

1 INTERACTION BETWEEN PATENT PROTECTION AND ACCESS TO ESSENTIAL MEDICINES - THE POTENTIAL CONFLICT BETWEEN RIGHTS TO HEALTH AND PROPERTY RIGHTS

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ABSTRACT

In many human rights treaties and national constitutions, health and property rights are considered fundamental rights. As a manifestation of such rights, access to essential medicines must be taken into consideration, along with the right of the patentee who generated them. As there is no express hierarchy of such rights, it is necessary to seek to harmonize them with the aim of achieving two objectives: (1) health protection; and (2) new and better medicines for the treatment of diseases. This article will analyse several approaches pursued in different jurisdictions and recommend the best approach for achieving these objectives. Among possible solutions, it will adhere to the 'essential content of rights'.

Keywords: *Patents, essential medicines, compulsory licence, principle of proportionality, and rule of law*

I. INTRODUCTION

The issue to be addressed in this article is complex. The intention is to provide grounds for a fair and balanced solution to the potential conflict which may arise from the interaction between patents and access to essential medicines.¹ This article seeks to demarcate the content of each of those rights, highlight the circumstances under which a conflict may arise, and address the proportionality judgment as a proposed solution. It briefly structures the main premises and conclusions and considers the Brazil case in further detail. Ultimately, it advocates

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¹ Frederick M Abbot, 'Intellectual Property and Public Health: Meeting the Challenge of Sustainability' (2011) Global Health Programme, Working Paper n 7 (The Graduate Institute, Geneva, Global Health Programme) 7; Alynna C Smith, 'Intellectual Property Rights and the Right to Health: Considering the Case of Access to Medicines' in Christian Lenk, Nils Hoppe and Roberto Andorno (eds), *Ethics and Law of Intellectual Property. Current Problems in Politics, Science and Technology* (Ashgate 2009) 47 at 62.

harmonization of rights that is very close to the principle of proportionality.

The issue is part of a more extensive debate. For many years in the academic world there have been strong adherents in favour of the coexistence of intellectual property and human rights.² Two perspectives have existed side by side: on the one hand, some academics advocate a conflicting coexistence, which emphasizes the negative impacts of intellectual property on rights such as freedom of speech, health, safety or education; on the other hand, others are proponents of a model that establishes an equilibrium or synchronized coexistence between both types of rights. In my view, the latter perspective will gain more relevance in the coming years.

Far from formulating a complete conclusion, the analysis in this article must be supplemented with additional issues related to this subject, such as the effectiveness of the patents system as an instrument of innovation, the political and economic management and distribution of expenses in those countries that require such medicines, the global allocation of funds in science and technology, and the functioning of the sanitary system as a whole. Additionally, particular consideration must be given to the cost-effectiveness ratio of treatments, the interaction between innovation, intellectual property, and sanitary regulation, and the effectiveness of local and international court systems. Any change in the above elements or subsystems will have a bearing on the solution to either the problem as a whole or a specific case, respectively.

Then, when reflecting on a specific instance, a resolution system of the apparent dispute must be applied. The author of this article stresses the idea of 'apparent' as he asserts that rights are inherently complementary or collaborative among themselves. The reasonableness analysis is the best system to achieve a harmonization of rights. Far from a theoretical or abstract proposal, the factual assumption must be analysed. These are the grounds upon which a specific case should be approached, such as the compulsory licence for Efavirenz, which was ordered by the Brazilian Government.

II. SETTING OUT THE PROBLEM - PREMISES AND KEY FACTORS

The following are some basic premises upon which this article relies:

² Willem Grosheide, *Intellectual Property and Human Rights. A Paradox* (CIER-Edward Elgar Publishing Limited 2010).

(a) Health and life are fundamental rights entrenched in constitutions and international human rights treaties.³

(b) Intellectual property has been recognized in international instruments and is also included in fundamental rights and guarantees. In some cases, recognition is specific and in others it is achieved by integrating property or estates.

(c) Occasionally, these two rights seem to be incompatible and there appears to be potential conflict between health and medical patents, whenever the availability of some medicine should be scarce due to an exclusive right or an extremely high price, thus rendering that medicine unaffordable.

