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RIGHTS TO LIFE AND HEALTH

VS.

PATENTS ON MEDICINES

*NOT JUST A CONFLICT – ACCESS TO AFFORDABLE
MEDICINES AS A POSSIBLE CHOICE*

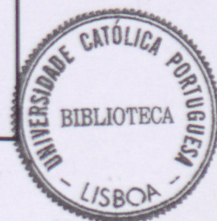
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LIST OF ABBREVIATIONS

Amer J Comp L	American Journal of Comparative Law
BRIC	Brazil, Russia, India and China
Bul WHO	Bulletin of the World Health Organization
CESCR	Committee on Economic, Social and Cultural Rights
Charter	Charter of Fundamental Rights of the European Union
Dav L Rev	U.C. Davis Law Review
Doha Declaration	Declaration on the TRIPS Agreement and Public Health
ECHR	European Convention of Human Rights
ECJ	European Court of Justice
ECom	European Commission
Econ Pol W	Economic and Political Weekly
ECtHR	European Court of Human Right
Em Int L Rev	Emory International Law Review
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
Eu IP Rev	European Law Review
Eu L J	European Law Journal
Fem Econ	Feminist Economics (Journal)
Geor J Inter L	Georgetown Journal of International Law
Harv L Rev	Harvard Law Review
Hast Int & Comp L Rev	Hastings International and Comparative Law Review

ICESCR	International Covenant on Economic, Social and Cultural Rights
Ind J Glob Leg Stud	Indian Journal of Global Legal Studies
Inter Aff	International Affairs (Journal)
Int J Const L	International Journal of Constitutional Law
J Health Econ	Journal of Health Economics
J Ind L Inst	Journal of Indian Law Institute
J IPR	Journal of Intellectual Property Rights
J L & Tec	Journal of Law & Technology
L Dev Rev	The Law and Development Review
Max Planck UNYB	<i>Max Planck Institute for Comparative Public Law and International Law</i>
MNCs	Multinational corporations
NGO	Non-governmental organization
R&D	Research and development
TFEU	Treaty on the Functioning of the European Union
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
Van J Trans L	Vanderbilt Journal of Transnational Law
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

*Healing is a matter of time,
but it is sometimes also a matter of opportunity.*

Hippocrates, Precepts, Chapter 1

I. INTRODUCTION

Pharmaceuticals have become an essential tool for the promotion of global health. The discovery of Aspirin at the end of the 19th century, of penicillin in the middle of the 20th and of drugs that reduce the negative effects of HIV/AIDS and cancer in the 21st century illustrates how medicines are a milestone in the improvement of human health.

Despite the many pharmaceutical advances brought on by globalization, one third of the world's population still has no access to essential drugs.¹ However, the fact that many diseases are preventable or treatable nowadays, but that many people cannot afford the high prices charged by the pharmaceutical multinational corporations (MNCs) under the patents quasi-monopoly rights, is rather worrying.

Patents are effective tools in the promotion of innovation in the pharmaceutical sector, since they enable originator companies to recoup their research and development (R&D) investments and only allow for generic competition after their expiry term. Nevertheless, many MNCs artificially extend the period of patent exclusivity by patenting trivial secondary elements of their drug products when the underlying patent is nearing expiry – a phenomenon usually referred to as 'ever-greening'. The follow-on patents lengthen the exclusive rights over medicines and keep generic competitors off the market. In addition, the majority of the world's poor population cannot afford brand-named patented drugs that do not have a generic alternative.

Historically, each nation decided how to tackle this type of issues and many countries did not usually grant patents on medicines. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) changed this situation by imposing a twenty years patent protection on all World Trade Organization (WTO) Members, including those in the pharmaceutical field. As patent protection is no longer optional, the key question is to what degree nations can use their discretion to promote maximum access to drugs.

This paper concerns the conflict between the obligations under patent laws and the access to medicines, a conflict that, at its core, counterbalances intellectual property rights and human rights. Generally, this conflict sounds exceedingly dry: patents are commonly deemed to be a

¹ Sigrid Sterckx (2009), 'Lack of access to essential drugs: A story of continuing global failure, with particular attention to the role of patents', in Christian Lenk et al. (eds.), *Ethics and Law of Intellectual Property – Current Problems in Politics, Science and Technology*, Ashgate Publishing Limited (hereinafter *Ethics and Law*), p.175

topic accessible only to those with skills in sciences, and human rights are many times seen as lacking practical relevance. In trying to deconstruct such assumptions, our goal is to comprehend patents and enhance the importance of human rights through the analysis of a case study.

The dissertation starts with a presentation in Chapter II of the main characteristics of the rights to health and life and intellectual property rights, explaining the need to adopt a human rights approach when analyzing patents on medicines, and lastly, describing the drawbacks of ever-greening patents. Chapter III provides a study of the *Novartis v. India*² case as an expression of the conflict between the referred rights. Chapter IV elects the proportionality principle as an appropriate means to solve the conflict of rights and applies the three-prong test to the case study. Chapter V shifts the focus to the European legal framework and, based on the climate of change regarding EU unitary patent, proposes an innovative legal solution to face ever-greening. Finally, Chapter VI closes the paper by drawing the conclusions of the study.

² *Novartis AG and another v. Union of India and others*, Madras High Court [2007]

II. LINKING INTELLECTUAL PROPERTY RIGHTS AND HUMAN RIGHTS

Intellectual property rights and human rights have largely evolved independently, even though the connection between them has always lingered discreetly in the background. The broadening scope of patents in areas related to basic needs, such as health, highlighted the obvious link between these two fields.³

In the last decade the debate about the relationship between intellectual property rights and human rights has been at the center stage of the agenda of various international forums such as the WTO, the World Health Organization (WHO) and the United Nation Human Rights Council. In fact, the adoption of the TRIPS Agreement has made clear how intellectual property may impose serious constraints to the observance of numerous human rights.

In the pharmaceutical field, too much protection of patent rights has a direct impact on the effective defense of the rights to health and life. As Cullet pointed out, there is ‘a direct link between patentability of drugs on one hand and, on the other, the availability of medicines, the realization of the right to health and ultimately of the right to life’.⁴ This idea is reinforced by Smith when presenting drugs as ‘both commodities that are the product of an IP-centric market system, and ‘essential’ goods that can contribute significantly to quality of life and even to basic human survival’.⁵

Thus, the need for a coherent articulation of the States’ international obligations in both the intellectual property and the human rights areas becomes clear.

II.1. RIGHTS TO LIFE AND HEALTH

Human rights are considered to be universal, vested in each person by virtue of their common humanity. Building upon the idea of human dignity, which requires that every person be

³ Philippe Cullet (2003), ‘Patents and medicines: the relationship between TRIPS and the human right to health’, 79(1) *Inter Aff*, p.139

⁴ Cullet (2003), p.151

⁵ Alyna C. Smith (2009), ‘Intellectual Property Rights and the Right to Health: Considering the Case of Access to Medicines’, in *Ethics and Law*, p.70

treated as an end and not as a means, international human rights provide rules synthesizing the value judgments sometimes lacking in the international intellectual property regime.⁶

Medicines are increasingly considered vital not only to improve the most basic aspects of human quality of life, but also to ensure human survival. Therefore, when one talks about pharmaceutical patents one must inevitably think about the need to protect the rights to health and life.

According to a *naturalistic* perspective, the two foremost capabilities as human fundamental rights are ‘life’ and ‘basic health’, thus justice requires that everyone should effectively enjoy these rights.⁷ In fact, ‘[f]or people suffering from debilitating illness, drugs are akin to basic necessities, like food and water that can preserve, improve and prolong life’.⁸

From a *positivistic* viewpoint, these two rights must be protected since they are enshrined in numerous international agreements. The right to health first emerged as a social right in the WHO Constitution, albeit only in its preamble which determined that ‘[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being’.

Meanwhile, the Universal Declaration of Human Rights (UDHR) established in Article 3 that ‘[e]veryone has the right to life’ and in Article 25(1) that ‘[e]veryone has the right to a standard of living adequate for the health and well-being of himself and his family, including (...) medical care’.

The right to life is also established within Article 6 of the International Covenant on Civil and Political Rights. At the same time, the binding International Covenant on Economic, Social and Cultural Rights (ICESCR) appears as the foundational treaty agreement detailing the progressive realization of the right to health. Thus, Article 12(1) obligates States Parties to ‘take steps’ towards the fulfillment of the universal ‘right of everyone to the enjoyment of the highest attainable standard of physical and mental health’. Then, Article 12(2) lays out in a more concrete fashion a non-exclusive list of the specific steps that should be taken by States

⁶ Xavier Seuba (2008), ‘Human Rights and Intellectual Property Rights’, in Carlos M. Correia and Abdulqawi A. Yusuf (eds.), *Intellectual Property and International Trade – The TRIPS Agreement*, Klumer Law International, p.392

⁷ Martha Nussbaum (2003), ‘Capabilities as Fundamental Entitlements: Sen and Social Justice’, 9 *Fem Econ*, p.41

⁸ Smith (2009), p.62

to achieve the fulfillment of this right. Under this Covenant, States are to ensure that other international agreements that they subscribe do not adversely impact the right to health.⁹

Whether adopting a *naturalistic* perspective – certain norms are basic, simply because they are given by the commands of reason (or nature, or God), so they cannot be violated – or a *positivistic* viewpoint – once a right has been recognized in international law it assumes the role of a preeminence, so it must be enforced –, there is consensus regarding the existence of a universal right to health, a direct derivative from the right to life.¹⁰

The right to health is an inclusive right which can be broken down into more specific entitlements, including for instance the right to the prevention, treatment and control of diseases, as well as the right of access to essential medicines. Access to medication is an economic and social right which demands action and positive measures from the States.

The ‘General Comment 14’¹¹ of the Committee on Economic, Social and Cultural Rights (CESCR) elaborates on the obligations of States to ensure the right to health, which must contain four ‘essential elements’: (a) *availability* of public health, (b) *accessibility* to everyone, (c) *acceptability* of the culture and ethics of the individuals and (d) an adequate *quality*.¹² The ‘accessibility’ prong has multiple dimensions, namely the economic accessibility requiring medication to be affordable for all, including socially disadvantaged groups.

Conceiving access to medication as an integral part of the human right to health entails moral and legal imperatives for States to ensure its effectiveness.¹³ This consideration seems to be assimilated in the TRIPS Agreement which, although providing for a relatively high standard of intellectual property protection, admits some exceptions based on human rights defense. In this sense, Article 27(2) provides for the exclusion from patentability of those inventions which commercial exploitation shall be prevented in order to protect human life and health.

⁹ CESCR, *IP Statement*, para. 12: ‘any intellectual property regime that makes it more difficult for a State party to comply especially with core obligations in relation to health (...) is inconsistent with the legally binding obligations of the State party’.

