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## **Intellectual property rights and public health: an impediment to access to medicines and health technology innovation? \***

**SUMMARY:** 1. Pharmaceutical patents, the access to essential medicines and the question of innovation - 2. The actual and/or potential between the rights of inventors, international human rights law, trade rules and public health. The everlasting controversy on the allegedly adverse impact of intellectual property protection on access to medicines and health technologies - 3. Are human rights and intellectual property law really in conflict? A relation of interpretation, not of conflict - 4. Conclusions.

### **1 - Pharmaceutical patents, the access to essential medicines and the question of innovation**

The immense advancement in knowledge, science and technology that has characterized the last century and half has profoundly improved medical innovation and the health of millions of people. In a relatively short period, the discover of successful vaccines (like polio or the recent introduction of a vaccine for rotavirus), the development of triple-drug antiretroviral (ARV) therapy to cure AIDS, new treatments for tuberculosis, malaria, hepatitis C, cancer and many other non-communicable diseases (NCDs), as well as new therapies based on discoveries in genetics, personalized therapies based on molecularly-targeted medicines, stem-cell based medicines, have substantially contributed to reduce some of the most common killers associated with chronic and catastrophic diseases. All these medical innovation, health technologies and new medicines have resulted into a drastic reduction in deaths, thus transforming many of the formerly deadly and incurable diseases from death sentences into manageable diseases.

Yet, in spite of this notable advancement, more than nearly one third of the world population is left behind without access to the benefits of the

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above-mentioned advances and continue to die, being denied the access to health care, including affordable, safe, efficacious and quality medicines, vaccines, diagnostics and medical devices, necessary to prevent and treat illness<sup>1</sup>. Notwithstanding a rapid increase in technological and economic potential, that in principle implies an enhanced ability to overcome problems related to poverty and poor health, recent years have seen an actual deterioration in health status in many countries, largely as a result of HIV/AIDS, still one of the leading cause of death in some locations (like in sub-Saharan Africa) and in populations that are typically excluded or marginalized<sup>2</sup>; but also because of a resurgence in other infectious diseases and a growing burden of non-communicable diseases, which are estimated to kill worldwide around 50 million people per year<sup>3</sup>. Many more efforts are needed to fully eradicate a wide range of diseases and addressing many different persistent and emerging health issues<sup>4</sup>. Particularly, there is the need of huge investments in important health emergency and the necessity for innovators to consider how drugs and new technologies can reach those most in need<sup>5</sup>. In addition, there is a precise responsibility of governments to find the proper solution to ensure access for all, without discrimination, to medicines, particularly to essential medicines, that are affordable, safe, efficacious and of quality<sup>6</sup>.

These concerns explain why the current intellectual property (hereinafter: IP) system is at the very centre of the global cross-cutting discussion on the existing obstacles to providing access to medicines and health technologies as fundamental elements of the full realization of the human right to health. Intellectual property rights are in fact a very

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<sup>1</sup> WHO, *The World Medicines Situations Report of 2011*, available at: [www.who.int/medicines/areas/policy/world\\_medicines\\_situation/en/](http://www.who.int/medicines/areas/policy/world_medicines_situation/en/); WHO, WORLD BANK (2015), *Tracking Universal Health Coverage: First Global Monitoring Report*, available at: [http://apps.who.int/iris/bitstream/10665/174536/1/9789241564977\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/174536/1/9789241564977_eng.pdf?ua=1).

<sup>2</sup> GLOBAL COMMISSION ON HIV AND THE LAW, *Risks, Rights & Health* (2012), available at: [www.hivlawcommission.org/index.php/report](http://www.hivlawcommission.org/index.php/report).

<sup>3</sup> On global burden of diseases and global health risks see WTO, WIPO, WHO (2013), *Promoting Access to Medical Technologies and Innovation. Intersections between Public Health, Intellectual Property and Trade*, Geneva, pp. 25-30 (hereafter *The Trilateral Study*).

<sup>4</sup> National immunization and mandatory vaccines programmes, like the recent one enacted by the Italian Government, are a highly effective public health tool for the prevention of illness and the spread of infectious diseases. More information available at: [www.salute.gov.it/portale/temi/p2\\_5.jsp?area=Malattie%20infettive&menu=vaccinazioni](http://www.salute.gov.it/portale/temi/p2_5.jsp?area=Malattie%20infettive&menu=vaccinazioni).

<sup>5</sup> *The Trilateral Study*, p. 9.

<sup>6</sup> Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14. The right to the highest attainable standard of health*, Doc. E/C.12/2000/4 of 11 August 2000.



important structural *determinant* of health<sup>7</sup>. Many elements and legal and policy instruments relating to the IP and international trade system touch both on innovation and on access and are therefore relevant at the international level. International trade is vital for access to medicines and other medical technologies<sup>8</sup>. At least four of the multilateral trade agreements of WTO, the leading normative organization on international trade, affect public health in various ways, particularly in areas of safety, diagnostic devices and medicine quality, trade in health services, such as the WTO General Agreement on Trade in Services (GATS), the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), the WTO Agreement on Technical Barriers to Trade (TBT) and the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In addition, other international health standards and rules have important implications for health, for example, the *Codex Alimentarius*, and the Framework Convention on Tobacco Control (Geneva, 16 June 2003). Nevertheless, this article will focus only on the TRIPS Agreement and its patent system. This is because the patent system has been widely used for medical technologies by the pharmaceutical sector, that continuously stands out in terms of its dependence on *patents* and *protected data* against unfair commercial use to capture returns to research and development (R&D)<sup>9</sup>.

The impact of patents on *access* is a complex area that needs a particular focus. At the international level, the debate has centred on the

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<sup>7</sup> WHO, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, 2006 (hereinafter: *CIPIH Report*); M. EL SAID, A. KAPCYNISKI, *Access to Medicines: The Role of Intellectual Property Law and Policy, Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law*, 7-9 July 2011, available at: [www.hivlawcommission.org](http://www.hivlawcommission.org); *The Trilateral Study*, pp. 53-86.