(d) A solution-oriented method or system should be established by taking into consideration that the potential conflict between fundamental rights will be equally present in other ambits, aside from intellectual property rights.⁴

(e) A generic solution method should be established in national and international environments by considering that the potential conflict is equally present in other areas of intellectual property rights: copyright and the right to education, intellectual property rights and freedom of speech, patents and farmers' rights, freedom of speech and trademarks, copyright and consumers' rights, etc.⁵

(f) Consequently, the method or system could be similar to that utilized to resolve other conflicts between fundamental rights.

In keeping with this simplified reasoning, it is also worth noting the existence of a common good pertaining to the international community consisting of patients, medical doctors, sanitary agents, not-for-profit organizations, inventors and researchers,

governments, and manufacturers of generic drugs.⁶ The premises to be verified in that regard are:

(a) It can be established that both the health and creativity of all members of the community are basic human goods, in the sense that all members can have their own stake in them, with no regard to the extent to which those goods are used and enjoyed individually, regardless of their actual concrete existence here and now.⁷

(b) Human goods, as desirable values and grounded on the human condition, give rise to natural rights.⁸

(c) Members of the community have common shared interests. Thus, in both a national and international community, we believe that all members are entitled to life and health. That is why the common good will always be the driving force of any community, and the community as a whole will have its own common good.⁹

(d) In order to move on from this level of generality to operative conclusions, the relations, aims and property of that community, in particular, must be detailed.

(e) In the case under analysis, it is possible to note that there is an international community of patients and inventors in need of each other.

⁶ Holger Hestermeyer, *Human Rights and the WTO – The Case of Patents and Access to Medicines* (Oxford University Press 2007). Common good can be sustained beyond conflicts of interests among the parties involved. As stated by Abbot, 'There is an inherent logic in the position of the OECD governments and originator companies, and there is a reasonable justification for developing countries and their local industries to oppose that logic. The consequence is a continuing struggle for an equilibrium point at which the originator multinational companies are earning an adequate return on investment, while developing countries have access to medicines at prices that are reasonably affordable.' Frederick M Abbot, 'Intellectual Property and Public Health – Meeting the Challenge of Sustainability' 14.

⁷ John Finnis, *Natural Law and Natural Rights* (Clarendon Press Oxford 1980) Chs 1-2.

⁸ Javier Hervada, *Introducción crítica al derecho natural* (Universidad de Piura 1ª Ed Peruana 1999).

⁹ The common good of a community, in particular, is outlined in TRIPS Article 7:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

³ The terms 'fundamental rights', 'constitutional guarantees' or 'human rights' are not equivalents. They are to be distinguished based on the theoretical background supporting them, their field of application, and their effectiveness. However, I will refer to them interchangeably in this paper.

⁴ Virgilio Afonso da Silva, 'Comparing the Incommensurable: Constitutional Principles, Balancing and Rational Decision' (2011) Vol 31 n 2 OJLS 273, 274.

⁵ Jakob Cornides, 'Human Rights and Intellectual Property – Conflict or Convergence?' (2004), *Journal of World Intellectual Property* 7.2, 135.

The following, therefore, contain some general propositions that will both activate consensus and serve as a starting point to seek a solution for the potential conflict:

- (a) A patient's health through access to medicines is a positive thing that is suitable for every human being.
- (b) Access to medicines must be prioritized.
- (c) Diseases or death that may be attributed to limited access to required medicines must be avoided.
- (d) The supply of medicine to a patient in need is a valuable action.
- (e) The search for new and better medicines must be promoted.
- (f) Those who benefit society with better medicines, through their effort or investment, deserve an award.
- (g) Those who have invested time, effort and capital to obtain new property cannot be deprived of such property without fair compensation.

Broadly speaking, it could be asserted that there are no clashes, but rather the common good is manifested through coexisting and complementary rights. In all societies, the authority exercises distribution of common goods and assigns rights through norms, some of which are principles and others are rules. The former are deontological judgments, lacking the required precision to command, prohibit, or allow the conduct of agents with respect to others. That is the reason why principles will then have to be established by enacting proper rules assigning specific rights to their beneficiaries, including provisions as to who has the duty to give certain objects to others or else refrain from engaging in certain conduct.