¹⁰ Fisher (2006), p.641

¹¹ CESCR, *General Comment No. 14, The right to the highest attainable standard of health*, August 11, 2000, E/C.12/2000/4

¹² *Ibid.*, para.12

¹³ Holger Hestermeyer (2004), ‘Access to medicines as a Human Right’, *Max Planck UNYB*, p.113

Similarly to other economic and social rights, the right to health is evidently subject to criticism for being vague in content and intersecting with too many other rights.¹⁴ Nevertheless, its protection is binding to all ICESCR Member States and, therefore, national and international intellectual property regimes protecting patents on medication must be consistent with Member States' obligations to ensure the progressive realization of full enjoyment of the right to health.¹⁵ There are minimum entitlements in the absence of which States are in violation of their core obligations under public health policies.¹⁶

II.2. PHARMACEUTICAL PATENT RIGHTS

The term intellectual property refers broadly to the creations of the human mind. Intellectual property protects the interests of creators by providing them with property rights over their creations.¹⁷ Within this wide body of law, industrial property is the field which regulates patents.

A patent may be defined as the granting of a right by the State to the inventor to exclude others, for a limited period of time, from making, using or selling a new and useful invention without the inventor's permission, at the risk of sanction from the State.¹⁸

By offering the inventor exclusive rights to exploit the invention and simultaneously stop others from using it without consent, patents represent derogation from the principle of free trade. The constraints of such derogation are balanced with the limitation on time of the protection, defining patents as 'time-bound monopolies rights'.¹⁹ Once this term has expired, the general public is free to use the invention. Competition starts when the patent ends, and generic forms of the products previously protected become commercialized at much lower prices. This characteristic defines patent rights as restricted and not absolute rights.

The literature on intellectual property argues two main reasons to defend the grant of patents, the first concerning the necessary incentives for the inventor and the second regarding general

¹⁴ David Fidler (1999), *International Law and infectious diseases*, Oxford University Press, cited in Cullet (2003), p.148

¹⁵ CESCR, *Follow-up to the day of the general discussion on article 15.1.c*, December 14, 2001, E/C.12/2001/15, para. 11

¹⁶ *Ibid.*, para. 12

¹⁷ WIPO, *Understanding Industrial Property*, Publication No. 895(E), p.3

¹⁸ Philip W. Grubb & Peter R. Thomsen (2010), *Patents for Chemicals, Pharmaceuticals, and Biotechnology*, Oxford University Press, p.3

¹⁹ Cullet (2003), p.140

public benefits. These reasons are provided by the utilitarian theory,²⁰ which strike to balance between the individual exclusive rights to compensate inventions and the general rights for a widespread public enjoyment of such inventions.

Indeed, patents are able to secure the intellectual and economic investments in the creation of new inventions. By making the future more predictable for inventors, patents encourage the development of new products and procedures. In Lenk's words, 'if the invention of new products and procedures is not rewarded adequately, it is far less attractive to engage in such activity'.²¹ Grubb adds that in the absence of such incentive, the technological development would be much slower and more difficult.²²

In addition, patents not only benefit inventors in particular but also the public at large, since they enable everyone to participate in the knowledge acquired. Actually, the exclusive rights given to the patent's holder are counterbalanced by the disclosure of the invention so that everyone benefits from scientific advancement. Grubb notes that '[w]ithout patents, it may be rational for the owner of intellectual property to keep such information secret'.²³

The specific category of patents on medicines, which refers to extremely valuable social products, contains particular motivations for protection that add to those already mentioned. The private sector, albeit critical contributions from public or publicly funded research institutions, assumes the main role in the pharmaceutical industry. MNCs have developed a high degree of specialization in the often complex, long and expensive work of conducting R&D to generate therapeutic products. Accordingly, some authors claim that the pharmaceutical industry, more than any other industry in the fields of chemistry, is interested in using patents for their classical purpose of excluding the competition for a limited time.²⁴

First of all, the protection of drug patents is essential to incite innovation in a vital area of society such as health. Innovation in medicines has enabled patients to benefit from treatments that were unimaginable a few decades ago. Drug patents are justified on the reasoning that the increase they provide in social welfare, by encouraging the creation of new

²⁰ William Fisher (2001), 'Theories of Intellectual Property', in Stephen R. Munzer (ed.) *New Essays in the Legal and Political Theory of Property*, Cambridge University Press, p.169

²¹ Christian Lenk (2009), 'Exclusive Property Rights in Biosciences: An Ethical Discussion' (2009) in *Ethics and Law*, p.127

²² Grubb (2010), p.6

²³ Lenk (2009), p.123

²⁴ Grubb (2010), p.424

medicines, outweighs the social welfare costs of protecting patentees' prices from competition.²⁵

Gerald Mossinghoff, former president of Pharmaceutical Research and Manufacturers of America, underlined that '[f]or the private sector pharmaceutical industry, which has been the primary source of new therapies for the past four decades, *there is little incentive to provide an ever-increasing commitment to research unless there are reasonable expectations of financial return*'.²⁶

Secondly, the production of drugs requires pharmaceutical firms to invest a lot of effort and money during a long period of time in which they run some risks. Therefore, MNCs are said to deserve the financial returns from strong patent protection which allow them to compensate the R&D costs, the time spent and the uncertainty characterizing the industry.²⁷

In fact, to bring a new drug into the market requires a huge monetary investment on safety and efficacy testing. Moreover, this approval process before marketing is long, since the path covered by a drug from the laboratory to the moment it is available to the public is extensive. In an attempt to estimate the duration of such a process, Grubb concludes that 'the period from the first patent filing to the marketing of the new drug is therefore typically anywhere from seven to fourteen years'.²⁸ Additionally, many of the pharmaceutical researches are based on uncertainty, which means that midway through the investigation they may be considered unfeasible. As a result, drug prices should recover not only the money spent on testing the drug that is finally marketed but also the investment on other compounds that did not reach this final stage.

Thirdly, patents on medicines are justified on the grounds that it is relatively easy and cheap to copy an existing drug. If pharmaceutical manufacturing capabilities could imitate valuable drugs they would sell them at prices far below those charged by the original innovators, because they would have no R&D costs. In the absence of patent protection, an imitator who

²⁵ William W. Fisher and Talha Syed (2006), 'Global Justice in Healthcare: Developing Drugs for the Developing World', 40 *Dav L Rev* (2006), p.667

²⁶ Gerald J. Mossinghoff (1987), 'Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide', 2 *J L & Tec*, p. 307 (emphasis added)

²⁷ Timothy Bazzle (2011), 'Pharmacy of the developing world: reconciling intellectual property rights in India with the right to health: TRIPS, India's Patent system and essential medicines', 42(3) *Geor J Inter L* (2011), p.798

²⁸ Grubb (2010), p.424

carries none of those costs can produce the compound in his backyard laboratory, offer it at a much lower price and still make a profit.

After all, who would be willing to invest large amounts of money in a new product knowing that an imitator could copy it as soon as it was marketed? If everyone could make a profit immediately after the disclosure of new knowledge there would be no interest in dedicating resources to the task of creating it. Support of free-riding by generic imitators would slacken technological innovation.

From an economic perspective, the patent system allows companies to charge higher prices than the marginal price of production and distribute them to the first generation of patients, who are expected to absorb the cost of producing a drug. Only after the patent expires can the competition in the generic version bring the price closer to the marginal cost.²⁹

In the absence of patent protection for drugs, sales by imitators with no research overheads would destroy any possibility of the inventor recovering his investment and consequently the investment would simply not be made. One might say that unless pharmaceutical firms continue earning reasonable profits, they will simply stop innovating altogether and everyone will be worse off.³⁰

The recognition of the importance of patents regulation led to the implementation of the TRIPS Agreement, a founding component of the WTO. This agreement marks the first time in international law that States agreed to provide minimum standards of binding and enforceable intellectual property rights protection, opening a new era in the history of intellectual property. The TRIPS establishes the minimum common international denominator of intellectual property rights, requiring its Members to extend twenty-year life spans for patents, to recognize both process and product patents, and to establish protectable subject-matter.

The scope of patentability is laid down in Article 27(1) of the TRIPS which determines ‘novelty’, ‘inventive step’, and ‘industrial application’ as the three requirements for a patent to be granted. *Novelty* usually means that the product must have some new characteristic which is not yet known in the body of existing knowledge – referred to as ‘prior art’ – within its technical field. *Inventive step* is used as a synonym of non-obviousness, meaning that the

²⁹ Cullet (2003), p.141

³⁰ Fisher (2006), p.669

product should not be deduced by a person with average knowledge of the technical field. *Industrial applicability* refers to the utility of the invention in terms of practical use or of some kind of industrial applicability.³¹ Notwithstanding these generally perceived concept definitions, Article 27(1) does not set any guidelines to define those requirements, leaving countries a certain discretionary margin to determine their own standards of patentability.

Additionally, the invention must be a patentable subject matter, which means that it cannot fall within any of the exceptions contained in Article 27(2) and (3) of the TRIPS. Article 27(2) specifically allows States to restrict the patentability of inventions if they pose a threat to human life and health. These exceptions are not exhaustive; therefore Members may add supplementary exceptions, provided that patents are ‘available and patent rights enjoyable without discriminations as to the place of invention, field of technology and whether products are imported or locally produced’.³² Thus, exceptions to patentability under the TRIPS Agreement are ‘open-ended’.³³

Although some flexibility for national governments is given, concerns have arisen regarding the TRIPS compatibility with the full enjoyment of human rights. In this context, the Declaration on the TRIPS Agreement and Public Health (Doha Declaration) was signed and the WTO Members put forward their belief that the TRIPS be considered as supportive of public health. The declaration affirms that Member States must interpret the TRIPS obligations in such a way as to allow them to foster, and not work against, their public health goals.³⁴

It seems clear that economic incentives for R&D are essential to promote the discovery of new medical solutions. Even if there are plausible reasons for the existence of patent rights, one cannot forget that access to medicines at affordable prices, as a means to guarantee rights to health and life, is a concern which must be at the center of patent regime discussions.

³¹ WIPO, *Understanding Industrial Property*, p.6

³² Second part of Article 27(1) of the TRIPS. The principle of non-discrimination is enshrined in Articles 3 and 4 of the TRIPS.

³³ Feroz Ali Khader (2008), ‘Transcending Differences: The Challenge for Pharmaceuticals in the Post-TRIPS Indian Patent Regime’, 13 *J IPR*, p.425

³⁴ Doha Declaration, para. 4

II.3. HUMAN RIGHTS APPROACH TO INTELLECTUAL PROPERTY

Intellectual property rights do not have a straightforward qualification as human rights or economic rights. Even though human rights and intellectual property are now becoming increasingly ‘intimate bedfellows’,³⁵ it is not quite clear whether this proximity extends the status of a human right to intellectual property or if it remains part of the ordinary legislation.

References to intellectual property on human rights instruments, such as in Article 27(2) of the UDHR and Article 15(1) of the ICESCR, may lead to the conceptualization of intellectual property as such, as a human right. According to this view, the centrality of protecting intellectual property rights is nurturing both creativity as an intrinsic expression of human dignity, and the common good.³⁶

However, the idea that inventors have a natural right to their creations falls to the ground when one thinks about patents on drugs. Even if pharmaceutical inventions involve human efforts, it might be far-fetched to say that their goal is to protect pharmaceutical inventors’ human dignity.³⁷ Therefore, the right to be granted a patent is usually basically seen in an economic perspective as an ordinary right, without the strengthened force of human rights.

