Right of Health: Recent Trend on Patent System*

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Abstract

This paper aims to understand whether and how States cooperative approach can effectively protect fundamental values having transnational characters (State A' pollution impact on State B' environment and health protection). Particularly, the analysis proposes a focus on sustainable development and globalization process to see whether there has been a move from an economic oriented society to a different one, keener in implementing fundamental values, specifically health protection. Accordingly, the paper focuses on recent normative and jurisprudential international and domestic trend aimed at implementing health protection, at cost of decreasing economic rights. Reference is made to compulsory license system recently in art. 31 bis TRIPs and EU Regulation n. 953/2008. Besides, domestic and international judges, along with arbitrators are ruling making health protection prevailing over economic rights. The analysis lead to conclude that a cooperative approach may result in an effective implementation of fundamental values having transnational character.

Keywords: *Health protection; Compulsory License System; Sustainable Development Goals; economic rights v. fundamental values; Cooperation among States.*

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1. Introduction

"*Nowadays human rights raise a problem not of legitimization but of implementation*" [(1)].

After the so called "dark ages"[(2)], which witnessed the rise of despotism and of a generalized "call for hate"[(3)], the International Community agreed on the strong need to recognize human rights and to confer upon them a legal value; the only moral value had indeed proved not to be enough[(4)].

The first decade in the aftermath of the Second World War has thus witnessed the bloom of international treaties, declarations, covenants, and soft law provisions, proving that human beings have rights for the mere fact to be human being[(5)]. At this (?) date, it seems even possible to qualify law on human rights as a sub system of international law[(6)], implemented by autonomous judicial

(1) N. Bobbio, L'era dei diritti, Einaudi, 2015, p. 34.

(2) See H. Arendt, Eichmann in Jerusalem: A Report on The Banality of Evil, 1963.

(3) See M. Koskenniemi, The Gentle Civilizer of Nations, Cambridge, 2001.

(4) S. Besson, The Egalitarian Dimension of Human Rights, A. Etinson (eds.), Human Rights: Moral or Political? Oxford, 2018; S. Besson, The Morality of Conflict. Reasonable Disagreement and the Law, Oxford, 2005.

(5) See i.e., European Convention on Human Rights and fundamental Freedoms, 1952; 1966 International Covenant on Economic, Social and Cultural Rights; 1966 International Covenant on civil and political Rights; all the conventions enacted by the International Labor Organization between 1948 and 1976; American Convention on Human Rights, 1969 and so on.

(6) Colangelo, A System Theory of Fragmentation and Harmonization, New York University Journal of International law & Politics, 49, 2016; A. Roberts, Clash of Paradigms: Actors and Analogies Shaping the Investment Treaty System, in American Journal of International Law 45 (2013); Ost, van de Kerchove, De la pyramide au réseau? Pour un théorie dialectique du droit, 2012 ; Schultz, The Concept of Law in Transnational Arbitral Legal Orders and some of its Consequences, 2 Journal of International Dispute Settlement 59, 2011; A. Bjorklund, S. Nappert, Beyond Fragmentation, New Directions in International Economic Law: in Memoriam of Thomas Wälde, in Weiler, Baetens (eds.), Martinus Nijhoff Publishers, 2011; Hay, Borchers, Symeonides, Conflict of Laws, Hornbook Series, 2010 Paulus, The International Legal System as a constitution, in Dunoff, Trachtman (eds.), Ruling the World, Constitutionalism, International law, and Global Governance, Cambridge, 2009; Conforti, Unité et Fragmentation du droit international: glissez Mortels, n'appuyez pas", Revue général du droit international publique, 2007; A. Lindroos, Addressing Norm Conflicts in a Fragmented Legal System: The Doctrine of Lex Specialis, Nordic Journal of International Law, 2005; Paulus, Commentary to Fischer-Lescano & Ghunter Teubner: The legitimacy of international law and the role of the State, Michigan Journal of international law, 2004; Mus, Conflicts between Treaties in International Law, Netherlands International Law Review, 1998; Teubner, The King's Many Bodies: The Self deconstruction of Law' hierarchy, Law and Society Review, 1997; Simma, Pulkowski, Of Planets and the Universe : Self-contained Regimes in International law, European Journal of International Law, vol. 17, n. 3; Simma, Self-Contained Regimes, Netherlands Yearbook of International Law, 1985; Van Aaken , Fragmentation of International Law: The Case of International Investment Protection, in Finnish Yearbook of International Law, 2006; Panhuys, van Leeuwen Boomkamp (eds.), Van Asbeck, International Society in search of a Transnational Legal Order, Sijthoff, 1976; P. Pescatore, L'ordre Juridique des communautés européennes, étude des sources du droit communautaire, Bruylant, 1975 ; Raz, The Concept of Legal System. An introduction to the theory of legal system, Oxford, 1970; Jenks, The Conflict of Law making treaties, British Yearbook of international law, 1953 de Vattel, Le droit des gens ou principes de la Loi Naturelle, appliqués à la conduite et aux affaires des nations et des Souverains, vol. I, Book II, Ch. XVII, 1758.

or *quasi*-judicial mechanism(7), having international or regional character(8).

Nowadays, the problem seems to have shifted from the recognition of human rights to how to integrate the protection of such human rights and fundamental values into economic rights.

The subject is massive; therefore this paper will specifically focus on how the international community is moving to increase and guarantee health protection at risk of decreasing profit.

