential medicines and accessibility of such medicines, although does not define what amounts to 'essential' medicines. This is an example of the lack of clarity on terminology previously discussed in Chapter 1. General Comment 14 also provides that the right to health facilities in Article 12(2)(d) includes the provision of essential medicines. Accessibility is considered in economic terms rather than geographical or physical terms and therefore means that health facilities, goods and services must be affordable for all.[543] Therefore the right of

[540] United Nations General Assembly, 'Draft International Covenant on Human Rights: Annotation, prepared by the Secretary-General' (1 July 1955) UN Doc A/2929, P.320
[541] General Comment No. 14 (n 112)
[542] ibid 8
[543] ibid 12

access to essential medicines is specifically adopted as part of the ICESCR through General Comment 14.[544]

The specific legal obligations on Member States include obligations to respect, protect and fulfil the right to health[545]. The obligation to respect includes an obligation on Member States to refrain from marketing unsafe medicines[546], obligations to protect involve duties on Member States to enact legislation or national policies to secure equal access to health care and services provided by third parties, including to control the marketing of medicines and ensuring that third parties do not limit access to health-related services[547]. General Comment 14 clarifies that availability of affordable essential medicines is a critical component of the right to the highest attainable standard of health, by outlining that access to essential medicines is a core obligation of states.[548] 'While this is an important clarification, there is no elaboration on how this obligation is to be realised. Given that states' ability to ensure availability of medicines, and therefore meet this obligation, is linked to resource availability, developing states may be unable to fully realise this right due to resource constraints. However, General Comment 3 does address such a situation, providing that a state has to show that they have made every effort to use all available resources to satisfy those minimum core obligations.[549]

(c) International obligations of States parties under ICESCR Article 12

General Comment 14 provides guidance on the actions to be taken by States parties. This includes defining the actions under Article 12(2)(c) regarding control of diseases as States parties individual and joint efforts to make available relevant technologies[550], which may be relevant in terms of new medicines under patent and generic production, and highlights the extraterritorial responsibility to cooperate with other States. The General Comment

[544] T Bhatt 'Amending TRIPS: A New Hope for Increased Access to Essential Medicines' (2008) 33 Brook. J. Int'l L. 597, 622
[545] General Comment No. 14 (n 112) 34-37
[546] ibid 34
[547] ibid 35
[548] ibid 43
[549] General Comment No. 3 (n 536) 10; A Nolan and M Dutschke 'Article 2(1) ICESCR and States Parties' Obligations: Whither the Budget?' (2010) 3 European Human Rights Law Review 280, 287; A Chapman. 'A "Violations Approach" for Monitoring the International Covenant on Economic, Social and Cultural Rights' (1996) 18 Human Rights Quarterly 23, 31; P Alston and G Quinn, 'The Nature and Scope of the States Parties' Obligations under the International Covenant on Economic, Social and Cultural Rights' (1987) 9 Human Rights Quarterly 156, 178
[550] General Comment No. 14 (n 112) 13

also clarifies that the right to health includes accessibility of health facilities, goods and services without discrimination, and ensuring that health expenses do not disproportionately burden the poor in comparison to the wealthier sector of the population.[551] Therefore, states have an obligation to promote affordable essential medicines for all, not just those who are able to pay the current costs for the provision of health goods and services.

The international obligations of States also include the obligation to respect the right to health in other countries and to prevent third parties, such as companies, from violating the right in other territories as far as possible[552]. States are also required to facilitate access to health facilities, goods and services in other countries, have an obligation to ensure that their actions as members of international organisations take due account of the right to health, and should refrain at all times from imposing embargoes or similar measures restricting the supply to another State of adequate medicines[553]. However this is not an absolute requirement as States are only required to do so as far as it is possible for them to do so, which may be difficult to monitor, particularly in relation to developing countries that have resource constraints. Coomans argues that the CESCR has not provided an in-depth clarification of the international obligations of states, and this has led to the use of different terms and weak language on the nature of states' commitments[554]. The lack of clarity on the notion of international obligations could present uncertainties for states if the extent of their obligations is not clearly defined. It is also difficult to see how States could be held accountable for failing to meet such obligations. However, this reflects that States parties have to recognise the importance of international assistance among a range of stakeholders in achieving full realisation of the right to health, and access to medicines.

The extraterritoriality of State obligations under the ICESCR are evident in General Comment 3[555] which elaborates on Article 2(1)[556], emphasising that international cooperation for the realisation of the rights enshrined in the ICESCR is an obligation of all States, and without international cooperation and assistance the full realisation of these

[551] ibid 12
[552] ibid 39
[553] ibid 39-41
[554] F Coomans, 'The Extraterritorial Scope of the International Covenant on Economic, Social and Cultural Rights in the Work of the United Nations Committee on Economic, Social and Cultural Rights' (2011) 11 Hum Rts L Rev 1, 34
[555] General Comment No. 3 (n 536)
[556] International Covenant on Economic, Social and Cultural Rights (n 2) Article 2(1)

rights will not be attainable for all Member States[557]. General Comment 14 also clarified that States are bound by their obligations under the ICESCR when acting as a member of an international organisation[558]. Not only must States have due regard to their human rights obligations in the negotiation of international agreements, but they also have to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, as far as they are able to do so. This proposes that WTO Member States are required to consider their human rights obligations in the negotiation of trade agreements and must therefore consider how such agreements affect the right to health including access to medicines, and also suggests that Member States are obliged to take positive actions for furtherance of the right to health in other countries. Such obligations are particularly pertinent in relation to access to medicines, and ensuring that the related rights of all individuals in all states are upheld.

The utility of Concluding Observations[559]

[557] General Comment No. 3 (n 536) 14

[558] General Comment No. 14 (n 112) 39

[559] A systematic, chronological review of the Concluding Observations of the CESCR has been undertaken, in consideration of their relevance to accessing medicines: Luxembourg E/1991/23, Tunisia E/1980/WG.1/SR.5, United Republic of Tanzania E/1980/WG.1/SR.5, Ecuador E/1980/WG.1/SR.4, Ecuador E/1980/WG.1/SR.5, Norway, E/1980/WG.1/SR.5, Romania E/1980/WG.1/SR.7, Mongolia E/1980/WG.1/SR.7, Chile E/1980/WG.1/SR.9, Hungary E/1980/WG.1/SR.7, Finland E/1980/WG.1/SR.6, Tunisia E/1980/WG.1/SR.6, Germany E/1980/WG.1/SR.8, Chile E/1980/WG.1/SR.8, Philippines E/1980/WG.1/SR.11, Australia E/1980/WG.1/SR.12, Bulgaria E/1980/WG.1/SR.12, Germany E/1980/WG.1/SR.10, Denmark E/1980/WG.1/SR.10, Australia E/1980/WG.1/SR.13, Cyprus E/1980/WG.1/SR.17, Colombia E/1980/WG.1/SR.15, Russian Federation E/1980/WG.1/SR.14, Sweden E/1980/WG.1/SR.15, Ukraine E/1980/WG.1/SR.18, Poland E/1980/WG.1/SR.18, Romania E/1980/WG.1/SR.16, Belarus E/1980/WG.1/SR.16, Jamaica E/1980/WG.1/SR.20, Spain E/1980/WG.1/SR.20, Poland E/1980/WG.1/SR.19, United Kingdom of Great Britain and Northern Ireland E/1980/WG.1/SR.19, Madagascar E/1981/WG.1/SR.2, Syrian Arab Republic E/1981/WG.1/SR.4, Germany E/1981/WG.1/SR.8, Germany E/1981/WG.1/SR.10, Austria E/1981/WG.1/SR.8, Iraq E/1981/WG.1/SR.12, Senegal E/1981/WG.1/SR.11, United Kingdom of Great Britain and Northern Ireland E/1981/WG.1/SR.16, United Kingdom of Great Britain and Northern Ireland, E/1981/WG.1/SR.17, Canada E/1982/WG.1/SR.1, Italy E/1982/WG.1/SR.3, Italy E/1982/WG.1/SR.4, Panama E/1982/WG.1/SR.5, Barbados E/1982/WG.1/SR.3, Canada E/1982/WG.1/SR.2, Japan E/1982/WG.1/SR.12, Japan E/1982/WG.1/SR.13, Mexico E/1982/WG.1/SR.14, Mexico E/1982/WG.1/SR.15, Libya E/1983/WG.1/SR.16, Libya E/1983/WG.1/SR.17, India E/1984/WG.1/SR.6, India E/1984/WG.1/SR.8, Venezuela (Bolivarian Republic of) E/1984/WG.1/SR.7, Venezuela Bolivarian Republic of) E/1984/WG.1/SR.8, Russian Federation E/1984/WG.1/SR.9, Venezuela (Bolivarian Republic of) E/1984/WG.1/SR.10, Peru E/1984/WG.1/SR.11, Russian Federation E/1984/WG.1/SR.10, Rwanda E/1984/WG.1/SR.10, Sweden E/1984/WG.1/SR.14, Spain E/1984/WG.1/SR.12, Spain E/1984/WG.1/SR.14, Rwanda E/1984/WG.1/SR.12, Philippines E/1984/WG.1/SR.15, Belarus E/1984/WG.1/SR.13, Belarus E/1984/WG.1/SR.14, Belarus, E/1984/WG.1/SR.15, Ukraine E/1984/WG.1/SR.13, Ukraine E/1984/WG.1/SR.14, Ukraine E/1984/WG.1/SR.15, Finland E/1984/WG.1/SR.17, Denmark E/1984/WG.1/SR.17, Mongolia E/1984/WG.1/SR.16, Yugoslavia E/1984/WG.1/SR.16, Sweden E/1984/WG.1/SR.16, Peru E/1984/WG.1/SR.18, Yugoslavia E/1984/WG.1/SR.18, Mongolia E/1984/WG.1/SR.18, Cyprus E/1984/WG.1/SR.18, Finland

E/1984/WG.1/SR.18, Ecuador E/1984/WG.1/SR.20, Denmark E/1984/WG.1/SR.21, Hungary E/1984/WG.1/SR.19, Hungary E/1984/WG.1/SR.21, Norway E/1984/WG.1/SR.19, Philippines E/1984/WG.1/SR.20, Norway E/1984/WG.1/SR.22, Cyprus E/1984/WG.1/SR.22, Ecuador E/1984/WG.1/SR.22, Colombia E/1984/WG.1/SR.22, Portugal E/1985/WG.1/SR.2, France E/1985/WG.1/SR.5, France E/1985/WG.1/SR.7, Portugal, E/1985/WG.1/SR.4, Bulgaria E/1985/WG.1/SR.9, Romania E/1985/WG.1/SR.10, Romania E/1985/WG.1/SR.13, Bulgaria E/1985/WG.1/SR.11, Australia E/1985/WG.1/SR.17, Nicaragua E/1985/WG.1/SR.15, United Kingdom of Great Britain and Northern Ireland E/1985/WG.1/SR.14, United Kingdom of Great Britain and Northern Ireland E/1985/WG.1/SR.17, Australia E/1985/WG.1/SR.18, Australia E/1985/WG.1/SR.21, Hungary E/1986/WG.1/SR.9, Austria E/1986/WG.1/SR.4, Zambia E/1986/WG.1/SR.4, Zambia E/1986/WG.1/SR.5 , Hungary E/1986/WG.1/SR.6, Iraq E/1986/WG.1/SR.8, Hungary E/1986/WG.1/SR.7, Austria E/1986/WG.1/SR.7, Zambia E/1986/WG.1/SR.7, Iraq E/1986/WG.1/SR.11, Poland E/1986/WG.1/SR.26, Poland E/1986/WG.1/SR.27, Poland E/1986/WG.1/SR.25, Chile E/C.12/1988/4, Democratic Republic of the Congo E/C.12/1988/4, Netherlands E/C.12/1989/5, Netherlands E/C.12/1989/5, Netherlands E/C.12/1989/5 paras. 193-228, Trinidad and Tobago E/C.12/1989/5 paras. 267-309, Cameroon E/C.12/1989/5 paras. 53-78, Canada E/C.12/1989/5 paras. 79-112, Rwanda E/C.12/1989/5 paras. 162-192, Netherlands E/C.12/1989/5 paras. 193-228, United Kingdom of Great Britain and Northern Ireland (Crown Dependencies) A/44/40 paras. 140-189, Philippines E/C.12/1990/3 paras. 113-133, Argentina E/C.12/1990/3 paras. 235-254, Costa Rica E/C.12/1990/8 paras. 159-195, Iran (Islamic Republic of) E/C.12/1990/8 paras. 196-212, Dominican Republic E/C.12/1990/8 paras. 213-250, Jordan E/C.12/1990/8 paras. 56-86, Afghanistan E/C.12/1991/4 paras. 55-94, Syrian Arab Republic E/C.12/1991/4 paras. 158-194, Hungary E/C.12/1992/2 paras. 133-154 Australia, E/C.12/1993/9, Kenya E/C.12/1993/6, Iran (Islamic Republic of) E/C.12/1993/7, Viet Nam E/C.12/1993/8, Lebanon E/C.12/1993/10, Canada E/C.12/1993/5, Iceland E/C.12/1993/15, New Zealand E/C.12/1993/13, Nicaragua E/C.12/1993/14, Senegal E/C.12/1993/18, Mexico E/C.12/1993/16, Germany E/C.12/1993/17, Morocco E/C.12/1994/5, Romania E/C.12/1994/4, Iraq E/C.12/1994/6, Uruguay E/C.12/1994/3, Mauritius E/C.12/1994/8, Belgium E/C.12/1994/7, Austria E/C.12/1994/16, Argentina E/C.12/1994/14, Jamaica E/C.12/1994/15, United Kingdom of Great Britain and Northern Ireland (Crown Dependencies) E/C.12/1994/19, United Kingdom of Great Britain and Northern Ireland E/C.12/1994/19, Mali E/C.12/1994/17, Suriname E/C.12/1994/18, Philippines E/1995/22(SUPP) paras. 216-220, Austria E/1995/22(SUPP) paras. 243-263, Dominican Republic E/1995/22(SUPP) paras. 206-210, Kenya E/1995/22(SUPP) paras. 159-164, Argentina E/1995/22(SUPP) paras. 221-242, United Kingdom of Great Britain and Northern Ireland (Crown Dependencies) E/1995/22(SUPP) paras. 264-304, 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Russian Federation E/C.12/1/Add.13 Saint Vincent and the Grenadines E/C.12/1/Add.21, United Kingdom of Great Britain and Northern Ireland E/C.12/1/Add.19, Dominican Republic E/C.12/1/Add.16, Iraq E/C.12/1/Add.17, Luxembourg E/C.12/1/Add.22, Azerbaijan E/C.12/1/Add.20, Uruguay E/C.12/1/Add.18, Nigeria E/C.12/1/Add.23, Netherlands E/C.12/1/Add.25 Netherlands (Antilles) E/C.12/1/Add.25, Netherlands (Aruba) E/C.12/1/Add.25, Sri Lanka E/C.12/1/Add.24, Poland E/C.12/1/Add.26, Israel E/C.12/1/Add.27, Germany E/C.12/1/Add.29, Cyprus E/C.12/1/Add.28, Switzerland E/C.12/1/Add.30, Canada E/C.12/1/Add.31, Iceland E/C.12/1/Add.32, Ireland E/C.12/1/Add.35, Denmark E/C.12/1/Add.34 Solomon Islands E/C.12/1/Add.33, Tunisia E/C.12/1/Add.36, Argentina E/C.12/1/Add.38, Armenia E/C.12/1/Add.39, Bulgaria E/C.12/1/Add.37, Mexico E/C.12/1/Add.41, Georgia E/C.12/1/Add.42, Italy E/C.12/1/Add.43, Egypt E/C.12/1/Add.44, Congo E/C.12/1/Add.45, Mongolia E/C.12/1/Add.47, Jordan E/C.12/1/Add.46, Kyrgyzstan E/C.12/1/Add.49, Sudan E/C.12/1/Add.48, Australia E/C.12/1/Add.50, Portugal E/C.12/1/Add.53, Morocco E/C.12/1/Add.55, Belgium E/C.12/1/Add.54, Finland E/C.12/1/Add.52, Serbia

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Japan E/C.12/2002/12, Poland E/C.12/1/Add.82, Solomon Islands E/C.12/1/Add.84, Slovakia E/C.12/1/Add.81, Georgia E/C.12/1/Add.83, Estonia E/C.12/1/Add.85, Iceland E/C.12/1/Add.89, Brazil E/C.12/1/Add.87, Luxembourg E/C.12/1/Add.86, Israel E/C.12/1/Add.90, New Zealand E/C.12/1/Add.88, Russian Federation E/C.12/1/Add.94, Republic of Moldova E/C.12/1/Add.91, Guatemala E/C.12/1/Add.93, Democratic People's Republic of Korea E/C.12/1/Add.95, Yemen E/C.12/1/Add.92, Ecuador E/C.12/1/Add.100, Greece E/C.12/1/Add.97, Kuwait E/C.12/1/Add.98, Lithuania E/C.12/1/Add.96, Spain E/C.12/1/Add.99, Chile E/C.12/1/Add.105, Chile E/C.12/1/Add.105/Corr.1, Azerbaijan E/C.12/1/Add.104, Denmark E/C.12/1/Add.102, Malta E/C.12/1/Add.101, Italy E/C.12/1/Add.103, China E/C.12/1/Add.107, China (Hong Kong) E/C.12/1/Add.107, China (Macau) E/C.12/1/Add.107, Zambia E/C.12/1/Add.106, Serbia, E/C.12/1/Add.108, Norway E/C.12/1/Add.109, Bosnia and Herzegovina E/C.12/BIH/CO/1, Uzbekistan E/C.12/UZB/CO/1, Austria E/C.12/AUT/CO/3, Libya E/C.12/LYB/CO/2, Slovenia E/C.12/SVN/CO/1, Canada E/C.12/CAN/CO/4, Canada E/C.12/CAN/CO/5, Canada E/C.12/CAN/CO/4, Canada E/C.12/CAN/CO/5, Mexico E/C.12/MEX/CO/4, Liechtenstein E/C.12/LIE/CO/1, Monaco E/C.12/MCO/CO/1, Morocco E/C.12/MAR/CO/3, Morocco E/C.12/MAR/CO/2, El Salvador E/C.12/SLV/CO/2, Tajikistan E/2007/22, San Marino E/C.12/SMR/CO/4, Paraguay E/C.12/PRY/CO/3, Belgium E/C.12/BEL/CO/3, Costa Rica E/C.12/CRI/CO/4, Ukraine E/C.12/UKR/CO/5, Latvia E/C.12/LVA/CO/1, The former Yugoslav Republic of Macedonia E/C.12/MKD/CO/1, Nepal E/C.12/NPL/CO/2, Finland E/C.12/FIN/CO/5, Hungary E/C.12/HUN/CO/3, Netherlands (Antilles) E/C.12/NLD/CO/3/Add.1, Costa Rica E/C.12/CRI/CO/4/CORR.1, France E/C.12/FRA/CO/3, Benin E/C.12/BEN/CO/2, Bolivia (Plurinational State of) E/C.12/BOL/CO/2, India E/C.12/IND/CO/5, Nicaragua E/C.12/NIC/CO/4, Sweden E/C.12/SWE/CO/5, Kenya E/C.12/KEN/CO/1, United Nations Interim Administration in Kosovo E/C.12/UNK/CO/1, Philippines E/C.12/PHL/CO/4, Cyprus E/C.12/CYP/CO/5, Brazil E/C.12/BRA/CO/2, Cambodia E/C.12/KHM/CO/1, Australia E/C.12/AUS/CO/4, United Kingdom of Great Britain and Northern Ireland E/C.12/GBR/CO/5, United Kingdom of Great Britain and Northern Ireland (Overseas Territory) E/C.12/GBR/CO/5, United Kingdom of Great Britain and Northern Ireland (Crown Dependencies) E/C.12/GBR/CO/5, Poland E/C.12/POL/CO/5, Madagascar E/C.12/MDG/CO/2, Chad E/C.12/TCD/CO/3, Democratic Republic of the Congo E/C.12/COD/CO/4, Republic of Korea E/C.12/KOR/CO/3, Kazakhstan E/C.12/KAZ/CO/1, Colombia E/C.12/COL/CO/5, Afghanistan E/C.12/AFG/CO/2-4, Algeria E/C.12/DZA/CO/4, Mauritius E/C.12/MUS/CO/4, Switzerland E/C.12/CHE/CO/2-3, Dominican Republic E/C.12/DOM/CO/3, Uruguay E/C.12/URY/CO/3-4, Netherlands (Aruba) E/C.12/NLD/CO/4-5, Netherlands (Antilles) E/C.12/NLD/CO/4-5, Netherlands E/C.12/NLD/CO/4-5, Sri Lanka E/C.12/LKA/CO/2-4, Netherlands (Antilles) E/C.12/NLD/CO/4-5/CORR.1, Netherlands (Aruba) E/C.12/NLD/CO/4-5/CORR.1, Netherlands E/C.12/NLD/CO/4-5/CORR.1, Russian Federation E/C.12/RUS/CO/5, Yemen E/C.12/YEM/CO/2 Turkey E/C.12/TUR/CO/1, Germany E/C.12/DEU/CO/5, Republic of Moldova E/C.12/MDA/CO/2, Turkmenistan E/C.12/TKM/CO/1, Argentina E/C.12/ARG/CO/3, Estonia E/C.12/EST/CO/2, Israel E/C.12/ISR/CO/3, Cameroon E/C.12/CMR/CO/2-3, Peru E/C.12/PER/CO/2-4, Ethiopia E/C.12/ETH/CO/1-3, New Zealand E/C.12/NZL/CO/3, Spain E/C.12/ESP/CO/5, Slovakia E/C.12/SVK/CO/2, Mauritania E/C.12/MRT/CO/1, Iceland E/C.12/ISL/CO/4, Bulgaria E/C.12/BGR/CO/4-5, Equatorial Guinea E/C.12/GNQ/CO/1, United Republic of Tanzania E/C.12/TZA/CO/1-3, Ecuador E/C.12/ECU/CO/3, Congo E/C.12/COG/CO/1, Angola E/C.12/AGO/CO/3, Togo E/C.12/TGO/CO/1, Azerbaijan E/C.12/AZE/CO/3, Denmark E/C.12/DNK/CO/5, Iran (Islamic Republic of) E/C.12/IRN/CO/2, Jamaica E/C.12/JAM/CO/3-4, Japan E/C.12/JPN/CO/3, Rwanda E/C.12/RWA/CO/2-4, Belarus E/C.12/BLR/CO/4-6, Norway E/C.12/NOR/CO/5, Austria E/C.12/AUT/CO/4, Egypt E/C.12/EGY/CO/2-4, Bosnia and Herzegovina E/C.12/BIH/CO/2, Albania E/C.12/ALB/CO/2-3, Kuwait E/C.12/KWT/CO/2, Belgium E/C.12/BEL/CO/4, Gabon E/C.12/GAB/CO/1, Djibouti E/C.12/DJI/CO/1-2,

The issuing of concluding observations and recommendations to States parties offers guidance on implementation of their obligations under the treaty and can contribute to the scope and understanding of the treaty. The concluding observations can also facilitate the sharing of best practice through an interactive dialogue. Therefore, the concluding observations are of significance to this research in terms of contributing to the understanding of the scope of the right to health and access to medicines, and in monitoring states' compliance with their obligations under Article 12. The issue of access to medicines was raised in 6.6 percent of the concluding observations. Recommendations were made in relation to access to medicines in 3.2 percent of the concluding observations, and the CESCR referred to the right to health under Article 12 in all of these recommendations. The majority of the recommendations referred to access to medicines in general terms and did not provide a definition of the type of medicines to fall within the scope of 'medicine'. However, 31 percent referred specifically to HIV/AIDS medicines. The types of recommendation being made relate to ensuring that intellectual property standards in FTAs do not adversely affect access to medicines, facilitating access

Ukraine E/C.12/UKR/CO/6, Uzbekistan E/C.12/UZB/CO/2, China E/C.12/CHN/CO/2, China (Hong Kong) E/C.12/CHN/CO/2, China (Macau) E/C.12/CHN/CO/2, El Salvador E/C.12/SLV/CO/3-5, Indonesia E/C.12/IDN/CO/1, Monaco E/C.12/MCO/CO/2-3, Czech Republic E/C.12/CZE/CO/2, Lithuania E/C.12/LTU/CO/2, Serbia E/C.12/SRB/CO/2, Armenia E/C.12/ARM/CO/2-3, Portugal E/C.12/PRT/CO/4, Romania E/C.12/ROU/CO/3-5, Guatemala E/C.12/GTM/CO/3, Nepal E/C.12/NPL/CO/3, Montenegro E/C.12/MNE/CO/1, Slovenia E/C.12/SVN/CO/2, Viet Nam E/C.12/VNM/CO/2-4, Finland E/C.12/FIN/CO/6, Paraguay E/C.12/PRY/CO/4, Tajikistan E/C.12/TJK/CO/2-3, Gambia E/C.12/GMB/CO/1, Kyrgyzstan E/C.12/KGZ/CO/2-3, Mongolia E/C.12/MNG/CO/4, Venezuela (Bolivarian Republic of) E/C.12/VEN/CO/3, Chile E/C.12/CHL/CO/4, Uganda E/C.12/UGA/CO/1, Ireland E/C.12/IRL/CO/3, Thailand E/C.12/THA/CO/1-2, Burundi E/C.12/BDI/CO/1, Morocco E/C.12/MAR/CO/4, Iraq E/C.12/IRQ/CO/4, Greece E/C.12/GRC/CO/2, Sudan E/C.12/SDN/CO/2, Italy E/C.12/ITA/CO/5, Guyana E/C.12/GUY/CO/2-4, Canada E/C.12/CAN/CO/6, Namibia E/C.12/NAM/CO/1, Kenya E/C.12/KEN/CO/2-5, Honduras E/C.12/HND/CO/2, Burkina Faso E/C.12/BFA/CO/1, France E/C.12/FRA/CO/4, United Kingdom of Great Britain and Northern Ireland E/C.12/GBR/CO/6, Sweden E/C.12/SWE/CO/6, The former Yugoslav Republic of Macedonia E/C.12/MKD/CO/2-4, Angola E/C.12/AGO/CO/4-5, Costa Rica E/C.12/CRI/CO/5, Dominican Republic E/C.12/DOM/CO/4, Lebanon E/C.12/LBN/CO/2, Philippines E/C.12/PHL/CO/5-6, Poland E/C.12/POL/CO/6, Cyprus E/C.12/CYP/CO/6, Tunisia E/C.12/TUN/CO/3, Liechtenstein E/C.12/LIE/CO/2-3, Netherlands E/C.12/NLD/CO/6, Australia E/C.12/AUS/CO/5, Pakistan E/C.12/PAK/CO/1, Uruguay E/C.12/URY/CO/5, Sri Lanka E/C.12/LKA/CO/5, Russian Federation E/C.12/RUS/CO/6, Republic of Moldova E/C.12/MDA/CO/3, Republic of Korea E/C.12/KOR/CO/4, Colombia E/C.12/COL/CO/6, Mexico E/C.12/MEX/CO/5-6, Bangladesh E/C.12/BGD/CO/1, Spain E/C.12/ESP/CO/6, New Zealand E/C.12/NZL/CO/4, Central African Republic E/C.12/CAF/CO/1, Niger E/C.12/NER/CO/1, Turkmenistan E/C.12/TKM/CO/2, Argentina E/C.12/ARG/CO/4, Mali E/C.12/MLI/CO/1, Germany E/C.12/DEU/CO/6, Cabo Verde E/C.12/CPV/CO/1, South Africa E/C.12/ZAF/CO/1, Cameroon E/C.12/CMR/CO/4, Estonia E/C.12/EST/CO/3, Kazakhstan E/C.12/KAZ/CO/2, Bulgaria E/C.12/BGR/CO/6, Mauritius E/C.12/MUS/CO/5, Denmark E/C.12/DNK/CO/6, Israel E/C.12/ISR/CO/4, Senegal E/C.12/SEN/CO/3, Ecuador E/C.12/ECU/CO/4, Slovakia E/C.12/SVK/CO/3, Switzerland E/C.12/CHE/CO/4.

to HIV/AIDS medicines for patients, and ensuring health facilities and hospitals have supplies of medicines. Illustrative examples of these trends are discussed below.

(a) Impact of FTAs on access to medicines

The implications of trade agreements on access to medicines, entered into by developing countries was highlighted by the CESCR in its recommendations on the state report of Costa Rica[560]. The CESCR recommended that the State party should undertake to take steps necessary to assess any potentially adverse impacts of the Central American Free Trade Agreement (CAFTA) on the State party's obligations under the ICESCR in respect of access to generic medicines.[561] Specific concerns related to the data exclusivity provisions which went beyond the minimum standards set out in Article 39(3) TRIPS[562], and would delay the entry of the generic equivalent to the market. The CESCR recommendation illustrates that States are expected to monitor and assess the implications of such agreements on the Covenant rights even after the agreements have been entered into, as a continuous process of assessment and monitoring of compliance with the Covenant obligations. Costa Rica responded to this recommendation in its subsequent state report, confirming that assessments had been undertaken and that current challenges in enhancing access to medicines were not as a result of CAFTA.[563] The State's response to this recommendations provides an example of how the concluding observations can facilitate a constructive dialogue with states on how they can best discharge their obligations under the right to health.

Further attention on the impact of FTAs on the right to health was evident in the concluding observations of the state report of Peru in 2012[564]. As with CAFTA, concerns

[560] UNCESCR 'Consideration of Reports Submitted by States Parties under Articles 16 and 17 of the Covenant, Costa Rica, Draft concluding observations of the Committee on Economic, Social and Cultural Rights' (4 January 2008) UN Doc E/C.12/CRI/CO/4
[561] ibid 27
[562] P Pusceddu 'Access to Medicines in Developing Countries and Free Trade Agreements: The Case of the US-DR-CAFTA with Focus on Costa Rica' (2014) 19 JIPR 104, 105, Correa (n 336) 83; G Krikorian and D Szymkowiak, 'Intellectual Property Rights in the Making: The Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicine' (2007) 10 J World Intell Prop 388, 402
[563] UNCESCR 'Consideration of reports submitted by States parties under articles 16 and 17 of the International Covenant on Economic, Social and Cultural Rights, Fifth periodic reports of States parties due in 2012: Costa Rica' (30 April 2015) UN Doc E/C.12/CRI/5, 177-178
[564] UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Peru' (30 May 2012) UN Doc E/C.12/PER/CO/2-4

related to the data exclusivity provisions in the US-Peru FTA[565], and the impact on consumers due to delays in accessing generic medicines. The CESCR observations included recommending that the State party consider the impacts on Covenant rights before entering into similar free trade agreements, but went further than requiring the State party to merely consider the Covenant rights by recommending that the State party take active steps to secure the affordability, accessibility and availability of essential medicines, "if necessary through subsidies."[566] This suggests that there is an expectation on State parties to take positive steps to ensure that its population has access to affordable essential medicines, and if the medicines are not affordable, the State may have an obligation under the Covenant to subsidise that cost for its population. This could be seen to be 'rewarding' pharmaceutical companies for setting high or excessive prices for medicines, which is a controversial proposal as the pharmaceutical companies bear responsibility for setting excessive prices. However, such a bold stance by the CESCR might encourage states parties to take other positive actions to address affordability and accessibility concerns, for example through public health insurance plans or making full use of the TRIPS flexibilities, so that subsidies are not 'necessary'.

The CESCR has also provided direction to developed States on their obligations under the Covenant with regard to trade agreements, as evidenced in the concluding observations to Germany in 2018.[567] The CESCR expressed concern at the data exclusivity provisions imposed on developing countries by EU FTAs which delay access to affordable generic medicines, with harmful impacts on the right to health. The CESCR recommended that the State party carry out human rights impact assessments prior to the negotiation of FTAs to assess their impact on access to affordable medicines in developing countries.[568] The State was reminded of their international obligations in relation to Article 12, including that States parties have to respect the enjoyment of the right to health in other countries[569].

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[565] R Cartagena and A Attaran, 'A Study of Pharmaceutical Data Exclusivity Laws in Latin America: Is Access to Affordable Medicine Threatened' (2009) 17 Health LJ 269, 281; Lopert and Gleeson (n 339) 202; M Jorge 'The Peruvian Implementation of the US-Peru FTA: A Model for the World with Room for Improvement' (2010) 7(1) Journal of Generic Medicines 40, 43

[566] UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Peru' (30 May 2012) UN Doc E/C.12/PER/CO/2-4, 25

[567] UNCESCR 'Concluding observations on the sixth periodic report of Germany' (27 November 2018) UN Doc E/C.12/DEU/CO/6

[568] UNCESCR 'Concluding observations on the sixth periodic report of Germany' (27 November 2018) UN Doc E/C.12/DEU/CO/6, 14-15

[569] General Comment No. 14 (n 112) 39

This recommendation illustrates the CESCR's interpretation of the scope of States' parties obligations outside of their jurisdiction in relation to FTAs and the right to health. TRIPS outlines a minimum standard of IP rights protection, and so states can agree to a higher standard of IP rights protection in FTAs. Implementing a minimum standard of IP protection, rather than a maximum standard or a harmonised IP rights protection, has been considered in academic literature as a positive measure because of the degree of flexibility afforded to states in implementing the TRIPS provisions.[570] This flexibility is an advantage as it recognises the need to find a balance between the needs of developed and developing countries in relation to promoting trade and protecting IP rights. The recommendations of the CESCR highlight that although IP protection in TRIPS is not inherently incompatible with human rights, the inclusion of TRIPS-plus standards is problematic in relation to states' treaty obligations under Article 12 ICESCR.

(b) Examples of other key trends

The CESCR expressed concern regarding the number of HIV/AIDS cases in the concluding observations on the state reports of Venezuela[571] and Burundi[572], and recommended that the states take the necessary steps to ensure adequate coverage of antiretroviral medicines and to make them accessible to persons living with HIV/AIDS[573]. These reports provide guidance that HIV/AIDS medicines are types of medicines considered to be 'essential' under Article 12. The concluding observations on the state reports of Mali and Cameroon included recommendations to ensure the accessibility, availability and quality of health care in all regions, by improving the infrastructure of the primary health-care system and ensure that hospitals have a regular supply of medicines.[574] The CESCR acknowledged that the state party had made efforts to improve

[570] P Judd, 'Toward a TRIPS Truce' (2011) 32 Mich J Int'l L 613, 655; M Land, 'Rebalancing Trips' (2012) 33 Mich J Int'l L 433, 435; Kur and Ruse-Khan (n 252) 26

[571] UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Venezuela' (7 July 2015) UN Doc E/C.12/VEN/CO/3

[572] UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Burundi' (16 October 2015) UN Doc E/C.12/BDI/CO/1

[573] See also UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Venezuela' (7 July 2015) UN Doc E/C.12/VEN/CO/3, 29; and UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Burundi' (16 October 2015) UN Doc E/C.12/BDI/CO/1, 56

[574] UNCESCR 'Concluding observations on the fourth periodic report of Cameroon' (25 March 2019) UN Doc E/C.12/CMR/CO/4, 56; UNCESCR 'Concluding observations on the initial report of Mali' (6 November 2018) UN Doc E/C.12/MLI/CO/1, 46

health care, and the recommendation was for the purpose of addressing the problems relating to affordable health care in the State.[575] This recommendation shows that states are reporting on issues relating to medicines and are using the concluding observations process to receive guidance from the CESCR on how to meet their human rights obligations, forming a constructive dialogue.[576]

The concluding observations can also be used to recognise good practice. For example, the CESCR's concluding observations on Brazil's state report included welcoming measures the State party had taken to adopt compulsory licensing of HIV/AIDS antiretroviral drugs in order to make them affordable and enable the extension of treatment to all patients.[577] Recognition of good practices at international level through the concluding observations can provide helpful models to other states in addressing similar concerns. The findings from this review of the concluding observations illustrate that the CESCR is giving specific guidance to States parties on measures to enhance access to medicines as part of their treaty obligations in relation to the right to health. The limited data means that conclusions must be drawn with caution, but the recommendations which have been made are useful in terms of clarifying the scope of States' parties obligations under Article 12 in relation to access to medicines. The findings also highlight that the CESCR views TRIPS-plus provisions as a significant challenge to the promotion and protection of the right to health, which is a key theme emanating from the work of the UN human rights bodies.

IV. Conclusion

The interplay between the right to access to medicines and TRIPS has been recognised in academic literature.[578] This chapter has shown that this agenda is still at an early stage. The relatively low number of references to access to medicines in state reports and recommendation in the UPR shows limited state practice on the right to access to medicines within the UN human rights regimes. A more substantial body of practice is

[575] UNCESCR 'Concluding observations on the initial report of Mali' (6 November 2018) UN Doc E/C.12/MLI/CO/1, 45

[576] Mechlem (n 105) 924; B Toebes 'Towards an Improved Understanding of the International Human Right to Health' (1999) 21 Hum Rts Q 661, 666; O'Flaherty (n 524) 36

[577] UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Brazil' (12 June 2009) UN Doc E/C.12/BRA/CO/2, 3

[578] For example, Helfer and Austin (n 3); Correa (n 336); Hestermeyer (n 72); Chapman (n 72)

found within the UN human rights bodies, clarifying that access to medicines is within the right to health under Article 12 ICESCR. This body of practice also clarifies that there is no definition of 'medicines' or 'essential medicines'. Further, there is no prima facie conflict between human rights and TRIPS. However, particular challenges have been identified with regard to the use of FTAs by states to secure TRIPS-plus provisions. Such challenges include data exclusivity provisions going beyond those set out in TRIPS, which could lead to delays in generic medicines reaching the market, and have a detrimental impact on access to affordable medicines. The UN human rights bodies have also identified measures to promote reconciliation between human rights and WTO obligations, such as effective use of the flexibilities within TRIPS. Examples of good practice have also been highlighted, including carrying out impact assessments prior to agreeing FTAs.

The work of the UN human rights bodies highlights that access to medicines has been a growing concern for the Charter-based bodies as well as the CESCR. Although the reports are non-binding, and therefore the monitoring of the recommendations in the reports may be questioned, these sources provide a valuable contribution to the interpretation of the right to health and clear guidance on state obligations to achieve full realisation of this right. The work of the Charter bodies has contributed significantly to the normative development of the right to health, while the work of the CESCR illustrates that access to medicines is a key element of the right to health under Article 12 and states have minimum core obligations to ensure access to essential medicines. Therefore the lack of access to medicines within States parties could give rise to an issue under the ICESCR in respect of Article 12. There is prima facie compliance with UN human rights law in respect of the TRIPS Agreement, although challenges exist in relation to the TRIPS-plus provisions. These concerns may become more prevalent given the Trump administration's apparent favour towards bilateral trade agreements, and the UK's need to enter into such agreements as an individual State following Brexit, which could potentially lead to further TRIPS-plus provisions.

In particular, the actions of the pharmaceutical industry have been identified as a significant challenge. This has implications for the obligations of states, and the work of the Working Group on business and human rights may become more significant. Although the influence of the findings of the UN human rights bodies is limited on the pharmaceutical companies as they are not parties to, and therefore not bound by, the UN human rights instruments, the potential inclusion of business enterprises into National

Action Plans operationalizing the UN Guiding Principles would significantly alter this position. There are also implications with regard to the States' responsibility to seek assistance if they cannot comply with their ICESCR obligations due to resource constraints, and therefore support for a more collaborative and cooperative approach among all States should be encouraged, particularly if failure to uphold access to medicines may give rise to an issue under Article 12. As access to medicines is viewed as forming part of the Article 12 right within the UN human rights systems, it must be considered how this can be advanced in order to improve access to medicines for all.

Chapter 4: Advancing access to medicines as a right

Introduction

The previous chapter discussed how access to medicines has been addressed within the UN human rights framework. The chapter focussed in particular on the right to health under Article 12 ICESCR, and a key finding was that access to medicines forms part of the right to health under Article 12. It also showed that the access to medicines agenda is still evolving. This chapter explores whether this agenda can be advanced, shifting the focus on ICESCR from the Article 12 right to consider whether other ICESCR rights could also advance the protection of the right to access to medicines under international human rights law. For the purposes of this research, specific focus will be on Article 15 ICESCR. The dual nature of Article 15, in that Article 15 protects the rights of creators in their creations, and also protects the right of everyone to benefit from scientific progress, is of key relevance to this research. The importance of science and technology in the research and development of new medicines, and the link between Article 15 and the progressive realisation of the Article 12 right[579] is also relevant to the research. The chapter then moves to explore the actions being taken in the UN human rights framework more broadly to promote access to medicines as a right. Key recent developments will be considered, to examine how these developments advance the access to medicines agenda. Also, whether recommendations emanating from these developments could help states to meet their obligations under the right to access medicines.

Article 15 ICESCR outlines the right to take part in cultural life, the right to benefit from scientific progress and the rights of creators to the protection of the moral and material interests resulting from scientific, literary or artistic production.[580] Given the significance of TRIPS in relation to accessing medicines and the importance of the IP rights enshrined in TRIPS to global trade, the chapter will address the issue of whether IP rights are rights that form part of human rights under Article 15 ICESCR. This chapter will focus primarily on original documents of the UN human rights bodies to analyse how these bodies are addressing this provision, to evaluate the nature of rights of creators. The chapter will also draw on relevant academic literature in the analysis of the findings from

[579] A Müller, 'Remarks on the Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications (Article 15(1)(b) ICESCR)' (2010) 10(4) HRLR 765, 766

[580] International Covenant on Economic, Social and Cultural Rights (n 2) Article 15

this research. If IP rights did amount to human rights under Article 15, this could amount to a potential obstacle to the enjoyment of the right to access medicines. Issues could also arise in relation to the potentially incompatible obligations under Article 15 and Article 12, and how these could be reconciled within the UN human rights framework.

Given the dual nature of Article 15, the chapter will also explore whether Article 15 could contribute to advancing access to medicines through the right to benefit from scientific progress. The purpose of this research is to explore whether Article 15 could promote the creation of knowledge in a way that enhances access to medicines. The focus will primarily be on primary sources from the UN human rights framework, including the work of the relevant Special Rapporteurs, which elucidate the background and purpose of such a right. The purpose of this is to provide an understanding of the normative content of Article 15, to explore the interpretative guidance in relation to this right and its relevance to advancing access to medicines. This chapter will also refer to the emerging discussions[581] of this right in academic literature in the analysis.

The chapter then changes focus to explore key developments to promote access to medicines across the UN human rights framework. In particular, the discourse emanating from the recent expert consultation on access to medicines and the recommendations of the Secretary General's High Level Panel on Access to Medicines on how to improve the facilitation of access to medicines will be examined, and outcomes of such developments. The purpose of this is to explore whether the recommendations emanating from these developments promote enhanced understanding of how states can effectively meet their human rights obligations to enhance access to medicines under the ICESCR and TRIPS. Responses to the proposals will also be examined, in order to assess the utility of the work of the UN human rights bodies in furthering the access to medicines agenda.

I. The dual focus of Article 15

While the right to the highest attainable standard of health is a significant provision under the ICESCR in relation to securing access to medicines, the ICESCR also includes rights that are intended to protect the rights of creators under Article 15. Academic literature

[581] Lee notes that Article 15 ICESCR has received relatively little attention in academic literature. See JY Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines,* (Ashgate 2015) 155

has considered that these rights can conceivably have a significant impact on access to medicines as they can be utilised to protect the creators of works usually protected by IP legislation[582], including creators of new medicines. Consequently, the rights of creators must be considered as well as the rights of individuals with regard to accessing new medicines, an issue which may present difficulties for the Member States responsible for upholding the respective rights. Therefore it is important to examine the content of rights that protect creators, and how this affects the issue of securing access to medicines. Article 15 ICESCR[583] states:

"1. The States Parties to the present Covenant recognize the right of everyone:

(a) To take part in cultural life;

(b) To enjoy the benefits of scientific progress and its applications;

(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.

3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields." [584]

[582] Helfer and Austin (n 3) 171; R Okediji 'Does Intellectual Property Need Human Rights ' (2018) 51 NYU J Int'l L & Pol 1, 35-36; Yu (n 9) 1424-1427; D Matthews 'Intellectual Property Rights, human rights and the right to health' in W Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar, Cheltenham 2010), 119; Chapman (n 72) 877

[583] International Covenant on Economic, Social and Cultural Rights (n 2) Article 15

[584] ibid

Article 15(1) sets out the normative content of the right while Articles 15(2) to (4) set out the obligations of Member States. There are three components to the right comprised in Article 15(1), with the right of authors to benefit from the protection of the moral and material interests in their scientific productions under Article 15(1)(c) being the most significant in relation to consideration of the status of IP rights over medicines. However, the right to enjoy the benefits of scientific progress under Article 15(1)(b) is also an important provision with regard to the creation of new medicines which must also be considered. Article 15 ICESCR is a legally binding norm, so it is important to analyse the scope of these rights and how they have been interpreted in light of the work of the UN human rights bodies, to provide an enhanced understanding of the nature of these rights and their impact on enhancing access to medicines.

(a) Article 15(1)(c): The rights of authors of creative works

The right to benefit from protection of moral and material interests under Article 15(1)(c) ICESCR protects those who are responsible for authoring creative works in the form of a human right. This creates a potential complication regarding enhancing access to medicines as the recognised obstacles such as the pricing of essential medicines set by pharmaceutical companies may be seen to result from a right to receive the benefit of creating new medicines. Given the nature of IP rights of allowing pharmaceutical companies to benefit financially from the scientific progress in developing new medicines, it may be considered that IP rights are human rights under the wording of Article 15(1)(c).[585] Academic literature generally supports the view that protecting the interests of authors in their creative works is also a right which is protected within IP

[585] This thesis does not explore the status of intellectual property rights under the European Convention on Human Rights, or the Charter of Fundamental rights of the European Union, but it is pertinent to note that the status of intellectual property rights is different than under the ICESCR. There is protection for IP holders under the right to property under Article 1, Protocol 1 ECHR, and Article 17(2) of the Charter of Fundamental Rights provides the intellectual property shall be protected. See Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (ECHR), Article 1 of the First Protocol and Charter of Fundamental Rights of the European Union, [2000] OJ C 364/01, Article 17(2). For discussion on the status of IP rights under these instruments, see also W Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar, Cheltenham 2010), 14, 18-19; Cullet (n 61) 410-411; L Helfer, 'The New Innovation Frontier - Intellectual Property and the European Court of Human Rights' (2008) 49 Harv Int'l LJ 1; A Plomer, 'After Brustle: EU Accession to the ECHR and the Future of European Patent Law' (2012) 2 Queen Mary J Intell Prop 110, 130-1, 134; M Husovec, 'The Essence of Intellectual Property Rights under Article 17(2) of the EU Charter' (2019) 20 German LJ 840, 844-846.

provisions, but that Article 15(1)(c) protects the personal link between author and creation, while IP rights protect corporate interests[586]. This view suggests that such a distinction has been drawn because of the diverging purposes of Article 15(1)(c) and the wider human rights regime, and IP instruments. Therefore, whereas private companies derive significant benefit from the system of intellectual property law, this is not the case under the ICESCR where the core of the right is the link between the individual author and their creation.