Critics to a merely economic perspective of patent rights have been presented by authors³⁸ who believe that intellectual property cannot be an end unto itself, that is to say, a mere institution for the protection of private interests through the acquisition of economic benefits. Instead, it should be a mechanism destined to achieve human rights values.

The purpose of this paper is not to permanently solve such dichotomy but to call on the need of adopting a human rights perspective when thinking about patent rights. According to Chapman ‘[i]ntellectual property regimes seek to balance the moral and economic rights of creators and inventors with the wider interests and needs of the society’.³⁹ This definition combines not only an economic perspective, but also a human rights view of intellectual

³⁵ Peter K. Yu (2006), ‘Reconceptualizing Intellectual Property Interests in a Human Rights Framework’, 40 *Dav L Rev*, p.1041

³⁶ Audrey R. Chapman (1998), ‘A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science’, in WIPO, *Intellectual Property and Human Rights, Introduction*

³⁷ Holger P. Hestermeyer (2007), *Human rights and the WTO: The case of patents and access to medicine*, Oxford University Press, pp.154-157

³⁸ Seuba (2008), p.418

³⁹ Chapman (1998), *Introduction*

property, where human rights appear as a guideline to the formulation of the intellectual property regime.

The *human rights approach to intellectual property* aspires to give States the consciousness for the need to respect human rights while implementing patents' legislations. The CESCR Members have international obligations to ensure that the intellectual property rights recognized in their jurisdictions are established, granted, exercised, enforced, licensed, and otherwise used in a fashion that does not infringe upon human rights.⁴⁰ This approach entails the right of protection against possible harmful effects of scientific and technological development at the individual and collective levels.

The problem is that patent rights are rarely approached in a fashion congruent with human rights, be it by governments or by right holders.⁴¹ Quite the reverse, patents are mostly seen through the commercialization and privatization eye which places greatest emphasis on the profitability of science and its contributions to economic competitiveness. Market considerations only frame intellectual property as a way of encouraging investment and protecting the resources of the investor. It is therefore necessary to enhance human rights concerns within the intellectual property practices.

Recognizing the need to reconcile both perspectives, the TRIPS determines in its Article 7 that the intellectual property regime must engage in the 'promotion of technological innovation' and the 'transfer and dissemination of technology' so as to lead to 'social and economic welfare'. Moreover, Article 8 of the TRIPS declares that Members may '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', so long as these measures are 'consistent' with the TRIPS provisions.

Nonetheless, as Seuba points out, 'recognizing the links between the standards in the TRIPS Agreement and the promotion and protection of human rights is not the same as saying that the TRIPS Agreement takes a human rights approach to intellectual property protection'.⁴² In fact, the overall thrust of the TRIPS is the promotion of innovation through the provision of

⁴⁰ Rosemary J. Coombe (1998), 'Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by Recognition of Indigenous Knowledge and the Conservation of Biodiversity', 6 *Ind J Glob Leg Stud*, p.70

⁴¹ *Ibid.*, p.59

⁴² Seuba (2008), p.404

commercial incentives, the references to human rights only ruled as exceptions rather than guideline principles.

The adoption of a strict economic perspective in the context of pharmaceutical patents poses huge constraints on human rights to life and health. Underlying the importance of public health, the Doha Declaration reinforces the importance of Articles 7 and 8 of the TRIPS in as much as they provide Member States with a clear legal basis for the adoption of exceptions to patentability in order to protect human rights. Also noting that there are conflicts between the implementation of the TRIPS and human rights, under Resolutions 2000/7⁴³ and 2001/21⁴⁴ the UN Sub-Commission on Human Rights urged the WTO to take fully into account the States binding obligations under international human rights instruments.

As it becomes clear from the above, a human rights approach to intellectual property is essential when defining the legal contours of pharmaceutical patents which although with the goal of creating economic incentives for investment on R&D, must not drastically affect the affordability of medication. Hence, a concrete analysis of patent issues call for a human rights approach, namely regarding excessive prorogations of patent holders' rights.

II.4. EXPANDING PATENT RIGHTS HARMS HUMAN RIGHTS?

Although private and public sources coexist in pharmaceutical R&D, the truth is that in the last years the largest part of the total investment in pharmaceutical R&D has come from the private industry.⁴⁵ Unlike the public sector which must have a human rights approach to intellectual property, the industry's research agenda is mainly dominated by profit-marketing objectives. Therefore, MNCs rely heavily on the acquisition and enforcement of patents as a way of recouping their R&D investments.

As mentioned above, the protection of intellectual property rights is essential for ensuring the rights to health and life, since without incentives for innovation new drugs would not be developed, and consequently those rights would be at risk. Both the private inventors and society as a whole will profit from a patented invention, since the former can recoup the costs

⁴³ Sub-Commission on Human Rights, E/CN.4/Sub.2/RES/2000/7, para. 8

⁴⁴ Sub-Commission on Human Rights, E/CN.4/Sub.2/RES/2001/21, *Preamble*

⁴⁵ Carlos Correia (2004), 'Ownership of knowledge – the role of patents in pharmaceutical R&D', 82(10) *Bul WHO*, p.784

of R&D and the latter acquires knowledge about a new invention and is able to use it without extra investments once the patent expires.

The problem is that many MNCs, focused on preserving economic benefits, try to prorogate patents after the date of expiry and maintain exclusive rights by introducing merely incremental developments on drugs. The question then arises: should a patent be maintained longer than the twenty years limit determined by Article 33 of the TRIPS on the basis of minimal changes to the product?

An innovator company might not only obtain a patent on the active ingredient involved in the new drug, but also benefit from secondary patents relating to the same active ingredient. These follow-on patents might refer to new formulations and compositions, such as new dosage forms or channels of administration, or to chemical derivatives of existing active ingredients, such as new salts, esters, and so forth.⁴⁶ Since we are talking about additions or alterations to a known product, the concern arises when secondary patents do not protect truly inventions.

As Correia states, ‘[t]hough theoretically conceived to reward invention marked by considerable originality, the patent system is plagued with grants covering incremental, minor – in some cases trivial – developments’.⁴⁷ Incremental innovations are often introduced to extend the commercial benefits resulting from existing patents, particularly when original patents are near expiration and new patents can be used to prolong revenues obtained from market exclusivity.

Through creative layering, many MNCs exploit both lax patentability standards and errors in the patent examination process. They adopt different strategies to use patents offensively as a way of hindering and blocking potential generic competitors. One of those strategies is the so-called ‘life cycled management’⁴⁸ patent which covers salt or crystal forms, galenic formulations, uses and other subsidiary aspects, also referred to pejoratively as ‘ever-greening’.

⁴⁶ Chaudhuri (2009), p.283

⁴⁷ Correia (2004), p.785

⁴⁸ Grubb (2010), p.427

Ever-greening occurs when a manufacturer maintains exclusive rights over a product by obtaining additional years of patent protection on multiple attributes to a single product. In other words, if a patent is granted to a pharmaceutical product which only presents frivolous or marginal changes, such patent will be ever-greening since it increases the number of monopoly drugs, protects the sale of branded drugs and delays the entry of generics into the market.⁴⁹

Strategic secondary patents are usually unjustified in terms of the technical enhancement effectively obtained. Instead, the prorogation of patent grants is only used to restrain competition, detracting from the public domain knowledge that could be used by generic companies to sell drugs at much lower prices. Even supporters of strong patent systems such as Grubb, who sees no problem in granting secondary patents to genuine inventions, criticizes ever-greening by saying that ‘when companies, for example, attempt to stop generic sales of a drug by means of later patents on its metabolites, this is something that cannot be justified on any reasonable interpretations of patent law and only brings the industry into disrepute’.⁵⁰

In all fairness, such practice contradicts the objectives of intellectual property regime, as it endangers the general public’s right to enjoy the benefits resulting from scientific and technical creativity and, thus, the right of access to affordable medication. For that reason, a strict patentability criterion denying patent protection to known substances is crucial to ensure early entry of generic medicines in the market.⁵¹

Abuses of pharmaceutical patents lead to the malfunction of the system, affecting people’s rights to life and health. According to Article 8(2) of the TRIPS, WTO Members may adopt appropriate measures to prevent misuses of patents by holders. In a context of strong production of generics, India appears as a reference on the promotion of access to affordable medication. Making use of the referred TRIPS open clause, the Indian legislator enacted a pioneer norm which deals directly with the problem of ever-greening.

⁴⁹ K. M. Gopakumar & Tahir Amin (2005), ‘Patent (Amendment) Bill 2005: A Critique’, 40(15) *Econ Pol W*, p.1503

⁵⁰ Grubb (2010), p.428

⁵¹ K.M. Gopakumar (2010), ‘Product, Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime’, 3(2) *L Dev Rev*, p.332

III. CASE-STUDY: ILLUSTRATING THE CONFLICT

The patent system of India is a clear cut example of the conflict between human rights to life and health and intellectual property. The flourishing generic industry of India and the enhancement of access to affordable drugs clash with the strict intellectual property standards of protection imposed by international directives. In this context, *Novartis v. India* appears as a breakthrough case not yet definitively decided, that shows the problem of ever-greening and the need to balance the conflicting rights.

III.1. THE DOMESTIC LEGAL FRAMEWORK OF INDIA

A real understanding of the case-study implies a brief introduction to the Indian legal system, mainly to the Indian perception of the rights to life and health, the historical evolution of drug patent protection, and the Indian legal provision which addresses the problem of ever-greening.

FUNDAMENTAL RIGHTS: RIGHTS TO LIFE AND HEALTH

The protection of the rights to life and health is deeply rooted within the Indian legal framework, be it through express constitutional provisions and as a result of judicial recognition.

The Indian Constitution guarantees protection to a wide spectrum of human needs in two separate sections: the Fundamental Rights and the Directive Principles of State Policy. The first section protects individual rights, mainly those commonly recognized as civil and political rights. Within this section, Article 21 determines that ‘[n]o person shall be deprived of his life’, and consequently qualifies the right to life as a fundamental right. Conversely, the Directive Principles section describes how the State should attempt to achieve social and economic order based on justice. According to Article 47, ‘among its primary duties’ the State should raise the ‘the standard of living of its people and the improvement of public health’.

The protection of entrenched fundamental rights and the fulfillment of the Directive Principles have always been central features of the Indian Supreme Court activity. In *Francis Mullin v. Union Territory of Delhi*,⁵² the right to life was interpreted broadly as including ‘the

⁵² *Francis Mullin v. Union Territory of Delhi*, Supreme Court [1981]

right to live with human dignity and all that goes along with it, namely, the bare necessities of life'.⁵³

The Court realized that the right to life is meaningless unless protection is given to certain social rights which are the key features for living life with dignity. Thus, the Directive Principles section started to be interpreted in a dynamic and creative way, providing an essential input for the implementation of social rights such as the right to health.⁵⁴ In *Consumer Education & Research*⁵⁵ the Court explicitly held that '[t]he right to health (...) is an integral facet of [a] meaningful right to life to have not only a meaningful existence but also robust health and vigor'.⁵⁶ The Court concluded that the right to health and medical care is a fundamental right under Article 21.

