FACULTY OF LAW
Lund University

Aleksandar Ristanić

Using Compulsory Licenses to Facilitate Access to Medicines: The Indian Experience

JAMM05 Master Thesis

International Human Rights Law and Intellectual Property Rights
30 higher education credits

Supervisor: Professor Timo Minssen

Term: Spring 2016

Contents

Abstract

The attempts to make use of a compulsory licensing provision under the TRIPS Agreement brought human rights, notably, the right to health, into the foreground of the debate between patents and access to medicines. This whole thesis is about the existing tensions between the two regimes – patents and human rights. The growing scholarship that has been devoted to these tensions can be divided into two groups – those who believe that intellectual property and human rights are in a conflict and those who take the view that they are compatible and can coexist. This thesis takes the perspective of *coexistence* based on the premise that innovation and access, as major interests in the debate, are familiar to both patents and human rights. The thesis accordingly seeks to adopt a dialectic approach that tries to reconcile these two sides by critically scrutinizing the recent developments in relation to compulsory licensing. The thesis uses the Indian case of Bayer v. Natco as a vehicle to discuss the core issues arising from the debate between patents and human rights.

Preface

It has long been understood that health is the most precious of all possessions not only for individuals but also for the economic growth and internal stability of any nation. It is for these reasons that the patent protection of pharmaceutical compositions, which touches on this sensitive area, has been one of the most controversial subjects in intellectual property. I feel a great responsibility and honor that I have gotten an opportunity to write a thesis about this tremendously important topic.

I want to thank my supervisor, Professor Timo Minssen, whose patience and constructive comments have helped me to cope with this endeavor. I would also like to thank Peter Gottschalk and Aurelija Lukoseviciene, who introduced me to the amazing world of intellectual property and human rights. Many thanks also go to employees of the Center for International Intellectual Property Studies in Strasbourg, especially, Elena Izyumenko, Xavier Seuba and Teresa Calixto Lopez, for being with me during the writing of this thesis. My wonderful family and amazing friends also proved up to the task again. Thank you for that!

Last but not least, I am grateful to the Swedish Institute for providing me with the SI Scholarship for Western Balkans during my studies at Lund University.

Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
CESCR	Committee on Economic, Social and Cultural Rights
ECHR	European Convention on Human Rights and Fundamental Freedoms
ECtHR	European Court of Human Rights
FDI	Foreign Direct Investments
GATT	General Agreement on Tariffs and Trade
HIV	Human Immunodeficiency Virus
ICESCR	International Covenant on Economic, Social and Cultural Rights
IPAB	Intellectual Property Appellate Board
NDC	Non-communicable Disease
OECD	Organization for Economic Co-operation and Development
R&D	Research and Development
TRIPS	Agreement on Trade-Related Aspect of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Developments
UDHR	Universal Declaration of Human Rights
UNDP	United Nations Development Programme
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
WTO DSU	WTO Dispute Settlement Understanding

1. Introduction

1.1 Background

The treatment of medicines occupies a very special place in the policy of every state because of their indispensable role in promoting public health. For many years patent protection for pharmaceuticals was not available in many countries, as they were considered too important to be left at the mercy of patent owners. Tremendously expensive processes for research and development of new drugs then pushed for the policy change toward granting patent protection for pharmaceuticals. It was also realized that a public disclosure of the object of the patent, instead of keeping it as a secret, could further stimulate medical innovation. Due to the relative easiness with which once invented drugs can be copied, the patent protection has proved to be of the utmost importance especially for the pharmaceutical sector.[1] For this reason a system has been put in place, which grants an inventor, in exchange for his or her disclosure of the invention particularities, a patent or rather a negative right, which enables him or her to exclude others from making use of it for a limited period of time. In addition, certain exceptional policy tools, i.e. compulsory licensing, were provided in order to prevent monopoly abuses.

Nevertheless, many developing countries, with little, or no innovative pharmaceutical industry at all, refused to grant patents for drugs. The major blow to that policy occurred when the Agreement on Trade-Related Aspect of Intellectual Property Rights (the TRIPS Agreement or TRIPS) was signed as Annex 1C of the Agreement Establishing the World Trade Organization[2] (WTO) on 15 April 1994 and came into effect in January 1995. In exchange for favorable access to lucrative markets for their agricultural products and textiles, the developing countries accepted a package of minimum standards

[1] Chien, Colleen, "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?", 18 *Berkeley Technology Law Journal* 853 (2003), at pp. 864-865.
[2] Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, signed by ministers in Marrakesh on 15 April 1994.

for protecting and enforcing intellectual property rights, including an important new monitoring and dispute settlement mechanism.[3] The TRIPS Agreement largely incorporated the Bern and Paris Conventions[4] administered by the World Intellectual Property Organization (WIPO). The member states undertook to implement those minimal standards in their national laws with the expiration of the transitional periods (for the majority of countries it was January 2000 and for India and China that period expired on 1 January 2005). The major change was the obligation to provide a patent protection for "any invention, whether products or processes, in all fields of technology", including thus pharmaceutical products. The minimum term of patent protection was fixed at 20 years from the filing date of a patent application.

While the TRIPS Agreement has created a minimum standard for the world's intellectual property laws, it has also engendered strong concerns on the part of developing states about its impact on their generic manufacturers and access to generics accordingly. Concerns over access to medicines led developing countries to shift focus to flexibilities provided under TRIPS, showing a tendency towards their broader use that threatens to undermine the rights of patent owners.

Furthermore, once being used as a bargaining chip during the Uruguay Round, intellectual property has become inextricably intertwined with trade.[5] Since patents have been conceptualized exclusively as profit-driven rights, in order to justify their actions, developing countries began using human rights as limits to intellectual property rights. Access to medicines has been understood as an "essential component" of the right to health,[6]

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[3] Gervais, Daniel J., "State of the Art: The Changing Landscape of International Intellectual Property", 1(4) *Journal of Intellectual Property Law and Practice* 249, at p. 250.
[4] Berne Convention for the Protection of Literary and Artistic Works, Paris Act of the TRIPS 24 July 1971, as amended on 27 September 1979, 828 UNTS 222: Paris Convention for the Protection of Industrial Property, 20 March 1883, revised 14 July 1967, 21 UST 1583, 828 UNTS 305.
[5] Dreyfuss, Rochelle Cooper, "Patents and Human Rights: Where Is the Paradox?", in W. Grosheide (ed.), *Intellectual Property and Human Rights: A Paradox*, (Edward Elgar, Cheltenham/Northampton 2010), at p. 87.
[6] Hestermeyer, Holger, *Human Rights and the WTO: The Case of Patents and Access to Medicine*, (Oxford University Press, 2007), at p. xxxiv.

which has thus become an oft-used argument for a broad interpretation of the TRIPS flexibilities. As a response to this approach, industry and patent holder groups started making assertions that the protection of intellectual property has long been recognized as a basic human right, relying largely on the right to benefit from the protection of the moral and material interests resulting from scientific production (Article 27 of the Universal Declaration of Human Rights (UDHR)[7] and Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)[8]), but also on the right to property.[9] The resulting debate has created a questionable conflict between patents and human rights regimes overloaded with misconceptions and misunderstandings, defacing further both the problem and its solutions.

Nothing in this thesis is intended to claim that patent rights should be recognized as human rights. It rather takes the stance that, if human rights were to be used as a justification for the limitation of patent rights, than all health-related human rights should be taken into account, not only the right to health, or the right to life in the absence of an explicit provision on the right to health in domestic legislation. As Professor Peter K. Yu noted, "some aspects of patent rights are protected in international or regional human rights instruments while other aspects do not have any human rights basis. Thus, the arguments for or against recognizing patent rights as human rights are only valid with respect to some but not all aspects of patent rights"[10]. The access to medicines debate should not be understood as a mere conflict between the right to health and international patent law.

The case of compulsory licensing is the most prominent example of the expanded use of the TRIPS flexibilities. India as a well-known example of a

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[7] Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) (10 December 1948).
[8] International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3 (entered into force on 3 January1976).
[9] Matthews, Duncan, "Right to Health and Patents", in C. Geiger (ed.), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar, Cheltenham/Northampton, 2015), at p. 497.
[10] Yu, Peter K., "The Anatomy of the Human Rights Framework for Intellectual Property", forthcoming in 69 *Southern Methodist University Law Review,* (2016), available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2653148 (accessed on 18 May 2016), at p. 13.

state incorporating in its national law "to the fullest extent any safeguards and flexibilities"[11] contained in international intellectual property treaties is just the last in line among other countries that contributed to that tendency. A theme running throughout the Intellectual Property Appellate Board's (the IPAB's) decision in the case of *Bayer Corporation v. Natco Pharma Ltd* (the *Bayer/Natco* case)[12] was public health and access to medicine as a facet of the right to life under Article 21 of the Indian Constitution of 1949. Arguably, the Supreme Court of India was the forum where the issue could have been considered as a multidimensional problem involving also Article 15 ICESCR. Unfortunately, by rejecting the case in the prima facie stage the court failed to do that.

1.2 India

India is an overwhelmingly important country for the present discussion for at least two reasons. First, it is a massive subcontinent with an over 1.3 billion population. The country is literally seething with resources of all kinds. Global drug makers are looking at India as a growth opportunity, but remain concerned over intellectual property protection in a country that is also a leading supplier of cheap generic drugs to the developing world.[13] Second, under the Patents Act of 1970,[14] which brought major changes to the Indian patent regime after it became a sovereign state, the country developed one of the strongest pharmaceutical industries focused almost exclusively on reverse engineering. This development took place mainly thanks to the three major implications for the pharmaceutical industry, namely, only process patents were allowed in the area of pharmaceuticals,

[11] Matthews, "Right to Health and Patents". Supra note 9, at p. 499.
[12] *Bayer Corporation v. Natco Pharma Ltd.*, Order No. 45/2013, Intellectual Property Apellatte Board, Chennai.
[13] As Joanna T. Brougher observes, "67% of drugs produced in India are exported to developing countries and nearly 80% of all medicines distributed by the International Dispensary Association to developing countries are manufactured in India. Approximately 80% of ARVs used by Medicins Sans Frontiers are purchased in India and in some African countries, like Zimbabwe, about 90% of its HIV/AIDS generic drugs are imported from India" (Brougher, Joanna T., *Intellectual Property and Health Technologies: Balancing Innovation and the Public's Health*, Springer Science + Business New York (2014), at p. 190).
[14] Patents Act, 1970 (39 of 1970, 19 September 1970).

the term of patent protection for such processes was fixed at only seven years and an expeditious system of licenses of right was introduced specifically for this sector.[15] Accordingly, the impact that the TRIPS Agreement made on the Indian patent regime and its implications for drug producers and access to medicines has become an issue exceeding the borders of the mere country at stake. Having become a member of the WTO, India again opened its doors for research-based multinational companies. At the same time, it caused them a feeling of a lump in the throat when India decided, for the first time in its modern history, to employ the TRIPS amended provisions for compulsory licensing in the *Bayer v. Natco* case.

1.3 The purpose and the research question

Using the *Bayer v. Natco* case as a vehicle to discuss national implementation of the TRIPS flexibilities and utilization of compulsory licenses in the context of non-communicable diseases[16], this thesis endeavors to find out whether the recent developments in India in fact promote sustainable access to medicines. Putting this issue in the broader context of the relationship between intellectual property, generally – and patent rights in particular – and human rights, the thesis intends to contribute to a better understanding of the alleged debate (if the elimination of certain misconceptions inherent in that debate is a pretentious task for a master thesis).

1.4 Delimitations

The thesis reviews how developing countries, such as India, use the flexibilities of the TRIPS Agreement to increase access to medicines. It,

[15] Dhar, Biswajit and Gopakumar, K.M., "The Case of the Generic Industry in India", in R. Meléndez-Ortiz and P. Roffe (eds.), *Intellectual Property and Sustainable Development: Development Agendas in a Changing World* (Edward Elgar, Cheltenham/Northampton, 2009).

[16] Non-communicable diseases are not passed from person to person, such as cardiovascular diseases, cancers, chronic respiratory diseases and diabetes.

however, concentrates on the analysis of a mechanism of compulsory licensing, as one of the highly controversial aspects of the set out intellectual property regime. Other flexibilities of TRIPS are presented briefly in order to provide the whole picture of the environment created for patent-holding pharmaceutical companies. Compulsory licenses have long been present in patent law. They have been an oft-used mechanism for remedying certain patent abuses. However, relying on the TRIPS Agreement's silence on the possible grounds for issuing compulsory licenses, some developing countries have recently expanded their use to promote a variety of public interest goals, i.e. access to cheap medicines. The thesis concentrates on the latter use of compulsory licenses. Furthermore, there are well-known examples (e.g. Brazil, South Africa and Thailand) concerning the use of compulsory licenses, backed by human rights arguments, in the context of HIV/AIDS, which has been recognized as a genuine global problem afflicting millions of individuals.[17] This thesis focuses, however, on the example of access to medicines for non-communicable diseases in the absence of any declared national emergency.

As the thesis observes this controversy from a broader perspective of a discourse between intellectual property and human rights, it may be understood as an attempt to provide a solution for the innovation/access debate. It can be true only in so far as the thesis is a negative critique of the existing tendencies in that regard and an argument for a new international agency that would provide rewards for the development of new essential medicines without excluding the poor from their use, such as the Health Impact Fund.[18] Aidan Hollis and Thomas Pogge have published this proposal. Nevertheless, bearing in mind the scope of the thesis, this solution cannot be discussed here.

[17] Helfer, Laurence R., and Austin, Graeme W., *Human Rights and Intellectual Property: Mapping the Global Interface* (Cambridge University Press, 2011), at p. 91.
[18] Pogge, Thomas, "The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices", in T. Pogge, M. Rimmer and K. Rubenstein (eds.), *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press, 2010), at p.150.

1.5 Method and material

This thesis is based on the following materials:

- International instruments, such as the TRIPS Agreement, the UDHR, the ICESCR and Indian national law, as primary sources;
- General Comments and reports of various UN bodies, the WTO, WIPO and the WHO;
- Literature studies;
- Case law; and
- Electronic sources.

In the attempt to answer the posed research question, the thesis uses a doctrinal approach to analyze and systematize the relevant legal frameworks. The specific task of the thesis – balancing between the two legal regimes and examining the international framework and its national implementation – determines a number of considerations and the way in which the research method is employed.

Firstly, faced with the absence of a unified perception of patent law among various jurisdictions, the thesis attempts to shed some light on the notion "patent". In this regard, it chooses the two relevant philosophical theories – the natural rights and the utilitarian justificatory theory. The thesis provides a brief study of these two most influential theories, relying on the relevant scholarship.

Secondly, the thesis picks up the relevant provisions of the TRIPS Agreement and provides an analysis of the current state of law from a *de lege lata* perspective, based mainly on the literal, but also on the systematic interpretation.[19] Some historical explanations are also used where necessary. The analysis of the current international legal framework for patents is complemented by writings of legal scholars and jurisprudence.

[19] Pattaro, Enrico, *A Treatise of Legal Philosophy and General Jurisprudence*: *Volume 4 Scienta Iuris, Legal Doctrine as Knowledge of Law and as a Source of Law*, (Springer Science and Bussines Media, 2007), at p. 4.

The analysis of the current national legal setting for patents is based mainly on the literal interpretation of the provisions of the Indian Patents Act 1970. However, the comparative legal method is also applied in this part in order to illustrate the national implementation of the TRIPS Agreement's minimum standards.

The central part of the thesis is dedicated to the study of practical implications of provisions on compulsory licensing in the case of *Bayer v. Natco* and it is dominated by critical comments.

Thereafter, the thesis goes beyond the TRIPS Agreement and accounts for the consequences that the use of compulsory licenses may produce as well as certain alternatives for compulsory licenses. This endeavor relies primarily on literature studies and carefully selected empirical data.

Finally, a legal dogmatic method is applied also to define the international legal framework for human rights and demands for their implementation at the national level. Relying on the text of the Covenant, relevant General Comments and reports of various international bodies as well as the relevant literature, the thesis examines Articles 12 and 15 of the ICESCR together with their implications.

1.6 Structure

Following the introduction (chapter *one*), chapter *two* opens the discussion with an examination of the two main theoretical foundations of intellectual property. Human rights and utilitarian justificatory theories were arguably the most influential during the negotiations of the TRIPS Agreement. Indeed, the TRIPS Agreement, as it is today, clearly embodies both theories. At least, a brief presentation of these two theories is important for the present thesis since compulsory licenses, when issued, run counter to certain extent to the essence of a patent, although they do not break the patent completely.

Chapter *three* reviews the TRIPS Agreement rules relating to the mechanisms and flexibilities, which are available to the member states, to accommodate their public health concerns. Each of the selected and described sets of international rules is complemented with the examination of its implementation at the national level focusing on India.

Chapter *four* examines specifically the mechanism of compulsory licensing as provided under the TRIPS Agreement and under the Indian patent law.

Thereafter, chapter *five* seeks to critically analyze the case *Bayer v. Natco,* with focus on crucial issues that are considered to be the weak points of the decision at stake.

Chapter *six* indicates possible consequences which the extended use of compulsory licenses could produce. Furthermore, it deals with the role of national governments in carrying out their public health policies, arguing for a more cooperative approach.

Chapter *seven* turns to the relationship between human rights and patent law. In particular, this chapter criticizes the current tendencies of using the right to health in the so-called human rights-based approach to access to medicines. Through the parallel analysis of the two most relevant Articles within the ICESCR in this regard, namely, on the right to health and on the right to enjoy the benefits of scientific progress and its application and the right to the protection of the moral and material interests resulting from a scientific production, the chapter aims to indicate internal inconsistencies of that approach.

The concluding chapter *eight* briefly summarizes the main findings made in the precedent chapters.

