Promoting access to medicines: legal and conceptual appropriateness of "failure to work" as a ground for the compulsory license in the Bayer Nexavar case

University of Oslo
Faculty of Law

Candidate number: 8012
Deadline for submission: [05/15/2015]
Number of words: 16,262
15.05.2015

Abstract

The right to health started gaining acceptance since the foundation of the modern human rights movement at the end of the Second World War. It has been incorporated into many global and regional human rights instruments and national constitutions. Access to medicines (A2M) is the fundamental element of the right to health that is recognized in The Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights. However, the development in the international patent law can undermine A2M.

In the pursuit of promoting effective protection of patents, members of World Trade Organization adopted the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The Agreement heightened patent protection worldwide[1]. Patent protection standards were drawn from US law[2]. State Members were obliged to extent patent protection on socially important inventions such as medicines[3]. The extended patent protection increased prices of drugs and created a threat to A2M. Nevertheless, the Agreement has measures to promote A2M. These are called TRIPS flexibilities.

Compulsory license (CL) is one of the flexibilities under TRIPS[4]. CL is an authorization granted by a government to someone other than the patent owner to produce the drug without the patent owner's consent. The flexibility is a complex mechanism that consists of many elements. The central component of the CL mechanism is the ground for granting a CL because this element triggers the issuance of a CL. In the international patent law, grounds for CL are defined vaguely.

TRIPS does not expressly identify grounds for CL, but the Paris Convention for the Protection of Industrial Property (The Paris Convention) recognizes "failure to work" (F2W) as a ground for CL[5]. Many national laws have adopted the language of the Convention. For example, the Indian Patent Law incorporates F2W in the similar wording[6]. The Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) reconfirms the Indian legislator's choice by stating that the Member State has freedom to decide upon grounds upon which CLs are granted[7]. Despite being well established at the national level, F2W might be inconsistent with TRIPS[8] because the original

[1] Osenga (2012) p. 316
[2] Turrill (2013) p. 1557
[3] TRIPS, Art.27(1)
[4] TRIPS, Art.31
[5] The Paris Convention, Art.5(A)(2)
[6] The Indian Patents Act, Sec.84(1)(c)
[7] The Doha Declaration, Art.5(b)
[8] TRIPS, Art.27(1)

content of F2W demands local manufacturing of the patented invention. Issuing CL on the ground of F2W to promote A2M can reform the content of F2W, but it poses some conceptual difficulties.

CL has the goal to promote public interest in A2M. However, A2M is a category of human rights law and it does not originally belong to patent law. CL cannot be properly informed by such a category. In contrast, F2W is the endemic category to patent law and can trigger the granting of CL. A2M can reform the content of F2W, but conceptual difficulties arise due to differences between human rights law discourse and patent law discourse.

Legitimacy and conceptual appropriateness of F2W are not self-evident. Therefore, F2W content and its relevant provisions should be analyzed. Such concerns are sound because CL is a significant TRIPS mechanism that promotes A2M by limiting patent rights. Breaking patents can reduce pharmaceutical companies' initiative to develop new medicines and undermine A2M in the long-term perspective. Reviewing the Bayer Nexavar case, this paper attempts to establish legal and conceptual appropriateness of F2W and to determine if the ground can help to promote public interest in accessing medicines.

Abbreviations

F2W	Failure to work
A2M	Access to medicines
CL	Compulsory license
R&D	Research and development
ICESCR	International Covenant on Economic, Social and Cultural
UDHR	Universal Declaration of Human Rights
PAP	Patient Assistance Programs
TRIPS	The Agreement on Trade Related Aspects of Intellectual Property Rights
HIV/AIDS	Human immunodeficiency virus infection and acquired immune deficiency syndrome

Contents

1 Chapter One: Introduction

1.1 Research background

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the document that involves patent law and human rights. The Agreement sets forth patent law minimums for all Member States[9] and is considered a pro-patent Agreement[10]. Proponents of TRIPS claim that heightened patent protection promotes incentives to research new medicines. Opponents argue that extensive patentability increases prices on drugs. Working within the frame of TRIPS, states strive to fulfill their human rights obligations.

Before TRIPS, not all states provided patent protection to pharmaceuticals[11]. States concerned about access to medicines (A2M) could not provide patents for medicines, thereby avoiding the potentially high prices that might come with patents. Article 27(1) of TRIPS limited exclusions that countries can no longer promote access by denying patentability of drugs. Although TRIPS reinforces patent protection, it also includes some flexibilities, such as compulsory license (CL) to ease the conflict between patent rights and A2M.

CL is a license issued by the State authorizing a third party to perform acts covered by the patents against the will of the patent owner[12]. After TRIPS was adopted, around 100 countries had implemented CL under national law[13]. CL is effective in situations when a patent owner maintains artificially high prices on patented drugs. TRIPS does not limit CL grounds. The Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) proclaims that each member may freely determine the grounds upon which CL may be granted.

Delineating grounds for CL, policy makers face a dilemma. A broad formulation of CL grounds can result in the mechanism being employed frequently. Patients benefit from the frequent CL use because it brings affordable generics to the market. Nevertheless, the frequent use can undermine branded pharmaceutical companies' initiative to discover new drugs because CL can deprive them of monopoly profits. Defining CL grounds, a government seeks a compromise. Patent law provides guidance in delineating CL grounds.

The Paris Convention for the Protection of Industrial Property (the Paris Convention) recognizes F2W as a legitimate CL ground[14], and national laws endorse the Convention in this regard[15], but

[9] Martins (2014) p. 389
[10] Ho (2007) p. 1470
[11] Crook (2005) p. 531
[12] Kuanpoth (2015) p. 63
[13] Lybecker (2009) p. 222
[14] Wang (2014) p. 102
[15] Correa (2015) p. 45

the Convention does not define F2W content. It should be noticed that in national patent laws and legal literature F2W is also referred as "working requirement". Both terms will be equally used further in the paper. In the past, national laws linked F2W with local manufacturing of the patented product. Later, the states allowed to exploit patents merely through import. The Convention endorsed import at the international level. Even more, TRIPS conveys the most-favored-nation principle and the national treatment principle, two overarching doctrines of WTO[16], in the field of patent law[17]. Although F2W is acknowledged as a CL ground in the Convention and in national laws, its TRIPS-compliance should be questioned. An F2W legal assessment depends on its content, which in turn is problematic.

TRIPS prescribes that the term must be interpreted in a manner to protect public health. The Doha Declaration specifies TRIPS by putting an emphasize on A2M. As a result, patent law refers to the human rights category. A2M is stipulated in the Universal Declaration of Human Rights (UDHR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR). Thus, F2W content should be defined in the context of A2M. However, the correlation between F2W and A2M is complicated.

F2W and A2M belong to different discourses. There are crucial differences between patent law and human rights law such as private versus public character and territorial versus universal nature, to name a few. The framing of patents as being opposed to human rights leaves behind a legacy of acceptance that patents are and should not be expected to contribute anything other than private interests[18]. Three dominant conceptions, such as subjugation, integration and coexistence, describe the interface of patents and human rights. Analyzing the convergence of F2W and A2M under different conceptions can reveal if F2W is conceptually appropriate.

CL is the mechanism that can promote A2M at the cost of the initiative to research. F2W is the central element of the flexibility because it invokes the granting of CL. F2W has a great influence on the system's ability to promote A2M. Nevertheless, its influence is limited because external factors also affect CL. For example, the US Special 301 Trade Report 2015 called upon countries to eliminate F2W. Such political pressure leads to an over-compliance of TRIPS. Evaluating the ability of CL to promote A2M would require considering a myriad of external factors. Despite its limitations, F2W to a large extent determines the ability of CL to promote access. Therefore, revealing the legal and conceptual appropriateness of F2W will allow assessing the ability of F2W to promote access to medicines.

[16] Trebilcock (2005) p. 28
[17] Beier (1996) p. 189
[18] Gold (2013) pp. 186-187

1.2 Research questions

The main objective of this thesis is to analyze the strengths and weaknesses of using F2W to promote access to medicines. In order to attain this goal I need to answer the research question of whether the interpretation of F2W that was given in the Bayer Nexavar case is sustainable. In turn, to determine sustainability of this term, I need to answer two sub-questions. Firstly, whether F2W is allowed under TRIPS, whether its interpretation in the Bayer Nexavar case is in line with the Agreement. This sub-question is important for several reasons. F2W has a legacy as a tool of protectionism, but protectionism is banned by TRIPS. Even more, in the initial trial and at the appeal stage of the Bayer Nexavar case, F2W was provided with different interpretations. Such an inconsistent interpretation, even within one case, illustrates the problematic character of F2W. Secondly, I want to inquire if F2W is conceptually appropriate. This sub-question is crucial because originally F2W was not meant to facilitate access to medicines. Prima facie, F2W in the context of access to medicines seems misplaced.

1.3 Justifications for the research

The public interest in accessing medicines is an important human rights issue. A number of international statements and declarations over the last decade has addressed the global lack of such access[19]. However, the development that stems from TRIPS, such as the heightened patent protection of pharmaceuticals, exacerbates the issue. The elevated patent protection makes many medicines, currently available on the market, too expensive for millions of people around the world. Many drugs available in the developing world are only available to a small percentage of the population due to economic inequalities[20]. While this might be an acceptable outcome for certain commodities, such as luxury goods, it is unacceptable for life-saving medicines. In an attempt to limit the adverse impact of patent rights on public interest, TRIPS provided for CL. F2W serves as a justification for CL, but F2W is a controversial legal category. As an element of CL, F2W is important for promoting access to drugs in the TRIPS context. It is therefore worthwhile to inquire the legal and conceptual appropriateness of F2W as a ground for CL.

As far as the selection is concerned, it should be stated that India supplies 20% of the global market for generic medicines[21]. The country is the major supplier to emerging markets and has become

[19] Grover (2012) p. 236
[20] Ibid
[21] Waning (2010)

the biggest supplier to UN health care programs[22]. In particular, to countries like South Africa and Botswana, India helped to facilitate the global scale-up of HIV/AIDS pharmaceuticals[23]. The generics industry has earned India the nickname of "pharmacy of the developing world" because of the volume of generic medicines it exports each year[24]. Not only developing countries in Africa and other regions, but also India itself, have benefitted from Indian generics. Generics dominate the Indian pharmaceutical market and account for around 75 percent of the market by volume[25]. Nevertheless, patent rights can threaten the Indian generics industry. F2W justifying CL could protect the industry from excessive patent protection.

1.4 Methodology

Initially, I will use doctrinal analysis with its conventional dogmatic interpretation approach to establish the meaning and scope of relevant law provisions. Later, I will examine theoretical findings, which I will obtain through the doctrinal method, against the empirical administration of law in the Bayer Nexavar case. Next, I will make use of qualitative analysis to embrace broad and dynamic social-economic categories that exist in the world outside the law, such as public interest, patent social costs, etc. Qualitative analysis is difficult to perform because social-economic categories are even more "slippery" than legal ones[26]. A researcher is more exposed to bias in qualitative analysis than in others. Dobinson argues that doctrinal analysis is a particular form of qualitative analysis[27]. Qualitative analysis will require me to perform the process of selecting and weighing factual materials, taking into account their relevant social context. Doctrinal analysis is a quest for meanings in the relatively static environment of legal sources. In contrast, qualitative analysis occurs in the fast-changing environment with myriads of social context elements that may also include legal sources. Finally, I will employ quantitative analysis to obtain measures of relevant categories, such as the amount of times CLs were granted since the TRIPS Agreement was adapted; the amount of patentable medicines on the WHO "Model List of Essential Medicines" that feasibly can become a target of CL, etc. Quantitative analysis is considered more reliable because of the reduced intervention on the researcher's side. This type of analysis is allocated on the empirical edge of the methodological continuum and is mostly employed in natural sciences. Taking into account the nature of the subject, features of the research question

[22] Dhawan (2015)
[23] Lewis (2014) p. 1062
[24] Turril (2013) p. 1558
[25] Dhawan (2015)
[26] Ezzy (2002) p. 5
[27] Dobinson (2007) p. 22

and the methods employed, I will perform the legal empirical research of the evaluative nature with a descriptive component.