INTELLECTUAL PROPERTY RIGHTS: PRE AND POST TRIPS

After the Indian independence, it was desirable to enact a comprehensive patent system conducive to the promotion of national interests, thus encouraging the use of inventions and enhancing commercial development. Based on Ayyangar Committee recommendations, the Indian Patents Act, 1970 (Patents Act) was enacted and most of its provisions brought into force in 1972.⁵⁷

Prior to the migration to the TRIPS, India kept a deliberately weak and protectionist patent regime. The Patents Act only contemplated process patent protection on medication, excluding product patent protection. Whereas product patents cover the underlying substance of the invention, process patents merely shelter the formula according to which that substance was made. In the pharmaceutical sector, process patents are not a strong form of protection since usually there are many ways of producing a drug other than through the way covered by the process patent. Therefore, a clever inventor can easily reverse engineer generic versions of patented products by altering some steps in the production process. Although this solution

⁵³ *Ibid*, para. 6

⁵⁴ Sheetal B. Shah (1999), 'Illuminating the Possible in the Developing World: Guaranteeing the Human Right to Health in India', 32 *Van J Trans L*, p.466

⁵⁵ *Consumer Educ. & Research Ctr. v. Union of India*, Supreme Court [1995]

⁵⁶ *Ibid.*, para. 26

⁵⁷ See the history of the Indian patent system at <http://ipindia.nic.in/ipr/patent/patents.htm> (last visited on November 21, 2011)

could be criticized, the truth is that pharmaceutical patents only on the process were the option in numerous developed countries not so long ago.⁵⁸

The absence of product patent protection was one of the major factors for the remarkable growth of the pharmaceutical field in India, which today has one of the most advanced pharmaceutical industries among developing countries.⁵⁹ The lack of strong intellectual property rights conducted to an intense transfer of knowledge and competition among a large number of companies and, consequently, to the availability of medicines at lower prices. India's generic medicine infrastructure flourished within this pro-technology transfer environment and India raced to the forefront, providing essential medicines not only within its territory but also outside the country.

In fact, India's generic-friendly patent system strengthened the industry of generics and classified this country as the 'pharmacy of the developing world'.⁶⁰ According to data provided by Bazzle, 'India exports nearly 67% of its considerable output of generic medicines to developing countries, making it the main supplier of essential medicines to the developing world'.⁶¹

In 1995 India became a WTO Member, which required concessions on the intellectual property regime in order to obtain other WTO's benefits. Under Article 65 of the TRIPS, India was given ten years from the date of the Agreement's coming into force to implement product protection in pharmaceuticals.

With the purpose of complying with the TRIPS commitments, India made three critical amendments to the Patents Act: in 1999, with the goal of introducing exclusive marketing rights; in 2002, with the objective of complying with all the other obligations except product patent; and in 2005, to introduce the product patent regime.

⁵⁸ Germany and France only grant product patents since 1967, Switzerland since 1978, Canada since 1987, Spain and Portugal since 1992.

⁵⁹ Sudip Chaughuri (2009), 'Is product patent protection necessary to spur innovation in developing countries? – R&D by Indian Pharmaceutical Companies after TRIPS', in Neil Weinstock Netanel (ed.), *The global agenda – Global Intellectual Property and Developing Countries*, Oxford University Press, p.266

⁶⁰ See *Examples of the Importance of India as the 'Pharmacy of the Developing World'*, Médecins Sans Frontières (2007), at http://www.doctorswithoutborders.org/news/access/background_paper_indian_generics.pdf (last visited on December 16, 2011)

⁶¹ Bazzle (2011), p.786

Until the Patents Amendment of 2005, India continuously expanded its indigenous generic drug industry. However, this last amendment directly changed this trend, causing apprehension not only in India but across the developing world. The major concern was that the adoption of a TRIPS modeled intellectual property regime would thwart Indian's robust generic industry, increase drug prices and decrease pharmaceutical source choices,⁶² thereby necessarily depriving the world's most impoverished populations of access to affordable and high quality essential drugs.

Nonetheless, as noted above, the TRIPS Agreement provides 'only minimum standards of protection and does not set the universal common standard for the substantial aspects of the patent law'.⁶³ The inherent flexibility of the Agreement allows for national differences in the prosecution and protection of patents, making possible the challenge of ensuring affordable essential drugs.

In order to prevent abuses on the part of patent rights' holders and to avoid the maintenance of the high prices of drugs, the Indian legislator introduced a limited conceptualization of the patentable subject matter. In fact, the Patents Act does not merely restrict the scope of patentability to the inventions which pass the three-prong test of novelty, inventive step and industrial application as described in Section 2(1)(j), (ja) and (l); in addition, inventions must not fall under the long list of exceptions laid down in Sections 3 and 4.⁶⁴

SECTION 3(D)

A close list of exceptions to the patentable subject matter is not established under Article 27(2) of the TRIPS, which leaves Member countries flexibility to introduce further exceptions on the grounds of policy.

One of the critical concerns regarding possible abuses by patent holders is the patenting of known substances. To face such issue, the Indian legislator provided for Section 3(d) which in essence aims at preventing the prorogation of patents on known products simply due to the introduction of minor changes, a phenomenon already described as ever-greening.

⁶² Commission on Intellectual Property Rights (2003), *Integrating Intellectual Property Rights and Development Policy: Final Report of the Commission on Intellectual Property Rights*, p.29

⁶³ Gopakumar (2010), p.326

⁶⁴ Khader (2008), p.425

Section 3(d), as amended by the Patents Amendment 2005, lists out non-eligible patentable subject matter within the meaning of the Patents Act:

‘The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

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.’

This norm identifies three different ways of avoiding ever-greening by prohibiting patents on: (i) new forms of known substances; (ii) new uses of known substances; and (iii) the mere use of a known process, machine or apparatus. The present study will focus on the analysis of the more controversial first part of Section 3(d), and specifically on the derivatives of a known pharmaceutical substance which do not differ significantly from the existing drug regarding efficacy.

While radical innovations are protected if the three general requisites are met, minor innovations must pass a more restrictive test. It is not easy to reach consensus on what actually amounts to an incremental innovation and the extent to which such innovation should be protected. Thus, Section 3(d) establishes the criteria, drawing the line between admissible patents on incremental innovation and inadmissible ever-greening patents. It rules incremental innovation determining that a fresh patent on a known substance must only be granted if the applicant demonstrates an increase of efficacy of the known substance.

The first part of Section 3(d) is relevant to determine the novelty of a known substance. Non-obviousness also seems to be here at stake, since the enhancement of efficacy requires an inventive step. This norm might also be said to embody a utility test, since unless the new form has significantly enhanced utility over and above the form existing before, it is not

patentable. However, Section 3(d) goes further than the general requirements of patentability, expressly presenting a solution to combat ever-greening.

The in-built guideline to establish patentability of the new form of a known substance refers to two comparative concepts: 'known efficacy' and 'enhanced efficacy'. In other words, the 'enhanced efficacy' must be determined *vis-à-vis* the 'known efficacy'. As the first part of Section 3(d) mentions known substances, it is quite reasonable to assume that the efficacy of the substance will also be known. Therefore, the patent applicant must demonstrate the enhancement of efficacy of the known product. Having the 'known efficacy' as the benchmark, the Patent Controller then has to look at the alleged 'enhanced efficacy' and decide whether there has been a significant difference in the efficacy of the new form compared with the existing form.⁶⁵

Another explicit guidance comes directly from the explanation of Section 3(d). It treats salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of the known substance as the same substance. Therefore, subsequent patenting in any of the above-mentioned forms is prohibited.

Notwithstanding the purpose of Section 3(d) to control abuses of patent holders, some shortcomings were pointed out to this norm. First of all, the terms 'efficacy' and 'significant enhancement' are said to be too broad. More categorical rules would be preferable since they foster consistency, stability and predictability. However, determining arbitrary percentages of the efficacy enhancement to apply to all circumstances is not an optimal policy. It seems best to have a broader clause ensuring adaptability to social and technological changes, and to the particular circumstances of each case.⁶⁶

A related criticism is that the broadness of this provision might give room for interpretations by administrative and judicial authorities, which goes against the very legislative intent to prevent ever-greening patents. It may be easy for a MNC to say that a minor change in an existing substance is able to satisfy the requirement of 'enhancement of efficacy'. According to Gopakumar, this legislation is in practice often overlooked by the Patent Authority and

⁶⁵ Khader (2008), p.427

⁶⁶ Shamnad Basheer & T. Prashant Reddy (2008), 'The 'Efficacy' of Indian Patent Law: Ironing out the Creases in Section 3(d)', 5(2) *SCRIPTed*, p.257

patents are granted to drug applications contrary to Section 3(d).⁶⁷ Nevertheless, reducing such subversive effects does not mean the rule should be eliminated, as long as the legislator is aware of the negative impact of ever-greening patents when enacting this norm and defines his aims clearly.

Finally, one might say that Section 3(d) is incompatible with India's obligations under the TRIPS. Before contradicting this criticism, it is important to clarify that Section 3(d) refers to exceptions on patentability (Article 27 of the TRIPS) and not to exceptions on exclusive rights conferred by the patent (Article 30 of the TRIPS). Based on this premise, Section 3(d) does not violate Article 27(2) of the TRIPS; on the contrary, it fulfills the scope of the TRIPS' requirements and dilutes them in the Indian context.⁶⁸

After overcoming the criticisms to Section 3(d), it is possible to spot the commitment of this legislation in trying to avoid ever-greening patents in general and, within the pharmaceutical field, to protect human health and life.

III.2. NOVARTIS VS. INDIA

The *Novartis* case on the Glivec patent cleared the doubts and answered the fears of the skeptics by presenting a strict interpretation of Section 3(d). In order to fully understand the legal issues of the case it is essential to firstly provide its factual background.⁶⁹

After starting researches in 1960, Novartis discovered the 'imatinib', a free base which was a promising candidate to combat the enzyme causing chronic myelogenous leukemia. In 1993, Novartis filed a patent in the USA⁷⁰ covering this free base and all pharmaceutically acceptable salts. The compound was also patented in the EU⁷¹ and several other countries.

Researches and improvements were made on imatinib, and it was converted into a particular salt form named 'imatinib mesylate'. Based on this discovery, Novartis found that the most stable polymorphic form of the salt was the beta crystalline form. A patent application was

⁶⁷ Gopakumar (2010), p.348

⁶⁸ Adarsh Ramanujan & Rajarshi Sen (2009), 'Pruning the Evergreen Tree: Section 3(d) of the Indian Patents Act 1970', 31(3) *Eu IP Rev*, p.145

⁶⁹ Basheer (2008), pp. 235-238

⁷⁰ US Patent No. 5521184

⁷¹ European Patent No. 0564409

filed for the beta crystalline form of imatinib mesylate which was then formulated into the useful pharmaceutical drug Glivec.

