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Intellectual Property Rights and Health Rights: A Feasible Reform Proposal to Facilitate Access to Drugs in Developing Countries

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***Abstract*—**The non-effectiveness of certain codified human rights is particularly apparent with reference to the lack of access to essential drugs in developing countries, which represents a breach of the human right to receive adequate health assistance. This paper underlines the conflict and the legal contradictions between human rights, namely health rights, international Intellectual Property Rights, in particular patent law, as well as international trade law. The paper discusses the crucial links between R&D costs for innovation, patents and new medical drugs, with the goal of reformulating the hierarchies of priorities and of interests at stake in the international intellectual property (IP) law system. Different from what happens today, International patent law should be a legal instrument apt at rebalancing an axiological asymmetry between the (conflicting) needs at stake The core argument in the paper is the proposal of an alternative pathway, namely a feasible proposal for a patent law reform. IP laws tend to balance the benefits deriving from innovation with the costs of the provided monopoly, but since developing countries and industrialized countries are in completely different political and economic situations, it is necessary to (re)modulate such exchange according to the different needs. Based on this critical analysis, the paper puts forward a proposal, called Trading Time for Space (TTS), whereby a longer time for patent exclusive life in western countries (Time) is offered to the patent holder company, in exchange for the latter selling the medical drug at cost price in developing countries (Space). Accordingly, pharmaceutical companies should sell drugs in developing countries at the cost price, or alternatively grant a free license for the sale in such countries, without any royalties or fees. However, such social service shall be duly compensated. Therefore, the consideration for such a service shall be an extension of the temporal duration of the patent's exclusive in the country of origin that will compensate the reduced profits caused by the supply at the price cost in developing countries.

***Keywords*—**Global health, global justice, patent law reform, access to drugs.

I. Introduction

NOWADAYS, the right to access to medical drugs represents a specification of the human right to health [1], [2]. Indeed, it is well evident that the fulfillment of health rights involves access to drugs [3, p. 65, 66], [4, p. 7, 8], [5]. However, such a right seems to be in conflict with IP rights, in particular with the IP rights holder.

In this introduction, a preliminary legal philosophy discussion will be carried out on such a conflict, with particular regard to the conflict between the application of the human right to health and the practical outcomes of international patent law.

A legal contradiction is recognizable between human rights, in particular health rights, and international IP rights and international trade law. At first glance, the conflict between the intrinsic particularistic essence of economic factors and the universalistic character of human rights is evident [6, p. 118]. However, economics is not just a factual force that freely evolves; economics has a regulation in which players can act, even in the global market and in the international order. And, as it will be demonstrated in this paper, the economic interests of corporations with reference to access to essential drugs is today's first interest in the hierarchy of values, as established also through international law, in particular in the TRIPS Agreement [7], [8, p. 1050]. The TRIPS Agreement, in fact, is itself enough to cause the lack of access to generic advanced drugs [6, p. 27].

It is important to underline that medicines are the result of scientific research (so, by definition, inventive), followed by industrial Research and Development (R&D) activities and investments [9].

The cost for the development of a drug is indeed high, actually from its discovery/invention to its market authorization, it is a long, high-risk and very expensive process. Indeed, such development involves a series of processes and specific and well-regulated phases.

The average cost of such development is evaluated in 800 million Dollars. Taking into account such R&D costs, in order to-allegedly-encourage pharmaceutical industries, protecting them by competition, the international IP law system confers to such companies a monopoly, geographically and temporally extended, throughout the granting of patents. Concerning pharmaceutical products, however the stakeholders deserving protection are more than one: the inventor (broadly speaking, most of the time a University or a public research center), the pharmaceutical company that has increased the value of the invention, throughout the development and marketing of a product and, finally, the patients, so the population and the Countries which those populations belong to. The latter pole of interests, in the IP law systems chosen by most of the western countries, takes a minor place compared to the interest of pharmaceutical companies. In this framework, the above-mentioned formal and substantial contradiction arises: on the one hand, there is a universalizing trend that, with solemnity, enounces that health right is a human right:

"(1) *Everyone has the right to a standard of living*

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adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control. […]" and moreover "(1) [e]*veryone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits* […] [10].