<sup>8</sup> Trade stimulates competition, which in turn in principle reduces prices and amplifies the range of suppliers. Also tariffs on medicines, pharmaceutical ingredients and medical technologies, directly affect their accessibility. Access to foreign trade opportunities can create economies of scale to support the costs and uncertainties of medical research and product development processes. See *The Trilateral Study*, p. 14.

<sup>9</sup> Several other elements of the current IP system influence (positively or negatively, depending on how it is shaped and implemented) access to existing medicines and innovation; for example, trademarks and copyright can also exert monopolistic effects in the market that rival those associated with patents and with a far greater duration. The combined effects of different IP rights on the cost, distribution, accessibility of medicines and health technologies is beyond the scope of this short study that, therefore, will not consider other relevant aspects of IP system such as, among others, the relationship between trademarks and international non-proprietary names (INN) and copyright questions regarding the package insert of medicines.



*high price of patented* medicines used to treat HIV / AIDS. The dramatic story of the AIDS/HIV pandemic in late nineties has clearly illustrated how patent policy has critical implications for access to essential medicines and contributed to the growing recognition that strong patent law applied to developing countries could undermine access to essential health care, thus compromising the fundamental right to health, particularly when the costs have to be borne by patients themselves<sup>10</sup>. The cost of medicines is and remains a *critical* factor that limits access to health treatments: when a course treatment costs twice or more the monthly wage of people, it is clearly not affordable. High prices, sometimes *prohibitive* prices for life-saving treatments, medicines and health technologies under patent protection could be financially unsustainable in both public and private sectors, thus leaving too many people without access to the benefits of the medical innovations<sup>11</sup>. High prices do heavily impact on the right to health of poor people.

The fundamental *interrelatedness* between *poverty* and the *right to health* has been stressed by the Human Rights Council (HRC) in two resolutions on Access to Medicines and on Enhancing capacity-building in public health, approved on 30 June 2016<sup>12</sup>, as one of the *overreaching determinants* that hinder the realization of the right of everyone to the

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<sup>10</sup> E. 'T HOEN, *Private Patents and Public Health. Changing Intellectual Property Rules for Access to Medicines*, Amsterdam, 2016, pp. 3-4.

<sup>11</sup> A recent example is Sofosbuvir, an important breakthrough in the treatment of chronic hepatitis C, whose production cost is estimated to be US\$ 68-136 for a course of treatment. However, the company that holds the patent sells it for up to US\$ 84,000. In Europe a one-time treatment costs between 48,000 and 96,000 euros. Cancer also is a big money maker: global oncology sales by the pharmaceutical industry accounted for US\$ 100 billion in 2015 and, according to a recent study, are expected to rise to US\$ 147 billion in 2018 (see M. HARPER, *The Cancer Drug Market Just Hit \$100 Billion And Could Jump 50% In Four Years*, 5 May 2015, *Forbes/Pharma & Health Care*, available at: [www.forbes.com/sites/matthewherper/2015/05/05/cancer-drug-sales-approach-100-billion-and-could-increase-50-by-2018/](http://www.forbes.com/sites/matthewherper/2015/05/05/cancer-drug-sales-approach-100-billion-and-could-increase-50-by-2018/)). The cancer drug Imatinib (brand name Glivec) also demonstrates the huge differences between a monopoly price and a generic price. South Africa pays over US\$ 3,227 per patient per month for the branded product Glivec, while in India where the patent was not granted, the drug is priced at US\$ 170 for a month's treatment. In the U.S.A, the price of Glivec has nearly tripled since its introduction in 2001 and now costs US\$ 92,000 a year. See, E. 'T HOEN, *A Victory for Global Public Health in the Indian Supreme Court*, in *JPHP*, 2013, pp. 370-373.

<sup>12</sup> HRC, *Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, res. 32/15, Doc. A/HRC/32/L.32/Rev.1 of 1 July 2016; HRC, *Promoting the right of everyone to the enjoyment of the highest attainable standard of physical and mental health through enhancing capacity-building in public health*, res. 32/16, Doc. A/HRC/32/L.23/Rev.1 of 1 July 2016.



enjoyment of the highest attainable standard of physical and mental health, and thus the access to life-saving medicines and healthcare treatments<sup>13</sup>. The argument advanced by brand name global pharmaceutical industries, the Office of the United States Trade Representative, developed country governments, that the big problem *is not patents but poverty* is misleading, since the current trend to transform medicines and life-saving drugs into private commodities for sale at whatever prices permitted by the market, through the dramatic expansion of high levels of intellectual property protection, has much to do with the reduced access to essential medicines to those who need them most<sup>14</sup>. While, this interrelatedness is beyond the scope of this article, there are plenty of evidences that correlates poverty with high disease burden: illness can be both a cause and a consequence of poverty. Individuals who lack access to *essential medicines* disproportionately live in poor and in low and middle-income countries, or live on low incomes in many wealthy countries. Poverty affects purchasing power, and the inability of poor people to pay reduces effective demand which, in turn, affects the degree of interest of for-profit companies. The expense of serious family illness, including drugs, is a major cause of household impoverishment. *Chronic and catastrophic diseases remain one of the main factors that push households from poverty into deprivation*, since - in the absence of *universal* healthcare in many countries - most medicines and health services are paid *out-of-pocket*<sup>15</sup>. According to recent estimates, the current increase in health-care costs, that can be exorbitantly costly and largely unaffordable for governments, communities, families and individuals in both poor and rich countries, as well as the skyrocketing

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<sup>13</sup> The economic impact of pharmaceuticals is substantial - especially in developing countries. Most developed countries spend on pharmaceuticals less than one-fifth of total public and private health spending, while health spending in transitional economies represents 15 to 30% of the total; by contrast, in most low-income countries pharmaceuticals are the largest public expenditure on health (25 to 66%) after personnel costs and the largest household health expenditure. See OECD, *Focus on Health Spending, OECD Health Statistics 2015*, July 2015 available at: [www.oecd.org/health](http://www.oecd.org/health).

<sup>14</sup> S. K. KELL, *Trips-Plus Free Trade Agreement and Access to Medicines*, in LLR, 2007, (referring to the "poverty non patents line"), pp. 45-47.

