Human rights & intellectual property for universal access to new essential medicines

Perehudoff, Katrina; 't Hoen, Elisabeth

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CHAPTER 6

Human Rights and Intellectual Property for Universal Access to New Essential Medicines

Katrina Perehudoff*, Ellen 't Hoen**

*University Medical Center Groningen, Department of Health Sciences - Global Health Unit, University of Groningen, Groningen, The Netherlands

**University of Groningen, University Medical Center Groningen, Global Health Unit, Groningen, The Netherlands

6.1 INTRODUCTION

The 19th edition of WHO's Model List of Essential Medicines, published in 2015, contains several important medicines including for the treatment of cancer, tuberculosis and hepatitis C that are widely patented and highly priced (WHO, 2015). When WHO labels a medicine as essential this means that it must be made available and affordable to all. Such a label imposes human rights obligations on governments and industry to act to ensure access to essential medicines. The Essential Medicines List is therefore a tool for the practical implementation of the internationally agreed principle that intellectual property (IP) should not stand in the way of measures to promote the human right to health and access to essential medicines as a component of that right (WTO, 2001).

Yet, when a medicine is patented, unless licenses are available for patents related to the product, it will likely remain out of reach for many. The tension between finite health budgets and the human rights imperative to provide essential medicines is now felt by low-, middle- and high-income countries alike (Ploumen and Schippers, 2016). So, *how can governments with limited public health budgets ensure access to expensive, essential medicines in line with the right to health?*

This chapter illustrates how human rights principles can help governments, even those with the most modest budgets, take all possible action to ensure universal access to essential medicines. The key message is that governments have legally binding obligations to immediately take steps to provide essential medicines. These obligations arise from the right to health in international law and its authoritative interpretation by human rights experts on the Committee on Economic, Social and Cultural

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Rights. These steps include making a maximum of public resources available to finance essential medicines, particularly for the vulnerable and marginalised, and using those resources efficiently. Crucially, controlling medicines prices to ensure access to essential medicines is aligned with governments' duties under the right to health. In the case of high-priced patented medicines the TRIPS flexibilities can be effective tools to access lower priced generic medicines. Moreover, the right to health imposes duties on the international community of States and the pharmaceutical industry to respect and protect access to essential medicines (UN CESCR, 2000; Khosla and Hunt, 2008).

6.2 ACCESS TO ESSENTIAL MEDICINES IN THE ERA OF INTELLECTUAL PROPERTY AND HUMAN RIGHTS

6.2.1 The WTO TRIPS Agreement—Globalising Intellectual Property Rules

On 1 January 1995, the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into being. TRIPS were part of a set of international treaties agreed upon at the end of the Uruguay Round of trade negotiations which established the WTO (Uruguay Round, 1986). The TRIPS Agreement globalised intellectual property (IP) requirements that had only recently been adopted by rich nations. When the Uruguay Round of multilateral trade negotiations was launched in 1986, 49 of the 98 members of the Paris Convention excluded pharmaceutical products from patent protection, 10 excluded pharmaceutical processes and 22 excluded chemical processes (World Intellectual Property Organization, 1988). Countries varied in the periods of protection granted and/or set out conditions that restricted patent holders' rights (Dutfield, 2003).

Before TRIPS, pharmaceutical patent law, policies and practices differed among countries, particularly between developed and developing countries. As a result, developing countries had for many years been able to rely on countries such as India, Egypt, Israel, Jordan, Brazil and Argentina for their supply of affordable medicines. ('t Hoen, 2009) India's 1970 Patents Act, for example, provided for process patents but not product patents for medicines; this law encouraged the development of a generic pharmaceutical industry that reverse-engineered its own versions of new medicines that were often patented in other countries (Waning et al., 2010).

TRIPS signalled a fundamental change in that, for the first time, global minimum requirements for the creation and protection of IP were

enforceable through the WTO (World Trade Organization, 1994). The TRIPS Agreement requires WTO Members to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination (subject to the normal tests of novelty, inventiveness and industrial applicability) with a minimum duration of 20 years. A patent is the right granted to an inventor by a State, or by regional office acting for several States, to exclude others from commercially exploiting his invention for a certain period of time (World Intellectual Property Organization, 2017a). It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced. TRIPS imposed the new IP norms globally around the same time the HIV/AIDS epidemic took hold in the world and the call for access to AIDS treatment in the developing world had become loud.