Consequently, rights must be enunciated by specifying three concepts: an obligee, a beneficiary, and the action that must be undertaken, prohibited, or allowed.¹⁰ To understand the full right to health or how the right to patents is made effective, the provisions of international treaties or national laws are to be observed. If there is no consistency between enunciations and normative purposes, or in the absence of regulations that attribute rights or

impose duties, there needs to be a mechanism to remedy such a defect or omission in the legal regime.

Therefore, Article 8 from the TRIPS Agreement stipulates the following:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

However, the wording of the Article does not allow inferring what those necessary measurements are or what is compatible with the TRIPS Agreement.

The same applies to paragraph (1) of Section 25 of the Universal Declaration of Human Rights:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.

Similarly, the Constitution of the World Health Organization (WHO), enacted in 1946, stipulates the following:

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

These principles lead to natural questions: are these rights negative or affirmative rights, that is to say, is a specific conduct required or is it aimed at preventing interferences? Against whom can these rights be enforced? Are there affirmative conducts demanded, and if so, what are they?

In order to address these questions, some key notions must be established. First, it must be made clear that the State is the first passive subject in the obligation derived from right to health. As the patient is a member of a community, the community must ensure the right to life and health of each and all of its members. It is only indirectly that such an obligation affects individuals, either arising out of a contract with the patient (social security), or from a

¹⁰ This is the overall conception of Hohfeld's rights. WN Hohfeld, *Fundamental Legal Conceptions* (New Haven 1919).

delegation of a duty made primarily upon an organized community.¹¹

Consequently, pharmaceutical companies are not the subjects bound to fulfil the duty derived from the right to medicine. Their duty is to make medicines available in terms of quantity and quality, and to ensure that they are otherwise harmless and meet statutory requirements, which may include a duty to refrain from setting abusive prices.

The right of the patent holder, as already stated, is also considered a fundamental right. In other words, the same right is asserted in Article 17 of the Universal Declaration of Human Rights:

(1) Everyone has the right to own property alone, as well as in association with others [and] (2) [n]o one shall be arbitrarily deprived of his property.

Additionally, Article 27, paragraph (2) states:

Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author.

These rights were subsequently embodied in the International Covenant on Economic, Social and Cultural Rights:

¹¹ Even though the existence of a global community can be considered, and even if patients can be treated as its members, such community is not bound to ensure the right to health. An ethical mandate does not entail, per se, sufficient grounds to a claim under the law. That is the reason why the main player under a duty to provide health is still the state, this being conceived as a community to which the patient belongs. With regard to the existence of a global community but with obligations at a national level, Taubman's words are particularly useful:

This is because the extent to which the 'world's welfare' is influenced by international IP standards ultimately can only depend on choices and actions taken at the municipal level, under domestic laws and legal measures that apply and operationalize more abstract and remote international standards, and in so doing mediate and interpret them, in such a way that either delivers or denies the 'articulated standard of welfare.' Antony S Taubman, 'TRIPS Jurisprudence in the Balance: Between the Realist Defence of Policy Space and a Shared Utilitarian Ethic,' in Christian Lenk, Nils Hoppe and Roberto Andorno (eds), *Ethics and Law of Intellectual Property. Current Problems in Politics, Science and Technology* (Ashgate 2009) 117.

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

(a) [t]o take part in cultural life; (b) [t]o enjoy the benefits of scientific progress and its applications; [and] (c) [t]o benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

These rights, stated in the form of principles—not rules—must be harmonized with others. In this sense, Article XIII of the American Declaration of the Rights and Duties of Man establishes:

[r]ights to the [b]enefits of [c]ulture: [e]very person has the right to take part in the cultural life of the community, to enjoy the arts, and to participate in the benefits that result from intellectual progress, especially scientific discoveries.

He likewise has the right to the protection of his moral and material interests as regards his inventions or any literary, scientific or artistic works of which he is the author.'

From the perspective of a patent as a proprietary right, some key aspects have to be determined. Is intellectual property a human right? Do all intellectual property rights have the same hierarchy or rank? Is the right to patent a human right? Can they be considered absolute rights, even to the detriment of other needs in society? Can a company be a holder of human rights? Are pharmaceutical companies holders of human rights?