General Comment 17[587] provides authoritative guidance on the scope and interpretation of Article 15(1)(c). It highlights that the right under Article 15(1)(c) derives from the dignity of persons, emphasising that human rights are fundamental, permanent rights and therefore distinct from the temporary rights under IP systems which can be assigned or retracted.[588] It explicitly states that IP rights are not to be equated with the Article 15(1)(c) human right[589], providing unequivocal confirmation that IP rights are not human rights under this provision. This is confirmed by the drafting history of Article 15 which demonstrates that the inclusion of the protection of authors' rights under Article 15 was due to the fact that they were linked to the realisation of other rights.[590] Therefore the rights of authors should facilitate rather than restrict benefits of scientific progress[591]. It suggests that the UN human rights bodies and Member States never sought to enshrine this form of IP right as a distinct human right. This argument is persuasive as Article 15(1)(c) does not specify any method by which the moral and material interests of authors should be protected, and does not require that such rights should be protected by IP law.[592] Therefore it would be difficult to claim that this provision can be used to strengthen IP rights. In addition, General Comment 17 also states that the scope of protection provided

[586] Joseph (n 198) 215; P Yu 'Ten Common Questions about Intellectual Property and Human Rights' (2007) 23(4) Georgia State University Law Review 709, 730; Matthews (n 582) 124; HM Haugen, 'Intellectual Property -Rights or Privileges' (2005) 8 J World Intell Prop 445, 451; A Plomer, 'The Human Rights Paradox: Intellectual Property Rights and Rights of Access to Science' (2013) 35 Hum Rts Q 143, 151

[587] UNCESCR 'General Comment 17 (2005) The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (article 15, paragraph 1 (c), of the Covenant)' (12 January 2006) UN Doc E/C.12/GC/17

[588] ibid 1

[589] ibid 3

[590] Helfer and Austin (n 3) 179-180

[591] Helfer and Austin (n 3) 179-180

[592] Yu argues that this right could be protected by other means, including open source drug discovery, patent pools, and public-private partnerships. See Yu (n 9) 1421

for under Article 15 (1)(c) does not necessarily accord with intellectual property rights within intellectual property law.[593]

General Comment 17 also clarifies the normative content of Article 15(1)(c), which further distinguishes that Article 15(1)(c) is not intended to be relied upon by producers of medicines to protect their capacity to financially exploit their products. It affirms that only natural persons, and not legal entities such as pharmaceutical companies, are protected at the level of human rights.[594] Joseph argues that General Comment 17 of the CESCR clearly distinguishes IP rights from those protected under Article 15(1)(c).[595] The position under the European Convention on Human Rights (ECHR)[596] may be contrasted as legal persons can invoke rights under the ECHR[597]. It shows that Article 15(1)(c) is not intended to be relied upon by producers of medicines to protect their capacity to financially exploit their products. Also, there is a public interest in the products of pharmaceutical companies which should be duly contemplated, from which it may be argued that the public have a right under Article 15(1)(c) to benefit from the scientific progress in the creation of new medicines, by having access to them and benefitting from their effects. It is also established that the level of protection afforded to authors under Article 15(1)(c) is of a lower level than that which is enjoyed under IP protection regimes[598], further highlighting the differences in the content of the Article 15(1)(c) in comparison to the content of IP rights in national and international IP instruments.

The responsibilities placed on Member States include that States should prevent the use of the Article 15(1)(c) right for purposes contrary to human rights, including the right to health[599]. General Comment 17 also explicitly states that States parties have a duty to prevent unreasonably high costs for access to essential medicines.[600] This is a crucial statement as it makes explicit that States have a positive obligation to ensure that essential medicines are available at a reasonable cost. Academics have taken the view that General Comment 17 provides that States have an obligation to prevent uses of IP

[593] UNCESCR General Comment 17 (n 587) 2
[594] UNCESCR General Comment 17 (n 587) 7
[595] Joseph (n 198) 215
[596] Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (ECHR)
[597] An example of this is evident in the case of The Sunday Times v The United Kingdom App. no. 6538/74 (ECtHR 26 April 1979)
[598] UNCESCR General Comment 17 (n 587) 10
[599] ibid 35
[600] ibid 35

that result in socially damaging effects[601]. It suggests that, rather than having a duty to uphold IP rights as human rights, States have a duty to restrict IP rights of creators where the exercise of such rights could be detrimental to the rights of others. Furthermore, General Comment 17 states that although States parties are accountable for upholding the Covenant rights, they are urged to consider regulating the responsibilities on the private business sector, private research institutions and other non-state actors to respect the rights recognised in Article 15(1)(c).[602] This is consistent with the UN Guiding Principles developed by John Ruggie, and General Comment 24 on State obligations under the ICESCR in the context of business activities, which were discussed in the previous chapter.

A consistent view emanating from the academic literature is that, while Article 15(1)(c) protects the author's material interests in the scientific production such as a new medicine, this right must be balanced in view of the benefit to the public to access the creation, as well as the other rights within the ICESCR[603]. Therefore, Article 15(1)(c) does not prioritise the interference of IP law including patents with the right to health and the enhancement of access to medicines. This is significant as if IP rights were construed to be human rights then this would produce a potential conflict between the human rights of creators of medicines and patients needing access to the medicines. Challenges could also have arisen for states in interpreting TRIPS in light of the right to access medicines, because of the human rights implications relating to the IP rights set out in TRIPS. However it is clear from the guidance of the UN human rights bodies that the Article 15(1)(c) right does not raise intellectual property law to a human right. Therefore, this removes one potential obstacle to advancing access to medicines.

(b) Article 15(1)(b): Right to enjoy the benefits of scientific progress

As IP rights do not amount to human rights under Article 15, and given the dual focus of Article 15, it is important to examine whether the provision can be used to promote access to medicines. In addition to the rights of authors under Article 15(1)(c), the right of everyone to enjoy the benefits of scientific progress under Article 15(1)(b) is also an

[601] Helfer and Austin (n 3) 192; Haugen (n 586) 454; Okediji (n 582) 32-33
[602] UNCESCR General Comment 17 (n 587) 55
[603] Plomer (n 586) 150; C Oguamanam, 'Indigenous Peoples' Rights at the Intersection of Human Rights and Intellectual Property Rights' (2014) 18 Marq Intell Prop L Rev [v], 287-288; Okediji (n 582) 21; Hestermeyer (n 72) 158

important provision in relation to accessing medicines, particularly new medicines. This right indicates that there is a human right for all to enjoy advancements in science including scientific productions resulting from such advances, without limitations based on economic reasons. This suggests that if a medicine exists but is not widely available to those who need it, they have a human right to enjoy benefits from it and therefore there is a duty on States to facilitate access to that medicine as part of their obligations to uphold the right. It is only relatively recently that the academic literature has examined the Article 15(1)(b) right.[604] The drafting history demonstrates that the drafters viewed all of the provisions under Article 15 as being interrelated and provides that intellectual property law must assure that intellectual property protection respects and promotes other components of Article 15, so that the rights of authors and creators should facilitate rather than restrain scientific progress and access[605]. It indicates that the drafters intended that Article 15(1)(b) should be supported by national intellectual property provisions, although they did not elaborate on the relationship between protecting the rights of creators and facilitating access to scientific developments. Several of the UN human rights bodies have sought to fill this gap and to develop understanding of how the Article 15(1)(b) right should be interpreted by states.

(i) Venice Statement

The United Nations Educational, Scientific and Cultural Organization (UNESCO) convened a number of expert meetings in 2009 aimed at elaborating the normative content

[604] A Chapman 'Towards an Understanding of the Right to Enjoy the Benefits of Scientific Progress and Its Applications' (2009) 8 Journal of Human Rights 1, 1; W Schabas 'Study of the Right to Enjoy the Benefits of Scientific and Technological Progress and Its Applications' in Donders and Volodin (eds), *Human Rights in Education, Science and Culture: Legal Developments and Challenges* (Ashgate/UNESCO, Aldershot 2007) 273; R Claude 'Scientists' Rights and the Human Rights to the Benefits of Science' in A Chapman and S Russell (eds), *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* (Intersentia 2007) 247; Müller (n 579) 765; Yu (n 9) 1378

[605] UNCESCR 'Implementation of the International Covenant on Economic, Social and Cultural Rights: Substantive issues arising in the implementation of the International Covenant on Economic, Social and Cultural Rights: Day of General Discussion "The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author (article 15.1 (c) of the Covenant)" organized in cooperation with the World Intellectual Property Organization (WIPO)' (3 October 2000) UN Doc E/C.12/2000/12, 23-24. See also A Chapman 'Core Obligations Relate to ICESCR Article 15(1)(c)' in A Chapman and S Russell (eds), *Core Obligations: Building a Legal Framework for Economic, Social and Cultural Rights* (Intersentia 2002), P.314; Matthews (n 582) 122; M Green 'Drafting History of the Article 15(1)(c) of the International Covenant on Economic, Social and Cultural Rights', background paper submitted for the CESCR's day of general discussion on Article 15(1)(c) ICESCR' (27 November 2000) UN Doc E/1.12/2000/15, 45

of the Article 15(1)(b) right. It acknowledged that the right is intrinsically linked to other human rights including the Article 12 right to heath, and that the realisation of numerous social, economic, cultural and political human rights is dependent on the sharing of scientific progress.[606] This led to the drafting of the Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications[607]. The Statement considered four concerns with regard to the Article 15(1)(b) right, namely, the neglect of the Article 15(1)(b) right, the elucidation of the core content, State obligations and international cooperation[608]. The content of the Venice Statement is based on the views of the participating experts, and not those of UNESCO or any other intergovernmental organisation, and such views are not intended to be binding upon such organisations[609]. Therefore, the Statement was not intended to be legally binding. However, given that the meetings included experts from WTO, WIPO, UN human rights bodies including the CESCR[610], the Venice Statement provides important guidance on the meaning of the right to enjoy the benefits of scientific progress.

The Venice Statement noted that the acceleration of scientific progress had led to growing inequalities between States including in the development of medicines.[611] The Statement noted that advances were driven by market considerations that did not correspond with health needs of all, therefore affecting the right to health.[612] It was observed that although private actors are primarily responsible for scientific progress, the right of the individual to enjoy the benefits of his scientific production must be balanced with the rights of the population to share in the benefits.[613] It was further suggested that sharing of such benefits was not based on participation in the progress[614], so individuals and communities have a right to enjoy the benefit regardless of whether they have played a role in generating a benefit. The proposed normative content of the right included the freedom of sharing of information for the development of science or technology, equal

[606] United Nations Educational, Scientific and Cultural Organization, *The Right to Enjoy the Benefits of Scientific Progress and its Applications*, (UNESCO Paris 2009), SHS/RSP/HRS-GED/2009/PI/H/1, <http://unesdoc.unesco.org/images/0018/001855/185558e.pdf> (accessed 27/04/2020), 5
[607] ibid 13
[608] ibid 4
[609] ibid 11
[610] Yu (n 9) 1392-3; Lee (n 581) 162; Müller (n 759) 766
[611] United Nations Educational, Scientific and Cultural Organization, *The Right to Enjoy the Benefits of Scientific Progress and its Applications*, (UNESCO Paris 2009), SHS/RSP/HRS-GED/2009/PI/H/1, <http://unesdoc.unesco.org/images/0018/001855/185558e.pdf> (accessed 27/04/2020), 13-14
[612] ibid 13-14
[613] ibid 14
[614] ibid 15

access and participation of all public and private actors and non-discriminatory access to the benefits of scientific progress and its applications[615]. It suggests that the Article 15(1)(b) right could be a useful tool in allowing pharmaceutical companies and generic manufacturers to secure access to research and development into new medicines to treat the most prevalent diseases, as well as gaining information on scientific progress in developing new medicines to treat neglected diseases.

The view that Article 15(1)(b) could be used to further other rights, such as the right to health, is also supported in the literature.[616] The right to health includes access to essential medicines[617], and so the Article 15(1)(b) right could potentially take this further. Academics have suggested that essential medicines need to be 'created' through scientific research and development, in addition to being made 'accessible'[618]. Improving physical accessibility in terms of the development of new medicines is a key issue emanating from this research, distinct from reducing cost of medicines. However, the current absence of clarification from the CESCR on the content of the Article 15(1)(b) right and the obligations of states undermines its utility in being employed alongside the right to health.[619] This could be addressed in a General Comment by the CESCR on the normative content of the Article 15(1)(b) right and the obligations of states, which would be useful in order to provide the necessary clarity. Müller argues that although the Venice Statement made non-binding proposals as to the content of the Article 15(1)(b) right, the reporting process to the CESCR could be helpful in clarifying the obligations on States under this right[620].

The Venice Statement also made proposals with regard to the obligations on States, considering that a State duty to protect should include taking measures to prevent

[615] ibid 16
[616] A Houston, 'A Scientific Approach to Intellectual Property and Health: Innovation, Access, and a Forgotten Corner of the Universal Declaration of Human Rights' (2014) 13 J Marshall Rev Intell Prop L 794, 810; M Scanlon, G MacNaughton, and C Sprague 'Neglected Population, Neglected Right: Children Living with HIV and the Right to Science' (2017) 19(2) Health and Human Rights 169, 177; L London, H Cox, and F Coomans 'Multidrug-Resistant TB: Implementing the Right to Health through the Right to Enjoy the Benefits of Scientific Progress' (2016) 18(1) Health and Human Rights 25, 27
[617] As discussed in Chapter 3 of this thesis.
[618] Scanlon, MacNaughton, and Sprague (n 616) 177; London, Cox, and Coomans (n 616) 27
[619] Y Donders 'The right to enjoy the benefits of scientific progress: in search of state obligations in relation to health' (2011) 14(4) Medicine, Health Care, and Philosophy 371, 380; Scanlon, MacNaughton, and Sprague (n 616) 177
[620] Müller (n 579) 783

third parties from utilising science and technology to the detriment of human rights[621]. It was also proposed that the duty to fulfil should include the adoption of frameworks to promote the development of science and technology in a manner consistent with human rights, and to provide opportunities for public engagement in decision-making about science and technology and their development[622]. Admittedly, these proposals are *de lege ferenda*, but indicate that the Article 15(1)(b) right could develop so as to oblige States to facilitate the dissemination of research and information between pharmaceutical companies to further the development of a particular medicine, benefitting the wider population by potentially providing a required medicine reaches the market more expeditiously. Donders argues that although the issue of limited resources affects investment in R&D, the development of medicines to treat widespread diseases has done much to improve life expectancy so it is crucial that states invest in scientific developments and share the benefits[623]. This view suggests that states should take a more balanced approach to the protection of knowledge and the development of new medicines, and should commit to more publicly funded R&D facilities. This could address challenges around the development of medicines for 'neglected' diseases, and benefit the wider population by potentially providing a required medicine reaches the market more expeditiously. However, a state's budgetary constraints may be an obstacle to such a proposal, particularly for developing states that do not have sufficient domestic manufacturing capacity and therefore would need greater investment to develop this. The proposals also indicate that States have a duty to allow the public to actively participate in determining the course of progression. This could provide that advances in medicine will not be primarily driven by market considerations, but by the collective assessments of need by a range of public and private actors.

The Venice Statement also recognised tensions between the Article 15(1)(b) right and IP regimes, but asserted that there is a collective responsibility to ensure that profit for private business enterprises is not prioritised over benefit for all[624]. McBeth argues that the interests under Article 15(1)(c) are balanced with the right of everyone to enjoy

[621] United Nations Educational, Scientific and Cultural Organization, *The Right to Enjoy the Benefits of Scientific Progress and its Applications*, (UNESCO Paris 2009), SHS/RSP/HRS-GED/2009/PI/H/1, <http://unesdoc.unesco.org/images/0018/001855/185558e.pdf> (accessed 27/04/2020), 17

[622] ibid

[623] Donders (n 619) 375

[624] United Nations Educational, Scientific and Cultural Organization, *The Right to Enjoy the Benefits of Scientific Progress and its Applications*, (UNESCO Paris 2009), SHS/RSP/HRS-GED/2009/PI/H/1, <http://unesdoc.unesco.org/images/0018/001855/185558e.pdf> (accessed 27/04/2020), 15

the benefits of scientific progress under Article 15(1)(b), and the ordering of these provisions in Article 15 emphasises that public benefit outweighs proprietary interests.[625] Plomer also argues that UNESCO's work was aimed at limiting the impact of IP rights on access to essential goods.[626] These views suggest that Article 15(1)(b) may be relied on to counteract an assertion that a scientific advancement, such as the development of a new medicine, should be subject to the protection of authors rights under Article 15(1)(c). This does accord with the guidance on Article 15(1)(c) in General Comment 17, discussed above, that States parties have a duty to prevent unreasonably high costs for access to essential medicines.[627] It also reflects that no tension should exist in relation to states discharging their obligations under Article 15(1)(b) and Article 15(1)(c), as Article 15(1)(b) should be prioritised.

Article 15(1)(b) has been described as a "neglected right"[628], suggesting that it could be utilised more effectively by individuals and communities to gain enjoyment of scientific advancements, and the Venice Statement is significant as a first step in understanding the normative content of the right.[629] This point is supported by the fact the General Comment 17 only applies to Article 15(1)(c). However, Müller notes that promoting realisation of this right may be challenging for countries that do not have the resources to comply with the obligations proposed in the Venice Statement[630]. Although individuals may assert a right to access to a medicine, it is the State which is obligated to uphold this right and therefore bear the associated costs of doing so. This would not provide a solution to ensuring that medicines are affordable for all unless States were to implement legislative frameworks which involved engagement with the scientific community, pharmaceutical enterprises and other relevant private actors to address cost implications in securing the right to enjoy the benefits of scientific progress, such as medicines. As has been noted in the literature, a major challenge is the fact that developments in science and medicines are generally undertaken by private companies that are directed by commercial interests[631]. However, the discussion in the previous chapter of the Guiding Principles developed by John Ruggie, and General Comment 24

[625] McBeth (n 198) 136
[626] Plomer (n 586) 147
[627] UNCESCR General Comment 17 (n 587) 35
[628] Müller (n 579) 765
[629] ibid 767
[630] ibid 782
[631] Schabas (n 604) 280; Claude (n 604) 260; Donders (n 619) 380

highlights that States parties do have extraterritorial obligations to take steps to prevent and remedy infringements of ICESCR rights due to the activities of business entities, including pharmaceutical companies.

There is a need to clarify the Article 15(1)(b) right and the obligations of states at national level, to provide further guidance to states on how to meet their obligations under this provision and how it fits with other obligations under the ICESCR. The expansive approach adopted in the Venice Statement, particularly in relation to states' obligations around the development of science and technology, may call into question the viability of the Statement. However, it could offer a useful starting point to contribute towards the drafting of a General Comment to clarify the normative content of the Article 15(1)(b) right. This could be particularly useful as the debate in the academic literature and the work of the UN human rights bodies to date reflects that the relevance of this right to enhancing access to medicines is increasing.

(ii) 2012 Report of Special Rapporteur in the field of cultural rights

Further guidance on the scope of the Article 15(1)(b) right was produced by the Special Rapporteur in the field of cultural rights[632]. Taken together with the Venice Statement, these reports make an important contribution to the discourse on the content of this right[633]. The Special Rapporteur's report aimed to mobilise dialogue between States and other stakeholders to clarify the Article 15(1)(b) right[634]. It set out the normative content of the right as having four elements; (1) access to the benefits of science by everyone, without discrimination; (2) opportunities for all to contribute to the scientific enterprise and freedom indispensable for scientific research; (3) participation of individuals and communities in decision-making; and (4) an enabling environment fostering the conservation, development and diffusion of science and technology.[635] These elements echo those proposed in the Venice Statement and in clarifying the content of the Article 15(1)(b) right. It affords an authoritative elucidation of the norms inherent in the right.

[632] UNHRC 'Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed: The right to enjoy the benefits of scientific progress and its applications' (14 May 2012) UN Doc A/HRC/20/26
[633] AB Skre and A Eide, 'The Human Right to Benefit from Advances in Science and Promotion of Openly Accessible Publications' (2013) 31 Nordic J Hum Rts 427, 435
[634] UNHRC 'Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed: The right to enjoy the benefits of scientific progress and its applications' (14 May 2012) UN Doc A/HRC/20/26, 4
[635] ibid 25

The report recognises that there may be a conflict between the Article 15(1)(b) right and IP rights, particularly TRIPS, but reiterates the statement in General Comment 17 that the rights of authors are not to be equated with IP rights, and authors' rights and IP rights can be limited in order to uphold other human rights[636]. The report indicates that the right of authors under Article 15(1)(c) must be balanced with the Article 15(1)(b) right. This is echoed in the literature. For example, Shaver argues that the development of IP law, particularly through TRIPS, has undermined the dissemination of knowledge as a global public good outlined in Article 15.[637] Eide argues that the Special Rapporteur has adopted a similar argument, which is reflected in the recommendations in the report.[638] The report focuses on the benefits of scientific progress for all as a key element of the right, and contends that there was no evidence to support the supposition that scientific inventiveness is only stimulated by legal protection[639]. This calls into question the argument that there is a need for strong IP protection in pharmaceuticals in order to encourage research and development, and that scientific creativity in relation to medicines can be stimulated in other ways.

The report made a number of recommendations relating to medicines, notably that States ensure that innovations essential for a life with dignity reach everyone and identify priority needs of marginalised populations[640]; that States and other stakeholders develop incentives to disconnect research and development from the price of products and encourage companies to join the Medicines Patent Pool[641]; and that States safeguard against encouraging privatisation of knowledge and explore a minimalist approach to IP protection, as well as developing creative mechanisms for protecting the financial interests of creators and the human rights of individuals[642]. The recommendations also suggest that there should be a change in approach to promoting innovation and sharing of information emanating from such innovation, rather than protecting this information and therefore restricting its use and benefit for all. The report also made recommendations to UN human rights bodies including that the CESCR to comprehensively review Article 15

[636] ibid 57
[637] L Shaver, 'The Right to Science and Culture' (2010) 2010 Wis L Rev 121, 154. See also W Hein and S Moon, *Informal Norms in Global Governance Human Rights, Intellectual Property Rules and Access to Medicines*, (Routledge London 2013), 4
[638] Skre and Eide (n 633) 438
[639] UNHRC 'Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed: The right to enjoy the benefits of scientific progress and its applications' (14 May 2012) UN Doc A/HRC/20/26, 65
[640] ibid 74(a)
[641] ibid 74(l)
[642] Ibid 74(o)

and consider adopting a new General Comment covering all of the rights under Article 15[643].

Significantly, the report was welcomed by the Human Rights Council, which adopted a resolution[644] in July 2012 to request the OHCHR to convene a seminar in 2013 to discuss the scope of Article 15(1)(b), and the relationship with Article 15(1)(c). The resolution was adopted without a vote at the thirty first meeting[645], reflecting consensus by States. This suggests that some of the proposals outlined in the Venice Statement could be more viable than first thought. The report on the seminar[646] was published in 2014, which highlighted that the participants had provided examples of initiatives and good practice to improve global access to the benefit of IP[647]. Examples included open access repositories for the sharing of scientific information.[648] The report noted that the WHO had turned its attention to new innovation models which separated the costs of research and development from the price of the product[649]. The report concluded that significant adjustments were needed in the international IP system to ensure a balanced system which aligns with human rights standards[650]. This suggests that the current IP system prioritises the interests of the IP creators and owners to the detriment of the human rights of the individual.

(iii) *2015 Report of Special Rapporteur in the field of cultural rights*

The Special Rapporteur in the field of cultural rights developed the discourse from the 2012 report in a 2015 report which focused on patent policy and Article 15 rights[651]. It

[643] UNHRC 'Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed: The right to enjoy the benefits of scientific progress and its applications' (14 May 2012) UN Doc A/HRC/20/26, 75(b)
[644] UNHRC Res 20/11 (2 July 2012) UN Doc A/HRC/20/L.18, 11
[645] UNHRC 'Report of the Human Rights Council on its twentieth session' (14 November 2013) UN Doc A/HRC/20/2, 33-36
[646] UNHRC 'Report of the United Nations High Commissioner for Human Rights - Report on the seminar on the right to enjoy the benefits of scientific progress and its applications' (1 April 2014) UN Doc A/HRC/26/19
[647] A Plomer, *Patents, Human Rights and Access to Science,* (Edward Elgar Cheltenham 2015), 132
[648] UNHRC 'Report of the United Nations High Commissioner for Human Rights - Report on the seminar on the right to enjoy the benefits of scientific progress and its applications' (1 April 2014) UN Doc A/HRC/26/19, 34-35
[649] ibid 20
[650] ibid 43
[651] UNGA 'Report of the Special Rapporteur in the field of cultural rights' (4 August 2015) UN Doc A/70/279. The first of the reports focused on copyright policy and Article 15 rights; UNHRC 'Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed: Copyright policy and the right to science and culture' (24 December 2014) UN Doc A/HRC/28/57

reiterated that although the ICESCR provides for the progressive realisation of rights, States do have an immediate obligation to ensure that legal provisions do not inappropriately encumber the enjoyment of human rights[652]. It demonstrates that States must act immediately to address patents legislation which restricts enjoyment of human rights such as the right to health, and access to medicines. The report also restated that Article 15(1)(c) does not recognise a human right to protection of IP to the same standard as set out in international IP treaties[653]. Although 'author' does include inventors, a strong personal link must exist between the inventor and the invention, as the right cannot be relied upon to challenge patent provisions providing adequate protection of financial interests[654]. It clearly designates the parameters of the Article 15(1)(c) right by confirming that the right cannot be relied upon by inventors to seek strengthened IP protection. This is particularly relevant in relation to inventors within pharmaceutical enterprises that will not be able to use Article 15(1)(c) to seek strengthened legal protection over its patented pharmaceuticals. Furthermore, the report clarified that the right to the protection of moral and material interests cannot be relied upon by States to defend patent laws that inadequately respect the Article 15(1)(b) right.

The report highlighted that where patent protection is so robust as to prevent a compulsory licence being issued, there is potentially a human rights infringement. The report also stated that the human rights system requires that patents do not extend so far as to interfere with an individual's dignity or wellbeing, giving the example of when a patent holder's right is so strong as to make compulsory licensing unfeasible[655]. Compulsory licensing is an important exception to patent protection in TRIPS, and this statement proposes that the obligations of states Article 15(1)(b) means that the State must take appropriate measures to enhance equitable access to scientific progress, including by supporting the use of compulsory licensing. This also reflects that compulsory licensing is viewed within the UN human rights framework and by the WTO as an important tool to enhance access to medicines, and that the Article 15(1)(b) right could be relied upon to promote the use of compulsory licensing.

[652] UNGA 'Report of the Special Rapporteur in the field of cultural rights' (4 August 2015) UN Doc A/70/279, 14
[653] ibid 32
[654] ibid 34
[655] ibid 47

A significant conclusion emanating from the report was that there is no human right to patent protection under Article 15.[656] This is an important statement as it would preclude pharmaceutical enterprises from seeking to strengthen IP protection in medicines in the form of a human right which Member States are obligated to uphold, such as through FTAs and other international IP legislative instruments. The report also recommended that States ensure that there is transparency in the negotiations of international IP agreements[657]. States must also ensure that pharmaceutical companies benefitting from patents disclose information on costs of developing medicines, as well as the sums reinvested in research and development[658]. This would ensure that pharmaceutical companies are held publicly accountable for the efficiency of their spending on developing medicines, and would also either prove or disprove the argument that patent protection is necessary to protect the large sums of money invested in research and development. However, it may be challenging for states to monitor the cooperation and participation of pharmaceutical companies in the sharing of this information.

The report stated that patent legislation should not place limitations on the right to health unless the State complies with the Article 4 ICESCR[659] exception[660]. It also noted that States have a human rights obligation not to adopt or support IP provisions which would prevent them from utilising the TRIPS flexibilities and therefore reconciling patent protection with human rights[661]. This is an important conclusion as it indicates that States which accept TRIPS-plus provisions in international agreements could be in breach of their human rights obligations. The report also recommended that the UN convene an independent, high-level body to review proposals for a new IP regime for pharmaceutical products that would be consistent with international human rights law and safeguard inventors' rights[662]. Any proposals for a new IP regime for pharmaceutical products are unlikely to gain support, and are likely to meet resistance from

[656] ibid 90
[657] ibid 92
[658] ibid 94
[659] Article 4 states that: 'The States Parties to the present Covenant recognize that, in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.' International Covenant on Economic, Social and Cultural Rights (n 2) Article 4
[660] UNGA 'Report of the Special Rapporteur in the field of cultural rights' (4 August 2015) UN Doc A/70/279, 100
[661] ibid 104
[662] ibid 113

pharmaceutical companies in particular. However, the recommendation to convene a high-level panel was followed in 2015 with the convening of the High-Level Panel on Access to Medicines, discussed below.

The 2012 and 2015 reports of the Special Rapporteur are not binding on states, and it remains to be seen how these reports will influence IP law at national level. However, the Human Rights Council, and hence States, took note of the work of the Special Rapporteur and did not raise any objections to the content of the reports[663]. Academics have noted the role of international NGOs in ensuring positive domestic action is taken following a Special Rapporteur's report, particularly in relation to access to medicines[664]. The reports have also contributed to the discourse on the scope within TRIPS for states to balance social, intellectual, and economic objectives, through effective utilisation of the TRIPS flexibilities[665], as well as contributing to clarification of the normative content of Article 15.

II. Expert consultation on access to medicines

In seeking to clarify IP rights in the context of human rights, the work of the Special Rapporteur in the field of cultural rights has evidently added to the work of the Special Rapporteur on the right to health on the human rights issues relating to access to medicines. In 2009 the Human Rights Council[666] endorsed the recognition that access to medicines is a fundamental element in achieving progressive realisation of the right to the highest attainable standard of health.[667] It invited the OHCHR to convene an expert

[663] See UNHRC 'Report of the Human Rights Council on its twentieth session' (14 November 2013) UN Doc A/HRC/20/2, 10, 81-85; UNHRC 'Report of the Human Rights Council on its twenty-eighth session' (8 July 2015) UN Doc A/HRC/28/2, 160

[664] D Matthews 'NGO Coalitions and the Global Access to Medicine Campaign: The Impact of Intellectual Property Rights on Developing Countries' in J Howell (ed), *Global Matters for Non-Governmental Public Action* (Palgrave 2012), 68; Okediji (n 582) 22; Hein and Moon (n 637) 10

[665] R Cooper Dreyfuss 'Patents and Human Rights: The Paradox Reexamined' in C. Geiger (ed.), *Intellectual property and access to science and culture: conflict or convergence?*, CEIPI-ICTSD Publication Series on Global Perspectives and Challenges for the Intellectual Property System, Issue 3, Geneva/ Strasbourg, 2016 (Forthcoming); NYU School of Law, Public Law Research Paper No. 15-35, 8-9

[666] UNHRC Res 12/24 (12 October 2009) UN Doc A/HRC/RES/12/24. The resolution was adopted without a vote. The draft resolution was sponsored by Brazil and co-sponsored by Bolivia (Plurinational State of), Bosnia and Herzegovina, Colombia, Cuba, the Dominican Republic, Ecuador, Egypt, India, Kyrgyzstan, Nicaragua, South Africa and Venezuela (Bolivarian Republic of). Subsequently, Algeria, Angola, Argentina, Bangladesh, Belarus, Burkina Faso, Chad, Chile, Guatemala, Kyrgyzstan, Maldives, Mexico, Nigeria, Pakistan, Panama, Peru, the Philippines, Thailand and Viet Nam joined the sponsors. (See UN Doc A/HRC/12/50, 167-171)

[667] ibid 7

consultation to exchange views on human rights considerations relating to this issue.[668] It shows that the issue of access to medicines had become a significant concern which the Human Rights Council viewed as an obstacle to the realisation of achieving the highest attainable standard of health for all[669].

In 2011 the Special Rapporteur on the right to health reported on the expert consultation to the Human Rights Council[670], stating that the "right to health requires a company that holds a patent on a lifesaving medicine to make use of all the arrangements at its disposal to render the medicine accessible to all"[671]. The expert consultation was convened by the OHCHR and participants included representatives from Member States, international organisations, non-governmental organisations and independent experts, although it was noted that no representatives from pharmaceutical companies attended the consultation[672]. The objective of the consultation was to facilitate a discussion on "human rights considerations relating to the realisation of access to medicines as one of the fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health"[673]. It provides further confirmation that access to medicines is a core part of the right to health[674].

The consultation comprised two panels, with the first panel discussing access to medicines as a fundamental component of the right to health. Stephen Marks of the Harvard School of Public Health noted that access to medicines derived from Article 15(1)(b) as well as Article 12[675]. Chandrashekhar Dasgupta of the CESCR highlighted

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[668] ibid 7

[669] The resolution was adopted without a vote. The draft resolution was sponsored by Brazil and co-sponsored by Bolivia (Plurinational State of), Bosnia and Herzegovina, Colombia, Cuba, the Dominican Republic, Ecuador, Egypt, India, Kyrgyzstan, Nicaragua, South Africa and Venezuela (Bolivarian Republic of). Subsequently, Algeria, Angola, Argentina, Bangladesh, Belarus, Burkina Faso, Chad, Chile, Guatemala, Kyrgyzstan, Maldives, Mexico, Nigeria, Pakistan, Panama, Peru, the Philippines, Thailand and Viet Nam joined the sponsors. (See UN Doc A/HRC/12/50, 167-171)

[670] UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Expert consultation on access to medicines as a fundamental component of the right to health' (16 March 2011) UN Doc A/HRC/17/43

[671] ibid 47

[672] ibid 1-2. It was noted that Novartis had submitted a letter in which it regretted not being available to participate in the consultation.

[673] ibid 1

[674] Hein and Moon (n 637) 4; CF Wu 'Transnational Pharmaceutical Corporations' Legal and Moral Human Rights Responsibilities in Relation to Access to Medicines' (2012) 7 Asian J WTO &Int'l Health L & Pol'y 77, 91

[675] UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Expert consultation on access to medicines as a fundamental component of the right to health' (16 March 2011) UN Doc A/HRC/17/43, 9

the obligations of states to achieve full realisation of the right to health, including through international assistance stemming from Article 2(1) and Article 12, while also noting that TRIPS-plus standards that prevented use of the TRIPS flexibilities were unacceptable if they restricted access to medicines[676]. Richard Laing of the WHO noted that in most countries public sector procurement obtained medicines at a reasonable cost, however this was not the case in the private sector, although the availability of generic medicines was lower in the public sector compared with the private sector[677]. Laing recommended that governments adopt a rights-based approach to national health policies, specify their obligations with regard to access to medicines, and establish monitoring and accountability mechanisms[678]. Representatives of some unnamed states expressed concerns about developing countries being pressured into entering into TRIPS-plus standards and not using the TRIPS flexibilities, the impact of poverty and pricing, as well as research that prioritises diseases which predominantly affect developed countries[679]. State representatives also noted concern over counterfeit medicines and how they may undermine IP regimes, with states requesting to be part of talks between WHO and WIPO on IP[680]. It highlights the differing objectives of certain states which have strong IP regimes and those states which have to rely on the research and manufacturing capacity of other states to produce the medicines they require.

The discussions of the first panel reflect common themes emanating from the literature[681], with participants with a human rights and health perspective advocating a rights-based approach to enhancing access to medicines. The recommendation to states to introduce more rigorous accountability and monitoring in relation to the cost of medicines proposes that state could do more to effectively regulate the cost of medicines at national level. The responses of state participants highlight problems with regard to resources as well as pressure to accept TRIPS-plus standards, reflecting the wider factors which impact upon access to medicines beyond simply high pricing. Establishing monitoring and accountability mechanisms at national level could improve the monitoring of pricing set by pharmaceutical companies, but state responses highlight the

[676] ibid 10-11
[677] ibid 12
[678] ibid 16
[679] ibid 21
[680] ibid 22, 24
[681] See examples: P Hunt and R Khosla, 'The Human Right to Medicines' (2008) 8 SUR - Int'l J on Hum Rts 99; Hestermeyer (n 72); Joseph (n 198); Helfer and Austin (n 3)

complexities in addressing the issue of access to medicines. Stricter regulation of pricing does not address all of the concerns the states have raised. It is also significant to note that states responses did not dispute that access to medicines is a fundamental part of the right to health. This supports Hein and Moon's view that by 2011 there was widespread acceptance that access to medicines should be universal, and not arbitrarily blocked by patent protection[682]. It is evident that states want to be part of the discussion on how to improve access to medicines, and state responses indicate that they would welcome support and substantive advice on how to address the key challenges they face at national level. Therefore, the establishment of an expert body on medicines and health innovation, comprised of experts including those who participated in the consultation, would be useful to provide a regular forum to take forward this discourse.

The second panel discussed the emerging issues and existing obstacles to providing access to medicines as a fundamental component of the Article 12 right. Key obstacles were stated to be inadequate supply chains, inequitable pricing, poor information on access to medicines and weak accountability for failing to secure access to medicines[683]. The discussion showed that there was consensus that negotiations on TRIPS-plus standards should be closely monitored, and that more guidance should be provided to states on the legitimate use of the TRIPS flexibilities[684]. The contribution from Médécins Sans Frontières noted that the WHO Global Strategy and Plan of Action was positive, but its effectiveness depended on the inclination of states in implementation[685]. Representatives of unnamed states expressed concern that too much responsibility was placed on governments, particularly developing states, asserting that international organisations and pharmaceutical companies should have more responsibility in relation to removing obstacles to access to medicines[686]. A growing, urgent need to ensure that multinational companies adopt a corporate social responsibility

[682] Hein and Moon (n 637) 7

[683] UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Expert consultation on access to medicines as a fundamental component of the right to health' (16 March 2011) UN Doc A/HRC/17/43, 41

[684] ibid 36

[685] ibid 34. This view was also stated in the 2017 review of the Global Strategy, which outlined that although the aim and objectives of the Global Strategy were still relevant, but a key problem was lack of implementation. See also World Health Organization, *Overall programme review of the global strategy and plan of action on public health, innovation and intellectual property: Report of the review panel*, November 2017 <https://www.who.int/medicines/areas/policy/GSPA-PHI3011rev.pdf?ua=1> (accessed 27/04/2020)

[686] ibid 41

approach was also articulated[687]. It indicates the significance of the UN Guiding Principles on Business and Human Rights[688], discussed in the previous chapter.

The report noted that while States have primary responsibility for enhancing access to medicines, numerous actors also have a role, including pharmaceutical companies[689]. The report made a number of suggestions directed at States including that States should establish a competent legal framework in order to realise the right to access to medicines; ensure that medicine-related health priorities are not weakened in favour of business priorities; take measures to ensure equality for all individuals and groups, such as disadvantaged minorities; and establish accountability and monitoring mechanisms for access to medicines.[690] However, there is little to encourage the States and the private business sector to take positive actions to progressively realise access to medicines, which was identified as a concern in previous reports. Also, although the report stated that the expert consultation identified the need for a reliable system for the supply of medicines that are affordable for all[691], the report did not go far enough so as to propose the substantive details of such a system. It places the onus on the States to take the proposed steps to enhance access to medicines in order to comply with their human rights obligations. However, as the report itself observed, the responsibility to improve access to medicines for all is collective. Therefore, it would have been useful for the consultation to have made suggestions which related to the responsibilities of non-State actors and other stakeholders, particularly those participating in the consultation, to assist States to achieve this goal, in order to fulfil the objective of the consultation.

United Nations Secretary-General's High-Level Panel on Access to Medicines

In November 2015 the then UN Secretary-General Ban Ki-moon convened a High-Level Panel on Access to Medicines with the aim of reviewing and finding solutions for resolving policy incoherence between the rights of inventors, public health, international

[687] ibid 26
[688] United Nations Office of the High Commissioner for Human Rights, *Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework* (n 494)
[689] UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Expert consultation on access to medicines as a fundamental component of the right to health' (16 March 2011) UN Doc A/HRC/17/43, 45
[690] ibid 49(a),(b),(c),(g)
[691] ibid 45

human rights law and trade rules with regard to health technologies.[692] This is a significant development in advancement of access to medicines as the Panel included a range of stakeholders with a remit to find more extensive and viable solutions to enhance access to medicines and medical technologies.[693] Therefore it is important to examine the findings of the Panel to explore the efficacy of the recommendations made in helping states to interpret and implement their obligations under TRIPS and the ICESCR to enhance access to medicines.

The Panel comprised fourteen members and two co-chairs from developed and developing countries, including representatives from non-governmental organisations, the pharmaceutical industry, and experts in law, domestic government policy, IP trade and development[694]. The mandate of the Panel was to look at the competing interests of health and trade and to find a solution within the parameters of the existing international legal frameworks on human rights and trade respectively[695]. A background paper recognised that there have been substantial efforts by various actors[696] to address the issues with regard to particular diseases or access issues specific to low income countries. However, more radical proposals were needed to modify the current incentive systems for innovation.[697] It suggests that the UN Secretary-General viewed that the work done to date had been ineffective in tackling this global issue due to a lack of coordinated efforts between the various actors, with such efforts being relatively low level, as well as a reactive approach to challenges that arose in specific areas. The paper also emphasised

[692] United Nations Secretary-General's High-Level Panel on Access to Medicines , *United Nations Secretary-General's High-Level Panel on Access to Medicines: Terms of Reference* (2015) <http://www.unsgaccessmeds.org/reports-documents/> (accessed 27/04/2020), 3

[693] United Nations Secretary-General's High-Level Panel on Access to Medicines, *Background Paper: Existing and prior work, initiatives and proposals to improve innovation and access to health technologies,* prepared by Brook Baker, with the High-Level Panel Secretariat at UNDP in collaboration with UNAIDS (2015) <http://www.unsgaccessmeds.org/reports-documents/> (accessed 27/04/2020), 40

[694] United Nations Secretary-General's High-Level Panel on Access to Medicines, 'The Panel', <http://www.unsgaccessmeds.org/new-page/> (accessed 27/04/2020)

[695] United Nations Secretary-General's High-Level Panel on Access to Medicines, *Background Paper: International legal norms: the right to health and the justifiable rights of inventors,* prepared by Richard Elliott, with the High-Level Panel Secretariat at UNDP in collaboration with UNAIDS (2015) <http://www.unsgaccessmeds.org/reports-documents/> (accessed 27/04/2020), 22

[696]The paper reviewed the initiatives of a wide range of organisations on supporting innovation and access to health technologies, including the work of the WHO Commission on Intellectual Property Rights, Innovation and Public Health and the work of the WTO resulting in the Doha Declaration. ibid

[697] United Nations Secretary-General's High-Level Panel on Access to Medicines, *Background Paper: Existing and prior work, initiatives and proposals to improve innovation and access to health technologies,* prepared by Brook Baker, with the High-Level Panel Secretariat at UNDP in collaboration with UNAIDS (2015) http://www.unsgaccessmeds.org/reports-documents/ (accessed 27/04/2020), 39

that innovators must be rewarded.[698] It highlights that the UN human rights system recognises that a balancing of these competing interests has been undertaken, although Okediji argues that, despite considerable political pressure regarding the right to health, this balance has not been successful to date[699]. A second background paper also considered the competing obligations under international human rights law and international trade law and confirmed that as part of its mandate the Panel had to consider the "recognised and entrenched legal intellectual property rights under international or domestic laws, but also the foundational position of human rights in the international legal system."[700] The final report was to be submitted to the Secretary-General in June 2016, with the intention of making the report available to the General Assembly to take appropriate action on the findings of the report.

The Panel's final Report was released on 14 September 2016[701]. It noted the importance of Sustainable Development Goal 3[702] as a device in realising the right to health, stating that while medical innovation has contributed to improving health for millions of people, the current health innovation model was inadequate to respond to the growing emergence of communicable diseases.[703] The Report discussed the effect of TRIPS and FTAs, arguing that several contributions to the Panel indicated a gradual departure from human rights in the implementation of IP law and policy, both under TRIPS and in recent trade agreements.[704] It asserted that the necessary balance between the human right to health and trade and IP law would be met if the provisions under

[698] ibid 40
[699] Okediji (n 582) 44
[700] United Nations Secretary-General's High-Level Panel on Access to Medicines, *Background Paper: International legal norms: the right to health and the justifiable rights of inventors,* prepared by Richard Elliott, with the High-Level Panel Secretariat at UNDP in collaboration with UNAIDS (2015) <http://www.unsgaccessmeds.org/reports-documents/> (accessed 27/04/2020), 22
[701] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72)
[702] The 2030 Agenda for Sustainable Development was adopted by the UN General Assembly on 25 September 2015 (UNGA Res 70/1 (21 October 2015) UN Doc A/RES/70/1), and includes 17 Sustainable Development Goals (SDGs), which follow on from the Millennium Development Goals. The SDGs are not legally binding but Member States are expected to implement measures to achieve the SDGs. Goal 3 is to ensure healthy lives and promote well-being for all at all ages, and specifically includes providing access to medicines for all. See UNGA Res 70/1 (21 October 2015) UN Doc A/RES/70/1, Goal 3, 3.b. Human Rights Council Resolution 35/23 also underlines access to affordable medicines as part of the 2030 Agenda (See also UNHRC Res 35/23 (23 June 2017) UN Doc A/HRC/RES/35/23, Target 3.8) and the report of the UN High Commissioner for Human Rights pursuant to this resolution stated that access to medicines "evokes one of the core obligations under the right to health" (See also UNHRC 'Contributions of the right to health framework to the effective implementation and achievement of the health related Sustainable Development Goals: Report of the United Nations High Commissioner for Human Rights' (20 April 2018) UN Doc A/HRC/38/37, 16
[703] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) 7
[704] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) 19

TRIPS and the Doha Declaration were properly followed, and significantly it noted that more recent FTAs had included dispute resolution mechanisms which permitted private enterprises to challenge national legislation that would deny them of future profit.[705] It highlights the particular difficulties for states to comply with human rights responsibilities when the actions of private enterprises which are not bound by such obligations, have a major influence in trade agreements and policy. The Report also observed that the Member States that are parties to TRIPS have not implemented the flexibilities that protect health as vigorously as they have enforced the provisions that protect IP rights[706]. It reaffirms the importance of TRIPS and its flexibilities[707], and suggests that States have not done enough to ensure that the health rights of individuals are upheld in the same manner as the IP rights of private businesses. However, there may be several reasons for this. The more robust enforcement mechanisms within the WTO forum compared with enforcement of human rights norms may greatly influence the actions of States. Issues such as resource constraints are also relevant.