In this same perspective, the right to health seems to be a universal human right also by taking into account the International Covenant on Economic, Social and Cultural Rights, that under Article 15 1 (c) states:

"*The States Parties to the present Covenant recognize the right of everyone: a. To take part in cultural life; b. To enjoy the benefits of scientific progress and its applications; c. To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author*." [11].

On the other hand, it is recognizable an intrinsically particularistic right to an economic approach by the single pharmaceutical company, which is considered as universal in international law (since it results self-executing and able to be effective), in the IP System (such as in the TRIPS Agreement), as well as in praxis. Such imbalance becomes very relevant (and morally relevant) in the case of essential drugs for endemic diseases in developing countries. Of the two, one: either the return of investments for pharmaceutical companies is explicitly declared as a universal right (with all the consequent antinomies and contradictions in the international order), or the hierarchy of the relevant stakeholders shall be urgently reexamined. The moral pressure deriving from the responsibility that each person and each institution has, according to Pogge's demonstrations, in order to reach the effectiveness of human rights [6, p. 49, 50], can be the starting point to obtain the reforms that are morally and legally necessary as a consequence of the contradictions in international and IP law. Patents are an institution that contain and relate to different interests at stake. However, the interest of the patient, of the "last user", appears to be lacking, or at least heavily minor. For the sake of clarity: patents provide the same regulation for mobile phones producers and for producers of inhibitors of retroviral proteins which inhibit HIV. Actually, to be precise, not even the same, but stronger for patents on drugs, since the owners can obtain an extension period for the retrieval of the clinical trial time period.

Patent law restricts *de facto* the access to drugs by conferring for twenty years to the holder the possibility to sell the pharmaceutical product in a monopoly regime [12, p. 297-300], [13], [14, p. 321] [15]-[19]. For this reason, it has been argued that health rights are fulfilled also by mean of the effective access to drugs [6, p. 53], [20], [21, p. 16]. Moreover, a violation of a human right made by a State triggers a series of legal consequences, not necessarily tied one to another, in the international community. The vagueness of such actions is a well-known problem in international law: such actions can be the most different, from reports, to inspections, to recommendations, to judgments, all depends on who the player is and which international institutions has been appealed. This can be explained with the fragmentation of international law, for which there is an overlapping of international institutions and therefore conflicts can arise among them. In international law sovereignty is represented by single legislative, judiciary and executive bodies with binding universal powers. Such fragmentation is even more recognizable with the presence of the so called soft law [3, p. 504]. Such uncertainty plays a relevant role in maintaining the *status quo*. However human rights exist in any case and are universally recognized. Therefore, in this argumentation legal and philosophical issues overlap conducing to a general uncertainty regarding the concrete applicability of human rights and in particular of health rights [21, p. 17], [22, p. 545].

In this regard, it can be observed that the universalization of human rights as such, does not necessarily conduce to their fulfillment or actualization. The right of the pharmaceutical companies to have profits worldwide [3, p. 504, 505] [8, p. 1066, 1067], [23] is not explained nor morally justified (it is justified through economic, theories that link innovation to patents [12], [24]). Even if such profits are *due* because of an asserted retrieval of R&D costs, such a need shall have to be balanced with the human right to health. In this sense, patents are a legal instrument that might conduct to a substantial injustice [22, p. 552 and ff.], [25, p. 26]. Patent law and its application shall be reformed because, involving different stakeholders, it is a potential instrument that could be used in order to obtain more equality between people in different countries. In this sense, international patent law could be an instrument able to stabilize symmetry (axiologically) between the conflicting needs at stake, reformulating the hierarchies of priorities.

II. Human Right to Health

By interpreting human rights ethically, the right to health [2] represents a moral necessity; however, the argumentation will follow on the effective extent of the right to health from a legal point of view. In this perspective, and in particular for the inclusion of the right to access to drugs within health right, it's important to refer to the General Comment No. 14, *The Right to the Highest Attainable Standard of Health* (art. 12), U.N. Doc. E/C.12/2000/4 (2000) (following, the Comment or the General Comment).