We can also establish that property, being in itself a right, is subjected to the restrictions imposed at the time it is granted and those derived by applicable legal rules. In my view, then, the right to property would not be affected if the patent is not granted by virtue of legislation that was duly enacted and does not result from arbitrariness. Still, a human right to property (or a fundamental guarantee) could be invoked if a patent holder is unjustly deprived of his own property or full enjoyment of that property, or, if the patent is not granted, because of an arbitrary decision.

These premises are applied to medical patents. This is mainly because investment in research and development with a view to future returns generates an expectation to earn compensation. Undoubtedly in all legal systems such investment is property. And

this is because it is largely the way in which our global society has decided to assign resources to award innovation in medicine. Such pressures apply with more force in the scientific and industrial sectors because the market failures in the generation of information are much more evident. Rapid and easy imitation of products is not comparable to the extensive, costly, and high risk activity involved in researching new products and launching them on the market for the first time.

III. SOLUTIONS AVAILABLE

The attempt to solve the potential conflicts between fundamental rights is not new. In some countries, rights or privileged freedoms are ordered into a hierarchy. Other countries, in turn, resort to a balancing test. Some legal experts and courts favour the application of the theory of external limits.

In European case law, the proportionality principle, which originated in the German Federal Court, is utilized.¹² These are all methods that intend to achieve objectivity or rationality in a decision that resolves conflicting rights, values or principles. The intention is to safeguard the rule of law and the principle of due process.¹³

Undoubtedly, this type of mechanism must be applied to the conflict to which we have referred. Some authors even consider that the so-called three-step rule test is a concrete application of the proportionality principle to the conflicts involved in intellectual property rights.¹⁴

As part of this search, the author is more in favour of the solution provided by legal experts on the essential content of rights.¹⁵ This involves, first of all,

¹² Tor-Inge Harbo, 'The Function of the Proportionality Principle in EU Law' (2010) *European Law Journal* Vol 16 n 2, 158.

¹³ Laurence R Helfer, 'The New Innovation Frontier? Intellectual Property and the European Courts of Human Rights' in Paul LC Torremans (ed) *Intellectual Property and Human Rights* (Kluwer Law International 2nd Edition 2008) 25.

¹⁴ Christophe Geiger, 'The Constitutional Dimension of Intellectual Property' in Paul LC Torremans (ed) *Intellectual Property and Human Rights* (Kluwer Law International 2nd Edition 2008) 101 at 131; see also H Grosse Ruse-Khan 'Proportionality and Balancing within the Objectives for Intellectual Property Protection' 161.

¹⁵ In this respect, see Fernando Toller, 'Resolución de los conflictos entre derechos fundamentales, una metodología de interpretación constitucional alternativa a la Jerarquización y el Balancing Test' in Eduardo Ferrer MacGregor (ed) *Interpretación Constitucional* Vol II (Editorial Porrúa 2005) 1199. See also Pedro Serna Bermúdez and Fernando Toller, *La interpretación constitucional de los*

demarcating the material and formal aspect of each right. Then, an assessment on the facts must be undertaken, so as to determine which right is at stake in the case under analysis. This amounts to analysing each situation individually. Just like the case of the proportionality principle and the reasonableness judgment, the specific case must always be borne in mind. Thus, it will be necessary to determine at least the following elements of each right at stake:

(a) For what purpose or purposes may the State suspend or else limit the right of the patent holder and the right of the owner to uncontestedly preserve their proprietary interests or receive the payment requested?

(b) Who is the holder of each right (the clash will be between the government, which wants to favour a group of patients and the holder of the essential medicine)?

(c) Who must observe or enforce such right, or, who is the subject under duty to fulfil certain conducts in relation to the other subject and vice versa?

(d) What are the sense, scope, and conditions for the exercise of each of those rights, including time and other circumstances and conditions for its enforcement?

(e) Under what conditions does the holder of the intellectual property right lose entitlement thereof, and what are the conditions for the lawful exercise of each of those rights through the causes of action stated in the claim?

(f) What are the powers and faculties enjoyed by the holder in case of infringement by the subject under a duty to comply with the State, and in case of breach by the government, what are the powers of the patent holder?