<sup>15</sup> Rightly, therefore, res. 32/15 stresses the need of *universal health coverage* that implies that "all people have access without discrimination to nationally determined sets of the needed promotive, preventive, curative, palliative, and rehabilitative essential health services, and essential, safe, affordable, efficacious, and quality medicines and vaccines, while ensuring that the use of these services does not expose users to *financial hardship*, with a special emphasis on the poor, vulnerable, and marginalized segments of the population".



prices for life-saving medicines, vaccines and treatment for rare diseases, push 150 million people into impoverishment every year<sup>16</sup>.

The evolution of multilateral debate over the past decade has also recognized that innovation and access are strictly intertwined; access without innovation would simply mean a declining capacity to meet an evolving global disease burden. As declared by the US delegate to WTO “there can be no access to drugs that have not been developed”<sup>17</sup>. Patents, in principle, promote *innovation* by providing incentive to invest in R&D. Nearly every important medicine of the last century-and-a-half, including antibiotics, vaccines, HIV treatments, cancer and cardiovascular medicines, owes its existence to the R&D activities of the (biotech)pharmaceutical industry. Yet, the role of intellectual property right (IPR) rules in innovation and how to enhance their effectiveness are matters of continuing debate<sup>18</sup>. The current way to finance and make available important pharmaceutical innovations begs the question whether the patent system, globalised through the WTO TRIPS Agreement, is really the most efficient way to go about it; or if is it possible to design a different system, aimed at stimulating pharmaceutical innovation that all can afford.

An important factor that hinders innovation and access to (essential) medicines and medical innovation is in fact the lack of sufficient investments in R&D in important public health needs. Under the prevailing IP model, pharmaceutical and biomedical industry recoups the costs of its R&D through high drug prices protected by patents monopolies and data and market exclusivities. The result of such market-oriented and profit-driven innovation approach is that very rarely new health technologies are developed for health conditions which cannot deliver back high return profits or sufficient return on investment. This is, for example, the case for bacterial infections that require antibiotics. Multi-drug resistant (MDR) Gram-negative bacteria are one of the major risks to modern medicine; notwithstanding the fact that most antibiotics, with the exception of the most recent ones, are off patent, every new antibiotic has proven exponentially much more expensive than its predecessors and has not attracted much investments in research, since it typically offers little

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<sup>16</sup> *The Lancet Editorial: Reducing the Cost of Rare Disease Drugs*, in *The Lancet*, 2011, p. 746.

<sup>17</sup> *WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS)*, 8-9 November 2016, *Discussion of the UN High-Level Panel Report on Access to Medicines*, available at: [www.wto.org/english/news16\\_e/trips\\_08nov16\\_e.htm](http://www.wto.org/english/news16_e/trips_08nov16_e.htm).

<sup>18</sup> A.D. SO, C. OH., *Approaches to Intellectual Property and Innovation That Meet the Public Health Challenge of AIDS*. Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law, 7-9 July 2011.



pecuniary reward for year of costly research<sup>19</sup>. Secondly, medical innovation has historically failed to address major diseases that are endemic in the developing and least developed world. At present, most research and development for medicines, vaccines, diagnostics and related health technologies are based on financial potential rather than the needs of the poorest and most marginalized communities. Rare and neglected diseases that affect disproportionately small and poor proportions of populations have not traditionally attracted enough investments. Despite the fact that neglected tropical diseases (NTDs) count for approximately 12% of total disease burden, only 4% of therapeutic products for these diseases has been registered in the last decade<sup>20</sup>. This situation can easily be explained by the low purchase power of people disproportionately affected by such diseases. The recent Ebola outbreak in West Africa, which killed more than 11,000 people, and the highly infectious Zika virus, spreading far and fast, with devastating consequences being linked with microcephaly, also highlight how the lack of incentives for research and development resulted in the absence of effective health technologies available to respond to these public emergencies of international concern<sup>21</sup>. Finally, paediatric formulations for diseases that affect children also remain scarce<sup>22</sup>.

To sum up, also the current patent-based incentive model for R&D has led to systematic underinvestment in diseases that do not represent a

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<sup>19</sup> CENTER FOR DISEASE DYNAMICS, ECONOMICS AND POLICY, *The State of the World's Antibiotics* (2015), Washington, available at: [http://cddep.org/about\\_cddep](http://cddep.org/about_cddep); *The Review on Antimicrobial Resistance* (2016), *Tackling Drug Resistant Infections Globally: Final Report and Recommendations*, available at: [http://amr-review.org/sites/default/files/160518\\_Final%20paper\\_with%20cover.pdf](http://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf). According to the *CIPRIH Report*, p. 109, even if a new antibiotic may itself cost significantly more than its predecessors, still the overall cost of treatment may make economic and financial sense because the treatment time is shorter, compliance better and less overall ancillary health services are requested, provided that the price for new drugs keeps pace with evolving disease burden, improves public health and remains affordable (with robust governmental incentives and new business models).

<sup>20</sup> B. PEDRIQUE, N. STRUB-WOURGAFT, C. SOME, P. OLLIARO, P. TROUILLER, N. FORD, B. PÉCOUL, J.-H. BRADOL (2013), *The Drug and Vaccine Landscape for Neglected Diseases* (2000-11): *A Systematic Assessment*, in *LGH*, pp. 37, 379.

<sup>21</sup> S. MOON, D. SRIDHAR, M.A. PATE, A.K. JHA, C. CLINTON, S. DELAUNAY, V. EDWIN, M. FALLAH, D.P. FIDLER L. GARRETT, E. GOOSBY, L.O.GOSTIN, D.L. HEYMAN, K. LEE, G.M. LEUNG, J.S. MORRISON, J. SAAVEDRA, M. TANNER, J.A. LEIGH, B. HAWKINS, L.R. WOSKIE. P. PIOT, *Will Ebola Change the Game? Ten Essential Reforms before the Next Pandemic. The Report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola*, in *The Lancet*, 2015, pp. 2204-2221. See also CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) (2016), *2014 Ebola Outbreak in West Africa - Case Counts*, available at: [www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html](http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html).

<sup>22</sup> UNAIDS Programme Coordinating Board, Thirty-Fifth Meeting, 9-11 December 2014, *Agenda item 6: Gap analysis on paediatric HIV treatment, care and support*, Geneva.



profitable market, such as: diseases that disproportionately affect people with little or no ability to pay (so-called “Type II and III”)<sup>23</sup>; diseases for which markets are fragmented or small; and diseases for which the treatments need to be preserved and that cannot be aggressively marketed, such as antibiotics.