1.5 Structure of thesis

Thesis comprises of three main parts. Following the introduction, the second chapter gives a brief overview of CL. The chapter aims to review different elements of the CL system. Firstly, grounds for CL are considered. F2W is compared to other grounds to define its normative weight. More, the scope and the duration of CL are discussed to determine how F2W influences these elements. Then, the interface between F2W and the remuneration for the patent CL are reviewed. Further, exclusions and exceptions under TRIPS are reviewed. The review describes the shift in patent regulation and its implications for F2W. Next, the chapter proceeds to consider relations between F2W and the interests that are balanced by CL.

The third chapter aims to explore the conceptual convergence of F2W and A2M. It examines the correlation under three major conceptions. Then, the chapter continues to review different international and national laws searching for A2M content because it has a significant descriptive value for F2W. The discussion in this chapter will be used in the last chapter to assess the ability of F2W to strike a balance between patent rights and the public interest in accessing medicines.

The last chapter briefly introduces the history that predates the litigation. Then, it moves to analyze the decision rendered by the Controller of Patent in Mumbai (the Controller) and the judgment delivered by the Intellectual Property Appellate Board in Chennai (The Board). The chapter culminates with the test of theoretical findings on F2W against its authoritative interpretation in the Bayer Nexavar case.

Lastly, thesis sums up the major points of discussion and concludes with few foresight notes on the future of F2W as a ground for CL.

2 Chapter Two: Compulsory License Overview: Focus on "Failure to Work"

2.1 The Operation of the Compulsory License Regime

CL is an authorization that is granted by the government without the permission of the patent owner[28]. The fact that CL operates with the previously granted patent suggests that the subject matter must be patentable[29]. As a result, CL is an exception to patent infringement rather than an exclusion from patentability. Most countries have provisions for CL, either under their patent law like India or through anti-trust legislation like the US. Under TRIPS[30], countries have the right to issue such licenses to promote competition and increase the affordability of patented inventions[31] and to remedy abuses of unexploited patents to clog the register[32]. Even more, in light of the important role that CL could play in contemporary patent law, WTO reaffirms its members' right to grant such licenses in the Doha Declaration. One of the main themes in the Declaration is that patent protection should be implemented in a manner that permits WTO members to protect public health and promote A2M[33]. The Paris Convention provides countries with the right to take legislative measures for the grant of CL to prevent abuses of patent rights[34]. Neither the Agreement nor the Convention limit the grounds or reasons for granting CL; countries can only use the grounds that are allowed by their national legislation. However, the Paris Convention mentions F2W as an example. Many states incorporated this example in their legislations[35]. The Agreement states that the conditions under which a compulsory license is granted should be regulated in accordance with TRIPS[36]. Therefore, the development of an appropriate national legislation is crucial.

Following the guidance of the Doha Declaration, WTO members have adopted the relevant CL legislation and made use of the CL scheme to meet the demands of public health. For instance, in recent years Brazil, India, Taiwan, and Thailand have issued CLs on pharmaceuticals that treat deadly diseases. The practice of CL varies from country to country. For example, in Brazil CL is occasionally used by the government as a tool to threaten drug companies to reduce prices. Asian countries have granted CLs that have led to considerable international controversy among local governments, patent owners, and their home countries. Most of these CLs concern citizens' A2M, pharmaceutical companies' incentive to invest in research and development (R&D) for new drugs,

[28] Timmermans (2000)
[29] Frankel and Lai (2015) p. 153
[30] TRIPS, Art.31
[31] Correa (2000) p. 93
[32] Blakeney (1996) para. 8.19
[33] Wang (2015) p. 192
[34] The Paris Convention, Art.5(A)(2)
[35] The Patent Act 1977 (UK), Sec.48A(1)(a); The Patent Act 2013 (NZ), Sec.164(2)
[36] TRIPS, Art.31

and the correct interpretation of relevant international treaties. For the reason that practice of CL significantly affects patent owners' profits from the domestic market and control over their inventions, most of them are against such practices[37]. On the other hand, increasing drug prices have troubled governments in developing countries where lack of access to affordable medicines imperils the health of their citizens. Although many countries made use of CL, relative to the large number of patents now in effect in WTO member states, the frequency and the numbers of CLs to date have still been low[38].

The infrequent use of CL is used as an argument against the CL system. While it is true that in some countries, e.g. the UK, few CLs have been issued, other countries, among them developed countries such as the US, have granted a large number of compulsory licenses[39]. However, regardless of whether or not CL is used frequently, provisions for CL are needed, because they will encourage the patent owner to behave correctly. They give a sign to the patent owner that in the case of abuse of rights or non-availability of the product, a third party could be allowed to use the invention. CL prevents malpractice and misuse of the monopoly rights. In fact, one of the most important aspects of the CL system is its impact on the actual behavior of the patent owner[40]. The system is therefore a necessary element of patent law. Nevertheless, to ensure that the system can be used effectively, it is important to carefully state the grounds and conditions for its use in national legislation. CLs should be used for reasons related to the public interest in accessing medicines.

2.1.1 Recognized grounds

In the context of F2W, the term "work" was initially aimed at local manufacture[41], and it predates WTO and TRIPS. The Paris Convention provides the scope for CL at the domestic law level and it allows the national legislation to grant a CL if a patent is only exploited through import. In contrast, TRIPS prescribes that patent rights shall be enjoyable even if products are imported[42]. Therefore, under TRIPS, import can satisfy local working requirement[43] or avoid F2W. Denying

[37] Shen (2015) p. 292
[38] Liu (2012) pp. 679, 681
[39] Timmermans (2000)
[40] Ibid
[41] Ibid
[42] TRIPS, Art.27(1)
[43] Gervais (2012) p. 492

import as a fulfilment of F2W may violate the principle of technological neutrality expounded by TRIPS[44]. F2W relying on local manufacturing may contradict TRIPS.

The interface between TRIPS and the Paris Convention in relation to F2W is ambiguous. Article 2(2) of TRIPS incorporates the Paris Convention into TRIPS states: "[n]othing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention"[45]. Therefore, it is reasonable to conclude that the patent working requirements of the Paris Convention and the CL provisions of TRIPS are grounds for CL. Nevertheless, this is not the full picture, and the way the Convention and TRIPS function together is relevant. TRIPS neither eliminates the Convention nor derogates from it, but the Convention equally cannot be used to defeat the safeguards that TRIPS requires for licenses. Therefore, the recognition under the Convention does not render F2W TRIPS compatible per se. The recognition of F2W at the national level should also be addressed.

CL exists to ensure local working of patents or avoid F2W that public expectations can be met[46]. The Paris Convention provides that countries shall have the right to take legislative measures providing for the grant of CL to prevent, for example, F2W[47]. Countries have responded to the provision by adopting relevant laws. For instance, the UK Patent Act 1977 also contains terms such as "not being so worked to the fullest extent that is reasonably practicable"[48]. Even more, Australian patent law uses the phrase that "the reasonable requirements of the public with respect to the patented invention have not been satisfied". The phrase implies that the invention is not being worked on a commercial scale in Australia when this is possible[49]. In addition, Indian patent law recognizes F2W in terms such as "the patented invention is not worked in the territory of India". Despite the slightly different wording, it is evident that F2W has a wide recognition at the national level.

As stated above, CL provisions of the Paris Convention are incorporated into TRIPS, but the incorporation of F2W is not straightforward. TRIPS implicitly provides, other than F2W, grounds for CL. The Agreement refers to grounds by explicating the conditions under which CL may take place. For instance, TRIPS recognizes such a ground as the patentee's refusal to deal[50]. Hence, CL becomes a potential remedy to different anti-competitive practices, depending on the competition laws of member states. In addition, TRIPS refers to national emergency, government use, and cross

[44] Bonadio (2012) pp.722-724
[45] TRIPS, Art.2(2)
[46] Cornish (2010) paras 7-40 and 21-22
[47] The Paris Convention, Art.5(A)(2)
[48] The Patent Act 1977 (UK), Sec.48A(1)(b), the section deals with CLs for patentees who are non-WTO proprietors
[49] Patent Act (AU), Sec.133(2)(a)(ii)
[50] TRIPS, Art.31(b)

licensing, to name a few. TRIPS reduces the international recognition of F2W by not mentioning it. Hence, the ground is somewhat neglected at the international level. Apart from statutory recognition, F2W has gained some acceptance by customary law.

As mentioned above, TRIPS implicitly refers to some CL grounds, but these are not exhaustive[51]. Article 31 does not delineate any limits as to what can be a ground for CL[52], and some CL grounds lack international norms. For example, there are no relevant norms about the CL that may be granted as a consequence of anti-competitive conduct. In contrast, international norms have formed around F2W due to the frequent national application of the ground. Reichman argues that Article 31 magnifies the legitimacy of every complying government's right to resort to CL whenever its domestic self-interest so requires[53]. He claims that it offers a blank canvas for what can constitute a ground. In turn, Blakeney argues that member states seeking to implement CL may rely on Article 7 and 8 of TRIPS to glean CL grounds, other than those referred to in Article 31. Therefore, theoretically, many CL grounds can be deduced many from the articles, but these grounds will lack the international norms that have formed around them. Thus, the ample application at the national level have provided F2W with a customary law status. The relation between F2W and other CL conditions should be discussed.

CL can only be granted if the granting process considers applications on their individual merits. Different circumstances result in different modalities of CL. For instance, a CL issued on the F2W ground will be different from a CL that is issued on the ground of anti-competitive conduct. The ground that invokes the granting of CL determines other CL conditions. If a CL is invoked on an The F2W ground, it has certain consequences for such CL conditions as scope and duration, prior negotiation and remuneration. Hence, F2W is important for other CL conditions.

2.2.2 Scope and duration

The controversy over the appropriate scope of CL was one of the reasons that TRIPS negotiation were initiated[54]. At the early stage of negotiation, texts such as the Anell Draft and the Brussels Draft tended to limit the issuance of CL. The final text of the Agreement does not limit CL grounds, but it imposes some requirements that the state issuing a CL must fulfill. Governments avail themselves of the right to grant CL, but the granting procedure varies from country to country. For instance, while in Brazil the president is in charge to order a CL, in the US, the Federal Trade

[51] Correa (2000)
[52] Van den Bossche (2008) pp.788-789
[53] Reichman (2010) p. 591
[54] Madieha (2013) p. 208

Commission, the US Department of Justice or private parties[55] may bring actions in the courts to obtain a CL. In comparison, granting CL in India relies on administrative and judicial procedures. The possible scope and duration of CL should be analyzed in the context of the F2W ground because these elements are important for promoting A2M. Scope and duration imply the range of relief that can be granted in a CL[56]. Considering scope and duration of CL, Reichman argues that the "practical ramifications of Article 31 may ultimately depend on a combination of state practice at the local and regional levels and subsequent legislative or judicial action at the international level"[57]. In determining the scope of the reliefs granted by way of CL, governments consider different criteria that are provided by TRIPS. Article 31(c) of TRIPS states: "[t]he scope and duration of such use shall be limited to the purpose for which it was authorized …"; therefore purpose is important for the scope and duration of CL. Choosing a purpose, governments exercise a great discretion in determining the form of relief to be granted, as well as its lifespan. The basic purpose behind the issuance of a CL should be the overriding interest. The scope of CL should be considered together with the duration because they are coterminous with each other and because both of them rely on the relevant public interest[58].

Supposedly, the relevant purpose that is described in Article 31(c) TRIPS is related to the public interest for the issuance of the CL mentioned in Articles 7, 8 TRIPS and Paragraph 4 of the Doha Declaration. For example, in the context of the public interest in A2M, the scope of the CL should be limited to medicines that are necessary to address the health needs. The CL cannot be issued for "medicines" in general or as an entire class, but it must be limited to specific technology[59]. A government can authorize the CL of a specific drug, but not all anti-retroviral therapy[60]. The relevant base of patients should limit the scale of drug production. In order to accommodate public health needs, CL must enable either the production or the import of drugs. In determining the terms of a CL for the purposes of public health, the issuing authorities must take into account interests of the licensee and patent owner. The scope of the CL must take into account several things, such as the nature of the invention, the ability of the compulsory licensee to work the invention to the public advantage, and the risks that the compulsory licensee has to undertake providing capital and working the invention. Like voluntary licenses, CLs can be limited to persons, time, place, manufacture, use, or sale. It might be necessary to impose restrictions with regard to the field of

[55] Reichman and Hasenzahl (2003) p. 10
[56] Madieha (2013) p. 209
[57] Ibid, p.16
[58] Madieha (2013) p. 210
[59] Osenga (2012) p. 318
[60] Ibid

application, the territory, or the amount of production[61]. For instance, if a CL was invoked on The F2W ground, the notion 'working' implies that the invention is being put into use or manufactured in the country. F2W obliges the compulsory licensee to manufacture the product in the country where the patent was issued rather than import the patented good.