(g) Finally, which freedoms and rights are to be enjoyed by the patent holder claiming such right?

derechos fundamentales: una alternativa a los conflictos de derechos (La Ley 2000); Juan Cianciardo, 'El ejercicio regular de los derechos: análisis y crítica del conflictivismo' (Ad-hoc 2007); Juan Cianciardo, *El principio de razonabilidad: del debido proceso sustantivo al moderno juicio de proporcionalidad* 2a. ed. (Ábaco 2009); Juan Cianciardo, *Principio de proporcionalidad y concepto de derecho: una aproximación desde las tesis del positivismo jurídico* (Ad-Hoc 2009).

These questions emerge when a rule is being challenged, be it specific or hypothetical. As an illustration, a hypothetical rule could be: 'Given the scarcity of necessary doses to suit the needs of a population, and as it is a patented drug and with no therapeutical substitute, the State shall apply a compulsory licence, by allowing third party suppliers to ease the required production, thereby disregarding the patent or paying a royalty.' If that were the rule, where there is a possible factual occurrence and a legal consequence arising therefrom, the judge should consider the following:

- (a) Does the rule have a constitutionally socially relevant purpose?
- (b) Is there an adequate relationship between means and the purpose sought?
- (c) Are these prescriptions necessarily required?
- (d) Is there a reasonable proportion between the results and the impediments reached through such prescriptions?
- (e) Is the essential content of the right respected?
- (f) Is the content included within the reasonable functioning sphere of such right?

The hypothetical rule presented is therefore precise, but drafted in an abstract sense. However, specific cases naturally go hand in hand with their own exclusive facts. The aim is to analyse a solution of justice for the event occurring here and now, and this includes adjectival circumstances and the procedures sought. The rule created herein will be contrasted systematically with the whole legal regime, including international treaties subscribed by the State, the relevant constitution, and constitutional guarantees, statutory rules, etc.

Thus, the rule must make provisions for a country in particular, the precise pathology, the alternative methods, the substitute products, the functioning of the sanitary system of that specific community, the price within a contained economic system, the number of affected patients, the specific epidemic situation, etc. If justice, in its typical sense, consists of giving each his due, we must specify what we mean by 'each' i.e. who is the one that gives, and who receives? And further, what is given and received, and what is actually 'due'?

One way of illustrating the application of the essential content of rights could be the case of compulsory licences granted in accordance with TRIPS Article 3 or pursuant to paragraph 6 of the

subsequent Declaration on the TRIPS Agreement and Public Health. This article will analyse cases in which a compulsory licence is a solution in keeping with the standards for a case in particular, as explained above.¹⁶

IV. COMPULSORY LICENCES

In this final section, the author attempts to apply the concepts formerly outlined in a case of compulsory licence that occurred in Brazil. The case of compulsory licence was selected, for it consists of a device designed in such a way that the rights of the patent holder can be suspended in the event of an emergency, consistent with the needs of the population.¹⁷

The relevance of this case is rooted in the peculiar situation encountered in Brazil. On the one hand, this is a country with a remarkable level of economic development and a large population. On the other, it has its own capacity for the production of medicines and a well defined position in international forums, where intellectual property is negotiated.¹⁸

During the 1980s and 1990s, several social organizations, including groups representing persons infected with HIV, based their petitions on the Constitution to claim free access to retroviral medicine. They also claimed these had to be produced by the state. As part of their claim, they

¹⁶ Nuno Pires de Carvalho has, so far, concluded that a mistake has been made in granting compulsory licences, either because of the reasons given, or because of the low compensation established or the failure to specify a beneficiary. Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* 3rd Edn (Kluwer Law International 2010) 227, 425, 426.

¹⁷ Under Article 31 of the TRIPS Agreement and the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001. For an analysis of the background of this Declaration, as stipulated in Javier Nuñez, 'Acuerdo sobre los ADPIC y Salud Pública. Evolución de la cuestión en la Organización Mundial de Comercio y la posición asumida por la República Argentina en las negociaciones' in Gustavo Schötz (ed.), *Patentes y Medicinas Esenciales* (Heliasta 2013).