6.2.2 HIV and the Drive for Change in Intellectual Property

In the late 1990s, the magnitude of the AIDS crisis drew attention to the fact that millions of people in the developing world did not have access to the medicines they needed to treat disease or alleviate suffering.

The high cost of HIV medicines focused attention on the relationship between patents and drug prices. The difficulties that developing countries experienced in paying for new essential medicines that were needed to treat the millions of people that were dying of AIDS raised concerns about medical patents. In 2000, only one in a thousand people living with HIV in Africa had access to treatment (Gellman, 2000). Highly active antiretroviral (ARV) treatment was available in wealthy countries and had changed AIDS from a death sentence into a manageable chronic disease. But the ARV medicines were available only from originator companies, who controlled the patents. They produced small quantities carrying paralysing price tags—US$10,000 to US$15,000 per person per year (Perez-Casas et al., 2001).

The generic industry, mainly from India played an important role in changing the course of HIV treatment. The 1970 Indian Patents Act, which then still excluded pharmaceutical product patents, provided the legal framework for large scale generic production of ARVs including innovative fixed-dose combinations (FDCs) and paediatric formulations ('t Hoen, 2016).

The establishment of the early AIDS treatment programs in developing countries such as Brazil and Thailand in the late nineties and early 2000 were possible, in part, because key pharmaceuticals, primarily '1st line' HIV

drugs were not patent-protected and could be produced locally at much lower costs ('t Hoen, 2016).

However, in many other countries, there were patent barriers to the supply of generic ARVs. And a number of patent related trade and legal disputes broke out. A much publicised dispute was the legal case mounted by 39 drug companies in 1998 against South Africa over changes to the Medicines Act aimed at facilitating the import and use of lower priced medicines claiming the changes were unconstitutional and in violation of South Africa's obligations under TRIPS (Pharmaceutical Manufacturers, 1998). The legal action by the companies caused global outrage and confronted with a global public-relations disaster coupled with a weak legal case the companies dropped the suit in 2001. However, these events had propelled the issue of access to medicines and patents onto the international political agenda including at the WTO where African countries had put the topic on the agenda of the TRIPS Council ('t Hoen, 2002).

6.2.3 The Emergence of Access to Essential Medicines in the Right to Health

Global disparities in access to expensive and lifesaving ARVs were met with calls from activists for equal access to treatment as a human right. Ensuing political arguments embraced a human rights approach to push for reform and to negotiate affordable prices (Wirtz et al., 2016). A human rights perspective centres on the value and dignity of each person. Certain inalienable, basic rights—namely the right to the highest attainable standard of health—must be guaranteed out of respect for one's dignity and worth. A right to health does not convey a right to a healthy life; instead, it establishes that all people are entitled to an equal opportunity to achieve the highest attainable standard of health (Daniels et al., 2015).

The right to health first emerged as a social right in the World Health Organization (WHO) Constitution and the Universal Declaration of Human Rights (World Health Organization, 1948). However, one of the most important affirmations of the right to health is in the binding global agreement, the International Covenant on Economic, Social and Cultural Rights (ICESCR) of 1966. The ICESCR recognised the right to health and directed governments to take measures to prevent and treat diseases, and ensure to all access to medical services in the event of illness. Over 165 countries have ratified the ICESCR and, as a result, those governments (called States parties) are now legally obliged to protect and promote the Covenant rights in their national context (United Nations Office of the High Commissioner

for Human Rights, 2017). In some cases, the right to health in international law can also be enforced in domestic courts (Hogerzeil et al., 2006). In 2013, the ICESCR Optional Protocol entered into force, allows individuals to submit complaints that allege a violation of their social rights, including the right to health (United Nations General Assembly, 2008). This landmark instrument creates the first-ever forum for individuals to claim their health rights before an international tribunal empowered to issue decisions on national governments (Forman, 2016). However, State commitment to the Optional Protocol is voluntary and only claimants in the 22 ratifying countries (to date) may submit a complaint, which limits the global applicability of this instrument and its potential to advance the enjoyment of health rights (United Nations Office, 2017).