Invoking a CL on The F2W ground, a government may seek to remedy the non-availability of medicines[62]. Therefore, the licensing terms must ensure that the drugs produced under the CL reach the target audience; namely, medicines must be affordable to ordinary people and available gratis to certain groups. In some cases, if local production is not commercially feasible, CL may involve import of drugs from overseas by the compulsory licensee. Countries such as Malaysia, Ecuador, Ghana, Indonesia, Rwanda, and Thailand have issued CLs for the purpose of import of generic drugs from other countries. Cheaply imported drugs offer an easy solution to non-availability of patented drugs at affordable prices. Nevertheless, in absence of a local generic industry, invoking a CL on the F2W ground can hardly facilitate the public interest in A2M. The lifespan of the CL must also correspond to the nature of public interest. The time depends on the nature of the invention and the urgency of the problem. For example, a complex technology such as medicines would require a long working-out period. Due to their complexity, it is normal for medicine CLs to endure for the remaining duration of the patent term. In addition, other factors determine the duration of a CL. The redress needed to remedy life-threatening epidemics must be of a sufficiently long period to contain the spread of the disease. A number of CLs for communicable and non-communicable diseases have endured for the remaining period of the patent term[63]. For instance, Indonesia granted long-term CLs of retroviral drugs in 2005. However, in some cases, despite the urgency of health problems, governments issue CLs with a rather short lifespan. Thailand issued CLs for retroviral drugs in 2006 and 2007 for a short period, but these were renewed in 2010[64].

Setting the timeframe of a CL, the compulsory licensee should not be deprived obtaining a reasonable compensation and an adequate return on R&D because otherwise, he or she will have no incentive to apply for a CL. This may require extending the scope and duration of a CL beyond what would actually be necessary in the light of the relevant public interest. Such an approach is confirmed by the fact that Article 31(g) TRIPS does not demand the termination of a CL on the sole ground that the circumstances, which led to the granting of a CL, have ceased to exist[65].

[61] Stoll (2009) p. 571
[62] Madieha (2013) p. 211
[63] Madieha (2013) p. 212
[64] Kuanpoth (2015) p.
[65] Lamping (2014) p. 690

Considering F2W in the context of CL duration, it should be noticed that F2W implies no restrictions on the duration of a CL and that a CL may have a long or short lifespan.

Interpreting Article 31(c) TRIPS, one has to be mindful of the purpose for which CL has been issued. National experiences show the latitude of discretion possessed by authorities in issuing CL. Reichman argues that there is an expansive concept of public interest that will shape the discourse on CL[66]. The notion of CL must take into account all the noble aspirations contained in the preamble of TRIPS, particularly Articles 7 and 8. According to Reichman, "all these provisions arm developing and least-developed countries with legal grounds for maintaining a considerable degree of domestic control over intellectual property policies in a post-TRIPS environment, including compulsory licenses"[67]. CLs must be carefully crafted to reach the specific purpose for which they are issued, such as promoting A2M.

2.1.3 Prior Negotiation

Article 31(b) TRIPS states, "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 …" and therefore a CL applicant is obliged to conduct a prior negotiation before seeking a CL. The wording of Article 31(b) has provoked discussions about the nature of prior negotiation; sometimes it may become an obstacle for issuing a CL. For example, in Thailand, the patent owner of the AIDS drug "efavirenz" argued that the CL violated TRIPS because the Thai government did not engage in prior negotiation before issuing the CL[68]. Article 31(b) of TRIPS demands that a CL applicant must first undertake negotiation with the patent owner. Considering the nature of prior negotiation, it should be noticed that developed countries insisted on the condition because it would safeguard patent rights from being abrogated unjustifiably, but the nature of prior negotiation is not evident from TRIPS. It is not obvious if prior negotiation is a substantive CL ground or a procedure that a CL applicant must fulfill before he or she may be granted a CL. The "ground theory" treats prior negotiation as a substantive CL ground and relies on the document issued by the International Bureau of the World Intellectual Property Organization (WIPO) that states that "failure to obtain a voluntary license under reasonable terms within a reasonable period" is listed as one of the six most widely adopted grounds for a CL in developing countries[69].

[66] Reichman and Hasenzahl (2003) p. 11
[67] Ibid
[68] Kuanpoth (2015) p. 66
[69] Lin (2015) p. 167

The "ground theory" implies that the refusal to license on reasonable commercial terms would constitute an abusive use of patent rights and therefore would trigger the CL. Consequently, according to theory, if a qualified person tries to obtain a voluntary license on reasonable commercial terms, but the patentee does not grant his or her consent within a reasonable period, it would constitute an independent ground for a CL. Hence, if the "ground theory" is the proper interpretation of TRIPS provisions then prior negotiation is an independent CL ground. In contrast, the proponents of the "procedure theory" claim that prior negotiation under TRIPS is merely a procedure. Therefore, the patent owner enjoys the right to refuse a voluntary license even if a CL applicant has offered reasonable commercial terms, while the CL applicant must make efforts to negotiate a voluntary license before he or she can file a CL application[70]. It is not clear what interpretation of prior negotiation is appropriate, but TRIPS negotiating history may shed some light on this point.

Initially, Japan suggested the prior negotiation clause as a procedural safeguard for patent owners, and Switzerland supported Japan by proposing a similar provision that elevated the procedural dimension of prior negotiation. It appears that historically the clause was envisaged as a condition rather than an independent ground. The literal reading of the provision implies that prior negotiation requires the CL applicant to make efforts to obtain a voluntary license before filing a CL application, but scholars argue that the word "negotiation" is somewhat misleading. TRIPS does not require the CL applicant and the patent owner to actually talk and discuss with each other to reach an agreement[71]. The provision requires the applicant to make efforts to seek a voluntary license in good faith, but TRIPS does not set qualitative and quantitative criteria for them, although the plural form - "efforts" - is used here. Considering the negotiating history of TRIPS, and the Japanese position in particular, it appears that continued efforts of the CL applicant are not required and that a single attempt would fulfill the requirement. It appears that prior negotiation has a procedural character and therefore is subjugated to the ground on which a CL has been invoked.

Some grounds, such as national emergency or circumstances of extreme urgency that are stipulated in Article 31(b) TRIPS, may eliminate prior negotiation and a mere notification of the patent owner will be sufficient. In comparison, a CL that has been invoked on The F2W ground indispensably entails prior negotiation. The finding on the obligatory character of prior negotiation in case of F2W will be used in the last chapter to consider the ability of F2W to promote A2M.

[70] Liu (2009) pp. 115, 121-122
[71] Lin (2013) p. 170

2.1.4 Remuneration

Remuneration is a condition of CL because it represents the well-established principle that a patent owner should be rewarded. John Stuart Mill wrote: "[T]he inventor ought to be both compensated and rewarded … will not be denied … it would be a gross immorality of the law to set everybody free to use a person's work without his consent, and without giving him an equivalent"[72]. Even before TRIPS, almost all national patent laws besides the US law required the CL licensee to pay adequate remuneration to the patent owner. Hence, the US did not require the payment of remuneration if a CL was granted as a remedy against anti-competitive conduct[73]. Preceding TRIPS at the international level, the Paris Convention did not require the payment of remuneration for CL, but Article 31(h) TRIPS changed it by stating that "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization". The agreement does not define "adequate remuneration", but only provides "paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization". The vague wording of the article has provoked discussion among commentators.

Välimäki argues that adequate CL remuneration should be considered differently in different situations. For example, if a CL strives to promote A2M, the objective will be to lower the price on drugs. Pursuing the objective, remuneration should be lower than reward under a voluntary license, but it should not be so low as to prevent parallel trade and decrease incentive to innovate. In contrast, if a CL aims to remedy an anti-competitive practice, remuneration should be lower than the regular level, or the patent owner should be denied any reward to reflect the punitive character of the CL, and therefore the adequate remuneration in such a case can be zero[74]. National experiences indicate that governments invoking CLs to safeguard the same public interest such as public health set different remunerations. For example, invoking CLs on the ground of public non-commercial use for purposes of public health service, the Thai government imposed on the CL licensee a 0,5% royalty[75]. In comparison, invoking the CL on the F2W ground for the purpose of safeguarding public health, the Indian Intellectual Property Appellate Board set the royalty at 7%[76]. Therefore, different CL grounds result in different royalty rates. This observation will be used in the last chapter to elaborate on the capacity of F2W to promote A2M.

[72] Mill (2004) p. 271
[73] Lin p. (2013) p. 180
[74] Välimäki (2011)
[75] The Decree of the Thai Department of Disease Control, para.5(3)
[76] Bayer v. Natco para.54

2.2 Compulsory License among other patent limitations

Patent law includes two kinds of limitations for patent rights. The first type of limitations implies exclusion, and therefore abstract theories, discoveries, and methods of treatment are excluded from patent protection. In turn, the second kind of limitations involves exceptions, also referred to as "exceptions", "defences", and "permitted acts", to name a few[77], that excuse from liability uses that would otherwise violate the patentee's rights. Exceptions include situations when a person is able to use a patent on payment of a royalty; such exceptions are usually referred to as CLs.

Justification for the same exclusions or exceptions varies in different countries. The Canadian Supreme Court excluded animals from patentability on the basis that they did not fall within the definition of invention[78], while in Europe, animals are excluded because of public policy[79]. Bringing another example in this regard, the US Supreme Court stated that natural phenomena, mental processes, and abstract intellectual conceptions were excluded from patentability explicably because these are the "basic tools of scientific and technological work"[80], i.e. the exclusion was policy oriented; while in Europe, discoveries were excluded because they were "abstract", "intellectual", and "non-technical" in character. Similar to exclusions, different rationalities justify the same exceptions to the patentee's rights.

Providing justifications for exceptions, states refer to the core rationale behind patent law and become unavoidably engaged in weighing different interests. CL as a patent law exception relies on a variety of justifications in different countries, but it always involves the weighing of the incentive to invest in R&D against other social-economic goals, such as public health. States engage in the cost-benefit analysis that strives to preserve the high level of incentive to research at a low social cost. Exceptions reflect the fact that a significant goal of patent law to safeguard the incentive to R&D sometimes collides with other goals that have a higher importance, and CLs exemplify such a state of affairs. Sometimes countries such as India, Brazil, and Thailand rely on CLs to promote public health on the cost of the incentive to R&D. The current paradigm of patent limitation is undergoing changes.

TRIPS provoked important developments in patent law by changing the forum of influence that international norms came to play a significant role, and the Agreement reversed the expansion

[77] Cook et al. (2010)
[78] Harvard College v. Canada
[79] Bently (2015) p. 316
[80] Brenner v. Mason

process that had been occurring over the last century[81]. The limitation of exclusions is the objective on the way to achieve the goal of patent regime harmonization, which relies on the principle of universal patent protection. In turn, the principle demands that patents should be available "in all fields of technology", and TRIPS maintains in this regard that state members cannot exclude pharmaceutical products and processes from patent eligibility[82]. TRIPS had the profound impact on exclusions in national law, namely, it reduced dramatically the number of subject matters that were previously excluded from patentability, and therefore very few modern national patent laws contain exceptions relating to food or medicines. While the position in relation to exclusions is relatively straightforward in the post-TRIPS patent law, the situation in relation to exceptions is more complicated. International patent law reduces the number of exclusions, but it does not limit exceptions that states can incorporate in their patent laws, and therefore states enjoy the considerable discretion in implementing exceptions in their patent legislations.

However, Article 30 TRIPS limits the discretion by imposing a three-step test that implies that prospective exceptions must be duly limited, but they must not unreasonably conflict with the normal exploitation of the patent, or unreasonably prejudice the legitimate interests of the patent owner. Reviewing the Canada-Pharmaceutical case in 2000, the WTO Panel employed the three-step test to consider the regulatory review and stockpiling exception. The regulatory review or "Bolar" exception allowed generic manufacturers to use patented medicines in order to obtain marketing approval for their generic analogues, while the stockpiling exception allowed generic manufacturers to accumulate generics so the manufacturers could enter the market as soon as the relevant patent expired. The panel upheld the regulatory review exception, but found the stockpiling exception to be inconsistent with TRIPS[83], and therefore provoked the strong criticism based on Paragraph 4 of the Doha Declaration[84]. Considering the developments within the international patent law, it should be noticed that exceptions such as CLs prosper in the post-TRIPS landscape.