¹⁸ These characteristics are the main sources of concern for multinational companies, especially when the need for compulsory licences emerges. 'Despite the way this issue has been featured in the press, the drug companies are not worried about a poor country overriding patents to meet an internal public health emergency. The concern is over the potential to legalize intellectual property theft in places such as India and Brazil, where low-cost manufacturers would exploit wider latitude to produce knock-off drugs for export.' Sidney Taurel, 'The Campaign against Innovation' in Michael A Santoro and Thomas M Gorrie (eds), *Ethics and the Pharmaceutical Industry* (Cambridge University Press 2005), 326, 327.

contended that compulsory licences had to be applied, if necessary, by limiting the rights of pharmaceutical companies in relation to certain products.¹⁹

Efavirenz, under the trade name Stocrin®, is an antiretroviral (ARV) drug produced by Merck, Sharp & Dohme (MSD), for the treatment of HIV, which facilitates once daily dosing. In 2003 the Ministry of Health of Brazil began negotiations with the laboratories aimed at obtaining better prices. During a specific phase of the negotiation process, the Ministry of Health of Brazil threatened to implement compulsory licences for Merck's ARV. The compulsory licence granting process was activated after the medicine was declared of public interest. MSD had a seven-day term to make a pronouncement, after which it made an offer of US\$ 1.10 per pill. The offer was rejected by the government, which granted the compulsory Efavirenz licence. An initial term of five years was established, which could in turn be extended for an additional five years.

Royalties were fixed at 1.5 per cent over the prices to be paid by the Ministry of Health of Brazil to importers or local manufacturers. Medicines subject to compulsory licences cannot be traded, but only purchased and distributed by the Ministry of Health of Brazil for the sanitary assistance of populations infected with HIV/AIDS.²⁰ As stipulated by such

¹⁹ The strategy of compulsory licences in Brazil is strengthened by the capacity that the country has to produce a generic drug, thus creating a run on the resources that poorer countries may have access to, and which exclusively depend on imports. As stated by Laurence R Hefner and Graeme W Austen in *Human Rights and Intellectual Property: Mapping the Global Interface* 130-131. Also in WCV Rodrigues and O Soler, 'Licença compulsória do efavirenz no Brasil em 2007: contextualização' (2009) *Rev Panam Salud Publica* 26(6) 553. Aspects of the political debate can be found in W Flanagan and G Whiteman, 'AIDS is Not a Business – Study in Global Corporate Responsibility – Securing Access to Low-Cost HIV Medicines' 70.

²⁰ The Executive Order allows both local manufacturing and imports from countries with no patent protection. Those in favour of the decision considered that innovation would not be affected, since sales of developing countries only account for 11 per cent of worldwide sales of pharmaceutical companies, and Latin America only accounts for 4 per cent of such sales. It is estimated that companies will not refrain from investing due to losing part of their sales in these markets. But it is also true that Brazil represents one of the ten major countries worldwide in the field of medicines, as stated in Gabriela Costa Chaves, 'Perguntas e respostas sobre o licenciamento compulsório do medicamento Efavirenz no Brasil' (2007) Associação Brasileira Interdisciplinar de AIDS (ABIA) paragraph 12; Fernando Lopes Ferraz Elias, 'Patente de medicamento: a questão do licenciamento compulsório do Efavirenz'

provisions, at least one of the following necessary conditions for the grant of a compulsory licence would have to be met: abuse, public necessity or national emergency.²¹

The other aspect to be considered is the time period: this must be precise and appropriate for the circumstances of a given case. Granting a compulsory licence until the termination of the patent implies depriving it of its content, as stipulated in Articles 31(a) and (c) of the TRIPS Agreement.

In the case under analysis, the time period was five years, which was later extended for an additional five-year period. Besides, as the government delivered the medicine under a compulsory licence scheme to the entire population, the market for such medicine ceases to exist for the patent holder.

In the reasonableness judgment, a question arises first whether the political measure of the Brazilian Government fulfilled a constitutional and socially relevant purpose. This was undoubtedly the case, as it is necessary to cater for the health of the population affected.