The Report noted gaps in innovation and access particularly in relation to neglected diseases, which predominantly affect developing countries, and encouraged the further development of mechanisms which incentivise health innovation while delinking the cost from the price of the final product.[708] The Report stated that States have a significant responsibility in respect of funding research and development of medicines because of their obligations to their citizens to progressively realise the right to health under Article 12.[709] Bagley argues that the Report shows that the global community is not getting the best mix of medicines needed.[710] This view highlights that despite significant developments in science and health technologies in recent decades, such developments are not translating into greater access to medicines. The Report stated that States have a significant responsibility in respect of funding research and development of medicines because of their obligations to their citizens to progressively realise the right to health under Article 12. It was also noted that ensuring State accountability is impeded by the lack of transparency in trade negotiations, as well as a lack of coordination with non-

[705] ibid
[706] ibid 20
[707] G Persad, 'Examining Pharmaceutical Exceptionalism: Intellectual Property, Practical Expediency, and Global Health' (2019) 18 Yale J Health Pol'y L & Ethics 157, 162
[708] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) 29
[709] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) 31
[710] M Bagley, 'The Morality of Compulsory Licensing as an Access to Medicines Tool' (2018) 102 Minn L Rev 2463, 2485

government agencies and international organisations. An additional difficulty is that there is a lack of accountability for private enterprises. Although some companies have corporate social responsibility policies, there is no obligation to do so. The Report also commented on the lack of transparency in relation to funding costs and clinical trial data, which may also impede the development of new medicines as well as the sharing of data and information promptly for the benefit of all.

(a) Recommendations of the Panel

The Report made several recommendations aimed at resolving inconsistencies between policies encouraging innovation and access. Recommendations relating to improving physical access to medicines included that States should reinforce the current legal position by facilitating the use of compulsory licensing through legislation, and to support the use of TRIPS flexibilities by WTO Member States[711]. Houston and Beall argue that the Report concludes that the Paragraph 6 system should be revised, but fails to provide specific guidance on steps that could be taken to increase the use of the system.[712] This suggests that the panel missed the opportunity to progress the discourse on how the Paragraph 6 system might be improved so that it can be utilised more effectively for the benefit of developing states. Solovy argues that while the Report recognises the flexibility in issuing a compulsory licence, it ignores the limitations and requirements in relation to compulsory licences set out in Article 30 TRIPS[713]. This assumes that the Report took the view that it should be relatively easy to obtain a compulsory licence, and did not take into account the limitations on the issuing of a compulsory license in Article 30, which protect the rights of the IP holder. Solovy further argues that from a policy perspective, the overuse of compulsory licensing could undermine the credibility of a state's patent system.[714] This rather expansive view appears to contradict the point that the limitations under Article 30 do not make it 'easy' for states to obtain a compulsory licence. To utilise compulsory licensing under Article 30 would also be a legitimate use

[711] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) 27
[712] A Houston and R Beall, 'Could the Paragraph 6 Compulsory License System Be Revised to Increase Participation by the Generics Industry: Lessons Learned from a Unheralded and Unsuccessful Attempt to Use Canada's Access to Medicines Regime' (2018) 12 McGill JL & Health 227, 231
[713] E Solovy and P Krishnamurthy, 'TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High Level Panel Report on Access to Medicines' (2017) 50 Geo Wash Int'l L Rev 69, 121
[714] ibid 122

of an exception to patent protection under TRIPS that has been agreed by Members. Therefore, states should not be subject to external pressure not to utilise Article 30, and should be able to seek recourse through the WTO DSB if subjected to such pressure from another Member.

The Report also recommended that States that are subject to pressures, from other States or the private sector, which undermine their use of the TRIPS flexibilities should report such practices to WTO.[715] This suggests that the Panel wished to encourage States that seek to promote access to health, including medicines, through international agreements such as TRIPS that, should they be challenged by other States or other private enterprises, they would be supported by the UN human rights bodies and WTO. It also indicates that States that may attempt to undermine their commitments under international agreements, such as TRIPS, through FTAs may be subject to challenge. The Report also recommended that the WHO maintain an international database of prices of patented and generic medicines in countries where they are registered[716], highlighting that in order to improve the inconsistencies in policy with trade and health, international organisations and non-governmental organisations have responsibilities to assist States in achieving this objective. However, this could also raise the issue of transparency, as accurate and quality data on pricing would need to be provided consistently for such a database to be effective.

The Report also made recommendations relating to promoting innovation in the development of new medicines. It recommended that additional funding models should be implemented which would stimulate innovation where there is no market incentive to develop particular medicines[717], such as public-private partnerships and prizes for innovators. This would delink the research and development costs from the price of the end product, which could lead to more equitable prices for medicines so that they are more widely available for the population. Further recommendations included that States increase government funding for health innovations, particularly in developing and least developed countries[718], and that the UN Secretary-General should establish an independent review body to assess progress on health technology innovation and access, as well as monitoring implementation of the recommendations of the Panel and progress on the 2030 Agenda for Sustainable Development[719]. This would further increase

[715] ibid
[716] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) 37
[717] ibid 31-32
[718] ibid 31
[719] ibid 37

accountability of States with regard to their obligations under the right to health, and may strengthen the current accountability and enforcement mechanisms within the UN human rights systems.

The Report also made recommendations with regard to the monitoring of biomedical and pharmaceutical companies, recommending that they should be required to report on actions they have taken to promote access to health technologies[720], and governments should require the disclosure of all costs relating to the production and distribution of medicines. This would add a measure of accountability for private companies, and may also compel them to justify their expenditure on research and development, particularly if they wish to take advantages of the more innovative funding schemes proposed. Yu notes that the Report is an example that the issue of sharing test data is becoming more significant, and that the right to health has been used to justify the disclosure of data on pharmaceuticals in academic literature.[721] Greater transparency over research and development costs may also give an indication of the efficiency of the process, as well as the return on public investment in medicine development[722]. The reporting obligations may have the added effect of showing that the pharmaceutical industry is not only of commercial interest but delivers a valuable contribution to society. Reporting obligations on pharmaceutical companies could also form part of the regulation of such companies by states under the Guiding Principles, discussed in the previous chapter.

While the recommendations in the Report were welcomed by the outgoing Secretary-General Ban Ki-moon[723], it was evident that the recommendations were reached by consensus, and due to the diverse backgrounds of the contributors it is clear from the individual commentaries[724] annexed to the Report that diverging views over the recommendations remain. Following the publication of the Report, the Secretary-General

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[720] ibid 37

[721] P Yu, 'Data Exclusivities and the Limits to Trips Harmonization' (2019) 46 Fla St U L Rev 641, 667; T Lemmens and C Telfer 'Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency' (2012) 38 AM. J.L. & MED. 63, 66

[722] S Moon, 'Powerful Ideas for Global Access to Medicines', (2017) 376(6) New England Journal of Medicine 505 DOI: 10.1056/NEJMp1613861, 2

[723] United Nations Press Release, 'Universal Access to Medicines, Technologies Essential for Human Well-being, Secretary-General Says, Encouraging Compliance with Health Panel's Findings', SG/SM/18293-DEV/3255, 22 November 2016, <https://www.un.org/press/en/2016/sgsm18293.doc.htm> (accessed 27/04/2020)

[724] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) Annex 1: Commentaries, 53

encouraged all stakeholders to review the recommendations and to develop a way forward in appropriate fora to ensure access to medicines for all[725].

The commentaries highlight that there was a lack of consensus over a number of themes considered by the Panel, with members Jorge Bermudez (former UNITAID Executive Director, Unit Chief for Medicines, Vaccines and Health Technologies Unit at PAHO/WHO), Winnie Byanyima (Executive Director of Oxfam International and former MP, Uganda) and Shiba Phurailatpam (formerly with United Nations Development Programme and ActionAid International) stating that the Report should have been bolder to include recommendations such as a new IP regime for pharmaceutical products and calling for sanctions on TRIPS-plus provisions in FTAs.[726] Persad argues that these Panel members would have gone further and eliminated rights over certain subsets of medicines.[727] Their position that IP and costs of medicines are crucial barriers to access echoes a core issue in the discourse, but ignores wider factors such as inadequate health care infrastructures and states' resource constraints.[728] Conversely, a dissenting commentary from Andrew Witty asserted that the Report overstates the use of the TRIPS flexibilities and cautioned against implementing an alternative system without a thorough risk assessment of potential negative consequences in doing so.[729] Cadillo Chandler has argued that implementing another IP system may lead to overlap with the current system and may not address the problems that have been experienced with attempts to adapt and amend TRIPS.[730] Implementing another IP system also may not position the issue of securing access to medicines in a rights-based framework.

Andrew Witty further argued that delinking product prices from development costs may be difficult as the costs of research and development are not always evident at the outset[731], which may suggest that increasing publicly funded research could lead to increases in national debt. However it is important to note that the Panel's Report was to address policy incoherencies and stimulate debate on the issue in a high-level forum, and

[725] United Nations Press Release, 22 November 2016 (n 723)
[726] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) Annex 1: Commentaries, Jorge Bermudez, Winnie Byanyima and Shiba Phurailatpam, 53
[727] Persad (n 707) 162
[728] Persad (n 707) 163
[729] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) Annex 1: Commentaries, Andrew Witty, 57
[730] D Cadillo Chandler, 'The never-ending story of access to medicines' (2016) 8(1) World Intellectual Property Organization Journal 54, 62
[731] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) Annex 1: Commentaries, Andrew Witty, 56

therefore some points may need further exploration and development in order to advance an efficacious response to the issue of enhancing access to medicines for all. While it is pertinent to appreciate that the precise expertise of the respective commentators may influence their views, the divergence of opinion in the various commentaries highlights the difficulties the Panel experienced in finding consensus in achieving recommendations to secure access to medicines, reiterating the complex nature of the issue. It also indicates that the Report may have the support of civil society organisations[732], but is less likely to be supported by the pharmaceutical industry.

Prior to the publication of the Panel's final report, concerns as to the scope of the Panel's remit were expressed by biotechnology and biopharmaceutical enterprises[733]. Concerns included that the Panel should not only focus on IP but should take a broader approach to consider other factors that affect access to medicines, such as trade barriers.[734] The submission also commented that international IP systems have contributed to improving global health[735]. This indicates apprehension among the biotechnology industries that the Panel report would recommend a reconstruction of the international IP system which could lead to international pressure to modify the existing operation of their enterprises. Persad argues that the report focused its analysis and criticism on holders of IP rights when other stakeholders, including civil society organisations, and national governments, have a role to play in improving access to medicines.[736] Although this is a reasonable view, it is important to note that the mandate of the Panel was to address tension between rights of inventors, human rights law, trade rules and public health, rather than a wide-ranging review of all reasons for which medicines and health technologies are unaffordable. Solovy argues that the report does not afford sufficient credit for the role of patent protection in the creation of medicines.[737] However, the report does

[732] Organisations such as Oxfam and Médécins Sans Frontières have expressed support for the Panel's recommendations; See also: Oxfam, 'Report of the UN Secretary-General's High-Level Panel on human rights and medicines: Oxfam's response' <http://policy-practice.oxfam.org.uk/publications/report-of-the-un-secretary-generals-high-level-panel-on-human-rights-and-medici-620085> and Médécins Sans Frontières, 'Doctors Without Borders Response to Report from UN Secretary-General's High-Level Panel on Access to Medicines' <https://www.doctorswithoutborders.org/what-we-do/news-stories/news/doctors-without-borders-response-report-un-secretary-generals-high> (accessed 27/04/2020)

[733] International Council of Biotech Associations written submission to UN High Level Panel on Access to Medicines, 'Letter from representatives of the Biotechnology industry to the High-Level Panel' 14 July 2016, <http://www.unsgaccessmeds.org/reports-documents/> (accessed 27/04/2020)

[734] ibid

[735] ibid

[736] Persad (n 707) 159

[737] Solovy and Krishnamurthy (n 713) 76

explicitly recognise the vast contribution of the pharmaceutical and biotechnology industries, and that such contributions have been largely stimulated by incentives underpinned by IP.[738] The Panel also included representation from the pharmaceutical industry, as noted above, to provide a measure of balance and to represent the interest of rights holders.

Forman argues that the Panel report "offered an important testing ground for promoting an intellectual property system that didn't simply enhance protection of the public interest as an externality to its ethos of advancing trade interests, but that located this system within the broader system of international law".[739] Therefore, the Panel could have taken the opportunity to address the fragmentation of international law specifically in relation to trade law, human rights and access to medicines. However, Forman argues that the report added little to what were already existing policy proposals, and so the Panel missed this opportunity to progress the issue of access to medicines.[740] The Panel did make some innovative proposals including those relating to delinking of product prices from research and development costs, although the Report did not propose wide reform[741]. This could be viewed as a missed opportunity, considering the range of participants and their relative expertise. Kirby argues that the global community needs to find a solution to enhance access to medicines, and this will be achieved by finding consensus among the relevant stakeholders, rather than through combative steps[742]. It is also important to note that the Panel had a relatively narrow mandate, so it may not have been feasible to make assertions which could exceed the specific mandate of the Panel.

(b) WHO, WTO and WIPO Responses to the Panel's recommendations

The WHO has outlined its support for the Panel report, with the Director-General stating that the work of the Secretariat covers many of the recommendations in the Panel report in his report on access to medicines in March 2018[743]. Examples are provided in

[738] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) 55; See also Okediji (n 582) 59
[739] L Forman, 'The Inadequate Global Policy Response to Trade-Related Intellectual Property Rights: Impact on Access to Medicines in Low- and Middle-Income Countries' (2016) 31 Md J Int'l L 8, 19
[740] ibid 20
[741] L Forman, I Abdillahi and J Samuel, 'Assessing the UN High-Level Panel on Access to Medicines Report in Light of the Right to Health' (2016) 5 Laws 43, P. 4 (doi:10.3390/laws5040043), P.9
[742] M Kirby, 'Human Rights and Global Pharma Converge' (2018) 18 QUT L Rev 163, 170
[743] World Health Organization 'Addressing the global shortage of, and access to, medicines and vaccines:

Appendix 3 of the Director-General's report which outlines recommendations of the report of the High-Level Panel and the WHO's activities, including that the WHO is providing technical support to countries on the use of the TRIPS flexibilities[744], and is advocating for increased transparency on costs of R&D[745]. Following from the report of the Director-General, a roadmap on access to medicines and vaccines has been drafted[746] in consultation with Member States, which outlines the programming of WHO's work on access to medicines and vaccines for the period 2019-2023, including specific actions and key deliverables for each of the strategic areas prioritised in the roadmap[747]. The document notes that the WHO will take the report of the High-Level Panel into account when addressing the area of application and management of intellectual property to contribute to innovation and promote public health[748]. The work of the WHO indicates that it is implementing recommendations of the report relevant to its mandate. The fact that the roadmap has been drafted in consultation with states demonstrates that states are engaging in commitments to enhance access to medicines as outlined in the document.

The Panel's report was also discussed within the WTO Council following a request by Member States Brazil, China, India and South Africa to place it on the agenda[749]. In the report to the Council on the annual review of the implementation of paragraph 6 of the Doha Declaration[750], India restated concerns that the paragraph 6 process was too burdensome and supported the Panel's recommendation to revise TRIPS to include a distinct compulsory licence mechanism for pharmaceutical products[751]. Brazil also highlighted the report's recommendations that national governments should implement legislation that incorporates an efficient and accessible compulsory licensing

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Report by the Director-General' 19 March 2018, A/71/12, 31 <http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_12-en.pdf?ua=1> (accessed 27/04/2020)

[744] ibid Appendix 3, 2.6.1

[745] ibid Appendix 3, 4.3.4(a)(i)

[746] World Health Organization, 'Roadmap for access to medicines, vaccines and health product 2019-2023: comprehensive support for access to medicines, vaccines and other health products' <https://apps.who.int/iris/handle/10665/330145> (accessed 27/04/2020)

[747] ibid P.7

[748] World Health Organization, 'Roadmap for access 2019-2023: Comprehensive support for access to medicines and vaccines: Zero draft v2', P.9 <https://www.who.int/medicines/access_use/Roadmap_Englishv2.pdf?ua=1> (accessed 27/04/2020).

[749] World Trade Organization, 'Annual Report (2016) of the Council for TRIPS', 18 November 2016, IP/C/75, 15.1

[750] World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, 'Annual Review of the Decision on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Report to the General Council', 23 November 2016, IP/C/76

[751] ibid Appendix 1, 24

provision for medicines[752], while South Africa also underlined this recommendation[753]. The WTO General Council took note of the report of the TRIPS Council and the accompanying statements in its annual report[754]. It remains to be seen whether any of the Panel's recommendations will be adopted by the WTO[755]. However given the fact that the first amendment to TRIPS emanating from the Doha Decision entered into force on 23 January 2017[756], just three months after the Panel's report was published, the WTO may decide that real progress in securing access to medicines can be made through this amendment, rather than seeking to make further amendments which may take a similar length of time to agree and to implement.

The Panel's report was discussed in the WIPO Standing Committee on Law of Patents in December 2016. The EU statement was critical of the narrow mandate of the Panel, suggesting that it ignored more common issues that affect lack of access to medicines[757]. It also highlighted that none of the recommendations were supported by all members of the Panel and declined to support some of the recommendations including the proposals for revision of TRIPS[758]. This opposition to the findings of the report was also reflected in the US, with the US Chamber of Commerce asserting that the report failed to consider issues such as excessive tariffs and weak distribution systems which affect access to medicines, and commented that the recommendations would place the UN itself above national governments in administering IP rights[759]. However, Moon argues that the real concern over the recommendations could be because the report

[752] ibid Appendix 1, 25
[753] ibid Appendix 1, 41
[754] World Trade Organization, General Council, 'Annual Report (2016)', 21 December 2016, WT/GC/182, 7.2
[755] The 2017 Annual Report of the General Council and the 2018 Annual Report of the Council for TRIPS did not include any further discussion on the recommendations in the Report. See also World Trade Organization, General Council, 'Annual Report (2017), 4 December 2017, WT/GC/191 and World Trade Organization, 'Annual Report (2018) of the Council for TRIPS', 21 November 2018, IP/C/81. There are no further updates as at March 2020.
[756] World Trade Organization, 'WTO IP rules amended to ease poor countries' access to affordable medicines', 23 January 2017, <https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm> (accessed 27/04/2020)
[757] Delegation of the European Union to the UN and other international organisations in Geneva, 'World Intellectual Property Organization, Standing Committee on Law of Patents - 25th session Patents and Health, 14 December 2016, EU Opening Statement' <https://eeas.europa.eu/delegations/un-geneva/17248/wipo-standing-committee-law-patents-25th-session-patents-and-health_en> (accessed 27/04/2020)
[758] ibid
[759] US Chamber of Commerce, 'U.S. Chamber Condemns UN Report Attacking Patents', 14 September 2016 <https://www.uschamber.com/press-release/us-chamber-condemns-un-report-attacking-patents> (accessed 27/04/2020)

requires broad modifications to the current model of research and development for the benefit of all countries, where previously the issue of securing access to medicines has centred on lower pricing for developing countries[760]. It suggests that the Panel's report underlined a shift in approach to the problem of enhancing access to medicines to viewing it as an issue which affects all countries, not only developing and least developed countries, and therefore a global response is needed to advance solutions that are constructive in all countries.

The response of the UN General Assembly was the adoption of a resolution[761] including a request to the UN Secretary-General to promote discussion among Member States and relevant stakeholders on policies to promote access to medicines, innovation and health technologies, while considering relevant reports including the Panel's report[762] and also the trilateral report of WTO, WIPO and WHO[763]. In December 2017 the UN General Assembly adopted a further resolution in which it decided to hold a high-level meeting on universal health coverage in 2019[764], and stated that universal health coverage implies that all people have equal access to essential, affordable, effective and quality medicines.[765] The resolution was adopted without a vote, and Thailand and the US made statements emphasising the importance of equitable access to safe, effective medicines.[766] Following the meeting the General Assembly adopted a resolution committing to achieving universal health coverage by 2030[767]. The resolution also committed to several actions relating to medicines which echo the Panel's recommendations, including increased transparency of pricing[768], delinking R&D costs from prices[769] and appropriate incentives in development of new medicines[770]. The resolution was also adopted without

[760] Moon (n 706) 1
[761] UNGA Res 71/159 (18 January 2017) UN Doc A/RES/71/159. The Resolution was adopted by the General Assembly of 15 December 2016 without a vote at the 63rd plenary meeting. The draft resolution was proposed by Argentina, Bangladesh, Brazil, France, Indonesia, Japan, Liberia, Monaco, Morocco, Norway, Senegal, South Africa and Thailand (See UNGA 'Argentina, Bangladesh, Brazil, France, Indonesia, Japan, Liberia, Monaco, Morocco, Norway, Senegal, South Africa and Thailand: draft resolution Global health and foreign policy: health employment and economic growth' (8 December 2016) UN Doc A/71/L.41).
[762] UNGA Res 71/159 (18 January 2017) UN Doc A/RES/71/159, 23
[763] WTO, WIPO, WHO, (n 354). This report is also discussed in Chapter 1.
[764] UNGA Res 72/139 (15 January 2018) UN Doc A/RES/72/139, 24
[765] ibid 6
[766] UNGA 'Seventy-Second Session, 72nd plenary meeting' (12 December 2017) UN Doc A/72/PV.72, 2,6
[767] UNGA Res 74/2 (10 October 2019) UN Doc A/RES/74/2
[768] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) 50
[769] ibid 53
[770] ibid 51

a vote,[771] reflecting consensus by States on the resolution. A statement from the EU stated the need for a comprehensive outlook, working towards access to affordable medicines[772], and Switzerland stated its commitment to a system that encourages R&D in the area of innovative medicines.[773]

Other recent developments concerning access to medicines

(a) High-level meeting on ending HIV/AIDS

The General Assembly held a high-level meeting on ending HIV/AIDS in June 2016[774] which included discussion of the issue of ensuring access to medicines for all persons living with HIV/AIDS. The summary report by the Human Rights Council for consideration at the high-level meeting included the recommendation that IP rights should not take precedence over public health as there is also a right for everyone to enjoy the benefits of scientific progress[775]. The report also stated that IP rights should not be allowed to take precedence over the right of all persons living with HIV/AIDS to have access to life-saving medicines[776]. This statement from the Human Rights Council indicates that the right to benefit from scientific progress should be balanced with the author's rights under Article 15 ICESCR and also emphasises that there exists a right to access to essential medicines, specifically for treating HIV/AIDS in the context of this report. This position is in line with the position taken by the Panel[777], as well as the position of other UN human rights bodies.

The report of the Secretary-General also highlighted the importance of supporting research and development for health technologies, as well as ensuring affordability by

[771] UNGA Res 74/2 (10 October 2019) UN Doc A/RES/74/2
[772] UNGA 'Seventy-fourth Session, 14th plenary meeting' (10 October 2019) UN Doc A/74/PV.14, 8
[773] ibid 9
[774] United Nations General Assembly, '2016 High-Level Meeting on Ending AIDS', <http://www.hlm2016aids.unaids.org/index.php/en/home/> (accessed 27/04/2020)
[775] UNHRC 'Summary of the Human Rights Council panel discussion on the progress in and challenges of addressing human rights issues in the context of efforts to end the HIV/AIDS epidemic by 2030' (26 April 2016) UN Doc A/HRC/32/25, 35(c)
[776] UNHRC 'Summary of the Human Rights Council panel discussion on the progress in and challenges of addressing human rights issues in the context of efforts to end the HIV/AIDS epidemic by 2030' (26 April 2016) UN Doc A/HRC/32/25, 35(c)
[777] Forman, Abdillahi and Samuel (n 741) 4

aligning public health aims and trade policies under a human rights framework[778], suggesting that affordability may be regulated effectively within a rights-based agenda. The General Assembly also adopted a political declaration on HIV/AIDS to commit to measures to ensure access to medicines, including generic medicines and health technologies, and noted the convening of the High-Level Panel on Access to Medicines by the Secretary General[779].

(b) Human Rights Council Resolution 32/15

The thirty-second session of the Human Rights Council held in July 2016 resulted in the adoption of a resolution on access to medicines[780], which reiterated the request for States to collaborate on proposals to support delinking new research and development costs from the prices of medicines that predominantly affect developing countries[781]. This is a similar request to the recommendation on delinkage in the High-Level Panel's subsequent Report, indicating a measure of overlap between the work of the Human Rights Council and the High-Level Panel, and highlights an important trend in the work of the UN human rights bodies. The resolution also includes the Human Rights Council decision to convene a panel discussion at its thirty-fourth session to discuss good practices and key challenges relevant to access to medicines as one of the fundamental elements of the right to health, inviting the United Nations High Commissioner for Human Rights to liaise with states and other stakeholders regarding the panel discussion and to prepare a report on the panel discussion to be submitted to the Human Rights Council[782]. The panel discussion suggested by the Human Rights Council appears to have a broader mandate than the High-Level Panel, and therefore may add to the discussion on securing access to medicines for all as a fundamental element of the right to health under Article 12 ICESCR. Panellists reiterated the call for the Secretary-General to establish an inter-agency taskforce on health technology innovation and access[783]. This could potentially be significant in order

[778]UNGA 'On the fast track to ending the AIDS epidemic: Report of the Secretary-General' (1 April 2016) UN Doc A/70/811, 75(j)
[779] UNGA Res 70/266 (22 June 2016) UN Doc A/RES/70/266, 60(i). The resolution was adopted without a vote.
[780] UNGA, *Report of the Human Rights Council* (United Nations New York, 2016) UN Doc A/71/53, Resolution 32/15, 210. The Resolution was adopted without a vote
[781] ibid 212
[782] ibid 213
[783] UNHRC 'Summary of the panel discussion on access to medicines: Report of the United Nations High Commissioner for Human Rights' (24 May 2017) UN Doc A/HRC/36/19, 41

to provide a platform for discourse on a key recommendation of the High-Level Panel, although such a taskforce may not have a mandate to consider broader issues that affect access to medicines.

The report of the panel discussion noted that most States supported the Report of the High-Level Panel, and explicitly encouraged countries to implement its recommendations[784]. This is very significant as it indicates that States are willing to engage with the recommendations in the Report and to take actions to implement the recommendations. The need for improved transparency of costs and pricing was also highlighted[785], as well as the need to gather the views of stakeholders, including governments and pharmaceutical companies, on the fundamental changes that needed to be made to the current innovation model[786]. This highlights the importance of the availability of data on R&D costs to assess the pricing of medicines, and also that an effective collaboration on delinking costs and prices needs to include not only States but all other relevant stakeholders, including pharmaceutical companies. To get pharmaceutical companies to agree to disclose their R&D costs could be challenging. Disclosing this data could be a condition of receiving funding or a grant, for example if the company was receiving public funding for a particular project and was required to account for how the money was spent. This could raise the question of whether there is a role for competition law to regulate anti-competitive conduct or excessive pricing[787], although this question is beyond the scope of this thesis[788].

To envisage how pharmaceutical companies could be compelled to disclose such data, the US provides an example. State legislatures have passed laws on medicines pricing, including measures to increase pricing transparency and disclosure of costs in states including Vermont in 2016, and Nevada, California and New York in 2017.[789]

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[784] ibid 35

[785] ibid 40

[786] ibid 41

[787] C Waelde and A Brown 'A practical analysis of the human rights paradox in the intellectual property law: Russian Roulette' in W Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar, Cheltenham 2010), P.205; J Reichman, 'From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement' (1996) 29 New York University Journal of International Law & Politics 11, 30; J Love and T Hubbard, 'Prizes for Innovation of New Medicines and Vaccines' (2009) 18 Annals Health L 155, 159; D Opderbeck, 'Patents, Essential Medicines, and the Innovation Game' (2005) 58 Vand L Rev 501, 525

[788] The limitations of this thesis are outlined in Chapter 1.

[789] H Brennan and A Kapczynski and C Monahan and Z Rizvi, 'A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health' (2016) 18 Yale JL & Tech 275, 320; S Whitelaw and N Fiorentino and J O'Leary, 'Drug Pricing - The Next Compliance Waterloo' (2018) 44 Mitchell Hamline L Rev 1165, 1185-6; J Curran, 'The New York Pharmaceutical Cost Transparency Act: How a Narrow View

Provisions include requiring a manufacturer to report to a state body on financial and non-financial factors that contributed to the increase in price of a medicine.[790] Remedies for violations include injunctive relief and fines of $10,000 USD for each violation.[791] However, these laws are subject to challenge by the pharmaceutical industry for constitutional violations, infringement of trade secrets and patent law.[792] Further criticism of the legislation is that only some of the relevant information on pricing is required to be disclosed, and pricing of newly introduced medicines is not covered.[793] While it is clear that the pharmaceutical industry does not favour this approach, the passing of this legislation shows that at national level governments are pursuing price transparency to redress excessive pricing as a legitimate policy goal.[794] Other States could learn from, and build upon, the experiences of the US states and the challenges faced in seeking to address the issues of excessive pricing of medicines at national level.

Measuring the success of the UN human rights bodies' work

The UN human rights bodies have appreciated that there are a number of issues which have a detrimental effect on securing access to essential medicines, as evidenced by the thematic issues addressed by these bodies above. The work carried out by the various bodies has clarified that the human right to the highest attainable standard of health under Article 12 is potentially infringed by the failure to remove barriers to access to essential medicines. In addition, the clarification of the scope of the rights under Article 15, particularly the right of everyone to enjoy the benefits of scientific progress, has elucidated another dimension to the access to medicines debate. The focus has shifted from the content of creators' rights and instead highlighting the right of everyone to benefit from scientific creations and technologies, including new medicines[795].

Furthermore, the convening of the expert consultation on access to medicines and the Secretary-General's High-Level Panel on Access to Medicines demonstrates an

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of the Prescription Drug Pricing Puzzle Renders a Well-Intentioned Bill Irrational ' (2016) 82 Brook L Rev 315, 316; T Hemphill, 'Legislating Drug Price Transparency' (2017) 40 Regulation 4, 4

[790] Whitelaw and Fiorentino and O'Leary (n 789) 1186; Hemphill (n 789) 4

[791] Hemphill (n 789) 5

[792] Whitelaw and Fiorentino and O'Leary (n 789)1186, 1192; Hemphill (n 789) 4

[792] Hemphill (n 789) 6

[793] Curran (n 789) 325; Hemphill (n 789) 5

[794] Whitelaw and Fiorentino and O'Leary (n 789) 1186, 1202

[795] Chapman (n 604) 1; Schabas (n 604) 273; Müller (n 579) 765; Yu (n 9) 1378

elevation of the discourse to a position of principal concern within the UN human rights system and a central human rights issue for Member States to address in order to comply with their human rights obligations. The Panel's report also identified gaps in the practice of states with regard to the types of new medicines that are being developed, and in the funding of research and development of new medicines.[796] This highlights the report's utility in demonstrating discontinuities between the states' methods of attempting to improve access to medicines domestically, and may also indicate that a more collaborative approach between states could be useful.

The ability to monitor states parties' compliance with their international human rights obligations and the authority to make them accountable for violations of such obligations is fundamental to ensuring that the rights of all are upheld. Sellin asserts that "to be truly effective human rights must be justiciable and enforceable"[797]. However, the international human rights framework does not have an effective mechanism to enforce human rights obligations.[798] Sellin suggests that enforceability can and should be dealt with in states parties' domestic courts[799], and this would be a less costly and more expedient course of action for claimants. Self-administration of states' obligations by their courts is also beneficial as such obligations may be enforced at national level consistent with the highest attainable standard of that state. It could also be useful to have an international mechanism of enforcement to ensure a uniform recognition of the applicable UN human rights principles. This could also assist the domestic courts when applying these principles, although interpretation of such principles would still be the role of the courts, where the specific application of such principles may vary across jurisdictions. In Member States which have problems with regard to corruption within the court system, such litigation may be unsatisfactory, particularly if it involves trade concerns. Therefore, it raises the question of how the UN human rights framework can effectively compel states parties to comply with the conclusions and recommendations of its bodies without an effective system of enforcement. This applies to all human rights,

[796] Okediji (n 582) 42-43, 59
[796] Bagley (n 710) 2485; Kirby (n 742) 168
[797] Sellin (n 327) 116
[798] J Trachtman, 'Who cares about international human rights?: The supply and demand of international human rights law' (2012) 44 International Law and Politics 851, 862; Hestermeyer (n 72) 86; Kaufmann and Meyer (n 61) 67
[799] Sellin (n 327) 116

not only the issue of access to medicines. The Optional Protocol to the ICESCR[800], which came into force in May 2013, includes procedures for the CESCR to receive communications from individuals on violations of ICESCR rights by States parties[801], and also includes an inquiry procedure where the CESCR can investigate violations, make recommendations and receive responses by States parties.[802] This provides a mechanism for individuals to hold states to account for infringements of ICESCR rights. Due to the relatively low number of states which have ratified the Optional Protocol[803], it remains to be seen how effective this complaints mechanism will be. However, it could promote cooperation and dialogue between the CESCR and States parties, which could strengthen the protection of ICESCR rights at national level.[804]

III. Conclusion

The work of the UN human rights bodies shows that access to medicines is a core element of the right to health, and it is also important in relation to rights to enjoy scientific progress. It is evident that human rights of creators do not trump the right to health, and the rights of creators cannot be expanded to encompass associated IP rights in IP agreements and mechanisms[805]. It is also clear that IP rights do not amount to human rights under Article 15(1)(c) ICESCR. Therefore, there is no conflict between Article 15 and Article 12 in relation to access to medicines and IP, and Article 15 does not present an obstacle to advancing access to medicines. The work of the UN human rights bodies shows that the rights of creators should not be unduly favoured and must be balanced with the public interest the products of scientific progress, such as new medicines. This aligns with the position in relation to the right to health under Article 12.

[800] Optional Protocol to the International Covenant on Economic, Social and Cultural Rights: resolution adopted by the General Assembly (5 March 2009) UN Doc A/RES/63/117
[801] ibid Article 2
[802] Ibid Article 11
[803] The Optional Protocol is binding on States parties who have ratified the ICESCR and the Optional Protocol. As of March 2020, twenty-four states have ratified the Optional Protocol. See United Nations Office of the High Commissioner for Human Rights, 'Status of Ratification Interactive Dashboard' (n 539)
[804] B Griffey, 'The Reasonableness Test: Assessing Violations of State Obligations under the Optional Protocol to the International Covenant on Economic, Social and Cultural Rights' (2011) 11 Hum Rts L Rev 275, 327; C Courtis 'The Optional Protocol to the International Covenant on Economic, Social and Cultural Rights: A New Instrument to Address Human Rights Violations' (2012) 3(4) Global Policy 484, 485
[805] UNHRC 'Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed: The right to freedom of artistic expression and creativity' (14 March 2013) UN Doc A/HRC/23/34, 79

Further, the UN human rights systems have promoted the linked right of all to enjoy the benefits of scientific progress, including access to new medicines under Article 15(1)(b). The growing discourse on Article 15(1)(b) is also constructive in promoting access to medicines as a right. It supports the findings in the previous chapter that individuals have a right to access to essential medicines. It challenges the position that medicines created by private pharmaceutical enterprises should be subject to strong IP protection over their products. It also places emphasis on the responsibility of Member States to fulfil their obligations to individuals under this right, alongside the right to health, in respect of ensuring access to medicines for all. Some of the proposals in relation to the scope of the right could be viewed as expansive, but the consensus among States in the subsequent resolutions could indicate some viability. The drafting of a General Comment on Article 15(1)(b) would provide further clarification on the scope and content of the right.

Recent developments emanating from the UN human rights framework also add to the understanding of how states can interpret their human rights obligations in a manner that enhance access to medicines at national level. A key theme is that a balance between the IP system and human rights has not been successfully achieved, which accords with the findings in earlier chapters. Themes also include the delinking of R&D costs from pricing of medicines, increased transparency on costs and the importance of utilising the TRIPS flexibilities. Promoting the use of compulsory licensing is also a key theme which is consistent with findings in earlier chapters. The findings from this chapter indicate that Article 15(1)(b) right could be relied upon to promote the use of compulsory licensing. Recommendations emanating from these developments, including the UN Secretary General's High-Level Panel on Access to Medicines, have found support at intergovernmental level, and broad consensus among States on subsequent resolutions incorporating some of the recommendations, is significant in terms of advancing the access to medicines agenda.

The work of the UN human rights bodies infers that a cohesive, uniform, international strategy is required to address the issue of securing access to essential medicines. The UN human rights system, with primary responsibility for upholding international human rights, has focused its recommendations on modifications to the current international IP system, including a new framework for research and development into new medicines. Therefore, the responses of the relevant stakeholder organisations and Member States to these recommendations will be critical in developing the proposals

of the UN human rights bodies in a positive manner. A collaborative approach among principal stakeholders at international level will be key. It is evident that states may experience challenges in implementing the recommendations at national level, including measures to improve pricing transparency and the disclosure of test data by pharmaceutical companies. Therefore, more practical guidance on how states could effectively implement specific measures to enhance access to medicines could be helpful, to help states ensure that they effectively meet their human rights obligations as well as their obligations under TRIPS.

Chapter 5: Case Study – Canada

Introduction

The previous chapters have explored the issues arising from the international trade forum and the UN human rights systems specifically in relation to the enhancement of effective access to medicines. These include that access to medicines is part of the right to health under Article 12 ICESCR. Secondly, although the patent protection under TRIPS can impact on access to medicines, there are exceptions to this protection which can be utilised to enhance access to generic medicines. There is no inherent conflict between TRIPS and human rights, but the implementation of TRIPS-plus standards of IP rights protection creates tension. The role and responsibilities of private pharmaceutical companies in enhancing access to medicines is also a key challenge. The country case studies will explore how the state has complied with its obligations to implement TRIPS standards and its obligations to enhance access to medicines as part of the right to health.

The subject of the first study will be Canada. The methodology for selecting the States that will be the subject of a case study involved identifying the States which are WTO Members and have ratified the ICESCR, and applying a series of indicators in the form of a table, set out in Annex II. After identifying the States that were both WTO Members and had ratified the ICESCR[806], the first indicator applied was which countries were classified as developed or developing[807]. All States that were also EU Member States were excluded as the States are subject to EU law as well as their domestic laws. Providing a discussion on EU law and its implications in addition to the legal rules of the UN human rights mechanisms and the WTO trade forum would present the need for additional analysis that would extend beyond the scope of the case studies and this thesis. The next step involved identifying the countries that were net importers of

[806] This information was extracted from the official websites of the respective organisations as at March 2017; see also World Trade Organization, 'Understanding the WTO: The Organization; Members and Observers' <https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm> (accessed 27/04/2020) and United Nations Office of the High Commissioner for Human Rights, 'Status of Ratification Interactive Dashboard' (n 539)

[807] Data obtained from UN, *World Economic Situation and Prospects 2015*, (United Nations, New York 2015), 139-140 <http://www.un.org/en/development/desa/policy/wesp/wesp_archive/2015wesp_full_en.pdf> (accessed 27/04/2020)

pharmaceuticals and which were net exporters of pharmaceuticals[808], which highlighted that a low number of developed countries are net importers. Of the four developed States; Australia, Canada, Japan and New Zealand, New Zealand was eliminated because it was the only one of those States not to have received a visit from the Special Rapporteur on the right to health. There are several compelling reasons why Canada was chosen as a case study, including the fact that it is a net importer of medicines yet pharmaceuticals is a major export with the State being the tenth largest pharmaceutical market, the fact that it is a federal State and the issues this can raise in terms of implementing transnational norms. Also, the fact that the State has demonstrated some willingness to act on its international commitments in relation to developing States by adopting some national measures which aim to improve access to medicines.

The purpose of these studies is to explore whether states appreciate the interaction between their human rights obligations and their obligations under TRIPS at national level, and to evaluate how states are addressing possible tensions in order to discharge their obligations simultaneously under TRIPS and the ICESCR. This study will primarily focus on reviewing national legislation, policy documents and related case law, and will refer to relevant academic literature in the analysis of the findings. The first section of the study will examine the constitutional and legislative framework of the State to explore the extent to which the State has complied with its human rights obligations in relation to access to medicines, and the extent to which the State has implemented the patent provisions under TRIPS. The second section of this study will examine the health policy measures on access to medicines, to evaluate whether these measures effectively address possible tensions between the State's obligations under TRIPS and the ICESCR. The third section evaluates Canada's regulatory response to the impact of the private pharmaceutical industry, which has a crucial role in producing medicines, on its obligations to enhance effective access to medicines. The fourth section will conclude by evaluating the findings from this study.

I. Canada's Constitutional and legislative framework

[808] Data on net importation and net exportation of pharmaceutical products by states was taken from UN COMTRADE Database; United Nations, Department of Economic and Social Affairs, Statistics Division, Trade Statistics, *UN COMTRADE Database* <https://comtrade.un.org/data/> (accessed 27/04/2020)

(a) Constitutional landscape regarding a right to health and medicines

Canada is a federal jurisdiction, with the ten provinces also having separate legislative powers over matters relating to the individual province[809]. Federal and provincial legislative powers are set out in the Constitution Act 1867, providing that the federal government has exclusive powers over national matters such as health, finance and the military, while provincial governments have exclusive power over matters local to that province[810]. Canada has federal legislation relating specifically to patents under the Patent Act 1985[811], and also has federal legislation on human rights, with the Canadian Charter of Rights and Freedoms forming part of the Constitution Act 1982[812], as well as the Canadian Human Rights Act[813] which principally covers discriminatory practices.

Canada is a dualist state, and so international treaties to which it is a party have to be incorporated into national legislation.[814] Therefore TRIPS and the ICESCR treaties have to be translated into national law to become enforceable. As noted above, the Canadian Charter of Rights and Freedoms forms part of the State's Constitution. However this does not include economic or social rights.[815] At national level, Canadian courts have adopted a conservative approach to recognising socio-economic rights, including a right to health care.[816] Section 7 of the Canadian Charter of Rights and Freedoms protects the right to life, liberty and security of the person[817], providing scope to argue that social

[809] Government of Canada, Department of Justice, 'Where our legal system comes from' <http://www.justice.gc.ca/eng/csj-sjc/just/03.html> (accessed 27/04/2020)
[810] Constitution Act 1867, 30 & 31 Victoria, c. 3 (U.K.), S.91-S.92.
[811] Patent Act 1985 (R.S.C., 1985, c. P-4) (CA007)
[812] Constitution Act 1982 (80) 1982, c. 11 (U.K.), Schedule B <http://laws-lois.justice.gc.ca/eng/Const/page-15.html#h-38> (accessed 27/04/2020)
[813] Canadian Human Rights Act 1985 (R.S.C., 1985, c. H-6) <http://laws-lois.justice.gc.ca/eng/acts/H-6/page-1.html> (accessed 27/04/2020)
[814] K Glover, 'The Supreme Court in Canada's Constitutional Order' (2016) 21 Rev Const Stud 143, 155; G Remillard, 'Constitution Act, 1982: An Unfinished Compromise' (1984) 32 Am J Comp L 269, 280; C Dauvergne, 'How the Charter Has Failed Non-Citizens in Canada: Reviewing Thirty Years of Supreme Court of Canada Jurisprudence' (2013) 58 McGill L J 663, 685; L White, 'Understanding Canada's Lack of Progress in Implementing the UN Convention on the Rights of the Child; The Intergovernmental Dynamics of Children's Policy Making in Canada' (2014) 22 Int'l J Child Rts 164, 165
[815] C Jung, R Hirschl and E Rosevear, 'Economic and Social Rights in National Constitutions' (2014) 62 Am J Comp L 1043, 1053; Constitution Act 1982 (n 812)
[816] B Thomas and C Flood 'Putting Health To Rights: A Canadian View on Global Trends in Litigating Health Care Rights' (2015) 1 CJCCL 49, 58-59; M Jackman 'Charter Review as a Health Care Accountability Mechanism in Canada' (2010) 18 Health Law Journal 1, 27; B Porter 'A right to health care in Canada: Only if you can pay for it' (2005) 6(4) ESR Review 8, 10
[817] Section 7 states: Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice. See: Canadian

rights including access to medicines should be recognised under the Charter.[818] However, this argument has not found favour with the national courts. For example, in *Chaoulli v Quebec*[819] the Supreme Court stated that the Canadian Charter of Rights and Freedoms does not confer a free standing right to health care.[820] In *Canadian Doctors for Refugee Care v Canada*[821] the Federal Court concluded that Section 7 did not include a positive right to health care.[822]

Academics have taken the view that the courts have avoided rigorous review of health care decision-making partly by construing Section 7 as protecting only negative rights.[823] In relation to access to medicines, Section 7 has been successfully relied upon only to the extent that restrictions to access to medical marijuana under the Controlled Drug and Substances Act 1996[824] have been found to be incompatible with Section 7.[825] Thomas and Flood argue that courts have avoided oversight of health care resource allocation in deference to government policy, because of concerns about overstretching government budgets on health care.[826] An example of this concern is evident in *Allen v Alberta*[827], where the Court of Appeal concluded that as there is no free standing right to health care, spending priorities have to be taken into account, a decision which is outside the reach of the Constitution.[828] Ries argues that there are examples of deference where government decisions are affected by limited resources, but the Supreme Court has acknowledged that to simply accept Parliament's view in all such cases would diminish

Charter of Rights and Freedoms, s 7, Part 1 of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (UK), 1982, c 11.