The aim is then to scrutinize recent normative and jurisprudential trend endorsed within international Community , in order to see whether it is apt to implement Sustainable Development Goal n. 3 ("Goal 3") enacted in Agenda 2030 which specifically call States to *ensure healthy lives and promote well-being for all at all ages*(9).

More specifically, this paper will examine the link existing between patent rights and health protection, having in mind that one of the targets of Goal 3 is to "*Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective,*

(7) Norms that are part of a sub-system of international law, such as those of international economic law, investment law, sea law, environmental law, can be qualified as lex specialis, with all the consequences deriving from this qualification. Worth of mentioning are two effects: firstly, a provision of lex specialis will prevail in case of conflict with a provision of general character. Secondly, a norm of lex specialis can be used as an interpretative tool. This means that in case of conflict between two provisions, one protecting human rights and one of a general character, the former should guide the court's reasoning. According to the International Court of Justice, "it is well understood that, in practice, rules of [general] international law can, by agreement, be derogated from in particular cases or as between particular parties", International Court of Justice, Judgment, 20 February 1969 in North Sea Continental Shelf cases (Federal Republic of Germany v. Denmark and Federal Republic of Germany v. Netherlands), I.C.J. Reports 1969, par. 472, 61–6; in Continental Shelf (Tunisia/Libyan Arab Jamahiriya), International Court of Justice has underlined "it would no doubt have been possible for the Parties to identify in the Special Agreement certain specific developments in the law of the sea of this kind, and to have declared that in their bilateral relations in the particular case such rules should be binding as lex specialis", International Court of Justice, judgment, 24 February 1982, in Case concerning the Continental Shelf (Tunisia v. Libyan Arab Jamahiriya), in ICJ Reports 1982, par. 24. Again, in Southern Blufin Tuna, the International Tribunal for the Law of the Sea has recalled that while making art. 38 of the Statute of the Permanent Court of Justice lex specialis was given as an example of general principle, ITLOS, 27 August 1999, in 3&4, Australia v. Japan, New Zeland v. Japan, pars. 123. In his dissenting Opinion given in the Ambiatelos case law, judge Hsu made clear the "it is a well-recognized principle of interpretation that a specific provision prevails over general provision", International Court of Justice, judgment, 19 May 195, in Greece v. United Kingdom (Ambiatelos), para. 87. See also ILC, Report on Fragmentation, quoted, at 60-65; Lindross, quoted, at 66.

(8) A few years ago, Armin von Bogdandy has raised a provocative question, wondering whether the EU was or could be what be as a human rights organization Quoted by S. Besson, The European Union and Human rights: Towards a Post-National Human Right Institution, in Human Rights Law Review, p. 360.

(9) See https://www.un.org/sustainabledevelopment/health/.

quality and affordable essential medicines and vaccines for all"[10].

The question is then to understand whether the patent system as recently re-shaped can effectively implement health' protection, without impairing human rights. This approach departs from recent WTO Agreement on Trade Related Aspect of International Property Rights (TRIPs) amendment introducing compulsory license system for medicines.

In detail, section 2 will focus on sustainable development and globalization process to see how the move from an economic oriented society to another keener in implementing fundamental values happened. Section 3 will analyze the interaction between health protection and economic rights at international and regional level.

Particularly, it will scrutinize the compulsory license system as shaped within TRIPs and other legal provisions having regional character. Section 4 will deal with the querelle concerning the legitimacy of patent and compulsory license ("C.L.") system.

Lastly, section 5 will then scrutinize how national and international case law embraced the so-called "mission of integration" between fundamental values and economic right's protection.

All the above leads the analysis to conclude (section 6) that there is trend, shared at normative and jurisprudential level, aimed at effectively protecting fundamental values at "risk" of decreasing economic profit.

2. Sustainable Development and Globalization Process: A Clash Between Fundamental Values and Economic Rights

This paper takes for granted that human rights do not have problem of recognition. However, there is an urgent need to link them to an economic sphere. In other words, it has become essential to construct a bridge able to connect two (allegedly) opposite poles, fundamental values, on the one side, and economic rights, on the other.

This need, while not being a new one, it is still actual.

By the time human rights of third generation were recognized, barriers among States were dismantled and markets became open, as ever before.

This phenomenon, known as globalization, has both an economic and a social

(10) See https://www.un.org/sustainabledevelopment/health/.

character[11]. Accordingly, trade and flux of investments, of labor force and so on, have been favored, becoming faster and easier. Alongside markets' opening, connections among peoples and cultures became easier, simplifying the understanding of what was happening "aboard".

However, positive consequences have been shaded be some negative ones; indeed, globalization proved so far to impair at large-scale fundamental values.

What is pursued through globalization – mainly the increase of profit – seems to collide with an effective implementation of human rights. Just to make an example, an investor asking and obtaining protection of its legitimate expectation means, in turn, decreasing the host State's right to regulate in its national public interest, enhancing environmental, health or labor standard of protection "strong evidences of this derive from investment law field"[12].

It is a difficult task, because it requires balancing economic rights, which have individual nature, with fundamental values, which are collective in nature. However, both should be guaranteed, because they both are an integral part to sustainable development.