2. Justifications for patents

Patents have been around for centuries.[20] Oddly enough, any discussion about patents requires again and again consideration of some of the theories for their justification. As the debate on the scope of patent protection has never been settled, various theories invoked in different situations attempt to provide a reasonable explanation. These rationales of patents can be grouped into three categories, namely, those based on (1) natural rights, among which the Lockean labor theory is the most prominent; those based on (2) distributive justice, such as the reward theory; and those footing on (3) utilitarian (economic) arguments, of which the incentive theory is the most popular one.[21] The different theories are usually used cumulatively in order to justify the patent protection. Faced with criticism, many theories that appeared have been discredited. Nonetheless, it is widely accepted today that utilitarian ideas, accompanied by arguments based on natural rights, had a crucial impact on the multilateral intellectual property law as epitomized by TRIPS. Therefore, these two theories will be presented here.

2.1 Natural rights theory

In essence, natural rights justifications are premised on the basis that there is no distinction between property rights over tangibles and intangibles. Thus, every human being, an inventor alike, has an inherent right over his or her ideas.

The most commonly invoked natural rights justification for intellectual property is the Lockean labor theory. In his *Two Treaties on Government*, John Locke stated that "Labour being the unquestionable Property of Labourer, no Man but he can have a right to what that is once joined to, at

[20] One of the first patents appeared as early as 1421, when Fillippo Brunelleschi (1377-1446), the Florentine architect and engineer, had refused to disclose his invention of a cargo boat until the city of Florence granted him an exclusive right for a period of three years to exploit it.
[21] Sterckx, Sigrid, "Patents and Access to Drugs in Developing Countries: An Ethical Analysis", 4 *Developing World Bioethics* 1, (Blackwell Publishing Ltd*.,* 2004), at p .63.

least where there is enough, and as good left in common for others".[22] The theory has two starting points; that resources are initially commonly owned and that every person owns "the work of his hands".[23] Property springs from one's labor joined to commonly owned resources while the one can have the right to property only if she or he leaves "enough and as good for others" and does not waste it.[24]

Although Locke did not specifically refer to intangible objects, his theory of ownership was later recognized as a well-suited justification for intellectual property. The theory has since been widely accepted in Europe. Today, however, it remains relevant mostly as regards copyright law, as it appears to be not entirely convincing in relation to all aspects of patent law. Criticisms have been raised, in particular, about the fact that inventors have to pursue administrative proceedings in order to obtain a patent, that pharmaceutical patents are usually granted to companies rather than to actual inventors, that the theory disregards the cumulative nature of the inventive process and about its time-limited character.[25]

Nonetheless, as said, the natural rights theory played a crucial rhetorical role during the Uruguay Round in convincing developing countries to accept in their policies an effective and adequate protection for patents.[26] Article 27 of the TRIPS Agreement is a clear illustration of the implementation of the argument based on a natural rights premise, providing that the patent protection be available for all categories of inventions, including those that had been traditionally excluded from the protection in some developing countries.

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[22] Locke, John (1690), *Two Treaties of Government*, Book II, Chapter V.
[23] Ibid. (Locke), paragraph 27.
[24] Shiffrin, Seana Valentine, "Intellectual Property", in Goodin R.E, Pettit, P. and Pogge, T. (eds.), *A Companion to Contemporary Political Philosophy* (Blackwell Publishing 2007), Chapter 36, Blackwell Reference Online, available at: http://www.blackwellreference.com/subscriber/tocnode.html?id=g9781405136532_chunk_g978140513653237 (accessed on 1 May 2016).
[25] Adusei, Poku, *Patenting of Pharmaceuticals and Development in Sub-Saharan Africa: Laws, Institutions, Practices and Politics*, (Springer-Verlag Berlin Heidelberg, 2013), at p. 117.
[26] Ibid. (Adusei), at p. 116.

2.3 Utilitarian theory

Arguably, the most influential justification given to intellectual property protection is the utilitarian or instrumental argument, which emphasizes the results of an action to determine whether it is good or bad. An action is acceptable as long as it produces more positive than negative consequences for the public benefit. The utilitarian justification is clearly enshrined in the US Constitution, which states that 'The Congress shall have power […] To promote Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries'.[27] A temporary monopoly right is to be endured for the sake of more innovative activities and dissemination of knowledge, viz., of a long-term benefit.[28]

The utilitarianism is arguably the most relevant justification because it indicates simultaneously the balance between measures to encourage innovation and public access that is already central to the bargain underlying the concept of the patent. Inventors receive the incentive of a limited-term monopoly on the exploitation of the discoveries in exchange for making the details of those discoveries public.[29] As Professor Daniel J. Gervais noted, an instrumentalist version of utilitarianism has proved useful especially when the societal impacts of intellectual property are accounted, in order to clarify not merely whether intellectual property should exist, but rather what it should protect, in what circumstances and for which period of time.[30]

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[27] Article 1, Section 8, Clause 8 of the US Constitution.
[28] McManis, Charles R., "Human Rights as a Constraint on Intellectual Property Rights: The Case of Patent and Plant Variety Protection Rights, Genetic Resources and Traditional Knowledge", in W. Grosheide (ed.), *Intellectual Property and Human Rights: A Paradox*, (Edward Elgar, Cheltenham/Northampton 2010), at p. 278.
[29] Houston, Adam, "A Scientific Approach to Intellectual Property and Health: Innovation, Access, and a Forgotten Corner of the Universal Declaration of Human Rights", 13 *John Marshall Review of Intellectual Property Law* 794 (2014), at p. 796.
[30] Gervais, Daniel J., "State of the Art: The Changing Landscape of International Intellectual Property", 1(4) *Journal of Intellectual Property Law and Practice* 249, at p. 252.

A prominent example of the utilitarian approach to patents is the incentive theory, which is based on the two arguments, namely, "the incentive to invent and innovate" and "the incentive to disclose" argument.[31]

The first argument holds that the exclusive rights for at least a 20-year term enable inventors to recoup time and money invested in R&D and bringing a related product to market. Without that protection anyone would be able to copy an invention and compete with the original inventor by offering it at a lower price because copying does not incur costs for R&D and commercialization of the product. Hence, people would be less willing to make investments, which would further result in less invention and innovation. The patent system is therefore designed to incentivize the creation of inventions beneficial to society.[32]

The second argument reflects the "social contract" of the modern patent system – patentees are given exclusive rights in return for disclosing the invention to the public. "This is a worthy goal because if inventors are not encouraged to publish their invention, they might otherwise keep such information as a trade secret. The patent system, through this disclosure mechanism, also aims for the diffusion of technology and technological transfer."[33]

This theory is also not without criticism. Notably, concerns have been raised that the utilitarian justification does not apply equally to developed and developing countries. As Rajshree Chandra, for example, pointed out, "The patent system stimulates innovation only where industry sees the opportunity for increasing sales and market shares".[34] Indeed, one of the imperfections of the patent system relates to the lack of R&D for medicines targeting the diseases that affect very few people or diseases prevalent in

[31] Sterckx, "Patents and Access to Drugs in Developing Countries: An Ethical Analysis". Supra note 18, at pp. 66-67.
[32] Frankel, Susy and Lai, Jessica C., "Recognised and Appropriate Grounds for Compulsory Licences: Reclaiming Patent Law's Social Contract", in R. Hilty and Liu, K-C. (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward*, (Springer-Verlag Berlin Heidelberg, 2015), at p. 150.
[33] Ibid. (Frankel and Lai), at p. 150.
[34] Chandra, Rajshree, *Knowledge as Property: Issues in the Moral Grounding of Intellectual Property Rights*, (Oxford University Press, 2010), at p. 193.

poor countries, the so called "neglected diseases", or "tropical diseases". In spite of the strong patent protection in some countries, R&D of tropical diseases remains unacceptably low due to a weak monetary demand for them. This phenomenon is known also as the "global drug gap" or the "10/90 gap", because "90 per cent of global disease burden attracts ten per cent of research investments".[35]

Nevertheless, the incentives argument has been widely employed during the TRIPS negotiations. This led to the inclusion of its balancing factors, such as that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology…"[36] The TRIPS update of the social contract is also visible in Article 66(2), which stipulates that "Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base".[37]

[35] Ibid. (Chandra), at p. 192.
[36] Article 7 of the TRIPS Agreement.
[37] Article 66(2) of the TRIPS Agreement.

3. The TRIPS flexibilities

While setting obligations for WTO member states regarding the protection and enforcement of intellectual property, the TRIPS Agreement incorporates certain flexibilities permitting the members to use TRIPS-compatible norms in a manner that enables them to pursue their own public policies.[38]

3.1 Patentability criteria

First and foremost, Article 27(1) TRIPS requires member states to make patents "available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". TRIPS thus simply enunciates these essential patent law concepts such as invention, novelty, inventiveness and industrial applicability without defining them, which leaves a considerable discretion to states with how to apply those requirements in their national laws. The way these key terms are defined, however, can be of the utmost importance for both innovation and access to medicine. If a drug is unpatented it is in the public domain and anyone can produce it.[39]

An example of taking advantage of freedom and flexibilities under TRIPS is to be found in India's 2005 amendment to its Patents Act 1970. While finally allowing the patent protection for pharmaceutical products, India's patent law, Section 3(d), in particular, limits the number of patents that can protect a drug, providing two important exclusions from the scope of that protection. It excludes from the scope of inventions mere discoveries of (1) new forms of known substances – unless there is an enhancement of the known efficacy of that substance, and (2) new uses for known substances. In addition, the amendment provides a list of substances that would be

[38] WIPO web page, "Advice on Flexibilities under the TRIPS Agreement", http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html (accessed 17 May 2016)
[39] Ho, Cynthia M., *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, (Oxford University Press, 2011), at p. 92.

considered a new form of the same substance unless they differ significantly in properties with regard to efficacy.[40]

It did not take too long for the above-mentioned provision to put the international spotlight on Indian policymakers in the controversy surrounding Novartis's old cancer drug *Glivec* and its new improvement. The case concerned Novartis's[41] "mailbox" patent application of 1998 for *Glivec* (disclosed as beta crystalline form of *Imatinib mesylate*), which finally came up for consideration in 2005, when India became obliged to be fully TRIPS-compliant. Although Novartis had already obtained the patent protection for the improvement of the drug in other markets including the US, Switzerland, the EU and Japan[42], the Indian patent office refused to grant the patent following a pre-grant opposition filled by several other organizations as third parties to the patent application proceedings, which is another peculiarity of Indian patent law. The stumbling block for Novartis's application in India was the existence of the earlier patent, filled in the US and some other countries in 1993, directed to *Imatinib* as a "free base" molecule, which disclosed the salt as *Imatinib mesylate*.[43] As the subject matter of the new patent application was a variation of the existing drug or beta isomer of the already disclosed *Imatinib mesylate*, which, as such, had been explicitly declared unpatentable in the Patents Act, the crucial point for Novartis to prove was that the change had led to much improved therapeutic efficacy.[44] Novartis claimed that the new drug had the 30% increase in bioavailability, meaning it was more easily absorbed into the bloodstream.[45] Remaining unconvinced by the claim, the IPAB, the High Court of Madras

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[40] *The Patents Act 1970 (India), Section 3(d) Explanation*.– For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

[41] Novartis is a global healthcare company based in Switzerland.

[42] Pharmafile.com web page, www.pharmafile.com/news/186407/novartis-agrees-gleevec-patent-deal.

[43] Brougher, Joanna T., *Intellectual Property and Health Technologies: Balancing Innovation and the Public's Health*, Springer Science + Business New York (2014), at p. 186.

[44] Pharmafile.com. Supra note 42.

[45] Ho, "*Access to Medicine in the Global Economy*". Supra note 39, at p. 94.

and the Supreme Court, respectively, upheld the rejection of the *Glivec* patentability by the patent office.

In the meantime, Novartis filed a lawsuit to the High Court of Madras challenging Section 3(d)'s compliance with the TRIPS Agreement or the Indian Constitution. The court, however, declined to hear the challenge concerning the compliance with the TRIPS saying that the domestic courts were not the forum to address the questions on matters relating to international treaties and obligations. On the challenge that Section 3(d) was unconstitutional as violating Article 14 of the Constitution because it discriminated against the pharmaceutical sector, the court stated that the distinction arising from issues of different salt forms specific for pharmaceutical sector was justified.[46] Upholding the constitutionality of Section 3(d), the court noted that:

> *India, being a welfare and a developing country, which is predominantly occupied by people below poverty line, has a constitutional duty to provide good health care to its citizens by giving them easy access to life saving drugs. In so doing, the Union of India would be right, it is argued, to take into account the various factual aspects prevailing in this big country and prevent 'evergreening' by allowing generic medicine to be available in the market.*[47]

With the current stringent patentability requirements, provided by the Indian legislature, generic drug manufacturers in India certainly have the wind at their back. Whether this approach has negative repercussions for an incentive to the local development of new and useful drugs is very much open for debate.

[46] Brougher, "*Intellectual Property and Health Technologies*". Supra note 43, at p. 188.
[47] High Court of Judicature at Madras for W.P., *Novartis AG and another v. Union of India and others,* nos. 24759 and 24760 of 2006, 6 August 2007.

3.2 Parallel imports

Due to a range of market factors, companies often charge lower prices for medicines in one country than in another. Countries with limited resources can thus sometimes be inclined to purchase and import drugs from abroad at a lower price rather than buying it in its domestic market at the higher price. This practice is known as parallel importing.[48] In a normal situation, a patent owner would try to prevent such importation because a patent gives the right to prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling or importing for these purposes the patented product.[49] Whether the patent owner will be able to do so depends largely on the importing nation's treatment of exhaustion of intellectual property rights.

The patent owner will not have the right to control the movement of its patented product, if a country's patent law recognizes the regime of international exhaustion considering the patent owner's rights exhausted after the first unrestricted sale anywhere in the world.[50] On the contrary, in the US and the EU, which adopt the principle of national and regional exhaustion respectively, the patent owner maintains such a right notwithstanding its disposal of patented goods abroad.

Under the TRIPS Agreement, member states are free to decide which regime of exhaustion they will apply. The TRIPS Agreement subjected the right to prevent imports of the patented invention to the provision of Article 6, which expressly excluded the issue of the exhaustion of intellectual property rights from the scope of the WTO dispute settlement as long as states do not apply different exhaustion rules to different WTO members.

India has made a distinctive implementation of this TRIPS flexibility providing that it will not consider as an infringement of patent rights any importation of patented products by any person from a person who is duly

[48] UNAIDS, WHO and UNDP Policy Brief, "Using TRIPS Flexibilities to Improve Access to HIV Treatment".
[49] Article 28(1)(a) of the TRIPS Agreement.
[50] Ho, "*Access to Medicine in the Global Economy*". Supra note 39, at p. 170.

authorized under the law to produce and sell or distribute the product.[51] It appears that India went a step further from the traditional scope of international exhaustion as the exclusive right would be considered exhausted under its patent law even if the product was put on the market abroad without the consent of the patent owner, such as the situation of compulsory licensing. The Indian expansion of the principle of international exhaustion is rather controversial and may even be beyond TRIPS.[52]

3.3 The Bolar exemption

Another important exception to patent rights permitted under TRIPS (Article 30) is the possibility of making use of an inventor's pharmaceutical drug without authorization of the patent owner in order to obtain a regulatory approval of a generic product before the patent expires. This enables the early launch of a generic product after patent expiry and promotes further R&D. This flexibility is known as the Bolar exemption named after the US generic manufacturer Bolar, which once lost the case against Roche for using its patented active pharmaceutical ingredient.[53] Nonetheless, the case prompted the US government to enact the so-called Hatch-Waxman Act permitting generic manufacturers to experiment with patented drugs and produce them in limited quantities for research.[54]

The Indian Patents Act lays down the exemption in Section 107A(a) securing that any act of making, constructing, using selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates it will not be considered an infringement.[55]

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[51] Section 107A(b) of the Indian Patents Act 1970.
[52] Ho, "*Access to Medicine in the Global Economy*". Supra note 39, at p. 108.
[53] US Federal Circuit, *Roche Products v. Bolar Pharmaceutical*, no. 733 F2d 858, 1984.
[54] Singh, Manisha and Anuragini, Priya, "Helping the Generic Market: The Bolar Exemption", *Lexology,* 17 June 2015, available at http://www.lexology.com/library/detail.aspx?g=b9ce644b-e24a-41c2-99b4-e0f6e2bc28c5. (accessed on 19 May 2016).
[55] Section 107A(a) of the Indian Patents Act 1970.

4. Compulsory licensing of patents

4.1 Compulsory licensing under the TRIPS Agreement

In addition to non-defined patentability rules, a limited term of protection, a practice of parallel importation and exceptions to patents under Article 30, the TRIPS Agreement in Article 31 allows also "other use without authorization of the right holder". This is one of the most important *flexibilities* recognized under the TRIPS Agreement, commonly known as compulsory licensing. Due to political reasons, the TRIPS negotiators deliberately avoided using the term 'compulsory licensing' during the Uruguay Round, having considered it excessively strong wording, broaching the sensitive topic of the expropriation of property rights. Yet the term in question has been used in the Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001.[56]

A compulsory license would enable a government to license the use of a patented invention to a third party or a government agency without the consent of the patent owner in exchange of a fixed royalty. It is to be noted that a compulsory license does not break a patent absolutely, as the patent holder is still able to prevent all those without a license from the use of the patented invention.[57] Nevertheless, with the capacity to deprive the patent owner of its exclusive rights over the patented invention, which is the essence of the patent right, it should be regarded as an extreme measure with the potential to strike at the heart of the patent system.