It was not until 2000 that the content and meaning of the right to health was further defined to include essential medicines. At the height of the HIV/AIDS pandemic, the Committee on Economic, Social, and Cultural Rights (CESCR), a collection of human rights experts and scholars, interpreted the scope of the right to health in the seminal General Comment No. 14. This authoritative guidance document operationalises the right to health by outlining how States parties can implement and report on this right, and ultimately fulfil their responsibilities under international law (UN CESCR, 2000). General Comment No. 14 signals several fundamental 'core obligations' of States parties. Core obligations indicate the basic minimum aspects of the right to health that must be achieved in order to give meaning to the right (UN CESCR, 1990). Unsurprisingly, the provision of essential medicines defined by WHO appears here as a core duty (see UN CESCR, 2000). Additionally, State parties have the core obligations to ensure non-discriminatory access to and equitable distribution of health facilities, goods and services (UN CESCR, 2000). When read together, General Comment No. 14 compels State parties to provide essential medicines equitably with attention to the needs of the worst-off, including vulnerable and marginalised groups, free of discrimination. In summary, the Committee's interpretation obliges States to guarantee access to essential medicines without discrimination, and that they violate the right to health when they reduce the level of access to essential medicines (Perehudoff et al., 2016).

While General Comment No. 14 brought greater recognition to essential medicines as part of the right to health, important ethical and economic questions remained. *How can governments with limited public health budgets ensure access to expensive, essential medicines in line with the right to health?* The human rights approach does not automatically create an immediate right for

everyone to treatment at any cost. The subsequent sections of this chapter will illuminate how the right to health implores governments.

6.2.4 Doha Declaration on TRIPS and Public Health

The struggle to assure access to affordable antiretroviral medicines for the treatment of HIV/AIDS was instrumental in the adoption of the Doha Declaration on TRIPS and Public Health by the World Trade Organisation ministerial meeting in 2001 ('t Hoen et al., 2011). The Doha Declaration recognised the effect of intellectual property protection on medicines prices. It affirmed the sovereign right of governments to take measures to protect public health, including, but not limited through the use of compulsory licensing and parallel importation (see Doha Declaration, 2017). See Box 6.1 for examples of TRIPS flexibilities most relevant for access to medicines.

BOX 6.1

Examples of TRIPS flexibilities most relevant for access to medicines (World Intellectual Property Organization, 2010)

Compulsory Licenses and Public non-commercial use (Government use)

Provision that allows third parties including the government to make use of a patent without the consent of the patent holder. For example, countries have used this provision to allow importation or production of lower priced generic medicines after price negotiations with the patent holder failed and in procurement of antiretrovirals. A recent example is from the US State of Louisiana where the cost of purchasing new antivirals such as sofosbuvir and ledipasvir + sofosbuvir for its 35,000 uninsured and Medicaid-dependent residents with Hepatitis C is unaffordable at a price of $764 million. In 2017 the State health authorities proposed issuing government-use licenses to purchase lower-cost generic forms of these antivirals (Tribble, 2017).

An amendment to the TRIPS Agreement adopted on 23 January 2017 provides for special compulsory licensing to produce and export generic medicines to countries that lack sufficient local pharmaceutical production capacity (World Trade Organization, 2017) to make effective use of compulsory licensing. These provisions existed as a temporary waiver since August 30, 2003.

Exclusion from patentability

While excluding an entire field of technology such as medicines or food is not possible anymore since the adoption of the TRIPS Agreement, the agreement does allow that certain inventions are excluded from patentability under certain conditions, including protection of human health.

Exhaustion of rights (parallel import)

International exhaustion of patent rights, permitted under TRIPS, means that the patent holder cannot use the patent to control subsequent dealings with the product once he/she put a product on the market. This provides countries with the possibility to shop around globally for the best priced medicine of that supplier. This is also known as 'parallel import or 'parallel trade' and countries are fee to determine the exhaustion regime. The European Union for example has regional exhaustion allowing parallel trade within the Union (European Union, 1957).