Over time, this collision stressed the need to agree on instruments apt to protect fundamental values at a collective dimension. Accordingly, over the past 30 years, there has been an extensive policy-making process to switch to a new approach aimed at pursuing Sustainable Development (SD). In 1987, the Burtland Report firstly tried to define the that the time fairly new concept of Sustainable Development, stating that: "*sustainable development meets the needs of the present without compromising the ability of future generations to meet their own needs"*[13]. The concept in itself does not focus on limiting economic activities but rather on re-directing development in order to ensure the potential for long-term sustained yields. The necessity is to include sustainability at the heart of development, having in mind its three dimensions: social, economic, and environmental[14]. Through this way, the United Nations

(11) According to the Cambridge Dictionary, Globalization means the increase of trade around the world, especially by large companies producing and trading goods in many different countries. See, for all, M. Steger, Globalization, a very short Introduction, 2017.

(12) See supra ff. 8.

(13) World Commission on Environment and Development, Report of the World Commission on Environment and Development: Our Common Future, UN. Doc. A/42/427, Development and International Co-operation: Environment, 16 June 1987.

(14) For literature on this point, see: Marie-Claire Cordonuer Segger, Markus W Gehring, Andrew Newcombe, Sustainable development in world investment law, Kluwer Law International, The Netherlands, 2011; Philip McMichael, Development and Social Change: A Global Perspective, SAGE Publications, Inc, 2016; S. Toulmin, Forecasting and Understanding, in Foresight and Understanding: An Inquiry into the Aims of Science (1961);

sought to create a bridge between developed and developing States in order to solve serious problems of environmental degradation and lack of social and economic development.

Core principles of SD became explicit in 2000 when international community agreed on the UN Millennium Development Goals(15). The widespread consensus reached on the need to switch direction has taken States to abide by sustainable development, acting both at the individual and at the collective level. As for the individual level, each State has to align its policies on, i.e., environmental and health protection at standard defined at supranational level . As for the collective level, instead, developed States have at least moral obligation to help developing ones. This entails that states have to cooperate, given that there is at stake the protection of values that are shared among all.

At date, SD core principles have been updated and substituted by the Sustainable Development Goals, recently endorsed in Agenda 2030(16).

This latter is a comprehensive, far-reaching, and people-centered set of universal and transformative goals and targets. For the present analysis, reference is made to the right to health, as enshrined in Goal 3, setting out the need to ensure healthy lives and promote well-being for all at all ages.

3. The International and Regional Legal Framework on Health Protection

Recent normative trends shed doubts on whether the new system of compulsory license effectively implements Goal 3, thus raising health protection concerns(17). As clearly summarized, "*the rational and the social purpose of patent protection is to provide an incentive for technological change and in particular for further investments into R&D in order to make new inventions*"(18).

"The patent issue" seems to underlie two competing perspectives(19). Theoretically, demand for long lasting patent rights struggles with the need

(15) General Assembly, Resolution adopted on 18th September United Nations Millennium Declaration, 2000, UN Doc. A/55/L.1.

(16) General Assembly, Resolution adopted on 25th September 2015 Transforming our World: the 2030 Agenda for sustainable development, UN Doc. A/70/L.1.

(17) (See WIPO Guidelines and Manuals of National/Regional Patent Offices, available here: http://www.wipo.int/patents/en/guidelines.html.

(18) See, N. Boschiero, Intellectual Property Rights and Public Health, in L. Pineschi (eds.) La tutela della Salute nel diritto internazionale ed Europeo tra interessi globali e interessi particolari, Scientifica, 2016 at 280.

(19) This in turn leads, at least at the theoretical level, to the topic of fragmentation Report of the Study Group of the ILC, finalized by M. Koskenniemi, doc. A/CN.4/L.682 of 13 April 2006, p. 19.

to guarantee highest standard of health protection. However, it is of outmost importance to balance the above-mentioned rights given that, while being opposite, they are strictly interrelated. Health protection cannot be improved without investments, which, in turn, are not made without strong guarantee of profit[20]; in sum, no innovative drugs without long lasting patent (this meaning, without increasing economic return)[21].

Normative provisions at both the international and regional level have evolved towards a new direction apt to provide a balanced relation between patent's holder rights and health protection.

Particularly, at international level, it is worth mentioning the TRIPs[22] amendment announced on 23 January 2017, but firstly suggested in 2001, during the Doha Declaration on *TRIPs Agreements and Health Protection*[23], which states at par. 3 that: "*We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices*". As a consequence, the new enacted art. 31-bis states at para. 1 that "*The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in section 2 of the Annex to this Agreement*".

The subsequent sections of art. 31-bis either control the amount of the remuneration due by importing States to exporting ones (para. 2) or introduce instruments to enhance the power and to facilitate the production of economies of scale (para. 3). Section 4 limits chances to challenge measures taken according to art. 31-bis; lastly, section 5 makes clear that obligations and rights provided for in this article do not prejudice rights otherwise conferred by the TRIPs. As such, art. 31-bis seems to cover all phases – conferral, costs,

(20) See C. Correa, J. Vinuales, Intellectual Property Rights as Protected Investments: how open are the Gates, in Journal of International Economic Law, 2016.

(21) N. Boschiero, at 278.

(22) See, J. Watal, A Taubman (eds.), The Making of the TRIPs Agreement, Personal insights from the Uruguay Round Negotiation, WTO, 2015; A. Taubman, H. Wager, J. Watale (eds.) A Handbook on the WTO TRIPs Agreement, Cambridge, 2012; T.T. Nguyen, Competition, Law, Technology Transfer and the TRIPs Agreement, Implications for developing countries, EE, 2010, M. Correa, Trade Related Aspects of Intellectual Property Rights, Cambridge, 2007; N. Pires de Carvahlo, The TRIPs Regime for Patent Rights, Kluwer International Law, 2010.