Then, the political decision is also appropriate when it comes to the ratio between means and the purpose sought, as the purpose originally envisaged by the governor or legislator is achieved. Indeed, by achieving a reduction of prices there are more chances to achieve the universal treatment of affected patients.

http://www.cedin.com.br/revistaeletronica/volume4/arguivos_pdf/sumario/art_v4_XII.pdf

²¹ In all cases in which a compulsory licence was granted, the parties first had to attempt to obtain a voluntary licence (Section 31 of the TRIPS Agreement). This requirement was apparently met by the Brazilian Government, which made a specific petition: the price paid by Thailand. According to Pires de Carvalho, the Brazilian Government indicated that the licence was granted by virtue of its public and non-commercial use. In truth, the requirement would have sufficed, so as to avoid preliminary negotiations (TRIPS Article 31.(b)). The Government received an offer by MSD that it approved. Pires de Carvalho, *The TRIPS Regime of Patent Rights*, 445. The Brazilian policy brought about significant changes in access to retrovirals. Savings are said to amount to US\$400 million a year, through a reduction of prices. This information is provided by Sigrid Sterckx, 'Lack of Access to Essential Drugs: a Story of Continuing Global Failure, with Particular Attention to the Role of Patents' in Christian Lenk, Nils Hoppe and Roberto Andorno (eds), *Ethics and Law of Intellectual Property - Current Problems in Politics, Science and Technology* (Ashgate 2009) 175, 177.

Third, it must be verified whether those prescriptions are necessarily required or not, and whether those are the only method available to such an end. The answer is not so simple in this case. The state has undertaken to provide a system-wide sanitary coverage. To this end, estimates need to be made in keeping with the budget and resources available. Considering the terms under which the government sets out the requirement, there are apparently no resources for the purchase of medicines, when, in fact, the core of the argument concerns the savings obtained. The situation of Brazil seems to be totally different from that of African countries, or even the case of Thailand, a country chosen as a benchmark by the Ministry of Health of Brazil.

Ultimately, the means utilized should be the one that least undermines the rights of other players involved and is the least detrimental. This last aspect is not easy to evaluate in a litigation process. The way a government administers its resources is not subject to revision by the courts. In developing countries where there is a significant need for education, security, health, housing and the like, health expenses compete against the appropriation of resources. In poorer countries, the combination of needs and interests will be a different one. After all, priorities are not to be ascertained by judges, as the task of distribution is not inherent to them, but to the other powers of the State.²²

The work that is within the scope of the judge or court is to ensure that there is no infringement of a right that was originally granted. In that case, the right of a patent holder to receive compensation is contested.²³ In this respect, the author's opinion is

²² The appropriation of resources is a very complex task. Budgetary allocations must be jointly conducted by the executive and judicial branches. It is not an action that, in principle, should be in the hands of the judiciary. Still, if a right has been granted, and a budgetary allocation is required for its exercise or enjoyment, a judge can step in to enforce such performance against other branches of government, either individually or collectively. Such was the holding of the Argentine Supreme Court in *Hospital Británico de Buenos Aires c/ Estado Nacional (Ministerio de Salud y Acción Social)*. 13/03/2001. Fallos 324:754. See also 300:1282; 301:771; 251:53; 'Ramos, Marta Roxana y otros c/ Buenos Aires, Provincia de y otros s/ amparo' 12/03/2002, Fallos 325:396.

²³ Although Flanagan and Whiteman state that granting the compulsory licence was due to the abuse on the part of MSD, I have not found any debate or grounds being raised by the Brazilian Government to support such a position. According to Flanagan and Whiteman in 'AIDS is Not a Business: A Study in Global Corporate Responsibility – Securing Access to Low-cost HIV Medications' (2007) in *Journal of Business Ethics* 73: 65, what was actually being challenged here is a 'necessary' savings to suit customers'

negative. Saving is not a sufficient motive to violate a right. Invoking necessity is simply not enough; rather, a well grounded argument process is required.²⁴

The fourth question that arises is whether the decision is proportionate, that is, whether there is a sound balance between the results derived from the prescription and the impediments thereby obtained. In this respect, the aim is to determine whether this is the best solution, rather than the only one. The intended purpose is assisting a universe of patients who are under the wing of the State. What is being prevented is profiting from the patent in an economic sense, except for the limited royalty earned by the compulsory licence. MSD is prevented from selling its product directly. If the government catered for the needs of all the population for free, there would be no market available, whatever the price may be.²⁵

needs. Such was the action undertaken by the Ministry of Health, when considering that the success of the anti-AIDS campaign had many advantages from the point of view of low morbidity of patients. Further, the overall outcome has been a positive economic result. As stated in the Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property Rights and Development Policy* (London 2002 <<http://www.iprcommission.org>>), 42:

So, although the NSAP is expensive, the costs avoided due to reduced illness, hospitalization and other impacts of HIV/AIDS are beginning to balance the budget. The MHB estimates that in 2001, the final cost of NSAP, incorporating reduced morbidity expenditure, was negative.