Regulatory review exemption

A generic manufacturers use this exemption to conduct the necessary research to prepare the registration dossier to apply for marketing authorisation of the generic product before patent expiry of the product. This enables swift generic market entry upon patent expiry. This is also known as the 'Bolar' exception ('t Hoen, 2016).

Research exemption

Allows the use of patented material for scientific research so as to not hamper scientific progress.

Transition periods

TRIPS provided for different implementation deadlines for the TRIPS Agreement or certain provisions of TRIPS for developing and least-developed countries. Most of these transition periods have now expired with the exception of those for LDCs. Today LDCs benefit from the broadest transition flexibility because they are not required to be TRIPS compliant until 2021. A separate LDC pharmaceutical waiver, resulting from the Doha Declaration on TRIPS and Public Health in 2001 allows them not to grant and/or not to enforce existing IP rights on pharmaceutical products. This waiver will be in place until at least 2033 (World Trade Organization, 2013).

Paragraph 4 of the Doha Declaration on TRIPS and Public Health establishes primacy of public health when implementing the TRIPS Agreement. It reads:

> *We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm 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. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.*

The declaration further extended the deadline of the transition period for least developed countries (LDCs). Members for the implementation of phar-

maceutical product patents and the protection of undisclosed test data from 2006 to at least 2016 (Council for Trade-Related Aspects of Intellectual Property Rights, 2015). It also waived the obligation to enforce such rights until at least 2016 (Council for Trade-Related Aspects of Intellectual Property Rights, 2015). This waiver was important because many LDCs had already granted patent protection for medicines. In 2015 the LDC waivers were extended to 2021 for the TRIPS implementation waiver and 2033 for the pharmaceutical waiver (Council for Trade-Related Aspects of Intellectual Property Rights, 2015). The Ministerial meeting further promised a solution to the restriction TRIPS puts on the effective use of compulsory licensing by limiting it to the supply 'predominantly for the domestic market' (see Doha Declaration, 2017). This restriction caused problems for countries without (sufficient) production capacity that rely on importation for their supply of medicines to make effective use of compulsory licensing. Solving this problem became subject to a separate process at the TRIPS Council which adopted in 2003 the so called 'August 30 decision' setting out rules for compulsory licensing for export purposes. This temporary waiver was adopted as an amendment (Art.31*bis*) to the TRIPS Agreement in 2005 and came into force on 23 January 2017 (WTO, 2017).

6.2.5 Patents and New Essential Medicines

The patent disputes around HIV medicines, the offer of the Indian drug manufacturer Cipla of a triple first line ARV treatment of less than a dollar a day, the global mobilisation around HIV and the plans for a global financing mechanism to pay for the treatment of HIV in low and middle-income countries caused a qualification program, established in 2003 provided the necessary regulatory framework to allow smooth international trade in generic ARVs[1] ('t Hoen et al., 2014).

However, such mechanisms for other new and patented essential medicines only now begin to emerge. The 19th edition of WHO's Essential Medicines List (2015) contains several important medicines including for the treatment of cancer, tuberculosis (TB) and hepatitis C (HCV) that are widely patented and highly priced (see World Health Organization, 2015). The robust generic competition that brought down prices of early HIV medicines has become harder to achieve, both for newer HIV medicines

[1] In 2017 the WHO launched a pilot project for prequalifying biosimilar medicines to expand access to these expensive cancer treatments in low- and middle-income countries. The pilot concerns rituximab for non-Hodgkin's lymphoma and chronic lymphocytic leukaemia, and trastuzumab to treat breast cancer.

in countries that cannot benefit from the licenses of the Medicines Patent Pool and for medicines to treat other diseases that have a major impact on global public health—notably hepatitis C, cancer and tuberculosis, all of which can be better treated with the effective, and unfortunately highly-priced, new medicines added to the EML in 2015.

The high prices of the new essential medicines illustrate the challenges to access in the post-TRIPS era. Governments must act to ensure availability of essential medicines (Gray et al., 2015). Yet, mandatory patenting of new essential medicines has entrenched price-setting power within the commercial industry, reducing the effective authority of governments. Monopoly pricing of medicines routinely precludes wide access to people in need while tying the hands of the government to intervene. This now has become a global issue. The continued rise of the prices of cancer medications is of particular concern. In the UK NICE has recommended against making the breast cancer medicines trastuzumab emtansine available through the National Health Service because of the high price while recognising that the medicine is effective (NICE, 2016). In the US around a quarter of cancer patients cannot afford their care of those, 18% do not comply with their prescription medication (Crow, 2017).