(23) Declaration on the TRIPs agreements and Public Health Doha WTO Ministerial 2001: Trips WT/Min (01)/DEC/2 adopted on 14 November 2001. See P. Vandoren, J.C. Van Eeckhaute, The WTO Decision on Section 6 of the Doha Declaration on the TRIPs Agreement and Public Health – Making it work, in Jour of world Intellectual Property, 2003.

challenges – through which a compulsory license can be enacted (actually, TRIPs phrases: "*use without authorization of the right holder*").

In sum, art. 31-bis TRIPs extends a system of compulsory licenses, according to which a State is obliged to recognize license of production, or of export, of pharmaceutical products in a country with insufficient or lacking capacities of production. WTO members will thus amend their national legislation opting for a regime working either as exporters or importer, or both. Worth of notice is also the fact that the TRIPs welcomes flexibilities even on compulsory license system, meaning that different regimes are provided for in order to prevent abuse and anti-competitive practices(24).

Art. 31-bis TRIPS is also noticeable, given that it could effectively implement Goal 3 which call States to "*ensure healthy lives and promote well-being for all at all ages*"(25). This holds true, given that compulsory license system allows States which have proved to be in need to have medicines at more affordable costs.

However, there is a likely negative side. The States' right to decide whether to be an importer, an exporter or both may be at the origin of State' shopping practices: investments in pharmaceutical sector could potentially be dislocated where chances to be object of compulsory licenses are lower.

Regarding legislation having regional character, it is worth of notice that even the European Union has provided for a truly effective system of patent protection. Worth of notice is EU Reg. n. 953/2003(26). For present analysis

(24) W. Zhuang, Interpreting Patent–Related Flexibilities in the TRIPS Agreement for Facilitating Innovation and Transfer of ESTs, in W. Zhuang, W. Zhuan, Intellectual Property Rights and Climate Change. Interpreting the TRIPs Agreement for Environmentally Sound Technology Cambridge, 2017; E. F.M.'t Hoen, Private Patents and Public Health, AM Publication, 2017; M. Azam, Intellectual Property and Public Health in the Developing World, in Open Book Publishers. See also, UNCTAD-UNIDO Discussion Paper, TRIPS Flexibilities and Anti-Counterfeit Legislation in Kenya and the East African Community: Implications for Generic Producers.

(25) UNGA Resolution adopted on 25th September 2015 Transforming our World: the 2030 Agenda for sustainable development (2015) UN Doc. A/70/L.1. M. Gehring, M.C. Cordonier Segger, A. Newcombe, Sustainable Development in World of Investment Law, Kluwer Law International, 2010; S. Schill, C. Tams, R. Hofmann, International Investment Law and Development: bridging the gap, Frankfurt Investment and Economic Law Series, 2015; Z. Hull, The Philosophical and Social Conditioning of Sustainable Development, Vol. 3, 2008; G. Fievet, Réflexions sur le concept de développement durable: prétentions économiques, principes stratégiques et protection des droits fondamentaux, Revue Belge de droit international, 2001.

(26) UE Regulation N. 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines, U.E. OJ. L. 135; Commission Staff Working Document Executive Summary of the REFIET Evaluation of the Council Regulation (EC) 953/2003 to avoid trade diversion into the European Union of certain key medicines, Brussels, 7 April 2016, SWD (2016) 125 final. On the topic, see C. Seville, EU Intellectual Property Law and Policy, EE, 2016; A. Ilardi, The New European Patent, 2015.

purposes, it suffices to say that overall, EU Reg. n. 593/2003 encouraged pharmaceutical producers to make available essential drugs to listed developing State (nearly 80).

On one side, as stated in the preamble: "*Many of the poorest developing countries are in urgent need of access to affordable essential medicines for treatment of communicable diseases (4) therefore price(?) segmentation between developed country markets and the poorest developing country markets is necessary to ensure that the poorest developing countries are supplied with essential pharmaceutical products at heavily reduced prices(5)*".

On the other side, to encourage patent holders' adhesion, art. 12.2 of the Regulation states that: "*this Regulation shall not interfere with intellectual property rights or rights of intellectual property owner*".

Overall, it seems that the EU Regulation introduces a system which, if working properly, will balance between rights and protection of both, patent' holder and patients.

4. A Critical Assessment on the Compulsory License System

Patent regime has always raised concerns given that patent are sources of property rights, and this indirectly deprives others of a free use of what has been object of patent. This is especially true when the products subject to patents are pharmaceutical products.

A balance has thus always been sought between the need to boost science and research and the need to guarantee profits to those having firstly invested in the patented product. Having in mind normative framework examined in the previous section, it is possible to analyze if and how the compulsory system introduced at supranational level balance economic and health rights.

In this regard, it seems that the compulsory license system could represent a feasible way to tackle the problem. Accordingly, if the system, as recently shaped, worked correctly, then profits could be guaranteed and States in need would have the right to exploit patents and increase health protection within their boundaries(27). Despite this, concerns have been raised regarding the need to introduce a more permissible system of patents, such as that recently

(27) See F.M. Schrerer, J. Watal, Post Trips Options for Access to patented Medicines in Developing Nations, in Journal of International Economic Law, 2002, 913; P. Drahos, Developing Countries and International Property Standard-Setting, in Journal of World Intellectual Property, 2002, 52; H.E. Bale, The Conflicts Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals, in Journal of International Economic Law, 1998, 637.

enacted in TRIPs, instead of dismantling it.