[818] A Gross 'Is There a Human Right to Private Health Care?' (2013) 41(1) The Journal of Law, Medicine & Ethics 138, 140; Thomas and Flood (n 816) 58-59; Jackman (n 816) 27; Porter (n 816) 10

[819] Chaoulli v Quebec (AG) [2005] 1 S.C.R. 791, 2005 SCC 35. This case concerned a challenge to legislation prohibiting private health care insurance for services covered by public health care insurance.

[820] ibid 104

[821] Canadian Doctors for Refugee Care v Canada (Attorney General), 2014 FC 651

[822] ibid 570; V Sinha, L Sossin and J Meguid 'Charter Litigation, Social and Economic Rights & Civil Procedure' (2017) 26 Journal of Law and Social Policy 43, 62

[823] C Flood and B Chen 'Charter Rights & Health Care Funding: A Typology of Canadian Health Rights Litigation' (2010) 19 Annals Health L 479, 482-483; Thomas and Flood (n 816) 67; Jackman (n 816) 15; C Flood and A Gross 'Litigating the Right to Health: What Can We Learn from a Comparative Law and Health Care Systems Approach' (2014) 16(2) Health and Human Rights Journal 62, 66

[824] Controlled Drugs and Substances Act (S.C. 1996, c. 19)

[825] See examples: R v Parker (2000), 49 OR (3d) 481 (CA); Hitzig v. Canada, 2003 CanLII 30796 (ON CA); Allard v. Canada, 2016 FC 236

[826] Thomas and Flood (n 816) 61

[827] Allen v Alberta, 2015 ABCA 277

[828] ibid 52

the role of the courts in upholding constitutional rights.[829] The restrained approach of the courts emphasises the need for policy coherence on health care and medicines among government departments. The courts should provide an avenue for rigorous judicial review of government spending on health care including medicines in light of the fundamental rights set out in Section 7 of the Charter.[830] Academics have observed that the wording in Section 7 is almost identical to Article 21 of the Indian Constitution[831], and that Indian courts have interpreted the right to life as imposing a positive duty on the State, incorporating health rights into the fundamental rights to life and liberty.[832] For example, in *Paschim Banga Khet Samity v State of West Bengal*[833] the Indian Supreme Court concluded that lack of provision of adequate medical facilities for emergency treatment amounted to a breach of the claimant's fundamental right to life under Article 21.[834] Therefore, the Canadian courts are not restricted to a narrow interpretation of health rights by the wording of the Charter.

Currently, the approach of the national courts means it is unlikely that individuals will be able to rely on their national charter of rights to claim a right to access to health care including essential medicines. The courts should also provide an avenue for accountability in relation to the State's positive obligations to progressively realise the right to health including access to essential medicines under Article 12 ICESCR.[835] Article 12 does provide that states must take action as far as their resources allow, but as discussed in Chapter 3 of this thesis, states do have immediate obligations to take concrete steps towards full realisation of this right.[836] What is not evident is the state being challenged over this approach in relation to access to medicines. A broader recognition of health rights including access to medicines could be achieved if the courts were to interpret the Charter rights in light of the State's obligations under the Article 12 ICESCR right to health.[837] Jackman argues that the lack of justiciability in ensuring health care

[829] N Ries, 'Legal Rights, Constitutional Controversies, and Access to Health Care: Lessons from Canada' (2006) 25 Med & L 45, 54. Ries refers to the Supreme Court decision in *RJR-MacDonald Inc. v. Canada (Attorney General), [1995] 3 Supreme Court Reports 199* [136]
[830] Jackman (n 816) 27
[831] The Constitution of India, 26 January 1950 <https://www.india.gov.in/my-government/constitution-india/constitution-india-full-text> (accessed 27/04/2020). Article 21 states: 'No person shall be deprived of his life or personal liberty except according to procedure established by law.'
[832] Jung, Hirschl and Rosevear, (n 815) 1050-1; Thomas and Flood (n 816) 59
[833] Paschim Banga Khet Samity v State of West Bengal [1996] 4 SCC 37 (Indian Supreme Court)
[834] ibid 4, 9
[835] Jackman (n 816) 27
[836] General Comment No. 14 (n 112) 30
[837] Thomas and Flood (n 816) 59; Gross (n 818) 140; Porter (n 816) 10-11

decision-making complies with Canada's constitutional or international human rights obligations is a major deficiency in the State's approach to accountability.[838] However, given the current approach of the courts in applying the state's Charter to health care, such claims might see little chance of success.[839] This highlights the importance of embedding rights at national level, to ensure that there is alignment with the obligations and responsibilities that the State has committed to at international level. This would also provide a means for individuals to hold the State to account in the national courts where their rights have been infringed.

(b) Canada's Access to Medicines Regime

Canada was one of the first countries[840] to amend its patent law following the Implementation Decision relating to paragraph 6 of the Doha Declaration, resulting in Canada's Access to Medicines Regime (CAMR)[841]. The Government of Canada passed *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*[842], in May 2004. The Act, along with a supporting set of regulations, established the legal framework for Canada's Access to Medicines Regime, which aimed to make it easier to provide essential medicines to developing states. This legal provision was only relied upon once, when a batch of generic antiretroviral medicines was exported to Rwanda in 2008. The introduction of this legislation in Canada is an illustration of how the State has taken measures to implement the Doha Declaration and its interpretation of the provisions in TRIPS for the promotion of access to medicines. Therefore it could be viewed that the State was trying to uphold its obligations under the international trade rules and its UN human rights obligations under the ICESCR, including its extraterritorial obligations, and it is important to see a developed State taking this action for the purpose of improving access to medicines in developing States. However, the fact that this provision has only be used once shows that it is not achieving its intended objectives.

[838] M Jackman, 'The Future of Health Care Accountability: A Human Rights Approach' (2016) 47 Ottawa L Rev 441, 455
[839] Flood and Chen (n 823) 482-483, 494
[840] As of July 2015, 51 WTO Members had adopted specific implementation provisions into national law at varying levels of detail. See Kampf, (n 316) 6
[841] J Cohen-Kohler, L Esmail and A Perez Cosio, 'Canada's Implementation of the Paragraph 6 Decision: is it Sustainable Public Policy?' (2007) 3 Globalization and Health 12, 1
[842] An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa) (S.C. 2004, c. 23) <http://laws-lois.justice.gc.ca/eng/AnnualStatutes/2004_23/page-1.html> (accessed 27/04/2020)

Criticisms of CAMR include the limited list of pharmaceutical products that were subject to compulsory licensing for export[843], the limit of two years on the term of the compulsory licence[844], and additional conditions imposed on non-WTO Member developing countries that wish to be added to the schedule of eligible importing countries.[845] It is important to analyse the criticisms of CAMR to evaluate whether the regime could work more effectively to enhance access to medicines.

(i) Limited list of pharmaceutical products

During the parliamentary debate on the Bill, it was stated that the decision to include the limited list "represents a compromise solution between those who wanted a narrow list of eligible medicines and those who wanted no list at all"[846]. It was also stated that the list's utility was as a "tool to expedite the process of acquiring a compulsory licence for those products that have been found to be safe, effective and of high quality".[847] This outlines that the list was meant to be for guidance and was intended to be flexible, so that other medicines could be subject to a compulsory licence once they had satisfied safety and quality standards. However, during the debate, it was argued that the list should not be expanded to include two more medicines, for reasons including that they did not appear on the WHO list of essential medicines[848]. Therefore the list could potentially have a limiting effect on the scope of the Act, as the reference to the WHO list may narrow the possibility of new medicines being added to the CAMR list if they do not appear on the WHO list.

Since the enactment of this legislation, two more medicines have been added to the list, although this process was fairly lengthy, taking up to seven months rather than a matter of days as anticipated during the parliamentary debate.[849] Therefore although it is

[843] R Elliott, 'Pledges and pitfalls: Canada's legislation on compulsory licensing of pharmaceuticals for export' (2006) 1 Int J Intellectual Property Management 94, 100
[844] ibid 107
[845] P Goodwin, 'Right Idea, Wrong Result – Canada's Access to Medicines Regime' (2008) 34 American Journal of Law & Medicine 567, 581
[846] HC Deb 28 April 2004, vol 139, col 1705, Hon. Joe Fontana (Parliamentary Secretary to the Prime Minister (Science and Small Business), Lib.), (CAN)
[847] HC Deb 28 April 2004, vol 139, col 1705, Hon. Joe Fontana (Parliamentary Secretary to the Prime Minister (Science and Small Business), Lib.), (CAN)
[848]HC Deb 28 April 2004, vol 139, col 1715, Hon. Larry Bagnell (Parliamentary Secretary to the Minister of Indian Affairs and Northern Development, Lib.), (CAN)
[849] Goodwin (n 845) 579

possible to update the list to include medicines to meet the specific needs of developing countries that wish to acquire a compulsory licence under this regime, it appears to be a protracted and inefficient process, which could deter developing countries from utilising this regime to acquire medicines that do not already appear on the list. Goodwin has argued that pressure from branded pharmaceutical companies was a factor in retaining such a list, because of their view that it would provide a way of ensuring that compulsory licences were not used for commercial purposes.[850] However, this goes beyond what was agreed within the WTO, where there was no requirement for a list included under the paragraph 6 system[851]. Therefore this may serve as an example to other developed States considering implementing a regime modelled on CAMR that their branded pharmaceutical industries may seek to influence the development of such a regime, asserting their IP rights in their medicines. As it is the government's responsibility to ensure that the State is meeting its international human rights commitments, it is important that governments do not prioritise the views of the branded pharmaceutical industry over other considerations when developing such a regime.

(ii) Two-year limit on the term of the compulsory licence

The reasoning for placing a two-year limit was so that the purchasers were not committed to a long-term contract for a particular medicine and should have the flexibility to take advantage of obtaining newer, more effective medicines[852]. This suggests that such a limit was for the benefit of the developing States, to ensure that they were not committed to purchase a medicine from a specific manufacturer without the opportunity to make a more cost-effective agreement in the market. However, Elliott argues that the limit has the effect of restricting the generic pharmaceutical manufacturers' ability to compete in the market[853], as the relatively short term of the licence may limit the ability of the manufacturers to recoup the initial costs of producing the generic medicine[854]. Placing such a time limit may protect the parties involved from being committed to a long-term commitment which may not amount to an advantageous agreement. However, having a

[850] ibid 580
[851] Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (n 287)
[852] Elliott (n 843) 107
[853] ibid
[854] ibid

limit of just two years may not provide generic manufacturers that obtain a compulsory licence with enough time to build a market or profile for their generic medicines before their licence expires. If they decided to apply for another compulsory licence, going through the process would delay the ability of the generic producers to continue to sell their products. There would also be a possibility that they were unsuccessful in obtaining another compulsory licence, which would mean that they could no longer take advantage of any market profile that they had previously built.

The reasoning behind paragraph 6 is to find an efficient solution to the problem of access to available, affordable medicines in developing countries, particularly in emergency situations.[855] The primary goal of CAMR is to promote access to medicines in developing countries.[856] Therefore, this raises the question of whether there is a need for generic manufacturers to build a commercial market, and whether this is a relevant consideration where the compulsory licence is issued to address an emergency need for a specific medicine. However, there does need to be an incentive for generic manufacturers to take part in the regime. The lack of commercial incentives for generic manufacturers has been identified as an issue with CAMR, as it is difficult for the generic manufacturer to recoup the investment for producing the generic version of the medicine where it is produced for one country for a limited period.[857] Therefore, to make CAMR more functional, the commercial motivations of generic manufacturers need to be taken into account in order to encourage them to engage in the regime. This echoes the recommendation of the UN Secretary-General's High-Level Panel on Access to Medicines, to find a solution to make the objective of paragraph 6 more achievable in practice.[858]

(iii) Additional conditions on non-WTO Members

The additional conditions on non-WTO Members include a declaration of the adoption of measures to prevent diversion of the products to unintended markets and the

[855] M Abbas and S Riaz 'WTO "Paragraph 6" system for affordable access to medicines: Relief or regulatory ritualism?' (2018) 21 J World Intellect Prop 32, 45
[856] Houston and Beall (n 712) 242
[857] Abbas and Riaz (n 855) 41; H Mathur 'Compulsory licensing under section 92A: Issues and concerns' (2008) 13(5) Journal of Intellectual Property Rights 464, 467; Cohen-Kohler, Esmail and Perez Cosio, (n 841) 3-4; Houston and Beall (n 712) 242-243
[858] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) 9

requirement that the pharmaceutical products under the compulsory licence are not used for commercial purposes[859]. The schedules of countries eligible to import medicines under CAMR are organised according to level of development and WTO membership, with non-WTO members able to be added upon request and subject to satisfaction of these additional conditions.[860] The Canadian government's review of CAMR noted that the branded pharmaceutical industry supported such specifications with the view that this would ensure that medicines were only exported to countries with genuine public health needs[861]. However, Elliott argues that these conditions were included with the aim of restricting potential competition for such medicines being generated within the importing country's market[862]. Such competition could contribute to reducing prices and improving access in that country, and therefore the conditions appear contrary to the spirit and purpose of the legislation. Elliott also highlights that such conditions may also be difficult to satisfy for non-WTO members without comprehensive public healthcare schemes and where medicines are predominantly accessed through private pharmacies[863], and so could limit the number of non-WTO States that can satisfy the eligibility conditions under CAMR. Therefore it appears difficult to justify why non-WTO members should be subject to conditions that WTO Members do not have to satisfy, particularly as this distinction is not a requirement of the WTO.

(iv) Proposals for reform

Given the criticism of CAMR, and the fact that the regime has not been utilised since 2008, it is pertinent to explore whether the State is considering reform of the regime, to address the challenges in using the regime to enhance access to medicines for developing countries. In 2009 a Bill[864] was presented in the House of Commons proposing several

[859] Goodwin (n 845) 581
[860] Government of Canada, *Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act,* (Industry Canada, Ottawa 2007), ISBN 978-0-662-05338-5, 7-8 <http://publications.gc.ca/site/eng/322851/publication.html> (accessed 27/04/2020)
[861] ibid 8
[862] Elliott (n 843) 105
[863] ibid 105-106
[864] Parliament of Canada, House of Commons, *Bill C-393, An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 40th Parliament, 3rd Session (March 3, 2010 - March 26, 2011) <http://www.parl.ca/DocumentViewer/en/40-2/bill/C-393/first-reading/page-24> (accessed 27/04/2020)

amendments to CAMR. However the Bill did not pass a second reading in the Senate[865], with the dissolution of the government following a no confidence vote in March 2011[866], and the Bill was not proceeded with by the new government[867]. As at March 2020, there has been no further action taken by the government to make CAMR more workable. Kohler et al argue that legislative reform of CAMR is needed, and for it to be a workable provision it needs to be combined with other initiatives.[868] Tsai also argues that greater incentives for generic pharmaceutical manufacturers should be introduced[869]. The objective of this legislation was to enhance effective access to medicines for developing states in Africa[870], so the purpose was not primarily to ensure that generic manufacturers derive a profit as a result of their participation. However, in realistic terms if there is little incentive in participating then it could be difficult to attract the interest of pharmaceutical companies in participating in the scheme. Esmail and Kohler also argue that further input from the developing countries may lead to improved policies to achieve affordable access to medicines[871]. This view conveys that for such a scheme to work there needs to be a multilateral approach to ensure that the needs of all stakeholders are considered, so that there is a less unbalanced outcome.

While the Canadian government has expressed its commitment to engaging in initiatives to enhance the provision of medicines to developing countries, particularly through monetary donations to NGOs[872], there appears to be little evidence from the government that the above proposals would gain sufficient support to ensure their adoption. Therefore, it is difficult to assess whether such proposals would be workable

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[865] Parliament of Canada, 'LegisInfo', 'Bill C-393, An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act', 'Status of the Bill', <http://www.parl.ca/LegisInfo/BillDetails.aspx?Bill=C393&Language=E&Mode=1&Parl=40&Ses=3> (accessed 27/04/2020)

[866] BBC News, US and Canada, 'Canadian government falls after no-confidence vote', 25 March 2011, <http://www.bbc.co.uk/news/world-us-canada-12865339> (accessed 27/04/2020)

[867] Parliament of Canada, 'LegisInfo', 'Senate Public Bill', 'S-208, An Act to amend the Patent Act and the Food and Drugs Act (drugs for international humanitarian purposes)', 41st Parliament, 1st Session (2 June 2011 – 13 September 2013) <http://www.parl.ca/LegisInfo/BillDetails.aspx?Language=E&billId=5344957> (accessed 27/04/2020)

[868] J Kohler et al, 'Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort?' (2010) 5(3) Healthcare Policy 40, 46

[869] G Tsai, 'Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes under the WTO Doha Declaration'(2009) 49 Virginia Journal of International Law 1063, 1081-1083

[870] ibid 1089

[871] L Esmail and J Kohler, 'The politics behind the implementation of the WTO Paragraph 6 Decision in Canada to increase global drug access' (2012) 8(7) Globalization and Health, 11-12

[872] Government of Canada, *Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act* (n 860) 39

for other states considering implementing a similar model. Also, the State may need to be reminded of its obligations with regard to the right to health under Article 12 ICESCR, to ensure that achieving effective access to medicines for all is prioritised.

(c) Patent Law

The constitutional landscape has been discussed above to consider how the State is interpreting and implementing its human rights obligations into national law in relation to access to medicines. Canada has provided for pharmaceutical patents in its national law since 1993[873]. S.79 of Canada's Patent Act 1985[874] covers patented medicines and although there were few major impacts on the Act resulting from the implementation of TRIPS, there were two significant challenges to the Canadian patent legislation under the WTO dispute resolution mechanism, which are discussed in Chapter 2 of this thesis. The term of patent protection was challenged in *Canada - Term of Patent Protection*[875] which resulted in an extension of the term from seventeen to twenty years, contrary to the views of the Canadian generic pharmaceutical industry. The provisions relating to stockpiling and the regulatory review exceptions were challenged with partial success in *Canada – Patent Protection for Pharmaceutical Products*[876], the outcome being the stockpiling of generic medicines in anticipation of the expiration of the patent was not consistent with Article 30 of TRIPS and the provision was repealed from the Patent Act. The outcomes of both cases can be seen to most significantly impact upon the State's generic pharmaceutical industry. In both cases the effects of the decisions were to extend the period of time for which generic manufacturers had to wait to legally enter generic medicines into the market, compared to the legal position prior to the implementation of TRIPS in Canada.

Two recent cases presented significant challenges to the State's patent law and to enhancing access to medicines; *Eli Lilly and Company v. Government of Canada*[877] and

[873] C Field, 'Negotiating for the United States' at 140 in J Watal and A Taubman (eds), *The Making of the TRIPS Agreement: Personal insights from the Uruguay Round negotiations* (World Trade Organization, WTO Online Bookshop 2015)
[874] Patent Act 1985 (n 811) S.79
[875] *Canada-Term of Patent Protection*, WT/DS170/AB/R, adopted 12 October 2000. See also Chapter 1 for further discussion of the case.
[876] *Canada – Patent Protection for Pharmaceutical Products,* WT/DS114/R, adopted 7 April 2000
[877] Eli Lilly and Company v. Government of Canada, (ICSID Case No. UNCT/14/2)

AstraZeneca Canada Inc v. Apotex Inc[878]. Given their importance to access to medicines in Canada, these decisions will be analysed to evaluate the impact on access to medicines, and to consider whether the State is responding to potential tensions between patent law protection and the right to health arising from the cases.

(i) Eli Lilly and Company v. Government of Canada

The case of *Eli Lilly and Company v. Government of Canada*[879] has been described as a case of "immense importance"[880] in relation to pharmaceutical patents. The claimant sought to challenge the 'promise' doctrine, a Canadian law doctrine applied by Canadian courts when deciding upon usefulness in determining patentability[881] under Section 2 of the Patent Act 1985. The 'promise' doctrine was advantageous for generic pharmaceutical companies as they could apply to the court for the annulment of a patent granted to another pharmaceutical company, if the evidence of the patented medicine's utility did not fulfil its promise in the patent application. The claimant argued that the interpretation and application of the utility criteria under Canada's Patent Act by the Canadian courts, through the 'promise' doctrine, was a violation of Canada's obligations under NAFTA[882]. The claimant asserted that the 'promise' doctrine contravenes Canada's intellectual property obligations in Chapter Seventeen of NAFTA, because the 'promise' doctrine imposed a significantly higher burden on the patentee than the standard of utility required by NAFTA.[883] It was argued that the revocation of the patents was in breach of Canada's Chapter Eleven obligations under NAFTA to protect investors of other State parties to NAFTA from expropriation of their investments under Article 1110 and to guarantee their fair and equal treatment under Article 1105. Therefore, it was argued that Canada had failed to protect the claimant's intellectual property rights and had failed to protect the company's investment.

[878] AstraZeneca Canada Inc. v. Apotex Inc., 2017 SCC 36 <https://www.canlii.org/en/ca/scc/doc/2017/2017scc36/2017scc36.html> (accessed 27/04/2020)
[879] Eli Lilly and Company v. Government of Canada (n 877)
[880] L Hsu, *Trade, Investment, Innovation and Their Impact on Access to Medicines: An Asian Perspective,* (Cambridge University Press, Cambridge 2016), 78
[881] ibid 208
[882] Eli Lilly and Company v. Government of Canada, Notice of Arbitration, 13 September 2013, <http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C3544/DC4612_En.pdf> (accessed 27/04/2020)
[883] ibid 68

This case provides an example of the wider criticism of investor-state dispute resolution.[884] The reliance on Chapter Eleven of NAFTA by the investor claimant is significant because such an outcome would indicate that the State has an obligation to protect the patents of private pharmaceutical companies as an investment where they are unsuccessful in arguing they have the right to protection of their intellectual property by the State. The claim was ultimately unsuccessful, with the tribunal finding that the invalidation of the Zyprexa and Strattera patents through application of the 'promise' doctrine did not violate the claimant's legitimate expectations under Article 1110 or 1105. The tribunal determined that the claimant was not able to demonstrate that the 'promise' doctrine was a radical departure from the traditional utility doctrine applied by the other States parties to NAFTA[885]. However the case is an example of an intellectual property dispute being heard within the investor-state dispute settlement mechanism in NAFTA, indicating that pharmaceutical companies may seek to rely on the terms of a free trade agreement to try to achieve a more favourable outcome in terms of protecting their IP rights in their products than they may obtain in a national court.

This case also provides an example of the impact that FTAs can have on national measures to improve access to medicines. Although the claim was unsuccessful, this case highlights that the Canadian courts had developed the 'promise' doctrine to ensure that a pharmaceutical patent could not be enforced unless the product matched the description contained in the patent application. However, the patent holding pharmaceutical company concerned attempted to circumvent this legal doctrine under the terms of NAFTA for the purpose of extending the patent to a product that the patent was not originally issued to cover. This highlights that holding pharmaceutical companies to account for failing to respect measures to promote access to medicines may present a challenge for states, which is a key theme emanating from previous chapters.

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[884] An evaluation of the criticisms of ISDS is beyond the scope of this thesis, but is relevant to the extent that the *Eli Lilly* case provides an example of the debate on this issue. For discussion on the debate around ISDS see examples: G Kahale, 'Rethinking ISDS' (2018) 44 Brook J Int'l L 11; S Schill 'Reforming Investor–State Dispute Settlement: A (Comparative and International) Constitutional Law Framework' (2017) 20(3) JIEL 649, 650; N Patel 'An Emerging Trend in International Trade: A Shift to Safeguard Against ISDS Abuses and Protect Host-State Sovereignty' (2017) 26 MINN. J. INTL. L. 273, 302; S Puig and G Shaffer 'Imperfect Alternatives: Institutional Choice and the Reform of Investment Law' (2018) 112 AM. J. INT'L L. 361, 408

[885] Eli Lilly and Company v. Government of Canada, (ICSID Case No. UNCT/14/2), Final Award (16 March 2017), 227 and 389 <https://icsid.worldbank.org/en/Pages/cases/casedetail.aspx?CaseNo=UNCT/14/2> (accessed 27/04/2020)

(ii) AstraZeneca Canada Inc v. Apotex Inc

Following the decision in the *Eli Lilly and Company v. Government of Canada*[886], which found that the medicines in question did not satisfy the utility requirement under Section 2 of the Patent Act 1985, the decision by the Canada Supreme Court in *AstraZeneca Canada Inc v. Apotex Inc*[887] may be of concern to Canadian generic manufacturers. While the former claim concerned Canadian legislation but was heard by an ICSID arbitral tribunal, the latter case concerned similar issues over the 'promise' doctrine as in the *Eli Lilly* claim, but was heard by the Canada Supreme Court. Therefore, *AstraZeneca Canada Inc v. Apotex Inc* is a case which concerned the application and interpretation of this Canadian legal norm by the Canadian courts. The decision of the Canada Supreme Court in this case is particularly significant for both branded and generic pharmaceutical companies because it offers an authoritative interpretation of this doctrine, which may have implications in relation to the validity of several pharmaceutical patents granted in Canada.

The Federal Court held that AstraZeneca's patent on the medicine Esomeprazole was invalid under the 'promise' doctrine, as the utility requirement for an "invention" under Section 2 of Canada's Patent Act was not met, because the patent only fulfilled one of the two promises of utility that were made to obtain the patent.[888] However, the Supreme Court overturned this decision on the basis that the 'promise' doctrine was not the correct method of determining whether the utility requirement under Section 2 of the Patent Act 1985 had been satisfied[889]. It was stated that the doctrine was an interpretation of the utility requirement that was incompatible with the Patent Act because the doctrine determines the standard of utility that is required by reference to the promises stated in the patent, and if there are several promises of utility, all promises have to be fulfilled for a patent to be valid.[890] In delivering the judgement, Rowe J stated that this was "excessively onerous"[891], and inconsistent with the wording of the Patent Act.[892] It was held that where there are multiple promises of utility, they should not all need to be

[886] Eli Lilly and Company v. Government of Canada (n 877)
[887] AstraZeneca Canada Inc. v. Apotex Inc. (n 878)
[888] ibid 10
[889] ibid 24
[890] ibid 36-37
[891] ibid 37
[892] ibid 36

fulfilled, as Section 2 requires a 'useful' subject-matter and "a single use makes a subject-matter useful"[893]. The Act did not specify the degree of usefulness required so "a scintilla of utility will do"[894]. This amounts to a high level of IP protection, which could reduce the latitude for generic versions of medicines.

This decision is worrying as Canada has so recently been successful in the investor-state dispute resolution arbitration in the *Eli Lilly*[895] case on similar arguments to this case. The 'promise' doctrine developed by the Canadian courts sought to prevent the extension of patent protection, by ensuring that the patented product matches the utility promised in the patent application under the criteria for patentability under Section 2 of the Patent Act 1985. However, this decision could lead to the widening of the scope of patents to products with little utility. It may now be more difficult for the validity of a pharmaceutical patent to be challenged following this decision and it may also be argued that this approach differs from the purpose of the patent legislation, which is to protect inventions that are new and useful. The decision could also have a detrimental impact on access to more affordable generic medicines in the State.

This case an example of the tension that can exist between IP and access to medicines at national level. The decision indicates that the Canadian judicial authorities are prioritising the interests of patent holders over the rights of the population to have access to medicines under Article 12 ICESCR.[896] It is important to note that the Canadian Supreme Court did not give any consideration to the rights of Canadian citizens in relation to access to medicines as part of their Article 12 ICESCR right to health. This decision strengthens the position of patent holding pharmaceutical companies, and the interventions in the case by numerous intellectual property organisations show the

[893] ibid 48
[894] ibid 55
[895] Eli Lilly and Company v. Government of Canada (n 877)
[896]The US under the Trump administration sought to renegotiate the terms of NAFTA. A new United States-Mexico-Canada Agreement was signed on 30 November 2018, and is expected to enter into force in the Summer of 2020 (See Reuters, 'New North American trade pact to take effect July 1: USTR' 24 April 2020 <https://www.reuters.com/article/us-usa-trade-usmca/new-north-american-trade-pact-to-take-effect-july-1-ustr-idUSKCN2263H0?il=0> (accessed 27/04/2020)). Protections for investors have been stripped out, leaving only the non-discrimination provisions. The main norm which is been removed is fair and equitable treatment. It is also worth noting the shift from arbitration in investment tribunals, to national courts. Therefore the norms elucidated in the *Eli Lilly* case may be unlikely to be followed. See also Office of the United States Trade Representative 'Agreement between the United States of America, the United Mexican States, and Canada Text', Chapter 14 <https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between> (accessed 27/04/2020)

pressure that the courts were under to reach this decision[897]. It is also concerning to note this decision since it was made after the publication of the final report of the UN Secretary-General's High-Level Panel on Access to Medicines, which recommended that governments should only award patents when "genuine innovation" has occurred[898].

(d) Conclusions from Section I

The review of the State's national and legislative framework has highlighted that the State has an appreciation of the tension which can arise between IP rights protection and access to medicines in developing countries, as it has taken legislative measures to implement the Doha Declaration. While this is commendable, CAMR has not provided an effective measure to enhance access to medicines, and there appears to be little appetite for reform to make the regime more workable. The State could do more at national level to enhance access to medicines, as the recent *AstraZeneca* decision could lead to extension of patent protection for medicines and therefore a lack of affordable access to generics. By taking full account of the right to health under Article 12 ICESCR and interpreting Charter rights in light of the ICESCR, the State may be able to address possible tensions more effectively in order to discharge their obligations under TRIPS and ICESCR.

II. National healthcare provision and medicines

In addition to examining the State's legislative framework, health policy measures on enhancing access to medicines will also be examined. The purpose of this review is to evaluate whether the State is effectively enhancing access to medicines in order to meet their obligations under TRIPS and the ICESCR, through government commitments at national level.

(a) Healthcare provision across provinces within the State

[897] AstraZeneca Canada Inc. v. Apotex Inc. (n 878) 21. Apotex was not permitted to re-open the trial on the validity of the patent by the Federal Court (See Apotex Inc. v. AstraZeneca Canada Inc. 2018 FC 181, 30-36)

[898] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) 27

Canada has a health care system funded by the federal government known as Medicare. However, instead of a single national plan within this system there are 13 provincial and territorial health care insurance plans, with the provincial governments being responsible for the delivery of health care services for their citizens[899]. These plans are funded by the federal government and cover basic services, but citizens who require prescription medicines would have to obtain private health insurance to cover these costs, or pay for the medicines directly[900]. This could lead to disparities in access to medicines across provinces as not every citizen may be able to purchase private health insurance to cover their prescription medicines needs, or bear the costs themselves and therefore the medicines they require may be unobtainable. As the provincial governments are responsible for purchasing medicines, they have a key role in enhancing access to medicines within their province. The provincial governments have taken steps to address potential disparities in access to medicines across provinces through collaborative efforts to achieve greater value for pharmaceuticals for publicly funded medicine programmes through the pan-Canadian Pharmaceutical Alliance (pCPA).[901]

The pCPA aims to increase access to medicines, achieve lower pricing, and improve consistency of coverage across provinces by utilising the collective negotiating power across the provinces.[902] The pCPA has reported that, as of April 2018, these collaborative efforts have resulted in over two hundred completed joint negotiations on brand name medicines and price reductions on over sixty generic medicines.[903] This suggests that the pCPA has had a notable impact on attaining more cost effective medicines for public medicines plans, which may help to make more generic as well as branded medicines accessible for patients. Milliken et al argue that the work of the pCPA has not yet made a significant impact on the overall proportion of new medicines listed across provinces, although it was noted that only a relatively low number of medicines

[899] Government of Canada, 'Canada's health care system' <https://www.canada.ca/en/health-canada/services/canada-health-care-system.html> (accessed 27/04/2020)
[900] Government of Canada, 'Health care in Canada' <http://www.cic.gc.ca/english/newcomers/after-health.asp> (accessed 27/04/2020). See also S Dean, 'Canada's Landmark Chaoulli Decision: A Vital Blueprint for Change in the Canadian Health Care System' (2007) 13 Law & Bus Rev Am 417, 420-421; L Rose and R Rose, 'The United States, Canada, and the United Kingdom - A Comparative Analysis of Healthcare Policies and Their Impact on the Elderly' (2010) 4 J Int'l Aging L & Pol'y 33, 46-47
[901] The Council of the Federation, Canada's Premiers, 'Health Care Innovation Working Group' <http://www.canadaspremiers.ca/health-care-innovation-working-group/> (accessed 27/04/2020)
[902] The Council of the Federation, Canada's Premiers, 'The pan-Canadian Pharmaceutical Alliance' <http://www.canadaspremiers.ca/pan-canadian-pharmaceutical-alliance/> (accessed 27/04/2020)
[903] ibid

had been the subject of the pCPA negotiation process.[904] This view explains that while the pCPA's work to reduce the cost of medicines may mean that those medicines are more accessible, there has not yet been a notable improvement in the availability of new medicines to patients across the State, and therefore accessibility to new medicines has not been enhanced. The federal drug plans are participating in the pCPA, and the support of the federal government for the pCPA may illustrate that it can have a meaningful impact on enhancing access to new and existing branded and generic medicines across the State. However, following a visit to Canada in 2018, the Special Rapporteur on health stated that the efforts of the pCPA remain insufficient to benefit uninsured persons or those who are privately insured.[905]

The introduction of a national medicines benefit programme could potentially be beneficial to ensure all Canadians are afforded the same level of access to medicines. This may be a more equitable system, because this implies that such a strategy would provide more reliable supplies of essential medicines which would be available across the whole State, and therefore discrepancies in availability between provinces may be minimised. The funding of provincial health insurance plans by the federal government and the outcomes of these plans in terms of lack of coverage for prescription medicines also highlights that to enhance access to medicines there needs to be effective implementation of measures to enhance access as well as available funding to invest in improvements to health care. However the work of the pCPA, including collective negotiating resulting in savings in medicines costs and aims to continue developing the alliance, provides evidence of the utility of cross-province strategies for enhancing access to medicines. In 2019, the Advisory Council on the Implementation of National Pharmacare recommended that the Canadian government implement a national pharmacare programme and outlined a plan to implement this between 2019 and 2027.[906] This is an

[904] D Milliken et al, 'Comparison of drug coverage in Canada before and after the establishment of the pan-Canadian Pharmaceutical Alliance' (2015) BMJ Open 5:e008100. doi:10.1136/bmjopen-2015-008100, 8 <http://bmjopen.bmj.com/content/bmjopen/5/9/e008100.full.pdf> (accessed 27/04/2020)

[905] UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health: Visit to Canada' (19 June 2019) UN Doc A/HRC/41/34/Add.2, 40

[906] Government of Canada, *A Prescription for Canada: Achieving Pharmacare for All; Final Report of the Advisory Council on the Implementation of National Pharmacare*, June 2019, (Health Canada Ottawa) <https://www.canada.ca/content/dam/hc-sc/images/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare/final-report/final-report.pdf> (accessed 27/04/2020). The Advisory Council on the Implementation of National Pharmacare was created by the Canadian government as part of the 2018 Budget, to recommend options on how best to move forward on this issue. See also Government of Canada, 'Budget 2018'

important step, although it highlights that the political will of the government is crucial to the implementation of the plan. This is an important factor for consideration for other states in relation to making provision for national medicines programmes. It will be interesting to note the actions of the Canadian government in relation to the proposals of the Advisory Council, and whether the plan is adopted in the State.

(b) National Pharmaceuticals Strategy

The National Pharmaceuticals Strategy was designed to improve access to affordable medicines including by improving access to new medicines, enhancing cost-effectiveness in purchasing medicines, and achieving consistency over pricing for generic medicines[907]. Key elements of the Strategy included ensuring increased access to generic medicines at prices which were consistent with other states, improved purchasing strategies and enhanced access to new medicines for neglected diseases and unmet health needs[908]. The implementation of this Strategy as part of the wider scheme to improve health equality could suggest that the federal government recognised that the issue of providing effective access to medicines for all Canadians was an important element of the wider issue of improving health, as reflected in Article 12 ICESCR. However, the recognition of the State obligations with regard to the right to health including medicines is not explicitly stated. This lack of vertical and horizontal policy coherence is a key concern which has been highlighted by John Ruggie in several of his reports to the UN on the human rights harm that can be caused by business and the State's duty to protect all human rights from corporate-related human rights abuses.[909]

<https://www.budget.gc.ca/2018/docs/themes/advancement-advancement-en.html> (accessed 27/04/2020)

[907] Government of Canada, 'ARCHIVED - A 10-year Plan To Strengthen Health Care', <https://www.canada.ca/en/health-canada/services/health-care-system/health-care-system-delivery/federal-provincial-territorial-collaboration/first-ministers-meeting-year-plan-2004/10-year-plan-strengthen-health-care.html> (accessed 27/04/2020)

[908] Federal/Provincial/Territorial Ministerial Task Force on the National Pharmaceuticals Strategy, *National Pharmaceuticals Strategy*, June 2006, (Health Canada, Ottawa 2006), ISBN 0-662-49443-1, 9 <https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/hcs-sss/alt_formats/hpb-dgps/pdf/pubs/2006-nps-snpp/2006-nps-snpp-eng.pdf> (accessed 27/04/2020)

[909] See also: UNHRC 'Promotion of all Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including the Right to Development: Business and human rights: Towards operationalizing the "protect, respect and remedy" framework; Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises: Summary' (22 April 2009) UN Doc A/HRC/11/13, 8; UNHRC 'Report of the Special Representative of the Secretary General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie: Business and human rights: further steps toward the operationalization of the "protect,

In 2009 the Health Council of Canada conducted a review of the National Pharmaceuticals Strategy.[910] The review highlighted that there is a need for a consistent approach among the provinces and territories in implementing the Strategy so that it is a more effective device for enhancing access to medicines nationally. The review noted that some provinces had made advances in implementing parts of the Strategy. For example, provinces such as Ontario and Newfoundland made legislative changes to amend their approach to purchasing medicines, and British Columbia and Alberta explored the option of purchasing medicines together[911]. The report concluded that although some of the individual provinces and territories had taken steps to implement some of the key objectives, there was also a need for collective measures to ensure that Canadian citizens benefited from the Strategy[912].

A review of the federal government's 10-Year Plan to Strengthen Health Care[913] was published in 2012 by the Standing Senate Committee on Social Affairs, Science and Technology[914], which included a review of the National Pharmaceuticals Strategy. This review illustrated that although the National Pharmaceuticals Strategy set out key objectives to be met in order to improve access to medicines for Canadians, advancing the Strategy has been problematic due to disparities in implementing the objectives across the provinces. The review observed that the progress of the Strategy had been mixed, with inequities in the provision of medicines still existing across the State and the cost of new specialised medicines was also problematic[915]. The review also noted that although some provincial jurisdictions had made progress in pursuing generic medicine pricing and purchasing strategies which were leading to some savings, there was still a funding gap

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respect and remedy" framework' (9 April 2010) UN Doc A/HRC/14/27, 5, 12, 18; UNHRC 'Report of the Special Representative of the Secretary General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie: Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework' (21 March 2011) UN Doc A/HRC/17/31, 11-12

[910] Health Council of Canada, *A Status Report on The National Pharmaceuticals Strategy: A Prescription Unfilled*, (Health Council of Canada, Toronto 2009), ISBN 978-1-897463-46-8, 17 <https://healthcouncilcanada.ca/files/2.35-HCC_NPS_StatusReport_web.pdf> (accessed 27/04/2020)

[911] ibid 21

[912] ibid 29

[913] The 10-Year Plan to Strengthen Health Care (10-Year Plan) was agreed by First Ministers in September 2004. See Standing Senate Committee on Social Affairs, Science and Technology, *Time for Transformative Change: A Review of the 2004 Health Accord*, (Senate Canada, 2012), v <https://sencanada.ca/content/sen/Committee/411/soci/rep/rep07mar12-e.pdf> (accessed 27/04/2020)

[914] ibid

[915] ibid 58-59

with regard to the cost of pharmacy services to provide the medicines to the population[916]. The review recommended that the federal, provincial and territorial governments work together to develop a national programme to ensure access to medicines for all, including price controls and frameworks to ensure improved quality of medicines, and working with private health insurance companies on strategies regulating costs[917]. This also demonstrates that a comprehensive collective national strategy could be more effective in achieving these goals. Calls for a pan-Canadian strategy have been made by stakeholders including the Canadian Medical Association[918]. This suggests that there is national support for such a scheme from the medical profession, although it appears that such a strategy would need to be implemented and regulated by the federal government in order to seek to achieve the desired improvements in attaining affordable medicines.

The outcome of this review highlights findings which accord with the key concerns relating to access to medicines emanating from the UN human rights bodies, discussed in Chapter 3 of this thesis. The finding that deficiencies in funding for pharmacy services suggested a lack of physical accessibility to these medicines emphasises the linkage between affordability and accessibility of medicines, and the importance of ensuring that affordable medicines can be readily obtained by patients. It also highlights that it is important to ensure that funding is allocated appropriately to support the facilitation of supply of medicines to patients. The findings of the review also highlighted that where cross-provincial alliances are formed, the utility of such alliances may be enhanced by advancing an effective, overarching strategy to incorporate facilitating the supply of medicines to citizens in addition to the acquisition of medicines at more affordable cost.

(c) Indigenous Peoples

[916] ibid 57
[917] ibid 59
[918] Canadian Medical Association, *National Pharmacare in Canada: Getting There from Here. Submission to the House of Commons Standing Committee on Health*, 1 June 2016, 10 <https://www.cma.ca/sites/default/files/2018-11/national-pharmacare-canada-e.pdf> (accessed 27/04/2020). See also Canadian Nurses Association, *Pan-Canadian Pharmaceutical Strategy: Recommendations to Improve Access to Affordable Prescription Medications. Brief prepared for the House of Commons Standing Committee on Health*, May 2016, 6 <https://www.ourcommons.ca/Content/Committee/421/HESA/Brief/BR10594161/br-external/CanadianNursesAssociation-e.pdf> (accessed 27/04/2020). See also J Daw and S Morgan 'Stitching the gaps in the Canadian public drug coverage patchwork? A review of provincial pharmacare policy changes from 2000 to 2010' (2012) 104 Health Policy 19, 24

A key theme emerging from the measures taken in Canada to enhance effective access to medicines is ensuring that the specific health needs of the indigenous peoples are identified and addressed. This is particularly significant as in addition to the reference to rights of indigenous peoples in UN human rights instruments such as the ICESCR, the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)[919] was adopted by the UN General Assembly in 2007[920] for the purpose of protecting the individual and collective rights of indigenous peoples. In 2010 Canada endorsed the principles in the UNDRIP and in May 2016 confirmed full support of the UNDRIP[921]. Specific issues relate to access to prescription medicines, and secondly that intellectual property law may be utilised to appropriate traditional medicines and materials, and indigenous peoples may require legal measures in order to protect their culture and resources.

(i) Access to prescription medicines

Health concerns regarding indigenous peoples in Canada were noted during the first visit of the Special Rapporteur on the rights of indigenous peoples in 2004[922], with rates of HIV/AIDS, diabetes and tuberculosis considerably higher than among other Canadians[923]. One of the recommendations of the Special Rapporteur was that the Canadian Government should intensify measures to close the gap between aboriginal and

[919] UNGA Res 61/295 'United Nations Declaration on the Rights of Indigenous Peoples' (2 October 2007) UN Doc A/RES/61/295

[920] UNGA Res 61/295 (2 October 2007) UN Doc A/RES/61/295 was adopted by the UN General Assembly without reference to a Main Committee. See UNHRC 'United Nations Declaration on the Rights of Indigenous Peoples' (12 September 2007) UN Doc A/61/L.67 and Add.1

[921] Government of Canada, 'United Nations Declaration on the Rights of Indigenous Peoples' <http://www.aadnc-aandc.gc.ca/eng/1309374407406/1309374458958> (accessed 27/04/2020); B Gunn, 'Overcoming Obstacles to Implementing the UN Declaration on the Rights of Indigenous Peoples in Canada' (2013) 31 Windsor YB Access Just 147, 173-174

[922] As part of the thematic Special Procedures, a Special Rapporteur on the rights of indigenous peoples was first appointed in 2001 by the Commission on Human Rights. The mandate of the Special Rapporteur includes the examining of ways to overcome existing obstacles to the full and effective protection of the rights of indigenous peoples, and to formulate recommendations and proposals on appropriate measures to prevent and remedy violations of the rights of indigenous peoples. See also UNCHR 'Indigenous Issues, Human rights and indigenous issues, Report of the Special Rapporteur on the situation of human rights and fundamental freedoms of indigenous people, Rodolfo Stavenhagen; Addendum: Mission to Canada' (2 December 2004) UN Doc E/CN.4/2005/88/Add.3

[923] ibid 40

non-aboriginal peoples in relation to health care provision[924]. Several initiatives have been introduced and supported by the Canadian government for the purpose of improving the health of indigenous peoples. These measures and initiatives demonstrate that the Canadian government appreciates that the disparities between access to appropriate health care services between indigenous and non-indigenous peoples in Canada needs to be addressed. However, while there are some examples of enhanced relationships leading to improved understanding of the specific needs of indigenous peoples, there appears to be little evidence of significant improvement in the availability of medicines to treat diseases which need the most urgent attention in these communities.