The Comment qualifies the scope of ICESCR's Article 12 and therefore of the right to health, recognizing it in its availability, accessibility and acceptability as well as of the health structures, goods (so including medical drugs) quality, services and programs, which must result available within the Country.

That said, it is interesting to see that the un-fulfillment of the right to health, and the lacking access to drugs can be connected to poverty of many populations [20]. The framework of this circumstance is a system of norms that does not balance the interest at stake of developing countries with

commercial interests.

III. Right to Health and IP Rights

A. Introduction of a Dichotomy: Inventor and Investor

Having analyzed the legal extent of human right to health, the relation between IP rights, and in particular patent law and regulations and human right to health will be examined in this paragraph [3, p. 91], [26], [27].

In order to better understand the relation between IP rights and health rights, an analysis of the interests at stake in patent law will be carried out. On the one hand there is the investor, that is the sponsor of the industrial development, on the other hand the final user, that is the consumer and more generally the society altogether. Patent law is born, at the beginning, to reward the inventor for its talent providing the exclusive regime, [4], [28]. However, patent law has, during the history, shifted the accent of the reward to the inventor in the direction to favor the investor. In this shift, a scission between the inventor and the investor arises: the protection of the inventor is sustained by the theories of IP as a natural right [28]-[31], the protection of the investor is sustained by economic theories for which the patent represents the best incentive for technological innovation [12, p. 294 and ff.]. It is well evident that theories of the second group have taken the first place and that the patent system, as it is today, protects the investor more than the inventor, by seeing the results of the regulation and the concrete circumstances of innovation processes. Then, IP law sustainers claim that the weak role of the final consumer and the problematic effects that arise from it, such as the lack of access to drugs protected by patent, is justified by the natural right of the inventor who has the right to receive a reward for its inventive effort.

Nowadays, given how the research and development proceeds, it is not the inventor that arrives to the industrial exploitation of a patentable invention. This is particularly true in the pharmaceutical field, given the amount of R&D costs needed in order to obtain the patent on the drug and the market authorization. In this perspective the inventor, such as the individual scientist, is no more considered the major stakeholder. Doctrine and Jurisprudence focalize on the investor's right to obtain a reward for the economic efforts that were needed to obtain the patentable product.

B. The Dichotomy: Right to Health and IP Rights

That said, what is even more at stake in the pharmaceutical field is the right to health of the final consumers. In other words, international patent law influences human right to health of patients that are the holders of a fundamental interest at stake. However, in the hierarchy of values of patent law patients are the lastly considered stakeholders.

Technological innovation has been recognized as a fundamental competitive factor in market globalization. Therefore, its protection through the grant of the patent exclusivity has become necessary for western companies. Actually, without such IP protection, companies could not ensure an adequate profit given the investments that are always larger in pharmaceutical field. This is the framework that has moved industrialized countries to settle TRIPS Agreement. Therefore, TRIPS Agreement has assumed a high political and strategic significance: in the TRIPS interpretation, the interests of economic and technological most developed countries prevail on others [32, p. 9-12].

Moreover, even if technological innovation and the advantage of companies have represented the goal to pursue, opinions that argue the possibility that the TRIPS Agreement can have some restraining effects on these same goals arise [33], besides, and in addition to, the effect of the worsening of the access to medical drugs matter.

It's also true that, in the analysis of the interests at stake, concretely realized and not, in international IP regulation and more specifically for what is here of interest (industrial patents), it can be observed that the detailed description that the inventor is obliged to make at the moment of the patent application represents an interest that can be considered collective [4, p. 16, 17]. Third parties are thus able to access to the "receipt" in order to reproduce or utilize the invention once the patent exclusivity expired or even to invent improvements on the preceding invention. Such an obligation on the patent holder has a double face: on the one hand, this rule protects the inventor, *rectius* the holder, since the latter will easily prove a patent infringement. On the other side, the collectivity is protected since it will have *free* access to innovation. Doctrine's opinion is to recognize that such an obligation is very important to discourage the industrial secret regime [14, p. 318 and ff.], [34].