Some part of the academia has in fact not welcomed compulsory license regime stating that "*It is doubted whether CL regime can effectively work as optimal solution, at least in the short term*"[28]. Particularly, the new system will carry three negative effects. Firstly, C.L. enhances the capabilities of importing States to produce pharmaceutical products (so called industrial benefit) only in those few countries already capable of efficient drug manufacturing. Reference is made, for instance, to India[29], Brazil[30], and South Africa[31].

Secondly, regarding the economic side, C.L. regime decreases significantly the costs [of production of the product? License fees?], but this is not enough. Pharmaceutical products will still result unaffordable by those millions of people who earn daily two or even one dollar pro capita, as often reminded by J. Stiglitz[32].

Thirdly, C.L. regime will soon hurdle States to engage an effective cooperation between those with know-how and those not having it. These latter will rely on C.L. system instead of developing their own pharmaceutical industry. As a reaction, instead of providing for best-selling price, it should be favored a system boosting cooperation among States to develop further, while reducing cost and making products available at a large scale.

As stated: "*it cannot be denied that the efficacy if any solution of the overall health care emergency requires that use of those essential drugs, sometimes complex even on individual basis, be guided and monitored according to the best possible medical practice in the given, so often dramatic, situations, where the majority of population might not be served by, and thus accustomed to, an effective regular an scientifically based system of medical care*"[33].

(28) See G. Ghidini, Developing Countries' access to patented Essential Drugs. Are compulsory licenses the optimal means?, in H. Bercovitz, Estudios sobre Propriedad industrial e intellectual y derecho de la competencia, 2008.

(29) For an analysis on the topic, reference is made to S. Mukherejee, The Journey of Indian Patent Law Towards TRIPs Compliance, IIC, 2004.

(30) E. Massard da Fonseca, Reforming pharmaceutical regulation: A case study of generic drugs in Brazil, Policy and Society, vol. 33, 2017, pp. 65-76; N. Arzeno, R. Diaz, S. Gonzalez, Brazil's Generic Drug Manufacturing Success and the policies that permitted it, 2004.

(31) See S.R. Benatar, Health care reform and the crisis of HIV and AIDS in South Africa, The New England Journal of Medicines, 2004, 81-92; S. Sacco, A comparative study of the implementation In Zimbabwe and south Africa of the international law rules that allow compulsory licensing and parallel importation for HIV/AIDS drugs, The American University of Cairo, 2004. See also https://www.whoownswhom.co.za/store/info/4557

(32) J. Stiglitz, The Price of Inequality, Norton & Company, 2012.

(33) G. Ghidini, quoted, at. 514.

Our tenet is different. Patent regime and C.L. system seem to have more positive than negative effects and, together, they can significantly implement Goal 3.

To better understand our position, it seems useful to link art. 31 bis TRIPs, EU Regulation and, generally, compulsory license' system, with all articles enacted in their respective sources of law(34).

In so proceeding, a determination to balance (allegedly) competing rights and needs result clear straight form TRIPs Agreement's Preamble(35). Particularly, this latter clearly claims that the aim of the Agreement is to: "*reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade*".

Further, art. 7, titled Objectives, states that: "*The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology,*

(34) It goes without saying, that international rules on interpretation state that treaties clauses are to be read one through the other (see the Vienna Convention on the law of the treaties, 1969, art. 31-33). Vienna Convention on the Law of the Treaties, art. 31: "1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose. 2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes: (a) Any agreement relating to the treaty which was made between all the parties in connexion with the conclusion of the treaty; (b) Any instrument which was made by one or more of the parties in connexion with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty. 3. There shall be taken into account, together with the context: (a) Any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; (b) Any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation; (c) Any relevant rules of international law applicable in the relations between the parties. 4. A special meaning shall be given to a term if it is established that the parties so intended". According to Sands: "Article 31(3)(c) … appears to be the only tool available under international law to construct a general international law by reconciling norms arising in treaty and custom across different subject matter areas. Article 31(3)(c) is of interest for these reasons … [It] has a potentially generic application, which could encompass the relationships between other areas and other norms, including human rights and development, trade and labor, and even the law of the sea and human rights", Sands, Treaty, Custom and the Cross-fertilization of International Law, Yale Human Rights & Development Law Journal, 1998, vol. 1, pp. 85–105; see also Corten, Klein (eds.), The Vienna Conventions on the Law of the Treaties, a Commentary, Oxford University Press, Oxford, 2011; Crema, Investor Rights and Well-Being Remarks on the Interpretation of Investment Treaties in Light of Other Rights, in Treves, Seatzu, Trevisanut, Foreign Investment, International Law and Common Concerns, Routledge. 2013; Sinclair, The Vienna Convention on the Law of Treaties, Manchester University Press, 1984, p. 98

(35) H. Yamane, Interpreting TRIPs: Globalization of Intellectual Property Rights and Access to Medicines, Bloomsbury Publishing, 2018; J. Malbon, C. Lawson, Interpreting and Implementing the TRIPs Agreement: is it fair?, E-Elgar, 2008.

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". Lastly, art. 8, called *Principles*, confer States: "*the right to 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, this, of course, provided that the measures enacted are consistent with other TRIPs provisions*".

Bearing in mind the above-mentioned provision and reading them together lead to conclude that, overall, TRIPs might provide for a balanced system of property-economic rights and human rights-health protection.