The TRIPS Agreement does not expressly require that states should make available compulsory licenses. Moreover, it does not dictate any limitations on the subject matter that can be licensed. Although there has been a strong

[56] Bonadio, Enrico, "Compulsory Licensing of Patents: The Bayer-Natco Case", 34(10) *European Intellectual Property Review* 719 (2012), at p. 720.
[57] Ho, "*Access to Medicine in the Global Economy"*. Supra note 39, at p. 127.

opposition by pharmaceutical companies and patent proponents to compulsory licensing of drug patents, the current state of affairs provides that any nation may issue a compulsory license on any patent.[58]

Article 31 rather lays down a number of procedural requirements with which states that opt for the issuance of compulsory licenses must comply. Among those conditions that intend to safeguard the minimum of a patent owner's interests is a license seeker's obligation to try first to obtain a voluntary license through negotiation with the patent owner. Furthermore, there are obligations imposed on states to provide the patent owner with adequate compensation and an opportunity to challenge a decision to issue a compulsory license. TRIPS expressly stated that each application for a compulsory license would be considered on its individual merits,[59] introducing thus a novelty in that there will be no automatic licenses for an entire class of technology.[60] Such a possibility of "licenses of right" relating to pharmaceutical patents or food, for example, existed in Canada and India. It provided that anyone interested in exploiting a patent was automatically entitled to a compulsory license after the expiration of a certain period as provided by Article 5A(4) of the Paris Convention.[61]

4.1.1 Grounds for compulsory licenses

One of the biggest ambiguities in the TRIPS Agreement is that it does not specify or limit the grounds upon which licenses can be granted. Although the Agreement refers to some of the possible grounds for granting compulsory licenses, such as a situation of national emergency, other circumstances of extreme urgency,[62] public non-commercial use[63],

[58] Ho, "*Access to Medicine in the Global Economy"*. Supra note 39, at pp. 128-129.
[59] Article 31(b) of the TRIPS Agreement.
[60] Ho, "*Access to Medicine in the Global Economy"*. Supra note 39, at p. 128.
[61] UNCTAD/ICTSD, *Resource Book on TRIPS and Development*, Cambridge University Press (2005), at p. 462.
[62] Article 31(b) of the TRIPS Agreement states that the requirement of prior negotiation may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.
[63] Article 31(b) of the TRIPS Agreement further states: In the case of public non-commercial use, where the government or contractor, without making a patent search,

anticompetitive use[64] and blocking patents[65], in principle, it leaves states free to decide on virtually any appropriate ground for them.[66] This approach has been supported by paragraph 5(b) of the Doha Declaration, which states that "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted".

Although these other grounds are not without contestation today, at least one of them in fact has been long present in both national and international instruments. The Paris Convention of 1883 recognized the right of member states to grant compulsory licenses to remedy abuses of patent rights, specifying explicitly "failure to work" as a ground.[67] As is known, Article 5A of the Paris Convention has been incorporated by reference into the TRIPS Agreement via its Article 2(1) and so still produces an effect upon member states.[68] Indeed, it may be argued that if the TRIPS negotiators had intended to exclude local working, they could have done so, as they expressly did in relation to the provisions on compulsory licenses in the Washington Treaty on Intellectual Property in Respect of Integrated Circuits.[69] On the contrary, it appears that the US proposal made during the Uruguay Round to abandon the local working requirement as a ground of

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knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government the right holder shall be informed promptly;

[64] Article 31(k) of the TRIPS Agreement reads: Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive […].

[65] Article 31(l) of the TRIPS Agreement reads: where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent") […].

[66] Ho, "*Access to Medicine in the Global Economy"*. Supra note 39, at p. 130.

[67] The Paris Convention for the Protection of Industrial Property (1883), Article 5A reads:
(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.
(4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

[68] Correa, Carlos, "The Use of Compulsory Licences in Latin America", in R. Hilty and Liu, K-C (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward*, (Springer-Verlag Berlin Heidelberg, 2015), at p. 48.

[69] Ibid. (Correa), at p. 49.

compulsory licenses and to permit them only as a remedy for an adjudicated violation of competition laws or a measure for combating a declared national emergency was rejected.[70]

However, even accepting that the failure to work is a valid ground, a dispute concerning the notion of "work" could still be deemed open. Namely, the question whether the term "local working of the invention" is to be regarded solely as a physical manufacturing in a certain territory, or whether it could also be considered as including importation, is yet a matter of interpretation.

Historically, under the circumstances of undeveloped international trade, when states were limited to the goods and services within their own borders, the lack of local manufacturing of a patented product would certainly be seen as a failure to work the patent and an abuse of the patent right leading to compulsory licensing.

Today, however, in a world in which the majority of states are members of the WTO, with all available global rules facilitating international trade, a strict requirement for local manufacturing could arguably be considered outdated. The principle of harmonious interpretation of the Paris Convention and the TRIPS Agreement has been used as an argument for the prolongation of life of the local working clause. The other way round, the provision of the Paris Convention at issue, should be interpreted, inter alia, in light of the very first sentence of the TRIPS Agreement, which clearly stipulates the member states' commitment "to reduce distortions and impediments of international trade" and to repress barriers to legitimate trade. Accordingly, there may be strong arguments that the proper interpretation of the notion of *working* would include importation of the patented invention. The issue of the interpretation of the term *working* arose in the *Bayer v. Natco* case. It will therefore be discussed in the respective and concerned upcoming chapter.

[70] Ho, "*Access to Medicine in the Global Economy"*. Supra note 39, at p. 132.

As noted earlier, compulsory licenses can be issued in order to satisfy certain stated public interests, i.e. national emergency, blocking patents for the use of subsequent dependent inventions or anticompetitive practices. However, the use of compulsory licenses has been relatively recently extended to cover other public interest goals, such as the broader access to patented pharmaceuticals by reducing their price. While this expansion strictly speaking may be regarded to be in compliance with TRIPS, given the freedom that states enjoy in this respect, it certainly diminishes the original exceptional nature of compulsory licensing.

4.1.2 Procedural requirements

Drafters of the TRIPS Agreement attempted to provide some kind of compensation for these practically limitless possibilities for creation of new grounds for issuing licenses by setting forth some procedural requirements and terms that governments are obliged to employ. Some of those requirements and terms can be bypassed in cases of issuing compulsory licenses for special purposes enumerated in the Agreement. Their strict observance, however, is expected in all other cases of general compulsory licenses.

The TRIPS Agreement does not impose any requirement on the time when the license can be sought, which means that it can be done at any time during the patent term. However, such a constraint exists in the Paris Convention under which "[a] compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last".[71] Accordingly, except for failure to work, governments would be allowed to issue compulsory licenses at any time.[72]

Furthermore, in order to promote predictability and to strengthen the position of patent holders, the TRIPS Agreement stipulates that a license

[71] Article 5A(4) of the Paris Convention of 1883.
[72] Ho, "*Access to Medicine in the Global Economy"*. Supra note 39, at p. 133.

seeker must make efforts to obtain voluntary authorization from them on reasonable commercial terms and that such efforts have not been successful within a reasonable period of time. This requirement could be waived only in cases of national emergency, other extreme urgency or public non-commercial use. Although the provision expressly imposes an obligation to engage in prior negotiations as a prerequisite for the use of a compulsory license in all other situations, its wording still leaves room for a debate on how much effort should be put into it. As we will see in the case of *Bayer v. Natco*, patent owners and consumers are likely to diverge significantly on this issue.

As to the terms of compulsory licensing, the TRIPS Agreement requires that the scope and duration of a license will be limited to the purpose for which it was authorized[73], that they must further be non-exclusive[74] and non-assignable[75] and that they are predominantly used for the supply of the domestic market[76]. TRIPS has also provided for a possibility of termination of a license if and when the circumstances that led to it ceased to exist and were unlikely to reoccur.[77]

Among the provisions that aim to protect the patent owner's interests are also the requirement for adequate remuneration in each case of compulsory licensing as well as an opportunity to challenge both the decision to issue a compulsory license and the compensation awarded.[78]

4.1.3 The Doha Declaration

The possibility that any and all drug patents may be subject to compulsory license, accompanied with the freedom to establish the grounds for their issuance under TRIPS, have made them an important tool for governments to reduce the price of patented pharmaceuticals and assure their availability to the public. In order to enable governments to maneuver its policy into a

[73] Article 31(c) of the TRIPS Agreement.
[74] Article 31(d) of the TRIPS Agreement.
[75] Article 31(e) of the TRIPS Agreement.
[76] Article 31(f) of the TRIPS Agreement.
[77] Article 31(g) of the TRIPS Agreement.
[78] Ho, "*Access to Medicine in the Global Economy"*. Supra note 39, at p. 137.

fair balance between intellectual property and public needs, the TRIPS Agreement offered the named flexibilities to be interpreted in the light of objectives and principles set forth in Articles 7 and 8.

Article 7 states that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to its transfer and dissemination, to the mutual advantage of producers and users, in a manner conducive to social and economic welfare and to a balance of rights and obligations. Article 8 further stipulates that states may, in formulating their laws, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, observing the TRIPS provisions. Unfortunately, driven by short-term interests, governments often fail to strike a proper balance between public interest in broader access to patented drugs and patent owners' right to exploit their exclusive rights, thus shifting a burden to address the problem of access to medicines solely on pharmaceutical companies.

Growing concerns over the price of medicines, especially those for infectious diseases, and their availability led to a round of talks at a WTO Ministerial Conference in Doha in 2001. This resulted in the adoption of the Declaration on TRIPS and Public Health (Doha Declaration), which has been widely considered as an appropriate interpretative tool[79] for the scope of the TRIPS flexibilities and its impact on issues pertaining to access to medicines.[80]

While recognizing that intellectual property protection is important for the development of new medicines[81], the Doha Declaration clarifies that the Agreement should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to

[79] Ho, "*Access to Medicine in the Global Economy"*. Supra note 39, at p. 129.
[80] Unni, V.K., "Compulsory Licensing of Pharmaceutical Patents in India: Whether Natco Decision Will Meet the Global Benchmarks?", 37(5) *European Intellectual Property Review* (2015), at p. 297.
[81] Paragraph 3 of the Doha Declaration.

promote access to medicines for all.[82] In Paragraph 5, the Doha Declaration has emphasized in particular the right of member states to grant compulsory licenses under Article 31 of TRIPS, reaffirming the freedom to determine the grounds upon which such licenses are granted. However, the attention is drawn to the situations of public health crises, which can constitute the state of national emergency or extreme urgency, especially in respect of malaria, tuberculosis, HIV/AIDS and other epidemics.[83]

The special achievement of the Doha Round was the recognition of a problem created by the requirement, under Article 31(f), on compulsory licenses to manufacturing products predominantly for a domestic use. This limitation has been identified as an obstacle to an effective use of compulsory licensing for many countries with insufficient or no manufacturing capacities. In 2003, the WTO General Council came up with the solution to that problem in the form of a waiver for Article 31(f) by which a country unable to develop pharmaceuticals would be permitted to import such products. This finally resulted in an amendment to Article 31(f) (Article 31bis) which has allowed countries with sufficient capacities to issue compulsory licenses to their domestic producers to manufacture generic substitutes for patented pharmaceuticals and export them to a needy country, providing that both the exporting and importing country fulfill certain criteria.[84]

4.2 Compulsory licensing in India

This section briefly presents the current compulsory license provisions in the Indian Patents Act 1970, which were introduced by the Patents (Amendment) Act of 2002, slightly amended by the Patents (Amendment) Act of 2005, and were designed to be TRIPS compliant. India's years long hesitation to enable patenting of pharmaceutical products resulted in the adoption of a very liberal compulsory licensing regime.

[82] Paragraph 4 of the Doha Declaration.
[83] Paragraph 5 of the Doha Declaration.
[84] Brougher, "*Intellectual Property and Health Technologies*". Supra note 43, at pp. 179-180.

Under Section 84 of India's existing patent law, any interested person may apply for a compulsory license three years after the grant of a patent on any of the following grounds: if the reasonable requirements of the public have not been satisfied, if a patented drug is not available at a reasonably affordable price or if the patented invention is not worked in India. In addition to a number of grounds that are expressly mentioned in the TRIPS Agreement, the Indian Patents Act, relying on the given freedom in that regard, has thus introduced the two new grounds, namely, "the reasonable requirements of the public" and "a reasonably affordable price". Furthermore, as can be seen, even though TRIPS has been silent on the issue of the timing (except for the non-working ground, under the Paris Convention, which requires at least the three years period lapse after the patent issuance), India decided to differentiate between various types of compulsory licensing, adopting the three-years period only in respect of those three specific grounds.

A possibility that practically any person interested can make an application for a compulsory license is yet another peculiarity of the Indian patent law, which places an additional burden on patent owners. In addition to this, under Section 146 of the Patents Act 1970, patentees and licensees in India have an obligation to submit to the Controller information about the extent the patented invention has been commercially worked in India (Form 27). In accordance with the law, the Controller may then decide to publish that information. Indeed, in 2012 the Indian Patent Office, for the first time, published the Form 27s submitted by patent holders. Hence, potential compulsory license seekers in India may also benefit from the statutory requirement of periodical reporting of working of patents, which obviously contain "a significant amount of competitive information".[85]

When evaluating an application for the grant of compulsory license, the Controller shall consider, in particular, the nature of the invention; the time

[85] Lin, Michael, "Licensing and Working of Patents in India: An Update", 29 July 2013, *IPKat*, available at http://ipkitten.blogspot.se/2013/07/licensing-amd-working-patents-in-india.html. (accessed 2 May 2016).

which has elapsed since the sealing of the patent; the measures already taken by a patentee or a licensee to make full use of the invention; the applicant's ability to work the invention to benefit the public; the applicant's capacity to undertake the risk in providing capital and working the invention; and whether the applicant has made efforts to obtain a voluntary license on reasonable terms and conditions and such efforts have not been successful within a reasonable period (normally no more than six months) as the Controller may deem fit.[86]

The Patents Act has also attempted to explain the scope of the ground "reasonable requirements of the public". It has first noted that this requirement would cover situations of the patent holder's refusal to grant a license on reasonable terms, to such an extent that it causes a prejudice to an existing trade or industry or the development of any new trade or industry or commercial activities in general. Furthermore, it would cover various situations of issuing licenses under unreasonable terms or situations when the patentee simply fails to take steps to meet the demand of the patented product in an adequate manner. Lastly, the Act has clarified that the domestic production under any circumstances should not be hindered by importation.[87]

The Patents Act has finally provided that the Controller of Patents, when considering applications, has to observe, in particular, the two main objectives of compulsory licenses, namely, that patented inventions are to be worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable, provided that the interests of patent holders are not unfairly prejudiced.[88]

[86] Article 84(6) of the Indian Patents Act 1970.
[87] Article 84(7) of the Indian Patents Act 1970.
[88] Article 89 of the Indian Patents Act 1970.

5. Bayer v. Natco case

The following section shows how India has applied its TRIPS compliant patent law in practice.

5.1 Background of the case

In the center of the dispute concerning the first-ever compulsory license in India was Bayer's[89] patented medicine *Sorafenib*.[90] The drug has proved to be useful in the treatment of advanced stage liver and kidney cancer. Bayer first obtained a patent on the drug in the US in 1999. Following further development of *Sorafenib*, it launched it in 2005, under the brand name *Nexavar*. Since then, Bayer has been producing and marketing the drug internationally. In 2008, it finally obtained a patent on *Sorafenib Tosylate*[91] in India and launched it also under the trade name *Nexavar*. At the time when the drug was launched, Bayer was charging around US$ 5,500 per patient per month in India. In 2010, the well-known Indian generic manufacturer Cipla, which had the second largest share of the local drugs market,[92] started selling a generic version of *Nexavar* for a much lower price of around US$ 580 per month, having faced Bayer's suit for patent infringement.

Another generic drug manufacturer in India, Natco Pharma, applied for the grant of a compulsory license on the *Sorafenib* patent before the Indian Controller General of Patents[93] ("the Controller") in 2011. Natco based its application on Section 84(1) of the Indian Patents Act 1970, which reads as

[89] Bayer Corporation, 100 Bayer Road, Pittsburg, PA 15205-9741, USA, has been ranked as the sixteenth largest global pharmaceutical enterprise (GlobalData's pharmaceutical revenue figures).
[90] Carboxy Substituted Diphenyl Ureas
[91] Patent No. 215758
[92] Kulkarni, Kaustubh and Foy, Henri, "Analysis: India cancer ruling opens door for cheaper drugs", *Thompson Reuters*, 13 March 2012, available at http://www.reuters.com/article/us-india-drugs-idUSBRE82C0IN20120313. (accessed on 30 April 2016).
[93] The Indian Office of the Controller General of Patents, Designs and Trade Marks administers the Indian Patent Office. It is a subordinate office of the Indian Government and in general administers the Indian Law on Patents, Designs and Trade Marks.

follows:

84. Compulsory licenses. –
(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:
(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
(b) that the patented invention is not available to the public at a reasonably affordable price, or
(c) that the patented invention is not worked in the territory of India.

In its landmark decision of 9 March 2012, the Controller found that the requirements for each of the three grounds were separately met, any of those being sufficient to order the grant of a compulsory license. Therefore, it granted the license to Natco and effectively stripped Bayer of its exclusive right to the medicine. Bayer then appealed to the Intellectual Property Appellate Board ("the IPAB"). Pending the appeal it also lodged a petition to stay the Controller's order, but this was denied.[94] On 4 March 2013, the IPAB upheld the Controller's decision to grant the license with certain modifications. Bayer thereafter unsuccessfully approached the Bombay High Court, which merely refused to interfere with the IPAB's ruling.[95] On 12 December 2014, the Indian Supreme Court dismissed a petition against the High Court decision and finally put an end on Bayer's three and a half years long efforts to protect its intellectual property right. The Supreme Court's refusal to grant leave to appeal fits into the prevailing opinion that the requirements for all the three grounds mentioned in the Indian Patents Act had been easily satisfied.