As it has been observed ICESCR Article 15 (1) represents the balance between two interests at stake: the individual and the collective rights of all human beings to enjoy the benefits of scientific progress (as drugs) on the one side, and the author/inventor's right to benefit from the protection of moral and material interests resulting from the scientific production, on the other. Such Article recognizes moral interests of the inventor because of the identification with his/her creation, but, compared to human rights, such interest brings to inconsistency, since it is not at the same level of protected values [8, p. 1048], [23], [36, p. 412, 413, 416]. However, the letter of the Article does not confer to the inventor a monopoly on the invented product, as patent law does [36, p. 412, 413, 416]. In any case, today's science is no longer in a framework where the single scientist discovers by itself its innovations for which such a personal connection between inventor and product should be justified. Nowadays, the process of innovation is done by groups of scientists in universities or in public or private research institutes.

C. TRIPS Plus

Developing countries have recently gone under Western countries pressure in order to provide restrictive clauses in their national IP laws, even if not provided by TRIPS itself: this is the consequence of bilateral TRIPS *plus* Agreements. Countries do not have any international obligation in order to subscribe such agreements, however Brazil, China, Central America countries "had" to sign such commercial Agreements

with US and the European Union. Some of them consist in the extension of the patent duration over the twenty years term already provided by TRIPS, or in clauses that limit the competition for generic drugs. TRIPS *plus* is ineffective and inconsistent with human rights declarations and not symmetric between Western and Developing countries.

The TRIPS Agreement provides the "compulsory license" as an exceptional system in order to enable Developing countries to tackle health emergencies. Nevertheless, such system seems to be inadequate to this scope and very difficult for developing countries to apply [35, p. 75 and ff.].

The lack of balance between human rights and IP rights belonging to pharmaceutical companies is now clear. Such asymmetry is very likely due to a lack of balance between developing countries interests and those of industrialized ones [38]-[42, p. 352, 353].

D. Exhaustion Principle

In order to complete our view on the international IP rights regime, the exhaustion principle ought to be mentioned. Such principle describes the moment in which the patent holder loses the right to control the sale of its product under the protection of its patent. Once its right is exhausted, the patent holder can no more impede the commercialization of the patented product. In case of National Exhaustion regimes, the patent holder can stop the importation in case the first sale occurs in another State. Vice versa, in of the International Exhaustion regime, the commercialization of the product in another State conducts to the exhaustion of the holder rights also in its State. Such regime allows parallel imports in the territory, while National Exhaustion regimes do not and help the segregation of the markets [37, p. 129-149].

Thus, it is the adopted exhaustion regime that determines whether the patent holder still has its right to control the importation of such product, or not.

That said, in the Uruguay Round the exhaustion regimes has been one of the most controversial issues of the negotiations. Article 6 of TRIPS is neutral on the issue:

> "*For the purposes of dispute settlement under this Agreement, subject to the provision of Article 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights*".

Such provisions allow each Member State to decide for its own regime, stating an "*agreement to disagree*" [43]. The exhaustion principle is intrinsic to immaterial conception of IP and the States throughout international exhaustion can allow parallel importations of patented drugs.

Ituku [59, p. 378, 379] believes that TRIPS considers, on one hand, patent as an immaterial right, for example for their time limitation and because, differently from a *res*, a patent can be granted and used in several *different territories at the same time*; on the other hand, patents are characterized as material rights in the moment they are confused with the objects that incorporate them (*i.e.* pills) from which instead they should be independent. With such idea, countries can oppose to parallel importations against developing countries, by choosing a National Exhaustion regime. The justification is in Article 6 of TRIPS. Ituku believes that a strong conception of patents as immaterial goods, could enhance parallel importations and access to drugs [59, p. 378, 379].

IV. Trading Time for Space

A. Global Justice Problem

Given the conflict in international law between health rights and IP rights [3], [4], the need of a reform of the current patent system that takes into account all the interests at stake can be claimed.