The same conclusion holds true if one analyzes EU Regulation n. 953/2008, which, in general, allows patent holders to retain exclusive powers of productions and distributions(36).

However, Regulation n. 953/2003 introduces a system of compulsory license providing countries with adequate pharmaceutical products, when needed. This will in turn prevent parallel import, given that member States' compulsory license system works only to fill the need of the country requiring it. In *Pharmon v Hoechst*, the European Court of Justice clarified that in order for parallel imports to be legal, the consent of the patentee to grant a license to the licensee is compulsory(37).

It would have caused a great negative impact to impose compulsory license, while not granting control over parallel reimport. In sum, reading provisions within the overall context helps to understand that Regulation n. 953/2003 balances patent holder profit (meaning in turn R&D) and health protection(38).

In sum, international and regional provisions seem not to pose a genuine normative conflict of (allegedly said) non-composable rights(39). On the contrary, they seem to represent a good balance between the two.

To reach this conclusion, it suffices to interpret relevant provisions among all others in the given source of law, in order to "*give rise to a set of compatible international obligations, based on human rights approach in policies and*

(36) See supra ff. n. 28.
(37) See, ECJ, Case 19/84 Pharmon BV v Hoechst AG, 1985, in ECR 2281
(38) Contra G. Ghidini, quoted.
(39) J. Pauwelyn, Conflicts of Norms in Public International Law. How WTO relates to other Rules of international Law, Cambridge, 2003.

programs"[40]. This allows seeing a strong interconnection between the world of pharmaceutical products, mostly connected to patent system, and that of health protection.

What it is really lacking are new effective models of R&D. To reach that end, while no further TRIPs amendments are needed, a specific agreement on R&D seems to represent the solution. For this, however, it will be necessary to wait for a long time.

Given the above potentially positive scenario, it seems worthwhile to examine the impact of the patent regime on international investment treaties. In this context, new European investment agreements are particularly deserving of attention. Since the entry into force of the Lisbon Treaty, the European Union has been working hard in shaping its investment policy.

Inevitably, while negotiating investment treaties, the EU had to decide how to treat IP protection in general and patent protection in particular. As a consequence, along with a chapter focused on IP, patent regime also raises interest with the context of the investment chapter, given that foreign investors can apply for a patent that, once conferred, is qualified as a protected investment[41].

Accordingly, it is noteworthy that new EU investment treaties include provisions according to which granting a (compulsory?) license in a manner consistent with TRIPs (along with EU Regulation 953/2003) does not entail expropriation, either direct or indirect. As for now, Comprehensive Economic and Trade Agreement between Europe and Canada[42], today under provisional application, includes some provisions dealing with patent regime in general and few others, focused on link between patent, investment and health.

Namely, art. 20.3, titled "Public Health Concerns", refers to the TRIPs agreement and, moreover, "*recognize[s] the importance of the Doha Declaration on the TRIPs Agreement and Public Health […] in interpreting and implementing the rights and obligations under this Chapter, the Parties*

(40) See N. Boschiero, at 286.

(41) C. Correa, J. Vinuales, Intellectual Property Rights as Protected Investments: How open re the Gates? Journal of International Economic Law, 2016, 91-120; J. Hsu, Y. T., Patent rights protection and foreign direct investment in Asian countries, Economic Modelling, Vol. 44, 2015.

(42) EU-Canada, Comprehensive Economic and Trade agreement. See Council Decision (EU) 2017/37 of 28 October 2016 on the signing on behalf of the European Union of the Comprehensive Economic and Trade agreement, between Canada, on the one part, and the European Union and its Member of the other part, EU OJ L. 11, 14 January 2017. For an overview on IPRs see http://trade.ec.europa.eu/doclib/docs/2012/august/tradoc_149866.pdf.

shall ensure consistency with this Declaration". This means that C.L. system designed in Doha Declaration first, then in art. 31-bis TRIPs, apply also under CETA. Besides, if these latter provisions are read in conjunction with those provided in investment chapter, it follows that a State can exercise its sovereign right to regulate in public interest without having the measure challenged by foreign investor(43).

Indeed, Annex 8-A, titled "Expropriation", states that "*For greater certainty, except in the rare circumstance when the impact of a measure or series of measures is so severe in light of its purpose that it appears manifestly excessive, non-discriminatory measures of a Party that are designed and applied to protect legitimate public welfare objectives, such as health, safety and the environment, do not constitute indirect expropriations*".

State concerns on "health" and related with IP are, therefore, tackled according to TRIPs Agreement. As such the investor holding a patent right will not have many chances to challenge national measures through which, i.e. a patent compulsory license is enacted, or a right of exploit patent's right is suspended or prohibited because of national health reason.

5. Recent Rulings on Health Protection

Having clarified the normative framework, it is now time to examine the most recent jurisprudential approach on health' matter. National and international courts, along with arbitrators, seem keener in implementing fundamental values, at cost of reducing economic return.

In particular, judges and arbitrators are taking into strong and high consideration both health and environmental protection. As a consequence, it often happens that States and/or private operators are deemed to bear direct, or indirect, obligations to protect and guarantee fundamental values and, in case of failure to abide by them, to bear responsibility for the relevant breach.

With respect to national rulings, it is interesting to see that some courts have been adjudicating instances of human rights violations allegedly committed by State itself. In *Urgenda v. The Netherlands*(44), a Dutch court condemned the respondent State, The Netherlands, on the grounds of negligence for failure

(43) See H. Ruse-Khan, Challenging Compliance with International Intellectual Property Norms in Investor-State Dispute Settlement in Journal of International Economic Law, 2016.