The post-TRIPS period shows a continuation of the standardization process such as further standardization of exceptions that relies on bilateral treaties, particularly free trade agreements, which set TRIPS-plus standards. The important WTO state members such as the US, the EU, and Japan support the standardization. In its submission for Special 301 US Trade Report 2015, championing to eliminate F2W and other CL grounds, the Pharmaceutical Research and Manufacturers of America maintained that a CL for a patent covering a medicine is granted only

[81] Bently (2015) p. 325
[82] Correa (2007) p. 271
[83] Mercurio (2014) p. 13
[84] Bently (2015) p. 327

when there is a true health emergency and as a measure of last resort[85]. Promoting the TRIPS-plus standard, developed countries selectively export their patent law, focusing on the export of protections rather than exceptions. But succeeding in this is difficult[86]; it requires convincing the poorest countries to adopt the same as or a higher patent protection than exists in developed countries and the inclusion of a broader group of states, such as in multilateral negotiation in the WTO. This is something bilateral negotiation cannot provide, and therefore the future of the TRIPS-plus regime is uncertain. The trend that currently dominates patent law discourse is characterized by the growing reliance on exceptions, such as when the need to limit patent rights arises and policymakers rely on creating new exceptions rather than excluding subject matter. The increased reliance on exceptions as a way of limiting patent rights can be seen in the proliferation of CLs[87]. Many countries made use of CL provisions to ensure A2M, and therefore the shift from exclusions to exceptions in the international patent law elevated the role of CLs. Such reliance is the consequence of the fact that TRIPS limits the extent to which exclusions can be used to implement policy goals, and therefore, in Europe, exclusions were replaced by the "inventive step" as a way of reining patent rights[88].

Similar to setting high standards for the "inventive step", CLs can be also considered as a way of drifting away from the patent regulation that relies on exclusions. While exclusions imply the blunt all-or-nothing nature, which remove rather than balance or reduce incentives to invest in R&D, CLs can allow policymakers to develop nuanced ways of reconciling conflicting interests. This CL feature stems from such grounds as F2W, that provide CLs with their necessary flexibilities. Hence, the central role of CLs, among other patent limitations, depends on relevant grounds. This finding will be considered in the last chapter in relation to the capacity of F2W to promote A2M.

[85] PhRMA Special 301 Submission 2015 p. 109
[86] Flynn et al (2012) p. 202
[87] Reichman (2009) p. 250
[88] Bently (2015) p. 329

3 Chapter Three: The Interface between Human Rights and Patent Law: The Correlation between Access to Medicines and "Failure to Work"

3.1 The convergence of Access to Medicines and "Failure to Work"

In the previous chapter, it was established that Article 27(1) of TRIPS diminishes the feature of F2W, such as local manufacturing, and therefore, having this feature somewhat neglected, F2W became an uncertain legal category. Searching for a sustainable interpretation for the CL ground, it is reasonable to refer to Article 8(1) TRIPS and Article 4 of the Doha Declaration which maintain that the CL mechanism should be interpreted and implemented in a public health protective manner and, in particular, to promote A2M. The articles are also applicable in relation to working requirement due to the fact that it constitutes a part of the CL mechanism, and therefore the need to consider A2M, the category of the human rights discourse, arises. Numerous human rights instruments recognize A2M, while some of these legal documents provide the content of A2M. In this chapter, I will review relevant theories on the interface between human rights and patent law to consider different justifications for interpreting F2W in the light of A2M.

3.1.1 Subjugation

The subjugation approach exists in many variations, but all of them frame patent rights as conflicting with fundamental human rights. They prioritize human rights over patent rights. Endorsing the subjugation approach, the United Nations Commission on Human Rights (the Commission) stated that, "conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights" [89]. In addition, the Committee on Economic, Social and Cultural Rights (the ESC Committee) maintained "any intellectual property regime that makes it more difficult … to comply with … obligations in relation to health … [that are] set out in [ICESCR], is inconsistent with the legally binding obligations of the State party"[90]. According to the Commission, when resolving these conflicts states should recognize "the primacy of human rights obligations over economic policies and agreements"[91]. Scholars uphold this approach, for instance, Drahos and Brathwaite argue that, "in any principled national legal system, basic human rights to health … take precedence over (trump) utilitarian considerations"[92]. Moreover, Paul Torremans claims that, "this solution imposes itself in the view of its proponents because in normative terms human rights are fundamental and of higher importance than

[89] Resolution 2000/7 pmbl. para.11
[90] ICESCR Statement para.12
[91] Resolution 2000/7 para.3
[92] Drahos (2002) p. 200

intellectual property rights"[93]. In advancing the framing of human rights and patent rights as being in conflict, scholars point to real life cases, such as HIV/AIDS medication being unavailable to the millions infected in Sub-Saharan Africa or pharmaceutical companies neglecting third-world diseases. In particular, Hoachem Sun provides a typical example of this approach and argues that intellectual property laws should be shaped in the public health perspective[94], he cites CL as a valuable tool to achieve the protection of human health within the context of intellectual property regimes[95]. Supporting the subjugation approach, Brinkhof asserts that the patent law history and the analysis of human rights instruments reveal that patent rights lack the human rights status, and therefore, in the event of a collision, patent rights, being subordinate to human rights, must yield[96].

While the subjugation approach seems conceptually straightforward, it has some ambiguities. If patents imperil the right to health, the subjugation approach requires human rights to trump patent rights by providing various mechanisms for this "trumping" to occur[97]. One popularly held view claims that in the situation of a clear conflict between human rights and patents, limitations on patent rights within national legislation should be created[98]. If framed narrowly, a conflict arises only when two legal rules are mutually inconsistent such that the state's compliance with one rule necessarily compels it to violate another. Some human rights such as the prohibitions on slavery and torture are categorical rules whose jus cogens status gives them undisputed primacy over other obligations, but the human rights that intersect with patent rights, such as the right to health, are open-textured. Therefore, it is unclear which international human right being breached is sufficient to trigger the subjugation of patent rights. Moreover, allowing human rights to suppress patent rights, the approach does not indicate how explicit a violation of those human rights must be before subjugation is required.

3.1.2 Integration

By giving patent rights a human rights status, the integration approach assimilates patent rights into human rights analysis[99] and regards patents as a part of human rights law, whereas the subjugation approach introduces human rights considerations into patent policy and views patent rights and human rights as distinct and potentially conflicting areas of law. Proponents of the

[93] Torremans (2008) pp.195-196
[94] Sun (2003) p. 103
[95] Ibid p. 107
[96] Brinkhof (2012) p. 153
[97] Gold (2013) p. 188
[98] Lazzarini (2003) p. 123
[99] Matthews (2012) pp. 120

integration approach argue that patent rights are essentially the same as property in tangible assets, and therefore must be secured by the same legal guarantees. Drawing on the Constitution of the US and the American Declaration on the Rights and Duties of Man, Giovanetti and Matthews assert that the protection of patent rights has long been recognized as a basic human right and those concerned about human rights made a conscious and concerted effort to ensure that patent rights are protected[100]. Approaching patent rights as human rights in the context of CL, scholars point to the human right to profit from one's invention that is stipulated in Article 27(2) UDHR that states, "[e]veryone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author".

Defending a human right status of the right to profit from one's invention, Chapman refers to Article 15(1) ICESCR that maintains, "the right of everyone … [t]o benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author". According to her, the rights of creators are not just good in themselves, but should be understood as essential preconditions for cultural freedom and scientific progress[101]. Postulating that the rights of the creator are not absolute but conditional on contributing to the common good and welfare of society, the integration approach makes an implicit balance between the rights of inventors and the interest of the wider society more explicit. Envisioning an implementation of this approach, she asserts that human rights considerations should impose conditions on the manner in which patentees' rights are protected in intellectual property regimes and assure that the rights of the patentee facilitate rather than constrain access[102]. Considering property provisions made by international human rights instruments covering patent rights, scholars regard patent and other intellectual property rights as being incorporated into the family of core human rights at the international level. Integration arguments adopt a point that is logically removed from the specific language of patent law instruments such as TRIPS.

Whereas the subjugation approach takes patent law to have a fixed meaning that are subject to human rights analysis, the integrated approach determines the meanings of patent rights and other human rights in conjunction with one another[103]. While the subjugation approach implies that the inalienable nature of human rights prevents the actual creator of the invention to assign his or her

[100] Giovanetti and Matthews (2005)
[101] Report E/C.12/2000/12 para. 599
[102] Report E/C.12/2000/12 para.585
[103] Gold (2013) p. 189

rights to an employer[104], the integration approach suggests that a group or a community can be a creator, and therefore enjoy human right protection[105].

Nevertheless, the integrated approach raises some concerns. Firstly, Article 27(2) UDHR neither refer to the words "patents" or "inventions", nor the term "scientific production" is necessarily a synonym for the term "invention". The overall tenor of the article is of extreme vagueness as to what might be understood under "the right to protection", and therefore it is not evident that "the right to protect" includes patent protection. Secondly, Article 15 ICESCR and Article 27(2) UDHR have a similar formulation, so the same points about the uncertain legal wording can be made. In particular, the term "benefit" in Article 15 ICESCR is a subtle and open category that includes many things, such as public recognition for being the inventor, or the reception of a prize or medal as a reward for one's efforts, but it may exclude patent rights. For instance, in the former Soviet Union, inventors were granted not patent rights, but merely a certificate. However, the Soviet Union did not introduce a reservation to Article 15 ICESCR, so it is likely that providing inventors with a certificate was regarded as a sufficient reward in the light of the term "benefit"[106]. Finally, framing patent rights as human rights would seriously undercut the utilitarian justification of patents, which requires states to undertake a careful balancing of interests of inventors, users and public, and put such balancing under the weight of the natural rights discourse that is inhered in human rights[107]. Likewise, viewing patents as part of human rights has damaging consequences because patents can potentially be used as a "weapon to expand patent rights against the desires of impoverished peoples to manufacture or distribute inexpensive versions of patented drugs"[108].

3.1.3 Coexistence

Rather than regarding patents and human rights as pursuing opposite goals, as in the subjugation approach, or as two mutually modifying instantiations of universal human rights, as in the integrated approach, the coexistence conceptual framework views human rights and patent law as independent discourses that are essentially compatible. Despite the fact that regimes operate at different levels, in the long term, patent rights and human rights are in a mutually supportive relation that increases human welfare by promoting both innovation and access. Heifer argues that, intellectual property rights and human rights may be understood to be concerned with the "same

[104] Gordon (2012) p. 167
[105] Matthews (2012) pp. 119
[106] Brinkhof (2012) p. 149
[107] Gold (2013) p. 189
[108] Gordon (2012) p. 157

fundamental question", namely, "defining the appropriate scope of private monopoly power that gives authors and inventors a sufficient incentive to create and innovate, while ensuring that the consuming public has adequate access to fruits of their efforts"[109]. In the UN human right system, the coexistence approach was endorsed in numerous documents such as the High Commissioner's report on TRIPS Agreement[110], the statement WTO on the relationship between human rights and TRIPS[111], and General Comment No. 17 on creators' rights[112]. Separating human rights and patent rights, General Comment No. 17 describes human rights as being fundamental since they are inherent to the human person as such, whereas intellectual property, inter alia, patent rights, are first and foremost means by which States seek to provide incentives for inventiveness and creativity[113].

Many scholars endorse the coexistence approach providing it with a variety of different perspectives. Van Overwalle argues that human rights serving as a counter balance can rectify patent rights that are centered too one-sidedly on economic calculus[114]. According to him, patent law is a widely accepted tool that fosters the public interest in economic expansion and technological progress, but this traditional economic interpretation, which had prevailed for quite some time in legal doctrine[115], became outdated. There is a clear need for a contemporary interpretation of the public interest component in patent law, and therefore human rights should be factored into patent law, through the gateway of public interest, so a modern interpretation of public interest may accommodate present-day needs. A plausible way to update the public component is to "desacralize" and anatomize it in various concrete emanations in a series of legislation. An analysis of the public interest concept in legal discourse, in particular, in civil law, administrative law, to name a few, demonstrates that public interest is a mosaic encompassing of morality, health safety, protection of public health. The human rights pantheon offers a welcome supplement to the current public interest concept in patent law by adding such as human dignity, food security and access to medicines.