There is an embedded conflict between government obligations under IP law and obligations under human rights law that will need to be resolved to ensure that public authorities can take effective actions to ensure access to new essential medicines. To this end, the Committee on Economic, Social and Cultural Rights instructs governments to balance an inventor's right to benefit from his scientific innovations against other human rights, including the right to health and the public interest in broad access to health-related products (UN CESCR, 2006).

In 2015, the UN Secretary-General established a High-Level Panel on access to medicines (UNHLP) specifically to recommend solutions for the problems resulting from the incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies (United Nations Secretary-General, 2017). The Panel's recommendations, which were published in September 2016, seemed to indicate that a better balance between protecting human rights and the rights of inventors is possible within the current TRIPS framework. In contrast, the UNHLP's predecessor, The Commission on HIV and the Law, had recommended that the WTO urgently suspend TRIPS obligations with regards to essential pharmaceutical products for low and middle-income countries pending the outcome of a review of TRIPS by the UN.

The Commission also suggested new innovation systems including a R&D treaty for pharmaceuticals (Global Commission on HIV and the Law, 2012). In the same vein, the UNHLP report did indeed recommend the start of negotiations for a global agreement on the coordination, financing and development of health technologies including a binding R&D agreement that delinks the cost of R&D from end prices. Such an agreement could become an alternative to the current market exclusivity-based pharmaceutical innovation model that makes it difficult to escape high medicines prices.

The following sections of this chapter will explore the human rights imperative for governments to ensure access to essential medicines and concrete government action to uphold their human rights responsibilities.

6.3 HUMAN RIGHTS OBLIGATIONS OF GOVERNMENTS

6.3.1 Maximum Available Resources

Governments have a primary legal obligation to take steps to realise health rights by continuously increasing health budgets through domestic sources. The obligation to move as expeditiously and effectively towards the full realisation of health rights implies governments should finance therapies which offer best health value for money (UN CESCR, 1990). Efficient resource allocation requires governments to prioritise medicines for public financing and to take steps to reduce the cost of essential medicines. The vital influence of medicines prices on their ranking means that reducing the price of an effective medicine may trigger its reimbursement.

Although States hold primary responsibility to realise their core obligations, this duty is shared by the international community of foreign governments and other actors, which can supplement domestic pharmaceutical funding. This assistance can be a valuable step to afford a universal basic package of essential medicines in low- and lower-middle-income countries where public spending on medicines is demonstrably insufficient (see Wirtz et al., 2016; General Comment, 2000).

Health systems are depleted and patients suffer when governments fail to uphold these tenants of the right to health. Faced with few avenues to acquire expensive medicines, patients seek government-funded access through their national courts. Much of the medicines litigation in the early-2000s was driven by HIV/AIDS patients pursuing State-financed access to high-cost, lifesaving anti-retrovirals. Since then court claims have drastically increased in number, particularly in Latin America (Biehl et al., 2012; Norheim and Wilson, 2014).

In recent years, trastuzumab has been at the centre of such court claims that arose from the unfortunate combination of high prices commanded by the manufacturer and insufficient government budget. For example, in 2006 New Zealand's Health Technology Assessment Agency, Pharmac, concluded that a 12-month regimen of trastuzumab would be effective for early stage HER2-positive breast cancer; however, it would increase the budget for cancer treatments in public hospitals by 45%, causing Pharmac to recommend against its reimbursement largely on financial grounds (Manning, 2014). Such legitimate resource limitations do not absolve States of their human rights responsibilities to take further steps to augment the available resources through international cooperation and to use the range tools at their disposal to lower the costs of medicines.