Being the first of its kind in the history of the 1970 Indian Patents Act, the

[94] Intellectual Property Appellate Board, Chennai, Order No. 223 of 2012, 14 September 2012.
[95] Justice M.S. Sanklecha: "We don't see a reason to interfere with the order passed by IPAB and, therefore, the case is dismissed."

Bayer v. Natco ruling has been considered to set a trend for other generic companies to start requesting compulsory licenses. Accordingly, it has triggered utterly opposite reactions. Of course, global pharmaceutical manufacturers have received it with concern. The various groups campaigning for cheap access to drugs, on the other hand, welcomed the decision. The case is also notable because it is only the second time a state issued a compulsory license for a drug used to treat a chronic disease rather than an infectious disease, after Thailand did so on four drugs between 2006 and 2008.[96] It is to be noted further that *Nexavar* is not a life-saving drug, but a life-extending drug with the potential to extend the life of a patient suffering from kidney cancer by 4-5 years, and 6-8 months in the case of liver cancer.[97]

Even though both the Controller and the IPAB came to the same conclusion, their approach to the dispute differs slightly on particular aspects. While the Controller largely focused on various statistical data submitted by the parties in its analysis of the substantial issues of the case, the IPAB made an approach from the public health perspective in the context of the right to life under Article 21 of the Indian Constitution.[98] The IPAB's decision is thus a good illustration of a national right to health-based approach to the problem of access to medicine. Both decisions will be presented in the following text, but due to the given reasons more emphasis will be on the IPAB's ruling.

5.2 The Controller's decision

The very beginning of the Controller' decision was promising. It rightly pointed out that it was a fine balance between the rights and obligations of an inventor as well as those of the society that was at stake in the case. Moreover, it emphasized that this fine balance was inherent in the patent

[96] Kulkarni and Foy, "Analysis: India cancer ruling opens door for cheaper drugs". Supra note 92.
[97] The Controller of Patets Mumbai, *Natco Pharma Ltd. v. Bayer Corporation*, Compulsory License Application No. 1 of 2011, 9 March 2012, at p. 6.
[98] Sood, Mansi, "Natco Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India", 6 *NUJS Law Review* 99 (2013), p. 104.

system itself, which rewards inventors in lieu of their contribution towards the society. That reward consists of an exclusive right to exclude others for twenty years from using a patented process or from making, using, offering for sale, selling or importing for those purposes a patented product without an inventor's consent. In return, the society is benefiting from the enrichment of knowledge that comes into the public domain, which can be utilized to further invent in the future. "This cycle goes on and on to take the nation towards socio-economic prosperity."[99] The Controller concluded that a patent system encourages the inventor to disclose his invention to the public. Without it, the inventor "may prefer to keep it as a trade secret, which may result in innovative sluggishness, thereby adversely affecting the prosperity of a nation."[100] Regrettably, apart from mentioning this in the overview section, there is not much of a balancing exercise in this respect in the further text of the Controller's decision.

Dealing with the specific grounds for the grant of a compulsory license, the Controller first found, from the documents submitted by the parties, that the patent holder had made available only an insignificant portion of the drug to the public since the grant of the patent in India, namely to a little above 2% of the eligible patients. This led it to conclude that the reasonable requirements of the public had not been satisfied (Section 84(1)(a)).[101] At this point, the Controller rejected to take into consideration that a generic version of the drug was also available in the Indian market at the relevant time.

As to the question of the price of the patentee's drug *Nexavar*, the Controller held that it had to be construed predominantly with reference to the needs of the public, and without taking into account the patentee's cost of R&D and reasonable gain, as Bayer instead suggested. It observed that the public had not bought *Nexavar* due to the price of Rs 280,000 (around US$ 5,500) for a therapy of one month, which had completely been

[99] The Controller of Patents. Supra note 94, at p. 2.
[100] Ibid. (The Controller), at p. 2.
[101] Ibid. (The Controller), at pp. 22 - 24.

unaffordable to many Indian patients. Although the public, obviously, did not even need to buy Bayer's *Nexavar* as long as they had at their disposal Cipla's cheaper version, the Controller again briefly rejected to consider Cipla's role in the market. Thus the Controller held that the price was not reasonably affordable to the Indian public (Section 84(1)(b)).[102]

Dealing with the issue that the patented invention had not been worked in the territory of India, by way of its interpretation of the provisions of the Paris Convention, the TRIPS Agreement and the relevant national law, the Controller came to the conclusion that the patented product could be considered as being worked locally, only if it was physically manufactured to a reasonable extent in the territory of India.[103] As Bayer, even after the lapse od four years from the date of the grant of the patent, failed to do so by itself or by granting a voluntary license to anyone else, the Controller held that the third ground for issuing a compulsory license had also been satisfied.[104]

Bayer ultimately requested adjournment of the application for a compulsory license for one year, under Section 86 of the Patents Act,[105] in order to work

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[102] The Controller of Patents. Supra note 94, at pp. 35 - 36.
[103] Unni,"Compulsory Licensing of Pharmaceutical Patents in India". Supra note 80, at p. 301.
[104] The Controller of Patents. Supra note 94, at pp. 39 - 45.
[105] Section 86 of the 1970 Indian Patents Act reads as follows:
86. Power of Controller to adjourn applications for compulsory licenses, etc., in certain cases.
(1) Where an application under section 84 or section 85, as the case may be, is made on the grounds that the patented invention has not been worked in the territory of India or on the ground mentioned in clause (d) of sub-section (7) of section 84 and the Controller is satisfied that the time which has elapsed since the sealing of the patent has for any reason been insufficient to enable the invention to be worked on a commercial scale to an adequate extent or to enable the invention to be so worked to the fullest extent that is reasonably practicable, he may, by order, adjourn the further hearing of the application for such period not exceeding twelve months in the aggregate as appears to him to be sufficient for the invention to be so worked:
Provided that in any case where the patentee establishes that the reason why a patented invention could not be worked as aforesaid before the date of the application was due to any State or Central Act or any rule or regulation made thereunder or any order of the Government imposed otherwise than by way of a condition for the working of the invention in the territory of India or for the disposal of the patented articles made by the process or by the use of the patented plant, machinery, or apparatus, then, the period of adjournment ordered under this sub-section shall be reckoned from the date on which the period during which the working of the invention was prevented by such Act, rule or regulation of order of Government as computed from the date of the application, expires.

the patent to its "fullest extent that is reasonably practicable". In that regard, Bayer proposed to modify the Patient Assistance Program, which it ran at the time, in a way that it would reduce the price of the drug at Rs. 30,000 (around US$ 580), as charged by Cipla, for a large number of patients who could not afford the original price. However, the Controller dismissed this proposal on the grounds that such philanthropic actions could not provide the working of the invention on a commercial scale to an adequate extent. Besides, it refused to take into account the proposed measure as being subsequent to the making of the application. The request for adjournment of the application was therefore rejected.[106]

When issuing the compulsory license, the Controller ordered that the price of the licensed medicine would not exceed Rs. 8,880 (around US$ 170) for a pack of 120 tablets, required for one-month treatment. It granted the license solely for various uses of the patented drug within the territory of India. The Controller finally fixed the royalty to be paid to the patentee at the rate of 6 per cent of the net sales of the drug at a quarterly basis.[107]

5.3 The IPAB's decision

The IPAB broadly confirmed the impugned compulsory license.[108] Nevertheless, it explicitly approached the dispute from the broader context of the public interest stating frequently throughout the order that the proceedings were "neither against the inventor, nor against [or in favor of] the compulsory license applicant, but purely based on public interest."[109] As a reference in addressing important questions, it used the Report on the Revision of Patents Law by Shri Justice N. Rajagopala Ayyangar and the TRIPS Agreement, but also the Patents and Design Amendment Bill and the Code of Federal Regulations of the US.

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(2) No adjournment under sub-section (1) shall be ordered unless the Controller is satisfied that the patentee has taken with promptitude adequate or reasonable steps to start the working of the invention in the territory of India on a commercial scale to an adequate extent.

[106] The Controller of Patents. Supra note 97, at pp. 51 - 54.

[107] Ibid. (The Controller), at p. 61.

[108] Intellectual Property Appellate Board, Chennai, Order No. 45 of 2013, 4 March 2013.

[109] Ibid. (IPAB), at p. 47.

5.3.1 Procedural objections

The IPAB first dealt with Bayer's allegations in regard to procedural shortcomings. Although these questions were of a purely legal nature, shifting the burden off the compulsory license seeker has already been indicative of characteristics of the public interest the Board intended to employ. It dismissed Bayer's remark that it had not been given an opportunity to plead at the prima facie stage. According to the IPAB, the relevant rule regulating this early stage of the procedure provided the Controller with the discretionary power to decide whether to hear the parties or not.[110]

The IPAB further moved to decide about Natco's efforts to obtain a voluntary license from the patentee on reasonable terms and conditions, as a prerequisite for granting a compulsory license under Section 84(6)(iv).[111] This measure has been required in view of the compliance with Article 31(b) of the TRIPS Agreement, which likewise says that "use without authorization of the right holder may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time." The Indian Patents (Amendment) Act of 2005 has explained that the "reasonable period" for these prior negotiations should not exceed a period of six months. Unfortunately, neither the TRIPS Agreement nor the Indian Patents

[110] Ibid. (IPAB), at p. 5-7.

[111] Section 84 (6)(iv) of the Indian Patents Acts 1970 reads:
(6) In considering the application field under this section, the Controller shall take into account, –
[…] (iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit: Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anticompetitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application.
Explanation. — For the purposes of clause (iv), "reasonable period" shall be construed as a period not ordinarily exceeding a period of six months.

Act has elucidated upon other specific terms of the provision such as "efforts to obtain" and "reasonable terms and conditions". In its ruling on the issue, the IPAB, however, provided a worrisome interpretation of the above-mentioned provisions, lowering the applicant's expected obligations to negotiate with the patentee from "efforts" to an "attempt" to obtain" a voluntary license.[112]

It appears that Natco approached Bayer by a letter of 6 December 2010, warning it that the patented drug was too expensive and that they would be able to make the product available to the public in India at much lesser cost (namely, Rs 10,000 for one month therapy). Hence, they requested the grant of a voluntary license to market the drug on reasonable terms and conditions, leaving it to Bayer to respond within 14 days. As the patentee refused this proposal, the Board concluded that there was no requirement for another attempt under Section 84(6)(iv) and denied Bayer's appeal on this ground. The IPAB disagreed with Bayer's contention that the single letter sent by Natco, without specifying what terms and conditions Natco was willing to accept, could not be deemed as a serious effort to reach a license agreement.[113] It is to be noted that a guideline for the proper content of a proposal for a voluntary license could have been found in the UNCTAD Resource Book on TRIPS and Development, according to which a license generally includes a payment of a royalty, the scope of use and other terms, such as the duration of the license term, additional technology as well as export restrictions.[114] Natco's proposal did not include any of those. The IPAB's interpretation is thus potentially problematic because it unequivocally excludes the need for any prior negotiations about the terms of a compulsory license. Moreover, it unnecessarily favors compulsory license applicants at the expense of patent holders.

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[112] Sood, "Natco Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India". Supra note 95, at p. 105.
[113] IPAB. Supra note 108, at pp. 7-10.
[114] Lin, Xiuqin, "Prior Negotiation and Remuneration for Patent Compulsory Licensing: Practice, Problem and Proposal", in R. Hilty, M. R. and K-C. Liu (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer-Verlag Berlin Heidelberg, 2015), at p. 172.

Dealing with the last procedural objection that Natco had failed to give evidence to support its compulsory license application, the IPAB held that there was no specific requirement under the Patents Act to support such an application. Without taking into consideration this objection, it merely concluded that this would have anyway posed a procedural lapse that could not have set aside the order.[115]

5.3.2 Substantive issues

Turning then to the substantive issues, the IPAB again referred to the Ayyangar Report, the TRIPS provisions and its own Patents Act from which it extracted four decisive points for its decision, namely that patents were not granted for an import monopoly of the patented article, that they should not impede protection of public health, that they must balance the rights and obligations and make the benefits of patented invention at reasonably affordable price to the public.[116]

a) The reasonable requirements of the public

Thereafter, the Board addressed Bayer's contention that its patented invention was not *Nexavar*, but *Sorafenib Tosylate* and that Cipla's marketing of the infringing product *Soranib* should be taken into account when considering whether the reasonable requirements of the public under Section 84(1)(a) of the Patents Act had been satisfied. Bayer argued in particular that an injunction against Cipla had never been granted and that accordingly the entire sales of the drug must be accountable, notwithstanding the outcome of patent infringement proceedings that were pending at the time. Cipla was merely directed to maintain accounts of its sales of the infringing products.[117] Bayer complained that it was put in an unfavorable environment.[118] On one hand, a toleration of the patent infringement, which enabled Cipla to sell the drug at a lower price, had indubitably struck Bayer's market, as patients who bought a generic version

[115] IPAB. Supra note 108, at p. 11.
[116] Ibid. (IPAB), at p. 14.
[117] Ibid. (IPAB), at pp. 18-20.
[118] Sood, "Natco Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India". Supra note 98, at p. 108.

of the drug did not need to buy a patented one. On the other hand, if not taking into account Cipla's supply, the resulting reduction of Bayer's market share would inevitably lead to the grant of compulsory license on the ground of its inability to market a sufficient medical product for the public.

The IPAB rejected Bayer's argument. Relying on the language of the Patents Act, it found that the reasonable requirement of the public had to be met only by the patentee or its licensees and not by anyone else. It noted that in accordance with Section 83(1)(g) patents were granted to make the benefit of the patented invention available at a reasonably affordable price. This Section clearly indicated the *quid pro quo* nature of the patent system, where a patent was granted in exchange for a duty of the person to whom it was granted to make the benefit of the invention available to public at reasonably affordable price. Furthermore, the grant of compulsory license was merely relevant to patented inventions, according to the wording of the Patents Act. Unlike the Controller, the IPAB refused to give particular weight to the possibility that Cipla could decide, or be forced, to withdraw its product from the market leaving many needed patients without care. Nevertheless, it concluded that Cipla's presence in the market, having been itself litigious, was irrelevant for the purpose of a consideration of the first ground for issuing a compulsory license.[119]

b) Reasonably affordable price

On the issue of whether the drug was available to the public at a reasonably affordable price, Bayer and the IPAB essentially disagreed on one major point. Namely, while the former opined that the price of the patented product had to be construed from the viewpoint of both the public and a manufacturer/innovator, the later took the stand that it had to be done solely with reference to the public. This part of the IPAB's ruling is perhaps the best illustration of the existing tensions between pharma patent holders and public health as it highlights some of the major standpoints in the discourse. Likewise, it clearly shows India's stance in the debate.

[119] IPAB. Supra note 108, at pp. 21-23.

In this regard, Bayer primarily argued that the nature of the invention, the number of patients and the presence of other medicines should be taken into account. The drug at issue was only a palliative drug unable to cure cancer but only to keep the quality of life at a reasonable level. The number of patients was not high and the patentee needed more time to fully market the invention. It was noted, for instance, that *Nexavar* had been granted an orphan drug status in the US and in Europe, since there had been fewer than 200,000 patients for each of its indications. In particular, Bayer denied that it had abused its patent in India by charging an excessive monopolistic price, as *Nexavar's* price was similar to the price of comparable drugs in other countries. Bayer was also concerned because the Controller failed to take into consideration the R&D expenditure involved in the patent when fixing the price for the drug through the grant of compulsory license. It further emphasized the importance of establishing health insurance schemes and the concept of differential pricing due to the existence of different classes in the Indian society, where many Indians were actually able to pay the original price for the drug. Lastly, Bayer submitted that it had had an effective Patient Assistance Programme, where the price for the drug was fixed much lower than the commercial price on a physician's recommendation letter.[120]

As regards Bayer's submissions concerning the nature of the medicine and the role of rival drugs in the market, the IPAB considered the statutory three-year period sufficient to work the invention in India and to meet the demand at a reasonably affordable price. It further held that references to differential pricing and the insurance schemes were irrelevant for the present case. Likewise, it found that the R&D costs were neither particular to the drug, nor to India, and, as such could not assist in deciding what the public could afford reasonably.

On the issue of Bayer's Patient Assistance Programme, the IPAB took somewhat different approach to that of the Controller in relation to "matters subsequent to the making of the application". Reiterating the public interest

[120] Ibid. (IPAB), at pp. 24-27.

objective of the compulsory license procedure, it left it open for the patentee to adopt subsequent measures, i.e. to bring down the price, in order to market and make available the product to the public. Nevertheless, the IPAB affirmed the Controller's ruling on the grounds that the extent of the philanthropic proposal was not sufficient to be regarded as satisfying the requirements of Section 84 of the Patents Act. The IPAB thus concluded that the second ground for issuing a compulsory license was also satisfied on the sole account that the price of the patented drug had exceeded the purchasing capacity of the general public.[121]

c) Not worked in the territory of India

Appealing the Controller's findings that Bayer had failed to manufacture *Nexavar* in India, in contravention of the "local working requirement" (Section 84(1)(c)), Bayer argued that it was not economically feasible to set up a manufacturing facility for the drug in India and that importation was a permitted and preferable option.[122] Since the Indian law provided only that the third alternative ground for issuing a compulsory license would be met, if the patented invention was not worked in the territory of India, the divergence between the parties then emerged over the definition of the term "worked". Contrary to the Controller's opinion that working of the patent in the territory of India meant only the physical production of the medicine in India, Bayer contended that working of the patent could be covered also by importation.

The discussion about the lack of local manufacturing of a patented product as a ground that enables compulsory licensing is an old one. Although not expressly stipulated by Article 5A of the Paris Convention, such an option could arguably be allowed by that provision. Under the TRIPS Agreement, however, the issue of local working is not addressed. Instead, following a long debate between developed and developing countries during the Uruguay Round negotiations, a compromise was reached in the form of

[121] Ibid. (IPAB), at pp. 33-39.
[122] Ibid. (IPAB), at p. 41.