Coping with all these difficulties means finding new ways of supporting innovation and wider access, including rational selection and use of medicines; affordable prices; reliable health and supply systems; new incentives for R&D of drugs and health technologies and, finally, a *IP regime* for pharmaceutical products able to ensure that all people receive the quality and essential health services they need.

## **2 - The actual and/or potential between the rights of inventors, international human rights law, trade rules and public health. The everlasting controversy on the allegedly adverse impact of IP protection on access to medicines and health technologies**

All the above mentioned concerns about the patent’s role on access and innovation in the context of health technologies, along with the necessity to strike a right balance between the duty to fulfil both international obligations in the TRIPS Agreement and in international human rights law, have repeatedly reaffirmed in the last two decades by several UN political and expert bodies<sup>24</sup>. As said above, in 2016, the United Nations HRC

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<sup>23</sup> According to the WHO (*CIPIH Report*, p. 85), there is no evidence that the implementation of the TRIPS Agreement in developing countries has significantly boosted R&D in pharmaceuticals on Type II (such as HIV / AIDS and tuberculosis; both diseases are present in rich and poor countries, but more than 90% of cases are in the poor countries) and particularly Type III diseases (that are overwhelmingly or exclusively incident in the developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness). Type II diseases are often termed *neglected diseases* and Type III diseases *very neglected diseases*. For these kind of diseases, insufficient market incentives are the decisive factor. Development and innovation in respect of these kind of diseases normally imply significant involvement by the public sector or philanthropic organizations and funding.

<sup>24</sup> Sub-Commission on Human Rights res. 2000/7, *Intellectual Property Rights and Human Rights*, 17 August 2000 (adopted without a vote); Sub-Commission on the Promotion and Protection of Human Rights, res. 2001/21, *Intellectual Property Rights and Human Rights* (adopted without a vote), Doc. E/CN.4/Sub.2/2001/L.11/ Add.2 of 16 August 2001; Commission on Human Rights, *Report of the High Commissioner, The Impact of the Trade Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, Doc. E/CN.4/Sub.2/2001/13 of 27 June 2001, paras 11-12; Office of the High Commissioner for Human Rights, 5<sup>th</sup> WTO Ministerial Conference, Cancun, Mexico, 10-14 September 2003,





adopted two important resolutions on access to medicines and on enhancing capacity-building in public health, reaffirming that both are fundamental elements for achieving the full realization of the right to health<sup>25</sup>. The resolutions have been proposed by a number of developing countries, many of which not even member States of the HRC. These countries - supported by a high number of additional co-sponsors - have again chosen the UN fora to raise the relation between intellectual property rights, trade agreements and access issues. The Council took note of the *actual or potential conflicts* that exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights “in relation to, inter alia, restrictions on access to patented pharmaceuticals and the implications for the enjoyment of the right to health”. While intellectual property rights have the important function of providing incentives for innovation, they can, in some cases, obstruct access by pushing up the price of medicines. HRC res. 32/15 expressly recognizes “that the protection of intellectual property is important for the development of new medicines” but it also expressed its “concerns about its effects on prices”.

The finding that there are actual and potential conflicts between the WTO’s implementation of the agreement on TRIPS and the realization of the right to health, came after some authoritative conclusions reached in 2012 by the Global Commission on HIV and the Law (an independent body of eminent persons tasked by the Programme Coordinating Board of the Joint UN Programme on HIV/AIDS) that a growing body of international

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*Human Rights and Trade; Commission on Human Rights, Report of the Special Rapporteur, Paul Hunt, on The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, 1 March 2004, Doc. E/CN.4/2004/49/Add.1 of 1 March 2004; HRC, Report of the Special Rapporteur, Anand Grover, on The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Doc. A/HRC/11/12 of 31 March 2009; HRC, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Expert Consultation on Access to Medicines as a Fundamental Component of the Right to Health, Doc. A/HRC/17/43 of 16 March 2011; HRC, The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health in the Context of Development and Access to Medicines, res. 17/14, Doc. A/HRC/RES/17/14 of 14 July 2011; Special Rapporteur in the Field of Cultural Rights, The Right to Enjoy the Benefits of Scientific Progress and Its Applications, Human Rights Council, Doc. A/HRC/20/26 of 14 May 2012, para. 59; HRC, Access to medicines in the context of the right of everyone to the enjoyment of the of the highest attainable standard of physical and mental health, res. 23/14, Doc. AHRC/23/L.10/Rev.1 of 11 June 2013, (adopted by a vote of 31 in favor to 0 against, with 16 abstentions); Patent policy and the human right to science and culture, Report of the Special Rapporteur in the field of cultural rights, Doc. A/70/279 of 4 August 2015, para. 4.*

<sup>25</sup> HRC, res. 32/15 and res. 32/16, *supra*, note 12.



trade law is hindering the right to health of millions and that new solutions are needed to incentivize innovation and increase access to treatment<sup>26</sup>. Consistent with the findings and recommendations of the Global Commission, and in line with his synthesis report on the post-2015 development agenda and the recently adopted Sustainable Development Goals, the United Nations Secretary-General Ban Ki-moon convened in November 2015 a *High-Level Panel on innovation and access to health technologies* (hereafter HLP). Again, the HLP's terms of reference called for it to

“review and assess proposals and recommend solutions for remedying the *policy incoherence* between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies”.

In order to significantly improve innovation and access to medicines, vaccines, diagnostics, and related health technologies across the world, the Panel has therefore been tasked with proposing solutions to address the *misalignment* between these three different and overlapping spheres. The HLP realised its final report, which contains a lot of important findings and recommendations, in September 2016<sup>27</sup>. A key aspect of the HLP report, a vision interestingly shared also with the Secretariat of WTO<sup>28</sup>, is the necessity to encourage “coherence” for public health at all levels. According to the Panel, the main reason for the actual policy incoherencies derives from the fact that policies that have a bearing on access to health technologies and that are associated with trade, intellectual property, health and human rights

“were developed with different objectives and at different periods in history. Each is governed by its own legal and regulatory regime and each imposes obligations that may not align with the others. Trade and intellectual property rules were not developed with the goal of protecting the right to health, just as human rights doctrine does not primarily concern itself with promoting trade or reducing tariffs. Policy incoherencies arise when legitimate economic, social and

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<sup>26</sup> GLOBAL COMMISSION ON HIV AND THE LAW, *Risks, Rights and Health* (2012), *Executive Summary*, pp. 14-16.