Health Canada[925], the federal department for health in Canada, oversees a health programme for indigenous peoples, the First Nations and Inuit peoples, which provides access to prescription medicines as well as policies to transfer to the indigenous peoples greater administrative responsibilities over their health care programmes[926]. Health Canada has provided eligible indigenous groups with supplementary health benefits for particular services such as prescription medicines that would not otherwise be available to them[927]. However an evaluation of the health planning activities for indigenous peoples undertaken by Health Canada[928] in 2016 highlighted that there were still problems including limited resources to address immediate need and a lack of qualified professionals providing pharmacy care[929]. This suggests that the federal government was engaging with the recommendations of the Special Rapporteur to bridge the gap in non-indigenous health care provision between indigenous and non-indigenous peoples, but that there may still be limitations on the accessibility of resources including essential medicines. Therefore the benefits of the strategic plan could be restricted due to resource

[924] ibid 101
[925] Government of Canada, 'Health Canada – a partner in health for all Canadians' <https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/partner-health-canadians.html> (accessed 27/04/2020)
[926] Health Canada, *First Nations and Inuit Health Strategic Plan: A shared path to improved health*, (Minister of Health, Health Canada, Ottawa, 2012) ISBN: 978-1-100-21186-2, 11-18, <http://publications.gc.ca/collections/collection_2013/sc-hc/H34-258-2012-eng.pdf> (accessed 27/04/2020)
[927] ibid 11-18, 7
[928] Health Canada and the Public Health Agency of Canada, Office of Audit and Evaluation, 'Evaluation of the First Nations and Inuit Health Branch's Health Planning and Quality Management Activities 2010-2011 to 2014-2015', 26 September 2016, <https://www.canada.ca/content/dam/hc-sc/documents/corporate/transparency/corporate-management-reporting/evaluation/2010-2011-2014-2015-first-nations-inuit-health-planning-quality-management-activities/hpqm-psgq-eng.pdf> (accessed 27/04/2020)
[929] ibid P.28

constraints and an evaluation of the reasons for this may help to inform the objectives and implementation of the strategy. The lack of expertise in pharmacies may also be detrimental to enhancing understanding of the benefits that prescription medicines can offer to indigenous peoples, which could in effect limit access to effective medicines for these peoples.

There is evidence of the introduction of measures to facilitate the participation of indigenous peoples in the province of British Columbia, where the British Columbia Tripartite Framework Agreement on First Nation Health Governance[930] was introduced in 2011 with the purpose of ensuring that indigenous peoples in the province could fully participate in decision-making and delivery of health services and programmes[931]. In October 2013, as part of this framework agreement Health Canada transferred its responsibilities regarding health services delivery to the First Nations Health Authority (FNHA), the first pan-province health authority for indigenous peoples in Canada[932]. The FNHA provides a health benefits programme which funds approved medicines for eligible indigenous peoples[933]. The implementation of the FNHA demonstrates that the importance of engagement with the indigenous peoples is a key factor in improving health care for indigenous peoples, as well as the importance of inter-government collaboration in order to facilitate a framework for the purpose of achieving this aim. This framework is still developing[934] but if there is clear evidence that it has enhanced access to medicines then the framework could offer an example for other provinces to follow to improve access to medicines for their indigenous peoples. This also highlights that disparities exist in relation to the health services available to indigenous peoples as well as non-indigenous peoples across the provinces.

(ii) Traditional resources and medicinal knowledge

[930] British Columbia Tripartite Framework Agreement on First Nation Health Governance, 13 October 2011, <https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fniah-spnia/alt_formats/pdf/pubs/services/tripartite/framework-accord-cadre-eng.pdf> (accessed 27/04/2020)
[931] ibid Section 2.1
[932] First Nations Health Authority, 'About the FNHA', <http://www.fnha.ca/about/fnha-overview> (accessed 27/04/2020)
[933] First Nations Health Authority, 'Pharmacy', <http://www.fnha.ca/benefits/pharmacy> (accessed 27/04/2020)
[934] First Nations Health Authority, *Annual Report 2018-2019*, <https://www.fnha.ca/Documents/FNHA-Annual-Report-2018-2019.pdf> (accessed 27/04/2020)

Intellectual property rules can be used to further human rights goals for indigenous peoples, in relation to protecting their traditional knowledge. This particular human rights objective is to further their right to self-determination[935], to freely pursue their economic, social and cultural development, which comprises having control over their indigenous natural resources, such as traditional medicines and medicinal resources. Therefore it is pertinent to examine how the State is utilising intellectual property rules to further this human rights objective for the benefit of its indigenous population and to satisfy its obligations with regard to upholding the right to self-determination of its indigenous peoples. It is also pertinent to identify any issues experienced within the State when trying to achieve these objectives, which could be informative to other states which also have indigenous populations. The recognition of the rights of indigenous peoples in relation to their traditional medicines is evident in Article 12 ICESCR, with General Comment 14 providing guidance to states with indigenous peoples to implement the provisions under Article 12 ICESCR[936]. The ICESCR also recognises the rights of indigenous peoples with regard to their traditional knowledge and resources, such as medicinal resources, under Article 15.[937] Therefore government and health services need to ensure that indigenous peoples have access to non-traditional medicines as well as supporting the use of traditional medicines as part of the State's obligations under the ICESCR.

The CESCR's concluding observations for Canada published in 2006 addressed concerns over the protection of indigenous culture including traditional knowledge[938], and recommended that Canada adopted a strategy in the area of intellectual property for the protection of traditional knowledge of its indigenous peoples[939]. The recommendation has implications for the issue of access to medicines as it highlights that there may be

[935] United Nations Declaration on the Rights of Indigenous Peoples (n 919) Article 3
[936] General Comment No. 14 (n 112) 27
[937] General Comment 21 provides that as part of the right of everyone to take part in cultural life under Article 15(1)(a), States parties must take measures to recognise the rights of indigenous peoples to develop and control their natural resources. General Comment 17 also provides that as part of the protection of the author's moral and material interests under the Article 15(1)(c) right, States parties should adopt measures to ensure the effective protection of the interests of indigenous peoples relating to their productions, which are often derived from traditional knowledge. See UNCESCR 'General Comment No. 21: Right of everyone to take part in cultural life (art. 15, para. 1 (a), of the International Covenant on Economic, Social and Cultural Rights)' (21 December 2009) UN Doc E/C.12/GC/21, 36; UNCESCR General Comment 17 (n 587) 32
[938] UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Canada' (22 May 2006) UN Doc E/C.12/CAN/CO/4-E/C.12/CAN/CO/5
[939] ibid 67

issues within the State relating to the misappropriation of traditional knowledge including traditional medicines and resources. Therefore, there could be a need for the State to introduce sustainable measures to ensure that these peoples do have access to their indigenous medicines, as part of their human right to health under Article 12 ICESCR. Gervais argues that IP law in Canada generally does not deal with customs and practices of indigenous peoples.[940] This raises the question of whether the State should address this concern by introducing specific IP protection for traditional knowledge.[941] The participation of the indigenous peoples in the development of health services to meet their specific needs could facilitate the inclusion of provisions to protect and enhance the use of traditional medicines by these peoples so that their cultural practices and traditions are preserved and upheld.[942] This also illuminates how the human rights of indigenous peoples could serve as a catalyst for the expansion of the existing IP regime so that IP protection effectively protects the collective rights of indigenous peoples and that indigenous peoples can assert and enforce their legal rights against infringers.

Although there does not appear to be a formal process in place to offer the indigenous peoples a forum to seek protection from the exploitation of their traditional knowledge and resources by private enterprises, the Canadian Network on Corporate Accountability[943] may offer an example of such a process. The Canadian Network on Corporate Accountability is a civil society organisation which advocates for regulations to ensure that Canadian extractive companies working abroad[944] respect human rights, including the rights of indigenous peoples, and the withdrawal of government support for companies that are non-compliant[945]. The Network also advocates that those who have had their rights infringed by a Canadian extractive company should have access to Canadian courts as well as access to a human rights Ombudsperson in order to seek a

[940] D Gervais, 'Spiritual But Not Intellectual - The Protection of Sacred Intangible Traditional Knowledge' (2003) 11 Cardozo J Int'l & Comp L 467, 493

[941] S Kaur Verma, 'Protecting Traditional Knowledge: Is a Sui Generis System an Answer' (2004) 7 J World Intell Prop 765, 797, 803-5

[942] N Adelson 'The Embodiment of Inequity: Health Disparities in Aboriginal Canada' (2005) 96(2) Can J Public Health S45, S59

[943] Canadian Network on Corporate Accountability <http://cnca-rcrce.ca> (accessed 27/04/2020)

[944] This organisation does not advocate for the respect of human rights by Canadian extractive companies over ancestral lands of indigenous peoples in Canada.

[945] Canadian Network on Corporate Accountability, 'What we do' <http://cnca-rcrce.ca/about-us/what-we-do/> (accessed 27/04/2020)

remedy[946]. While this organisation specifically advocates in the extractive industry, some of the principles upheld by the organisation in relation to corporate social responsibility could be applied to the pharmaceutical industry, and the protection of traditional knowledge and resources from use without appropriate permission. The proposals for a human rights Ombudsperson as well as regulations to ensure appropriate compensation may help to preserve the traditional knowledge and medicines of indigenous peoples, and provide a formal process for holding pharmaceutical companies accountable if they believe that their rights in relation to these resources have been infringed.[947] It is important to note that these proposals remain as such, and therefore it is uncertain how successful such a regulatory system would be. However, some of the principles could be transferable to the pharmaceutical industry and provide a formal process that the indigenous peoples could engage with and participate in, to secure their rights over the use of their traditional medicines.

Concerns have also been raised by UN human rights bodies in relation to how TRIPS-plus provisions in FTAs can negatively affect the protection of indigenous peoples' traditional medicines and resources.[948] As a result the Special Rapporteur on the rights of indigenous peoples stated an intention to place a focus on several issues which could include access to culturally appropriate health care and traditional medicines as part of her investigations over a three year period to 2017[949]. This is potentially a significant statement with regard to the protection of traditional medicines as it demonstrates a concentrated effort to ensure that indigenous peoples have control over, and therefore access to, their traditional medicines when States enter into such agreements, in a human rights context. This could be particularly significant for Canada given the trend towards TRIPS-plus provisions under FTAs such as NAFTA. This also suggests that the standards of IP protection under TRIPS may not be the most appropriate degree of protection to

[946] Ibid. See also P Simons, 'Canada's Enhanced CSR Strategy: Human Rights Due Diligence and Access to Justice for Victims of Extraterritorial Corporate Human Rights Abuses' (2015) 56 Can Bus LJ 167, 177, 191-192

[947] L Shipton 'Canada's Mining Industry in Guatemala and the Right to Health of Indigenous Peoples', Health and Human Rights Journal; Perspectives, August 2017, <https://www.hhrjournal.org/2017/08/canadas-mining-industry-in-guatemala-and-the-right-to-health-of-indigenous-peoples/> (accessed 27/04/2020)

[948] The Special Rapporteur on the rights of indigenous peoples also observed that trade agreements entered into by states can directly affect the development agenda of indigenous peoples within those states, with TRIPS provided as an example due to the implications on their rights to traditional knowledge including medicinal plants. See UNHRC 'Report of the Special Rapporteur on the rights of indigenous peoples, Victoria Tauli Corpuz' (11 August 2014) UN Doc A/HRC/27/52, 50

[949] ibid 52

afford to traditional knowledge.[950] International human rights law specifically in relation to indigenous peoples has the potential to act as a catalyst for impacting on the IP regime, although it does not appear that this has occurred in the State. However the outcome of such focus following the end of the three year review period outlined by the Special Rapporteur has not been explicitly outlined. This would be helpful as guidance for other states regarding their human rights responsibilities specifically to indigenous peoples and their health needs.

(d) Conclusions from Section II

The review of the State's national commitments in relation to health provision show that some measures have been implemented to improve access to medicines nationally through addressing cost, such as the National Pharmaceuticals Strategy. Challenges include meeting the specific needs of minority groups which may be more particularly affected by lack of access to medicines. Addressing the challenges affecting indigenous peoples in relation to access to medicines and protecting traditional medicines could be made more prominent in government policy. Therefore, the national policies could go further to secure a collective, collaborative response to enhancing access to medicines at national level in line with the State's international obligations.

III. Regulating the pharmaceutical industry

A key challenge for states in implementing health policies to enhance access to affordable medicines is the role of pharmaceutical companies in the research and development, and pricing of medicines. This section will analyse regulatory provisions implemented in Canada with regard to the cost and development of medicines, to evaluate how the State is responding to the impact of a private industry, which has a crucial role in producing medicines, on its obligations to enhance effective access to medicines while also appropriately protecting the IP rights of that industry in accordance with its obligations under TRIPS . The purpose of this review is to examine whether the State is effectively addressing possible tensions between protecting the IP rights of pharmaceutical

[950] R Barsh, 'A Social Theory of Fair Trade, with Special Reference to Indigenous Peoples' (2002) 96 Am Soc'y Int'l L Proc 279, 280

companies and its human rights obligations in relation to enhancing access to medicines. There is a strong presence of both branded and generic pharmaceutical industries in Canada, and so the conflicting demands of these industries have to be balanced[951]. This highlights some of the complexity of the issues facing States in discharging their obligations simultaneously under TRIPS and ICESCR. The findings from this review could also inform understanding of the interaction between IP rights and the right to health at national level, and provide lessons to other states in effectively meeting their obligations under TRIPS and the ICESCR.

(a) Patented Medicine Prices Review Board

The Canadian government has implemented provisions relating to the monitoring and regulation of pharmaceuticals and their costs for the population of Canada. The Patented Medicine Prices Review Board (PMPRB) is a quasi-judicial body[952] created in 1987 and acts for the purpose of regulating the price of patented medicines to ensure that the prices paid by consumers are not "excessive"[953] under Section 85 of the Patent Act 1985. As a governmental body the PMPRB has a responsibility to comply with the State's UN human rights obligations although the language used to describe the citizens as 'consumers'[954] implies that the Board carries out its regulatory actions from a clear economic standpoint, which may detract from viewing the issues of affordable medicines in a rights-based context. While the PMPRB has a responsibility to citizens in terms of consumer rights, it could be beneficial to appoint a member of the Board with an understanding of the State's international and national human rights obligations, to include a more rights-based perspective in the exercise of its functions.

This expenditure on patented pharmaceuticals highlights that there is a notable gap between the sales of patented medicines and generic medicines. The 2017 report of the PMPRB noted that 61.5 percent of the total medicines sales in Canada were of

[951] IBP Inc, *Canada Investment, Trade Strategy and Agreements Handbook Volume 1 Strategic Information and Materials, Volume 1 Strategic Information and Materials*, (International Business Publications, Washington, 2016), ISBN: 1-6145-2146-6, 193

[952] Patented Medicine Prices Review Board, *Strategic Plan 2015-2018*, ISBN: 978-0-660-03054-8, 6 <http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/StrategicPlan/Strategic_Plan_2015-2018_en.PDF> (accessed 27/04/2020)

[953] Government of Canada, 'Patented Medicine Prices Review Board' <http://www.pmprb-cepmb.gc.ca/en/regulating-prices/regulatory-process> (accessed 27/04/2020)

[954] Patented Medicine Prices Review Board, *Strategic Plan 2015-2018*, (n 952) 25

patented medicines, an increase from 60.8 percent in 2016[955]. Consumers were spending more on patented medicines in 2017 compared to the previous year, although it was contended that this increase was not necessarily due to rising prices, with suggested other factors including an increase in the overall population, and increases in health problems requiring medicines[956]. The report also noted that in 2017, the Patented Medicines Price Index (PMPI) measured that the increase in patented medicines prices was, on average, less than the rate of inflation[957]. This portrays that in Canada the costs of patented pharmaceuticals are increasing, although the price of pharmaceuticals had risen at a lower rate than the prices of other goods and services. Therefore, such a rise in prices may not be prohibitive, although for vulnerable and minority groups any price increase in their essential medicines could be unaffordable. This demonstrates the need for greater alignment when addressing the issue of enhancing access to medicines. Key issues are not just lower prices and accessibility generally, but also include marginalised groups within the States and the specific measures that may be required to ensure their rights are also protected. This is also an important consideration for other states contemplating the advancement of a national mechanism based on the framework implemented in Canada.

Questions have been raised over the effectiveness of the current regime to meet its objective of ensuring pharmaceutical companies do not utilise their IP rights to charge excessive prices[958], due to the relatively high prices of patented medicines and low investment into research and development[959]. Morgan and Cunningham argue that the empirical evidence does not support the view that IP protection is an important determinant in investment in pharmaceutical research and development, with other factors including scientific innovation and access to clinical trials emerging as more important factors[960]. This view contradicts an accepted rationale of IP protection, being that strong IP rights encourage creators of medicines to research and develop new products because they can rely on their private legal rights to prevent their ideas from being utilised without permission. Lexchin argues that Canada's domestic position has

[955] Patented Medicine Prices Review Board, *Patented Medicine Prices Review Board Annual Report 2017,* July 2018, H78E-PDF, ISSN: 1495-0561, Statistical Highlights (i) <http://pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2018/2017_Annual_Report_Final_EN.pdf> (accessed 27/04/2020)
[956] ibid 22
[957] ibid 37
[958] Patented Medicine Prices Review Board, *Strategic Plan 2015-2018* (n 952) 4
[959] ibid 12
[960] S Morgan and C Cunningham 'The Effect of Evidence-Based Drug Coverage Policies on Pharmaceutical R&D: A Case Study from British Columbia' (2008) 3(3) Healthcare Policy 128, 148

seen increased emphasis on IP rights to encourage investment in research and development by pharmaceutical companies[961]. However, Lexchin also notes that "between 2010 and 2013 seven major multinational pharmaceutical companies have closed research facilities in Canada with a loss of over 1000 jobs"[962]. This suggests that the promise of strong IP rights protection is not itself enough to attract pharmaceutical companies to invest in research and development of medicines in the State, and other incentives need to be offered in order to stimulate the required investment.

The PMPRB is taking measures to adapt its framework for the purpose of enhancing its efficacy for consumers. The PMPRB has developed new strategic objectives for the period 2015 to 2018[963]. These objectives include consumer-focused regulation, enhancing public awareness of its mandate and reviewing its regulatory framework[964]. Therefore, although Canada has implemented a mechanism for monitoring of the pricing of patented pharmaceuticals, the variety of factors which affect pricing appear to make it difficult to develop a clear pricing strategy to regulate the pricing for the population. In 2019 Health Canada announced amendments to the Patented Medicines Regulations, which provide the framework by which the PMPRB regulates prices[965]. Amendments include new price regulatory factors allowing the PMPRB to assess the cost of a patented medicine against the health benefit, and added reporting requirements relating to these new factors[966]. The amendments aim to address the increasing cost of medicines, improve their affordability and could be an important development in the regulation of patented medicines pricing. They are intended to come into force on 1 July 2020[967], although as of March 2020 the amendments are subject to challenge by the pharmaceutical industry[968].

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[961] J Lexchin, 'Canada and access to medicines in developing countries: intellectual property rights first' (2013) 9 Globalization and Health 42, 6

[962] ibid

[963] Patented Medicine Prices Review Board, Strategic Plan 2015-2018 (n 952) 28

[964] ibid 25-26

[965] Government of Canada, 'Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements): SOR/2019-298', 8 August 2019, <http://www.gazette.gc.ca/rp-pr/p2/2019/2019-08-21/html/sor-dors298-eng.html?wbdisable=false> (accessed 27/04/2020)

[966] ibid; Government of Canada, 'Forward Regulatory Plan 2019-2021: Regulations Amending the Patented Medicines Regulations' <https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/forward-regulatory-plan/plan/patented-medicines.html> (accessed 27/04/2020)

[967] ibid

[968] CBC, 'Pharma industry launches court challenge of federal regulatory changes' <https://www.cbc.ca/news/politics/ottawa-pharma-lawsuit-1.5273643> (accessed 27/04/2020)

It is significant that the Patented Medicines Regulations amendments recognise that affordability is a major concern in relation to ensuring access to medicines. However, affordability of medicines is a broader issue than price regulation. Alignment with other organisations, intergovernmental bodies and other stakeholders is needed to address the complex nature of the issue of affordability. There is evidence that Canada has taken measures to try to make the cost of medicines more affordable. However, in order to fully meet its UN human rights obligations the State should prioritise the human rights of its population when entering into agreements or making policy decisions that directly or indirectly affect the right of its people to have effective access to medicines.

(b) The significance of the pharmaceutical industry

Canada is a net importer of pharmaceutical products[969], with pharmaceutical imports at a value of approximately $12.5 billion (USD) compared to pharmaceutical exports at a value of approximately $8 billion (USD) in 2018[970]. This trend appears to be less common in developed countries, as depicted in the table in Annex II. Key issues that underline Canada's position as a net importer of pharmaceutical products are the effect of regulatory obstacles in the development of new medicines and the availability of cheaper overseas imports, in addition to high demand for pharmaceuticals to meet the evolving needs of the population[971]. Regulation of medicines is important to ensure the safety and quality of new medicines for patients. However, to promote access to new medicines it may be useful to provide additional incentives for pharmaceutical manufacturers to encourage them to pursue the manufacturing and development process including taking the appropriate measures as far as possible to meet the requisite regulatory standard in order to market their product. It is also important for other states to understand the changing needs of the population for reasons such as health concerns related to ageing or other emerging factors affecting health. By doing so the state could

[969] UN COMTRADE Database (n 808); J Putnam 'Policy Options for Canada in the Knowledge-Based Economy' in J Putnam (ed), *Intellectual Property and Innovation in the Knowledge-Based Economy*, (Strategis 2008), 17-5

[970] UN COMTRADE Database (n 808)

[971] United States of America Department of Commerce International Trade Administration, *2016 Top Markets Report: Pharmaceuticals, A Market Assessment Tool for U.S. Exporters*, (U.S. Department of Commerce, International Trade Administration, Industry & Analysis (I&A), May 2016), 15 <https://legacy.trade.gov/topmarkets/pdf/Pharmaceuticals_Top_Markets_Reports.pdf> (accessed 27/04/2020)

take measures such as implementing procedures to address these needs to ensure that medicines are available in the state to treat long term conditions, in addition to serious diseases.

The pharmaceutical industry is of importance to the Canadian economy in terms of international trade and therefore medicines production in Canada may be targeted towards the needs of these markets. Between 2011 and 2016 the export of pharmaceuticals increased by 132.2 percent, and grew by 12.8 percent in 2016, making pharmaceuticals Canada's ninth biggest export and 2.2 percent of Canada's total exports.[972] Over half of Canada's pharmaceutical production is exported, and this is primarily to the US[973]. The needs of the overseas market could potentially contrast with the needs of the domestic market and may mean that the Canadian pharmaceutical industry does not primarily aim to meet the health needs of the Canadian population, but those of the export market instead. Lexchin argues that pharmaceutical companies gain a clear economic advantage in getting their products to the market as soon as possible[974], so it is in the interests of the companies and their shareholders to produce products that are the most marketable and lucrative. However these products may not necessarily address the key health needs of Canadian citizens. Also, only one of the top ten leading pharmaceutical companies in Canada, accounting for half of total Canadian pharmaceutical sales in 2017, is under Canadian ownership[975]. Ownership of the companies might have an impact on target markets for these companies, as non-Canadian owned pharmaceutical companies may not primarily focus on the health needs of Canadian citizens with regard to their research and development models. However other factors such as the commercial objectives of the companies and the demands of the

[972] Global Affairs Canada, Government of Canada, 'Canada's State of Trade: Trade and Investment Update 2017, ISSN: 1926-4283, 66 <http://publications.gc.ca/collections/collection_2017/amc-gac/FR2-8-2017-eng.pdf> (accessed 27/04/2020)

[973] F Palumbo, C Mullins, A Slagle and J Rizer 'Policy Implications of Drug Importation' (2007) 29(12) Clinical Therapeutics 2758, 2760; J Arfwedson 'Re-importation (Parallel Trade) in Pharmaceuticals' Institute for Policy Innovation, Policy Report 182, July 2004, 17 <https://www.ipi.org/docLib/PR182-ParallelTrade.pdf-OpenElement.pdf> (accessed 27/04/2020); J Kobak and J De Douhet 'Must Canada Become the Drugstore to the World? (2005) 18 International Trade and Finance Association: International Trade and Finance Association 15th International Conference, 8; Government of Canada, 'Pharmaceutical Industry Profile' > 'Canada's Pharmaceutical Sector' > 'International Trade' <https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html> (accessed 27/04/2020)

[974] J Lexchin, *Private Profits Versus Public Policy: The Pharmaceutical Industry and the Canadian State*, (University of Toronto Press, Buffalo, 2016), ISBN: 978-1-4426-4917-0, 59

[975] Government of Canada, 'Pharmaceutical Industry Profile' > 'Canada's Pharmaceutical Sector' > 'Leading Companies' <https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html> (accessed 27/04/2020)

international, not only domestic markets, may have significant impacts on the innovation, research and development structures of these companies.

(c) The branded pharmaceutical industry

As noted above, both the branded and generic pharmaceutical industries have strong presence in the State. A key tension in between IP rights and access to medicines is that patented medicines are sold at a high price, which makes them unaffordable for those who need them. Therefore, it is pertinent to explore the impact of the branded industry on access to medicines, and whether access to medicines could be enhanced in the State through the branded industry[976]. A 2013 government report on Canada's pharmaceutical industry[977] observed that the Canadian pharmaceutical industry had to transform in order to deal with global pressures on the industry including the expiration of patents for many lucrative medicines[978]. The report stated that the pace of growth of the Canadian pharmaceutical industry has slowed since its peak in 2001[979], with suggested reasons being restrictive pricing for branded and generic pharmaceuticals, and low usage in public medicines plans in the Canadian market[980] due to the level of benefit that such new medicines would provide. This could provide an example of why the cost of medicines is still considered to be excessive for Canadians by the PMPRB and also why there were difficulties in implementing pricing and purchasing strategies under the National Pharmaceuticals Strategy. The report also stated that Canada's market growth in the global pharmaceutical industry would be affected by competition from new emerging markets[981] and suggested that the government should implement tax incentives and subsidies in order to encourage growth[982]. This highlights that enhancing the availability of new, quality medicines is an important factor in improving access to medicines in the

[976] In 2012, seven of the top ten leading pharmaceutical companies in Canada in terms of sales were branded pharmaceutical companies. See J Lexchin, 'Drug pricing in Canada' in ZUD Babar (ed), *Pharmaceutical Prices in the 21st Century*, (Springer, Switzerland 2015), 28

[977] Industry Canada, Government of Canada, 'Canada's Pharmaceutical Industry and Prospects', 2013, ISBN: 978-1-100-23167-9, <https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/hn01768.html> (accessed 27/04/2020)

[978] ibid 5

[979] ibid 6 (Fig.1)

[980] ibid 9-10

[981] ibid 26

[982] ibid

State. Other incentives, in addition to the protection of IP rights, may also be needed to stimulate innovation and development of new medicines in the State.

Proposals to engage in collaborative efforts to improve access to medicines have emerged from the pharmaceutical industry, but there appears to be little evidence of real commitment to implementing measures that promote access to medicines for all. Innovative Medicines Canada is an association of over fifty research-based pharmaceutical companies, and a key aim is to enhance access to new, innovative medicines for Canadian citizens, which is balanced with the aim of ensuring that innovators can rely on the legal protection of their ideas through an enterprising IP system.[983] As part of the objective to develop associations Innovative Medicines Canada together with other stakeholders created the Canadian Consensus Framework for Ethical Collaboration[984], which states that it is intended to promote patients' best interests including by forging effective collaborations between health providers, researchers and the pharmaceutical industry with regard to innovation and knowledge transfer. This also includes developing codes and principles for ethical collaboration, as well as systems for reporting breaches of such standards, to ensure accountability of the respective stakeholders[985].

Leading pharmaceutical companies in Canada such as Apotex and Novartis Canada[986] have corporate social responsibility statements. However, they do not appear to include explicit commitments on promoting or enhancing access to medicines for all. They are also not parties to the UN Global Compact[987], a voluntary initiative of the UN to support companies to adopt social responsibility policies to advance societal aims, such as the UN Sustainable Development Goals[988]. These statements are not binding and there

[983] Innovative Medicines Canada, *2016 Annual Report*, <http://innovativemedicines.ca/wp-content/uploads/2015/05/2016_Annual-Report_Web_EN_Final.pdf> (accessed 27/04/2020), 22
[984] Canadian Consensus Framework for Ethical Collaboration <http://innovativemedicines.ca/wp-content/uploads/2016/06/IMC_CONCENSUS_2016_HR_nobleed.pdf> (accessed 27/04/2020)
[985] ibid 3-4
[986] See also Apotex, 'Corporate Responsibility' <http://www1.apotex.com/global/about-us/corporate-responsibility>; and Novartis Canada, 'Ethical Business Conduct' <https://www.novartis.ca/en/ethical-business-conduct> (accessed 27/04/2020)
[987] United Nations Global Compact, 'Our Participants' <https://www.unglobalcompact.org/what-is-gc/participants> (accessed 27/04/2020); JP Therien and V Pouliot, 'The Global Compact: Shifting the Politics of International Development' (2006) 12 Global Governance 55, 55; J Ruggie 'Reconstituting the Global Public Domain — Issues, Actors, and Practices' (2004) 10(4) European Journal of International Relations 499, 516; J Cohen-Kohler and Laura C Esmail, 'Scientific Misconduct, the Pharmaceutical Industry, and the Tragedy of Institutions' (2007) 26 Med & L 431, 444
[988] United Nations Global Compact, 'Who We Are' > 'Our Mission' <https://www.unglobalcompact.org/what-is-gc/mission> (accessed 27/04/2020)

appears to be little by way of engagement with the Canadian government and relevant stakeholders to develop frameworks to enhance access to medicines through more affordable purchasing structures, or through enhanced accessibility to medicines which are most needed. This highlights difficulties for the State, in seeking to comply with its human rights obligations, to impose obligations on private pharmaceutical companies to promote access to medicines through their business activities. The CESCR also recognised the impact of private business enterprises on the rights enshrined in the ICESCR, expressing concern over the conduct of corporations, particularly as it was difficult to seek access to a judicial remedy as a result of such conduct, and existing accountability mechanisms were not always considered to work efficiently[989]. This highlights the importance of coherence between state actions at national and international level in relation to meeting the State's obligations on medicines under international human rights law. There is evidence of pharmaceutical companies engaging with the issue in relation to voluntary associations, but there appears to be little evidence of these measures resulting in effective outcomes for the promotion of access to medicines, which may be because of their voluntary nature.

The members of Innovative Medicines Canada agree to be bound by its code of ethical practices[990], and the guiding principles of the Code state that the members are expected to be held accountable for their business practices[991]. However the Code also outlines that it "provides a mechanism for Members to establish and maintain an ethical culture through a committed, self-regulated approach"[992], which does not suggest an objective and effective accountability mechanism as envisaged by the UN human rights bodies. The Canadian Generic Pharmaceutical Association (CGPA), which represents manufacturers and distributors of generic pharmaceuticals, has claimed that the Innovative Medicines Canada members, the branded pharmaceutical companies, are failing to meet their commitments on investment in research and development. The 2015 annual report of the PMPRB shows that branded pharmaceutical companies spent around 4.9 percent of their annual revenue on research and development, less than half of the

[989] UNCESCR 'Concluding observations on the sixth periodic report of Canada' (23 March 2016) UN Doc E/C.12/CAN/CO/6, 15

[990] Innovative Medicines Canada, *2018 Code of Ethical Practices*, <http://innovativemedicines.ca/wp-content/uploads/2018/06/Code-Formatted_Regular_EN-2.pdf> (accessed 27/04/2020)

[991] ibid 5

[992] Ibid. See also R Habibi, L Guénette, J Lexchin, E Reynolds, M Wiktorowicz, and B Mintzes 'Regulating Information or Allowing Deception? Pharmaceutical Sales Visits in Canada, France, and the United States' (2016) 44(4) The Journal of Law, Medicine & Ethics 602, 604

agreed commitment of 10 percent promised when the Patent Act was amended in 1987[993]. Therefore, an effective strategy to incentivise branded pharmaceutical companies to reach their commitment to research and development investment needs to be developed.

There also appears little evidence of proposals for a framework to incorporate the UN Guiding Principles on Business and Human Rights[994]. This points to a lack of effective engagement with the recommendations and guidance from UN human rights bodies in relation to the actions of private pharmaceutical companies in the State. Therefore it may be beneficial for Canada to consider the implementation of a National Action Plan in accordance with the Guiding Principles in order to develop policy coherence across the provincial jurisdictions and with the pharmaceutical industry. As of March 2020, twenty-three states[995] have produced a National Action Plan, and another twenty-four states[996] are either in the process of developing a National Action Plan or have committed to doing so. Therefore it could be informative for Canada to learn from the experiences of these states in considering whether to implement a National Action Plan in Canada.

(d) The generic pharmaceutical industry

The generic pharmaceutical industry is of key significance for Canadian health services, and the benefits of generic medicines as cost effective alternatives to branded medicines are recognised within the State. Therefore, it is also important to explore the impact of the generic pharmaceutical industry on access to medicines in the State, and whether

[993] Canadian Generic Pharmaceutical Association, *The Real Story; Research and Development Spending by Brand-Name Drug Companies in Canada 1987-2015,* 1 <http://canadiangenerics.ca/wp-content/uploads/2016/10/TheRealStory_2016_Eng_Web.pdf> (accessed 27/04/2020)

[994] United Nations Office of the High Commissioner for Human Rights, *Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework* (n 494). The Working Group on the issue of human rights and transnational corporations and other business enterprises visited Canada in 2017 but did not make recommendations on medicines or the pharmaceutical industry. See also UNHRC 'Report of the Working Group on the issue of human rights and transnational corporations and other business enterprises on its mission to Canada' (23 April 2018) UN Doc A/HRC/38/48/Add.1

[995] The states are: UK, The Netherlands, Denmark, Finland, Lithuania, Sweden, Norway, Colombia, Switzerland, Italy, USA, Germany, France, Poland, Spain, Belgium, Chile, Czech Republic, Ireland, Luxembourg, Slovenia, Kenya and Thailand. See also United Nations Office of the High Commissioner for Human Rights, 'State national action plans on business and Human Rights' (n 503)

[996] These states are: Argentina, Australia, Azerbaijan, Guatemala, Greece, India, Indonesia, Japan, Jordan, Latvia, Malaysia, Mauritius, Mexico, Mongolia, Morocco, Mozambique, Myanmar, Nicaragua, Pakistan, Peru, Portugal, Uganda, Ukraine and Zambia. See also United Nations Office of the High Commissioner for Human Rights, 'State national action plans on business and Human Rights' (n 503)

access to generic medicines could be enhanced. The pricing of generic medicines in the State is a barrier to access. In 2018 generic medicines were used to fill 71.8 percent of all prescriptions in Canada[997]. Law et al note that Canadians pay the second highest medicines prices[998] and a key issue is that the State does not have a uniform medicines pricing strategy for medicines. However, there is further disparity in relation to the pricing of generic medicines. While the PMPRB regulates price increases of patented medicines[999], in the case of generic medicines provincial governments pay a percentage of the cost of the original patented medicine[1000]. In 2010 an amendment to the pricing of generic medicines was also introduced in Ontario[1001] to reduce the price of generic medicines from 50 percent to 25 percent of the cost of the branded version, and Law et al argue that despite initial concerns from the pharmaceutical sector the measure has reduced expenditure on generic medicines[1002]. Law et al suggest that by moving away from pricing based on the patented medicine to a more competitive market-based system would lead to further reductions in the cost of generic medicines in the province, and across the State[1003]. This could potentially provide an example of the importance of delinking the cost of patented medicines from the cost of generic medicines in order to make generic medicines more accessible for a wider range of people. However this would only be effective if there is more than one generic manufacturer of a particular medicine in demand, in order to generate the competition in the market to keep the costs at an accessible level.

In addition to the cost of generics, maintaining effective availability and accessibility of generic medicines also present challenges to enhancing access to medicines in the State. The CGPA has reported on some of the issues it sees as acting as

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[997] Canadian Generic Pharmaceutical Association, 'Sustainable Healthcare' > 'Market Trends' <http://canadiangenerics.ca/sustainable-healthcare/market-trends/> (accessed 27/04/2020)

[998] M Law, A Ystma and S Morgan 'The Short-Term Impact of Ontario's Generic Pricing Reforms', (2011) PLoS ONE 6(7): e23030. doi:10.1371/journal.pone.0023030, 1

[999] S Morgan, P Thomson, J Daw and M Friesen 'Canadian policy makers' views on pharmaceutical reimbursement contracts involving confidential discounts from drug manufacturers', (2013) 112 Health Policy 248, 249

[1000] This purchasing method originated from compulsory licensing provisions under the Patent Act which were designed to allow generic medicines to compete with patented medicines while such medicines were still under patent, and provincial medicines plans set prices for generics at a percentage of the patented medicine . The compulsory licensing provision was abolished from the Patent Act by the Patent Act Amendment Act 1992 but this pricing method remained across the State. See Law, Ystma and Morgan (n 998) 1

[1001] Law, Ystma and Morgan (n 998) 1

[1002] ibid 3

[1003] ibid

barriers to getting generic medicines to the Canadian markets, such as pressure to reduce costs of generics and Canadian patent laws potentially preventing new generics reaching the market[1004]. This is particularly pertinent in Canada given the data on the usage of generic medicines to fill prescriptions. The CGPA highlighted that Health Canada has an obligation to improve the existing regulatory framework to encourage the introduction of new generic medicines into the Canadian market and "to help ensure that they stay on the market based upon patient demand"[1005]. The CGPA also called on Health Canada to work together to align Canada's regulations on generic medicines with those of other states in order to facilitate global product development[1006] which would in turn benefit generic manufacturers by enabling them to introduce more generic medicines into the market, resulting in lower prices for patients and the Canadian healthcare system. This suggests that the federal government needs to take positive measures to enhance continued access to new generic medicines, and that a change in approach as well as greater collaboration with stakeholders globally could have a positive impact on the accessibility and usage of generic medicines. It could ensure that the State is discharging its national and extraterritorial obligations in relation to enhancing access to medicines under the ICESCR.

A key concern highlighted by the work of the UN human rights bodies in relation to access to medicines is the inclusion of TRIPS-plus standards of patent protection in FTAs, which have a detrimental impact on access to generic medicines. El Said argues that Canada has been "active in perusing an international TRIPS-plus agenda" through its participation in a number of international TRIPS-plus arrangements.[1007] Pursuing such an agenda would be cause for concern in light of the national policy measures discussed

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[1004] Canadian Generic Pharmaceutical Association, *Ensuring a Consistent Supply of Safe, Effective and High Quality Generic Medicines for Canadians*, (Deloitte, 17 October 2016), 22 <http://canadiangenerics.ca/wp-content/uploads/2016/11/10.17.16DeloitteGlobalSupplyChainReport_ENG_FINAL.pdf> (accessed 27/04/2020). See Also A Hollis 'Generic drugs in Canada: an examination of tiered pricing' (2015) 187(14) CMAJ 1033, 1034; K Lynas 'Pharmacists in Canada challenged to deal with drug shortages'(2010) 143(4) CPJRPC 164, 164; A Hollis and P Grootendorst 'Canada's New Generic Pricing Policy: A Reasoned Approach to a Challenging Problem' (2015) 11(1) Healthcare Policy 10, 11

[1005] Canadian Generic Pharmaceutical Association, *Ensuring a Consistent Supply of Safe, Effective and High Quality Generic Medicines for Canadians*, (Deloitte, 17 October 2016), 22 <http://canadiangenerics.ca/wp-content/uploads/2016/11/10.17.16DeloitteGlobalSupplyChainReport_ENG_FINAL.pdf> (accessed 27/04/2020)

[1006] ibid

[1007] M El-Said, 'TRIPS-plus, Public Health and Performance-Based Rewards Schemes Options and Supplements for Policy Formation in Developing and Least Developed Countries' (2016) 31 Am U Int'l L Rev 373, 422

above which focus on health of citizens, in particular on access to medicines, and would cause tension with the State's obligations under the right to health. Canada is a party to two high-profile FTAs. The Comprehensive Economic and Trade Agreement (CETA)[1008] provisionally came into force on 21 September 2017[1009], and the Trans-Pacific Partnership (TPP)[1010] renamed the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)[1011] came into force on 30 December 2018[1012]. The State has been criticised for failing to comply with the recommendations of the UN human rights bodies[1013] to undertake a human rights impact assessment on the impact of the TPP on access to generic medicines.[1014] National reports on the benefits and challenges of the TPP did not make specific reference to the impact of the TPP on access to medicines.[1015] The intellectual property chapter in the TPP caused considerable debate during the

[1008] Government of Canada, 'Text of the Comprehensive Economic and Trade Agreement – Table of contents' <http://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/toc-tdm.aspx?lang=eng&_ga=2.107954882.1188313843.1500217978-411669541.1500217978> (accessed 27/04/2020)

[1009] World Trade Organization, ' EU-Canada' <http://rtais.wto.org/UI/PublicShowMemberRTAIDCard.aspx?rtaid=619> (accessed 27/04/2020)

[1010] Government of Canada, 'Consolidated TPP Text – Table of Contents' <http://international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/tpp-ptp/text-texte/toc-tdm.aspx?lang=eng> (accessed 27/04/2020)

[1011] Center for Strategic and International Studies, 'From TPP to CPTPP', 8 March 2018, <https://www.csis.org/analysis/tpp-cptpp> (accessed 27/04/2020)

[1012] See also: World Trade Organization, 'Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)' (n 352)

[1013] See also; United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) 28; UNCHR 'Report submitted by the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Paul Hunt, Addendum Mission to Peru' (4 February 2005) UN Doc E/CN.4/2005/51/Add.3, 48; UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Peru' (30 May 2012) UN Doc E/C.12/PER/CO/2-4, 25; and UNCESCR 'Consideration of reports submitted by States parties under Articles 16 and 17 of the Covenant Concluding observations of the Committee on Economic, Social and Cultural Rights, Switzerland' (26 November 2010) UN Doc E/C.12/CHE/CO/2-3, 24

[1014] The Canadian HIV/AIDS Legal Network submitted a brief to the House of Commons Standing Committee on International Trade on the TPP in October 2016 as part of its public consultation conducted from February 2016 to February 2017. See Aidslaw/Canadian HIV/AIDS Legal Network, 'Brief to the House of Commons Standing Committee on International Trade on the Trans-Pacific Partnership', 31 October 2016, <http://www.aidslaw.ca/site/brief-to-the-house-of-commons-standing-committee-on-international-trade-on-the-trans-pacific-partnership/?lang=en> (accessed 27/04/2020)

[1015] See also: Parliament of Canada, House of Commons Canada, Report of the Standing Committee on International Trade, *The Trans-Pacific Partnership Agreement: Benefits and Challenges for Canadians* (n 1077); Parliament of Canada, House of Commons Canada, *Government Response to the Sixth Report of the Standing Committee on International Trade*, <http://www.ourcommons.ca/DocumentViewer/en/42-1/CIIT/report-6/response-8512-421-190> (accessed 27/04/2020); Global Affairs Canada (Office of the Chief Economist), Government of Canada, 'Economic Impact of Canada's Potential Participation in the Trans-Pacific Partnership Agreement', <https://international.gc.ca/economist-economiste/analysis-analyse/tpp_ei-re_ptp.aspx?lang=eng> (accessed 27/04/2020)

drafting and negotiations, with sustained criticism from academics and civil society organisations.[1016] Concerns were raised over data exclusivity provisions in Article 18.50 which would have the effect of delaying the entry into the market of generic medicines. For example, exclusivity on undisclosed test data on small-molecule medicines of at least 5 years for new pharmaceutical products plus either 3 years for new indications, formulations or methods of administration or 5 years for combination products containing a chemical entity that has not previously been approved[1017]. Concern was also expressed over wide-ranging civil and criminal penalties for IP rights infringements which go beyond TRIPS[1018]. Several of the IP provisions in the chapter were subsequently suspended[1019]. These provisions include articles on patentable subject matter, test data protection and technological protection measures.[1020] Médécins Sans Frontières argue that the trade ministers negotiating the agreement have "suspended many of the damaging provisions that would have restricted access to medicines and vaccines, a victory for millions of people who rely on affordable medicines worldwide."[1021] The suspension of the provisions is a positive outcome in relation to access to generic medicines. However, by engaging with the recommendations of the UN human rights bodies to undertake impact assessments on health including medicines, before agreeing terms in FTAs, the State could ensure that it is fulfilling its obligations with regard to furthering access to medicines as part of the right to health under Article 12 ICESCR. This also highlights the importance of policy coherence across government departments in relation to enhancing access to medicines.