Article 27(1) TRIPS, which in the relevant part reads as follows: [123]

[…] patent rights shall be enjoyable without discrimination as to […] whether products are imported or locally produced.

Opinions about the scope of this provision differ greatly. Many interpreters of the TRIPS Agreement believe that both the Paris Convention and the TRIPS provisions on compulsory licensing have to be read together with Article 27 TRIPS. Accordingly, orders requiring local manufacturing are likely to violate the principle of non-discrimination between imports and local production, as enshrined in that article. This interpretation could be supported by the fact that the non-discrimination clause in Article 27(1) was added partially when parties could not agree on the wording under Article 31 concerning local working requirement.[124]

On the contrary, there are scholars who argue that TRIPS' non-discrimination clause has no bearing upon the provisions on compulsory licensing.[125] By way of interpretation of the TRIPS regulations, they conclude that there is no limitation on the right of countries to establish compulsory licenses on ground other than those explicitly mentioned in the Agreement.[126] Professor Carlos Correa, for example, suggests, relying on the interpretation rules from Articles 31 and 32 of the Vienna Convention on the Law of Treaties, that Article 27(1) should be read only in conjunction with Article 28(1) of the TRIPS Agreement. According to him, while Article 27(1) does not specify whether products that are *imported or locally produced* are patented or infringing products, Article 28(1) defines patent rights as negative or exclusionary rights ("the rights to prevent third parties from using in various forms, without authorization, patented invention"[127]). He infers, therefore, that the patent rights mentioned in Article 27(1) TRIPS do not provide any positive right in relation to products imported or locally

[123] Correa, "The Use of Compulsory Licences in Latin America". Supra note 68, at p. 47.
[124] Ho, "*Access to Medicine in the Global Economy"*. Supra note 39, at p. 132.
[125] Correa, "The Use of Compulsory Licences in Latin America". Supra note 68, at pp. 48-49.
[126] Kuanpoth, Jakkrit, *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future*, (Edward Elgar Cheltenham, 2010), at p. 33.
[127] Correa, "The Use of Compulsory Licences in Latin America". Supra note 68, at p. 48.

produced but only a negative right to exclude interference by infringing products of third parties – either imported or locally produced.[128] Article 27(1) TRIPS, as such, thus, does not allow a patent owner to fulfill its duty to work the patent in a country by resorting merely to importation.

It is true that many developed countries have amended their laws, eliminating a local working requirement as a basis for compulsory licensing, in order to comply with the TRIPS Agreement, or, in general, to promote "transborder activities in an increasingly globalized world market".[129] However, a significant number of countries still have such a rule. Clarification as to the compliance of that requirement with TRIPS has never come from the adjudication body of the WTO either. The US once brought a case before the WTO dispute settlement body against Brazil, which explicitly allowed in its Patent Law that a compulsory license could be granted, if the object of the patent was not exploited, the patent product was not manufactured and the patent process was not fully used within the Brazilian territory.[130] However, the US and Brazil resolved the dispute between themselves and the US withdrew its complaint. Brazil agreed to alert the US in case of their intention to issue a compulsory license against a US patent holder, but it has never had to erase the impugned provision.

Hence, the Indian Patents Act contains similar compulsory license provision for non-working, but a complaint has never been raised under the WTO DSU in order to assess its compatibility with TRIPS. Being aware of the described ambiguity, the IPAB wisely avoided to take a firm stand on this issue. Unlike the Controller, the Board left some room for considerations when the *working* of the patent could include importation. The Board first referred to the specific paragraphs of the Ayyangar Report, which indicated the benefits of the local manufacturing of the patented product. While praising the relevance of those paragraphs, it however acknowledged the possibility of different interpretation of the term *working* in light of the

[128] Ibid. (Correa), at p. 48.
[129] Ibid. (Correa), at p. 47.
[130] Article 68 of the Brazilian Industrial Property Code of 1996.

TRIPS Agreement as a later document.

Due to the lack of the definition of the term *working* in the relevant International Conventions, the IPAB then turned to the reading of its own Patents Act, which used both the words *working* and *import* in various sections, but clearly indicated different activities. Although it pointed out, in particular, that patents were not granted merely to enable patentees to enjoy a monopoly for the importation of the patented articles (Section 83(b)), it accepted that in some cases *working* could be done only by way of import. Whether the working requirement would be satisfied only by local manufacturing or by importation of the patented invention was contingent on the specific circumstances of each singular case. The IPAB considered that Bayer had failed to argue properly why it had been unable to manufacture *Nexavar* in India, which in turn justified the third ground for issuing a compulsory license.

Lastly, on the question of an adequate remuneration payable by Natco in respect of the license, the IPAB increased the royalty rate from six to seven per cent of the net sales of the drug on a quarterly basis. Although the IPAB accepted the upper limit of the royalty rate fixed by the Controller under the UNDP's guidelines, it decided to take into consideration arguments concerning discrepancies between profit margins of Bayer and those acquired by distributors of *Nexavar*.

6. Controversies surrounding compulsory licenses

There is little doubt that the Indian patent law, even as interpreted by the Controller and the IPAB in the *Bayer v. Natco* case, does not meet the TRIPS requirements. India definitely provides a good example of how to employ a compulsory license regime in order "to best promote short-term access to medicine in a manner consistent with TRIPS"[131]. However, if a country is genuinely determined to promote the public interest, short-term solutions must not be the main feature of the policy created to achieve that goal.

Anticipating the rise of compulsory licensing all over the world, Shamnad Basheer, an Indian academic specializing in intellectual property, has pointed out that compulsory licensing is a "middle path between extreme patent protectionism and patent abolitionism".[132] Compulsory licensing may be considered a "middle path" in the context of anticompetitive practices and national emergencies. However, the recent developments concerning the expanded use of compulsory licenses in the context of drugs for non-communicable diseases in nonemergency situations and outside the context of patent abuses suggest a worrying trend that resembles more patent abolitionism. Instead of creating a more collaborative strategy, governments of some developing countries in their efforts to ensure access to patented medicines often boil down the whole problem to the restriction of an already limited monopoly of patentees. Such an approach raises concerns that social costs of compulsory licenses may override benefits of increased access.[133]

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[131] Ho, "*Access to Medicine in the Global Economy"*. Supra note 39, at p. 141.
[132] Chatterjee, Patralekha, "India's First Compulsory License Upheld, But Legal Fights Likely to Continue", *Intellectual Property Watch*, 4 March 2013, available at: http://www.ip-watch.org/2013/03/04/indias-first-compulsory-licence-upheld-but-legal-fights-likely-to-continue/ (accessed on 5 May 2016).
[133] Reichman, Jerome H., "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options", 37(2) *Journal of Lam, Medicine & Ethics* 247 (2009), at p. 253.

The major concerns are that compulsory licensing of pharmaceuticals hurts innovation; threatens the international dissemination of technology; and imposes the risk of retaliation against developing countries. The thesis discusses these issues one by one. Thereafter, it considers the role of national governments in addressing the issues that surround compulsory licensing.

6.1 The impact of compulsory licensing on innovation

It is well known that the development of a new drug is a high-risk, timely and costly endeavor[134], intensifying the importance of the patent incentive.[135] By offering a limited exclusive right to produce, sell and use their inventions, the patent system enables pharmaceutical companies as patentees, to recover their R&D costs as well as to invest in the improvement of existing and the creation of new products. This is concurrently the main premise upon which the patent system is built.[136] It is sometimes suggested that widely used compulsory licensing may negatively impact the incentive for innovation offered by the patent system. Compulsory licenses usually deprive pharmaceutical companies of significant amounts of revenue, which further causes the reduction of funds available for R&D and reinvestment. Moreover, being exposed to the risk of governmental arbitrariness in issuing such licenses, research-based drug companies may choose to redirect or lay aside their R&D investment or even prefer a trade secret to patent protection.[137]

The opinions are, however, divided whether compulsory licenses have a

[134] For example, a survey conducted by the Tufts Center for the Study of Drug Development has found that the cost of developing a prescription drug that gains market approval can reach US$ 2.6 billion. In addition, another US$ 312 million is spent on postapproval development – studies to test new indications, formulations, and dosage strengths. The survey has further indicated ever rising costs, estimating that the cost of bringing a drug to market has more than doubled in the past ten years (Mullin, Rick, “”Cost to Develop New Pharmaceutical Drug Now Exceeds $s.5B”, *Scientific American, Chemical and Engineering News*, 24 November 2014 (accessed 6 May 2016).
[135] Chien, “Cheap Drugs at What Price to Innovation”. Supra note 1, at p. 865.
[136] Ibid. (Chien), at p. 853.
[137] Ibid. (Chien), at p. 874.

negative effect on R&D and innovation accordingly. Different understandings exist even when it comes to empirical data. In the case of Canada, for example, Pires de Carvalho noted that its routine policy of issuing compulsory licenses led to the closure of several research-based pharmaceutical companies and to the emergence of the industry specialized in generics.[138] Reporting on the same case, the Eastman Commission also acknowledged that Canada's broad compulsory license system resulted in the development of its generic drug industry. However, it found no significant effect on innovation in Canada.[139]

A number of conducted surveys show that compulsory licenses do not necessarily result in a decline in innovation.[140] The problem with those surveys is that they focus mostly on compulsory licenses issued in developed countries in order to address antitrust violations.[141] A possible impact on future pharmaceutical innovation of compulsory licenses issued in developing countries on the grounds of public health is yet to be measured. Serious studies in this regard are desirable, given especially developing countries' long-term interest in building independent innovative pharmaceutical industries capable of satisfying the demand of local consumers.[142]

In any case, research to date has identified at least two factors that are relevant for establishing the interconnectedness of compulsory licenses and innovation. These factors are the predictability of the licensing and the significance of the market affected by the license.[143]

The research has indicated that unpredictable licenses usually pose little threat for pharmaceutical innovation. It concluded that the "element of surprise" and the "unpredictable nature" of "sporadic" licenses covering

[138] Bonadio, "Compulsory Licensing of Patents: The Bayer-Natco Case". Supra note 56, at p. 728.
[139] Chien, "Cheap Drugs at What Price to Innovation". Supra note 1, at p. 876.
[140] Ibid. (Chien), at p. 857.
[141] Ho, "*Access to Medicine in the Global Economy"*. Supra note 39, at p. 153.
[142] Bonadio, "Compulsory Licensing of Patents: The Bayer-Natco Case". Supra note 56, at p. 728.
[143] Chien, "Cheap Drugs at What Price to Innovation". Supra note 1, at p. 879.

only existing inventions often make it impossible for companies to change their course in anticipation of the license.[144] On the contrary, a general order for licensing of future inventions would be capable of making such an influence. It is interesting here to see how the *Bayer v. Natco* license fits in this scenario. The case at stake concerned the non-voluntary licensing of an existing drug that was clearly unpredictable to the patentee. Although it was believed that India's first license was just one of many that would come, to date it has remained the only compulsory license issued. Nevertheless, the broad interpretation of national and TRIPS provisions concerning compulsory licensing by the Indian Patent Office leaves no doubt for many patent holders that they can easily find themselves in a similar situation as Bayer.

Another important factor is the significance of a relevant market for patent owners as potential inventors. Compulsory licenses granted in very significant markets should produce a major impact on innovation. Closely related to this correlation is the issue of a type of a disease and its relating medicine. Broadly speaking, there are two groups of diseases and medicines created to cure them. First, there are diseases that are common to both developed and developing countries and medicines proved useful to both of these groups. Such medicines are those for diabetes, heart diseases, the various forms of cancer and AIDS. Second, there are diseases specific for certain developing countries, such as malaria, tuberculosis or specific HIV strains found in some African countries.[145]

In regard to the first group, it has been argued that compulsory licenses issued in developing countries for drug patents that primarily aim developed country markets have little impact on overall R&D. As long as the patentees' exclusive right is preserved in wealthy markets, where they can recoup their costs, there should be no negative effect on innovation in general.

[144] Ibid. (Chien), at p. 885.
[145] Ibid. (Chien), at p. 892.

Nonetheless, the mere fact that most wealthy markets do not impose compulsory licenses does not mean that pharmaceutical companies' interests in those markets are safe. Concerns still remain, in particular, because of the practice of parallel importation, which is by the way perfectly legal under the TRIPS Agreement. It is true that many developed countries apply the principle of national exhaustion (or regional exhaustion within the EU) or they have laws prohibiting parallel imports. However, there are still not enough safeguards that "global drugs"[146] produced under compulsory licenses in developing countries might not reach the wealthy markets through parallel importation and thus undermine the drug companies' profits.[147]

While it may be argued that primary rich markets could save innovation in case of licenses of drugs appropriate for both developed and developing countries, the situation would be different, if imposed licenses covered medicines being developed specifically to treat diseases associated with developing countries. As in this case developing market becomes the primary market, the elimination of patent exclusivity is likely to remove completely the incentive for innovation. This could further cause companies to avoid such markets altogether.[148]

The best example regarding the problem of absence of appropriate medicines caused by the lack of incentive for their production are tropical, neglected and poverty-related diseases. Due to a very low value of relevant markets, there has been virtually no R&D in respect of drugs for such diseases by research driven companies. If by any chance such R&D is undertaken, the detrimental effect of compulsory licenses in this area must be avoided.

Taking again the example of the *Bayer v. Natco* case, it should be noted that *Nexavar* belonged to the first group of drugs being applicable equally to rich

[146] Global drugs are drugs created for rich markets but are also useful in developing countries (see Chien, supra note 1, at p. 892).
[147] Ho, "*Access to Medicine in the Global Economy"*. Supra note 39, at p. 154.
[148] Chien, "Cheap Drugs at What Price to Innovation". Supra note 1, at p. 894.

and developing markets. It may thus be argued that Bayer had been actually able to recoup its R&D costs in primary markets. However, even assuming that *Nexavar* was perfectly adapted to the conditions in India and that no further examination was necessary (although Bayer claimed the opposite), one could still argue that the compulsory license in question, in fact, reduced the incentives to invest in local research and development. Bearing in mind the current state of the Indian pharmaceutical sector, there are still many reasons for companies to turn to the much cheaper copying of drugs. This compulsory license case does not indicate the contrary.

6.2 Compulsory licenses and dissemination of technology

Opinions likewise diverge as to whether compulsory licenses encourage or deter the transfer of technology from industrialized to developing and least-developed states. It seems that both positions can be defended and the ultimate answer again lies in a reasonably struck balance between public interest in accessing and exploiting patented technologies and patentees' private interests.

Some thinkers believe that there is no clear link between the level of intellectual property protection a developing country provides and foreign direct investments (FDI). They rely on the evidence, coming from e.g. China or India, which show that, if a country has a lot to offer in terms of economic opportunities, it will be able to attract massive amounts of FDI, notwithstanding the adequacy of its intellectual property protection.[149] In line with this is the assumption that countries with insufficient industrial capacities can freely use compulsory licenses as an efficient tool to trigger the transfer of patented technology. This, however, depends very much on the importance of patents for certain types of industry. Having in mind the complexity of drug development, on one hand, and the relative easiness with which patented drugs can be copied, on the other, patent protection proved

[149] Reichman, "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options". Supra note 130, at p. 256.

to be crucial for the pharmaceutical industry.[150] Accordingly, pharmaceutical companies tend to be much more sensitive to the lenient policy on compulsory licensing than other industries. This fact may presumably discourage them to enter local markets with research-based products.

Admittedly, a compulsory license mechanism could be a factor that would prompt patent holders to loosen their sometimes excessively restrained position and engage freely in negotiations on voluntary licensing of their technologies. In this light, developing states, which are genuinely interested in making available new patented techniques to domestic industries, should create such compulsory license schemes that put primacy on negotiations with patent holders, to their mutual benefit.

6.3 Retaliation against developing countries issuing compulsory licenses

Another risk that states, which issue a compulsory license, may face is that either drug companies, or powerful governments retaliate against them.

The first known retaliation by a drug company occurred following Thailand's compulsory license on Abbott's HIV drug *Kaletra*. Abbott responded to this compulsory license by threatening with withdrawal of its application to sell certain drugs in Thailand, including the latest version of its HIV drug *Aluvia*, which was specially suited for hot climes. Furthermore, Abbott announced that it would offer this drug at a reduced price to developing countries provided they would not issue compulsory licenses.[151] Although, companies retaliation by not selling or pricing would not pass over without public resentment, as was the case with Abbot, such and similar actions, being unaddressed by the TRIPS Agreement, remain a chip that patent owning companies will not hesitate to use.

[150] Chien, "Cheap Drugs at What Price to Innovation". Supra note 1, at p. 865.
[151] Ho, "*Access to Medicine in the Global Economy"*. Supra note 36, at p. 150.

In addition, there have been opinions that compulsory licenses might be useless because they do not guarantee transfer of technology or know-how, which can prevent licensees of working inventions with the same level of quality and safety and at a lower cost than the originator.[152] Patentees may oppose compulsory licenses by refusing to disclose in applications the most efficient know-how on how to work the invention. Under these circumstances, even if a compulsory license is granted, it may be difficult or even impossible for the licensee to work the invention successfully, and thus no transfer of technology would take place.[153] Indeed, there have already been concerns that patent holding companies faced with threats of issuing compulsory licenses increasingly turn to the protection of processes through know-how and trade secrets instead of patents. Such practices can further hamper the use of compulsory licenses in situations of real extreme urgency.