In the light of the approaches mentioned above, it should be noticed that there are two central flaws in attempting to combine human rights and patent law within a single discourse. First, whereas human rights and patent rights are *rights*, they derive from different normative orders, and therefore have different justifications[116]. While a justification for human rights stems from moral

[109] Helfer (2011) p. 73
[110] Report E/CN.4/Sub.2/2001/13 para.11-12
[111] Report E/C.12/2000/18 para.13
[112] Comment E/C.12/GC/17 para.35
[113] Comment E/C.12/GC/17 para.1
[114] Van Overwalle (2012) p. 237
[115] Ibid p. 242
[116] MacCormick (1998) p. 301

and political theory, patent rights obtain its justification from cost-benefit analysis. Second, whereas human rights operate at the international level and speak to universal principles, patent rights reside at national level and speak to the domestic interest. Human rights derive from international conventions and customary law. In contrast, up until the 1980s, patent law resided primary at the domestic level and, despite the adaptation of the international trade rules surrounding patent law, patents did not fully change their locus to the international level. Being patronized by the international trade rules at the international level, patent law was diminished in terms of its structure and became a right that the state had no choice but to recognize.

Weakening the normative orders underlying the human rights and patents, an attempt to commensurate the discourses may lead to human rights being treated as contingent rights or patent rights being considered having a basis in moral theory[117]. Framing discourses as being commensurable would turn the logic that patents are a tool of the state by actually requiring the state to enforce patents, and therefore the state would no longer be able to justify a failure to enforce patents by referring to its internal needs. The coexistence approach is more promising it is free of the assumption that human rights and patent rights are commensurable and recognizes that human rights and patent law are informed by different normative and legal orders. Being far from abandoning the ideals of human rights, the coexistence approach strengthen them by enabling the discourse over how best to construct a domestic innovation system that is responsive to human rights concerns by reinterpreting the notion of public interest. The findings on the approaches will be used in the last chapter to determine which approach the Indian regulator adopted in the Bayer Nexavar case.

3.2 The Content of Access to Medicines

The right of access to public health is proclaimed in UDHR, which stipulates that "[e]veryone 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"[118]. Even more, the right is equally guaranteed in ICESCR, which maintains that "[states] recognize the right to everyone to the enjoyment of the highest attainable standard of physical and mental health"[119]. Likewise, the Oviedo Convention provides that "[p]arties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health

[117] Gold (2004) p. 263
[118] UDHR, Art.25(1)
[119] ICESCR, Art.12(1)

care of appropriate quality"[120]. Hence, states are required to strike an adequate balance between their obligations in relation to the right to health and the moral and material interest of authors. Moreover, a confluence of several factors such as the spread of HIV/AIDS, tuberculosis and a growing awareness of the adverse consequences of those pandemics have engendered the assentation that the right to health encompasses a right of access to lifesaving medicines.

A rapid evolution of the normative content of A2M occurred in the decade following the adaptation of General Comment No. 14 on the right to health, which states that "the right to health must be understood as a right to the enjoyment of … goods [that are] necessary for the realization of the highest attainable standard of health"[121]. In addition, statements endorsing A2M appeared in numerous human rights documents such as the UN General Assembly Declaration[122], the resolution of the Commission on Human Rights[123], the Report of the Special Rapporteur on the right to health[124], and General Comment No. 3 of the Commission on the Rights of the Child[125], to name a few. Commentators have bolstered these statements with analyses that draw upon other human rights, including the right to life, the right to share in the benefits of scientific progress, and the right to non-discrimination[126]. Numerous documents assert the universal right of access to pharmaceutical and medical technologies without expressly indicating whether those technologies are protected by patents or what the consequence of such protection is. Few of the documents that have been mentioned above address the issue of patented medicines indirectly. For instance, General Comment No. 3 asserts that the Convention on the Rights of the Child requires state parties to "ensur[e] that children have sustained and equal access to … HIV-related drugs"[127]. Presumably, patents protect these medicines, but the comment urges states to "negotiate with the pharmaceutical industry in order to make the necessary medicines locally available at the lowest cost possible"[128]. Likewise, the Declaration of UN General Assembly on HIV/AIDS asserts that "the cost, availability and affordability of drugs and related technology are significant factors [relating to access to medicines] and that there is a need to reduce the cost of these drugs and technologies in close collaboration with the private sector and pharmaceutical companies"[129]. In the light of the relation between patents and A2M, it should be noticed that according to several commentators the progressive realization approach undermines the universality of A2M and

[120] The Oviedo Convention, Art.3
[121] E/C.12/2000/4 para.9
[122] A/RES/S-26/2 para.26
[123] E/CN.4/RES/2002/32, para.1
[124] E/CN.4/2004/49, para.61(c)
[125] CRC/GC/2003/3, para.28
[126] Helfer (2011) p. 114
[127] CRC/GC/2003/3, para.28
[128] Ibid
[129] A/RES/S-26/2 para.24

provides insufficient guidance to states concerning their legal obligations[130]. In response to this criticism, General Comment No. 14 provided a detailed normative content of the right to health that would allow states to comply with their obligations, inter alia, in relation to A2M. Being highly influential on subsequent interpretations and analyses of the right by governments, judges, and commentators, the comment asserts that the right to health contains such essential elements as availability, accessibility, acceptability and quality[131]. In the light of the Declaration of UN General Assembly on HIV/AIDS, it appears that the most relevant features for A2M would be availability and accessibility, since A2M is narrower in scope than the right to health, that includes health facilities, services and medical ethics, to name a few.

3.2.1 Availability and Affordability

General Comment No. 14 treats A2M as only one facet of a broader cluster of issues relating to the availability, accessibility, acceptability, and quality of the determinants of health[132]. Considering availability, the ESC Committee maintains that this element requires a state to take measures to make available "[f]unctioning public health and health care facilities, goods and services, as well as programs"[133]. The composition of these "health goods" will vary depending on numerous factors, among them the developmental level of a country. Bearing in mind the progressive realization of A2M, availability implies that a state should strive to ensure the reasonable quantum and the expanded range of medicines that includes, inter alia, the most advanced drugs to meet the needs of its population[134].

According to the ESC Committee, accessibility has four overlapping dimensions such as non-discrimination, physical accessibility, and affordability. The last aspect of accessibility implies that payment for medicines is based on the principle of equity, that poorer households are not disproportionately burdened with health expenses compared with richer households, and information accessibility[135]. Granted CLs indicate that a national patent regulator gives primary consideration to such aspects of accessibility as physical accessibility and affordability[136]. It should be noticed that human rights treaty monitoring bodies and NGOs regularly express their concern with the lack of physical accessibility of drugs. For example, the Austrian Research

[130] Helfer (2011) p. 106
[131] E/C.12/2000/4 para.12
[132] Helfer (2011) p. 144
[133] E/C.12/2000/4 para.12(a)
[134] Shen (2015) p. 296
[135] E/C.12/2000/4 para.12(b)
[136] Bayer v. Natco para.21

Institute ÖBIG Forschungs- und Planungsgesellschaft mbH (ÖBIG FP), in its concluding observations for Poland, expressed its concern thus: "depending on where the patient lives, he/she has different access to medicines [and] patients living in rural areas have more limited access to medicines [than patients living in major cities do]"[137]. The same concerns are common in the concluding observations of the CRC Committee. For instance, in its observations for Guinea Bissau, it expressed concern for "the limited access to, capacity and quality of health-care services, including in terms of distance between people's homes and health facilities … and the limited availability of affordable and appropriate medication"[138]. It therefore recommended that the state party "significantly improve children's access to … medication … by strengthening the quality and capacity of health infrastructure"[139]. Financial accessibility, i.e. affordability, is an enduring concern for human rights. A health system that is beyond the financial means of people cannot be said to promote the effective enjoyment of the right to health. ÖBIG FP in its report observed that "in terms of affordability, the patient co-payment has been noted as very high in Poland. In 2007, private pharmaceutical expenditure amounted to 62% of the total pharmaceutical expenditure"[140].

It should be noticed that General Comment 14 recognizes that while States are ultimately responsible for compliance with the Covenant, all members of society, including the private business sector, have responsibilities regarding the realization of fundamental elements of the right to health, such as physical accessibility and affordability. The ESC Committee noticed that "[v]iolations of the right to health can occur through the direct action of States or other entities insufficiently regulated by States"[141]. The obligation to protect the right to health includes the commitment to prevent individuals, groups or corporations from impeding A2M. Being unambiguous about A2M when it is concerned about health policy or drugs distribution, General Comment 14 states that "the failure to adopt or implement a national health policy designed to ensure the right to health for everyone [or] take measure to reduce the inequitable distribution of health … goods [constitutes a violation of the obligation to fulfill][142]". It appears from the comment that if patent policy is contiguous to health policy, the first one should be shaped in such a way to avoid a violation of the obligation to fulfill.

[137] ÖBIG FP (2009) p. 23
[138] CRC Report CRCCRC/C/15/Add.177
[139] Ibid para. 35(b)
[140] ÖBIG FP (2009) p. 23
[141] E/C.12/2000/4 para.48
[142] Ibid para. 52

4 Chapter four: The analysis of the Bayer Nexavar case

4.1 Bayer Corporation in India

In the 1990s, Bayer Corporation, an internationally renowned manufacturer of innovative drugs, invented a compound called "Sorafenib", useful in the treatment of advanced stage liver and kidney cancer. Bayer first applied for a patent in the US Patent and Trade Mark Office in January 1999. Improving "Sorafenib", the patentee created the invention called "Sorafenib Tosylate". In 2005, the new drug was launched under the trade name Nexavar for treatment of Renal Cell Carcinoma-RCC (kidney cancer). Subsequently, the medicine received additional approval for treatment of Hepatocellular Carcinoma-HCC (liver cancer) in 2007. Nexavar stops the growth of new blood vessels and targets other important cellular growth factors. It is not a life-saving drug, but a life extending one, i.e. in the case of kidney cancer the life of a patient can be extended by 4-5 years, while in the case of liver cancer the life of a patient can be extended by about 6-8 months. The pharmaceutical corporation has also obtained patents for the same drug in many European countries. After examination under the provisions of the Indian Patent Act, the patent was granted to the corporation in March 2008. Relying on the patent, the patentee received the regulatory approval for importing and marketing the drug, and launched it, as well as in other countries, under the brand name Nexavar in India. Bayer Corporation manufactured the drug outside India, and the sale of Nexavar depended completely on import. During the first year after the patent was granted the patentee did not import the drug at all, while in 2009 and 2010 the corporation imported the medicine only in small quantities. Bayer Corporation set the price on the drug at 280 428 rupees (more than 5000 USD) as a cost for monthly therapy. In 2011, Natco Pharma Limited (Natco), a leading Indian manufacturer and distributor of various generic drugs, approached Bayer Corporation with a voluntary license request to manufacture and sell Nexavar, but the corporation declined the request. Being unable to negotiate a voluntary license, Natco filed an application for CL under Section 84(1) of the Indian Patent Act in July 2011. In the application, Natco proposed to sell the drug at a price of 8800 rupees (less than 200 USD) for one month of therapy. Accepting the range of CL grounds raised by Natco, among them F2W, the Indian Controller of Patents (the Controller) granted the generic drug manufacturer the CL. Appealing the decision, the patentee challenged the interpretation of F2W as being in violation with the TRIPS Agreement.

4.2. Before the Indian Controller of Patents in Mumbai

As has been mentioned above, a CL that can be issued under Article 31 TRIPS is subject to strict requirements that limit states' freedom of action in this regard. These conditions are more stringent

than the ones in the Paris Convention, in particular Article 5(A)(2) that provides that states shall have the right to take legislative measures providing the grant of CLs on the F2W ground. The article also adds that CLs should be refused if the patentee justifies his or her inaction by legitimate reasons. The provision neither mandates strict requirements for the issuance of a CL, nor covers other types of CLs than the ones that are issued on the F2W ground. Article (5)(A)(2) of the Paris Convention has been incorporated into TRIPS along with Article 5(A)(1). Despite the fact that the latter provision is not related to CLs directly, it is relevant for the purposes of the analysis. The article states that import of patented products by the patent owner does not entail forfeiture of the patent. Considering this provision, the Controller of Patents in the Bayer Nexavar case concluded that the mere import of patented goods might still entail "something less than forfeiture, such as a compulsory license"[143]. Therefore, in the case at hand, the Controller held that the mere import of a patented medicine does not bar the issuance of the CL. The year following the one in which the patent was granted, Bayer did not import Nexavar into India at all. Three years later, in 2011, the corporation imported and sold merely 593 boxes of drugs, while the annual demand for the medicine was about 70 000 boxes[144]. Following the logic of the Controller in relation to Article 5(A)(1), it could be argued that a local production of Nexavar by Bayer or a licensee authorized by it would prevent the granting of the CL. However, this did not occur in the case.