Although initially Novartis did not file a patent application for imatinib in India, because at the time the law in India did not provide for product patents for pharmaceuticals, Novartis came up with a 'mailbox application' in 1998⁷² for the beta crystalline form of imatinib mesylate.

Pursuant to the Amendment of 2005 to the patent regime in India, Novartis' mailbox was opened and examined. It claimed that the active ingredient in Glivec was more effective than the imatinib free base, since it displays better bioavailability properties, i.e. it is more easily absorbed into the blood. For this purpose, Novartis submitted evidence to the Assistant Controller demonstrating an increase in bioavailability of up to 30%.

However, there was opposition to the grant of a patent from several generic drug companies and a non-governmental organization (NGO) on the basis of Section 25(1) of the Patents Act. It is worth noting that through this norm the Indian system provides for a pre-grant opposition mechanism, 'an effective tool for individuals to challenge patent applications for drugs that would unduly burden the availability and affordability of essential medicines'.⁷³ The Assistant Controller of Patents rejected the patent application⁷⁴ on the grounds that the claimed invention lacked novelty because it was previously anticipated and obvious. In addition, since the beta crystalline form was only a polymorph of imatinib mesylate, that is, a new form of a known substance under Section 3(d), Novartis failed to demonstrate a significantly enhanced 'efficacy'. The Assistant Controller concluded that '[t]he present patent specification does not bring any improvement in the efficacy of the beta crystal form over the known substance'.⁷⁵

Aggrieved with such order, Novartis approached Madras High Court with two writ petitions,⁷⁶ not only seeking a reversal of the Assistant Controller's order, but also challenging Section 3(d) compatibility with TRIPS, as well as its constitutionality. The Court immediately declined to exercise jurisdiction over the claim that the amended Section was violating the

⁷² As per Article 70(8)(a) of the TRIPS, all applications claiming pharmaceutical inventions were to be accepted and put in a 'mailbox' to be examined when product protection was implemented.

⁷³ Bazzle (2011), p.807

⁷⁴ *Novartis AG v. Natco Pharma and others*, Indian Patent Office, Application No.1602/MAS/1998 (25 January 2005)

⁷⁵ *Ibid*, para. 11

⁷⁶ W.P. Nos. 24759 and 24760 of 2006, High Court of Madras

TRIPS, stating that the proper venue for this challenge was the WTO Settlement Board, thus focusing its analysis on the constitutional validity of Section 3(d).

Novartis argued that Section 3(d) violated the fundamental right to equality enshrined in Article 14 of the Indian Constitution, due to the use of vague and arbitrary expressions, as well as stating that Section 3(d) left a great deal of discretion to the Patent Authority concerning the determination of whether the subject matter would be patentable or not.

However, the Court disagreed with both of these contentions. On the one hand, according to jurisprudential decisions, vagueness and arbitrariness are not justifications to strike down legislation. Nevertheless, the Court clarified the meaning of ‘enhancement of known efficacy’ by determining that ‘if the discovery of a new form of a known substance must be treated as an invention, then the Patent applicant should show that the substance so discovered has a *better therapeutic effect*’.⁷⁷ Moreover, Section 3(d) was brought in with the precise goal of prohibiting ever-greening, so it cannot be blamed for lacking an explicit purpose.

On the other hand, it is permissible for the legislator to lay down broad policies and delegate powers of rulemaking to the statutory authority, mainly in areas of specific knowledge. The Madras High Court considered that ‘there are *in-built materials* in the amended section and the Explanation itself, which would *control/guide the discretion* to be exercised by the Statutory Authority’.⁷⁸

The *Novartis* case represents the first time in the Indian patent jurisprudence that a Court explicitly recognized the constitutional right to health⁷⁹ for the interpretation of patent law requirements.⁸⁰ The Court expressly declared that it ‘have borne in mind the object which the Amending Act wanted to achieve namely, to *prevent ever-greening*; to provide easy access to the citizens of this country to *life saving drugs* and to discharge their Constitutional obligation of providing *good health care to its citizens*’.⁸¹

⁷⁷ *Novartis*, para. 13 (emphasis added)

⁷⁸ *Ibid*, para. 16 (emphasis added)

⁷⁹ Following this jurisprudence there were other important cases ruling on the right to health; see *F. Hoffmann-La Roche and another v. Cipla Limited*, Delhi High Court [2008]; and *Bayer Corporation v. Union of India*, Delhi High Court [2010]

⁸⁰ Bazzle (2011), p.804

⁸¹ *Novartis*, para. 19 (emphasis added)

Even if the constitutionality of Section 3(d) seems to have been the right decision, the Court's approach leaves some empty space for a deeper legal reasoning. In fact, the Court's argumentation does not really focus on the central issue, which appears to be the achievement of an accurate balance between the rights to life and health and the right to a drug patent grant. In the present case, the grant of pharmaceutical patents is limited by the claim of a health governmental purpose, so the role of the Court is to determine whether such limitation is justified. Therefore, the analysis must be redirected to the balance of the opposing rights at stake.

The *Novartis* case is presently pending before the Indian Supreme Court, after an appeal filed by Novartis. The solution to be adopted by the court of appeal will have serious consequences, be it to the human health or to inventions related to pharmaceuticals, so the rationale must be strongly constructed.

The Indian Supreme Court is the highest judicial forum and the final court of appeal, having the role of federal court and guardian of the Constitution. This Court's constitutionally mandated jurisdiction is remarkably wide and varied, including the issue of writs in defense of the fundamental rights listed in the Indian Constitution. Since the Supreme Court is already familiar with the proportionality test, as we will see below, it would be surprising if it did not take advantage of this tool to analyze the opposing rights in the *Novartis* case.

IV. THE CHALLENGE: BALANCING THE CONFLICTING RIGHTS

The *Novartis* case expressly shows the conflict between the right to have a patent granted on medicines and the rights to health and life. On the one hand, pharmaceutical MNCs spend millions on R&D and fight for the maintenance of patent protection over drugs; on the other, the excessive prorogation of patents implies that millions of people would not have access to medication due to high drug prices. If this issue is analyzed from an economic standpoint, patents will be encouraged; but if the focus switches to a human rights approach, access to medicine becomes of prime importance.

For pro-patent supporters, denying private rights over medicines is perverse because it undermines the present economic system that is the driving force for pharmaceutical innovation. For people faced with the acute realities of disease and suffering, it is however

perverse to question the special status of medicines and the need for governments to adopt measures ensuring access to affordable drugs. The challenge is where to strike the right balance, keeping the pharmaceutical industry motivated to invest in R&D without denying medication to poor people.

This conflict does not have a straightforward solution. Pharmaceutical patents have the potential to improve health and life by providing incentives for the development of new drugs which alleviate or even cure serious diseases. In fact, '[t]he right to access medicines (...) depends in the first place on the existence (or likelihood of existence) of medicines'.⁸² On the flipside, pharmaceutical patents may restrict access to drugs by making available brand name medicines at prices much higher than those potentially practiced by generic companies.⁸³

Accordingly, Article 7 of the TRIPS recognizes the complex coexistence⁸⁴ between intellectual property, technological innovation and social and economic welfare, determining the need for 'a balance of rights and obligations'. The *Novartis* case, in which essential needs of the population contrast with property rights of patent owners, calls for a judicial review confronting the opposing interests.

IV.1. PRINCIPLE OF PROPORTIONALITY

The principle of proportionality is widely perceived as the preferred tool for managing disputes involving an alleged conflict between rights.⁸⁵ Proportionality requires weighing the various interests against each other and finding a fair balance among them. It considers whether the common interests protected through a government measure are sufficiently important to justify limitations to protected rights of individuals.

According to the conceptualization of Alexy, constitutional rights are perceived as principles, and since they are not absolute, they must be weighed against other principles. Rights as principles are 'optimization requirements',⁸⁶ which means that they must be enjoyed to the greatest extent possible with regard to the countervailing concerns. The balancing of the competing principles by a neutral Court does not give priority to any of them and it can be

⁸² Smith (2009), p.48

⁸³ Cullet (2003), p.143

⁸⁴ Bazzle (2011), p.794

⁸⁵ Tor-Inge Harbo (2010), 'The Function of the Proportionality Principle in EU Law', 16 *Eu LJ*, p.158

⁸⁶ Robert Alexy, *A Theory of Constitutional Rights* (2002), Julian Rivers (trans.), Oxford University Press, p.47

decided either way, depending on the different considerations weighed. In this context, the proportionality test appears as the framework to determine whether a right takes precedent over the other. Proportionality provides for an analytical structure in assessing whether limits imposed on a right are justified in a particular context.

The balancing method ‘allows the decision-maker a realm of discretion to weigh the different rights and interests implicated by the case against the background principles at stake’.⁸⁷ Proportionality is not intended to define what is right or wrong, but simply to facilitate an empirical determination of the measure of harm and benefit according to each value in conflict.⁸⁸

The term ‘proportionality’ is of extreme importance in the jurisprudential practice. The widespread acceptance of the proportionality doctrine is an undisputable fact. The principle of proportionality had its origins in the Prussian administrative law. It was then incorporated in the German constitutional law after World War II, and later adopted by the European Court of Human Rights (ECtHR), which helped spread the doctrine throughout Europe.⁸⁹ Nowadays, it is part of the constitutional legal analysis of many non-European countries, including India.

In *Bommai v. Union of India*,⁹⁰ the Indian Supreme Court established that the doctrine of proportionality is applicable to the field of constitutional law. More recently, the Supreme Court held in the *Teri Oat*⁹¹ case that:

‘By *proportionality*, it is meant that the question whether while regulating exercise of fundamental rights, the *appropriate or least restrictive choice* of measures has been made by the legislature or the administrator so as to achieve the *object of the legislation or the purpose of the administrative order*, as the case may be. Under the principle, the court will see that the legislature and the administrative authority «maintain a *proper balance between the adverse effects which the legislation or the administrative order may have on the rights, liberties*

⁸⁷ Stefan Sottiaux & Gerhard Schyff (2008), ‘Methods of International Human Rights Adjudication: Towards a More Structured Decision-Making Process for the European Court of Human Rights’, 31 *Hast Int & Comp L Rev*, p.119

⁸⁸ David M. Beatty (2004), *The ultimate Rule of Law*, p.169, cited in Moshe Cohen-Eliya & Iddo Porat (2011), ‘Proportionality and the Culture of Justification’, 59(2) *Amer J Comp L*, p.469

⁸⁹ Cohen-Eliya (2011), p.465

⁹⁰ *S.R. Bommai v. Union of India*, Supreme Court [1994], para. 62

⁹¹ *Teri Oat Estates Ltd. vs. U.T., Chandigarh and Ors.*, Supreme Court [2003]

*or interests of persons keeping in mind the purpose which they were intended to serve».*⁹²

The adoption of the proportionality test appears as an effective tool to manage conflicts in pluralistic and divided societies such as India, which is the world's most populous democracy, a nation of more than one billion people, speaking twenty three major languages and enjoying an astonishing religious, economic and social heterogeneity. Resorting to the proportionality principle is also justified when considering the central role played by the Supreme Court in sustaining democratic institutions, the rule of law and fundamental rights. In a constitutional system which is still maturing, the flexibility of proportionality allows the doctrine to develop naturally.⁹³

Although the proportionality test has been widely applied by many courts, commentators have nevertheless made criticisms to this method. Habermas opposes Alexy's theory, stating that the proportionality principle does not establish rational standards for balancing, then risking 'irrational rulings' through 'arbitrarily or unreflectively' weighing.⁹⁴

Based on this reasoning, other scholars consider that proportionality implies vague and ambiguous concepts, making it difficult to anticipate the outcome of the court decisions. A preferable approach would be a rule-based decision making, which can restrain decisional discretion and ensure clarity and consistency.⁹⁵ According to this point of view, legal certainty is essential to secure a stable legal framework for individuals.