6.3.2 Efficient Use of Government Resources

Trends in global pharmaceutical spending suggest that inefficiencies exist and they may inhibit progress towards universal access to essential medicines. The Lancet Commission on Essential Medicines Policies estimates that providing a basket of essential medicines in low and middle-income countries would cost between US$77.4 and 152.0 billion annually (Wirtz et al., 2016). This range is shadowed by the total global pharmaceutical sales, which are forecasted to reach $1.4 trillion in 2020 (Wirtz et al., 2016). In other words, the global community has sufficient funds to purchase basic essential medicines for all; however, realising that goal relies on political will and cost-efficient investments based on solidarity between nations.

6.3.3 Prioritising Medicines for Reimbursement

Progressive realisation justifies ranking treatments for reimbursement, with more cost-effective treatments being financed first (Perehudoff et al., 2016). The ranking system ensures that available resources are used as effectively as possible, thereby progressively realising the right to health for the largest number of people at the lowest possible cost (Perehudoff et al., 2016). Besides progressive realisation, a fair priority setting process should conform to human rights principles of transparency, consultation and accountability. The Accountability for Reasonableness framework for rationing healthcare fairly is a useful tool (Daniels and Sabin, 2008). It requires a fully transparent process that offers transparency will allow for meaningful consultation of consumers and patients, as well as a heightened understanding of the trade-offs (Vitry et al., 2016). A balanced

representation of stakeholders can ensure societal values are represented in the decision-making process while guarding against the involvement of a few vocal advocates representing only a fraction of patients in need of therapies (Hogerzeil, 2006).

6.3.4 Use of Price Control Mechanisms and TRIPs Flexibilities

Exerting control over medicines prices is in line with States' duty to provide an environment that facilitates the discharge of human rights obligations of the private business sector (see UN CESCR, 2000). In other words, the right to health empowers governments to take steps to structure and regulate medicines prices in order to ensure all essential medicines are available at a price that the health system and patient can afford ('t Hoen et al., 2016). Moreover, General Comment No. 17 addresses States' obligations to assure authors' rights to the material benefits of their inventions when there is an overarching public interest in broad access to health innovations. The Committee on Economic, Social and Cultural Rights has explicitly affirmed that private interests should not impede States parties ability to realise their minimum core obligations to the right to health (UN CESCR, 2006). The Committee notes that 'States parties thus have a duty to prevent unreasonably high costs for access to essential medicines,… from undermining the rights of large segments of the population to health…' (UN CESCR, 2006).

A government's tool box holds multiple instruments to regulate medicines prices. However, the introduction of price regulation is only as effective as its proper enforcement by the government.

When price control measures fail to yield affordable essential medicines, governments have the core obligation to use all means to provide essential medicines, including TRIPS flexibilities. Such use should include issuing of compulsory licenses and public non-commercial use by the government ('Government use' or 'Crown use') of a patent, not-granting or enforcing of medicines product patents by LDCs and other flexibilities that are contained in the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health (World Intellectual Property Organization, 2017b) (see Box 6.1 for other examples of TRIPS flexibilities). The use of the TRIPS flexibilities is not optional when failing to do so means that people suffer or die from lack of essential medicines. A government faced with having to deny access to essential medicines that could be made available if licenses were issued does not fulfil its obligations under human rights law.

6.4 PROTECTING ACCESS TO MEDICINES IN INTERNATIONAL FORA

States should prevent third parties, including the pharmaceutical industry, from violating or impeding others from fulfilling their obligations towards the right to health in other countries (UN CESCR, 2000). They should ensure that their actions as members of international organisations take due account of the right to health, specifically by ensuring that international agreements do not adversely impact the right to health (UN CESCR, 2000). However, evidence from international and bilateral agreements shows that some governments have failed to heed these human rights obligations in practice.

The trend in regional and bilateral trade agreements and in accession agreements with new WTO members to include TRIPS-plus provisions roll back much of the positive momentum represented by the Doha Declaration. TRIPS-plus provisions limit the instruments countries have at their disposal to realise the human right to access to essential medicines (Sell, 2007). The trend in international norm setting for patents reflects the IP agenda of large corporations that seek expansion of their monopoly positions in the market through patents and through other market exclusivity mechanisms.