<sup>27</sup> *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines. Promoting innovation and access to health technologies*, September 2016 (hereafter HLP Report), available at: [www.unsgaccessmeds.org/final-report/](http://www.unsgaccessmeds.org/final-report/).

<sup>28</sup> See UN SECRETARY GENERAL'S HIGH LEVEL PANEL ON ACCESS TO MEDICINES, *Building Momentum for the Coherence Agenda on Global Health*, Background note prepared by the Secretariat of the WTO, available at: <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/5716611627d4bd3a483b70a4/1461084438964/1603+HLP+WTO+background+paper+submitted.pdf>.



political interests and priorities are misaligned or in conflict with the right to health”.

Another critical element is the diverse accountability mechanisms and transparency levels of the three different areas (on the one side, human rights and public health characterized by vary and very often limited legal weight and enforceability; on the other side, the intellectual property-related accountability mechanism, very effectively regulated by the WTO Dispute Settlement Body, as well as by strong dispute settlement provisions found in free trade and investment agreement). Finally, according to the HLP key aspects of policy, incoherencies lie in the misalignment between market-based models for innovation and the need to obtain treatment for patients<sup>29</sup>.

The conclusions reached by the HLP on these types of specialized legal norms and institutions, that have developed largely independently from one another, in response to specific functional issues, that come with their own principles, their own forms of expertise and own “ethos”, are confirmed by the harsh and vigorous debate that has opposed in the last two decades, on the one side, an alliance of developing and least developed countries, non-governmental organizations and UN Human rights bodies campaigning for access to essential medicines and, on the other - opposite - side, the pharmaceutical industry and developed countries. Both groups defend two very different perspectives and views of patents rights and their impact on the human right to health<sup>30</sup>. The tensions between these two reasoning schemas reflect themselves, also, in different interpretation of many of the TRIPS provisions, whose language is sufficiently ambiguous to sometimes support both competing patent perspectives. The first perspective, shared by the international human rights community, is based on the assumption that patents are simply “privileges” inherently subject to limitations and exceptions. This is the idea constantly supported by the UN Human Rights Bodies that have extensively clarified the fundamental nature of the right to health and access to medicines and health technologies<sup>31</sup>, as affirmed (by States themselves) in numerous treaties and declarations, including the 1948 Universal Declaration on Human Rights, the International Covenant on Economic, Social and Cultural Rights (ICESCR, New York, 16 December 1966, Article 12), the WHO Constitution, as well as in many regional human rights instruments and many national constitutions<sup>32</sup>. This hard law is also supplemented by soft law norms

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<sup>29</sup> HLP Report, p. 16.

<sup>30</sup> C.M. HO, *Global Access to Medicine: The Influence of Competing Patent Perspectives*, in *FILJ*, 2016, pp. 29-39.

<sup>31</sup> *Supra*, note 24.

<sup>32</sup> R. ELLIOTT, *Background Paper: International legal norms: the right to health and the*



which include non-binding instruments adopted by States, such as the *Millennium Development Goals* (Target 8.E of Millennium Development Goals 8) and Sustainable Development Goal 3 of the *2030 Agenda for Sustainable Development*, adopted in September 2015 by 193 member States of the United Nations, with the aim to “Ensure healthy lives and promote well-being for all at all ages”, including a bold commitment to end the epidemics of AIDS, tuberculosis, malaria and other communicable diseases, to achieve universal health coverage, and provide access to safe, effective and affordable medicines and vaccines for all by 2030.

Human rights law, while recognizing that the full achievement of the right to health is a legal obligation of *progressive realization*<sup>33</sup>, also poses the strong presumption that “*retrogressive measures* taken in relation to the right to health are not permissible”, and constitute a violation of the right to health<sup>34</sup>. A conclusion, this, of particular relevance to the adoption by States of IP provisions, especially in respect of the *core minimum obligations* of the right to health that are deemed “*non-derogable*” and immediately binding on States, like ensuring the right to access to health technologies and essential medicines<sup>35</sup>.

The right to health is completed by the right of everyone (codified in ICESCR, Article 15.1 (b)) “to enjoy the benefits of scientific progress and its applications”<sup>36</sup>. As to the question whether intellectual property rights are themselves human rights, undoubtedly both the Universal Declaration of Human Rights (Articles 17 and 27) and the ICESCR (Article 15.1) recognize the right to property and the right to the protection of the moral and material interests resulting from artistic and scientific works. Nevertheless, at the heart of the debate lies a complex distinction between *individual* intellectual property rights and *community* rights<sup>37</sup>. In a General Comment

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*justifiable rights of inventors*, available at: [www.unsgaccessmeds.org/new-page/](http://www.unsgaccessmeds.org/new-page/).

<sup>33</sup> CESCR, *General Comment No. 14* cit., para. 31.

<sup>34</sup> CESCR, *Human rights and intellectual property: Statement by the Committee on Economic, Social and Cultural Rights*, UN Doc. E/C.12/2001/15 (2001), para. 13.

<sup>35</sup> CESCR, *General Comment No. 3, The Nature of States Parties Obligations*, Doc. E/1991/23 of 14 December 1990, para. 10; CESCR, *General Comment No. 14*, para. 43(a), (d), (e); United Nations Human Rights, Office of the High Commissioner, *Core Human Rights in the Two Covenants*, September 2013.

<sup>36</sup> HRC, *Report of the Special Rapporteur in the Field of Cultural Rights: The Right to Enjoy the Benefits of Scientific Progress and Its Applications*, Doc. A/HRC/20/26 of 14 May 2012, at paras 9-12; UNGA, *Report of the Special Rapporteur on the Right to Food: Seed Policies and the Right to Food: Enhancing Agrobiodiversity and Encouraging Innovation*, Doc. A/64/170 of 23 July 2009; R. ELLIOTT, *Background Paper*, *supra*, note 32, pp. 9-11.