The Controller pointed out that despite having manufacturing plants in India for several products, including oncology-related drugs[145], Bayer did not produce any pills of Nexavar. No obstacle prevented Bayer from manufacturing medicine locally or granting a voluntary license to other generics manufacturers including Natco[146]. The Controller rejected Bayer's argument that the small quantities of drugs required in India did not justify setting up manufacturing plants in the country[147]. Reaching its decision, the Controller relied on three provisions of the Indian Patent Act, i.e. Section 83(b), (c) and (f)[148]. The first provision states that patents are not granted merely to allow patent owners to enjoy monopolistic rights for the import of the patented goods. The second one provides that the issuance of patents should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. The third article states that the patentee enjoying his or her patent rights should not engage in practices which unreasonably restrain trade or jeopardize the international dissemination of technology. The Controller stressed that Section 83(c) and (f) are very important because provisions confirm the

[143] Natco v. Bayer p. 41
[144] Ibid p.22
[145] Ibid p. 37
[146] Ibid p. 45
[147] Ibid p. 39
[148] Ibid p. 43

principle that patent owners are obliged to contribute towards the national and international transfer of technology, and therefore their rights and obligations should be balanced. Reflecting on the issue of how the patentee could fulfill the dissemination of technology requirement, the Controller asserted that the patent owner should either produce the patented product himself or herself in loco or grant a local third party a license to manufacture it. Oddly enough, in this specific regard, the Controller did not refer to Article 7 TRIPS, which states that the protection of intellectual property should contribute to the transfer and dissemination of technological innovation, or Paragraph 5(b) of the Doha Declaration, which provides countries with the freedom to determine CL grounds. It appears that the Controller's findings do not give due consideration to the TRIPS debate surrounding F2W and may be in violation of TRIPS itself.

It is believed that Articles 5(A)(1) and 5(A)(2) of the Paris Convention as well as Article 31 TRIPS have to be read and interpreted together with Article 27(1) TRIPS, according to which "patents shall be available and patent rights enjoyable without discrimination as to … whether the products are imported or locally produced". In other words, this provision clarifies that if a national legislation imposes a local working requirement, like the Indian Patent Act, a patentee should have the opportunity to satisfy such requirement by demonstrating that it has imported the patented product in the country in question. There is no doubt that, contrary to what is affirmed by the Controller of Patents[149], under TRIPS the concept of F2W includes both the local production and the import of patented goods[150]. Article 27(1) has therefore an impact on the issuance of CLs. This conclusion is confirmed by the WTO Panel's decision in Canada - Patent Protection of Pharmaceutical Products - where it was held that the non-discrimination or technological neutrality principle under Article 27(1) also applies to Article 31[151]. It follows that, when resorting to CLs, states are not allowed to discriminate based on whether products are imported or locally manufactured. Hence, Article 27(1) should be interpreted as not allowing any limitation of patent rights, including the issuance of CLs, merely because the patentee does not produce the patented invention locally. Paragraph 5(b) of the Doha Declaration could not be invoked to justify the need of a local production requirement. As mentioned above, the paragraph should indeed be read in the broader context of TRIPS and in particular in the light of Article 27(1), which mandates the principle of technological neutrality. This interpretation of Article 27(1) is in line with the spirit and aim of TRIPS and WTO and jeopardizes neither the dissemination of technology nor the public interest in A2M. For instance, governments could still issue CLs if patented products imported by the patentee, or with his or her consent, do not satisfy the local demand, or are sold at an

[149] Ibid
[150] Pires de Carvalho (2010) p. 239
[151] The WTO Panel WT/DS114/R para.7.91

unaffordable price. This is what happened in the Bayer Nexavar case. Bayer did not import Nexavar in India at all in 2008. In 2009 and 2010, the corporation imported and sold at the high price just small quantities of the drug[152]. It is believed that relying on these circumstances interpreting working requirement would render a more TRIPS-compliant definition of F2W that would acquire support of both Article 27(1) TRIPS and Article 5(A)(1) of the Paris Convention. As has been explained above, the Controller based his incorrect finding on the local production requirement. Justifying its reasoning, the Controller referred to a certain provision of the Indian Patent Act, i.e. Section 83(b). This provision states that patents should not be granted merely to allow patent owners to enjoy monopolistic rights for import of the goods. Reliance on the national provision to justify its position neither provides a safe harbor for Indian CLs nor excludes the alleged infringement of Article 27(1) TRIPS. Due account must be taken of Article 27 of the Vienna Convention on the Laws of Treaties which maintains that "a party may not invoke the provision of its internal law as justification for its failure to perform a treaty".

Providing the interpretation for working requirement, the Controller envisaged F2W one-sidedly. In the part of the decision that is devoted to the F2W ground, the Controller referred only to Article 27(1) TRIPS, but he failed to refer to Article 8(1) TRIPS, which seems appropriate to mention due to the public health dimension of the case. Rather than adopting human rights wording and express F2W through such categories as availability and accessibility, the Controller adhered to the conservative reading of the term that dates back to the emergence of patent law when patents served as a mean of protectionism. The Controller relied on the category "commercial scale", further adding that this category is not sufficient and that it is "something more than that". From the wording of the decision, it appears that "something more than that" implies "local manufacturing". Both "a commercial scale" and "local manufacturing" are mainly economical terms, and therefore it is doubtful that they could accommodate the human rights dimension of the case. In contrast, elaborating on availability and accessibility of the drug as conditions of working requirement might strengthen the decision by giving due regard to the human rights aspect. The way that the Controller approached the issue may resemble the subjugation approach. Indeed, the TRIPS provision that obliges states to provide medicines with patents and their obligation in relation to health are not mutually exclusive per se. Thus, a state may fulfill its obligation in relation to health by regulating prices on medicines or launching national drug programs funded by the state, and therefore try to avoid engaging in issuing CLs. Nevertheless, it appears that the Controller did not adopt any approach, and failed to recognize the collision between different sets of rights at all. If the Controller adopted the subjugation approach, he would at least give some

[152] Natco v. Bayer p. 53

acknowledgment to A2M, providing the interpretation to working requirement. Moreover, if the subjugation approach has been employed, the Controller would assess F2W through the prism of the public interest in transfer and dissemination of technology rather than through the prism of A2M. Without reservation, absence of local manufacturing slows down the transfer of technology, but does not eliminate it since the patentee still has to reveal an invention to a national patent office. However, the Controller was especially insistent on the local manufacturing requirement, so one may conclude that he viewed the issue through the prism of protectionism denying the foreign patentee his patent rights on the mere ground of lack of local manufacturing. The Controller did not prioritize the public interest in transfer and the dissemination of technology over the public interest in A2M, which is disputable due to the background of the case, but would still be understandable in the light of the unsettled relations between the discourses; nevertheless, he embraced protectionism as the relevant public interest, which violates principles of TRIPS. Hence, the Controller provided the interpretation of F2W, which is neither legally appropriate nor sustainable under any of the approaches towards the interface between human and patent rights mentioned earlier. Such an interpretation not only diminishes the role of human rights in the patent law discourse, but it also imperils patients whose health depends on affordable Indian generics by rendering the Indian CL mechanism in violation with TRIPS and the generics industry vulnerable to quarrels under the WTO Dispute Settlement Understanding.

4.3 Before the Intellectual Property Appellate Board in Chennai

Appealing the decision of the Controller, Bayer claimed that the Controller erroneously concluded that the manufacture in India was necessary to meet the "working" requirement under Section 84(1)(c) of the Indian Patent Act[153]. According to him, deciding on the merits of the case, the Controller did not give due consideration to the relevant international provisions. Starting its analysis of F2W, the Intellectual Property Appellate Board (the Board) questioned whether "working" means "local manufacture"[154]. Further, the regulator went on assuming that if it would accept that mere import would satisfy the working requirement, such import would have to be done on *a commercial scale to adequate extent* and sold at *a reasonable price*[155]. Before going into details, it should be noticed that the wording adopted by the Board, such as "reasonable price", reminds of human rights language adopted in relation to A2M. Preliminary accepting import as a way to fulfill the working requirement, the regulator proceeded to tackle the term "working the

[153] Bayer v. Natco para.4(vi)
[154] Bayer v. Natco para.40
[155] Bayer v. Natco para.41

invention on a commercial scale". The Board referred to Bayer's previous submission on providing patients with the drug through its Patient Assistance Programs (PAP). The Board explained the term "working the invention on a commercial scale" by confronting it to PAP, and maintained that "[t]hese programmes are at the discretion of the appellant and not the market price"[156]. Moreover, the Board also endorsed the findings of the Controller in relation to PAP's insufficiency to fulfill the working requirement by stating that "[t]he Controller has held that the philanthropic proposals cannot be taken into account while construing the expression, 'working the invention on a commercial scale to an adequate extent'". Considering this explanation, it should be assumed that "working the invention on a commercial scale" implies that the drug is available at nobody's discretion and in an unlimited amount; unlike under PAP, which provided certain patient groups with cheaper medicines, the medicine should be sold at a regular market price. It appears that the regulator repeated itself by stating "reasonable price" and "the market price", since the terms, prima facie, imply the same meaning. However, it can be viewed as a way of putting emphasis on the affordability of the drug. The Board reviewed to which extent R&D costs might affect the market price by stating that "[t]he R&D costs cited are [not relevant and] what we have to look at is the market price … at which the invention is made available to the public"[157]. Hence, treating the R&D costs in this way is an indication of prioritizing A2M over the promotion of technological innovation, or more generally patients over patents. Next, the regulator narrowed its scope of inquiry to the sole term "work". Considering the term, the Board addressed two of Bayer's arguments. First, Bayer argued that due to the nature of the invention it was difficult for Bayer's Nexavar to enter the market because the corporation had to convince many oncologists so that they would prescribe the patented invention to their patients. The Board dismissed the argument because the three-year period after the patent was granted as prescribed by the Paris Convention[158] and the Indian Patent Act[159] had elapsed. More importantly, dismissing the argument the regulator concluded "three years would be sufficient for an inventor to work his invention in the territory of India and make the supply meet the demand at a reasonably affordable price"[160]. Thus, it is reasonable to assume that if Bayer did met the demand even through mere export, it would constitute "work". Second, Bayer claimed that due to the sales of CIPLA, a patent infringer that produced and sold the analog for Nexavar, the adequate supply was provided. The Board dismissed the argument concluding that the sales of CIPLA could not be taken into account because the obligation to provide the adequate supply lay only on the patentee. More importantly, the regulator

[156] Ibid
[157] Ibid
[158] The Paris Convention, Art.5(A)(4)
[159] The Indian Patents Act, Sec.84(1)
[160] Bayer v. Natco para.45

went on to emphasize the difference between what is meant by commercial sales and what is meant by patient support. Apparently, the aim of the Board was to demonstrate the dramatic difference in relation to the amount of drugs that could be provided through these forms of distribution. Even more, examining the term "commercial sales", the regulator pointed to the negligible amount of commercial sale units that were imported in 2010 and their prohibitively high price[161]. The relevant paragraphs of the decision reveal that the term "work" is consistently linked or accompanied by terms such as "reasonably affordable price", "adequate supply", or "meeting the demand", and for that reason it can be argued that the expression "working" in Section 84 takes color from these terms.