The text of CETA, an agreement between Canada and the EU, has also produced difficulties in relation to access to generic medicines. Petersen argues that CETA will

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[1016] See examples: D Halbert, 'The Curious Case of Monopoly Rights as Free Trade: The TPP and Intellectual Property and Why It Still Matters' (2017) 7 Journal of Information Policy 204, 218-219; A Kapczynski, 'The Trans-Pacific Partnership - Is It Bad for Your Health?' (2015) 373 New England Journal of Medicine 201, 201; B Baker 'Trans-Pacific Partnership Provisions in Intellectual Property, Transparency, and Investment Chapters Threaten Access to Medicines in the US and Elsewhere' (2016) 13(3) PLoS Med 1, 3; K Weatherall, 'Intellectual Property in the TPP: Not the New TRIPS' (2016) 17 Melb J Int'l L 257, 282

[1017] Pusceddu (n 351) 1059; D Gleeson, J Lexchin, R Lopert, and B Kilic 'The Trans Pacific Partnership Agreement, intellectual property and medicines: Differential outcomes for developed and developing countries' (2018) 18(1) Global Social Policy 7, 16

[1018] Halbert (n 1016) 218-219

[1019] See also: Government of Canada, 'Trans-Pacific Partnership Ministerial Statement' (n 348)

[1020] Government of Canada, 'Trans-Pacific Partnership Ministerial Statement' > 'Annex II – List of Suspended Provisions' <https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptpgp/annex2-annexe2.aspx?lang=eng > (accessed 27/04/2020)

[1021] Médécins Sans Frontières, 'MSF Welcomes Suspension of Harmful Intellectual Property Measures in New TPP Trade Deal' < https://msfaccess.org/msf-welcomes-suspension-harmful-intellectual-property-measures-new-tpp-trade-deal > (accessed 27/04/2020)

require Canada to implement stricter IP protection which will have an impact on the generic pharmaceutical industry, and bring Canada's IP protections into line with other leading economies, in order to continue investment with the EU[1022]. This appears contrary to the recommendations of the UN human rights bodies, including the UN Secretary-General's High-Level Panel, that states should resist the implementation of TRIPS-plus provisions in FTAs[1023]. Bill C-30[1024] which would become the Act to implement CETA into Canadian law, received Royal Assent on 16 May 2017, and contains amendments to the Patent Act which will have an impact on access to medicines. Section 59 of the Bill provides for patent holders to apply for certificates of supplementary protection in order to extend the patent term for a medicinal product[1025] for a maximum of two years[1026]. The purpose of the new system of patent term restoration is to compensate pharmaceutical companies for time lost between the filing of the patent application and receiving approval.[1027] The eligibility criteria for applying for a certificate is fairly wide[1028] and a broad range of medicines under patent may qualify for supplementary protection. This may lead to particular medicines marketed at a higher price for a longer period of time, and delay the entry of generic copies of such medicines to the market by up to two years.[1029] Lexchin and Gagnon argue that the introduction of

[1022] K Broch Petersen, 'A new legal landscape for the pharmaceutical sector? Analysis of articles 20.27 and 20.29 of CETA in context' (2016) 38(8) EIPR 499, 502-503

[1023] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) 27-28. Another example is the recently agreed United States-Mexico-Canada Agreement which requires that Canada increase the period of market protection for new biologic medicines (medicines made from living cells) from eight years to ten years. This could delay biosimilar biologic medicines reaching the market. See also Office of the United States Trade Representative 'Agreement between the United States of America, the United Mexican States, and Canada Text' (n 896) Article 20.49

[1024] Parliament of Canada, *Bill C-30(42-1) An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures*, (Royal Assent 16 May 2017) <http://www.parl.ca/DocumentViewer/en/42-1/bill/C-30/royal-assent> (accessed 27/04/2020)

[1025] ibid Section 59 (S.104-S.134)

[1026] ibid Section 59 (S.115(3))

[1027] El-Said, (n 1007) 415; J Lexchin and M Gagnon, 'CETA and pharmaceuticals: impact of the trade agreement between Europe and Canada on the costs of prescription drugs', (2014) 10 Globalization and Health 30, 3

[1028] Parliament of Canada, *Bill C-30(42-1) An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures*, (Royal Assent 16 May 2017) <http://www.parl.ca/DocumentViewer/en/42-1/bill/C-30/royal-assent> (accessed 27/04/2020), Section 59 (S.104-S.105)

[1029] P Fafard and Patrick Leblond, 'Closing the Deal: What Role for the Provinces in the Final Stages of the CETA Negotiations' (2013) 68 Int'l J 553, 555; J De Beer 'Applying best practice principles to international intellectual property lawmaking' (2013) 44(8) IIC 884, 893; P Grootendorst and A Hollis 'The 2011 Canada-European Union Comprehensive Economic and Trade Agreement: an economic impact assessment of the EU's proposed pharmaceutical intellectual property provisions' (2011) 8(2) Journal of Generic Medicines 81, 86

an extended term of patent protection could increase the total annual cost of patented medicines by 6.2 percent[1030]. Although Lexchin and Gagnon note that the Canadian federal government has stated that it will compensate provinces for the rise in medicine costs for their public medicines plans, they argue that the increased cost is still borne by the Canadian taxpayer, and people who pay for their medicines privately will not benefit from any compensation[1031]. Therefore, the government may be attempting to achieve a balance between implementing the more robust patent rights protection as part of its obligations under CETA, and ensuring that medicines are affordable. However it appears that this strategy will not adequately protect or fulfil the rights of all Canadian citizens in relation to accessing medicines.

There is evidence that the government recognises the concerns of the generic pharmaceutical industry and is attempting to introduce reforms to make it easier for generic manufacturers to produce copies of required medicines, which should benefit citizens as the generic product should be more affordable. Canada and the EU had intended for CETA to be in place provisionally in July 2017. However, a reason for the delay relates to the Canadian government providing clarification on regulatory amendments promised to generic manufacturers, intended to appease the industry as measures in CETA relating to extension of pharmaceutical patent terms would benefit the branded pharmaceutical industry[1032]. Although it has been stated that such regulatory change would occur outside of CETA itself, the pressure from the generic pharmaceutical industry for assurances of an end to 'dual litigation'[1033], had contributed to a delay in meeting the planned implementation date. This highlights a key problem faced by generic manufacturers in the production of generic medicines, and is an example of a potential conflict with branded pharmaceutical companies which could continue over a prolonged period of time.[1034] This also highlights that the government is trying to balance the interests of the branded and generic pharmaceutical industries at national level. However, a more central focus on the needs of patients, and greater alignment of national health and

[1030] Lexchin and Gagnon (n 1027) 4
[1031] ibid 5
[1032] J McGregor, 'CBC News: More trouble for Canada-EU trade deal, as drug changes delay implementation' 28 June 2017 <http://www.cbc.ca/news/politics/ceta-provisional-application-pharmaceutical-litigation-1.4179676> (accessed 27/04/2020)
[1033] 'Dual litigation' is a system which allows two proceedings between the same parties over the same patent and medicine.
[1034] A Falconi 'CETA: An Opportunity to Fix Canada's Broken Pharmaceutical Patent Linkage System' (2015) 27(3) Intellectual Property Journal 325, 328-329; Grootendorst and Hollis (n 1029) 88

trade policies, could ensure that the State takes full account of its human rights obligations in relation to access to medicines when negotiating such agreements.

(e) Conclusions from Section III

The review of the pharmaceutical industry in the state highlights that the high prices of branded and generic medicines is a key issue in the State. This means that ensuring consistent access and availability of medicines could present a challenge. The PMPRB is an important mechanism to promote access to medicines. However, the agreeing of TRIPS-plus measures in FTAs reflects a lack of consistency across government departments on policies relating to medicines. The State should ensure that its international obligations on health and access to medicines are taken into account when developing policy and decision-making impacting on access to medicines, to achieve a more balanced approach in line with its obligations under TRIPS and the ICESCR.

IV. Conclusion

In Canada, there are several federal and provincial government measures to try to reduce the cost of medicines to try to improve access to medicines within the State, and also in developing states. Good practices in relation to improving affordability of medicines include the PMPRB, which regulates pricing of patented medicines, to protect consumers from excessive pricing. The State also introduced legislation resulting in CAMR, which intended to improve access to medicines for developing states in Africa. Although these measures may not conclusively be described as successful, they demonstrate that the State has understood its responsibilities with regard to the implementation of TRIPS and the Doha Declaration. These measures also demonstrate that the State has recognised its human rights obligations on health, including access to medicines, by introducing standards to address some key problems affecting access. The practices of this State could also prove informative for other states that may consider implementing similar regimes and could learn lessons from Canada's experiences.

Canada is a net importer of pharmaceuticals and therefore strong IP rights protection may incentivise business enterprises to innovate and manufacture new medicines in Canada to grow domestic production, while increased competition from imports may contribute to lower prices of medicines. However, the cost of medicines

means that they are not accessible to all. There is no accountability mechanism which could be utilised by the State to hold companies accountable in relation to their social responsibility to enhance access to medicines, in compliance with the State's UN human rights obligations. Promotion of generic medicines is the main policy to improve affordability, but appropriate pricing strategies are needed to enhance access to generic medicines. It is evident that TRIPS-plus provisions have an adverse effect on the accessibility of cheaper generic medicines, although it appears that Canada and the other state parties to the CPTPP have addressed this concern by suspending several TRIPS-plus provisions in the CPTPP. The study also highlights the need for states to consider specific issues relating to access to medicines affecting minority groups, such as the gaps in the provision of services of prescription medicines for indigenous peoples and a specific need to protect traditional knowledge and medicines. Therefore, the position of social and economic rights in the Canadian legal system could be strengthened to take full account of the State's obligations under the right to health, and access to medicines.

The issues experienced in Canada highlight that enhancing effective access to medicines in Canada is a cross-jurisdictional issue with the federal government and the provincial governments all having significant roles. This has led to some disparities and inconsistencies in the level of provision of medicines across Canada, with variations in accessibility in different provinces. It could be argued that this reflects global disparities in securing access to medicines for all. While a single solution may not be suitable to address a complex issue, there may be a need for international collaboration between states on policy development, and an enhanced understanding of states' obligations in the context of rights in order to further improve access to medicines within their own state, and also extraterritorially. Despite the lack of an enforcement mechanism at international level, states have made commitments to uphold the rights within the ICESCR. Translating those commitments into effective national policy is crucial to further the enhancement access to medicines in a rights-based context.

Chapter 6: Case Study – Peru

Introduction

The subject of the second case study in this thesis will be Peru. As in the previous case study on Canada, this chapter will examine whether the State appreciates the interaction between its human rights obligations and obligations under TRIPS at national level, and evaluate how the State is addressing possible tensions in order to discharge its obligations simultaneously under TRIPS and the ICESCR. This study will primarily focus on reviewing national legislation, policy documents and related case law, and will refer to relevant academic literature in the analysis of the findings. Issues including the nature of Member States' human rights obligations on access to medicines, TRIPS-plus provisions and the impact of the private pharmaceutical sector, will be examined. The study will evaluate how state practice at national level might inform understanding of key issues on reconciling obligations under TRIPS and ICESCR. The study will also consider if there are examples of good practice to other states in effectively meeting their obligations.

As with the first case study, the methodology for selecting the state that will be the subject of this case study involves identifying the states which are WTO Members and have ratified the ICESCR, and applying the series of indicators in the form of the table set out in Annex II. The first indicator was which countries were classified as developed or developing[1035], and EU Member States were excluded as in the methodology in the previous case study[1036]. As is evident from the table in Annex II, there were a high number of states that are classified as developing. The next step involved identifying the countries that were net importers of pharmaceuticals and which were net exporters of pharmaceuticals[1037], which highlighted that most of the developing countries are net importers. Therefore, in order to narrow the field of potential states, further indicators had to be applied. The next indicator applied was states that had received a visit from the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health. This indicator was selected because by engaging with the relevant stakeholders and primary sources, the Special Rapporteur may have identified specific issues with regard to access to medicines in that State. Therefore

[1035] Data obtained from UN, *World Economic Situation and Prospects 2015* (n 807) 139-140
[1036] See Chapter 5, *Introduction*
[1037] UN COMTRADE Database (n 808)

the Special Rapporteur's report may be informative to other developing States to ensure that they meet their human rights obligations. By applying this indicator, the potential states were narrowed considerably. Peru was then selected as a case study because the State has adopted a range of measures to give effect to the right to health at national level, such as the inclusion of the right to health in its Constitution[1038]. Peru's participation in the Medicines Transparency Alliance project, which aimed to address challenges in accessing essential medicines, also highlights the validity of selecting this State as a case study, particularly as the State was selected due to its willingness to enhance access to medicines.

The first section of this study will examine the constitutional framework of the State to explore the extent to which the State has complied with its human rights obligations in relation to the right to health and access to medicines. The second section of this study will analyse specific measures implemented by the State to address the pricing of medicines, to evaluate whether they could enhance access to medicines. The third section will explore specific challenges in relation to access to generic medicines in the State and whether possible tensions may arise between the State's obligations under TRIPS and the ICESCR. The fourth section will examine the health policy measures on access to medicines, particularly for the most marginalised groups, to evaluate whether state policy is addressing wider issues which need to be considered to enhance access to medicines for these groups within the State. The fifth section will conclude by evaluating the findings from this study.

I. National Constitutional measures impacting upon access to medicines

The Constitution of Peru[1039] and its interpretation by the Constitutional Court provides an important example of the State's political commitment to enhancing access to medicines and its engagement in measures to promote this. The current Political Constitution of Peru[1040] came into force in 1993 and sets out the rights and duties of citizens. The right

[1038] The right to health is included in the Political Constitution of Peru. See also: Political Constitution of Peru 1993, <http://www.wipo.int/wipolex/en/details.jsp?id=6544> (accessed 27/04/2020); (English translation <http://www.congreso.gob.pe/Docs/files/CONSTITUTION_27_11_2012_ENG.pdf> (accessed 27/04/2020))

[1039] ibid

[1040] ibid

to protection of health is recognised in Article 7 of the Constitution[1041], which states that there is also a duty on citizens to contribute to its protection. Article 7 states that:

"Everyone has the right to protection of his health, his family environment, and his community, just as it is his duty to contribute to their development and defense. Any individual unable to care for himself due to physical or mental disability has the right to respect for his dignity and to a regime of protection, care, rehabilitation, and security."[1042]

A literal interpretation of this provision indicates that the right does not amount to a right to good health, but a right to achieve the highest level of health possible in the State, and have access to appropriate services to do so. This is comparable with the guidance on the normative content of Article 12 ICESCR[1043], set out in General Comment 14[1044], indicating that the State has understood the nature and content of the right to health under Article 12 ICESCR and this is reflected in the Constitution. Therefore, the national right to health is in line with international standards. Article 9 of the Constitution[1045] provides that the State is responsible for determining national health policy to provide equal access to all health services, and Article 11 provides that free access to health benefits is guaranteed by the State, through public, private or mixed entities[1046]. These articles do not explicitly include reference to medicines, although there is reference to health services, which include the provision of medicines.

The State has constitutional obligations to ensure that the right to health of the population is fulfilled. Sanchez-Moreno argues that the rights within the Constitution have not been embedded[1047], and due to the unstable political landscape[1048] of the State,

[1041] ibid Article 7
[1042] ibid
[1043] The ICESCR was ratified by Peru in 1978. See also United Nations Office of the High Commissioner for Human Rights, 'Status of Ratification Interactive Dashboard'(n 539)
[1044] General Comment No. 14 (n 112) 8
[1045] Political Constitution of Peru 1993 (n 1038) Article 9
[1046] Political Constitution of Peru 1993 (n 1038) Article 11
[1047] Peru is a dualist State. M Sanchez-Moreno, 'When a "Constitution" is a Constitution: Focus on Peru' (2001) 33(2) New York University Journal of International Law and Politics 561, 564
[1048] K Weyland, *The Politics of Market Reform in Fragile Democracies: Argentina, Brazil, Peru and Venezuela*, (Princeton University Press, Princeton and Oxford, 2002), 12-13; Congressional Research Service Report for Congress, 'Peru: Political Situation, Economic Conditions and U.S. Relations', RS22715, 6 September 2007, 1 <http://www.dtic.mil/dtic/tr/fulltext/u2/a472693.pdf> (accessed 27/04/2020)

the Constitution does not occupy a stable and authoritative position[1049]. Sandoval and Cáceres also state that the right to health is treated as a national aspiration rather than an entitlement that can be enforced against the State.[1050] The right to health is not contained in the first chapter of fundamental rights, but in the second chapter of social and economic rights[1051], which highlights that the status of the right to health within the Constitution does not amount to a fundamental right. Therefore, this suggests that the status of this principle is that it is not legally enforceable, but is instead a directive principle of State policy. However, the manner in which these provisions have been interpreted by the national courts provides authoritative guidance on the status of the right to health, and access to medicines in the State. The Constitution establishes a Constitutional Court which has a duty to hear writs of unconstitutionality[1052]. Several key decisions of the Constitutional Court in relation to the constitutional right to health have been instructive in clarifying the State's obligations in relation to the health of the population under the Constitution.

(a) *Azanca Alhelí Meza García [2003] 02945-2003-AA/TC*

When adjudicating on a petition against the Ministry of Health to provide medical care to an HIV/AIDS patient in *Azanca Alhelí Meza García [2003] 02945-2003-AA/TC*[1053], the Court considered whether the State had an obligation to provide comprehensive medical care for the protection of health, under Article 7 and Article 9[1054] of the Constitution.

(i) Access to medicines as part of the right to health in the Constitution

[1049] Sanchez-Moreno (n 1047) 593. A recent example of the political landscape in Peru is that in March 2018 the sitting President Pedro Pablo Kuczynski resigned amid allegations of corruption, and divisions in the government. See also BBC News, 'Peru political turmoil: President Martín Vizcarra sworn in', 23 March 2018, <https://www.bbc.co.uk/news/world-latin-america-43523076> (accessed 27/04/2020)
[1050] C Sandoval and CF Cáceres, 'Influence of health rights discourses and community organizing on equitable access to health: the case of HIV, tuberculosis and cancer in Peru' (2013) 9:23 Globalization and Health, doi:10.1186/1744-8603-9-23, 2
[1051] Political Constitution of Peru 1993 (n 1038) Chapters 1 – 2
[1052] Political Constitution of Peru 1993 (n 1038) Articles 201-205
[1053] Azanca Alhelí Meza García [2003] 02945-2003-AA / TC, Lima, Peru, (English translation <http://www.globalhealthrights.org/wp-content/uploads/2013/08/2945-2003-AA-TC-ENGLISH.pdf> (accessed 27/04/2020)
[1054] Article 9 states that 'The State determines the national health policy. The Executive Branch sets standards for and oversees its enforcement, and it is responsible for drafting and directing it in a pluralistic, decentralizing manner to facilitate equal access for everyone to health services. See Political Constitution of Peru 1993 (n 1038)

In this case, the Court took the approach of protecting the right to health by way of its connection with the fundamental right to life. The case involved a patient diagnosed with HIV/AIDS who argued that since her diagnosis she had not received comprehensive medical care, including appropriate medicines. It was also argued that in this case the State was not fulfilling its obligations to care for the health of the population, as compared with the treatment provided to patients with other diseases such as tuberculosis, in accordance with Article 7[1055]. In reaching its decision, the Constitutional Court stated that the right to health is not considered to be a fundamental right, but when the violation of the right to health compromises other fundamental rights, such as the right to life, this right acquires the character of a fundamental right[1056]. The Court stated that the right to health has an inseparable relationship with the right to life, so the State must protect this by strengthening health services[1057], and that the Article 7 right includes medical assistance, to the level allowed by public resources[1058]. This is a key statement as it indicates that the State is obliged to take positive measures to fulfil the right to health, and that this right includes provision of medical services, such as medicines. This also provides that treating life limiting or serious diseases such as HIV/AIDS including through provision of antiretroviral drugs, is an example of the situations where the Court will consider that if the non-fundamental right to health has been infringed, this provides an indicator that a fundamental right has been breached.

The Court's approach to treating the right to health as fundamental in this case also raises the issue of clarity around terminology. The Court is applying a specific meaning to "fundamental rights" in this case by categorising the right to health as a fundamental right due to the proximity to the right to life, which is a fundamental right. Problems with justiciability of social and economic rights include that such rights are too vaguely worded to be justiciable and the realisation of such rights depends on government policy[1059]. Therefore such rights are normally placed in a different section to fundamental

[1055] Azanca Alhelí Meza García (n 1053) Background
[1056] ibid 6
[1057] ibid 28
[1058] ibid 30
[1059] See also M Ssenyonjo, *Economic, Social and Cultural Rights in International Law*, (Hart Publishing, Oxford and Portland, Oregon, 2009), 5; Office of the High Commissioner for Human Rights, 'Key concepts on ESCRs - Can economic, social and cultural rights be litigated at courts?', <https://www.ohchr.org/en/issues/escr/pages/canescrbelitigatedatcourts.aspx> (accessed 27/04/2020)

rights in national constitutions, with Peru's national Constitution an example of this[1060]. This case illustrates the interdependence and indivisibility of rights and how the linking of rights can deliver tangible benefits for the individual when deployed by national courts. However it also highlights the uncertainty around the characterisation of the right to health as a fundamental right, as this right can only be enforced if the right to life has been infringed. Therefore the fragility of the enforceability of the right to health is evident as it is dependent on the degree of proximity to the right to life in each case. This presents difficulties for patients to identify whether they will be able to seek a remedy for a breach of their right to health in their national court. The ability of patients to pursue a remedy in their national court is significant as this would be more effective due to time and cost concerns.

The Special Rapporteur on the right to health observed that Peru was one of only four states parties that recognised access to essential medicines as a fundamental right[1061]. This suggests that the Court's interpretation of the right to health to include access to essential medicines, and the interpretation of the right to health as a fundamental right because of its close link to the right to life, has elevated access to essential medicines to the level of a fundamental right in specific cases. It is important to reiterate that access to essential medicines is not explicitly detailed in the Constitution, so this statement on the national position in Peru by the Special Rapporteur merits some qualification. However, the Court's interpretation of the right to health indicates that there is scope for the treatment of the issue of access to essential medicines as forming part of a national constitutional right. Therefore the recognition of this position by the Special Rapporteur highlights positive actions by the national court to enhance access to essential medicines in a rights-based context, and could provide an example to other states that have obligations under the ICESCR.

The Constitutional Court also appreciated the interaction between IP rights under TRIPS and human rights in relation to access to medicines at national level. The Court noted the State's commitments under TRIPS as a WTO Member[1062], observing that

[1060] Political Constitution of Peru 1993 (n 1038)

[1061] The other States being Mexico, the Philippines and the Syrian Arab Republic. See also UNHRC 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Expert consultation on access to medicines as a fundamental component of the right to health' (16 March 2011) UN Doc A/HRC/17/43, 14

[1062] World Trade Organization, 'Understanding the WTO: The Organization; Members and Observers' (n 806)

although IP protection is important for the development of new medicines, there are obvious concerns about the effect of such protection on prices[1063]. To address this tension, the Court called on the State to utilise the TRIPS flexibilities to fulfil its national objectives, including the transitional provisions.[1064] This demonstrates the value of embedding rights into national law, and also demonstrates the interplay between national and international mechanisms. This also indicates that securing access to new essential medicines in the State is a key concern, and that the pricing of such medicines may be prohibitive in terms of securing access to such medicines for the whole population.

(ii) The State's obligations under the constitutional right to health

The Court also set out the parameters of the State's obligations under the right to health. The Court emphasised that the economic and social rights within the Constitution are not to be considered as merely a declaration of good intentions, but as a commitment to clear and realistic goals[1065]. This highlights that although the right to health, including access to medicines, is not enforceable as a fundamental right under the Constitution, it is not enough to treat such rights as mere aspirations and the State must set genuine and achievable objectives for the fulfilment of this right. The Court recognised that as a developing country it is difficult to provide immediate policies for the benefit of the whole population, as such social rights depend on the means and resources available to the State[1066]. This is consistent with General Comment 14 which states that the ICESCR provides for the progressive realisation of the right to health[1067], further highlighting the comprehension of the normative content of the Article 12 right to health by the national court. This supports the embedding of international standards into national law so that they can provide effective remedies. However, the Court also stated that this is only a valid justification when the State does take positive actions to achieve fulfilment of this right as far as possible, such as care for low-income and poverty groups[1068], and that prolonged inaction cannot be justified as this would result in a constitutional omission[1069].

[1063] Azanca Alhelí Meza García (n 1053) 40
[1064] ibid 41-42
[1065] ibid 38
[1066] ibid 39, 49
[1067] General Comment No. 14 (n 112) 30-31
[1068] Azanca Alhelí Meza García (n 1053) 39
[1069] ibid 49

Therefore this highlights that although the State's level of development may cause limitations to the measures that the State is capable of implementing to achieve the highest attainable standard of health for the whole population, this is not a justification for taking no action. Such inaction would be contrary to the Constitution itself, and the State will be accountable for such failure to take steps to fulfil this right.

The outcome of this case was that the Court recommended that the State take tangible actions to achieve the patient's right to health, such as ensuring essential HIV/AIDS treatment, including medicines. Noriega argues that this is a significant case as the Court fully adopted the approach of protecting the right to health through its linkage with other fundamental rights, and in doing so the Court is developing a norm for the legal protection of the right to health through the protection of related constitutional fundamental rights[1070]. In this case the Court is setting a precedent for the legal enforceability of the right to health, through its link to other fundamental rights such as the right to life, under the national Constitution. The decision also emphasises that the right to health includes the provision of essential medicines, and therefore this case may also provide scope for legal enforceability of access to essential medicines as part of the right to health under the Constitution.

(b) *RJSA Vda. of R. [2007] 03081-2007-PA/TC*

In *RJSA Vda. of R. [2007] 03081-2007-PA/TC*[1071], which related to the care of a patient diagnosed with a mental health condition, the Court reiterated that the constitutional right to health did not amount to a right to be healthy, but guarantees access to adequate, quality health services, as far as public resources allow.[1072] This interpretation is consistent with the Court's interpretation in the *Azanca Alhelí Meza García* case[1073]. The Court stated that the enforceability of a social right always depends on three factors: the seriousness and reasonableness[1074] of the case; its connection with other fundamental rights; and budget availability.[1075] This suggests that there are qualifications to the constitutional

[1070] AI Noriega, 'Judicial review of the right to health and its progressive realisation: the case of the Constitutional Court of Peru' (2012) 1(1) UCL Journal of Law and Jurisprudence 166, 180
[1071] RJSA Vda. of R. [2007] 03081-2007-PA/TC, Lima, Peru
[1072] ibid 19
[1073] Azanca Alhelí Meza García (n 1053)
[1074] The Court did not outline the meaning of the term "reasonableness" in this context.
[1075] RJSA Vda. of R. (n 1071) 23

right to health being framed as a fundamental right, and the seriousness of each particular case would have to be justified in order to be able to enforce the right to health.

This test stemmed from the *Azanca Alhelí Meza García* case[1076], where the Court outlined that social and economic rights are how individuals can achieve full self-determination, and that the realisation of socio-economic rights and civil and political rights are interrelated and interdependent.[1077] Therefore, the Court stated that the State must establish basic public services as a minimum of action.[1078] Further, the Court stated that social rights must be interpreted as genuine claims of the citizen against the State if the legal effectiveness of the Constitutional mandates, and therefore the validity of the Constitution, is to be recognised.[1079] Although social rights are to be progressively realised the State is required to take concrete and quantifiable steps to implement public policies that ensure their realisation.[1080] The Court recognised that social rights cannot be demanded in the same way in all cases, due to budget constraints, and so judicial enforceability of social rights will depend on factors such as the seriousness and reasonableness of the case; its connection with other rights and the budgetary availability of the State, as long as concrete actions on its part can be verified.[1081]

The Court in *RJSA Vda. of R.*[1082] took this further, stating that the three factors outlined above must be taken into account, notwithstanding the progressive nature of the right to health in terms of budgetary considerations.[1083] Therefore, this test has evolved from examples of factors which should be considered, to factors that must be taken into account. Florian is critical of this approach, arguing that there are ambiguities regarding the determination of how social rights can be claimed in judicial proceedings.[1084] Florian argues that challenges could arise where there is no specific protection of a social right, or where such a right has not been recognised in any budget.[1085] These cases did not

[1076] Azanca Alhelí Meza García (n 1053)
[1077] ibid 10-11
[1078] ibid 12
[1079] A Oquendo, 'The Solitude of Latin America: The Struggle for Rights South of the Border' (2008) 43 Tex Int'l L J 185, 199-200; Azanca Alhelí Meza García (n 1053), 13
[1080] A Jenkins and S Ardalan, 'Positive Health: The Human Right to Health Care under the New York State Constitution' (2008) 35 Fordham Urb LJ 479, 509; Oquendo (n 1079) 200
[1081] Azanca Alhelí Meza García (n 1053), 32-33
[1082] RJSA Vda. of R. (n 1071)
[1083] ibid 23
[1084] F Florian 'The right to health in jurisprudence of the Peruvian Constitutional Court' (2014) 19Constitutional Thought 389, 407-408
[1085] ibid 408

elaborate on how this test should be applied, and the Court in *RJSA Vda. of R.*[1086] also did not elaborate on its reasoning for adopting the factors set out in the *Azanca Alhelí Meza García* case[1087] as a legal test. Therefore, it could be said that the Constitutional Court has not addressed all issues which could arise when applying this test. However, these cases do show that the Court has taken positive steps in achieving more comprehensive protection of health challenges, including access to medicines, and in cases where vulnerable individuals were affected.

As noted in the *Azanca Alhelí Meza García* case[1088], the Court highlighted that the right to health was to be protected because of its intrinsic connection with the right to life in that case. It is important to appreciate that the right to life is distinct from a patient's quality of life, which although important to the patient, is a subjective standard of wellbeing and cannot be described as a fundamental right. Therefore, as the right to health is not fundamental, it can only be protected in specific cases which have a strong right to life element, underlining the fragility of the protection of the right to health determined by the Court.

(i) The State's obligations v. resource constraints

The Court also observed that the close connection between life and health is recognised in domestic law and in international human rights law, to the extent that budget constraints cannot amount to a legitimate argument for denying a person health benefits, in such a way that their right to life is put at risk.[1089] Therefore a state's failure to comply with its obligations under the right to health due to lack of resources is not justifiable where this could result in a potential violation of the right to life. The patient's life could potentially have been at risk in this case as her antipsychotic medication was associated with a potentially life-threatening condition[1090]. The patient therefore required regular monitoring and a person with capacity to be in control of her medication[1091]. Therefore the Court recognised the State's international human rights law obligations in relation to resource availability, and is consistent with the position in General Comment 14. The

[1086] RJSA Vda. of R. (n 1071)
[1087] Azanca Alhelí Meza García (n 1053)
[1088] Azanca Alhelí Meza García (n 1053)
[1089] RJSA Vda. of R. (n 1071) 23
[1090] ibid 59-60
[1091] ibid 65

right to health also has real and meaningful content even though it is not a fundamental right.

General Comment 14 emphasises that if it is impossible for a State to comply fully with its obligations under Article 12 due to resource constraints, it has to justify that every effort has been made to use all available resources at its disposal in order to satisfy its obligations.[1092] Therefore if the State potentially has not fulfilled its obligations under Article 12, the burden of proof is on the State to show that it has taken positive actions to fulfil its obligations as far as possible, and utilised the maximum resources available to do so[1093]. This is also consistent with the recommendation of the Special Rapporteur that the State should develop a "pro-poor equity-based health policy"[1094] and allocate greater financial resources to the health sector in line with such a policy[1095], and the health national policy measures taken by the State as discussed above. General Comment 14 also goes further, stating that a State which is unwilling to use its maximum available resources for the realisation of the right to health is in violation of its obligations under Article 12.[1096] This indicates that if a State cannot discharge this burden, and therefore cannot justify the failure to utilise its available resources to fulfil its obligations under the Article 12 right to health, it could be in breach of those obligations. The Court's interpretation of the State's duty to utilise maximum resources available to meet its obligations under the right to health in national and international law, is therefore consistent with the State's UN human rights obligations.

(ii) The State's obligations in relation to medicines

This case outlined that lack of access to essential medicines is a concern in the State, in this case particularly for mental health conditions. In addition to outlining the State's responsibilities under the right to health, the Court also noted that the Ministry of Health

[1092] General Comment No. 14 (n 112) 47
[1093] General Comment 14 also goes further, stating that a State which is unwilling to use its maximum available resources for the realisation of the right to health is in violation of its obligations under Article 12. This indicates that if a State cannot discharge this burden, and therefore cannot justify the failure to utilise its available resources to fulfil its obligations under the Article 12 right to health, it could be in breach of those obligations. See also General Comment No. 14 (n 112) 47
[1094] UNCHR 'Report submitted by the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Paul Hunt, Addendum Mission to Peru' (4 February 2005) UN Doc E/CN.4/2005/51/Add.3, 28
[1095] ibid 38
[1096] General Comment No. 14 (n 112) 47

Ministerial Resolution No. 0943-2006-MINSA[1097] identified one of the main problems affecting mental health care in relation to the State's response as being limited access to health services and medicines[1098]. The inclusion of this statement in a ministerial resolution of the national health department reflects that securing access to medicines does form part of the provision of adequate health services, in accordance with the State's responsibilities under the constitutional right to health, as well as its UN human rights commitments.

The Court stated that the Ministry of Health should consider an expansion to the free delivery of medicines to ensure equitable access to medicines and taking into account limited resources[1099]. This reinforces that the cost of medicines is an issue identified as a potential barrier to accessing medicines in the State. This also identifies that the delivery of medicines should be a priority in the national budget, providing an example of how the Court applied the third factor of the enforceability test outlined above, being budget availability, in relation to medicines. The reference to equitable access underlines that the poorer regions may be particularly affected by lack of access, and that providing equitable access is particularly important where the State, as a developing country, has limited resources. As noted above, the Court identified that although the State may take into account its budget and resources constraints, this cannot amount to a justification not to fulfil the right to health. Therefore, the State should take actions to fulfil its national and international human rights obligations by securing access to essential medicines as far as the maximum available resources permit.

The Court also stated that for people who do not have economic capacity, the Ministry of Health must develop policy that allows access to medicines through adequate prices, as well as sufficient regulation of medicines to guarantee effective and quality medicines[1100]. This is consistent with the recommendation of the Special Rapporteur on health to develop a "pro-poor equity-based health policy"[1101], and suggests that equitable access to quality medicines should be a key element of such policy, to secure access for poor and vulnerable groups. This also highlights the importance of ensuring the

[1097] Ministerio de Salud/Ministry of Health Ministerial Resolution No. 0943-2006-MINSA, 6 October 2006, <ftp://ftp2.minsa.gob.pe/normaslegales/2006/RM943-2006.pdf> (accessed 27/04/2020)
[1098] RJSA Vda. of R. (n 1071) 42. See also Ministerial Resolution No. 0943-2006-MINSA (n 1097) P.21
[1099] RJSA Vda. of R. (n 1071) 43.F
[1100] ibid
[1101] UNCHR 'Report submitted by the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Paul Hunt, Addendum Mission to Peru' (4 February 2005) UN Doc E/CN.4/2005/51/Add.3, 28

availability of medicines of appropriate quality in the State, which can be achieved through regulatory mechanisms. The outcome of the case was that the patient was granted indefinite medical care, including the provision of essential medication for the treatment of her mental health condition. The decision of the Court indicates that, in fulfilment of its obligations in relation to the patient's constitutional right to health, the State has a duty to provide the essential medicines required by the patient as part of her ongoing mental health care.

This is a significant decision as the Court held that the patient had a right to access medicines necessary to her care, as part of her constitutional right to health. Also, her constitutional right to health was enforced against the State, requiring the State to take positive measures to fulfil its obligations to her. This could potentially be a useful decision in terms of clarifying the State's constitutional responsibilities on ensuring access to essential medicines, and highlighting that the Constitutional Court's interpretation of this right in this case was consistent with the State's international human rights commitments. This is also an important decision as it demonstrates the tangible benefits of Peru's approach to interpreting the right to health for the patient. The decision resulted in the necessary medicines being secured for the patient's care, and the test for enforceability of a social right applied by the Court was therefore effective in enhancing access to medicines in this case. Therefore this test could be a useful tool for courts in other jurisdictions to utilise when adjudicating on access to medicines and the competing obligations of the state with regard to the right to health and TRIPS.

(c) Other relevant decisions of the Constitutional Court

The Constitutional Court has also emphasised the significance of the link between the right to health and other fundamental rights in subsequent cases. In *Teofanes Ronquillo Cornelio [2007] 06057-2007-PHC/TC*[1102], where the appellant was not transferred to the favoured hospital to receive the optimum treatment for the diagnosed condition, the Court referred to the *Azanca Alhelí Meza García* case[1103], and highlighted that the right to health is inseparable from the right to life, so it is a fundamental right.[1104] The Court also stated that the State has a duty to guarantee the right to health, including by taking positive

[1102] Teofanes Ronquillo Cornelio [2007] 06057-2007-PHC/TC, Lima, Peru
[1103] Azanca Alhelí Meza García (n 1053)
[1104] Teofanes Ronquillo Cornelio (n 1102) 8

actions to promote the right.[1105] This position was also stated in *Carlos Gonzales La Torre [2010] 03425-2010-PHC/TC*[1106] where, although the case related to the hospitalisation of a prisoner and did not present a direct right to life or right to health issue, the Court outlined that the right to health is necessary for the exercise of the right to life itself, and has an inherent connection to the right to life, right to personal integrity and other fundamental rights that forms the right to health as an undeniable fundamental right.[1107] These decisions emphasise the importance of the right to health in terms of fulfilling the right to life, and also indicate that the close connection between the two rights elevates the right to health to the status of a fundamental right through the interpretation of these constitutional rights by the Constitutional Court. This interpretation is also consistent with the *Azanca Alhelí Meza García [2003] 02945-2003-AA/TC*[1108]case, suggesting that a body of jurisprudence on this issue has emerged in relation to the content and interpretation of the State obligations in relation to the constitutional right to health. This indicates that citizens can enforce their right to health against the State, in circumstances where they can show that there is a risk to their right to life if their right to health is not fulfilled. Therefore if the State fails to secure access to essential medicines in accordance with the constitutional right to health of its citizens, this delivers an accountability mechanism in addition to the State's UN human rights obligations[1109].

The Constitutional Court has sought to ensure the close alignment of national Constitutional rights with international human rights norms in cases involving human rights arguments. This has been observed by the CESCR, which has noted that Peru "had made huge advances in the constitutional interpretation of human rights"[1110]. This is a key statement which emphasises the importance of the national courts in interpreting the national and international human rights obligations of the State. The CESCR's concluding observations in 2012 noted that the Constitutional Court had issued several

[1105] ibid 12
[1106] Carlos Gonzales La Torre [2010] 03425-2010-PHC/TC, Lima, Peru
[1107] ibid 6
[1108] Azanca Alhelí Meza García (n 1053)
[1109] See also Chapter 2, *(iii) State obligations in relation to the actions of pharmaceutical companies;* and *III. United Nations Human Rights Treaty Monitoring Bodies*; and Chapter 3, *II. Expert consultation on access to medicines;* and *United Nations Secretary-General's High-Level Panel on Access to Medicines, (a) Recommendations of the Panel*.
[1110] UNCESCR 'Summary record of the 6th meeting; Consideration of reports (a) Reports submitted by States parties in accordance with articles 16 and 17 of the Covenant (continued), Combined second to fourth periodic reports of Peru' (9 May 2012) UN Doc E/C.12/2012/SR.6, 19

innovative judgements that had enriched constitutional law, and recognised that international human rights treaties were of immediate application[1111]. The concluding observations further noted that the Constitutional Court had on several occasions applied an expanded interpretation of the Article 12 right to health set out in General Comment 14[1112]. This is evident in several of the cases discussed above, and highlights that the Constitutional Court is engaging with the guidance of the UN human rights bodies on the State obligation in relation to the right to health, including access to medicines. This also highlights that this engagement has been recognised and supported by the relevant UN Treaty Monitoring Body, and provides an example of good practice to other Member States in the interpretation of international human rights commitments on health at domestic level. The State representative stated that the right to health care was guaranteed under the Constitution and the ICESCR and other international human rights treaties had been invoked in health-related cases before the Constitutional Court[1113]. This statement further reinforces that the national Constitutional Court provides recourse for citizens to enforce their human rights against the State domestically, and provides accountability and a remedy where the State has infringed their rights.

(d) Conclusions from Section I

The jurisprudence of the Constitutional Court shows that the Court is taking full account of the right to health under the Constitution in cases relating to access to medicines, and its interpretation of the right is in line with the State's obligations under Article 12 ICESCR right to health. These cases show the advantages of taking a rights-based approach to access to medicines, as this approach did enhance access to medicines for the patients concerned. The *RJSA* case also demonstrates the value of embedding rights from an international source into the national legal landscape. This jurisprudence also provides a good example of individuals enforcing their human rights at national level, providing a measure of accountability for the State to uphold its national and international obligations in relation to the right to health and access to medicines.

II. Measures to address the pricing of medicines

[1111] ibid 19
[1112] ibid 19
[1113] ibid 34

(a) The Medicines Transparency Alliance

There is evidence that Peru is willing to engage with concerns over the accessibility and affordability of medicines, with its participation in the Medicines Transparency Alliance project[1114]. The project "aimed to redraw the landscape of the pharmaceutical market – changing policies, behaviour and the balance of power"[1115] to address the challenges in ensuring that essential medicines are available to all. This statement indicates that the project had compelling aims to improve access to medicines through challenging the private pharmaceutical companies to adapt policies on pricing and marketing, and therefore it is important to evaluate the success of the project in achieving its objectives.

The Medicines Transparency Alliance (MeTA) was established in 2008 by the UK's Department for International Development (DfID) and supported by the WHO and the World Bank[1116], with the aim of enabling the sharing of information regarding medicine supply chain between governments, manufacturers and civil society organisations, to gain a better understanding of the problems, increase accountability and to facilitate changes to increase access to medicines[1117]. DfID invited seven countries, Ghana, Jordan, Kyrgyzstan, Peru, Philippines, Uganda and Zambia to participate in a pilot, that were chosen because access to medicines was limited but there was also an apparent willingness to address the problem in these countries[1118]. The MeTA Councils, which oversee the implementation of each State's programme, are made up of representatives from various stakeholder groups including government, civil society organisations, academics and business enterprises[1119]. Therefore, the pilot promoted a participative process among the various actors involved in the issue of enhancing access to medicines, which could be useful for furthering understanding of specific problems related to enhancing access to medicines, and for promoting collaboration and sharing of ideas between stakeholders to identify solutions.

[1114] World Health Organization, 'Essential medicines and health products' > 'Medicines Transparency Alliance (MeTA) Initiative' <http://www.who.int/medicines/areas/coordination/meta/en/> (accessed 27/04/2020)

[1115] Medicines Transparency Alliance (MeTA), *Medicines Transparency Alliance: A review of the pilot*, (MeTA London, 2010), 5

[1116] ibid

[1117] ibid 4

[1118] ibid 5

[1119] ibid 8

A significant lesson from the pilot is the importance of collecting data, including from pharmaceutical companies. All of the pilot countries established a MeTA Council to facilitate sharing of information and gathering of evidential data, although it is noted that the models implemented by each of the countries varied[1120]. The pilot proposed that each stakeholder disclosed information relating to the availability, price and quality of medicines, including medicine prices, manufacturing prices, health budgets and quantification and trade statistics[1121]. A review of the pilot carried out by DfID did note that the level of private sector engagement has varied from state to state[1122]. This suggests that there were issues in relation to ensuring that private companies disclosed the necessary data, although specific data on levels of engagement was not provided in the review to elaborate on this statement. The reluctance of pharmaceutical companies to disclose data due to its potential value or due to privacy concerns, was recognised in the DfID review which sought to address this through incremental disclosure of information which may be sensitive, or the holding of such information by a third party[1123]. As this is presented as a proposal to address difficulties in information sharing during the pilot, rather than a clear solution, further evidence of the utilisation of such a method would be useful in order to assess its potential efficacy for other states.

Another important lesson from the pilot is not only that the collection of data is important, but also how the data is collected and utilised. The United Nations Development Programme noted that MeTA led to increased participation in policy dialogue in the Philippines, as well as pricing and other transparency measures in Uganda, Zambia and Peru[1124], although inclusion of data to demonstrate the level of engagement with the private sector, and how this was facilitated, would be useful in order to provide an example of good practice to other states. However, Wirtz et al also argue that the Medicines Transparency Alliance was not as successful as many had hoped, with lessons learned including the length of time to engage stakeholders, and that careful disclosure of

[1120] ibid 13
[1121] ibid 18-19
[1122] ibid 19
[1123] ibid
[1124] United Nations Development Programme, *Fighting Corruption in the Health Sector: Methods, Tools and Good Practices*, (Democratic Governance Group, Bureau for Development Policy, New York, October 2011), 19 <https://www.undp.org/content/dam/undp/library/Democratic%20Governance/IP/Anticorruption%20Methods%20and%20Tools%20in%20Health%20Lo%20Res%20final.pdf> (accessed 27/04/2020)

data was essential.[1125] This suggests that this type of project may take a prolonged period of time to implement. Other states considering participating in a similar project would need to appreciate the commitment needed in terms of financial support and building relationships with the pharmaceutical sector, civil society organisations, and other participants. Stedman-Bryce et al further noted that transparency and information sharing between all stakeholders was needed, as well as consistent engagement[1126], which highlights that a level of trust between all of the stakeholders, including pharmaceutical companies, civil society organisations and governmental bodies needs to develop, in order to ensure the necessary data is disclosed, and that real transparency can be achieved. This also indicates that voluntary participation in such a project may create inconsistencies which impact on the efficacy of the project and therefore future projects may need to be underpinned by more rigorous participatory obligations.

The legacy of the MeTA pilot in Peru is the development of the Peruvian Observatory of Pharmaceutical Products[1127]. The MeTA pilot led to the drafting of legislation establishing the Observatory nationally and requiring all medicine manufacturers to publish their prices.[1128] The implementation of this type of observatory was also proposed in the health impact assessment by the Ministry of Health prior to the conclusion of the US-Peru FTA[1129], discussed further below. The purpose of the Observatory is to provide a public database of medicines prices, to allow the population to make an informed choice about where to purchase their medicines from, with the aim that this will help to lower prices of essential medicines.[1130] It has been stated that the Observatory is a useful tool for the population to be able to compare the prices of a range of pharmaceutical manufacturers, with around five thousand hits per day[1131]. This

[1125] V Wirtz et al, 'Essential medicines for universal health coverage', The Lancet Commissions, 7 November 2016, http://dx.doi.org/10.1016/S0140-6736(16)31599-9, 46

[1126] e-Pact (G Stedman-Bryce et al), *Medicines Transparency Alliance (MeTA) Evaluation: Testing MeTA's underlying intervention logic*, December 2015, P.28 <http://itad.com/wp-content/uploads/2016/05/MeTA-Evaluation-Final-Report.pdf> (accessed 27/04/2020)

[1127] Peruvian Observatory of Pharmaceutical Products <http://observatorio.digemid.minsa.gob.pe/?over=1> (accessed 27/04/2020) (translated)

[1128] Medicines Transparency Alliance (MeTA, *Medicines Transparency Alliance: A review of the pilot* (n 1115) 26

[1129] Ministerio de Salud del Peru, 'Evaluacion de los Potenciales Efectos Sobre Acceso a Medicamentos del Tratado de Libre Comercio Que Se Negocia Con Los Estados Unidos de America', Abril 2005, P. 253 <https://www.redge.org.pe/sites/default/files/MINSA-TLC-salud-Peru.pdf> (accessed 27/04/2020)

[1130] Medicines Transparency Alliance (MeTA), *Medicines Transparency Alliance: A review of the pilot* (n 1115) 26

[1131] World Health Organization, 'Medicines Transparency Alliance (MeTA): Pathways to Transparency, Accountability and Access; Cross-Case Analysis and Review of Phase II', 25 May 2016, P.64

indicates that this is a tool which is used regularly, although does not provide evidence that those who have used the tool have found a lower cost medicine as a result of the Observatory. It also does not indicate who has been accessing the information, which could be significant as DfID noted that under the MeTA pilot in Uganda a similar website was created, but the real users were private sector manufacturers and importers for the purpose of identifying gaps in the market[1132]. Therefore it is important for other states considering implementing such an observatory, to consider the users to whom the information is targeted, and the best way to ensure access to the data for them. Another potential issue is the level of access to the internet across the State, in order to ensure that patients can use the database.