Further, Investor to State Dispute Settlement (ISDS) mechanisms, often contained in trade agreements, are being used by the pharmaceutical industry to contest decisions by national patent offices and courts and as such have a chilling effect on any government's considerations to use the TRIPS flexibilities and on health regulation (Crouch, 2015). ISDS allows corporations to take legal action against countries to seek compensation for regulation that allegedly has negatively affected their investments. Concerns over the inclusion of ISDS in trade agreements are not imaginary. The drug company Eli Lilly relied on the investment chapter of the North American Free Trade Agreement (NAFTA) to sue the Canadian government over losses resulting from the invalidation of secondary patents related to atomoxetine (Strattera) and olanzapine (Zyprexa), medicines used to treat attention deficit hyperactivity disorder, schizophrenia and bipolar disorder (Public Citizen, 2015). In March 2017 the NAFTA Tribunal dismissed the case (Government of Canada, 2017).

ISDS can also be used as a tool to pressure governments to desist from using TRIPS flexibilities. In 2017, amid an ongoing debate about the high price of imatinib in Colombia, evidence has emerged that the manufacturer, Novartis, threatened the Colombian authorities with international

investment arbitration to allege that granting a compulsory license is a violation of the Swiss-Colombian bilateral investment treaty. Public Eye claims that this threat may have influenced the Colombian health authorities 'to stop short of pursuing a compulsory license' and instead use other price controls (Public Eye, 2017).

The United Nations Conference on Trade and Development (UNCTAD) maintains a database of ISDS cases, which counts over 600 cases (UNCTAD, 2017). In its 2015 World Investment Report, UNCTAD notes that developing countries 'bear the brunt of these claims' and that most claimants (i.e., the companies) come from developed countries (UNCTAD, 2015). UNCTAD adds that claims against developed country governments are on the rise.

TRIPS meant to protect against TRIPS-plus demands (see Box 6.2 for examples of TRIPS-plus demands.) TRIPS Article 1.1 states that countries are free but not obliged to implement more extensive IP protection than is required by TRIPS. One could call Article 1.1 of TRIPS the 'anti-TRIPS-plus clause'. While countries are free to adopt more stringent IP protection than TRIPS requires, by agreeing to the TRIPS standards they expected to

BOX 6.2

Examples of provisions that require more stringent IP standards than those contained in TRIPS or that limit flexibilities inherent in TRIPS ('TRIPS-plus') pursued in trade agreements by the US or EU that can delay the introduction of generic medicines and thereby affect access to medicines ('t Hoen, 2016):

Patent linkage: Prohibits granting of marketing approval by drug regulatory authorities during the patent term without the consent of the patent holder. These provisions effectively create a new function for medicines regulatory agencies in the enforcement of patents on medicines.

Data exclusivity: Prohibits for a certain period of time the use of pharmaceutical test data for drug regulatory purposes, which will delay the registration and thereby the marketing of generic medicines and bio products, regardless of the patent status of the product.

Extension of the patent term for pharmaceuticals beyond the 20 years required by the TRIPS Agreement, which will further delay generic competition (European Commission, 2012).

Extension of the scope of patent protection to allow known substances to be patented for each 'new use'.

Restrictions on the grounds for compulsory licensing.

Restrictions to parallel importation.

have struck a bargain that would protect them from pressures to further expand national levels of IP protection. These expectations were re-enforced when World Trade Organisation (WTO) members adopted the Doha Declaration on TRIPS and Public Health.

That bargain has been broken by the plethora of trade agreements containing TRIPS-plus provisions that have been concluded in the last decade, including after the adoption of the Doha Declaration on TRIPS and Public Health. The US and the EU are systematically seeking higher levels of IP protection in agreements with other countries that affect access to medicines and seriously hamper the full implementation of the Doha Declaration. TRIPS-plus law in the European Union, for example the EU's data exclusivity rules and the EU's opting out of the WTO August 30 decision in 2003 have rendered some key flexibilities useless. TRIPS-plus provisions are also found in WTO accession agreements with new WTO Members, including with LDCs (Abbott and Correa, 2007).

Governments that pursue a trade policy aimed at further limiting the TRIPS flexibilities are actively undermining the instruments that are indispensable for governments to realise their core obligation to provide essential medicines under the right to health. The Human Rights Council has affirmed that TRIPS-plus measures in trade agreements directly contravene General Comment No. 14 (Human Rights Council, 2017).