The case of the Thai compulsory licenses is also an example of national retaliation. Following their issuance of compulsory licenses in late 2006 and early 2007, the US placed Thailand under the Special 301 Priority Watch List Surveillance and threatened to terminate their preferential treatment under the Generalized System of Preferences.[154] Being unsatisfied with the level of protection of intellectual property rights in Thailand, the US thus clearly threatened to impose unilateral economic sanctions on the country. However, unlike retaliation by a company, unilateral retaliatory action undertaken by a government against another state, without using WTO DSU, would be in breach of WTO law. Under Article 23 of the WTO DSU, if a member state alleges that another member states violates the WTO Agreement, including TRIPS, it would be allowed to employ any sort of

[152] Kommerskollegium National Board of Trade, *The WTO Decision on Compulsory Licensing: Does It Enable Import of Medicines for Developing Countries with Grave Public Health Problems?* (2008), at pp. 36-37.
[153] Bonadio, "Compulsory Licensing of Patents: The Bayer-Natco Case". Supra note 56, at p. 727.
[154] Reichman, "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options". Supra note 133, at p. 258.

retaliation only after exhausting all available possibilities under the WTO dispute settlement system.[155]

The US deliberately failed to bring a dispute against Thailand before the WTO panel, avoiding the probability of rejection of its case. Given the freedom under TRIPS regarding the grounds for issuing compulsory licenses, it is likely that a similar action against India in respect of the relevant provisions, which have been materialized in the *Bayer v. Natco* case, would not be successful. Nevertheless, any country contemplating issuing a compulsory license should first design the strategy how to protect its legal rights and, in any case, be prepared to endure political pressure.

6.4 Compulsory licenses, access to medicines and the role of national governments

By granting a limited monopoly (currently for at least a 20-year term), patents simultaneously act to increase the incentive for innovation, but also prices of patented products. Professor Daniel J. Gervais described this situation as an apparent paradox of intellectual property where a society, in order to ensure access to new creations and inventions, limits that access.[156] Although patents increase drug prices and consequently to some extent reduce their affordability and accessibility, it is well known today that patents are not the only reason for why people cannot afford drugs.

Notably, there are many drugs that have already gone off-patent, opening opportunities for generic drug manufacturers. For instance, nearly 95% of pharmaceutical products for malaria and tuberculosis are off-patent. In the context of HIV/AIDS around 80% of antiretroviral drugs are off-patent.[157] For example, a study conducted between October 2000 and March 2001 on 15 antiretroviral drugs in 53 African countries showed that number of patented medicines ranged from zero in 13 countries to 13 in South Africa

[155] Ibid. (Reichman), at p. 258.
[156] Gervais, ”State of the Art: The Changing Landscape of International Intellectual Property”. Supra note 30, at p. 252.
[157] Brougher, ”*Intellectual Property and Health Technologies*”. Supra note 43, at p. 195.

with a median of only three.[158] Nevertheless, it appears that these countries have been greatly struggling with providing access to those pharmaceuticals to their needy populations. Another study from 2004 involving 319 drugs on the WTO Model List of Essential Medicines found that only seventeen of these were still effectively under patent in 65 developing (low and middle income) countries. The study concluded that it was poverty, not patents, that imposed greater limitation on access.[159] Also, for decades pharmaceutical products were not patentable in India, which has been called a 'pharmacy of the developing world' due to its generic drug production. Yet, India has one of the lowest levels of access to medicines.[160]

It is thus apparent that other issues, not related to patent law, are also responsible for the lack of accessibility to life-saving medicines. What comes to mind are inadequate health care and health infrastructure, absence of health insurance schemes, prevention etc. All those issues however require a strategic state action. The main objection here would be that there is a lack of a proactive role of national governments in addressing the problems immanent to access to medicines in developing and least developed countries.

Compulsory licenses, which target solely patent cost and eliminate "neither the production costs nor the problems associated with distribution and timely administration of the medicines",[161] cannot obviously be an integrated solution. Between unregulated monopoly pricing as one extreme and compulsory licensing as another, "there exist intermediate regimes based on price regulation, which are widely practiced in OECD

[158] Attaran, Amir and Gillespie-White, Lee, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?", 286 *Journal of American Medical Association* 15, (2001), at p. 1887.
[159] Attaran Amir, "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?", 23 *Health Affairs* 155 (2004), at p. 156.
[160] Yugank, Goyal, "Economic and Procedural Constraints of Compulsory Licenses for Medicines", in Hilty, M. R. and Liu, K-C. (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward* edited by (Springer-Verlag Berlin Heidelberg, 2015), at p. 451.
[161] Gervais, "State of the Art: The Changing Landscape of International Intellectual Property". Supra note 30, at p. 251.

countries".[162] A notable example is Canada, which, in 1992, shifted from its regime of aggressive use of non-voluntary licenses promoting the production of generic pharmaceuticals to a regime of price controls and nevertheless succeeded in keeping low prices of medicines.[163]

Instead of triggering disputes and described controversies by resorting to compulsory licensing, developing-country governments could employ in the alternative a variety of other possible courses of action which range from differential pricing to public procurements of medicines.

In the aftermath of the *Bayer v. Natco* case for example, many commentators questioned the issue of affordability of *Nexavar*, stating that there were elites in India who could have afforded the full price.[164] Discrimination against poor people in other countries who have to pay for innovation has been at stake, as poverty does not strictly follow political boundaries.[165] Indian authorities should have identified groups of needy patients among the limited number of those for whom *Nexavar* was suitable and purchase the drug for them under negotiated price. Likewise, the competent authorities could have made a scheme for providing generic substitutions of the drug for defined groups of patients only during the limited period until the patent expires.

A role of governments in promoting access to medicines in respect of their health policy, aside from the intellectual property policy, which would help to circumvent the controversial issues of granting compulsory licenses, has

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[162] Abbott, Frederick M. and Reichman, Jerome H., "The Doha Rounds Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions", 10(4) *Journal of International Economic Law* 921 (2007), at p. 970.

[163] Reichman, Jerome H. and Hasenzahl, Catherine, "Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS and an Overview of the Practice in Canada and the USA", UNCTAD-ICTSD Project on IPRs and Sustainable Development (2003), at p. 4.

[164] See Kulkarni and Foy, "Analysis: India Cancer Ruling Opens Door for Cheaper Drugs". Supra note 89; "There is huge wealth in India," Pfizer CEO Ian read told Reuters in London. "There are maybe 100 million people in India who have wealth equivalent to or greater than the average European or American, who don't pay for innovation. So this is going to have to be a discussion at some point."

[165] Outterson, Kevin, "Patent Buy-Outs for Global Disease Innovations for Low- and Middle Income Countries", 32 *American Journal of Law & Medicine* 159 (2006), at p. 171.

been subject of many recent discussions. In this regard, the most prominent is cooperation between the three international organizations with their specific responsibilities in this area, namely the WHO, WIPO and the WTO. In 2010 and 2011 they held the two Joint Technical Symposiums, on "Access to Medicines: Pricing and Procurement Policies"[166] and "Access to Medicines: Patent Information and Freedom to Operate"[167], respectively.[168] As a result of the cooperation, the organizations published in February 2013 a study on *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade*.[169] The aim of the study is to strengthen the capacity for "informed policy-making in areas between health, trade and IP",[170] focusing equally on access to and innovation of medicines. It has been recognized that "there is a need for a broad-based approach to access to medicines, which should include dimensions such as innovation, access and funding".[171] This approach is in line with the principles of the Doha Declaration, which emphasizes the freedom of Members to use, to the full extent, the TRIPS flexibilities in view of protecting public health, and, in particular, promoting access to medicines for all, but also stresses the need for the TRIPS Agreement "to be part of the wider national and international action to address these problems"[172].[173]

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[166] See WHO, WTO and WIPO, *Technical Symposium on Access to Medicines: Pricing and Procurement Policies* (July 2010), available at: https://www.wto.org/english/tratop_e/trips_e/techsymp_july10_e/trip_16july10_summary_e.pdf (accessed on 20 May 2016).
[167] See WHO, WIPO and WTO, *A Joint Technical Symposium on Access to Medicines: Patent Information and Freedom to Operate* (February 2011), available at: http://www.wipo.int/meetings/en/2011/who_wipo_wto_ip_med_ge_11/program.html (accessed on 20 May 2016).
[168] Kampf, Roger and Wager, Hannu, "The Role of the TRIPS Agreement in the Global Health Policy", *Stanford Journal of Law, Science and Policy* 17 (published online September 2011), at p. 39.
[169] WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade* (2013), available at: https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf (accessed on 20 May 2016).
[170] Ibid. (WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation*), at p. 9.
[171] Kampf and Wager, "The Role of the TRIPS Agreement in the Global Health Policy". Supra note 168, at p. 37.
[172] The Doha Declaration, pars. 2 and 4.

The 2013 study of the WHO, WIPO and the WTO has identified a variety of health systems-related determinants of access, such as differential pricing, various indirect taxes and mark-ups, which increase the price of medicines, procurement systems, patent information, local production and regulatory mechanisms for medicines. In particular, the study highlights the importance of a well-functioning health system, of which one aspect is "equitable access to essential medical products of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use". It notes that "while differential pricing can be used as a complementary tool to increase access, government commitment to provide access to medicines to those who cannot afford them remains essential".[174]

Similarly, in his Report on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, the UN Special Rapporteur on the Right to Health has identified and analyzed challenges and good practices with respect to access to medicines, not related to intellectual property. The report has focused on domestic policies affecting access to medicines, including local production, pricing, medicine lists, procurement, distribution, quality control and appropriate use of medicines.[175]

Domestic policies that can promote access to patented medicines, and, at the same time, preserve innovation as well as dissemination and transfer of technology are of particular importance for the present discussion. The main focus will therefore lie on price regulation and procurements strategies.

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[173] Kampf and Wager, "The Role of the TRIPS Agreement in the Global Health Policy". Supra note 168, at p. 37.
[174] WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation.* Supra note 169, at p. 155.
[175] Human Rights Council, UN Doc A/HRC/23/42, 1 May 2013, *Report of the Special Rapporteur on the Right of Everyone of the Highest Attainable Standard of Physical and Mental Health, Anand Grover, on Access to Medicines.*

6.4.1 Price controls

States have a legal obligation under the right to health to provide medicines that are economically accessible to all sections of the population.[176] Therefore, states are encouraged to apply appropriate price control strategies, which range from direct price controls, comparing prices to internal or external references to negotiated favorable prices. It is to be noted, however, that the successful price regulation requires the establishment of a transparent system through which such regulation can be applied. Many developed countries, where a substantial part of the population is covered by health insurance schemes, apply *therapeutic (or internal) reference pricing*, which allows for negotiating a reimbursement price of a medicine based on other existing drugs in its therapeutic class that are available in the same country.[177] Reference pricing can also be based on the prices of a drug in its therapeutic class available in other countries (*external reference pricing*).

Another, more restrictive form of regulation is a direct price control, when a government sets the sale price and prevents sales at any other price. The direct control method is based on costs of production, a profit margin as well as the distributors' mark-ups, which means that this method is applicable only in situations when these costs can be precisely estimated.[178]

Price controls can also be applied at various levels, such as the manufacturer, wholesaler or retailer level.[179] As the Special Rapporteur has found, distribution mark-ups, tariffs and taxes usually increase significantly the prices of medicines. States should accordingly revise their policies in regard to these add-on costs in order to lower or eliminate them and hence reduce the price of medicines.

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[176] Ibid. (Special Rapporteur's Report on Access to Medicines), at p. 8.
[177] Ibid. (Special Rapporteur's Report on Access to Medicines), at p. 9.
[178] WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation.* Supra note 169, at p. 157.
[179] Ibid. (WHO, WIPO and WTO), at p. 157.

Given the absence of health insurance schemes in many developing countries, where patients have to pay individually the whole price of prescription medicines out-of-pocket as well as the lack of reliable and documented evidence of actual costs of production, it may be difficult or even impossible for them to introduce a fair and working price regulation. While making efforts to establish such an infrastructure, in order to satisfy current needs for essential medicines, developing countries should probably focus on direct negotiation with manufacturers to ensure access to affordable drugs. In order to conduct these negotiations successfully, governments should obtain transparent information that is otherwise used in various forms of price controls.

6.4.2 Procurement

Efficient and transparent procurement of medicines is yet another important policy promoting access to medicines in sufficient quantities in all public health facilities. In order to be efficient, procurement strategies must be supported by proper selection and quantification of needed medicines, reliable patent information in the relevant jurisdictions, applied prices and the broader framework, including tariffs, taxes and health regulations.[180] States should thus initially identify medicines required to cover priority health care needs of the population by creating a national essential medicine list.[181] In this regard, the WTO Model List of Essential Medicines should serve as a guide for governments to identify their own priorities in respect of needed medicines. The medicines on this list are selected on the basis of disease prevalence, evidence on efficacy and safety and comparative cost-effectiveness.[182] While creating their national lists, governments should also take into consideration the respective particularities of the country and update the information regularly.

[180] Kampf and Wager, "The Role of the TRIPS Agreement in the Global Health Policy". Supra note 168, at p. 37
[181] Special Rapporteur's Report on Access to Medicines. Supra note 175, at p. 13.
[182] WHO, WTO and WIPO, *Technical Symposium on Access to Medicines: Pricing and Procurement Policies*. Supra note 166, at p. 3.

The intellectual property protection is not a criterion for the inclusion of a medicine into the list. Nevertheless, a quality national essential medicines list should contain information about the scope and legal status of intellectual property rights in regard to the relevant technology and products in a given market. To obtain the relevant patent information, governments can use the WIPO's *Patentscope*® portal,[183] but also national patent databases.[184]

In order to manage procurement successfully and optimize the use of financial resources, states are encouraged to develop "more scientific reliable and evidence-based methods for forecasting and quantification such as the use of computerized methods for quantification and reliance on data about actual consumption where there are reliable records available".[185]

Even more promising is a pooled procurement strategy, also known as "group purchasing" or "bulk purchasing", which has been defined as "purchasing done by one procurement authority on behalf of a group of facilities, health systems or countries".[186] Pooled procurement has proved especially useful because, on the one hand, "with the leverage of larger orders, states can achieve economies of scale and negotiate best prices."[187] On the other hand, originator pharmaceutical companies that cooperate with a procurement office are able to preserve market share and benefit from economies of scale and long-term prospect of supply, which enables them to lower their prices.[188]

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[183] *Patentscope*® provides a full text search in international patent applications under the Patent Cooperation Treaty.
[184] WHO, WTO and WIPO, *Technical Symposium on Access to Medicines: Pricing and Procurement Policies*. Supra note 166, at p. 4.
[185] Special Rapporteur's Report on Access to Medicines. Supra note 175, at p. 15.
[186] WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation.* Supra note 169, at p. 162.
[187] Ibid. (WHO, WIPO and WTO), at p. 162.
[188] Abbott and Reichman, "The Doha Rounds Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions". Supra note 162, at p. 973.

7. A human rights-based approach to access to medicines: what is missing?

7.1 Background

Arguments about the right to health have become a central focus of the relationship between patents and access to medicines in the aftermath of the HIV/AIDS pandemic. By the time this severe disease was recognized as a worldwide pandemic in 1984, it had already begun to reap rampantly its victims throughout the world, in particular, in sub–Saharan Africa. A 2008 report of the Joint United Nations Programme on HIV/AIDS (UNAIDS)[189] pointed out the disastrous scope of the pandemic, estimating that 25 million people have already died of HIV-related causes.[190] The pandemic has had devastating consequences in general, but especially in the poorest countries of the world, which were often the most heavily affected. The United Nations Development Programme (UNDP) revealed that HIV has inflicted "the single greatest reversal in human development in modern history".[191]

Outbreaks of the terrifying disease prompted the research into factors responsible for it and the development of a cure, which appeared in the market already in 1989.[192] However, that drug, as well as those that were subsequently developed, was so expansive that it was literally unaffordable to many patients even in the richest, let alone to the vast majority of those in the poorest countries of the world.[193]

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[189] The Joint United nations Programme on HIV/AIDS (UNAIDS) is an international effort to combat HIV/AIDS sponsored by ten UN specialized agencies.
[190] UNAIDS, the 2008 Report on the Global AIDS Epidemic, at p. 15.
[191] Ibid. (UNAIDS), at p.13.
[192] Although the research was based on a compound, which had already been in a public domain, and relied heavily on the US public funding, the British drug maker Burroughs Wellcome obtained a patent on *Azidothymidine* (AZT) and began marketing the drug under the trademark *Retrovir* in 1989.
[193] Houston, "A Scientific Approach to Intellectual Property and Health". Supra note 29, at p. 804.

The disparity between the needs for antiretroviral drugs and the inability to afford them has prompted an unprecedented action to provide the therapy, involving many governments, key global and regional bodies, public funds, private companies and organizations of people living with HIV.[194] The right to health became the central pillar of such campaigns. The Millennium Development Goals[195] included among others universal access to treatment for HIV/AIDS as one of its targets for achieving a broader goal to combat HIV/AIDS, malaria, and other diseases.[196]

Alongside with this fairly successful campaign, certain UN bodies, notably the Committee on Economic, Social and Cultural Rights (CESCR) in its Statement of 2001 indicated the possibility of tensions between intellectual property and human rights. The UN Sub-Commission on the Promotion and Protection of Human Rights in its Resolution 2000/7 was even more explicit stating that the TRIPS Agreement failed to adequately reflect the fundamental nature and indivisibility of all human rights. It has thus clearly conceptualized the relationship between international intellectual property and human rights law as an apparent conflict.[197]

At around the same time, certain countries facing the HIV/AIDS crisis, notably Brazil and South Africa, made the first attempts to articulate the universal right of access to medicines in order to strengthen the legal basis for issuing compulsory licenses for HIV treatment.[198] These attempts were largely backed by a provision on the right to health that the countries had enshrined in their constitutions.