The decision of the Peruvian government to address the issue of improving access to existing medicines indicates that pricing of patented and generic medicines in Peru has been identified as a barrier to access to medicines in Peru. This is a concern that has been recognised at international level and highlights a commitment by the national government to implement policy measures to combat this issue. All medicine sellers are required to enter their information into the database[1133], to ensure that the database provides an accurate reflection of medicines pricing across Peru. The WHO noted that around six thousand institutions report to the Observatory[1134], although the number of institutions required to comply was not stated. This data would have been useful in order to assess the level of compliance among the relevant institutions.

Peru has successfully established legislation to require the disclosure of information on pricing of medicines[1135]. This is an important provision to support the effectiveness of the Observatory, as it places a legal requirement on pharmaceutical manufacturers and sellers to provide the requisite information for the Observatory.

<http://apps.who.int/iris/bitstream/handle/10665/246257/9789241511209-eng.pdf?sequence=1> (accessed 27/04/2020)

[1132] DfID Human Development Resource Centre, *Evaluation of the Medicines Transparency Alliance Phase 1 2008-2010*, April 2010, P.82 <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/67685/eval-med-trnsp-all-phse-one-main-rpt.pdf> (accessed 27/04/2020)

[1133] Medicines Transparency Alliance Peru, *Working Together for Better Access to Medicines*, (World Health Organization 2015), WHO/EMP/PAU/2015.7, 5 <http://www.who.int/medicines/areas/coordination/country_activity_brochure-Peru.pdf?ua=1> (accessed 27/04/2020)

[1134] World Health Organization, 'Medicines Transparency Alliance (MeTA): Pathways to Transparency, Accountability and Access; Cross-Case Analysis and Review of Phase II (n 1131) P.64

[1135] UK Department for International Development annual review 2015, 13 <http://www.who.int/medicines/areas/coordination/meta/en/> (accessed 27/04/2020)

Article 1 of the Ministry of Health Ministerial Resolution No. 040-2010/MINSA states that all pharmaceutical establishments, public and private, operating in the country, must register with the National Price Information System for Pharmaceutical Products under the Directorate General of Medicines, Supplies and Drugs (DIGEMID), as well as supply information about the prices of the commercial offer of its pharmaceutical products.[1136] Article 6 provides that the information will be made available in the Observatory[1137], and Article 7 provides that institutions that fail to comply will be subject to sanctions[1138]. However, the enforcement of this provision also needs to be effective for the purpose of promoting and securing compliance. The 2015 DfID report[1139] which reported on the legislation does not provide information or data on the level of compliance or whether sanctions have been issued to companies for non-compliance, which would be useful to evaluate the efficacy of the Resolution in ensuring that private companies disclose the necessary data.

A key challenge is that although there are publicly funded health services in Peru and health insurance coverage available[1140], underfunding has led to patients purchasing medicines themselves[1141]. The DfID report further noted that the Observatory had highlighted price inequalities between public and private providers[1142]. This is significant as the MeTA Peru report noted that 87 percent of private health spending was paid out of pocket by consumers[1143], highlighting that there is a cost burden on patients in the State. The WHO has stated that the Observatory has highlighted that medicine prices are typically higher in private clinics[1144]. This suggests that the Observatory database was

[1136] Ministry of Health Ministerial Resolution No. 040-2010/MINSA, Article 1 <ftp://ftp2.minsa.gob.pe/normaslegales/2010/RM040-2010-MINSA.pdf> (accessed 27/04/2020). DIGEMID provides authorization of medical devices, and vigilance control on production, import, distribution. It also ensures the quality of products. See also: Peru Ministry of Health, 'What is the DIGEMID?' <http://www.digemid.minsa.gob.pe/Main.asp?seccion=39> (accessed 27/04/2020)

[1137] Ministry of Health Ministerial Resolution No. 040-2010/MINSA (n 1136) Article 6

[1138] Article 7 states that 'the breach of the provisions of the present ministerial resolution will be sanctioned, according to Chapter XIII - Of the security measures, infractions and sanctions of the Law No 29459, Law of the pharmaceutical products, medical devices and sanitary products' (translated). See also Ministry of Health Ministerial Resolution No. 040-2010/MINSA (n 1136) Article 7

[1139] UK Department for International Development annual review 2015 (n 1135) 13

[1140] See also World Health Organization, Global Health Workforce Alliance, 'Peru', <http://www.who.int/workforcealliance/countries/per/en/> (accessed 27/04/2020)

[1141] Oxford Business Group, 'New directions: Extending care and access to affordable medicine', <http://www.oxfordbusinessgroup.com/overview/new-directions-extending-care-and-access-affordable-medicine> (accessed 27/04/2020)

[1142] UK Department for International Development annual review 2015 (n 1135) 13

[1143] Medicines Transparency Alliance Peru, *Working Together for Better Access to Medicines* (n 1133) 2

[1144] World Health Organization, 'Medicines Transparency Alliance (MeTA): Pathways to Transparency, Accountability and Access; Cross-Case Analysis and Review of Phase II' (n 1131) P.63

making a positive impact on enhancing effective access to medicines by highlighting the issue of the varying pricing strategies for medicines, which impacts on affordability of medicines for all. This also suggests that the Observatory is fulfilling its objective of providing information on pricing of medicines, so that patients can identify and obtain a cheaper version. This reiterates the importance of making accurate and comprehensive data on medicines pricing publicly available so that patients can make an informed decision on where to obtain their medicines, and further highlights the importance of ensuring that pharmaceutical companies disclose the necessary data, to underpin the efficacy of the Observatory. It also indicates the importance of the availability of medicines by publicly funded providers, as these appear to be cheaper for patients.

However, the reports do not indicate whether the highlighting of such disparities had led to a reduction on prices in the private sector, which could also enhance access to medicines by providing a greater choice of affordable medicines. It is also not indicated whether there are specific medicines, or medicines to treat particular diseases which are notably higher, which could highlight whether there are any issues around access to particular medicines or groups of patients which need to be addressed in the State. As noted above the objective of the Observatory is to provide information on medicines pricing in the State, therefore although this data would be useful to provide a more comprehensive picture of the situation in relation to medicines costs, this may be beyond the scope of the Observatory.

(b) Participation and accountability of pharmaceutical companies

A key issue emanating from earlier chapters is securing the accountability of private pharmaceutical companies. Private companies are not parties to the UN human rights treaties and therefore do not have direct obligations in relation to the right to health of patients. The DfID review stated that transparency and disclosure are key elements of the pilot, and by making information on data including pricing, manufacturing costs available in the public domain, this increases accountability because it highlights where the problems in terms of barriers to access to medicines exist[1145]. In addition, it is stated that by engaging all of the stakeholders, including the national government, private

[1145] Medicines Transparency Alliance (MeTA), *Medicines Transparency Alliance: A review of the pilot* (n 1115) 20

enterprises and civil society organisations at the outset to define the objectives, there is a level of mutual accountability to attain the agreed goals[1146]. This highlights the importance of greater calibration of a legal, structural and policy nature in order to improve access to medicines within states. It also highlights that this level of accountability is linked to the level of disclosure by the actors, including pharmaceutical manufacturers, on costs of R&D and pricing of medicines. As the Observatory model has a monitoring function with the objective of protecting the population from prohibitive costs, it does not directly facilitate the accountability or regulation of pharmaceutical companies that set high prices for medicines. This may highlight bad practice of particular pharmaceutical companies, but does not necessarily ensure that they are accountable for that practice. However, there is the issue that these companies could be subjected to the courts of public opinion, for failing to meet their responsibilities to respect human rights including the right to health.[1147]

Vian et al argue that the success of MeTA in promoting accountability by the government and stakeholders in the pharmaceutical sector will depend on how well such measures are continued and sustained[1148]. Increased transparency of pricing is useful, but requires a voluntary commitment from the pharmaceutical sector as well as the other stakeholders to engage in this participatory process and the level of accountability that is involved, to ensure that accurate data can be obtained consistently and published. MeTA reported that there was little data available from the domestic pharmaceutical manufacturing sector[1149] or in relation to pharmacist dispensing fees[1150] in order to undertake a price comparison between the public and private sector. The quality of the data that is collected is also important, in order to achieve transparency so that MeTA has a credible accountability function in publicising inequitable pricing. A further issue that is highlighted is that private companies do not appear to have been issued with sanctions or other punitive measures for non-disclosure, which could strengthen the effectiveness

[1146] ibid

[1147] UNHRC 'Protect, Respect and Remedy: a Framework for Business and Human Rights, Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, Summary' (7 April 2008) UN Doc A/HRC/8/5, 54

[1148] T Vian et al, 'Promoting transparency, accountability, and access through a multi-stakeholder initiative: lessons from the medicines transparency alliance', (2017) 10(18) Journal of Pharmaceutical Policy and Practice (2017), DOI: 10.1186/s40545-017-0106-x, 10

[1149] Medicines Transparency Alliance (MeTA), *Pharmaceutical Sector Scan: Part of Component 1 of MeTA Baseline Assessments: Part II - Data Forms: Country: PERÚ*, (MeTA London 2010), P.12

[1150] ibid P.14

of the project and improve disclosure of information. However if they were compelled to disclose information this could impact negatively on the working of the body, as for example competitors could potentially utilise the information when setting their own R&D and pricing strategies. Pharmaceutical companies that are setting high prices for medicines in comparison to cheaper alternatives may be "named and shamed" by their prices being made public. This may provide negative publicity which could impact on sales and persuade the companies concerned to revisit their pricing strategies. However if there is no cheaper alternative then patients have no choice as to where to purchase their essential medicines and would have to pay the high price. Therefore this type of accountability may only be effective in specific circumstances.

The Observatory has provided more effective monitoring of medicine prices, being a useful source of information for policy makers and the health system[1151]. Therefore it does provide a useful function for patients. MeTA Peru stated that the implementation of the concept of the Peruvian Observatory of Pharmaceutical Products has led to the development of a medicines quality observatory and a medicines availability observatory.[1152] Therefore this recognises that there are other factors in addition to cost that may restrict access to medicines in Peru, which also need to be considered when developing a national strategy to enhance access to medicines. In addition to affordable medicines, such medicines need to be of good quality and they need to be available to all, in order to effectively enhance access to medicines. These are also key elements of the Article 12 ICESCR right to health, as stated in General Comment 14[1153], which the State has an obligation to fulfil. The replication of the Peruvian model to cover the availability and quality of medicines indicates that data on quality and availability, in addition to pricing, is useful to the government and civil society organisations when identifying measures to address barriers to access in Peru. The model implemented in Peru may therefore provide a suitable example to other States on the utility of gathering national data on the range of factors that affect access to medicines which can then be used to inform national strategies on ensuring access to medicines.

(c) Conclusions from Section II

[1151] Medicines Transparency Alliance Peru, *Working Together for Better Access to Medicines* (n 1133) 5
[1152] ibid
[1153] General Comment No. 14 (n 112) 12

The creation of the Observatory to address price inequalities is a positive measure, as patients have access to pricing information to help them find the medicines they require at the most affordable price. The Observatory provides a tool for monitoring medicines prices and may also add a form of accountability by highlighting disparities in pricing by pharmaceutical companies. The effectiveness of the Observatory relies on the cooperation of pharmaceutical companies to provide their data, which could present challenges in providing complete information to patients. The State's engagement in such measures to promote access to affordable medicines shows the appetite for enhancing access to medicines in Peru. However, this also highlights the wider challenge of addressing the role of private pharmaceutical companies in setting high prices for medicines, in order for states to meet their obligations simultaneously under TRIPS and the ICESCR.

III. Challenges in securing access to generic medicines

(a) Physical accessibility of generic medicines

In addition to concerns over pricing of medicines, physical accessibility to generic and biosimilar medicines is also a key concern[1154]. In 2009 the Law of Pharmaceutical Products, Medical Devices and Sanitary Products[1155] was introduced in Peru, covering the regulation of these products, including the safety and quality requirements for medicines and the performance of persons involved in the manufacturing, sale and export[1156]. The Act provides that the National Health Authority has the power to apply

[1154] UNCHR 'Report submitted by the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Paul Hunt, Addendum Mission to Peru' (4 February 2005) UN Doc E/CN.4/2005/51/Add.3, 48

[1155] Law No. 29459 on the Law of Pharmaceutical Products, Medical Devices and Sanitary Products, 26 November 2009 <http://www.leyes.congreso.gob.pe/DetLeyNume_1p.aspx?xNorma=6&xNumero=29459&xTipoNorma=0> (accessed 27/04/2020). The Directorate General of Medicines, Supplies and Drugs (DIGEMID), an agency of the Ministry of Health , is responsible at national level for ensuring the quality and efficacy of pharmaceuticals, including duties such as registering, and monitoring the registrations and marketing authorisations listed in the Law of Pharmaceutical Products, Medical Devices and Sanitary Products. See Ministry of Health, Directorate General of Medicines, Supplies and Drugs, 'What do we do?' <http://www.digemid.minsa.gob.pe/Main.asp?Seccion=641> (accessed 27/04/2020) (translated)

[1156] V Dongo, 'Law N° 29459 of pharmaceutical products, medical devices and sanitary products' (2009) 26(4) Peruvian Journal of Experimental Medicine and Public Health 517, 517 <http://www.scielo.org.pe/scielo.php?script=sci_arttext&pid=S1726-46342009000400014&lng=en&nrm=iso>. (accessed on 27/04/2020) (translated)

the limitations and exceptions set out in TRIPS and the Doha Declaration[1157] for the purpose of improving access to essential medicines[1158]. The 2009 regulations were introduced[1159] for pharmaceutical products for a market which was previously unregulated, including the regulation of generic medicines[1160]. In May 2014 the National Association of Pharmaceutical Laboratories (ALAFARPE), the representative organisation of the pharmaceutical industry in Peru[1161], filed a petition in the Peruvian courts seeking to prevent the sale of biosimilar medicines that were similar to products of the ALAFARPE companies where the quality and safety had not been verified[1162]. Torres López argues that the motive of this action was that the pharmaceutical companies under ALAFARPE, several of which were foreign companies, intended to prevent the commercialisation of generic medicines in Peru[1163]. This suggests that the pharmaceutical companies under ALAFARPE were seeking to protect their investment in their branded medicines and to ensure that generic alternatives did not provide competition for those products in the Peruvian markets, which may have had the effect of driving down the prices of those products. The court noted that in the first instance, the petition was upheld for reasons including the risk to the right to health of patients who choose biosimilar products which have not been proven to be safe and effective through pre-clinical and clinical studies which are comparable to those carried out on the original branded product[1164]. Therefore, DIGEMID was unable to grant registrations of these

[1157] Law No. 29459 on the Law of Pharmaceutical Products, Medical Devices and Sanitary Products (n 1155) Article 27

[1158] ibid

[1159] ibid

[1160] All medicines require marketing authorisation under Article 8 of Law No. 29459, although DIGEMID does provisionally authorise the use of medicines in limited circumstances, including where an emergency situation has been declared, and in public health situations where the need and unavailability of the medicines nationally is demonstrated. See also A Ehlers (ed), *Getting the Deal Through – Life Sciences 2017,* (Law Business Research London 2016), ISSN: 2042-4329, 74; C Rochette, 'The Impact Of Regulation On Market Access for Pharma Companies In Peru', 17 June 2015, <https://pharmaboardroom.com/article/the-impact-of-regulation-on-market-access-for-pharma-companies-in-peru/> (accessed 27/04/2020)

[1161] National Association of Pharmaceutical Laboratories (ALAFARPE), 'About Us' <http://alafarpe.org.pe/nosotros/> (accessed 27/04/2020) (translated)

[1162] F Torres López, 'The legal battles of the pharmaceutical monopoly', 11 March 2015, <http://ojo-publico.com/36/las-batallas-legales-del-monopolio-farmaceutico> (accessed 27/04/2020) (translated)

[1163] ibid

[1164] Corte Superior de Justicia de Lima, Cuarta Sala Especializada en lo Civil, Expediente Numero 8612-2014, Resolucion Numero Veintiuno, Lima 17 de Octubre 2016/ Superior Court of Justice of Lima, Fourth Specialized Chamber in Civil Matters, Case Number 8612-2014, Resolution Numero Veintiuno, Lima October 17, 2016, 3.11-3.12 (translated)

biosimilar medicines[1165]. This decision identified potential challenges relating to the accessibility of cheaper generic copies which existed but which had not been authorised by DIGEMID to be marketed in Peru.

In March 2016 the Peruvian government addressed this issue by introducing new regulations on generic medicines[1166], including clinical data requirements for biosimilar products[1167], to promote the use of generic medicines and to ensure their quality and safety. Subsequently the Superior Court of Justice revoked the ruling in favour of ALAFARPE, noting that the new regulations were focused on the guidelines of the WHO, and there was no decisive evidence that the management and supervision undertaken by DIGEMID was insufficient and did not comply with the legal provisions[1168]. The result of this decision is that DIGEMID is able to approve authorisations for biosimilar medicines, and therefore potentially enhance access to such medicines of appropriate quality and safety in Peru[1169]. In addition, this decision highlights the potential for promoting increased competition between branded and generic products in Peru, for the purpose of securing more affordable medicines for patients. The regulation of generic medicines to ensure their safety is a positive measure for the benefit of the health of Peruvian citizens, and can improve accessibility and availability of biosimilar and generic medicines of adequate quality, even if this was not the real motive of the pharmaceutical companies behind the ALAFARPE action. However, this situation does highlight potential problems with obtaining the appropriate authorisations to market medicines, such as administrative delays. This could lead to delays in getting these medicines to the market efficiently in Peru and providing physical access to generic and biosimilar medicines, although it does appear that the government is trying to address issues relating to physical access, and quality control, as well as time delays resulting from quality control procedures.

[1165] María del Carmen Alvarado Bayo et al, 'Peru', in R Kingham (ed), *The Life Sciences Law Review*, (5th ed, The Law Reviews, April 2017), VIII

[1166] Decreto Supremo No. 013-2016-SA, (March 1st, 2016) <http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Normatividad/2016/DS_013-2016.pdf> (accessed 27/04/2020); See also Ana Maria Agueda Chura Tito, Peru Ministerio de Salud, *Recent Trends in the Regulation of Biotechnological Products in Peru*, <https://cdn.ymaws.com/www.casss.org/resource/resmgr/cmc_euro_speaker_slides/2018_cmce_ChuraAna.pdf> (accessed 27/04/2020)

[1167] Chura (n 1166) 16

[1168] Superior Court of Justice of Lima, Fourth Specialized Chamber in Civil Matters, Case Number 8612-2014 (n 1164) 14

[1169] María del Carmen Alvarado Bayo et al (n 1165) VIII

(b) Quality of medicines

The availability of generic medicines as an affordable alternative to branded medicines is particularly important to the health care services in the State. In 2012 the CESCR reported that 98 percent of the medicines marketed in Peru were generic[1170]. A report by the Oxford Business Group in 2014 noted that due to the costs of production of medicines in Peru, the Ministry of Health chiefly purchased generic medicines[1171]. The General Law of Health states that medical practitioners should always prescribe a generic product if possible, and the patient should always be informed of the availability of a generic version of the required medicine where it exists[1172]. This provides an example of good practice to other states of the potential to increase the use of existing generic medicines if patients are given the appropriate information by health care providers, on the quality and use of generic medicines as a more affordable alternative to the branded version of the medicine. However, a challenge is ensuring that the affordable alternatives are of good quality.

The Oxford Business Group report suggested that patients may favour buying branded medicines at a higher cost than the generic equivalent because they believed that generic versions of medicines were of inferior quality[1173]. A reason for this could be the circulation of counterfeit medicines in the State. Counterfeit medicines are a major public health concern in Peru, and Medina et al argue that considerable efforts are needed in order to control this problem[1174]. A counterfeit medicine is described as an improperly manufactured product, in a deliberate and fraudulent manner, and may include products with incorrect ingredients or which have falsified labelling[1175]. Therefore counterfeit

[1170] UNCESCR 'Summary record of the first part (public) of the 8th meeting; Consideration of reports (a) Reports submitted by States parties in accordance with articles 16 and 17 of the Covenant (continued); Combined second to fourth periodic reports of Peru (continued)' (14 May 2012) UN Doc E/C.12/2012/SR.8, 3

[1171] Oxford Business Group, *The Report: Peru 2014*, (Oxford Business Group, 2014), ISBN: 9781907065941, 215

[1172] General Law of Health (Law No. 26842 of 1997), 20 July 1997, Article 26 (Digital Archive of the Legislation of Peru) <http://www.leyes.congreso.gob.pe/LeyNume_1p.aspx?xEstado=2&xTipoNorma=0&xTipoBusqueda=4&xFechaI=&xFechaF=&xTexto=&xOrden=0&xNormaI=26842&xNormaF=> (accessed 27/04/2020)

[1173] Oxford Business Group, *The Report: Peru 2014* (n 1171) 215

[1174] E Medina, E Bel and J María Suñé, 'Counterfeit medicines in Peru: a retrospective review (1997-2014)' (2016) BMJ Open 6, doi:10.1136/bmjopen-2015-010387, 1

[1175] ibid 2

medicines can relate to branded and generic medicines. Medina et al state that a real concern over counterfeit medicines is that the highest rates of counterfeit medicines were found in pharmacies[1176], which suggests an issue with the supply of legitimate medicines to pharmacies. This further affects the population's access to effective medicines and may result in a lack of confidence in health services to provide safe, reliable and efficacious treatments. This could also lead to patients seeking other methods of obtaining the medicines that they require, which could also be harmful if they acquire medicines without receiving adequate medical advice, or where the quality of such products is unclear. This would be particularly concerning where such patients are in need of essential, life-saving medicines.

Counterfeit medicines were shown to be most prevalent among national brands as opposed to imported medicines, and the counterfeiting of life saving medicines signifies a serious public health threat[1177]. The supply of counterfeit medicines being widely circulated in Peru restricts access to medicines as patients are not receiving the medicines that they need, and they may also not be aware of the health risks associated with these products, particularly if they are purchasing these medicines from legitimate sources such as pharmacies. In 2013 the OECD noted that ALAFARPE reported the measure of counterfeit medicines to be around $46 million[1178]. Therefore, the Peruvian government should take steps to prevent such products from reaching pharmacies, to ensure that patients are not purchasing or consuming potentially dangerous products. The right to health has several elements including that health goods must be of sufficient quality, requiring scientifically approved medicines,[1179] and also includes the specific legal obligation on the State to refrain from marketing unsafe medicines[1180]. Therefore, the Peruvian government has to take positive actions to address this concern as part of its obligations under Article 12 ICESCR.

A further benefit of the Peruvian Observatory of Pharmaceutical Products is that it has helped to counteract the entry into the market of counterfeit medicines, by alerting reporting authorities to informal suppliers who have tried to enter unregistered products

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[1176] ibid 6

[1177] OECD, *Overview of global counterfeit medicines*, 2013, P.20 <http://globalforumljd.com/new/sites/default/files/documents/virtualLibrary/OECD%202014%20Overview%20of%20global%20counterfeit%20medicines.pdf> (accessed 27/04/2020)

[1178] ibid

[1179] General Comment No. 14 (n 112) 12(d)

[1180] ibid 34

into the system[1181]. This is an important contribution to enhancing access to medicines of sufficient quality as such counterfeit medicines could have an adverse effect on health, and indicates that the model can be utilised to address other factors that impede access to medicines, in addition to cost. However, it would be useful for these observatories to collate full evidential data on the impact of this monitoring to be able to analyse the practical effects of these monitoring mechanisms.

(c) Data exclusivity and development of local generic medicines

Peru is reliant on importation of medicines[1182], which may impact on the State's ability to develop new medicines domestically to meet the specific needs of its population. The Special Rapporteur on health identified specific concerns relating to the right to health and access to medicines as including the potential impact of the US-Peru FTA on access to essential medicines in Peru[1183]. The CESCR also expressed concern that the State concluded the US-Peru Free Trade Agreement in December 2005, because it included TRIPS-plus provisions severely restricting future access to new and affordable generic medicines, which was particularly concerning in Peru as it was noted that the population relied heavily on affordable generic medicines.[1184] The inclusion of TRIPS-plus provisions in FTAs is a key concern emanating from the work of the UN human rights bodies in relation to access to medicines[1185]. Particular concerns included terms which have the effect of providing data exclusivity for pharmaceutical products[1186] as well as

[1181] World Health Organization, 'Essential medicines and health products' > 'Making medicine prices transparent in Peru', <http://www.who.int/medicines/areas/coordination/medprice_transparent_peru/en/> (accessed 27/04/2020)

[1182] Between 2011 and 2015 Peru's pharmaceutical imports increased from a value of approximately $586 million (USD) to approximately $802 million (USD), falling in 2016 to approximately $772 million (USD). By comparison, the pharmaceutical exports increased from approximately $36 million (USD) in 2011 to approximately $52 million in 2013, falling over the following two years to approximately $41 million (USD) in 2016. This indicates that Peru relies on importing medicines in order to meet the demands of the population and the fall in the value of pharmaceutical exports suggests that Peru does not have a large established pharmaceutical manufacturing industry. (See UN COMTRADE Database (n 808))

[1183] UNCHR 'Report submitted by the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Paul Hunt, Addendum Mission to Peru' (4 February 2005) UN Doc E/CN.4/2005/51/Add.3, 47

[1184] UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Peru' (30 May 2012) UN Doc E/C.12/PER/CO/2-4, 25

[1185] As discussed in Chapter 3 of this thesis.

[1186] World Trade Organization, 'RTA database > United States-Peru', Article 16.10(2)(a)-(c) <http://rtais.wto.org/UI/PublicShowMemberRTAIDCard.aspx?rtaid=180> (accessed 27/04/2020)

the extension of the patent term for the marketing approval process[1187]. These terms amount to TRIPS-plus provisions that could delay the development of local generic medicines[1188], could lead to a delay in getting new, essential medicines to patients, and therefore potentially contravenes the statements made on the promotion of access to medicines in the agreement[1189]. This highlights that states need to ensure greater consistency with regard to national policy on regulation and monitoring of medicines and international policy regarding terms in bilateral trade agreements, which may impact on access to medicines.

Cartagena and Attaran argue that the US-Peru FTA marked a change in the language used to define the data exclusivity provisions for pharmaceuticals, compared with earlier FTAs entered into by the US[1190], with Article 16.10(2)(b) providing that the exclusivity period shall "normally mean five years from the date on which the Party granted approval to the person that produced the data for approval to market its product"[1191]. Cartagena and Attaran argue that this wording provides unlimited scope to vary the term of data exclusivity[1192], which could lead to a longer period of data exclusivity being implemented. The inclusion of the word "normally" does suggest that there is some flexibility over the length of term, although the parties have agreed this term so the drafting of the term does indicate that the parties have agreed the five year period, as opposed to there being unlimited scope for varying the term[1193]. The term "normally" is also largely interpreted as setting out a general rule in a treaty. As such, the burden of departing from the general rule lies with the party wishing to depart from it, and this is usually a difficult burden to discharge. An example of this is evident in *US – Clove Cigarettes*[1194], where the Panel agreed that the inclusion of the term "normally" qualifies the length of an interval[1195]. On appeal, the Appellate Body stated that this meant that the burden was on the responding Member to make a prima facie case that the departure from

[1187] ibid Article 16.9(6)(c)
[1188] L Araujo and M Montagne, 'Effect of the US-Peru Free Trade Agreement on Peruvian New Drug Policies and the Registration of Pharmaceutical Products' (2013) 11(24) International Society for Pharmacoeconomics and Outcomes
[1189] World Trade Organization, 'RTA database > United States-Peru' (n 1186) Article 16.13(2)(a)
[1190] Cartagena and Attaran (n 565) 280
[1191] ibid 281
[1192] ibid
[1193] The treaty does not provide specific guidance on when parties can derogate from the five year term.
[1194] United States – Measures Affecting the Production and Sale of Clove Cigarettes, WT/DS406/R, adopted 2 September 2011
[1195] ibid 7.580

the general rule where the interval is "normally" a specified period is justified[1196]. In this case the Appellate Body found that the responding Member, the US, had failed to do so[1197]. Therefore, it is difficult to justify the argument that there would be unlimited scope for the variance of the term of data exclusivity.

In addition to the terms of data exclusivity in the US-Peru FTA, other terms within the FTA have also been highlighted as potentially being TRIPS-plus terms. It is pertinent to note that Article 16.9(2) explicitly recognises the flexibility contained in Article 27 of TRIPS, which allows WTO Members to exclude methods of medical treatment from patentability. This highlights that the Agreement supports an important flexibility in terms of production of new medicines. The inclusion in Article 16.9(6)[1198] of terms requiring patent authorities to monitor whether pharmaceutical products which form the subject matter of marketing approval applications are covered under existing patents, has been described as patent linkage[1199]. This is because the process would notify patent holders of competitors' products, and may also require that states deny marketing approval for products such as cheaper generic medicines if the approval is sought on the basis of data submitted by the patent holder for its products[1200]. This could be problematic in terms of developing a competitive market for medicines in Peru, given that currently the pharmaceutical market is relatively small. Hsu argues that such terms effectively create another layer of patent protection which clearly exceeds TRIPS, as this requirement creates a link between the marketing approval process for generic medicines and the status of the patented original medicines.[1201] This indicates that the state's marketing approval authority must not grant approval for a generic medicine if it is believed that the medicine may infringe an existing patent. This would essentially provide that the marketing approval authority is responsible for patent enforcement, which appears to be outside of the authority of the regulatory body. The effect of this could be to limit the physical accessibility to generic medicines as a cheaper alternative to the branded product. This further highlights the issue of the importance of national coherence across government to ensure consistency in policy on enhancing access to medicines. This is a key concern

[1196] United States – Measures Affecting the Production and Sale of Clove Cigarettes, WT/DS406/AB/R, adopted 4 April 2012, 289
[1197] ibid 296-297
[1198] World Trade Organization, 'RTA database > United States-Peru' (n 1186) Article 16.9(6)
[1199] L Hsu, 'Regulatory flexibilities and tensions in public health and trade – an Asian perspective' (2015) 10 Asian J. WTO & Int'l Health L & Pol'y 157, 174
[1200] ibid 174-175, and Lopert and Gleeson (n 339) 202
[1201] Hsu (n 1199) 175

which is recognised generally in the human rights arena, with an example being John Ruggie's 2008 report on business and human rights, in which he highlighted the adverse effects of domestic policy incoherence[1202].

The FTA states that, notwithstanding the data exclusivity terms under Article 16.10(2), a party "may take measures to protect public health"[1203] in accordance with the Doha Declaration and subsequent Implementation Decision, suggesting that the parties are entitled to take positive steps for the benefit of public health including access to medicines. Article 16.13 expands on this by outlining the states' commitments in relation to public health[1204]. Article 16.13(2)(a) states that the obligations under the agreement should not prevent the state parties from taking measures to protect public health by promoting access to medicines, in particular to treat epidemic diseases or a national emergency[1205]. In addition Article 16.13(2)(a) states that the provisions under Chapter 16 can and should be implemented in a way that supports each Party's right to protect public health, in particular, to promote access to medicines for all[1206]. This implies a positive duty on the states to interpret and apply the provisions in a way which promotes access to medicines, and also frames this as the state party's right, rather than obligation, to protect public health and to promote access to medicines. A dispute settlement tribunal would have to respond to any arguments made by the respondent State in reliance on Article 16.13. This is different from the situation, for example, of a trade law or investment law tribunal being asked to engage with a human rights norm which is external to the treaty under interpretation.

(d) Conclusions from Section III

The State's reliance on generic medicines makes it particularly important to have physical access to generic medicines of good quality. The implementation of regulations which include specific provision to utilise TRIPS and the Doha Declaration to enhance access

[1202] UNHRC 'Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights, including the Right to Development: Protect, Respect and Remedy: a Framework for Business and Human Rights: Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie' (7 April 2008) UN Doc A/HRC/8/5, 33
[1203] World Trade Organization, 'RTA database > United States-Peru' (n 1186) Article 16.10(2)(e)
[1204] ibid Article 16.13
[1205] ibid Article 16.13(2)(a)
[1206] ibid

to essential medicines provides an example of the State taking positive actions to meet its obligations simultaneously under TRIPS and the ICESCR. However, the possibility of extended patent protection in the US-Peru FTA, and the potential impact on access to generic medicines does present a possible tension between the State's obligations under TRIPS and the ICESCR, and highlights the importance of coherence on policy on medicines across government departments.

IV. Health policy measures for access to medicines for marginalised groups

(a) Access to medicines by the most marginalised groups

Improving access to medicines specifically for marginalised groups is a key concern in the State, and has been highlighted by UN human rights bodies[1207]. In April 2005 the Ministry of Health published a health impact assessment on the impact of the US-Peru FTA on medicines[1208], as noted above. Although this was not a human rights impact assessment, it does highlight that the national government recognised that there was a need to assess the effect of the FTA specifically on access to medicines in the State. The assessment concluded that the FTA would affect access to generic medicines, and that in the first five years of the FTA, between 700,000 and 900,000 people per year would be left without medicines if the national health budget or the incomes of the poorest households did not change.[1209] This emphasises the need for greater calibration when addressing access to medicines, to include not just lower costs and broad-scale accessibility, but also wider concerns including access to resources, quality of health services and the specific needs of minority and marginalised groups to ensure that their rights are protected. The assessment made several recommendations, including the creation of an observatory of prices made available to the public, to pressure the market to lower prices, and establishing norms to oblige companies to disseminate pricing

[1207] See examples: UNCHR 'Report submitted by the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Paul Hunt, Addendum Mission to Peru'(4 February 2005) UN Doc E/CN.4/2005/51/Add.3, 79; UNHRC 'Summary prepared by the Office of the High Commissioner for Human Rights, in accordance with Paragraph 15 (c) of the annex to Human Rights Council Resolution 5/1: Peru' (2 April2008) UN Doc A/HRC/WG.6/2/PER/3, 26

[1208] Ministerio de Salud del Peru, 'Evaluacion de los Potenciales Efectos Sobre Acceso a Medicamentos del Tratado de Libre Comercio Que Se Negocia Con Los Estados Unidos de America', Abril 2005, P. 253 <https://www.redge.org.pe/sites/default/files/MINSA-TLC-salud-Peru.pdf> (accessed 27/04/2020)

[1209] ibid P.251

information[1210]. As discussed above, an observatory of prices has been established in the State, which indicates that the State did engage with the recommendations of the health impact assessment, and provides an example of good practice to other states in relation to undertaking impact assessments prior to agreeing FTAs.

To enhance access to medicines for marginalised groups, it is not only important for the national government to increase spending on health care and medicines, but also to ensure that resources are allocated appropriately according to need. Other recommendations from the health impact assessment included the promotion of TRIPS flexibilities, strengthening of health insurance initiatives, and increasing the Ministry of Health budget to cope with additional spending on medicines.[1211] The Special Rapporteur on health also reported that the government devoted inadequate resources to the health sector, and that budget allocations for health care were inequitable[1212]. Such inequality could have a significant impact on marginalised groups, including the poorest of the population. The Special Rapporteur recommended that the State developed a 'pro-poor equity-based health policy' and allocated greater financial resources to the health sector in line with such a policy[1213].

The national government has implemented several measures to improve access to health care and medicines for marginalised groups. For example, in November 2019 the government introduced urgent measures to close the gap in the population without health insurance and introduce universal health coverage[1214]. The emergency decree states that this measure was introduced to guarantee protection of the Constitutional right to health, demonstrating the value of a rights-based approach to health care and medicines[1215]. The measure will be subject to progressive entry into force, and it will be important to assess the efficacy of the measure in improving access to medicines. However, it could provide a direct benefit to the poor and marginalised groups who would have been unable to afford health insurance.

[1210] ibid P.253
[1211] ibid
[1212] UNCHR 'Report submitted by the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Paul Hunt, Addendum Mission to Peru' (4 February 2005) UN Doc E/CN.4/2005/51/Add.3, 36
[1213] ibid 28, 38
[1214] Decreto de Urgencia Nº 017-2019 Decreto de Urgencia Que Establece Medidas para la Cobertura Universal de Salud/Decree of Emergency No. 017-2019 Emergency Decree Establishing Measures for Universal Health Coverage <https://cdn.www.gob.pe/uploads/document/file/431389/1831446-1.pdf> (accessed 27/04/2020)
[1215] ibid P.5

The national government has also implemented policy measures to improve access to health care and medicines for marginalised groups, and this has been highlighted through the UN human rights framework. In 2007 the Special Rapporteur recognised that Peru had implemented a National Plan of Human Rights (2006-2010)[1216], which included implementing a national drug policy guaranteeing the population access to quality generic medicines[1217]. Other initiatives included *la Cruzada Nacional por los Derechos y Responsabilidades Ciudadanas en Salud* (National Crusade for the Quality of Health Services)[1218], with the aim of the formulation of a comprehensive health policy based on the right to health and equity. Peru's engagement with the recommendations of the UN human rights bodies in the development of a national rights-based health policy was recognised during the peer review process of the UPR.[1219] The evaluation of the policy by the Special Rapporteur also suggests that this measure provides an instructive example for other States seeking to implement a health policy in compliance with their obligations under the right to health.

The UPR has given Peru the opportunity to highlight measures that the State had taken to improve health standards for marginalised groups in accordance with the right to health. During the first cycle, Peru stated that the State was engaging with participative programmes to address poverty, including designing social support programmes with significant resources for poor and marginalised communities [1220]. This also provides an example of the utility of the UPR in providing a reporting and review process for states to evidence measures taken to comply with their international human rights obligations. During the second cycle of UPR Peru highlighted that significant budget increases had been provided in the area of health, as well as an increase in the proportion of people enjoying health insurance[1221]. This may indicate an improvement in standards of health

[1216] UNHRC 'Compilation prepared by the Office of the High Commissioner for Human Rights, in accordance with paragraph 15(b) of the annex to the Human Rights Council Resolution 5/1: Peru' (9 April 2008) UN Doc A/HRC/WG.6/2/PER/2, 7

[1217] Ministerio de Justicia, Consejo Nacional de Derechos Humanos, *Plan Nacional de Derechos Humanos 2006-2010,* Anexo – Decreto Supremo No 017-2005-JUS, Dicembre 2005, P.305970, 3.2.3, R1, A8 https://www.mindef.gob.pe/informacion/documentos/Plan%20Nacional%20de%20DD.HH%202006-2010.pdf (accessed 27/04/2020)

[1218] UNHRC 'Compilation prepared by the Office of the High Commissioner for Human Rights, in accordance with paragraph 15(b) of the annex to the Human Rights Council Resolution 5/1: Peru' (9 April 2008) UN Doc A/HRC/WG.6/2/PER/2, 38

[1219] UNHRC 'Report of the Working Group on the Universal Periodic Review: Peru' (28 May 2008) UN Doc A/HRC/8/37, 27

[1220] ibid 48

[1221] UNHRC 'Report of the Working Group on the Universal Periodic Review: Peru' (27 December 2012) UN Doc A/HRC/22/15, 36

services, however academics have argued that although promising measures had been taken to improve health standards through a rights-based approach, the pace of this progress has slowed, in part due to the political landscape[1222]. This highlights the impact of the political will of the national government on compliance with the State's duties under the right to health, including enhancing access to medicines. Sandoval and Cáceres argue that advancing a practical health rights agenda has been difficult in Peru as although high-level policy statements have addressed health as a right, this has not been the case in the formulation of specific health policies.[1223] This indicates a need for greater coherence at national level on how to incorporate a rights-based approach in the development of health policies for specific issues. Haley et al also argue that another reason for the slowing of such progress is that the State's health care infrastructure is not currently adequately equipped to deal with the changing burdens on the health services, and that this created a barrier to primary health care.[1224] Therefore, in addition to an increase in resources, there is a need to use the resources effectively in combination with improvements to the health infrastructure in order for the State to fulfil its obligations under the right to health. This further highlights the need for greater alignment of the issues affecting health and access to medicines, to include these wider concerns.

An important and distinct issue in terms of the State's core minimum obligations under Article 2 ICESCR is that the State should take measures to secure efficacious access to generic medicines for the benefit of the whole population, including the poorest patients[1225]. General Comment 3 outlines that where any significant number of individuals is denied access to essential primary health care, the State is failing to fulfil its obligations[1226], and underlines that vulnerable members of society must be protected even where a State has severe resource constraints[1227]. This further highlights the complex nature of the issues surrounding access to medicines, with the need to enhance

[1222] A Frisancho, 'The right to health in Peru' in J Zuniga, S Marks and L Gostin (eds), *Advancing the Human Right to Health,* (Oxford University Press, Oxford, 2013), ISBN: 9780199661619, P.189. Since July 2016 there has been three changes of health minister. (See also Z Burstein and F Romaní, 'The Peruvian Journal of Experimental Medicine and Public Health in the national political context, Editorial', (2018) 35(1) Rev Peru Med Exp Public Health 5, doi:10.17843/rpmesp.2018.351.3593).

[1223] Sandoval and Cáceres (n 1050) 2; See also C Gianella et al, 'TB in Vulnerable Populations: The Case of an Indigenous Community in the Peruvian Amazon' (2016) 18(1) Health and Human Rights Journal 55, 63, 64-65

[1224] S Haley et al, 'Barriers to Primary Care in Lima, Peru', (2017) 9(2) World Medical & Health Policy, 164, 180

[1225] International Covenant on Economic, Social and Cultural Rights (n 2) Article 2(1)

[1226] UNCESCR General Comment No. 3 (n 536) 10

[1227] ibid 12

access for marginalised groups including the poorest sections of the population. The CESCR's concluding observations in 2012 noted the efforts of the State in promoting economic, social and cultural rights[1228], but expressed concern over inadequate access to and quality of health services, especially in remote areas[1229]. The CESCR recommended that the State take steps to improve access to and quality of health services, including addressing barriers to access[1230]. It is pertinent to note that the State reported that it had implemented a Coordinated National Health Plan (PNCS), based on a participative process and which set health objectives for the period 2007-2011[1231]. This highlights that the State did engage with the observations of the CESCR with regard to the provision of health services in the State and had taken positive measures to adopt a national health policy. The implementation of such measures was also reflected during the first cycle of UPR, as noted above. The CESCR also requested that the State provide disaggregated data on access and quality of health services in the State in its next report[1232], indicating that the CESCR required evidence of the efficacy of such measures in terms of enhancing access to quality health services for all sections of the population, including marginalised groups. This would allow for a more detailed examination of such measures by the CESCR, and therefore could produce examples of good practice for other jurisdictions to follow. It has not been reported whether the State provided the data requested by the CESCR[1233], although this could be included in the next state report.

[1228] UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Peru' (30 May 2012) UN Doc E/C.12/PER/CO/2-4, 3

[1229] ibid 20

[1230] ibid

[1231] Coordinated National Health Plan (PNCS) 2007-2011, Adopted by Ministerial Decision No. 589-2007/MINSA of 20 June 2007. See UNCESCR 'Implementation of the International Covenant on Economic, Social and Cultural Rights, Combined second to fourth periodic reports submitted by States parties under articles 16 and 17 of the Covenant: Peru' (20 January 2011) UN Doc E/C.12/PER/2-4, 193

[1232] UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Peru' (30 May 2012) UN Doc E/C.12/PER/CO/2-4, 20

[1233] See also UNCESCR (Pre-sessional working group 23–27 May 2011) 'Implementation of the International Covenant on Economic, Social and Cultural Rights; List of issues to be taken up in connection with the consideration of the combined second, third and fourth periodic reports of Peru concerning articles 1 to 15 of the International Covenant on Economic, Social and Cultural Rights (E/C.12/PER/2-4)' (14 June 2011) UN Doc E/C.12/PER/Q/2-4; UNCESCR 'Implementation of the International Covenant on Economic, Social and Cultural Rights; Consideration of reports submitted by States parties in accordance with article 16 of the International Covenant on Economic, Social and Cultural Rights: Peru; Replies by the Government of Peru to the list of issues (E/C.12/PER/Q/2-4) to be taken up in connection with the consideration of the combined second, third and fourth periodic reports of Peru (E/C.12/PER/2-4)' (12 March 2012) UN Doc E/C.12/PER/Q/2-4/Add.1; UNCESCR 'Summary record of the 6th meeting; Consideration of reports (a) Reports submitted by States parties in accordance with articles 16 and 17 of the Covenant (continued), Combined second to fourth periodic reports of Peru' (9 May 2012) UN Doc E/C.12/2012/SR.6; UNCESCR 'Summary record of the first part

(b) Indigenous peoples and access to medicines

As also noted in the case study on Canada, there are issues for indigenous peoples in Peru relating to access to prescription medicines and the protection of traditional medicines from appropriation. Underpinning these issues includes the rights of indigenous peoples to self-determination, including their rights to control their indigenous natural resources, such as traditional medicines. Sem argues that the pharmaceutical industry derives great benefit from traditional medicines, with Peru being a particularly abundant source of traditional medicines[1234]. Approximately 45 percent of the Peruvian population is indigenous[1235]. Williamson et al note that Peru's national health statistics are estimated by geographical area rather than ethnic group[1236]. This could result in inaccurate representations of the health needs of indigenous populations. Therefore, it is important to examine how these issues are addressed in Peru, and whether any lessons can be learned from the experiences of these States which could inform the development of indigenous rights and policy in other states.