<sup>37</sup> For an important discussion on this point see *Implementation of the International Covenant on Economic, Social and Cultural Rights*. Discussion paper submitted by A.R. CHAPMAN to the United Nations Committee on Economic, Social and Cultural Rights, Doc.



on the normative content of the ICESCR provision<sup>38</sup>, the UN Committee on Economic, Social and Cultural Rights (hereinafter: the Committee or CESCR) importantly noted that the right of “authors” to benefit from the protection of moral and material interests resulting from any scientific, literary or artistic productions, refers exclusively to *natural persons*. The implication of the General Comment is that there is *no human right* of companies to any particular form of protection for the legal rights which result from a patented invention: the entitlements of legal entities under intellectual property treaties *are not protected at the level of human rights*<sup>39</sup>. According to the Committee, there is a fundamental distinction between the *human rights of inventors* (which derives from the inherent dignity and worth of all persons) and the *legal rights* related to intellectual property. Human rights are *fundamental, inalienable and universal entitlements* belonging to individuals and, under certain circumstances, groups of individuals and communities

“whereas intellectual property rights are first and foremost means by which States seek to provide incentives for inventiveness and creativity, encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific, literary and artistic productions for the benefit of society as a whole”.

In contrast to human rights that are fundamental, universal entitlements that people inherently acquire by virtue of their birth,

“intellectual property rights are one policy tool among many for encouraging innovation and technological research and development (...) and are generally of a temporary nature, and can be revoked, licensed or assigned to someone else”<sup>40</sup>.

All the above commentaries and interpretations clearly support the idea of patents as a “privilege” that primarily protect business and

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E/C.12/2000/12 of 3 October 2000, paras 23-28; M. DUNCAN, *Intellectual Property Rights, Human Rights and the Right to Health*, in W. GROSHEIDE (ed.), *Intellectual Property Rights and Human Rights: A Paradox*, Cheltenham-Northampton, 2010, pp.118-140.

<sup>38</sup> CESCR, *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He or She Is the Author (article 15, paragraph 1(c), of the Covenant)*, Doc. E/C.12/GC/17 of January 2006.

<sup>39</sup> On the very different approach of the European Court of Human Rights on this issue, see H.A.M. WINFRIED, *Corporations and the European Convention on Human Rights*, available at: [www.mcgeorge.edu/Documents/Conferences/GlobeJune2012\\_Corporationsandthe.pdf](http://www.mcgeorge.edu/Documents/Conferences/GlobeJune2012_Corporationsandthe.pdf), pp. 43-68.

<sup>40</sup> *Supra*, note 38, para. 10.



corporate interests and investments; as such, it must be subject to limitations and exceptions in the public interest and yield to the right to public health whenever in contrast and/or in potential conflict with this fundamental human right and societal interests, such as low-cost access to medicines.

It is a shared view in the human rights community that the today's IP system, particularly within the area of pharmaceutical innovation, is "out of balance". The far most important barrier to access is deemed *strong intellectual property protection* that leads to high prices and limited access, due to the reduced quantity and availability of quality generic alternatives. Patents are believed to provide excessive financial rewards to patent holders, mostly large pharmaceutical companies, by allowing patent holders to use the *de facto* monopoly created by the patent to ask the highest possible price for their products, thus excluding from access those who cannot pay and preventing competition. Being *affordable* prices a critical determinant of access to (essential) medicines, *generic competition* is considered a key factor, among others, in driving prices down. An example may be found in the context of the AIDS/HIV pandemic when the ground reality drastically changed only by the competition brought about by generics industry that had played a significant role in pushing down the prices of off-patent products thus allowing nearly 15 million people to be on treatment<sup>41</sup>.

While prices of medicines and health technologies are influenced by a large variety of factors<sup>42</sup>, undoubtedly intellectual property rules play a

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<sup>41</sup> The fact that patent allows *per se* to maintain monopolistic prices is currently a strong concern in respect to the second- and third-line of antiretroviral drugs, whose costs remain significantly higher than that of the first-line antiretroviral drugs in developing countries. Access to these new antiretroviral drugs is critical for patients in developing countries who fail to benefit from first-line therapies and who have developed resistance to the first-line treatment. Similarly, the costs of new cancer medications have raised in the last decade at such a higher rate to make healthcare unaffordable *even* for health systems and individuals in high-income countries. See E. 'T HOEN, (2016), *supra*, note 10, p. 4; E. 'T HOEN, *The Global Politics of Pharmaceutical Monopoly Power. Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*, The Netherlands, p. 5; T. FOJO, C. GRADY, *How Much is Life Worth: Cetuximab, Non-Small Cell Lung Cancer, and the \$440 Billion Question*, in *JNCI*, 2009, pp.1044-1048; *HLP Report*, p. 21.

<sup>42</sup> A number of approaches and global policies may be adopted to ensuring that the prices of drugs and other products are as affordable as possible. Governments may employ direct price controls, reference pricing, and reimbursement limits; or resort to other different means including removing tariffs and taxes and regulating supply chain distribution mark-ups. Differential pricing applied by pharmaceutical companies can be also a complementary tool to increase access, by linking prices to the differing capacity to pay according to income levels within distinct markets. Another strategy for enhanced



role since the patents protection required by the TRIPS Agreement has brought to monopolistic prices, not justifiable to compensate for the real costs of R&D<sup>43</sup>. Patent-owing companies are also frequently criticized for spending much more money on the advertisement and promotion of drugs than on scientific research, especially in respect of inadequate research and development for the so-called “medicines for the poor”. Another area of strong concern is the peril of market economic concentration of global pharmaceutical firms and their political powerfulness on the western countries’ trade policymaking context in order to systematically obtain higher levels of protection through a number of venues<sup>44</sup>. Further, human rights activists and academics have recurrently outlined various forms of patent abuses of monopoly; the majority of current pharmaceutical patents are on drugs that had only been slightly changed, namely a “new form” not new molecules; yet both categories are currently being patented, needlessly making them more costly<sup>45</sup>. Other examples of abuses are the so-called “evergreen” patents that occur in regard of no incremental therapeutic values (for example when companies file and obtain patent, subsequent the original patent, for different dosage forms)<sup>46</sup>. Much emphasis has also been put on the bullying role of pharmaceutical firms, the US, and the EU trade

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access to medicines consists in developing local production capacity and leveraging technology transfer. See *CIPIH Report*, p. 109.