The fulfillment of the right to health needs, in many cases, the effective access to drugs by the patient; but IP law restricts *de facto* such access, by granting for twenty years to the patent holder the possibility to sell the pharmaceutical product in a monopoly regime and in a free price settlement regime [12, p. 297-300], [13], [14, p. 321] [15]-[19]. Access to drugs represents in a legal philosophical perspective a Global Justice problem [27, p. 552 and ff.], because it includes the issue of distribution of essential goods for human life in the global territory and it is interested by international law and human rights (and also by TRIPS Agreement, we shall add). This is why a more equal balance of all interests at stake is required, even if a common definition of Global Justice does not yet exist.

B. TTS: The Proposal

A first distinction among the diverse reform proposals lies between pull and push incentives: the former is focused on the profit expectation of the innovation (based on the provision of prizes for the innovation itself), the latter on the contribution given to the R&D cost through direct financing [44].

TTS represents a pull scheme, in particular an alternative model of international patent system, according to which pharmaceutical companies should be obliged to sell drugs in developing Countries at cost price, or to grant a license to such countries for free, meaning without any royalty or fee. Such social service shall receive a pay-back consideration that shall be an extension of the temporal duration of the patent's exclusive in the Country of origin.

The lacking profits caused by the supply at the price cost in developing countries will be therefore compensated with an intervention in the relevant State, represented by an extension of the duration of the patent: thus, a precise economic value can indeed be assigned to each month or year of extension of the exclusivity, for example by considering a month or a year of sales volume (turnover) in the referential western markets under the exclusive regime.

The TTS scheme would be set up as a supplementary protection certificate linked to a social investment, established by the accessibility to drugs in least developed countries, avoiding that each government should decide with political acts, every time, to grant acts in order to improve access to drugs.

It can be also hypothesized to integrate the consideration for the supply of drugs at cost price in poorest countries with a favorable taxation regime in origin countries [45]; the cost of

this taxation discharge should be sustained by the community and it should be measured with the effective sustainability and also followed by the internal consensus of Developed Countries.

C. Two TTS Models

It is useful to point out that one of the possible limits to the effectiveness of the TTS scheme is represented by the fact that it could not be an efficient incentive to R&D for neglected diseases. Such diseases, by definition, do not have a relevant market in origin countries and would not be interesting to invest in for pharmaceutical companies.

In this regard, a "crossed" TTS scheme could be proposed, whereby the pay-back exchange for the sale-at-cost price of a drug in Developing Countries is the extension of the patent time in developed countries on a different pharmaceutical product, which shall be relevant for that market.

In this second TTS scheme, the problem of the lack of incentives for neglected diseases could be avoided.

At this point it can be hypothesized to distinguish the TTS proposal in two different cases:

1. The case in which the drug cures only developing countries diseases (i.e. a product with no relevant market in developed countries): in this case the model grants patent protection to different drugs belonging to the same company. This case will be called the *Case of neglected diseases*.
2. The case of drugs that cure diseases that are interesting also for developed countries market: in this case the extension shall be provided for the same drug that will have two different prices, as the drug is being sold both in industrialized and in developing countries. This case will be called the *General TTS case*.

1. The Case of Neglected Diseases

This first proposal has been hypothesized in order to answer to the possible comment that the TTS scheme does not incentivize innovation for neglected diseases that do not have a market in western countries, such as malaria.

The time extension needs to be linked to the sales at low price in developing countries (space): the company shall recover the R&D costs incurred to bring the drug for a neglected disease to the market, via the time extension of patent protection worldwide.

2. The General TTS Case

In this case it is necessary to provide a temporal extension of the patent for a drug sold in developed countries as a pay-back for the sales of the same product at cost price in poor countries.

V. Trying to Overcome the Conflict between IP Rights and Human Rights

Having examined the relation between the human right to health and IP rights and given the conflict between the goals pursued by these two different rights, some considerations aimed to overcome such antinomy will be given.