The campaign for access to medicines, once being synonymous with access to medicines for HIV/AIDS, has, however, begun expanding to non-communicable diseases. According to the data revealed by the World Health Organization, once considered a problem limited to the "rich world", non-

[194] UNAIDS. Supra note 190, at pp. 134-138.
[195] U.N. Secretary General, Millennium Development Goals derived from the United Nations Millennium Declaration, signed in September 2000, available at: http://www.un.org/millenniumgoals/ (accessed on 15 April 2016).
[196] Ibid. (Millennium Development Goals), Goal 6.
[197] Matthews, "Right to Health and Patents". Supra note 9, at pp. 497-498.
[198] Ibid. (Matthews), at p. 502.

communicable diseases are growing quickly also in low- and middle-income countries where they cause 80% of deaths.[199] Patents are again considered the main culprit for a lack of accessibility of cures. Thailand was the first country which issued compulsory licenses in this context and India followed.

7.2 The current tendencies

The discussion whether access to medicine is a universal human right by virtue of the right to health and how it bears upon intellectual property is not purely theoretical as it can produce pragmatic consequences, if it was inferred that human rights could be outweighed only by other human rights.[200] Once established, the primacy of the right to health over patents would open the way for unrestricted limitation of the rights of patent owners. These assertions accordingly have not been left without a response. Supporters of strong intellectual property rights have found the justifications for their claims in the right to own private property.[201] Such justifications have been derived primarily from the view that there is the parity between intellectual property, on one hand, and property in tangible assets, on the other.[202]

The recent developments in Europe support this approach.[203] The European Court of Human Rights (the ECtHR) has consistently held that intellectual property falls under the scope of Article 1 of Protocol No. 1 to the European Convention on Human Rights (the ECHR), which guarantees the peaceful enjoyment of possessions.[204] Indeed, the ECtHR has on several occasions engaged in striking a fair balance between intellectual property rights and

[199] WHO, Fact Sheet, updated January 2015, "Noncommunicable Diseases", available at: http://www.who.int/mediacentre/factsheets/fs355/en (accessed at 28 April 2016).
[200] Dreyfuss, "Patents and Human Rights: Where is the Paradox?". Supra note 5, at p. 74.
[201] Yu, "The Anatomy of the Human Rights Framework for Intellectual Property". Supra note 10, at p. 39-47.
[202] Matthews, "Right to Health and Patents". Supra note 9, at p. 497.
[203] Yu, "The Anatomy of the Human Rights Framework for Intellectual Property". Supra note 10, at p. 39.
[204] See ECtHR, *Anheuser-Busch Inc. v. Portugal*, (no. 73049/01) of 11 January 2007.

other human rights and ruled in favor of intellectual property rights.[205] Furthermore, Article 17(2) of the Charter of Fundamental Rights of the European Union proclaimed explicitly the protection of intellectual property as a facet of the right to property.[206]

There are, however, strong arguments against the recognition of patent rights as the human right to property. First, objections have been raised about the absence of a legally binding provision on the right to property in international instruments. It has been noted, in particular, that while such an approach may be possible on the regional level (in Europe), an evident lack of consensus on the conception of property makes it unachievable on the international level. Furthermore, many human rights experts criticize the extension of human rights protection to cover corporations; or the adequacy of the right to property for the protection of intellectual property because it focuses mostly on material interest resulting from intellectual productions and disregards the moral interests, which are equally important.[207]

Moreover, the right to own private property seems not to be an adequate tool for balancing between innovation and access. There is not so much about this right that speaks about innovation, and there is even less, if anything, that speaks about access. The right to property-based approach to patents, thus, manifests the same one-sidedness as the right to health-based approach to access, which, on the contrary, focuses exclusively on short-term access to medicines. Although these two approaches have proven successful in counteracting each other, they equally fail to provide a feasible solution for the innovation/access debate.

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[205] See ECtHR, *Ashby Donalds and Others v. France*, (no. 36769/08) of 10 January 2013 and *Neij and Sunde Kolmisoppi v. Sweden*, (no. 40397/12) of 19 February 2013.

[206] Article 17 of the Charter of Fundamental Rights of European Union:

1. Everyone has the right to own, use dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary in the general interest.
2. Intellectual property should be so protected.

[207] Yu, "The Anatomy of the Human Rights Framework for Intellectual Property". Supra note 10, at p. 40.

In a parallel fashion, at the international level, commentators have raised arguments for the recognition of patent rights as human rights, based on the UDHR and the ICESCR under Articles 27 and 15, respectively. First, they rely on the text of these instruments, which explicitly recognizes "the right to the protection of the moral and material interests resulting from any scientific, literally or artistic production of which he is the author."[208] Moreover, the historical post World War II context, in which the instruments were drafted and which contained the concerns over the abuse of science and technology that had occurred during the war, as well as the fact that the patent protection was specifically discussed during the drafting, were also taken as arguments for the establishment of a human right to patent protection. Finally, it has been argued that every invention ultimately leads back to an individual creator who as such deserves the protection of his or her human right.[209]

By contrast, opponents of a human rights basis for patents usually point out the distinction between them and copyright.[210] In the case of copyright a human rights dimension is more evident because of the indivisibility of a protected expression and a creator's personality. They argue, however, that, in the case of patents, it is rather difficult to establish such a link.[211] Arguments against the recognition of patents as human rights are thus derived from the mere design of the patent system. It has been emphasized that that system does not always protect the first inventor's human rights, as there is often a distinction between the patentee and the actual inventor.[212] Furthermore, unlike copyrights which offer the protection for creations as long as they are original, notwithstanding the previous instances of a given intellectual property, patents offer the protection only to the first applicants,

[208] UDHR. Supra note 7, Article 27(2); ICESR. Supra note 8, Article 15(15)(c).
[209] Yu, "The Anatomy of the Human Rights Framework for Intellectual Property". Supra note 10, at pp. 7-10.
[210] Yu, Peter K., "Ten Common Questions About Intellectual Property and Human Rights", 23 Georgia State University Law Review 709 (2007), at p. 721.
[211] Dreyfuss, "Patents and Human Rights: Where is the Paradox?". Supra note 5, at pp. 80-81..
[212] Yu, The Anatomy of the Human Rights Framework for Intellectual Property". Supra note 10, at pp. 10-11.

unnecessarily excluding later independent inventors.[213] It has been said also that human rights should protect both material and moral interests resulting from intellectual productions, whereas inventors do not have the right to seek the protection of the integrity of their inventions.[214]

One of the most prominent opponents of the idea of patents as human rights, Professor Rochelle Cooper Dreyfuss, has raised concerns in particular over the elevating of the *right to full control over the information* to human rights. She claims that such a trend can have unfortunate pragmatic consequences because it goes directly against the utilitarian nature of patent law, which seeks to encourage the advancement of knowledge, providing justification for patents as long as they are useful.[215] In her opinion, the equation of patents and human rights, where any future incursion on a patent right needs to be justified by showing that it involves an interest categorized as a human right, leads to uncertainty of a court balancing, which can further result in "an environment less conducive to decisions to invest time and money in intellectual efforts".[216] To support her ideas, Professor Dreyfuss draws attention to the recent developments in the US, which show that the traditional confidence in the patent system has begun to be reconsidered. Notably, she takes the example of a relatively recent case concerning the patent infringement, *eBay, Inc. v. MercExchange, L.L.C.*,[217] where the US Supreme Court unanimously determined "the judge's power to consider whether 'the public interest would…be deserved by a permanent injunction', citing with approval a case suggesting that injunction relief could be denied when health care interests are at stake."[218]

As recently as October 2015, the Special Rapporteur in the field of cultural rights, Farida Shaheed, in her Report on Patent policy and the right to science and culture, pronounced that there is no human right to patent

[213] Ibid. (Yu), at p. 11.
[214] Ibid. (Yu), at p. 12.
[215] Dreyfuss, "Patents and Human Rights: Where is the Paradox?". Supra note 5, at p. 74.
[216] Ibid. (Deryfuss), at p. 74.
[217] The Supreme Court of the US, *eBay, Inc. v. MercExchnge, L.L.C.*, 547 U.S. 388, 394 (2006), citing *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2D 858 (1984).
[218] Dreyfuss, "Patents and Human Rights: Where is the Paradox?". Supra note 5, at p. 91.

protection under Article 15 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR). According to the Report patents are only one among many tools for encouraging innovation and technological research and development. As being in conflict with certain human rights obligations, patents should always be subjected to human rights law limitations.[219] At the same time, it has recognized the importance of the right to science and culture, which although not establishing a human right to patent protection, provides a particularly promising framework within which patent policy should be considered.[220]

The Report is clearly an outcry of two decades-long tensions between human rights and patent law. Like other attempts to provide a framework for intellectual property and human rights, it, however, raises more questions than it answers. In a somewhat conciliatory spirit, Professor Peter K. Yu concluded that "one can locate human rights support for only some but not all of patent rights."[221] The debate on the status of intellectual property is not unimportant as it can produce significant consequences. However, it appears that the resulting confrontation merely inhibits solutions.

As said, the human rights discourse in relation to access to medicines and patents has ascended in the aftermath of the first attempts to make use of a compulsory licensing provision under Article 31 of the TRIPS Agreement. It appears that the two most prominent rights in that discourse are the right to health and the right to science and culture. Therefore, a closer look at these two rights may be useful.

7.3 The right to health

As is shown in the part of the thesis discussing the *Bayer v. Natco* case, the IPAB approached the dispute concerning the compulsory license on Bayer's

[219] Special Rapporteur in the Filed of Cultural Rights, *Cultural Rights*, United Nations General Assembly, U.N. Doc. A/70/279, 4 August 2015, (by Farida Shaheed), at par. 90.
[220] Ibid. (Special Rapporteur's Report on Patent Policy), at par. 5.
[221] Yu, The Anatomy of the Human Rights Framework for Intellectual Property". Supra note 10, at p. 5.

drug *Nexavar* from a public health perspective in the context of the constitutional right to life. The *Bayer v. Natco* case is thus a clear example of the practical manifestations of using a human rights-based discourse to assert the right to health in the context of pharmaceutical product patents. The purpose of the present chapter is to explain whether the right to health is an appropriate tool for limiting the rights of patent holders. To do this, this chapter first examines the content of the right and the duties that it imposes on states.

The Constitution of the World Health Organization, which came into force in 1947, was the first international legal document that introduced the concept of a human right to health. It stated in its preamble that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social conditions." Two years later, the Universal Declaration of Human Rights (UDHR) proclaimed the right to medical care, along with other rights relating to food, housing, and social security.[222] While the UDHR itself does not have a direct binding effect, the same does not apply to the International Covenant on Economic Social and Cultural Rights (ICESCR), which has codified and further elaborated upon the right to health in Article 12, which stipulates:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The Steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
    (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
    (b) The improvement of all aspects of environmental and industrial hygiene;

[222] Universal Declaration of Human Rights, G.A. Res. 217A(III), at art. 25.1, U.N. GAOR, 3d Sess;, 1st plen. mtg., U.N. Doc. A/810 (Dec. 12, 1948), Article 25(1): "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control".

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.[223]

With 154 state parties, which have since adopted it, the ICESCR represents the most prominent among all instruments protecting the right to health. In accordance with Article 2(1) ICESCR, a state has a duty to take steps 'to the maximum of its available resources' to achieve 'progressively the full realization' of all the Covenant's economic, social and cultural rights, 'by all appropriate means, including particularly the adoption of legislative measures'. Although the right to health has been widely accepted, many commentators considered its scope to be too large and vague to enable the right to make a considerable impact.[224] The resource-dependent principle of progressive realization likewise undermines the universality of the right to health and leaves it open to the debate on the extent of the respective states' legal obligations in this regard under international and domestic law.

Nevertheless, the human right to health has been incorporated in many national constitutions and a number of adjudicatory bodies have had an opportunity to clarify its scope. Relying on reports on this state practice, the Committee on Economic, Social and Cultural Rights (the CESCR), which is the body in charge of monitoring the ICESCR, finally adopted, in 2000, a *General Comment*[225] (General Comment No. 14) on the right to health. General Comment No.14 has significantly contributed to the further development of a more precise framework for understanding the nature, scope and content of the right to health.[226]

[223] ICESCR. Supra note 8, Article 12.
[224] Holger, *Human Rights and the WTO: The Case of Patents and Access to Medicine*. Supra note 6, at p. 103.
[225] UN Committee on Economic, Social and Cultural Rights, CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant), adopted on 11 August 2000. UN document E/C.12/2000/4.
[226] Helfer and Austin, *Human Rights and Intellectual Property: Mapping the Global Interface.* Supra note 17, at p. 113.

In the first place, it emphasized that health is a fundamental right indispensable for the exercise of other human rights. Furthermore, this right has been defined to include access to essential medicines. The right to health framework contains the following essential elements that should be fulfilled by states in order to ensure access to medicines. First, medicines have to be available in sufficient quantities within a country. Second, medicines should be accessible to everyone without discrimination in terms of both physical accessibility and economic affordability. Third, medicines should be determined to be culturally and ethically acceptable to the population. Lastly, states have an obligation to ensure that health facilities, goods and services are also scientifically and medically appropriate and of good quality.[227]

Furthermore, like all other human rights, the right to health imposes three types or levels of obligations on states, namely the obligation to respect, protect and fulfill. The obligation to respect requires states to refrain from interfering directly or indirectly with the enjoyment of the right to health. The obligation to protect imposes duties to take measures that prevent third parties from interfering with the right to health. Finally, the obligation to fulfill requires states to take positive measures, that is, to adopt appropriate legislative, administrative, budgetary, judicial and other measures towards the full realization of this right.[228]

As such, the human right to health has proven to be a very powerful rhetorical tool in drawing attention to the debate over intellectual property and health. As stated in the Report of the High Commissioner on Economic, Social and Cultural Rights, "the starting point for a consideration of the operational aspects of IP systems with regard to access to drugs is that access to essential drugs is a human right".[229] Elaborating on the impact of the TRIPS Agreement on human rights and relying on the right to health,

[227] CESCR, (*General Comment No. 14)*, in paragraph 12.
[228] Ibid. (*General Comment No. 14)*, in paragraph 33.
[229] Report of the UN High Commissioner, *Economic, Social and Cultural Rights: The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*. UN document E/CN.4/Sub.2/2001/13 (27 June 2001), in paragraph 42.

the High Commissioner has successfully shifted the international focus on the issues of access to medicines. However, despite these rhetorical successes, the human right to health does not appear as an effective tool to addressing broader issues of innovation and access that are at the core of the debate on access to medicines.[230] For example, one can immediately see that the successful realization of the right to health requires not only expanding access to existing medicines, but also improving existing and innovating new solutions. As this right lacks an inherent balance between private interests of right holders, and public interests in innovation and access, it is not a promising tool for striking a proper balance within domestic and international intellectual property systems. On the contrary, the sole employment of the right to health in the interpretation of intellectual property instruments has framed the debate on intellectual property rights and access to medicines as a conflict between private and public interests, thus restricting unnecessarily the scope of both the problem and its solutions. As we shall see, "the problem from a policy maker's perspective is rather how to strike a balance between competing public interest, that is the long-term social objective of providing incentives for future inventions and creation, and the short-term objective of allowing people to access and use existing inventions and creations".[231]

7.4 The right to science and culture

Article 27 of the UDHR states that everyone has the right (1) "freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits", and to (2) the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." This dual aspect of participation and protection was later included in Article 15 of the ICESCR, which states:

[230] Houston, "A Scientific Approach to Intellectual Property and Health". Supra note 29, at p. 803.
[231] Anderson, Robert D. and Wager, Hannu, "Human Rights, Development, and the WTO: The Cases of Intellectual Property and Competition Policy", 9(3) *Journal of International Economic Law* 707 (2006), at p. 726.

1. The States Parties to the present Covenant recognize the right of everyone:
   (a) To take part in cultural life;
   (b) To enjoy the benefits of scientific progress and its applications;
   (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.
3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.
4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.[232]

Both of these provisions clearly reflect both human rights and utilitarian rationale underlying the intellectual property system.[233] As Professor Christophe Geiger noted: "The classical foundations of IP are placed in a stable balance in these instruments: on the one hand, the foundation of natural law by acknowledging an exploitation right and '*droit moral'* for the creator; and, on the other hand, the utilitarian foundation, because this acknowledgement has the promotion of intellectual variety and the spread of culture and science throughout society as a goal."[234] By referring to the words 'he' and 'everyone', the instruments have made a clear link to the individual creator, excluding thus legal entities from the protection on the level of human rights.[235] Furthermore, states are left with the significant

[232] ICESCR, Supra note 8, Article 15.
[233] Wager, Hannu and Watal, Jayashree, "Human Rights and International Intellectual Property Law", in C. Geiger (ed.), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar, Cheltenham/Northampton, 2015), at pp. 156-157.
[234] Geiger, Christophe, "Implementing Intellectual Property Provisions in Human Rights Instruments: Towards a New Social Contract for the Protection of Intangibles", in C. Geiger (ed.), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar, Cheltenham/Northampton, 2015), at p. 673.
[235] Ibid. (Geiger), at p. 673.

freedom as to how to provide a just remuneration for moral and material interests resulting from any scientific or artistic production. For all these reasons, the provisions from these two legal instruments have been perceived as the best example of a modern and balanced clause to regulate intellectual property matters.[236]

The CESCR has elaborated, through *General Comment No. 17*,[237] on Article 15.1(c) ICESCR in order to assist states in their pursuit to implement the provision. General Comment No.17, in particular, took a stance against the equation of intellectual property rights with human rights, emphasizing that the human right recognized in Article 15.1(c) "derives from the inherent dignity and worth of all persons" and that "this fact distinguishes this and other human rights from most legal entitlements recognized in intellectual property systems". It further states that "human rights are fundamental as they are inherent to the human person as such, whereas intellectual property rights are first and foremost means by which States seek to provide incentives for inventiveness and creativity, encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific, literary, and artistic productions for the benefit of society as a whole."[238]

As the right to benefit from the protection of interests arising from intellectual work, in fact, seeks to encourage more creative work, this right is 'intrinsically linked' to other rights recognized under Article 15 ICESCR. The relationship between them is described as 'mutually reinforcing' and at the same time 'reciprocally limitative'. Furthermore, as Article 15.1(c) has an economic dimension, it has been noted that it is 'closely linked' also to other rights contained in the ICESCR, i.e. the right to the opportunity to gain one's living by work, which one freely chooses (Article 6.1), to adequate remuneration (Article 7(a)) and to an adequate standard of living

[236] Ibid. (Geiger), at pp. 673-672.
[237] UN CESCR General Comment No.17 on 'The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author' (Article 15, paragraph 1 (c) of the Covenant), adopted on 21 November 2005. UN document E/C.12/GC/17.
[238] Ibid. (*General Comment No.17)*, in paragraph 1.