<sup>43</sup> Drug discovery and development is a complex, lengthy and costly activity. Widely quoted figures for a sample of medicines suggest that the average cost of developing a new drug is US\$ 800 million, or even much more. This sum supposedly includes the cost of capital, success and failure, but it has been questioned on methodological grounds and because the raw data for independent verification are not available. However, evidences show that the direct costs of developing a particular drug are much lower depending upon the therapeutic area, geographical focus and regulatory requirements. This is particularly true for products developed by public-private partnerships or because of prior investment in discovery research in universities and public research institutions. See, *CIPIH Report*, p. 17; on high prices that do not necessarily indicate essential innovation, see also E. ‘T HOEN (2016), pp. 126- 129.

<sup>44</sup> P. DRAHOS, *Securing the Future of Intellectual Property: Intellectual Property Owners and Thier Nodally Coordinated Enforcement Pyramid*, in *CWRJIL*, 2004, pp. 55-61.

<sup>45</sup> Only 15 % of new drugs - approved by the United States Food and Drug Administration from 1989 to 2000 - was for highly innovative priority new medical entities. Medicines were thus insensibly modified, and thereafter patented. See NATIONAL INSTITUTE FOR HEALTH CARE MANAGEMENT RESEARCH AND EDUCATIONAL FOUNDATION, Washington, D.C., *Changing Patterns of Pharmaceutical Innovation*, May 2002, p. 3, available at: [nihcm.org/pdf/innovations.pdf](http://nihcm.org/pdf/innovations.pdf).

<sup>46</sup> The CIPIH (*CIPIH Report* 2006, p. 134) defined *evergreening* as a term “popularly used to describe patenting strategies when, in the absence of any apparent addition therapeutic benefits, patent holders use various strategies to extend the length of their exclusivity beyond the 20-years patent term”.



policies with respect to the intellectual property and access to essential medicines in developing countries, particularly on the deceiving EU's attitude to handle generic medicines transiting the EU territory<sup>47</sup>.

Last, but not least, there is a very rich literature concerning the current worldwide trend for countries to enter into economic integration arrangements in various bilateral and regional configurations (regional trade agreements (RTAs), free trade agreements (FTAs), bilateral trade agreements (BTAs), or preferential trade agreements (PTAs)) - a development that is presenting significant systemic challenges for the multilateral system. As recently noted by the WTO, WIPO and WHO, these trade agreements have frequently taken the form of deep integration processes that include provisions on a wide range of regulatory policy areas, such as services and IP, imposing important changes in national laws, which directly affect the framework governing access to, and innovation in, medicines and medical technologies<sup>48</sup>. It is widely recognized that these trade agreements have progressively expanded and deepened patent and data protection on medicines and health technologies, further exacerbating policy incoherencies between the obligation of States to protect and enforce intellectual property rights (usually backed by a very powerful investor-State disputes) and their corresponding human rights obligations and public health priorities<sup>49</sup>. A number of provisions found in these trade agreements are labelled *TRIPS-Plus* provisions because they exceed the minimum standards for protection and enforcement required by the TRIPS Agreement and limit its inherent flexibilities in the TRIPS Agreement (or *TRIPS-Minus* insofar these provisions simply *omit* any TRIPS flexibilities). The most common examples are TRIPS-Plus demands that regularly figure on the list of the US and/or the EU trade talks and that delay the introduction of generic medicines in the market, such as: patent for new uses or methods of using known products; patent linkage; test data exclusivity periods; extension of patent terms for pharmaceuticals beyond the 20 years required by TRIPS Agreement for "unreasonable" regulatory or marketing delays; restrictions for compulsory licences and for parallel importation; prohibition of pre-grant or post-grant patent opposition; enhanced obligations regarding border measures, civil and administrative procedure, remedial provisions and the criminalization of certain violations beyond what is

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<sup>47</sup> See *infra* note 100. In addition, see WHO, *CIPRH Report, Main recommendations*, BWHO, 2006, p. 351; C. CORREA, *The Commission on IPRs, Innovation and Public Health. A Critique*, in *South Bulletin*, 15 April 2006, available at: <http://www.southcentre.org>.

<sup>48</sup> *The Trilateral Study*, pp. 83-85.

<sup>49</sup> *HLP Report*, pp. 9-10.





required by the TRIPS Agreement<sup>50</sup>. Asymmetries of power between powerful and poor countries, between corporation and citizens, fuel this awful trend, making difficult for developing countries to push back on TRIPS-Plus demands in bilateral or regional talks, or making harder for them to resist signing similar trade in future deals. In this respect, greater transparency and greater involvement of the health community, till now excluded from participation in these trade agreements, would greatly contribute solving the problem. *Transparency* is actually a recurring theme throughout the final HLP Report, that was very critical about the lack of transparency, surrounding - not only the costs of R&D, production, marketing, distribution and the end prices of health technologies<sup>51</sup> - but also bilateral and regional Free Trade and Investment Agreements, that are often negotiated in secrecy. A *paradigm shift* in transparency, a core component of good governance, would certainly provide a robust and effective accountability framework needed to hold all stakeholders responsible for the impact of their actions on innovation and access<sup>52</sup>.

The alternative perspective on patents lies on a very different “ethos” - a sort of *uber-right* schema<sup>53</sup> - that is defended by several western countries (home to big pharmaceutical companies) and by the same pharmaceutical companies; both strongly object both the wording of the HRC resolutions (although supportive of the overall goal of the resolution) and the recommendations contained in the above mentioned UN HLP Report. In various statements delivered in a general comment on the draft UN resolutions, the United Kingdom, Switzerland and the European Union, defined the recent UN resolutions unbalanced, due to an undue emphasis on the access to medicines and an inadequate simplification of the issue<sup>54</sup>.