Further, the Board moved on considering whether local working implies local manufacturing in the sense that the patented invention must be assembled in the country. Approaching the issue, the regulator proclaimed that the international conventions and Indian law must be read harmoniously. The regulator recalled the Controller's point that import could entail something less than forfeiture, such as CLs. Bearing this point in mind, the Board as the Controller referred to the Indian Patent Act and noticed that the law uses both the terms "working" and "import" in the same sections at the same time and not synonymously[162]. The regulator went on to consult with the general principles applicable to the working of patented inventions; in particular, he considered Section 83(b) which says that the patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented articles, and Section 83(c) which refers to the transfer and dissemination of technological knowledge. Further, the Board reviewed several provisions under Section 84, which regulates CLs; among these, 84(7)(e) that speaks of the working of invention being prevented or hindered by import, and 84(7)(a)(iv) that refers to the establishment or development of commercial activities in India being prejudiced. The selection of relevant articles and the tone of the paragraph reminds of the Controller's reasoning. Nevertheless, the Board arrived to quite a different conclusion by stating that "[i]n a given case there may be an invention which cannot be manufactured in India [or] an invention where the reasonable requirement of public itself is [so] small [that] setting up a factory just for the said purpose is not practicable" [163]. Hence, relying on the national patent law the regulator was somewhat willing to admit that in certain cases actual manufacturing in India is not obligatory to fulfill the working requirement. Then, proceeding to international patent law, the Board elaborated on the case-to-case nature of CLs and concluded that it cannot decide that "working" totally excludes or is synonymous to import. The regulator stated that the patentee must show why the patented invention could not be

[161] Bayer v. Natco para.47
[162] Bayer v. Natco para.51
[163] Ibid

locally manufactured; but a mere statement, as Bayer did in the case, is not sufficient and must be provided with evidence[164]. Despite the fact that the Board placed the burden of proof on the patentee, making him or her responsible to provide evidence of impossibility to manufacture the patented invention locally, it confirmed the right of the patentee to exercise his or her exclusive patent rights through mere export. Distinguishing its position from the position of the Controller, the regulator stated that "[the Controller is] of the opinion that the word "worked" has a flexible meaning, and to that extent we differ from the Controller"[165]. It should be recalled that the Controller elaborated on the local manufacturing obligations of the compulsory licensee and extrapolated these obligations on the patentee. It appears that such a way of assigning obligations is fallacious due to the nature of patent rights. Whereas the full set of patent rights originally belong to the patentee, the compulsory licensee receives the limited secondary set of patent rights, which is of a derivate nature in relation to the initial set of exclusive patent rights that is granted by a state to the patentee. Such a method of granting patent rights reflects one of the objectives of patent law, which is favoring the patentee. Therefore, similar to when it comes granting patent rights, the patentee should be privileged when it comes assigning obligations. The legal position that was adopted by the Board comes under this mode of reasoning because the patentee can still exercise his or her rights through mere export if an inexpediency of local manufacturing is proved, while the compulsory licensee, in any circumstances, cannot use his or her CLs to import the patented invention. Hence, concluding that the term "worked" has a flexible meaning that takes the color of "availability" and "accessibility" as well as maybe encompassing only import, the Board rendered Indian working requirement as being TRIPS-compliant.

The regulator centrally gave some consideration to the human rights aspect of the case. Starting an analysis with the human rights dimension, the Board referred to Paragraphs 4 and 6 of the Doha Declaration. Paragraph 6 was referred to for the sake of an appropriate legal analysis, which relied on justified legal terminology. Doing so, the Board confirmed its previous conclusion on Article 31 TRIPS that "other use without authorization of the right holder" includes CLs. Otherwise, India could hardly be considered as a WTO member, with insufficient or no manufacturing capacities in the pharmaceutical sector, to take advantage of Paragraph 6. In contrast, Paragraph 4 was mentioned due to reasons that are more substantial. Referring to the paragraph, the Board emphasized the discretion in granting CLs that are exercised by states when safeguarding the public interest such as A2M. Even more, pursuing this thread of reasoning, the regulator admitted A2M as "the running theme"[166]. Such an affirmative position in relation to A2M clearly indicates

[164] Bayer v. Natco para.52
[165] Ibid
[166] Bayer v. Natco para.20

that the Board acknowledged the collision between patent and human rights. As has been mentioned above, the regulator expressed F2W or the absence of working requirement in a variety of different terms such as "a commercial scale to an adequate extent", "reasonable price", "the market price", and "commercial sales", to name a few. Despite this diversity of legal terms, they can be boiled down to the two human rights categories "availability" and "affordability". As mentioned above, the subjugation approach implies that terms of patent law have fixed meanings, which in turn become subjects to human rights analysis. However, the opinion of the Board that the word "worked" has a flexible meaning, and that it therefore must be decided on a case-to-case basis, testifies against the fact that the regulator adopted the subjugation approach. Considering this co-existing approach, it should be recalled that the way through which the approach plays out in practice remains nebulous, but scholars agree on its main features such as human rights and patent rights cannot directly modify one another. Without reservations, reliance on "availability" and "affordability" in interpreting the term "work" indicates a direct conversion between the discourses. Thus, it can hardly be argued that the Board embraced the co-existing approach interpreting F2W. It appears that in defining the term, the regulator employed human rights categories. On a small scale, when the Board operated with large complex categories such as "a commercial scale to an adequate extent", "market price", or "a commercial scale", to name a few, it resembled patent law analysis. However, in a detailed approximation, when the regulator explained the term "a commercial scale to an adequate extent" by opposing it to PAP and broke the term up into minor categories such as "reasonable price" and "availability", it became evident that he engaged in a human rights analysis. The integration approach postulates that patent law does not have fixed meanings, but that they should be determined in conjunction with the relevant human rights categories. The board postulated pretty much the same thing by stating that "the word 'worked' has a flexible meaning". Therefore, it is reasonable to argue that the Board adopted the integration approach towards the interface between patent and human rights in the given case.

4.4 On the Ability of "Failure to Work" Promoting Access to Medicines

As discussed in the second chapter, F2W as a CL ground has some distinctive features among other CL grounds. F2W is the only one that is explicitly recognized at the international level, and it received such recognition quite early at the end of the nineteenth century when the Paris Convention was adopted, boosting the process of incorporation of F2W into the majority of national patent laws. Countries such as the UK, Australia, New Zealand and India, to name a few, recognize F2W as a CL ground in their national patent laws. The combination of the recognition of the ground at the international and national levels and its ample application by national patent offices provided F2W with a customary status that other CL grounds have not gained yet. Thereby, it is reasonable to argue that the exceptional status of F2W facilitates national authorities' resorting to CL when promoting A2M.

As has been observed above, invoking a CL on the F2W ground indispensably entails certain consequences in relation to scope and duration, prior negotiation and the payment of a royalty. Considering the relation between F2W and the scope and duration of a CL, it should be noticed that this relation is of a flexible nature. These consequences are not particularly pre-defined, but rather follow from the nature of F2W, such as "availability" and "affordability". The flexible nature, in turn, provides a national patent regulator with some discretion in tailoring a CL according to local needs and resources. Granting the CL in the Bayer Nexavar case, the Controller set such terms and conditions as a maximum price of the drug and the obligation of the license to supply at least 600 needy patients per year at a free cost[167], to name a few. It can be argued that these terms and conditions are inherently linked to F2W. The maximum price condition was aimed to ensure "affordability" by making the drug financially accessible to low income people. Moreover, the obligation to supply needy patients was designed to guarantee "availability" so that the drug would become available to poor patients, which otherwise under no circumstances could afford it. Therefore, despite the discretion in tailoring a CL, F2W indispensably entails "availability" and "affordability" when it comes to setting the terms and conditions of CLs. Hence, this feature of F2W reinforces the promotion of A2M.

As has been mentioned above, F2W necessarily entails prior negotiation and remuneration. Addressing the status of prior negotiation, the Board concluded that the single letter from Natco that contained an estimated price of the drug produced under a voluntary license constituted a "genuine attempt", and therefore the procedural requirement of the Indian patent law was fully met[168]. It is evident from the Controller's decision and the Board's order that this law treats prior

[167] Natco v. Bayer p. 61
[168] Bayer v. Natco para.16

negotiation as a condition of a CL rather than as an independent ground. It is reasonable to argue that despite the fact that prior negotiation prolongs the CL granting procedure and by this weakens A2M, in a long term prior negotiation promotes A2M because requiring a potential compulsory license to negotiate a voluntary licensee safeguards the patentee's interest in R&D so that he or she can invent new medicines in the future. The same logic is applicable in relation to remuneration. Despite the small amount being given to the patentee as a remuneration for a CL, he or she is still able to recover a certain part of the expenditure that has been spent on the R&D of the drug in question. Hence, it can be argued that F2W obligatory entailing prior negotiation and remuneration alleviates the most detrimental effects of CLs on the initiative to R&D and by this promotes A2M in the long-term.

Previously, in the second chapter, CLs were considered among other patent limitations and it was concluded that CLs are gaining a wider scope of application due to the decrease in the number of patent exclusions. Another reason for the proliferation of CLs in the post-TRIPS landscape is conditioned by its inherent flexibility. The Board traced this flexibility in details by analyzing the term "work" and stated that it has a flexible meaning, and therefore should be determined on a case-to-case basis. F2W demonstrated astonishing flexibility in its reconciliation of opposing public interests, such as the promotion of A2M and of technological innovation. It can be argued that, in the post-TRIPS environment, this feature of F2W reinforces the CL ground in promoting A2M.

In relation to conceptual dimension of the issue, it can be argued that interpreting F2W through human rights categories undoubtedly elevates human rights considerations in the patent law discourse. However, the prioritizing of A2M by the means of the integration approach may involve adverse implications for the both discourses. As has been observed above, framing patent rights as human rights would undermine the utilitarian justification of patent law. Patents would be viewed as policy ends themselves rather than means of achieving a variety of social goals ranging from wealth creation, through education, to health care. Moreover, it would contribute to a legal unpredictability of patent litigations that involve human rights. Such unpredictability, in turn, would create uncertainty among pharmaceutical companies making them delay or even withdraw their investment in R&D. Unwillingness of pharmaceutical companies to invest in R&D will have detrimental consequences for the human right to health, in particular to A2M. It appears that A2M being a positive human right obligation is predisposed for implementation through policymaking rather than through judicial forum. Positive obligations indispensable involve making decisions on allocation of resources in society. While judiciary can balance conflicting interest on occasional basis, it is in no position to take responsibility for the routine distribution of resources. Providing

coherent and holistic policy and legislation in relation to A2M and patents, policymakers would facilitate work of judiciary by safeguarding it from being put in position where it has to decide on priority of social goals. Therefore, it can be concluded that from the conceptual point of view, F2W has an adverse effect for the promotion of A2M.

5 Chapter five: Conclusion

5.1 Conclusion and recommendations

F2W is a developed and well established at the international and national levels CL ground. Originally emerged as a tool of protectionism it has evolved into a legal category that is able to safeguard the human right to health, in particular A2M. The recent developments in patent law such as the decrease in number of patent exclusions and TRIPS overcompliance rendered F2W as a handy instrument to curb the pharmaceutical companies' profit-seeking behavior.

Indian judiciary has managed to employ F2W to promote A2M. Doing this, it provided many middle and low-income patients with the drug that extended their lives from 6 mouths to 5 years. The relevant decisions reveal that F2W, in certain circumstances, allows the patentee to enjoy his or her patent rights through mere export. This feature of F2W suggests that does not violate the principle of non-discrimination, and therefore makes F2W TRIPS compliable. Having F2W in line with international patent law instruments, the Indian policymaker can be more confident making use of CL mechanism. A frequent use of CL contribute to a favorable climate for promoting A2M.

F2W has a flexible meaning that involves categories of human rights such as "availability" and "accessibility". This allows F2W to be very efficient in promoting A2M because the ground "speaks" human right language within the patent law discourse. Despite conceptual challenges that F2W faces. It can be argued that whereas shifting mode of regulation to policymaking and legislation is preferable, F2W provides a successful way of promoting A2M by limiting patents in judicial forum. In order to promote A2M, it is reasonable for other national judicial authorities to adopt the Indian approach towards interpretation of F2W, until a sustainable policy and legislation become available.

6 Chapter six: Bibliography

6.1 Reference Table

Conventions and treaties

UDHR	Universal Declaration of Human Rights. Paris. 10 December 1948.
ICESCR	International Covenant on Economic, Social and Cultural Rights. New York. 16 December 1966.
VCLT	Vienna Convention on the Law of Treaties. Vienna. 23 May 1969.
CRC	Convention on the Rights of the Child. New York. 20 November 1989.
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights. Marrakesh. 15 April 1994.
The Paris Convention	The Paris Convention for the Protection of Industrial Property. Paris. 20 March 1883.
The Doha Declaration	Doha Declaration on the TRIPS Agreement and Public Health. Doha. 14 November 2001.
The Oviedo Convention	Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. Oviedo. 4 April 1997.