In answer to these criticisms, it could be said that a more flexible balancing approach furthers accountability, extends dialogue about human rights values, and enhances fairness and substantive justice.⁹⁶ In fact, proportionality allows for flexibility in the development of the law and does not bind the court to a certain path, ideally conducting to the best solution possible regarding the concrete requirements of each case. In this sense, the categorical approach is inadequate because it does not allow for decision-makers to take into account all

⁹² *Ibid.*, para. 46 (emphasis added)

⁹³ Burt Neuborne (2003), 'The Supreme Court of India', 1 *Int J Const L*, p.477

⁹⁴ Jürgen Habermas (2007), *Between facts and norms: Contributions to a discourse theory of law and democracy*, William Rehg (transl.), Polity Press, p.259

⁹⁵ Frederick Schauer (1998), 'Playing by the Rules: A Philosophical Examination of Rule-based Decision-making in Law and in Life', *Oxford University Press*, pp.137-145, cited in Sottiaux (2008), p.120

⁹⁶ Kathleen M. Sullivan (1992), 'Foreword: The Justices of Rules and Standards', 106 *Harv L Rev*, p.66

the specificities of the particular case, possibly leading to unfair solutions, divorced from reality.

Other critics state that the proportionality doctrine is inconsistently applied and ultimately only serves as a fog that obscures what may be a results-oriented analysis. Even when a court alleges to be conducting a genuine proportionality analysis, it is only justifying the decision previously taken. Likewise, this doctrine is manipulated to reach a desired outcome and not the real path to achieve it.⁹⁷

Some judicial decisions might actually be subject to criticism, but one should not generalize such strong statements. Courts are composed by humans who, as a natural consequence of their humanity, may make mistakes. However, judges are typically seen as neutral, independent and more competent to evaluate the merits of facts within the existing legal framework through a rational analysis. They are, ideally, prepared to provide neutral and balanced judgments when conflicts of rights exist. The use of the proportionality test appears, generally, as a tool of judicial oversight to conduct a rigorous and searching examination of the competing rights at stake.

One cannot exclude the proportionality test on the basis that it might be misused until a better approach is found. With this in mind and although presenting flaws to the proportionality test, Kumm concludes that ‘there is no plausible way to constitutionalise the protection of rights that reflect the commitments of a liberal political morality that excludes proportionality analysis as an important feature of rights adjudication’.⁹⁸

Since *Novartis* is not a straightforward case, contrasting different rights and interests, it seems essential to adopt the available method which best answers the requirements of the case. Therefore, even with some disadvantages to the proportionality test, this seems to be the best tool to apply in the present case.

⁹⁷ Jeremy McBride (1999), ‘Proportionality and the European Convention on Human Rights’, in Evelyn Ellis (ed.), *The Principle of Proportionality in the Laws of Europe*, Hart Publishing, p.35

⁹⁸ Mattias Kumm (2007), ‘Political Liberalism and the Structure of Rights: On The Place And Limits of the Proportionality Requirement’, in S. Paulson and G. Pavlakos (ed.) *Law, Rights, Discourse: Themes of the Work of Robert Alexy*, Hart Publishing, p.166

IV.2. APPLYING THE THREE-PRONG PROPORTIONALITY TEST

The proportionality test has a three-prong structure which needs to be analyzed carefully:

- a) Suitability;
- b) Necessity;
- c) Proportionality *stricto sensu*.

The application of this test specifically to the *Novartis* case may be described with the following questions:

- a) Does Section 3(d) actually accomplish the objective of reducing ever-greening and improving health?
- b) Are there other approaches to reduce ever-greening that are more likely to be successful in protecting patent rights at a lower cost?
- c) Is the legislative objective of improving public health and life sufficiently important to justify the limitation of patent rights?

Before moving on with the proportionality test analysis, it is essential to mention that this test will be based not only on references to Indian domestic legislation, but also to international law. Since this is an international issue as it involves rights recognized under international agreements (UDHR, ICESCR, TRIPS), actors from different States (Novartis, with head office in Switzerland, and other pharmaceutical MNCs expect to enhance their patent rights) and worldwide consequences (access to medicines within India and other developing countries may be enhanced or restricted), the perspective to solve the case must also be internationalized. Therefore, one must take into account not only the Indian legislation but also international agreements to answer the questions posed by the proportionality test.

SUITABILITY

Suitability refers to the relationship between the means and the end of a legislative measure. It requires that a norm be suitable or appropriate to achieve the desired aim. The means is suitable when the desired result can be furthered with its help. On the contrary, a measure does not pass the suitability test when it is clearly not conducive to the aim pursued. At this

stage, the court only assesses ‘whether, at the time when the measure was adopted, it was manifestly unsuitable to achieve the desired end’.⁹⁹

A limiting measure such as Section 3(d) must be capable of achieving the legitimate aim pursued. In fact, the prevention of the ever-greening phenomenon appears as a legitimate aim in accomplishing the Indian national obligations to guarantee health care and life. Therefore the pursued aim is legitimated by the duty of the State to improve public health, as stated under Article 47 of the Indian Constitution.

The next question is whether the prohibition of patents on known drugs which do not provide an enhancement of the known efficacy is a suitable means to further the referred legitimate policy goal. A means is suitable if, after an empirical assessment,¹⁰⁰ it actually furthers the declared government policy goal. Ever-greening has been proven to be a real problem in the context of Indian patent applications, so Section 3(d) appears as an effective means to satisfy the Indian State’s interest in protecting the rights to health and life. As an empirical matter, the problem of inadequate prorogation of patents may be significantly mitigated, if not completely eliminated, by excluding from patentability drugs which do not really improve in innovation.

NECESSITY

Suitable measures may, however, be unduly harmful. Thus the court must apply the necessity test and assess whether the chosen measure is essential, even if appropriate to achieve the given goal. In other words, a measure is acceptable only if no less restrictive measures are available to achieve the legitimate objective pursued.¹⁰¹ Therefore, the limiting measure must be the least restrictive means to achieve the relevant goal, meaning that only measures causing minimum harm to the interests at stake should be chosen.

When opting between several possible measures the choice must be the least onerous one, the one which causes the least possible adverse consequences to the legal status of the part concerned. If there is an alternative measure available which can also further the State’s

⁹⁹ Nicholas Emiliou (1996), *The Principle of Proportionality in European Law - A Comparative Study*, Kluwer Law International, p.19

¹⁰⁰ Kumm (2007), p.138

¹⁰¹ Emiliou (1996), p.29

interest to a comparable degree and which does not violate the right in question, or violates it to a lesser degree, such alternative measure should be chosen.¹⁰²

A measure is necessary when another measure, equally effective but less restrictive, cannot be adopted. Likewise, the measure must be suitable to achieve the desired end, with a higher or at least the same intensity. Whether a measure is as effective as another must be decided *in concreto*.

It is not easy for the court to assess all alternatives to determine whether the one included in the norm is the least intrusive. According to Gunn,¹⁰³ a possible solution to solve this difficulty would be to firstly locate the burden of proof in the complainant's sphere and ask him to provide a *prima facie* case disclosing the existence of one or more less restrictive alternatives available in practice. Only after that would the burden shift to the State to prove that the alternatives proposed were not preferable to the statute at issue. Since this is not the actual regime, the court must always make an effort to see the big picture and define possible alternatives to the measure at hand.

A plausible way of analyzing the alternative measures available in the *Novartis* case is to look at the previous formula of Section 3(d) and compare it with the actual version. The Section 3(d) before the amendment provided that:

‘The mere discovery of any new property or mere new use of a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.’

This norm did not provide for the concept of ‘enhancement of the known efficacy’ and did not even establish an explanation for defining derivatives of known substances as being the same substance. Therefore, it is less restrictive of the patent holder's right to extend the patent on a known substance. The point is now to determine whether the two norms are equally effective. Actually, the new Section 3(d) imposes a more demanding criterion and is more efficient in combating ever-greening. If the legislator felt the need to improve and introduce an

¹⁰² Tarunabh Khaitan (2008), ‘Beyond reasonableness – A rigorous standard of review for Article 15 Infringement’, 50 (2) *J Ind L Inst*, p.184

¹⁰³ T. Jeremy Gunn (2005), ‘Deconstructing Proportionality in Limitations Analysis’, 19 *Em Int L Rev*, p.496

amendment to the previous provision, it must mean that the access to drugs at affordable prices was not being fully protected.

Another possible way to apply the necessity prong is to ask if the general requirements of innovation stated in Section 2(j), (ja) and (l) of the Indian Patents Act – clearly less restrictive than Section 3(d) – may be regarded as equally effective in preventing ever-greening. The criteria of novelty, inventive step and industrial application have the goal to restrict the granting of patents only to innovative products and may ultimately address problems of ever-greening by determining that the secondary patent's application does not accomplish such requirements. Notwithstanding this possible alternative, it seems that the government has plausible reasons to believe that the general requirements would not go as far as the direct prohibition of Section 3(d).

The necessity test entitles the legislator to a certain margin of discretion regarding the choice of the most suitable means. In fact, it is up to the legislator, an expert on the subject concerned, to analyze all the possible solutions to prevent ever-greening. The court only scrutinizes whether such selection was appropriate or not. In the present case, it seems that access to medicines at affordable prices after the end of the first patent protection could not be effectively achieved by means of measures less onerous than Section 3(d).

PROPORTIONALITY 'STRICTO SENSU'

The measure, although suitable and necessary, may be disproportionate if it imposes an excessive burden on the individual right that was limited. Proportionality *stricto sensu* is the final step of the analysis and consist of the actual process of weighing and balancing the different components of the case.¹⁰⁴ It requires a proper balance between the damage to the individual right and the gain to the community caused by the State measure. Proportionality prohibits measures where disadvantages to individual rights evidently outweigh the advantages to the community.¹⁰⁵

Likewise, the court is required to strike a fair balance between the rights of the individuals and the public interest, an essential component being the weighing of the limiting measure and of the aim pursued by the government when enacting such measure. For a measure to be

¹⁰⁴ *Ibid.*, p.494

¹⁰⁵ Emiliou (1996), p.32

proportionate, the court must conclude that, when compared, means and ends are not out of proportion. According to Alexy, the ‘law of balancing’ implies that ‘the greater the degree of non-satisfaction of, or detriment to, on principle, the greater must be the importance of satisfying the other’.¹⁰⁶

The decisive question at this stage is whether the increasing access to affordable medicines by the poor population in India and other developing countries through the reduction of ever-greening justifies the limitation of the pharmaceutical MCNs’ right to prorogate exclusive drug patent rights. In order to carry out a real weighing and balancing test, it seems essential to counterbalance the intellectual property rights with the human rights to health and life.