²⁴ The professional literature that usually justifies the application of a compulsory licence focusses on the lack of economic capacity to assist patients, as stated in Hestermeyer, *Human Rights and the WTO – The Case of Patents and Access to Medicines*, 138. That was not the case in Brazil. Comparing the prices of generic drugs with the original drugs, without considering the cost of development and without assuming the external nature of the research, is a clearly insufficient comparison and derived from a political discourse. The other aspect to be considered is the distinction between discretionary powers and arbitrariness, but that topic goes beyond the purpose of this paper.

²⁵ In the absence of sales, the 1.5 per cent royalty is not proportionate. There is a wide gap between the usual maximum royalty for voluntary licences in this field, which is closer to 15 per cent and the government proposal. The parties could have also raised the issue of calculating the royalty. By considering the few existing cases of compulsory licences, 1.5 per cent is too low and does not meet the standard of TRIPS Article 31(h), which stipulates that the 'economic value of the authorization' must be considered. See Hestermeyer, *Human Rights and the WTO – The Case of Patents and Access to Medicines*, 247.

The fifth aspect to be addressed is whether the political measure respects the essential content of the right. In that case, the intellectual property of the patent holder is at stake. Although compulsory licences potentially limit the right of the holder to commence operations, a fair compensation must be awarded.

Lastly, it is worth asking whether the measure is to be included within the reasonable operative sphere of such right. This refers to the right of the government to claim a given price or else allow for the manufacturing or importation by third parties that can meet this budgetary demand. The government's duty to provide free assistance to patients is not being challenged, but achieving the goals of the sanitary policy does ultimately affect the right to property. Needless to say, the state has its own discretionary margin. The problem lies in finding the limit without allowing for arbitrariness.

Ultimately, after applying a reasonableness analysis, the author's opinion is negative. The lack of an appropriate procedure and the reduced amount of the royalty are at the core of the discussion. Even more debatable and which typically belongs to the sovereign political power of Brazil, is the allocation of resources to health, particularly AIDS drugs, against hundreds of budgetary options for the distribution of honours, rank and wealth.

V. CONCLUSION: THE THREE-STEP RULE AS A MANIFESTATION OF THE ESSENTIAL CONTENT OF RIGHTS

The proportionality test that the author applied to the Efavirenz case, is generally thought to be made up of three steps:

- (a) The adaptation of the means chosen for the accomplishment of the aims sought;
- (b) the necessity to resort to these means for achieving the goal (i.e. ensuring that there are no other means conducive to that end and which may be less detrimental to potentially affected constitutional principles; and
- (c) the proportionality - in a strict sense - between the means and ends and that the principle satisfied by meeting such end will not sacrifice more important constitutional principles.

Both compulsory licences granted under Article 30 and other measures adopted by virtue of Article 8 of the TRIPS Agreement must be analysed as particular applications of the three-step rule or application of the proportionality judgment to the specific

problem.²⁶ As a conclusion, the author considers that, in the current state of economy of knowledge and productive and sanitary systems, patents are necessary for the better health of the population. However, it is evident that, given emergency situations, or in the absence of a market, patents can make it difficult to access medicines that derive from a system of global innovation. The absence of a market is particularly relevant in communities unable to afford those medicines, either during a specific crisis, or as a result of an endemic problem, particularly when incomes of the population to which medicines are addressed are recurrently low. The situation is more serious and its solution is not an easy one, especially when needed medicines are still being developed for diseases that currently have no cure. In the absence of a future market, the necessary investments are scarce to find a cure.

Compulsory licences imply a waiver to patents, at least during the persistence of a crisis. As this is a mechanism laid down in international agreements and local legislations, a solution derived from consensus can be found there, which may amount to the harmonization so vigorously intended. Although cases of application of the proportionality principle have not emerged so far, this would be the mechanism that should enable us to verify whether the compulsory licence has achieved a balance of rights in a given case. For that purpose, a case-by-case analysis must be undertaken, in order to determine whether the premises for regulation are present and whether fair compensation is provided.

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²⁶ Helfer, 'Intellectual Property and the European Court of Human Rights' 73.

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