6.4.1 Human Rights Obligations of the Pharmaceutical Industry

While the fulfilment of basic human rights is primarily a state obligation, in the case of patented medicines one also has to recognise the responsibility of the patent holding pharmaceutical company. After all, with patenting of essential medicines now more widespread, the power to determine who has access to such medicines has shifted to the private sector.

Major progress to establish the human rights obligations of the business sector, and the pharmaceutical industry, in particular, has been made by key human rights experts. During his term as UN Special Rapporteur on the Right to Health (2002–2008), Paul Hunt submitted a report to the UN General Assembly on guidelines for the pharmaceutical industry in relation to access to medicines. These include refraining from actions that limit accessibility, such as pursing stronger intellectual property protection, and also taking all reasonable steps to make new medicine accessible to those who need them.

UN special rapporteur on the right to health, Paul Hunt:

> *Society has legitimate expectations of a company holding the patent on a life-saving medicine. In relation to such a patent, the right-to-health framework helps to clarify what these terms, and expectations, are. Because of its critical social function, a patent on a life-saving medicine places important right-to-health responsibilities on the patent holder. These responsibilities are reinforced when the patented life-saving medicine benefited from research and development undertaken in publicly funded laboratories. (Paul Hunt, 2009)*

The right-to-health standards offer a normative framework against which companies can be held accountable, which is useful for monitoring companies' policies and actions. The Access to Medicines Index ranks pharmaceutical companies using this right-to-health framework to assess pharmaceutical companies' policies and behaviours with regards to access to medicines (Access to Medicines Index, 2017).

The Guiding Principles on Business and Human Rights (the 'Ruggie Principles') were endorsed by the Human Rights Council in 2009, and as such, are somewhat more forceful than Hunt's guidelines (Guiding Principles on Business and Human Rights, 2011). Business actors 'should avoid infringing on the human rights of others' and they should 'address the adverse human rights impacts with which they are involved' (Guiding Principles on Business and Human Rights, 2011).

Enforcement mechanisms to ensure that companies indeed act on their responsibility for human rights are lacking. Anand Grover, who followed Paul Hunt as Special Rapporteur on the Right to Health, sought to give the normative framework developed by Hunt teeth. He suggested establishing direct legal obligations for pharmaceutical companies at the international level and holding pharmaceutical companies directly accountable under international human rights law, including through direct compensation to victims and the granting of compulsory licenses (Grover et al., 2012).

6.5 CONCLUSION

The human rights framework defines clear 'core obligations' of national governments and the international community to provide essential medicines to all who need them. The principle of progressive realisation of the right to health implies that States should use the maximum of their available resources to ensure that services are provided expeditiously and on the basis of non-discrimination, while taking deliberate, concrete and targeted steps towards full realisation. States must allocate sufficient financing to provide a

universal package of essential medicines. Foreign governments have a shared responsibility to assist States lacking the resources to meet their core obligations in this area.

Adequate public financing alone will not necessarily yield universal access, particularly to expensive essential medicines. The obligation to use resources efficiently implores governments to prioritise medicines for public financing in a non-discriminatory, transparent and accountable manner. The need for efficiency implies that governments should not accept high prices of new medicines when the consequence of that high price is that proven effective medicines are not available to patients who need them. In such cases they should employ the legal and policy tools available to reduce them, including price control mechanisms and TRIPS flexibilities in case of patented medicines. The proposals for better international rules underpinning new ways of financing pharmaceutical innovation offer opportunities for reform in the global IP based pharmaceutical innovation architecture that currently relies on high pricing as its main resource mobilisation. In particular, the recommendation by the UNHLP and others to start negotiations for a treaty on pharmaceutical innovation based on the principles of delinkage would halt this reliance on high medicines prices for the financing of R&D should be followed up.

Human rights arguments for access to essential medicines should not only direct government and industry action, but should also be enforceable on these actors such as through the Optional Protocol to the ICESCR or an enforcement mechanism for the pharmaceutical industry. The international community has a shared responsibility to assist governments lacking adequate resources and to ensure international agreements are compatible with the right to health and do not infringe on access to essential medicines. Pharmaceutical companies have a duty under human rights law to ensure that the fruits of science are made available and affordable to all who need them.

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