As stated above, Alexy conceptualizes rights as principles, all at the same level without any priority among them. To conduct a neutral proportionality *stricto sensu* test, this rule must be used as the main guideline, since one cannot say *a priori* which of the rights must prevail in the concrete case. However, one must not ignore the negative impact patents may cause in worldwide access to medication, which led to a global movement for the implementation of a prioritizing scheme where the rights to health and life prevail.

From an *economic perspective*, the strongest argument of pro-patent prorogation defenders is based on the need to compensate the huge R&D investments made by pharmaceutical MNCs. Without going into further detail, it is important to observe that ‘estimates of costs of drug development are contentious, because there is no basic agreement on how these costs should be calculated’.¹⁰⁷ A US survey carried out in 2003 found that, up to 1999, the average cost of a new drug was US\$403 million, and that taking into account the cost of capital in view of the long period between research expenditure and a positive cash flow for the product, this figure doubled to US\$802 million.¹⁰⁸ However, such amount was hugely criticized by skeptics who accused the pharmaceutical MNCs of quoting costly R&D to justify the high costs of their products.¹⁰⁹ For instance in 2004, other economic studies determined much lower estimated

¹⁰⁶ Alexy (2002), p.102

¹⁰⁷ Grubb (2010), p.425

¹⁰⁸ J.A. DiMasi et al. (2003), ‘The price of innovation: New estimates of drug development costs’, 22 *J Health Econ*, p.166

¹⁰⁹ Donald Light & Rebecca Warburton (2005), ‘Extraordinary claims require extraordinary evidence’, 24(5) *J Health Econ*, p.1032

R&D costs, varying from US\$57 million to US\$71 million for the average new drug brought to the market.¹¹⁰

Although it is not easy to determine a precise value for R&D costs, the innovative pharmaceutical industry returns between 14% and 25% of its revenue on profits.¹¹¹ It is well-known that the pharmaceutical industry ranks among the most profitable businesses.¹¹² The criticism about the MNCs huge profits comes from NGOs, legal scholars and even scientists. For instance, Médecins Sans Frontières have developed a campaign named ‘Don’t trade our lives away’.¹¹³ Scholars such as Bazzle consider that the pharmaceutical MNCs ‘exploit stringent intellectual property rights to enrich themselves at the expense of the drug-consuming public’.¹¹⁴ Even Dr. Brucker, one of the Novartis scientist researchers who carried out much of the Glivec R&D, condemned Novartis for what he alleged as extremely high prices.¹¹⁵

Through a *human rights approach*, the rights to health and life result from the basic dignity of people to whom they pertain (at least if one adheres to the concept of human rights as natural rights), while intellectual property rights arise from the State-imposed economic system.¹¹⁶ These competing rights are characterized by a substantial difference: while intellectual property is limited on time and can be revoked and transferred, human rights are inalienable and timeless.

According to Cullet, ‘[t]he human right to health is clearly not a non-derogable right under present international law. However, if a hierarchy had to be established between human rights and intellectual property rights, it is likely that human rights would generally take precedence’.¹¹⁷ Lenk also states that ‘the health and life of people in developing countries are

¹¹⁰ Public Citizen (2001), *Rx R&D Myths: The Case Against the Drug Industry’s R&D Scare Card*, pp.5-6

¹¹¹ Hestermeyer (2007), *Introduction*

¹¹² *Ibid.*, p.159

¹¹³ See the official website at <http://donttradeourlivesaway.wordpress.com/tag/medecins-sans-frontieres/> (last visited on May 7, 2012)

¹¹⁴ Bazzle (2011), p.794

¹¹⁵ See Brian Drucker, ‘Don’t Abuse Patents’ Mint, August 15, 2007, at <http://www.livemint.com/2007/08/15003521/Don8217t-abusepatents-sci.html> (last visited on April 21, 2012)

¹¹⁶ Smith (2009), p.59

¹¹⁷ Cullet (2003), p.159

more important than property rights'.¹¹⁸ Thus, the interest of the community at large should generally prevail over the individual interest of pharmaceutical inventors.

Human rights constitute the basic framework that guides the State actions at the domestic and international levels. When implementing intellectual property rules, States must bear in mind their human rights obligations which include the duty to prevent abuses of rights by third parties, including non-State actors such as the pharmaceutical MNCs. By signing and ratifying international agreements in which these rights are enshrined, most countries have already acknowledged the primacy of human rights.

In 2001, the CESCR published a Statement¹¹⁹ noting that human rights 'are fundamental, inalienable and universal entitlements belonging to individuals', whereas intellectual property rights 'are instrumental, in that they are a means by which States seek to provide incentives for inventiveness and creativity from which society benefits'.¹²⁰ It adds that '[w]hereas human rights are dedicated to assuring satisfactory standards of human welfare and well-being, intellectual property regimes, although they traditionally provide protection to individual authors and creators, are increasingly focused on protecting business and corporate interests and investments'.¹²¹ Likewise, Article 15(1)(c) of the ICESCR should not be interpreted as giving intellectual property rights *prima facie* force over human well-being.

Demands for respect for human dignity above and beyond the protection of intellectual property also come via the Doha Declaration, which explicitly recognizes the primacy of health related considerations over strict economic interests, and implicitly accepts the right to health as preminent over the right of companies to the legal protection of their commodities.¹²²

When a right is only slightly restricted in favor of the achievement of a suitable and necessary State's interest, the impugned measure should be permissible. The more socially pressing the need – in this case the access to medicines –, the more legitimate the State's interest in protecting it to the detriment of individual private rights. In this case, the infringement is minor and the public interest is high.

¹¹⁸ Lenk (2009), p.135

¹¹⁹ See note 15

¹²⁰ *Ibid.*, para. 6

¹²¹ *Ibid.*

¹²² Smith (2009), p.68

From the balance presented above, it is possible to conclude that patents should not be prorogated after primary grant if there is no enhancement of known efficacy of a known substance. Maintaining patents on drugs with minimal changes on their characteristics using an overprotective intellectual property regime would be especially harmful in the context of access to medication and protection of life. In brief, when implementing Section 3(d), India was complying with its human rights obligations and developing a national framework of accountability, so that the solution achieved is proportional.

V. A GOOD SOLUTION FOR THE EUROPEAN UNION SYSTEM?

The EU legal system provides for both strong protection of human rights and intellectual property. The right to life is laid down in Article 2(1) of the European Convention on Human Rights (ECHR) as well as in Article 2(1) of the Charter of Fundamental Rights of the European Union (Charter). Moreover, the right to health is referred to in Article 35 of the Charter, stating that '[a] high level of human health protection shall be ensured'. On the other hand, Europe relies significantly on intellectual property rights to protect innovation. Intellectual property is contemplated in Article 17(2) of the Charter and is regulated under the European Patent Convention (EPC).

V.1. BRIEF CONTEXTUALIZATION: THE PATENT SYSTEM IN EUROPE

Patent protection is currently provided by two systems, neither of them standing on a EU legal instrument: the national patent system and the European patent system.

The national patent systems have been harmonized and in 1973 many European countries signed the EPC, also referred to as the Munich Convention. All EU Member States have signed this Convention and all States that wish to become part of the EU must adhere to it. The EPC is a self-contained system of law providing for the grant of patents in any or all the contracting States by means of a single patent application examined by the European Patent Office (EPO).

When compared to the TRIPS, the Munich Convention presents the three patentability requirements in a much greater detail (Article 52 of the EPC). The criterion of *novelty* (Article 54 of the EPC) considers that an invention is new if it is not part of the 'state of art', which is

defined as everything that was available to the public in written or oral form or in any other way, in any country, before the priority date of the invention. The *inventive step* (Article 56 of the EPC) implies an analysis of obviousness based on the ‘state of the art’ to a person skilled in the art. *Industrial application* (Article 57 of the EPC) refers to the possibility of making or using the invention in any kind of industry.

While determining the subject matter of patentability, Article 53 of the EPC only refers a few exceptions, mainly: (a) inventions contrary to ‘ordre public’ or morality, (b) plant or animal varieties or essentially biological processes for the production of plants or animals, and (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body.

The EPC allows an applicant to file a single patent application before the EPO which will analyze the requisites of patentability through a single procedure. If the application is accepted, the EPO grants a series of patent rights effective in each Member State where protection is sought. Although the EPC created a single system for granting patents, there is still no single patent valid for the whole EU legal order. As Grubb explains, ‘the European patent is not a single unitary patent, but is more like a bundle of national patents’.¹²³

Notwithstanding the advantages of having a European harmonized patent procedure, the current European patent system still presents drawbacks. A major problem is the high cost and complexity of obtaining comprehensive patent protection, making it inaccessible to many inventors. In fact, the overall validation cost of an average European patent reaches €32 thousand if validated for the whole EU and it is estimated that the actual validation costs are around €193 million per year in the EU.¹²⁴ In addition, the infringement disputes are adjudicated by national courts, which apply the law of their own country and may adopt different solutions regarding a single invention. These problems can only be addressed at the EU level, as in the absence of a EU legal instrument it would not be possible to uniform patent legal effects over several EU Members.

Efforts to provide a single unitary patent for the entire EU began even before the EPC was adopted. In a scenario of constant efforts towards European harmonization, this is a project

¹²³ Grubb (2010), p.31

¹²⁴ European Commission Proposal, 2011/0094 (CNS), April 13, 2011, p.1

still to be accomplished, with its legal basis in Article 118 of the Treaty on the Functioning of the European Union (TFEU).

The benefits of such unitary patent are the substantial reduction in patenting costs and complexity, mainly on what concerns translation and filing procedures, the simplification of the inventions protection throughout the European territory as a consequence of one single procedure, and the resolution of disputes litigation before a single centralized court.¹²⁵

Although this project has never come true, in 2011 the EU Commission launched a proposal for enhanced cooperation on unitary patent protection.¹²⁶ Notwithstanding the persistence of some barriers to the implementation of a EU unitary patent system, mainly linked to translation issues, this recent proposal created renewed expectations on the viability of the old project.

In what concerns the present study, it is essential to clarify that according to Article 2(b) and (c) of the proposed Regulation, a ‘European patent with unitary effect’ means a patent granted by the EPO under the rules and procedures laid down in the EPC, which will then benefit from the unitary effect in the territory of all participating Members States. This means that, in order to be considered an innovation, the EU unitary patent application is not subject to new requirements, but has to fulfill the provisions of Articles 52 and 53 of the EPC.