Cases

Harvard College v. Canada	Supreme Court of Canada, 5 December 2002
Brenner v. Mason	U.S. Supreme Court, 21 March 1966, 383 U.S. 519
European Communities v. Canada	WTO Dispute Panel, 18 August 2000, WT/DS114/R
Natco v. Bayer	Indian Controller of Patents Mumbai, 9 March 2012, C.L.A.No.l of 2011
Bayer v. Natco	Indian Intellectual Property Appellate Board Chennai, 4 March 2013, OA/35/2012/PT/MUM

National Legislation

Indian Patents Act (2005), New Delhi, 4 April, Act No. 15 of 2005

UK Patents Act 1977, as amended in 2014

Australian Patents Act 1990, Canberra, as amended in 2010, Act No. 83

New Zealand Patents Act 2013, Wellington, 13 September, Act No. 68

The Decree of the Thai Department of Disease Control, Ministry of Public Health issued on 29th January 2007

UN Documents

UN GA, Declaration of Commitment on HIV/AIDS, 2 August 2001, A/RES/S-26/2

CRC, General Comment No. 3, HIV/AIDS and the rights of the child, 17 March 2003, CRC/GC/2003/3

CESCR, General Comment No. 14, The Right to the Highest Attainable Standard of Health (Art. 12), 11 August 2000, E/C.12/2000/4

CESCR, General Comment No. 17, 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, E/C.12/GC/17

CRC, Concluding observations of the Committee on the Rights of the Child: Guinea Bissau, 13 June 2002, CRC/C/15/Add.177

CESCR, Report of the Special Rapporteur, Paul Hunt on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, 1 March 2004, E/CN.4/2004/49/Add.1

OHCHR, Access to medication in the context of pandemics such as HIV/AIDS, 22 April 2002, E/CN.4/RES/2002/32

CESCR, Report on the twenty-second, twenty-third and twenty-fourth sessions, 2001, E/C.12/2000/21

OHCHR, *Intellectual property rights and human rights.* 17 August 2000

Secondary Literature

Osenga, Kristen. *Get the balance right!: squaring access with patent protection*. In: Global Business & Development Law Journal. Vol.25 (2012), pp. 309-322

Turrill, Zoee Lynn. *Finding the patent balance: the novartis glivec case and the trips compliance of India's section 3(d) efficacy standard.* In: Georgetown Journal of International Law. Vol.44 (2013), pp. 1555-1589

Martins, Lilian. The right to health versus the right to property: conflicts between public welfare and private interests, the Brazilian approach. In: Law and Business Review of the Americas. Vol.20 (2014), pp. 381-398

Ho, Cynthia. *Drugged out: how cognitive bias hurts drug innovation*. In: San Diego Law Review. Vol.51 (2014), pp. 419-508

Crook, Jamie. *Balancing Intellectual Property Protection with the Human Right to Health*. In: The Berkeley Journal of International Law. Vol.23 (2005), pp. 524-550

Lybecker, Kristina. *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules*. In: The Journal of Law, Medicine & Ethics. Vol.37 (2009), pp. 222-239

Wang, Richard Li-dar. *Ancillary orders of compulsory licensing and their compatibility with the trips agreement.* In: The Marquette Intellectual Property Law Review. Vol.18 (2014), pp. 87-106

Correa, Carlos. *The Use of Compulsory Licences in Latin America.* In: Compulsory Licensing: Practical Experiences and Ways Forward. Berlin, (Springer) 2015. pp. 43-60

Kuanpoth, Jakkrit. *Compulsory Licences: Law and Practice in Thailand*. In: Compulsory Licensing: Practical Experiences and Ways Forward. Berlin, (Springer) 2015. pp. 61-78

Trebilcock, Michael, Howse, Robert. *The Regulation of International Trade*. 3rd Edition. New York, (Routledge) 2005

Beier, Friedrich-Karl, Schricker, Gerhard. *From GATTS to TRIPS: The Agreement on Trade-Related Aspects of Intellectual Property Rights.* 1st Edition. Munich, (Wiley-VCH) 1996

Gold, Richard. *Patents and human rights: a heterodox analysis.* In: Journal of Law, Medicine & Ethics. Vol.41 (2013), pp. 185-196

Grover, Anand. *Pharmaceutical companies and global lack of access to medicines: strengthening accountability under the right to health*. In: Journal of Law, Medicine & Ethics. Vol.40 (2012), pp. 234-249

Waning, Brenda. *A Lifeline to Treatment: The Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries*. 2010. http://www.biomedcentral.com/content/pdf/1758-2652-13-35.pdf [Visited 14 May 2015]

Dhawan, Atul. *2015 life sciences outlook. India.* 2015. https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2015-life-sciences-report-india.pdf [Visited 14 May 2015]

Lewis, Jacob. *Compulsory licensing: monster or myth?* In: UMKC Law Review. Vol.82 (2014), pp. 1055-1072

Ezzy, Douglas. *Qualitative Analysis: Practice and Innovation*. 1st Edition. Abingdon. (Routledge) 2002

Dobinson, Ian. *Qualitative Legal Research*. In: Research Methods for Law. Edinburgh. (Edinburgh University Press) 2007. pp. 16-45

Timmermans, Karin. *The trips agreement and pharmaceuticals.* 2000. http://apps.who.int/medicinedocs/pdf/h1459e/h1459e.pdf [Visited 14 May 2015]

Frankel, Susy. *Recognized and Appropriate Grounds for Compulsory Licences: Reclaiming Patent Law' s Social Contract.* In: Compulsory Licensing: Practical Experiences and Ways Forward. Berlin, (Springer) 2015. pp. 149-164

Correa, Carlos. *Integrating Public Health Concerns into Patent Legislation in Developing Countries.* 2000. http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf [Visited 15 May 2015]

Blakeney, Michael. *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement.* London. (Sweet and Maxwell) 1996

Shen, Chung- Lun. *Review of Granted Compulsory Licences.* In: Compulsory Licensing: Practical Experiences and Ways Forward. Berlin, (Springer) 2015. pp. 291-312

Liu, Kung-Chung. *The need and justification for a general competition-oriented compulsory licensing regime.* In: International Review of Intellectual Property and Competition Law. Vol.43(6) (2012), pp. 679-699

Gervais, Daniel. The TRIPS Agreement: Drafting History and Analysis, 4th Edition. London. (Sweet & Maxwell) 2012

Bonadio, Enrico. Compulsory licensing of patents: the Bayer-Natco case. In: European Intellectual Property Review. Vol.34(10) (2012), pp.719-728

Cornish William, David Llewelyn & Tanya Aplin, *Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights.* 7th Edition. London. (Sweet & Maxwell) 2010

Van den Bossche, Peter, *The law and policy of the World Trade Organization*, 2nd Edition. New York. (Cambridge University Press) 2008

Reichman, Jerome. *Compulsory licensing of patented pharmaceutical inventions: evaluating the options.* In: Research handbook on the protection of intellectual property under WTO rules. Cheltenham, (Edward Elgar Publishing Limited) 2010. pp. 589-622

Madieha, Ida. *Scope and Duration of Compulsory Licensing: Lessons from National Experiences.* In: Compulsory Licensing: Practical Experiences and Ways Forward. Berlin, (Springer) 2015. pp. 207-220

Reichman, Jerome. *Non-voluntary licensing of patented inventions: historical perspective, legal framework under TRIPS and an overview of the practice in Canada and the USA.* Geneva 2003. http://www.ictsd.org/downloads/2008/06/cs_reichman_hasenzahl.pdf [Visited 15 May 2015]

Stoll Peter-Tobias, Jan Busche & Katrin Arend, *WTO - Trade-Related Aspects of Intellectual Property Rights.* Leiden. (Martinus Nijhoff Publishers) 2009

Lamping, Matthias. *Declaration on patent protection: regulatory sovereignty under TRIPS.* In: International review of industrial property and copyright law. Vol.45(6) (2014). pp. 679-689

Lin, Xiuqin. *Prior Negotiation and Remuneration for Pa tent Compulsory Licensing: Practice, Problem, and Proposal.* In: Compulsory Licensing: Practical Experiences and Ways Forward. Berlin, (Springer) 2015. pp. 165-190

Liu, Xiaohai. *A study on patent compulsory license system in China—with particular reference to the drafted 3rd amendment to the patent law of the P. R. of China.* In: Patents and technological progress in a globalized world. Berlin, (Springer) 2009. pp. 115-126

Mill, John Stuart, *Principles of political economy with applications to social philosophy.* Indianapolis. (Hackett Publishing Company, Inc.) 2004

Välimäki, Elli. *Calculation of royalties in compulsory licensing of pharmaceutical patents in*

Europe – how much is justified? 2011. http://www.njcl.utu.fi/2_2011/elli_valimaki.pdf [Visited 15 May 2015]

Trevor Cook, Ashley Roughton & Phillip Johnson, The modern law of patents, 2nd Edition. London. (Lexis Nexis) 2010

Bently, Lionel. *Limiting Patents*. In: Compulsory Licensing: Practical Experiences and Ways Forward. Berlin, (Springer) 2015. pp. 313-332

Correa, Carlos. *Intellectual property and competition law: exploration of some issues of relevance to developing countries*. Geneva 2007. http://www.iprsonline.org/resources/docs/corea_Oct07.pdf [Visited 15 May 2015]

Mercurio, Bryan. *Patently Lacking: A Call for Systemic Review of Pharmaceutical Law and Policy--A Case Study of Hong Kong.* In: Asian Journal of WTO & International Health Law & Policy. Vol.9 (2014), pp. 63-122

Pharmaceutical Research and Manufacturers of America, *Special 301 Submission 2015*. 2015. http://www.phrma.org/sites/default/files/pdf/PhRMA-2015-Special-301-Rev.pdf [Visited 15 May 2015]

Flynn, Sean. *The U.S. proposal for an intellectual property chapter in the trans-pacific partnership agreement.* In: American University International Law Review. Vol.28 (2012), pp. 105-200

Reichman, Jerome. *Compulsory licensing of patented pharmaceutical inventions: evaluating the options.* In: Journal of Law, Medicine & Ethics. Vol.37 (2009), pp. 247-263

Drahos Peter, John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* London. (Earthscan Publications) 2002

Torremans, Paul, *Intellectual Property and Human Rights (Information Law).* Alpen Aan den Rijn. (Kluwer Law International) 2008

Haochen, Sun. *A wider access to patented drugs under the trips agreement.* In: The Boston University International Law Journal. Vol.21 (2003), pp. 101-136

Brinkhof, Jan. *On patents and human rights.* In: Intellectual Property and Human Rights: A Paradox. Cheltenham, (Edward Elgar Publishing Limited) 2012. pp. 140-154

Lazzarini, Zita. *Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil.* In: The Yale Human Rights and Development Journal. Vol.6 (2003), pp. 104-128

Matthews, Duncan. *Intellectual property rights, human rights and the right to health.* In: Intellectual Property and Human Rights: A Paradox. Cheltenham, (Edward Elgar Publishing Limited) 2012. pp. 118-139

Giovanetti, Tom. *Intellectual Property Rights and Human Rights.* 2005. http://www.ipi.org/docLib/IPandHumanRights.pdf-OpenElement.pdf [Visited 15 May 2015]

Gordon, Wendy. *Current patent laws cannot claim the backing of human rights.* In: Intellectual Property and Human Rights: A Paradox. Cheltenham, (Edward Elgar Publishing Limited) 2012. pp. 155-174

Helfer Laurence, Graeme W. Austin. *Human Rights and Intellectual Property: Mapping the Global Interface.* New York, (Cambridge University Press) 2011

Van Overwalle, Geerturi. *Human rights' limitations in patent law.* In: Intellectual Property and Human Rights: A Paradox. Cheltenham, (Edward Elgar Publishing Limited) 2012. pp. 236-271

MacCormick, Neil. *Norms, Institutions, and Institutional Facts.* In: Law and Philosophy. Vol.17 (1998), pp. 301-345

Gold, Richard. *The Reach of Patent Law and Institutional Competence*. In: University of Ottawa Law and Technology Journal. Vol.1 (2004), pp. 263-284

Pires de Carvalh, Nuno. *The TRIPS Regime of Patent Rights*, 2nd Edition. The Hague, (Kluwer Law International) 2005

Leopold Christine, Sabine Vogler. *Access to essential medicines in Poland*. 2009. http://www.haiweb.org/06102009/06%20Oct%2009%20OEBIG_Report_Access_to_Medicines_in_Poland_%20%28EN%29.pdf [Visited 15 May 2015]