(44) The English translation of the ruling is available from the website Urgenda and the website of the court, respectively: www.urgenda.nl/documents/VerdictDistrictCourt-UrgendavStaat-24.06.2015.pdf. and http://uitspraken.rechtspraak.nl/inziendocument?id=ECLI:NL:RB DHA:2015:7196.

to adequately regulate and curb Dutch greenhouse gas (GHG) emissions[45]. According to the Court, the State's failure to abide by international and national provisions on GHG emissions has impaired the environment, by worsening climate change, and, caused, albeit indirectly, a worsening of its citizens' health conditions.

With respect to arbitral proceeding, it is interesting to see how arbitral court have dealt with cases relating to health protection and investor' right.

A first reference is made to Ely Lily v. Canada, where a U.S. incorporated pharmaceutical company sued before Canadian national courts, first, and the arbitral tribunal, later, demanding compensation for damages caused by the refusal of Canadian' authorities to grant a patent renewal[46].

National judges dismissed claimant's demands because this latter failed to prove "*promise utility*", a condition to get patent renewal under Canadian law. In detail, according to national judges, over the last decade, while pending Ely Lily activity, Canadian case law evolved, narrowing down conditions required to get a product patented. Departing from the "*traditional utility*", recent domestic jurisprudence started to favor a "*promise utility*" doctrine according to which a mere scintilla of utility is not anymore sufficient for renewal[47]. According to investor, jurisprudent evolution impaired its legitimate expectation, thus infringing BIT in force. The arbitral tribunal refused dismissed claimants allegation on the assumption (which is a principle already stated by European Court of Human Rights) that, *inter alia*, national judges are better suited to guarantee national interest[48].

In this respect, the arbitrators pointed out that the evolution of Canadian

(45) As correctly stated, "the ruling marks the first successful climate change action founded in tort law as well as the first time a court has determined the appropriate emissions-reduction target for a developed state, based on the duty of care and regardless of arguments that the solution to the global climate problem does not depend on one country's efforts alone", see R. Cox, A Climate Change Litigation Precedent, Urgenda Foundation v. The State of the Netherlands, Centre for International Governance Innovation, 2015; see also R. Cox, The Liability of European States for Climate Change, in Utrecht Journal of International and European Law, 2014.

(46) UNCITRAL, No. UNCT/14/2, Ely Lilly and Company v. The Government of Canada, 16 March 2017.

(47) See F.-K. Philips, Promise Utility Doctrine and Compatibility Doctrine Under NAFTA: Expropriation and Chapter 11 Considerations, in Canada-United States Law Journal, 2016 at. 84; J. Reichman, Compliance of Canada's Utility Doctrine with International Minimum Standards of Patent Protection, in 2014 issue of the Proceedings of the 108th Annual Meeting of the American Society of International Law.

(48) Wide on this topic, see A. Micara, Tutela del marchio e competitività nell'Unione europea, Giappichelli, 2016.

jurisprudence did not entail an expropriation nor a frustration of claimant' legitimate expectation(49).

In abiding by national jurisprudence, arbitrators made indirectly prevail international interest related to a higher right protection. However, concerns arise with respect to their indirect claim that evolution of national jurisprudence might potentially lead to investment expropriation. Today, this is not a pressing concern, although it would have been preferable if arbitrators had rejected, without doubts, claims questioning legitimacy of the effects of national jurisprudence on foreign operators.

Another case worth mentioning is *Philip Morris v. Uruguay*, where the arbitrators ruled over the legitimacy of a national measure, aimed at imposing plain packaging for tobacco products(50).

The arbitral tribunal correctly noted that the host State retains its sovereign power to regulate in matters of public interest; therefore, the legislation subject to arbitral scrutiny (allegedly causing a prejudice to the investor's rights) was legitimate, provided that it was aimed at spreading knowledge of damages of smoking and at preventing health damages arising from smoking(51).

While writing this paper, a WTO panel released the much-awaited report on *Certain measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*(52).

For the purpose of present analysis, it is enough to say that the panel avoids scrutinizing the merit of the measures allegedly infringing on the WTO Agreements. However, the Panel rejected the claimants' demands on the assumption that none of these had been sufficiently proved(53).

This conclusion is noticeable because it seems to indirectly legitimize

(49) Ibid., paras. 321 ss...

(50) ICSID Case No. Arb/10/7, Award of 8 July 2016 Philip Morris Brands SARL, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay.

(51) On this subject see G. Zarra, Right to Regulate, Margin of Appreciation and Proportionality: Current Status in Investment Arbitration in Light of Philip Morris v. Uruguay, in Brazilian Journal of International Law, 2017, p. 95. For a parallelism with the recent trend on the topic within the EU, see E. Nanopoulos, R. Yotova, Repackaging Plain Packaging in Europe: strategic litigation and Public Interest Considerations, in Journal of international Economic Law, 2016.

(52) WTO, 28 June 2018, Report in case WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R, Certain measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging.

(53) https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds467_e.htm.

a national measure, enacted in order to protect public health. While it is undisputed that trademarks and goodwill associated with trademarks (in this case Company logo and name) are to be qualified as protected investment, the Panel dismissed the claimant's claim stating: "*that the Challenged Measures were a valid exercise by Uruguay of its police powers for the protection of public health introduction*"(54).