(Article 11.1).[239] It has been explicitly established that Article 15.1(c) rights must be balanced with other rights of the ICESCR.[240] Finally, the realization of this right is dependent on other human rights guaranteed in the International Bill of Human Rights and other international and regional instruments.[241]

This balance that is desirable in the relationship between different Article 15 rights and also other rights guaranteed in the Covenant is likewise immanent to the consideration of modern intellectual property systems.[242] As said, the main objective of the protection and enforcement of intellectual property rights is to "contribute to the promotion of technological innovation and to the transfers and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".[243] This corresponds with the objectives of Article 15.1(a) and (b) of the ICESCR, which recognize the right of everyone to take part in cultural life and to enjoy the benefits of scientific progress and its applications.[244]

Although the TRIPS Agreement clearly emphasizes the public interest rationale, there are opinions that it also seeks to protect the material interest recognized under Article 15.1(c) of the ICESCR. These opinions are derived mainly from the statement in the Preamble to the TRIPS Agreement, which recognizes that intellectual property rights are private rights. It should be noted also that the protection of intellectual property rights is "the main means by which states give effect to the fundamental rights deriving from Article 15.1(c)".[245]

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[239] Ibid. (*General Comment No.17)*, in paragraph 4.
[240] Ibid. (*General Comment No.17)*, in paragraph 22.
[241] Ibid. (*General Comment No.17)*, in paragraph 4.
[242] Anderson and Hannu, "Human Rights, Development, and the WTO". Supra note 231, at p. 723.
[243] Article 7 of the TRIPS Agreement.
[244] Anderson and Hannu, "Human Rights, Development, and the WTO". Supra note 231, at p. 723.
[245] Ibid. (Anderson and Hannu), at p. 722.

Oddly enough, even though Article 15 of the ICESCR provides the set of rights that balances the protection of the moral and material interests of innovators with a broader right of access to the benefits of such innovations or the broader public interest in promoting the benefit of the society as a whole, it has been rarely put into practical use.[246] Irrespective of whether the emphasis is on human rights or on the utilitarian rationale of patent law, "there is a need for careful social and economic analysis and empirical evidence when designing appropriate policy responses to best achieve" both the long-term and short-term social objectives.[247] Such a policy should include the consideration of Article 15 of the ICESCR because of its internal balance that is also inherent in intellectual property systems. As aptly observed by Dr Holger Hestermeyer: "New drugs are part of "scientific progress" and Article 15 grants everyone the right to enjoy the benefits of this progress and its applications, emphasized by paragraph 2's reference to States parties' obligation to take steps necessary for the 'diffusion', i.e. spreading of science".[248] By securing the protection of the moral and material interests of innovators, Article 15 also safeguards future innovation and creativity.

Looking at patents through the Article 15 ICESCR human rights lens provides a full spectrum of interest at stake, namely the private interest of right holders, the long-term interests of providing incentives for future innovations and the short-term interests of maximizing instant access. It further argues for the approach of coexistence between patent and human rights. In the long run, there is clearly no conflict, because exclusive rights, which are a necessary incentive tool, are granted only for a limited period of time. Once the term of protection has expired, protected works and inventions fall into the public domain and anyone is free to use them without prior authorization by the patent holder. Certain tensions between

[246] See in this regard Houston, "A Scientific Approach to Intellectual Property and Health". Supra note 29, at p. 808.
[247] Kampf and Wager, "The Role of the TRIPS Agreement in the Global Health Policy". Supra note 168, at pp. 38-39.
[248] Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*. Supra note 200, at p. 112.

patent and human rights can arise during the term of protection. It is then on governments to demonstrate perspicacity and to find the optimal balance while employing the intellectual property instruments available to enhance access.[249] In the context of the specific issue of access to medicines, Article 15 ICESCR requires therefore a broader evaluation of the TRIPS flexibilities, and should for this reason be at the core of government policy measures that genuinely seek to promote public health.

[249] Wager and Watal, "Human Rights and International Intellectual Property Law". Supra note 233, at pp. 158-159.

8. Conclusion

Western (Anglo-American and European) legal and moral conceptions of intellectual property in general and patents in particular are to a large extent based on the utilitarian incentives-based argument. Seeking to protect their economic interests, the group of industrialized countries successfully imposed their idea that the globalized incentives rationale of intellectual property would encourage innovation, foreign investments, transfer of technology and economic growth worldwide.[250] The TRIPS Agreement, which presents the first serious attempt to harmonize the protection of intellectual property internationally, particularly due to its strong enforcement mechanism, is thus imbued with the idea of utilitarianism. Consequently, the TRIPS Agreement has additionally been burdened by the expansion of that idea on developing countries, which appear not to be ready to accept it completely.

Indeed, since the inception of the negotiations of the TRIPS Agreement, it was clear that there was a stark division between developed and developing countries (sometimes called North-South divide). Many controversial issues were resolved by a last-minute compromise,[251] which further led to many gaps and ambiguities within the TRIPS Agreement. Those ambiguities have resulted in the absence of a uniform interpretation of the TRIPS provisions, which is particularly evident regarding the application of the flexibilities. A broad interpretation and, in particular, the strategy of combining the application of different flexibilities creates an uncertainty and distrust of the patent system in certain jurisdictions. The Indian example is illustrative of such an approach.

Through the analysis of the flexibilities enshrined in the TRIPS Agreement, with special emphasis on Indian intellectual property policies, this thesis has

[250] Adusei, "Patenting of Pharmaceuticals and Development in Sub-Saharan Africa". Supra note 25, at p. 121.
[251] Correa, Carlos, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, (Zed Books Ltd., 2000), at p. 106.

dealt with India's peculiar arrangement of global multilateral trade rules. By analyzing the cocktail of extreme measures undertaken by India, the thesis has shown that India has failed to create the business environment in which the research-based industry would feel confident while investing in innovation in healthcare.

The central focus of the thesis has been the Bayer/Natco case, which dealt with special provisions for compulsory licensing. The only compulsory license that has been granted in India so far has generated a vigorous debate and pressure on India (particularly by the US) to adopt changes in the functioning of its patent system. In particular, the thesis has indicated the detrimental effect of the extended use of compulsory licensing on innovation, and therefore on access to quality health and affordable medicines. Such an approach to patents, as has been taken in this compulsory license case, clearly undermines the state's genuine commitment to protect its public health.

The Indian authorities attempted to justify their broad interpretation of the flexibilities under TRIPS by the legitimate need to protect the right to health. As this thesis has shown, however, it appears that the current rhetorical strategy based on human rights, limiting patent rights and especially creating an artificial conflict between human rights and intellectual property rights, is far from being a feasible solution for the problem of access to medicines. The described vagueness inherent in the human rights-based approach to intellectual property further complicates the tension between patents and human rights, pertaining to the access to medicines. Patent law should rather be understood as being inextricably linked with human rights discourse, and the principal task for the judiciary when resolving the issues of limiting the patent rights for the benefit of the public would primarily be to strike a fair balance within that discourse.

Bibliography

Monographs

Adusei, Poku, *Patenting of Pharmaceuticals and Development in Sub-Saharan Africa: Laws, Institutions, Practices and Politics*, (Springer-Verlag Berlin Heidelberg, 2013)

Brougher, Joanna T., *Intellectual Property and Health Technologies: Balancing Innovation and the Public's Health*, Springer Science + Business New York (2014)

Chandra, Rajshree, *Knowledge as Property: Issues in the Moral Grounding of Intellectual Property Rights*, (Oxford University Press, 2010)

Correa, Carlos, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, (Zed Books Ltd. 2000)

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

Hestermeyer, Holger, *Human Rights and the WTO: The Case of Patents and Access to Medicine*, (Oxford University Press, 2007)

Locke, John (1690), *Two Treaties of Government*, Book II, Chapter V.

Reichman, Jerome H. and Hasenzahl, Catherine, "Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS and an Overview of the Practice in Canada and the USA", UNCTAD-ICTSD Project on IPRs and Sustainable Development (2003)

Kommerskollegium National Board of Trade, *The WTO Decision on Compulsory Licensing: Does It Enable Import of Medicines for Developing Countries with Grave Public Health Problems?* (2008)

Kuanpoth, Jakkrit, *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future*, (Edward Elgar, Cheltenham, UK, 2010)

Pattaro, Enrico, *A Treatise of Legal Philosophy and General Jurisprudence*: *Volume 4 Scienta Iuris, Legal Doctrine as Knowledge of Law and as a Source of Law*, (Springer Science and Bussines Media, 2007)

Articles

Abbott, Frederick M. and Reichman, Jerome H., "The Doha Rounds Public Health Legacy: Strategies for the Production and Diffusion of Patented

Medicines under the Amended TRIPS Provisions", 10(4) *Journal of International Economic Law* 921

Anderson, Robert D. and Wager, Hannu, "Human Rights, Development, and the WTO: The Cases of Intellectual Property and Competition Policy", 9(3) *Journal of International Economic Law* 707 (2006)

Attaran, Amir and Gillespie-White, Lee, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?", 286 *Journal of American Medical Association* 15, (2001)

Attaran Amir, "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?", 23 *Health Affairs* 155 (2004)

Geiger, Christophe, "Implementing Intellectual Property Provisions in Human Rights Instruments: Towards a New Social Contract for the Protection of Intangibles", in C. Geiger (ed.), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar, Cheltenham/Northampton, 2015)

Correa, Carlos, "The Use of Compulsory Licences in Latin America", in R. Hilty and Liu, K-C (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward*, (Springer-Verlag, 2015)

Chatterjee, Patralekha, "India's First Compulsory License Upheld, But Legal Fights Likely to Continue", *Intellectual Property Watch* (blog post), 4 March 2013

Chien, Colleen, "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?", 18 *Berkeley Technology Law Journal* 853 (2003)

Dhar, Biswajit and Gopakumar, K.M., "The Case of the Generic Industry in India", in R. Meléndez-Ortiz and P. Roffe (eds.), *Intellectual Property and Sustainable Development: Development Agendas in a Changing World* (Edward Elgar, Cheltenham/Northampton, 2009)

Dreyfuss, Rochelle Cooper, "Patents and Human Rights: Where Is the Paradox?", in W. Grosheide (ed.), *Intellectual Property and Human Rights: A Paradox*, (Edward Elgar, Cheltenham/Northampton 2010)

Gervais, Daniel J., "State of the Art: The Changing Landscape of International Intellectual Property", 1(4) *Journal of Intellectual Property Law and Practice* 249

Frankel, Susy and Lai, Jessica C., ""Recognised and Appropriate Grounds for Compulsory Licences: Reclaiming Patent Law's Social Contract", in R. Hilty and Liu, K-C. (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward*, (Springer-Verlag Berlin Heidelberg, 2015)

Ho, Cynthia M., *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, (Oxford University Press, 2011)

Houston, Adam, "A Scientific Approach to Intellectual Property and Health: Innovation, Access, and a Forgotten Corner of the Universal Declaration of Human Rights", 13 *John Marshall Review of Intellectual Property Law* 794 (2014)

Kampf, Roger and Wager, Hannu, "The Role of the TRIPS Agreement in the Global Health Policy", *Stanford Journal of Law, Science and Policy* 17 (published online September 2011)

Kulkarni, Kaustubh and Foy, Henri, "Analysis: India cancer ruling opens door for cheaper drugs", *Thompson Reuters*, 13 March 2012

Lin, Michael, "Licensing and Working of Patents in India: An Update", 29 July 2013, *IPKat*

Lin, Xiuqin, "Prior Negotiation and Remuneration for Patent Compulsory Licensing: Practice, Problem and Proposal", in R. Hilty, M. R. and K-C. Liu (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer-Verlag, 2015)

McManis, Charles R., "Human rights as a constraint on intellectual property rights: the case of patent and plant variety protection rights, genetic resources and traditional knowledge", in Intellectual Property and Human Rights, A Paradox, Edward Elgar Publisher Ltd. (2010)

Matthews, Duncan, "Right to Health and Patents", in C. Geiger (ed.), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar, Cheltenham/Northampton, 2015)

Outterson, Kevin, "Patent Buy-Outs for Global Disease Innovations for Low- and Middle Income Countries", 32 *American Journal of Law & Medicine* 159 (2006)

Pogge, Thomas, "The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices", in T. Pogge, M. Rimmer and K. Rubenstein (eds.), *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press, 2010)

Reichman, Jerome H., "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options", 37(2) *Journal of Lam, Medicine & Ethics* 247 (2009)

Shiffrin, Seana Valentine, "Intellectual Property", in Goodin R.E, Pettit, P. and Poge, T. (eds.) *A Companion to Contemporary Political Philosophy* (Blackwell Publishing 2007)

Sood, Mansi, "Natco Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India", 6 *NUJS Law Review* 99 (2013)

Sterckx, Sigrid, “Patents and Access to Drugs in Developing Countries: An Ethical Analysis”, 4 *Developing World Bioethics* 1, (Blackwell Publishing Ltd., 2004)

Unni, V.K., “Compulsory Licensing of Pharmaceutical Patents in India: Whether Natco Decision Will Meet the Global Benchmarks?”, 37(5) *European Intellectual Property Review* (2015)

Van Owervale, Geertrui, ”Human Rights’ Limitations in Patent law”, in W. Grosheide (ed.), *Intellectual Property and Human Rights: A Paradox*, (Edward Elgar, Cheltenham/Northamton, 2010)

Yu, Peter K., “The Anatomy of the Human Rights Framework for Intellectual Property”, forthcoming in 69 *Southern Methodist University Law Review* (2016)

Yu, Peter K., “Ten Common Questions About Intellectual Property and Human Rights”, 23 Georgia State University Law Review 709 (2007)

Yugank, Goyal, ”Economic and Procedural Constraints of Compulsory Licenses for Medicines”, in *Compulsory Licensing: Practical Experiences and Ways Forward* edited by Hilty, M. R. and Liu, Kung-Chung (Springer-Verlag 2015)

Wager, Hannu and Watal, Jayashree, “Human Rights and International Intellectual Property Law”, in C. Geiger (ed.), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar, Cheltenham/Northampton, 2015)

Legal and semi-legal instruments

Agreement on Trade-Related Aspect of Intellectual Property Rights

Berne Convention for the Protection of Literary and Artistic Works

Brazilian Industrial Property Code of 1996

Charter of Fundamental Rights of the European Union

Declaration on TRIPS Agreement and Public Health (Doha Declaration)

European Convention on Human Rights and Fundamental Freedoms

International Covenant on Economic, Social and Cultural Rights

The Patents Act 1970 (India)

The Constitution of the United States of America

The United Nations Millennium Declaration, Millennium Development Goals

Paris Convention for the Protection of Industrial Property

Report of the Joint United Nations Programme on HIV/AIDS of 2008

Report of the Special Rapporteur in the Filed of Cultural Rights, *Cultural Rights*, United Nations General Assembly, U.N. Doc. A/70/279, 4 August 2015, (by Farida Shaheed)

UNAIDS, WHO and UNDP Policy Brief, "Using TRIPS Flexibilities to Improve Access to HIV Treatment"

Universal Declaration on Human Rights

UN Committee on Economic, Social and Cultural Rights, CESCR General Comment No. 14 on 'The Right to the highest attainable standard of health' (Article 12 of the Covenant), adopted on 11 August 2000. UN document E/C.12/2000/4.

UN CESCR General Comment No.17 on 'The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author' (Article 15, paragraph 1 (c) of the Covenant), adopted on 21 November 2005. UN document E/C.12/GC/17

WTO Model List of Essential Medicines

WHO, WTO and WIPO, *Technical Symposium on Access to Medicines: Pricing and Procurement Policies* (July 2010)

WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade* (2013)

Online resources

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2653148

http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html

www.pharmafile.com/news/186407/novartis-agrees-gleevec-patent-deal

http://www.reuters.com/article/us-india-drugs-idUSBRE82C0IN20120313

http://www.who.int/mediacentre/factsheets/fs355/en

http://www.un.org/millenniumgoals/

https://www.wto.org/english/tratop_e/trips_e/techsymp_july10_e/trip_16july10_summary_e.pdf

http://www.wipo.int/meetings/en/2011/who_wipo_wto_ip_med_ge_11/program.html

https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf

Table of Cases

High Court of Judicature at Madras, *Novartis AG and another v. Union of India and others*, Nos. 24759 and 24760 of 2006, 6 August 2007

Federal Circuit, *Roche Products v. Bolar Pharmaceutical*, 733 F2d 858, 1984

Intellectual Property Appellate Board, Chennai, *Bayer Corporation v. Union of India and others*, Order No. 223 of 2012, 14 September 2012

The Controller of Patets Mumbai, *Natco Pharma Ltd. v. Bayer Corporation*, Compulsory License Application No. 1 of 2011, 9 March 2012

Intellectual Property Appellate Board, Chennai, *Bayer Corporation v. Union of India and others*, Order No. 45 of 2013, 4 March 2013

ECtHR, *Anheuser-Busch Inc. v. Portugal*, no. 73049/01, 11 January 2007

ECtHR, *Ashby Donalds and Others v. France*, no. 36769/08, 10 January 2013

ECtHR, *Neij and Sunde Kolmisoppi v. Sweden*, no. 40397/12, 19 February 2013