The implementation of a unitary patent calls for a Diplomatic Conference to revise the EPC in order to give the EPO the power to grant unitary patents. Within this revision, the EU will have the opportunity to discuss other subjects regarding intellectual property which also reflect EU concerns. As it was stated above, the EU has strong concerns regarding both intellectual property rights and human rights, so when it rethinks patents it must not forget its human rights obligations. Likewise, this environment of change may be the best occasion not only to revise aspects regarding unitary patent effects, but also to improve the patentability requirements for granting a unitary patent.

The future EPC amendment may be an opportunity to directly react to the problem of evergreening on pharmaceutical patents through a proposal to increase the exceptions to

¹²⁵ See ‘Summaries of the EU legislation’ at http://europa.eu/legislation_summaries/internal_market/businesses/intellectual_property/126056_en.htm (last visited on May 28, 2012)

¹²⁶ European Commission Proposal, 2011/0093(COD), April 13, 2011

patentability laid down in Article 53 of the EPC. A central and reliable granting procedure for all EU States is a key element to ensure the right balance between protection of intellectual property rights and human rights.

V.2. AN OPPORTUNITY FOR INSPIRATION

One of the unitary patent aims is to foster European innovation and competition capacities regarding countries with strong technology developments such as the US, Japan and the emerging BRIC (Brazil, Russia India, and China) economies. In the pharmaceutical field, patents on innovations must be granted and protected as an incentive for European pharmaceutical MNCs' investment in R&D for new and more effective drugs, and thus to enhance their competitive position in the world market. Conversely, secondary patents must be discouraged and only granted exceptionally, when they really relate to an innovation. Applications for non-innovative prorogation of patents have a detrimental effect on the European economy since they bar the generics from entering the market, reducing European competitiveness in an increasingly important area.

Additionally, ever-greening patents also have a negative impact on human rights since they preclude generic companies from making medicines available at lower prices, and thus restrict the rights to health and life. In a period of economic and financial crisis, access to medicines at affordable prices emerges as a social claim. This concern has already been expressed by the European Commission when stating that '[t]he pharmaceutical sector is essential for the health of Europe's citizens who need access to innovative, safe and affordable medicines'.¹²⁷ Therefore, human rights law must shape the framework on which intellectual property policies are drawn up, indicating the values that it should be pursuing.

European States have always understood health as a main governmental goal. Motivated by human rights concerns, they dedicated a significant portion of the global spending to R&D. However, governmental funding of R&D declined during the 80's and 90's as a result of budgetary constraints, economic pressures, and changing priorities. Likewise, the private

¹²⁷ European Commission (2009), *Communication of the Commission - Executive Summary of the Pharmaceutical Sector Inquiry Report*, p.1

sector role in terms of investment on pharmaceutical innovation grew considerably, resulting in R&D that is heavily reliant on patents and economic concerns.¹²⁸

In 2008 the European Commission launched a sector inquiry in the European pharmaceutical markets which showed that originator companies deliberately delayed generic entry in the market and prolonged the life cycle of their medicines through the misuse of the patent system, namely through secondary patenting on minor changes of active ingredients already covered by a primary patent.¹²⁹ A new sector inquiry was held in 2009 and confirmed that generic entry does not always take place as early as it could under the relevant legal framework, company practices being one of the causes of this delay.¹³⁰

EU countries started to understand that competition provided by generic medicines is essential both to keep public budgets under control, and to maintain widespread access to medicines to the benefit of patients. Competition with off-patent products enables sustainable treatment of more patients with less financial resources. According to the widely held position in the European Commission, ‘[a]ll actors should therefore ensure that generics can enter the market after expiry of patent and data exclusivity protections and compete effectively’.¹³¹

It is urgent that the EU lawmaker choose the course of action that is most likely to reduce ever-greening problems and conduct to the highest net social welfare, understood as ‘the greatest happiness of the greatest number’.¹³² Consequently, the proposal for the creation of EU Regulation on the unitary patent appears as an opportunity for the EU to express its concerns over ever-greening. During the Diplomatic Conference, the EU might raise the debate on whether or not patentability requirements are actually protecting innovations and excluding patents on minor variations of known products.

When thinking about solutions to reduce ever-greening patents, the EU legislator could be inspired by the Indian experience. Through comparative law, Europe could introduce an additional exception in Article 53 of the EPC similar to Section 3(d). This norm could help

¹²⁸ Correia (2004), p.784

¹²⁹ ECom (2008), *Pharmaceutical Sector Inquiry – Preliminary Report*, p.13 and 52

¹³⁰ See note 127, p.28

¹³¹ ECom (2008), *Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector*, p.7

¹³² Fisher (2006), p.602

the EU patent system to ‘filter out non-meritorious pharmaceutical inventions’,¹³³ and the access to medication at lower prices as well as the protection of the rights to health and life would be perfectly ensured.

As far as we know, Section 3(d) has no parallel in any other legislation around the world.¹³⁴ In fact, no other patent regime uses the specific term ‘efficacy’ to distinguish pharmaceutical inventions that are patentable from those which are not. Such uniqueness makes it interesting to analyze this norm deeper and to adopt it in other jurisdictions as a paradigm in the prevention of ever-greening.

It must be pointed out that a large part of Section 3(d) derives from the EU Directive on the Community code relating to medical products for human use, which provides for the concept of ‘efficacy’. Since this concept is already known in the European legal framework, it would probably not be difficult to transfer it to the patents field. In fact, Article 10(2)(b) of the Directive, while defining ‘generic medicinal product’, states that:

‘The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy.’

With all the necessary tools at hand to draft the new exception preventing ever-greening within Article 53 of the ECP, the challenge for the EU legislator is to find an optimal balance between the rights of patent owners and the needs of the general public. Through the proportionality test, the European legislator must weigh the competing rights by asking: Is the norm suitable to achieve its goal? Is it needed and is it the least damaging solution? Is it proportional *strictu sensu*?

Taking all the above into account, the new provision might read as follows:

‘European patents shall not be granted in respect of:
(...) d) the mere discovery of a new form of a known medical substance which does not result in the enhancement of the known efficacy of that substance.’

¹³³ Basheer (2008), p.234

¹³⁴ *Ibid.*, p.249

From the analysis of this norm, one can easily conclude that the proportionality test has been passed. In fact, the proposed exception is appropriate to achieve the goal of protecting health and the right to life, both legitimate aims pursued by the EU. Moreover, it is suitable to prevent the grant of ever-greening patents, since derivatives of known medical substances are considered to be the same substance unless they differ significantly in efficacy. Other less restrictive measures, such as directing the EPO to be aware of the ever-greening problem, are not as effective as introducing an explicit norm to fight it. Finally, the proposed norm does not outweigh the negative impact to the MNCs since it only concerns secondary patents, which means that the pharmaceutical inventor has already benefited from twenty years of exclusive patent rights.

Although ‘efficacy’ might be seen as an open concept not giving a straightforward answer regarding the eventual admissibility of a patent prorogation, the European courts – the European Court of Justice (ECJ) and the ECtHR – have a fair amount of experience on the application of the balancing and weighing test. Proportionality as a general principle of law within the ECJ has been developed in the *Fedesa*¹³⁵ and *Alpine Invest*¹³⁶ cases. Although the concept of proportionality is not specifically mentioned in the text of the ECHR, the jurisprudence of the ECHR has also used it when balancing opposing fundamental rights, as for instance in cases like *Sheffield and Horsham*,¹³⁷ and *Maurice*.¹³⁸ Therefore, the European courts will have a central role in fulfilling the term ‘efficacy’ through a case-by-case analysis.

This proposal is bold and ambitious, and will probably raise criticism. One might question the validity of selecting the Indian legal system as a source of inspiration for a European legislation. How can a developing country, with much less experience and knowledge about intellectual property and human rights, be an example to a country with a legal framework much more mature in both areas? India only has patents on product innovations since 2005 and many Indian practices are known to jeopardize human rights.¹³⁹ Although this might be a legitimate concern, the truth is that India faced the problem of ever-greening and, like no other legislation in the world, found a direct legislative answer to it.

¹³⁵ Case 331/88, *Fedesa and Others* [1990] ECR I-4023

¹³⁶ Case 384/93, *Alpine Investments* [1995] ECR I-1141

¹³⁷ Applications nos. 22885/93, 23390/94, *Sheffield and Horsham v. United Kingdom* [1998]

¹³⁸ Application no. 11810/03, *Maurice v. France* [2005]

¹³⁹ Just think about ‘untouchables’; although the Indian Constitution contains special provisions dealing with the abolition of the ‘untouchables’, namely Article 17, this remains a major social problem.

One might also criticize this proposal saying that it is naïf to consider that Section 3(d)'s focus is to provide medicines at affordable prices all over the world, since its sole goal is to defend the interests of Indian generic companies. Even if the Indian legislator only had the selfish aim to protect India's industry and economic growth, the truth is that Section 3(d) ultimately protects human rights and promotes the collective well-being.

And finally others might say that we are not at the height of the debate regarding unitary patents since it has been widely discussed for the last fourteen years without visible measures being taken. Even if it might be so, the truth is that when the right time to introduce amendments on the EPC comes, the debate has already been settled.

The aim of this paper is not to definitively determine which is the right or wrong way to face the ever-greening problem and to balance intellectual property rights with the rights to life and health. By no means are these issues exhaustive. All it seeks is to raise awareness to the problem and to unfurl the discussion, not merely in theory but also in practice.

VI. CONCLUSION

Patents assume a key role in the pharmaceutical sector, as they allow the MNCs to recoup and be rewarded for their often considerable investments on innovative efforts, thus granting access to medicines. However, limits must be imposed when the MNCs adopt strategies such as ever-greening patents to ensure continued revenue streams for their inventions.

The balance between the rights to life and health and the right to pharmaceutical patents does not have a straightforward solution, being necessary to adopt a case-by-case approach. The prorogation of the patent monopoly through ever-greening coupled with high prices of brand name drugs, result on the denial of the best treatment for people. The introduction of generic drugs immediately after patent expiration, without unnecessary delays, appears to be the solution for the promotion of general access to medicines at affordable prices.

The *Novartis* case is a clear-cut example of this problem. In our view, the High Court reached the right decision, even though it left space for a stronger argumentation. It would be surprising if the Indian Supreme Court did not base its rationale on the well-known proportionality test. This test will inevitably entail a human rights approach to the analysis of intellectual property rights.

If the Supreme Court does not adopt a pro-human rights position, its ruling will have a drastic impact not only on India, but also in a number of other countries which do not have the capacity to manufacture drugs themselves and depend on India's generics industry.

In a period of financial crisis in the Western world, the need to improve generics production is not only a topical issue of developing countries but also a concern felt within the EU territory. On the one hand, EU policy must boost valuable innovation and support competitiveness of the pharmaceutical industry, and on the other ensure an effective protection of the human rights to life and health. For this reason, ever-greening patents which delay the entry of generics into the market must be avoided. An audacious – but feasible – solution is to introduce an exception to patentability in Article 53 of the ECP, similar to Section 3(d) of the Indian Patent Act.

At the end of this diversified journey to search for the equilibrium between pharmaceutical patents and access to medicines at affordable prices, the importance of a human rights approach to intellectual property is easily perceived.

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