(i) Access to prescription medicines

There is a need to bridge the gap between indigenous peoples and non-indigenous services by enhancing the understanding of the services that the national government can provide for the benefit of the indigenous peoples. The concluding observations of the CESCR[1237] in 2012 expressed concern about the high percentage of the population, particularly in

(public) of the 8th meeting; Consideration of reports (a) Reports submitted by States parties in accordance with articles 16 and 17 of the Covenant (continued); Combined second to fourth periodic reports of Peru (continued)' (14 May 2012) UN Doc E/C.12/2012/SR.8; UNCESCR 'Summary record of the 7th meeting, Consideration of reports (a) Reports submitted by States parties in accordance with articles 16 and 17 of the Covenant (continued); Combined second to fourth periodic reports of Peru (continued)' (30 October 2012) UN Doc E/C.12/2012/SR.7

[1234] D Sem, 'Co-Developing Drugs with Indigenous Communities: Lessons from Peruvian Law and the Ayahuasca Patent Dispute' (2016) 23 Richmond Journal of Law & Technology 1, 10

[1235] Central Intelligence Agency, 'The World Factbook: South America: Peru', 'People and Society: Peru' <https://www.cia.gov/library/publications/the-world-factbook/geos/pe.html> (accessed 27/04/2020)

[1236] J Williamson et al, 'Health, Healthcare Access, and Use of Traditional Versus Modern Medicine in Remote Peruvian Amazon Communities: A Descriptive Study of Knowledge, Attitudes, and Practices', (2015) 92(4) The American Journal of Tropical Medicine and Hygiene 857. http://doi.org/10.4269/ajtmh.14-0536, 857

[1237] UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Peru' (30 May 2012) UN Doc E/C.12/PER/CO/2-4

remote areas, that does not benefit from health care coverage and recommended that the State take steps to address economic, social and cultural barriers to access to health care services[1238]. This suggests that marginalised groups including indigenous peoples in Peru do not have appropriate health facilities[1239] and services available to them, as required under the Article 12 right to health. This also suggests that there are several factors which have created such barriers, including that indigenous peoples may be failing to engage with necessary health services if they are available, because they are not culturally appropriate. Dongo states that in Peru the right to access medicines also involves acceptability of health services including the need to take into account the cultures of populations and their perceptions of health and disease[1240]. Therefore, meeting the needs of indigenous peoples and their cultural position on medicines and diseases is an important obligation of the State under the right to access medicines, and ensuring that specific health services and support are available and accessible to those groups forms part of the right of all citizens to have access to essential medicines in Peru. Such provisions would require consultation with indigenous peoples as part of their right to self-determination[1241] in order to achieve a collaborative relationship to facilitate the effective and appropriate treatment of the health needs of indigenous peoples.

Gianella et al argue that weaknesses in the health system, including the lack of timely diagnosis[1242] have a negative impact on treatment of indigenous peoples particularly in tuberculosis cases. Gianella et al also argue that there is a need to address low investment in health services, and poverty in order to address the risk of tuberculosis in indigenous peoples[1243]. This indicates that there is a direct link between the level of investment in services for indigenous peoples by the Peruvian government and quality of

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[1238] ibid 20

[1239] In the consideration of the State report prior to the CESCR's Concluding Observations in 2012, it was noted that only 40 percent of the indigenous population in the Amazon region had access to health care facilities, forcing huge numbers to travel to receive care, and around 30 percent turned to traditional medicine. See also UNCESCR 'Summary record of the first part (public) of the 8th meeting; Consideration of reports (a) Reports submitted by States parties in accordance with articles 16 and 17 of the Covenant (continued); Combined second to fourth periodic reports of Peru (continued)' (14 May 2012) UN Doc E/C.12/2012/SR.8, 17

[1240] Dongo (n 1156) 527

[1241] Effective participation in developing appropriate health care is a key element of the right to self-determination under the UNDRIP . Although the UNDRIP is a UN declaration and is not binding in international law, it does reflect the commitment of the signatories to the recognition of indigenous rights. Therefore the State has made a commitment to protect and fulfil this right when implementing policy affecting indigenous peoples. UNGA Res 61/295 'United Nations Declaration on the Rights of Indigenous Peoples' (2 October 2007) UN Doc A/RES/61/295, Article 3

[1242] Gianella et al (n 1223) 62

[1243] ibid 64

treatment for a disease known to be a specific risk to indigenous groups. This also underlines the importance of the facilitation of services for indigenous peoples who have specific needs and also are susceptible to specific risks to their health collectively. The issue of poverty also reiterates that the cost of medicines may act as a barrier to prescription medicines particularly for indigenous peoples, and suggests that the public health plans and health insurance programmes may not be accessible to, or suitable for, indigenous peoples.

Brierley et al state that there is some evidence of improved healthcare access for indigenous peoples in Peru over the last decade, although ongoing challenges with access to basic medical care still remain, including poverty, infrastructure and low education levels[1244]. Improvements were noted to result from factors including developing links to urbanised areas, and improved transportation reducing the length of time taken to travel to these groups[1245]. This highlights that a challenge in ensuring access to necessary health services and medicines for indigenous peoples in developing countries include addressing physical inaccessibility, such as improving the State infrastructure and links to health care services. It is also important that such services are culturally appropriate, so that indigenous peoples participate in the development of programmes to provide education on indigenous health care. However, Brierley et al argue that although these groups are situated in largely remote locations, financial constraints may be a greater barrier to health care, including medicines, than the distance from urbanised regions[1246]. Therefore, although indigenous peoples may have experienced some improvement in health services from stronger links to non-indigenous urban regions, this was not enough to address the combination of complex issues which restrict indigenous peoples from accessing health services including prescription medicines. Poverty is a significant concern in relation to indigenous peoples which can also act as a barrier to access to essential medicines. This emphasises the importance of greater alignment of these multifaceted and wide-ranging issues which impact on access to medicines.

Measures have been introduced which indicate that the government is taking positive actions to comply with its obligations regarding the rights of indigenous peoples to participate in the promotion of health services that affect them. The Directorate of

[1244] C Brierley et al, 'Healthcare Access and Health Beliefs of the Indigenous Peoples in Remote Amazonian Peru' (2014) 90(1) American Journal of Tropical Medicine and Hygiene 180, doi:10.4269/ajtmh.13-0547, 181-182
[1245] ibid 182
[1246] ibid

Indigenous Issues[1247] is a unit of the Ministry of Health which is responsible for promoting the development of health policies in coordination with the indigenous peoples and in consideration of their culture[1248]. Further, in 2016 the Sectoral Policy on Intercultural Health was adopted with the purpose of aligning indigenous and non-indigenous health systems, involving recognising indigenous medicines and an intercultural approach at all levels of care[1249]. Gianella et al argue that the State has a central role in developing policies and in the allocation of resources to improve access to health services, and therefore the focus should be on the State actions and making the State accountable for complying with its UN human rights obligations under the ICESCR Article 12 right to health[1250]. It would be useful for the State to monitor the implementation of these measures to evaluate their effectiveness in improving the level of health care, including access to essential medicines, for indigenous peoples. This could provide useful evidential data for other states considering implementing measures to further the rights of indigenous peoples nationally, in accordance with their international human rights obligations.

(ii) Traditional resources and medicinal knowledge

Several national legislative provisions recognise that supporting the use of traditional medicines is also part of the right of indigenous peoples to access essential medicines. Sem observes that although the Constitution of Peru does not directly protect the rights of its indigenous peoples, Article 68 does contain a provision to promote the conservation of biological diversity[1251], which includes traditional medicines and indigenous natural resources. The Peruvian government implemented the General Law of Health[1252] in 1997, which states that the promotion of traditional medicine is a key interest of the State[1253].

[1247] Supreme Decree that modifies the Regulation of Organization and Functions of the Ministry of Health, Supreme Decree No. 011-2017-SA, Article 2, 'Article 77A - Functions of the Directorate of Indigenous or Originating Peoples' <http://busquedas.elperuano.pe/normaslegales/decreto-supremo-que-modifica-el-reglamento-de-organizacion-y-decreto-supremo-n-011-2017-sa-1512131-7/> (accessed 27/04/2020) (translated)
[1248] ibid (g)
[1249] UNHRC 'National report submitted in accordance with paragraph 5 of the annex to Human Rights Council resolution 16/21: Peru' (23 August 2017) UN Doc A/HRC/WG.6/28/PER/1, 56
[1250] Gianella et al (n 1223) 65
[1251] Sem (n 1234) 28
[1252] General Law of Health (Law No. 26842 of 1997) (n 1172)
[1253] ibid Preamble XVII

In 2002 the Peruvian government also implemented the Law No. 27811, introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources[1254], to ensure the protection of the IP and traditional knowledge of indigenous peoples. The introduction of national legislation to enshrine indigenous rights over their traditional resources, protecting their access to their traditional medicines, reflects the State's recognition of the rights to protection of traditional knowledge and medicinal resources in Peru. Boza argues that this law also recognises that "traditional intellectual property rights are not fully effective in addressing the traditional knowledge problem"[1255]. This highlights that the State has taken positive action to address possible tensions in relation to IP rights and protecting the rights of indigenous peoples to their traditional medicines, in order to meet its obligations under TRIPS and the ICESCR. It also highlights the importance of careful calibration across government departments in order to address these complex issues.

The implementation of Law No. 27811 is an important development as it recognises that indigenous peoples have collective rights over their resources and creates legal obligations for the government to uphold those rights. Objectives of the Law No. 27811[1256] were to avoid patents being granted on the basis of indigenous knowledge without the appropriate recognition of the same[1257], to promote equitable distribution of the benefits derived from the use of the indigenous knowledge[1258], and to promote the use of the traditional knowledge for the benefit of not only the indigenous peoples, but for the benefit of everyone[1259]. The Law recognises the collective knowledge rights of indigenous peoples, and their authority to make decisions on the use of their traditional knowledge[1260]. Legislation introduced in 2004[1261] went further, to implement measures

[1254] Law No. 27811 of 24 July 2002, introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources, 8 August 2002 (Digital Archive of the Legislation of Peru <http://www.leyes.congreso.gob.pe/LeyNume_1p.aspx?xEstado=2&xTipoNorma=0&xTipoBusqueda=4&xFechaI=&xFechaF=&xTexto=&xOrden=0&xNormaI=27811&xNormaF=> (accessed 27/04/2020); English translation sourced from WIPO Lex <http://www.wipo.int/wipolex/en/details.jsp?id=3420> (accessed 27/04/2020))

[1255] RT Boza, 'Protecting Andean Traditional Knowledge and biodiversity Perspectives Under the U.S.-Peru Trade Promotion Agreement' (2006) 16 Currents: Int'l Trade L.J. 76, 77

[1256] Law No. 27811 of 24 July 2002 (n 1254)

[1257] ibid Article 5(f)

[1258] ibid Article 5(b)

[1259] ibid Article 5(c)

[1260] ibid Article 1

[1261] Law No. 28216 on the Protection of Access to Peruvian Biological Diversity and Collective Knowledge of Indigenous Peoples, 30 April 2004, (English translation sourced from WIPO Lex <http://www.wipo.int/wipolex/en/details.jsp?id=5752> (accessed 27/04/2020))

on the protection of biological resources and traditional knowledge[1262], and included the composition of a National Commission[1263] to oversee such protection, with functions comprising the tracking of applications for patents filed or granted abroad that related to biological resources or collective knowledge of the indigenous peoples of Peru[1264]. This could be a significant measure in protecting the use of traditional knowledge including traditional medicines from appropriation without consent in domestic patent applications and also extraterritorially, although seeking enforcement outside of national territory may be difficult and require the cooperation of the State in which the patent is filed. In practice, the legislation functions well to protect traditional knowledge, and is considered to be a model for other countries to protect their traditional knowledge.[1265] Peru also has considerable means of enforcement at domestic level, but a key challenge is using sanctions effectively against parties located outside of Peru.[1266] Enhanced international cooperation among states to protect traditional knowledge could be useful to support the measures implemented at national level.

Although there are legislative measures for the protection of the collective rights of indigenous peoples over their traditional resources including medicines, in practice there may be gaps in the efficacy of these legal measures. In 2012 the CESCR expressed concern that consultation and consent of indigenous peoples was not systematically sought in decision making processes relating to the exploitation of their traditional natural resources[1267]. The right to self-determination under UNDRIP includes participation in measures to determine their health measures, which include measures relating to traditional medicines and medicinal resources[1268]. This further indicates that states need to ensure greater coherence between their international human rights commitments and their domestic legislative provisions to enhance human rights nationally. The Special

[1262] ibid Article 1
[1263] ibid Article 3
[1264] ibid Article 4
[1265] A Haider 'Reconciling Patent Law and Traditional Knowledge: Strategies for Countries with Traditional Knowledge to Successfully Protect Their Knowledge from Abuse' (2016) 48 Case W Res J Int'l L 347, 360-361; M Sanchez 'Combating Biopiracy: Harmonizing the Convention on Biodiversity (CBD) and the WTO Treaty on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in Relation to the Protection of Indigenous Traditional Knowledge and Genetic Resources' (2012) 57 Ateneo LJ 142, 217
[1266] Haider (n 1265) 365; C Kwak, 'Alternative Dispute Resolution in Genetic Resources and Traditional Knowledge: Settlement at the World Intellectual Property Arbitration and Mediation Center' (2019) 29 J Arb Stud 75, 83
[1267] UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Peru' (30 May 2012) UN Doc E/C.12/PER/CO/2-4, 23
[1268] UNGA Res 61/295 'United Nations Declaration on the Rights of Indigenous Peoples' (2 October 2007) UN Doc A/RES/61/295, Articles 4, 5, 18, 27

Rapporteur on the right to health stated that the Peruvian government should ensure that training courses including training in the medical practices and traditions of indigenous groups should be provided, to help preserve the collective knowledge of the indigenous peoples[1269]. This could help to promote the specific rights of indigenous peoples with regard to their rights of access to medicines including traditional medicines. However, it would be important that any such provisions were developed in consultation with indigenous peoples as part of their right to self-determination, including the right to participate in development of health programmes affecting them. This may also further help the State to facilitate the building of relationships between the indigenous peoples and non-indigenous health services.

During the second cycle of UPR the national report of Peru[1270] disclosed that, in order to preserve the collective knowledge of indigenous peoples that is tied to biological resources, regulations were developed to provide for the functioning of a fund for the development of indigenous peoples that was set up under Law No. 27811[1271]. This indicates that, in addition to consultation, the protection of indigenous resources requires appropriate financial support from the government to protect the collective knowledge of indigenous peoples, and this had not initially been provided for under the legislation. This also provides an example of the State engaging with the work of the UN human rights bodies to improve protection of and access to traditional medicines for indigenous peoples, in line with their international obligations in relation to access to medicines.

As noted above, a key concern of UN human rights bodies is the inclusion of TRIPS-plus terms in FTAs. Sem argues that bilateral free trade agreements may lead to higher protection for IP rights and less protection for traditional knowledge as such rights are conceded by developing countries in return for other trade benefits[1272] in Peru. This suggests that the bargaining position of developing States during negotiations may result in disengagement with the international human rights of indigenous peoples and the obligations of States emanating from these rights. Although there are examples of TRIPS-plus terms being included in bilateral trade agreements, it is also evident that such

[1269] UNCHR 'Report submitted by the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Paul Hunt, Addendum Mission to Peru' (4 February 2005) UN Doc E/CN.4/2005/51/Add.3, 81.
[1270] UNHRC 'National report submitted in accordance with paragraph 5 of the annex to Human Rights Council resolution 16/21: Peru' (7 August 2012) UN Doc A/HRC/WG.6/14/PER/1
[1271] Law No. 27811 of 24 July 2002 (n 1254)
[1272] Sem (n 1234) 37

agreements may be negotiated to include terms which may promote access to medicines. Academics have argued that Peru's position with regard to the US-Peru FTA has been assisted by participation in the Andean Community, a transnational South American organisation comprising the governments of Bolivia, Colombia, Ecuador and Peru[1273] as a voluntary alliance for purposes including the enhancement of their bargaining power in trade negotiations.

The Andean Community has law-making powers, which are adopted nationally by the member states. Sem contends that the member governments have used the political influence afforded to them through participation in the Andean Community, operating as a regional group with enhanced political bargaining power, to benefit from the TRIPS flexibilities to enhance public health and to collectively resist pressure from States with a stronger bargaining position[1274]. Sem argues that this was central to securing protection for traditional medicines knowledge in the US-Peru FTA, with the result being that any medicines co-development enterprise with Peru must recognise the correlative traditional medicinal knowledge protections that have been created at national, regional and international levels, despite the original position of the US being that such protections should be administered through WIPO[1275]. This provides an example of developing States utilising a regional trade bloc to further the protection of the human rights of indigenous peoples over their traditional medical knowledge.

However, the International Institute for Environment and Development has argued that the protection of traditional knowledge has been undermined in the FTA due to the lack of provision to ensure that patents are not granted over traditional knowledge without the authorisation of the traditional knowledge holders[1276]. This could lead to increases in the number of patents being granted over traditional knowledge without the consent of the rights holders. This issue could be addressed by the inclusion of specific provisions in such agreements to require authorisations, to protect against the misappropriation of traditional knowledge of indigenous peoples. This also indicates that

[1273] See also S Bucher, 'The Protection of Genetic Resources and Indigenous Knowledge — Disclosure of Origin on the International and Latin-American Agenda' (2008) 39(1) IIC 35, 47; Sem (n 1234) 38; and Comunidad Andina, 'What is the Andean Community?', <http://www.comunidadandina.org/Seccion.aspx?id=%20189&tipo=QU&title=somoscomunidad-%20andina> (accessed 27/04/2020) (translated)
[1274] Sem (n 1234) 43
[1275] ibid 40
[1276] International Institute for Environment and Development, *Protecting Indigenous Knowledge against Biopiracy in the Andes*, (December 2006, IIED), 3

it is possible to uphold international human rights law in bilateral trade agreements, although the substantive realisation of this may depend on the relative political landscape and negotiating strengths of the respective parties. This also highlights that issues of a political as well as legal nature are significant to enhancing access to medicines, and therefore there is a need for greater alignment when addressing issues of protecting traditional medicines, and the wider issue of enhancing access to medicines.

(c) Conclusions from Section IV

The State's engagement with the recommendations of the UN human rights bodies highlights that it has taken measures to implement a rights-based approach to improving access to medicines for marginalised groups and indigenous peoples. There is evidence that the State appreciates the interaction between IP rights and human rights in relation to access to medicines at national level through the implementation of legislation to protect the rights of indigenous peoples over their traditional medicines. However, disparities still exist, with challenges including resources, health infrastructure and the political landscape. Therefore, consistency and coherence in policy across government departments is particularly important to address the wider issues impacting on access to medicines in relation to these groups.

V. Conclusion

This case study has evidenced several core issues in relation to enhancing access to medicines in Peru. These issues include ensuring physical accessibility to existing branded and generic medicines, and ensuring available medicines of appropriate quality. State has implemented several measures to address key issues, including the creation of the Peruvian Observatory of Pharmaceutical Products to highlight pricing inequalities This provides an important monitoring function, although challenges exist in providing accountability for inequitable pricing. Developing jurisprudence on the constitutional right to health and access to medicines in the Constitutional Court shows the value of a rights-based approach in relation to access to medicines, providing an accountability mechanism for individuals, and an example of good practice to other states. There is evidence of the State engaging with the recommendations of the UN Charter bodies, and the relevant Treaty Monitoring Body, the CESCR, and that this engagement is translating

into the development of national health policies to address health issues including access to medicines.

There are also specific issues relating to access for marginalised groups and indigenous peoples, including inequitable spending on health care and the need for culturally appropriate medical services. Broader concerns also include access to resources, the need for adequate infrastructure, and the connection with rights of self-determination and participation in decisions relating to health care for indigenous peoples. The study highlights that these factors also need to be taken into account by states when devising national health policy in relation to medicines. Wider issues impacting on access to medicines have also emerged, including the significance of transparency and disclosure of data by pharmaceutical companies on pricing of medicines, and securing accountability of pharmaceutical companies for obstructive pricing and costs. Potential restrictions to access to generic medicines as a result of TRIPS-plus terms in FTAs, as well as the circulation of counterfeit medicines, is a significant problem which needs to be addressed by the State, give the significance of generic medicines to the national health system. These findings also present key lessons for other states.

It is also evident that challenges exist in relation to weaknesses in the national health service, the cost of public services and health insurance initiatives. This emphasises how national political, structural and legal factors have an impact on state actions to enhance access to medicines, which is crucial for states to take account of when implementing domestic measures to enhance access to medicines. It highlights the importance of coherence across national government departments when implementing policy which impacts upon access to medicines. However, it is important to recognise that the Peruvian government is making positive steps to address the key issues, which indicates cause for optimism in terms of the potential to further enhance access to medicines for all sections of the population.

Chapter 7: Conclusion

This thesis explores whether a tension exists between the distinct regulatory frameworks of World Trade Law and UN Human Rights Law in relation to enhancing access to essential medicines. Specifically, tension between TRIPS and the ICESCR was explored. TRIPS sets out a minimum standard of patent protection to be implemented nationally by WTO Members, and a key concern is that such patent protection can contribute to higher pricing of patented medicines and restrict access to generic medicines. TRIPS also contains exceptions to patent protection which states can rely upon to promote public health. The UN human rights bodies have produced considerable guidance on the content of economic, social and cultural rights, including the right to health under Article 12 ICESCR. This has led to the clarification of the obligations of states as well as the rights of individuals, including that access to medicines forms part of the right to health. Key factors and challenges facing states in meeting their obligations under WTO law and their human rights obligations were examined. Examples include inconsistent interpretation and implementation of IP standards at national level, TRIPS-plus standards of patent protection in FTAs and ensuring that the pharmaceutical companies are accountable for practices, including high prices, which act as a barrier to access to medicines. This chapter will evaluate the outcomes of the research, raising questions relating to states' policy and measures on medicines and to suggest possible actions to improve the position. This chapter will also discuss several factors for consideration for states to address the wide-ranging issues affecting access to medicines, and to comply with their international obligations under TRIPS and the ICESCR.

I. Evaluating the outcomes of this research

An important finding from this research is that access to essential medicines forms part of the right to health under Article 12 ICESCR. The ICESCR is a legally binding treaty and the guidance from the UN human rights framework, in particular the CESCR, on the interpretation of this right is that access to essential medicines is a core part of the Article 12 right[1277]. The guidance in the form of reports of the UN human rights bodies is non-binding but is authoritative, as there is evidence that states are engaging with the

[1277] UNGA 'Right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (16 July 2019) UN Doc A/74/174, 55

recommendations of the CESCR in relation to enhancing access to essential medicines as part of their obligations under the Article 12 right. This research sought to address the question of whether patent law provisions under TRIPS could be interpreted so as to enhance access to medicines. Possible tension between TRIPS and the ICESCR and the manner that these agreements address access to medicines could present challenges to states, if complying with their obligations to implement patent provisions under TRIPS nationally may lead to a failure to discharge their obligations under the ICESCR. The discussion in Chapter 1 outlined that it is not possible to conclude that the right to health has primacy over trade norms in international law. A way of resolving tension between TRIPS and UN human rights law is by interpreting TRIPS in a manner that promotes the right to health, including access to essential medicines. Public health concerns can be taken into account by WTO Panels and the Appellate Body, and also national courts and policy makers, in the interpretation of TRIPS as part of its object and purpose, under Articles 7 and 8. This interpretative flexibility means that TRIPS could be interpreted in a manner conducive to public health, such as to enhance access to essential medicines. Where tension exists between states' obligations under TRIPS and the ICESCR, the general rule of treaty interpretation under Article 31 VCLT, in particular that any relevant rules of international law applicable in the relations between the parties shall be taken into account under Article 31(3)(c) VCLT[1278], could facilitate the Article 12 right to health being taken into account when interpreting TRIPS.

As discussed in Chapter 1, the WTO Appellate Body has confirmed that WTO agreements, and therefore TRIPS, cannot be read in isolation from international law. Therefore, the WTO panel or Appellate Body could take into account human rights law as tools for the interpretation of TRIPS, if this could be justified with reference to the object and purpose of TRIPS. However, it is evident from the decisions of WTO Panels, such as the *Canada – Patent Protection for Pharmaceuticals*[1279] case, that this approach is not being taken. It is noted that other key provisions have been interpreted in isolation from Articles 7 and 8 which provide interpretive context, and speak to the object and purpose of TRIPS, and so greater attention from the WTO DSB is merited due to the potential to provide a basis for a pro-development interpretative approach to TRIPS.[1280]

[1278] VCLT (n 47) Article 31(3)(c)

[1279] *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000

[1280] P Yu, 'TRIPS Enforcement and Developing Countries' (2011) 26 American University International Law Review 727, 768-772; D Harris, 'TRIPs after Fifteen Years: Success or Failure, as Measured by Compulsory Licensing' (2011) 18 J Intell Prop L 367, 382

Greater engagement with Articles 7 and 8 when interpreting other provisions would facilitate the balancing of rights under the respective international law frameworks.[1281] This is also consistent with the Doha Declaration, which stated that TRIPS should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health.[1282] This interpretative approach would be important in the dispute settlement practice in the WTO, and should also inform the actions of national courts and policy makers.

The outcomes from the case studies include that states can reconcile their competing obligations at national level in a manner that enhances access to essential medicines by taking a rights-based approach. The UN human rights bodies have done much work to clarify the content of the right to health under Article 12 ICESCR as including access to medicines. These bodies have also provided guidance to states as to how to effectively meet their human rights obligations. The case studies in this thesis show that the degree of protection of the Article 12 right to health differs across states. This is most clearly seen in the approach of the national courts in the respective states to upholding human rights principles. The national courts of Canada have taken a restrictive approach to upholding the right to health, whereas in Peru the more expansive approach of the Constitutional Court in interpreting the right to health has resulted in access to essential medicines for the patient in several cases.

The value of a human rights approach by the national courts is evident in the Peruvian cases discussed in this thesis as it provides a measure of accountability for states in relation to their international human rights obligations.[1283] The test applied by the Peruvian Constitutional Court in *RJSA Vda. of R*[1284] when adjudicating on cases concerning access to essential medicines is a mechanism which provides an example of good practice to other states. In this case, the Constitutional Court outlined that that the enforceability of a social right always depends on three factors: the seriousness and reasonableness of the case; its connection with other fundamental rights; and budget availability[1285]. This test provides flexibility in terms of enforcing a social right to help

[1281] Frankel (n 200) 22; Slade (n 200) 414
[1282] Doha Declaration (n 92)
[1283] K Perehudoff, N Alexandrov and H Hogerzeil 'Legislating for universal access to medicines: a rights-based cross-national comparison of UHC laws in 16 countries' (2019) 34 Health Policy and Planning 48–57, 48
[1284] RJSA Vda. of R. (n 1071)
[1285] ibid 23

patients requiring access to medicines, while also taking into account the arguments relating to resource constraints. The outcome of the case was a positive one for the patient concerned, and highlights the importance of individuals having a course of action at national level to call for the state to discharge its obligations in relation to essential medicines.

A related concern is additional pressures on the national health care systems, if access to medicines is awarded regardless of the cost[1286]. Increased burdens on the health budgets could have detrimental impact on the provision of other health services, which could also undermine health equity. Employing a test such as the one outlined by the Peruvian Constitutional Court above could address such concerns. Kapczynski argues that the national courts upholding the right to health and granting access to medicines has had important indirect effects, including triggering responses from other government departments that have improved the health care system, such as stronger price control measures.[1287] Although this litigation does not directly address the issue of costs of medicines, it could be part of a solution in terms of influencing changes in government policy towards accessibility and affordability of medicines within a state. This approach can also promote a dialogue between the courts and the government on finding solutions to the issue of protecting human rights and the economic factors regarding medicines[1288], as seen in the *Azanca Alheli Meza Garcia* case, where the Peruvian Constitutional Court invited the government to consider utilising tools such as compulsory licensing.[1289]

Patients in other Latin American states, including Colombia and Brazil, have been largely successful in litigation on access to medicines as part of the right to health, through an expansive interpretation of the right to health in the national constitution[1290]. Therefore, through the upholding of human rights principles by the national courts,

[1286] O Ferraz 'The Right to Health in the Courts of Brazil: Worsening Health Inequities?' (2009) 11(2) Health and Human Rights 33, 33–34; O Ferraz 'Moving the Debate Forward in Right to Health Litigation' (2016) 18(2) Health and Human Rights 265, 265-7

[1287] A Kapczynski 'The Right to Medicines in an Age of Neoliberalism' 10(2) Humanity 79, 85; H Brennan, R Distler, M Hinman and A Rogers, 'A Human Rights Approach to Intellectual Property and Access to Medicines', Yale Law School and Yale School of Public Health Global Health Justice Partnership Policy Paper No. 1. (August 2013), http://dx.doi.org/10.2139/ssrn.2323144, 22

[1288] Kapczynski (n 1287) 93

[1289] Azanca Alhelí Meza García (n 1053) 40

[1290] A Kapczynski (n 1287) 80 & 83-84; J Biehl, M Socal, and J Amon 'The Judicialization of Health and the Quest for State Accountability: Evidence from 1,262 Lawsuits for Access to Medicines in Southern Brazil' (2016) 18(1) Health and Human Rights Journal 209, 218; D Landau, 'The Reality of Social Rights Enforcement' (2012) 53 Harv Int'l LJ 189, 214; M Prado, 'The Debatable Role of Courts in Brazil's Health Care System: Does Litigation Harm or Help' (2013) 41 JL Med & Ethics 124, 125

patients have been afforded access to medicines. These illustrative examples reflect the value of a human rights approach to enhance access to medicines, and could be a useful example to other states in meeting their human rights obligations in relation to the Article 12 right to health. Litigation on medicines in Latin American states has led to greater access to medicines in response to individual cases[1291]. Questions have been raised over whether the right to health litigation adequately addresses the issue of health inequity, if only those who can afford to litigate would benefit.[1292] However, the results of a study of cases in Brazil showed that the poorest patients were to an extent benefiting from greater access to medicines in such cases.[1293] Therefore, poor patients have had a measure of success in holding the state accountable to their medical needs, although the study was only conducted in one state of Brazil[1294], therefore some caution should be taken in relation to evaluating how it reflects the position across Brazil.

It is evident from this research that a key policy for improving affordability of medicines is making generic versions of essential medicines available. The case studies, in particular the experience in Canada, highlights the importance of implementing appropriate pricing policies for generic medicines, to ensure that they are accessible for patients. The experience in Peru shows that making information on prices widely available could have a positive impact in terms of ensuring that patients have data on the most affordable versions of the medicines they require. The effectiveness of such a measure largely depends on the quality and accuracy of such data, which may in turn require the cooperation and participation of pharmaceutical companies. Also, having information on pricing is useful if there are alternatives to choose from. If only one version of the required medicine is available, then there is no choice over the price to be paid.

A related issue affecting the availability and accessibility of generic medicines in particular, is concern over the impact of potentially 'TRIPS-plus' terms in FTAs. It is evident from the work of the UN human rights bodies that while there is no inherent conflict between TRIPS and the Article 12 right to health, the agreeing of TRIPS-plus terms is problematic. The agreeing of higher standards of IP protection that go beyond TRIPS causes an imbalance in terms of states' ability to discharge their obligations

[1291] J Biehl, J Amon, M Socal and A Petryna 'Between the court and the clinic: Lawsuits for medicines and the right to health in Brazil' (2012) 14(1) Health and Human Rights Journal 36, 50
[1292] Kapczynski (n 1287) 80; Ferraz (n 1286)
[1293] Biehl, Amon, Socal and Petryna (n 1291) 48
[1294] ibid 38

simultaneously under TRIPS and the ICESCR. A challenge is the pressure placed on developing states to agree such measures as a trade-off, with the US being a developed state which has employed such a strategy[1295]. The undertaking of impact assessments on the effect of such terms on the right to health and access to medicines, prior to agreements being formalised have been proposed, and would show recognition of the states' obligations under the right to health. This would require a political commitment from states to undertake such an assessment, and to act on the outcomes of assessments if there was found to be a significant adverse impact on access to medicines.

II. Factors for consideration in addressing issues affecting access to medicines

States could do more to achieve a balance between their obligations under TRIPS and their human rights obligations by making more effective use of the exceptions to patent protection set out in TRIPS, under Articles 30 and 31. The criticism of the *Canada – Patent Protection for Pharmaceuticals*[1296] case and the interpretation of Article 30 advanced in this thesis could provide scope for use of Article 30 to permit a generic pharmaceutical manufacturer to use the patented medicine before the expiry of the patent in order to obtain regulatory approval. The generic manufacturer could then market the generic copy of the medicine immediately once the patent expires. This would prevent an extended term of patent protection for the patent holder, and therefore an extension of monopoly in the market. However, the patent holder would still retain monopoly for the full patent term, and so would not address the issue of monopoly pricing during this term.

More effective use of compulsory licensing under Article 31 TRIPS could also form part of the solution to enhance access to essential medicines. On 11th March 2020, the WHO declared the 2020 Coronavirus outbreak a pandemic.[1297] As part of the response to this global health crisis, several states including Chile, Ecuador, Germany and Canada have issued or proposed compulsory licenses relating to patented Covid-19 medicines, vaccines and other medical tools.[1298] Using compulsory licensing to facilitate entry of

[1295] J Watal, *Intellectual Property Rights in the WTO and Developing Countries*, (Springer Netherlands, 2001), 24, 42

[1296] *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000

[1297] BBC, 'Coronavirus confirmed as pandemic by World Health Organization' <https://www.bbc.co.uk/news/world-51839944> (accessed 27/04/2020)

[1298] E 't Hoen 'Covid-19 and the comeback of compulsory licensing', 23 March 2020, Medicines Law and Policy <https://medicineslawandpolicy.org/2020/03/covid-19-and-the-come-back-of-compulsory-licensing/> (accessed 27/04/2020)

generic competitors into the market will only be effective if the process is simple and user-friendly. The amendment to TRIPS to introduce Article 31*bis* was intended to address concerns that least developed countries could not utilise the compulsory licensing provision under Article 31 because of the domestic use requirement. The experience of Canada and Rwanda in utilising the compulsory licensing system under Article 31, and the difficulties in using it, was explored in Chapter 5. Criticisms included that the length of the process and administrative conditions required to be met obstructed use of the system for the purpose it was intended.[1299] The experience of Canada also shows that there needs to be effective legal infrastructure at national level to implement the system.[1300] Proposals for reform have been suggested, but there does not appear to be the political will in Canada to amend the national legislation.

In addition, fear of trade sanctions has been highlighted in the academic literature as a reason developing states have not made extensive use of the system.[1301] However, the threat of use of the system can also be a useful tool in terms of agreeing a voluntary licence, as this could increase developing states' bargaining power during negotiations.[1302] As it is the only amendment to TRIPS, having been accepted by the requisite number of WTO Members, encouraging use of the system should not meet significant criticism or challenge from states. Another concern relating to compulsory licensing is the potentially detrimental impact on innovation.[1303] However, where there is a need for R&D in medicines to treat diseases prevalent in developed and developing countries, the incentive to innovate remains, as the primary market would be the developed country.[1304] Where diseases are most prevalent in developing countries, there is already a lack of innovation in relation to medicines to treat neglected diseases. This is not the result of compulsory licensing[1305]. However, compulsory licensing would also not address this particular concern in relation to access to medicines to treat neglected diseases. A related point is that generic medicines are not free, so even if they are

[1299] Tsai (n 307) 1090
[1300] E Ng and J Kohler, 'Finding Flaws: The Limitations of Compulsory Licensing for Improving Access to Medicines - An International Comparison' (2008) 16 Health LJ 143, 171-172
[1301] T Manu, 'Assessing the Potential Impact of Intellectual Property Standards in EU and US Bilateral Trade Agreements on Compulsory Licensing for Essential Medicines in West African States' (2015) 23 Afr J Int'l & Comp L 226, 229
[1302] A McBeth 'When Nobody Comes to the Party: Why Have No States Used the WTO Scheme for Compulsory Licensing of Essential Medicines?' (2006) 3 NZYIL 69, 97; D Harris (n 1280) 395
[1303] Abbott and Reichman (n 70) 953
[1304] Reichman (n 163) 250; Lee (n 581) 234
[1305] Bagley (n 710) 2481; Manu (n 1301) 228-229

marketed at a lower price than the patented medicine, the lower price may not be enough to facilitate access if they are still unaffordable to the poor.[1306] Incentives for generic manufacturers could be provided to generate interest, as these are also private companies with the objective of making a profit, including being able to renew the compulsory licence without going through the whole process again.[1307]

Although not an exception to patent protection, states could also utilise the flexibility in TRIPS in relation to parallel importing of medicines. Parallel importation involves the importation of a patented medicine without authorisation of the patent holder from a country where the patent holder has marketed the medicine at a lower price. The exhaustion principle operating within IP law is that the patent holder's rights are exhausted once the patented product is placed on the market.[1308] The product can be purchased from a low cost market for resale within a market where the cost of the product is higher, which has the effect of increasing competition and lowering of the cost of the pharmaceutical product in that market. This may result in the patent holder reducing the cost of the product across all markets in order to compete with parallel imports. TRIPS provides under Article 6 that Members are free to determine their own way of addressing the issue of exhaustion of IP rights.[1309] TRIPS does not set out standards for the application of the exhaustion principle and therefore Members have the flexibility of adopting exhaustion regimes[1310] in national law for patented pharmaceuticals to achieve national public health needs.

[1306] McBeth (n 1302) 92

[1307] Ng and Kohler (n 1300) 171

[1308] F Abbott 'The TRIPS-Legality of Measures Taken to Address Public Health Crisis: Responding to USTR-State Industry Positions that Undermine the WTO' in D Kennedy and J Southwick (eds) *Political Economy of International Trade Law: Essays in Honor of Robert E. Hudec,*(Cambridge University press, Cambridge 2002) 311; C Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press, Oxford 2007) P.108; O Owoeye, 'Access to medicines and parallel trade in patented pharmaceuticals' (2015) 37(6) EIPR 359, 360

[1309] Article 6 states that "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

[1310] WIPO has summarised the type of exhaustion regimes as follows: "The concept of national exhaustion does not allow the IP owner to control the commercial exploitation of goods put on the domestic market by the IP owner or with his consent. However, the IP owner (or his authorized licensee) could still oppose the importation of original goods marketed abroad based on the right of importation. In the case of regional exhaustion, the first sale of the IP protected product by the IP owner or with his consent exhausts any IP rights over these given products not only domestically, but within the whole region, and parallel imports within the region can no longer be opposed based on the IP right. Where a country applies the concept of international exhaustion, the IP rights are exhausted once the product has been sold by the IP owner or with his consent in any part of the world." See World Intellectual Property Organization, 'International Exhaustion and Parallel Importation'

A potential challenge in using this flexibility is that pressure on developing countries to agree provisions to negate parallel importation and exhaustion of rights has meant that developing countries could not take advantage of this flexibility.[1311] The Doha Declaration explicitly stated that Members are free to establish their own exhaustion regimes without challenge,[1312] as an attempt to clarify the flexibility for Members and to counteract such political pressure. If developing countries adopt a regional exhaustion regime, this could help develop competition which would then help in ensuring access to medicines in many poor countries.[1313]

These measures within TRIPS could be utilised more effectively by states, to discharge their obligations under TRIPS and the right to health. However, it must also be recognised that these measures alone will not address the challenges for states to meet their obligations in relation to enhancing access to medicines. There are disparities among states in their capacity to address issues affecting access to medicines. This thesis has highlighted two key issues in relation to intellectual property law and access to medicines. One issue is where intellectual property, specifically patents enable monopoly pricing of medicines which creates a barrier to access to affordable essential medicines. Another issue is where intellectual property does not act as sufficient incentive for innovation in medicines to treat neglected diseases which are unlikely to generate a significant profit for the producers. In addition to addressing prohibitive and inequitable costs of essential medicines, there is also a need to encourage innovation, and research and development in neglected diseases. The case study of Peru provides an example that some developing states do not have the manufacturing capacity to produce affordable generic medicines and rely on imports. This presents challenges where medicines to treat diseases prevalent in a state do not exist. Therefore, at intergovernmental level, for example through the WHO, WIPO, WTO Trilateral Cooperation on Public Health, IP and Trade[1314], greater efforts could be made to explore ways in which research and development in neglected diseases could be promoted at national and international level.

<http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm> (accessed 27/04/2020)

[1311] K Balasubramanian, 'Access to Medicines and Public Policy Safeguards under TRIPS' in C Bellman, G Dutfield and R Meléndez Ortiz (eds) *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (ICTSD, Earthscan London 2003), 140; Joseph (n 75) 242

[1312] Doha Declaration (n 92) [5d]

[1313] Owoeye (n 1308) 368

[1314] WTO 'Trilateral cooperation on intellectual property and public health' <https://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm> (accessed 27/04/2020)

The current patent model does not operate to effectively promote innovation in this area, so new incentives apart from IP protection could be useful. Incentives could include prize or grant systems, which reward innovators for meeting objectives to develop a new medicine for a specified disease. Such schemes were recommended by the UN Secretary-General's High-Level Panel on Access to Medicines, and find support in academic literature[1315]. These incentives could be useful because of the delinking of the cost of the medicine with the research and development costs. Promoting global health innovation is important in terms of securing the right to health, and initiatives that encourage health innovation to address the needs of developing countries could have a positive impact on access to medicines. Also, global social impact funds such as the Global Health Investment Fund[1316], which facilitates investments in innovative global health companies, could also be part of the solution to promoting development of new medicines to treat neglected diseases. In addition to supporting innovation, funds such as the Fund for Global Health[1317] also have a role in advocating for increased funding for global health. Therefore, such initiatives can also place political pressure on governments to meet their obligations under the right to health. As access to medicines is a global issue, the importance of international assistance and cooperation is increasing, and under Article 2 ICESCR states parties have a duty to take steps to progressively realise Covenant rights, including through international cooperation. Therefore, increasing recognition of states parties' extraterritorial human rights obligations under the ICESCR is of growing importance.

The political will to implement effective measures to address challenges in securing access to medicines is also a key issue, which has been identified in this research. Examples include the lack of appetite to amend CAMR in Canada, and the issue of effectively addressing challenges of resource constraints in relation to providing adequate health services including medicines. This research has highlighted that minority groups, and indigenous peoples may have specific issues which impact on their ability to access

[1315] United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 72) 59. See also A Kapczynski 'Commentary: Innovation Policy for a New Era' 37 Journal of Law, Medicine and Ethics 264, 265; J Love and T Hubbard 'The Big Idea: Prizes to Stimulate R&D for New Medicines' (2007) 82 Chi-Kent L Rev 1519; F Suleman, M Low, S Moon and S Morgan 'New business models for research and development with affordability requirements are needed to achieve fair pricing of medicines' (2020) BMJ 368 doi: 10.1136/bmj.l4408

[1316] Global Health Investment Fund, 'About' <http://www.ghif.com/> (accessed 27/04/2020)

[1317] The Fund for Global Health, 'About us' <http://www.fundforglobalhealth.org/> (accessed 27/04/2020)

medicines that need to be addressed. As noted above, concerns have also been expressed around the use of FTAs to agree TRIPS-plus standards of IP protection, and international political pressure on developing states not to use the flexibilities within TRIPS. These are a range of complex issues which require robust government policy to effectively address the multifaceted challenges presented. There is a need to ensure that the policies of one government department do not adversely affect the policies of another government department in relation to medicines. Therefore, there is a need for consistency between government departments and policy in relation to commitments to enhance access to medicines.

It is the responsibility of states to comply with their respective obligations under TRIPS and the ICESCR to enhance access to medicines. However, the challenge of overcoming the impact of the private pharmaceutical companies on medicines pricing and research and development costs is a key issue emanating from this research. The UN human rights bodies have also recognised this issue, and the UN Guiding Principles on business and Human Rights, adopted by the Human Rights Council[1318], is an important development in setting out the human rights responsibilities of private companies, in addition to the obligations of states. The Guiding Principles have gained support from states, as discussed in Chapter 3, which reflects that there is a commitment at the international and national level to address actions of businesses that infringe human rights. The responsibility of states to implement regulatory regimes for businesses where human rights concerns arise, and therefore to regulate pharmaceutical companies, recognising their responsibilities in relation to the right to health, should be promoted[1319]. Intellectual property serves social objectives and is not an end in itself, so ensuring access for all to the benefits of scientific progress is in line with Article 15 ICESCR. Therefore, a rights-based approach could help to achieve a more even balance between commercial interests and public health objectives.

Patients being unable to obtain essential medicines due to cost and lack of availability is a global problem. This research makes a contribution to the academic literature by elaborating on the content of the right to health, and access to medicines as a legally binding norm that flows from the right to health. This research contributes to

[1318] UNHRC Res 17/4 (6 July 2011) UN Doc A/RES/17/4

[1319] J Ruggie 'The construction of the UN "protect, respect and remedy" framework for business and human rights: the true confessions of a principled pragmatist' (2011) 2 EHRLR 127; E Oke 'Defining the right to health responsibilities of patent-owning pharmaceutical companies'(2019) 1 IPQ 43

the academic debate on how TRIPS could be interpreted and implemented more effectively to enhance access to medicines, for states to discharge their obligations under TRIPS and their human rights obligations under the ICESCR. The research also adds to the academic discussion of how UN human rights bodies have elaborated on the scope of states parties' obligations and evaluates the guidance from UN human rights bodies on how states can meet their human rights obligations in relation to medicines. The research also contributes to the developing discourse on the key features of the right to benefit from scientific progress and how this right could support enhancing access to medicines. The case studies fill gaps in the literature on how states might reconcile their obligations under TRIPS and the ICESCR by addressing the issue from an international and national viewpoint, exploring the challenges faced by states in meeting their obligations under TRIPS and the ICESCR respectively. The studies also fill gaps in the literature in relation to how the complexities around enhancing access to medicines impact upon marginalised groups, which need to form part of the discourse on enhancing access to medicines for everyone, and make proposals as to how states may resolve tensions between their respective obligations under TRIPS and the ICESCR at national level. This chapter also outlines considerations to help inform initiatives at the national level and at the intergovernmental or international level to promote effective access to medicines, for the benefit of patients across all states.

This global concern is continuing to receive growing attention, particularly from UN human rights bodies, with the convening of the UN Secretary-General's High-Level Panel on Access to Medicines being a key example. This concern is likely to be magnified when a medicine is found to treat Covid-19. Knowledge of the issues affecting access to medicines is continuing to evolve. States have committed to the rights set out in TRIPS and the ICESCR and they have to meet their respective legal obligations under these international agreements. The primary responsibility to enhance access to medicines lies with states, but international cooperation and the regulation of pharmaceutical companies is also crucial, to prevent people from dying from treatable diseases due to lack of access to medicines. A rights-based approach can ensure a more balanced outcome so that the rights of individuals are promoted, protected and fulfilled.