Authors such as Pogge, who believe that the *status quo* in health field is unjust and that there is a moral obligation on individuals to stop contributing to this injustice and to formulate reforms in order to improve it, are conscious that, while there should be a common definition of *Global Justice*, such a common definition does not exist in each different culture and traditions. It can be argued that access to drugs is certainly a Global Justice problem, since it involves international laws and human rights (and TRIPS Agreement for IP right regulations).

As it has been argued, human rights and, among them, in particular the right to health, in the way they are formulated, do not enjoy the historical effectiveness they should have [46, p. 79, 80].

Human right to health, in other words, is unfulfilled in some particular and concrete realities. This does not happen among individuals, but in the relation between institutions and individuals [6, p. 75]. The formal declaration of human rights tackles the above-described gap, although it only holds them far away from the concrete application. There are rights in conflict with the human rights declarations. The reference here is evidently with IP rights that enjoy a causal importance, given the grant of monopolies to pharmaceutical drugs patent holders, enabling the relevant companies to maintain high prices, unaffordable for the most.

In this perspective, there are, on the one side, human rights (which bring with them the debate on their nature and on their function, but this aspect is not dealt with here) [6, p. 75], [70, p. 58], [47]-[58] that are formally enunciated – and among them the right to health – and, on the other side, there are the IP rights which are born to protect the intellectual and talented work that could not be delinked from its inventor, but that nowadays appear to be the bearer of particularistic interests, in no way all embracing, on an axiological level.

Once it has been seen the rights in conflict and it has been ascertained the supremacy *de facto* of the second over the first, it will be argued how these two rights can coexist without being in conflict.

It is well evident that the matter discussed in this paper and that moves forward to look for new arguments, concerns the reason for which a universal international declaration is ineffective. It could be argued that as much a declaration is universally enounced, as less it will be fulfilled by international players and as less its effectiveness will be in the concrete reality. It could be argued that particularistic norms find more effectiveness because they are much closer to concrete circumstances, by definition.

In this sense, a proceeding method of international law could be one that first it *looks at each* case of violence, oppression, domain, lack of recognizing or discrimination or at each problem of access to essential goods, then it *individuates* the relevant causes (even if they are norms) that contribute to maintain such circumstances and only consequently *introduces* in practice and contingency the relevant *re-cognized* human right, from that moment in a pragmatic way [85, p. 122, 123]. *Re-cognized*, in the sense that it will be referred to an existing law (either it will be coming

from a Declaration or it will be considered a natural law), knowing that one can re-cognize only what is already known; normative and effective value is conferred only with the recognition act of the relevant corresponding right to the concrete need [59]. The recognition is the relational passage: in other words, if the key moment is the recognition of the need that corresponds to an unfulfilled human right, the international system will then realize the necessary actions in order to remove the causes of the non-fulfillment or of the violations of human rights. Such is the case of a situation of particular *need* or *unease* [46, p. 103], arisen in a particular *space* in a particular *moment*, to which a relevant fundamental human right will be tied, so that if this human right is concretely applied it could be able to solve said *need* [89].

In this paper, it has been argued that legal matters are analyzed from general issues to particular issues, as civil law orders evolve. If human rights are such, because they are recognized and codified by countries or International organizations, there will always be a gap between such abstract law and the real facts and situations. In this sense, it is very important to see the consequences upon minorities or indigenous rights [56, p. 122, 123, 149]. Thus, it is here proposed to start from the particular and move to the general. According to this conception, TTS was conceived. Its focus started with a particular problem in a particular territory in a particular time (*i.e.* health emergency) and from that the attention has been brought to a corresponding general legal cause: TRIPS Agreement. Such a methodological approach seems more adherent to a common law evolution.

In this sense, TTS is not a universal declaration, but tries to change a universal norm that has particularistic interest and effects (the TRIPS Agreement). TTS tries to balance such a norm, towards human rights that have been damaged. Thus, TTS can be considered as an instrument, which illustrates a modality to get closer to human rights, in a field where they have not even been considered. The TTS proposal has started its work by giving the alarm of access-to-drugs deficits.

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