The arbitral tribunal in Urbaser v. Argentina follows the same line of reasoning. More specifically, in this proceeding arbitrators granted for the very first time a counter-claim raised by the respondent host State(55): "*based on the bona fide expectations that investments operation would indeed be made and would make it possible to guarantee, in the area in question, the basic human right to water and sanitation*"(56).

According to the tribunal: "*a host State accepting investments in the domain of the provision of water relies on the BIT to have the investor participating to its obligation under international law. It thus complies with the conclusion of the UN Committee on Economic, Social and Cultural Rights that "States parties should ensure that the right to water is given due attention in international agreements."444 This includes the possibility to consider matters related to the human right to water in the dispute resolution mechanisms provided for in such agreements*"(57).

Moreover, while dealing with the merit of the counterclaim, the arbitrators mentioned that: "*in this respect that international law accepts corporate social responsibility as a standard of crucial importance for companies operating in the field of international commerce. This standard includes commitments to comply with human rights in the framework of those entities' operations conducted in countries other than the country of their seat or incorporation*"(58).

All of the above-mentioned case-law shows that the adjudicatory system, whether national, international, or arbitral, is changing approach, trying to find a balance between the two opposite rights at stake: on one hand, the right

(54) Ibid., para. 351.

(55) ICSID Case No. ARB/07/26, Urbaser S.A. and Consorcio de Aguas Bilbao Bizkaia, Bilbao Biskaia Ur Partzuergoa v. The Argentina, Republic, para. 1140 ff. See F.M. Palombino, Il diritto all'acqua. Una prospettiva internazionalistica, Florence, 2017, p. 47 ff.

(56) Ibid., para. 1156.

(57) Ibid. para. 1209.

(58) Urbaser v. Argentina, cit., par. 1195; on the application of the Universal Declaration see L. Henkin, The Universal Declaration at 50 and the Challenge of Global Markets, in Brooklyn Journal of International Law, 25, 1999, pages 17-25.

to protect private operators' profits; on the other hand, the need to protect fundamental values at risk. In recent case law, these latter seem to have prevailed.

This in turn proves that the adjudicatory system is taking the task to protect and implement a sustainable approach very seriously, thus allocating upon operators, or even states, the responsibility for breach (through actions or omission) of human rights.

6. Conclusion

The present analysis allows some conclusions on the broad question related to the need to balance between two rights in (alleged) conflict but contemporarily relevant in a given relationship.

As stated at the beginning, globalization has seriously impaired the protection of fundamental values. To fix this, a cooperative and a collective action, shared by whole international community, are strongly required. Recent trends seem to prove that there is a push to allocate specific obligation, thus responsibilities, upon all actors(59).

Accordingly, States and international organizations, along with individual and juridical persons, have started to bear their own responsibility to implement a sustainable approach suitable to ensure fundamental values protection. The ones failing to protect such values bear responsibility and are condemned to pay damages or re-establish *status quo ante*.

In this context, the very recent conclusion reached by Inter-American Court of Human Rights on its Advisory Opinion in *Environment and Human Rights* deliver on 5th of February 2018(60) seems of outmost importance.

Here, for the very first time, an international tribunal recognized upon a State an extra-territorial positive obligation(61), staring that, if a company in State A causes transboundary environmental harm that adversely affects individual's

(59) S. Besson, The bearers of Human Rights' Duties and Responsibilities for Human Rights: a quite(r) evolution?, Social Philosophy & Policy Foundation, 2015; C. Barry, Global Institutions and Responsibilities: Achieving Global Justice, Oxford, 2005; Rawls, A Theory of Justice, Cambridge, 1971.

(60) Spanish version of the judgment can be found here: http://www.corteidh.or.cr/docs/opiniones/seriea_23_esp.pdf.
For a summary, see G. Vega-Barbosa, L. Aboagye, Human Rights and the Protection of the Environment: The Advisory Opinion of the Inter-American Court of Human Rights, EJIL Talk, February 2017.

(61) See, M. Milanovic, Extraterritorial Application of Human Rights Treaties, Law, Principles and Policy, Oxford, 2011.

life and physical integrity in State B, the damaged individual is within the jurisdiction of State A[62]. Part of the academia had already before took the chance to state that "*the state obligation to respect human rights is not limited territorially; however, the obligation to secure or ensure human rights is limited to those areas that are under the State's effective overall control*[63].

The Opinion has also a limit, given that the court has poorly reasoned on conditions legitimizing a State positive obligation. In the absence of clear guidelines conditions, interpretive task falls on judges in charge.

However, this Opinion will certainly soon become a precedent on which future judgment will rely upon. Indeed, while the fundamental value in the case at stake was environment, the same conclusion reached by the court may soon be copied in cases a request to protect health is raised. Once a positive extra-territorial obligation on State is recognized with respect to environmental issues, the same obligation can potentially be transposed for protection of the right to health or other fundamental rights. The Advisory Opinion of the Inter-American Court is therefore just a starting point.

In conclusion, normative and jurisprudential recent practice shows that there is a strong commitment shared by the international community in implementing a truly Sustainable Agenda. In particular, the analysis proves that, at least regarding health considerations, namely patent regime, a more sustainable approach, where health overcomes economic rights, is prevailing.

The path has been traced. It is now up to the whole international community to rigorously follow it.

(62) A. Berekers, A New Extraterritorial Jurisdictional Link Recognized by the IACtHR, in EJIL Talk, march, 2018.

(63) M. Milanovic, Extraterritorial Application of Human Rights Treaties, at 263.

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