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<sup>50</sup> See, for all, *HLP Report*, pp. 24-26. On the challenges faced by some developing (medicines producing and exporting) countries such as India, Brazil, Thailand, Malaysia, South Africa and Kenya see, E. 'T HOEN (2009), *supra* note 41, pp. 44-62.

<sup>51</sup> See also R.F. BEALL, A. ATTARAN, *Which Patent and Where? Why International Patent Transparency by Companies is Needed for Medicines*, in NB, 2016, pp. 923-926.

<sup>52</sup> See the section on “Governance, Accountability and Transparency” in the *HLP Report*, pp. 33.36.

<sup>53</sup> See C. M. HO, *supra*, note 30, pp. 34-49.

<sup>54</sup> Earlier, during informal consultations, the Netherlands, speaking for EU, wanted reference to ‘generics’ removed altogether and to replace the word “full” use of TRIPS flexibilities with “appropriate” use of TRIPS flexibilities, thus watering down the language. Those suggestions, fortunately, were not accepted and retained in the final text of res. 32/15. Mexico noted that it was extremely important to adopt all measures on economic, social and cultural rights in order to allow everyone to access the highest attainable health services, but that it was *unacceptable* to include into the resolution references to trade aspects and intellectual property rights, since the Council could not be used to establish precedents regarding human rights and international trade and intellectual property



On their part, the pharmaceutical industry released statements showing great disappointment in respect of the recent HLP recommendations, for having ignored the most common issues that hamper access to medicines and failed to recognize the complexity of the issue, as well as the many existing and innovative efforts already taking place to advance access to care in the last two decades<sup>55</sup>. According to the Biotechnology Innovation Organization (BIO), IP simply could not restrict access to medicines because the vast majority of essential medicines are no longer under patent<sup>56</sup>. The key to the success of the biotechnology industry is a *business model* based on making significant investments (often hundreds of millions of dollars) in early stage research and development with the hope that some of these investments and efforts will yield a commercial product.

This model has worked despite the fact that it is lengthy (often taking more than a decade) and that most biotechnology R&D investments and efforts do not result in a commercial product reaching the market<sup>57</sup>. All opponents stressed that both the HRC resolutions and the HLP mandates were too narrow since they did not analysed other important factors *unrelated to IP* that stand in the way of access to medicines, such as those outlined in the 2013 joint WHO-WTO-WIPO Trilateral Study, which include: inequalities between and within countries, poverty, tariffs and taxes on imported medicines or other barriers that can result in “unaffordability”, inefficient and inconsistent regulatory systems, inadequate transportation infrastructure, deficient distribution systems, a shortage of trained healthcare providers and facilities, corruption, to name a few<sup>58</sup>. Further, they objected that there is plain evidence that countries with little or no IP protections, or countries with a focus on *generic medicines*, still face significant challenges in providing much needed medicines to their

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instruments. Statements released are available at: [www.ip-watch.org/2016/07/01/access-to-medicines-resolution-adopted-by-un-human-rights-council/](http://www.ip-watch.org/2016/07/01/access-to-medicines-resolution-adopted-by-un-human-rights-council/); [www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=20223&LangID=E](http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=20223&LangID=E).

<sup>55</sup> Available at: [www.ip-watch.org/2016/09/14/un-high-level-panel-on-access-to-medicines-issues-landmark-report/](http://www.ip-watch.org/2016/09/14/un-high-level-panel-on-access-to-medicines-issues-landmark-report/); see also HLP Report, A. Witty’s Commentary, p. 56.

<sup>56</sup> According to a recent survey, the vast majority of the medicines on the WHO Essential Medicines List are not patented. For the 2015 list, that contains 409 medicines, only around 34 (8%) have been patented. A conclusion this that for big Pharma companies hardly provides the empirical evidence needed to justify reinventing the patent system that incentivized these drugs into existence. Additionally, LDCs are not required to introduce patents for any medicines before the year 2033 and few of those 34 medicines are patented in many other poorer countries.

<sup>57</sup> L. FEISEE, *Comments of the Biotechnology Innovation Organization (BIO)*, available at: [www.unsgaccessmeds.org/inbox/2016/2/28/the-biotechnology-innovation-organization](http://www.unsgaccessmeds.org/inbox/2016/2/28/the-biotechnology-innovation-organization). See also the counter-argument advanced by the CIPIH Report, *supra*, note 42,

<sup>58</sup> *The Trilateral Study*, p. 156 ff.



populations, since the availability of a medicine in a country even at the lowest possible prices, does not guarantee that the patient population in need of the medicine will actually be able to access it. The final implication is that even if patents were abolished tomorrow, it would make little difference to the cost or availability of most medicines used in developing countries.

This means that IP plays no role in the lack of access for these medicines and these countries<sup>59</sup>, while, weak and unpredictable IP laws in countries create a difficult, if not impossible environment, for the development of new medicines, and for providing the incentives necessary to introduce new and innovative medicines for populations that need them. Therefore, contrary to the “incoherence” described by the HRC and the HLP, the relationship between patents and medicines is (logically) quite the opposite: strong intellectual property rights are essential for robust medical innovation, which heavily rely on patent protections to generate investment into the development of these products. Rather than condemning intellectual property rights as the principle barrier to access, the incentives to innovate must be protected, not abandoned. This implies the necessity to *strengthen* IP laws to enable investors, companies and researchers to take the risks necessary to develop innovative medicines to reach those who need them most<sup>60</sup>.

### **3 - Are human rights and intellectual property law really in conflict? A relation of interpretation, not of conflict**

The two very different “ethos” and competing patent perspectives illustrated above, clearly bring the international lawyers to the topic of “fragmentation” and diversification of public international law that has been the subject of much scholarly attention over the last decade. In its seminal study on the “Fragmentation of International Law: Difficulties Arising From the Diversification and Expansion of International Law”, a Study Group of the International Law Commission (ILC), chaired by Martti Koskenniemi, reviewed the legal techniques to deal with situations in which multiple international norms co-exist, in relationships either of interpretation or conflict<sup>61</sup>. The techniques suggested to solve

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<sup>59</sup> *HLP Report*, A. WITTY’s Commentary, p. 56.

<sup>60</sup> *Ibidem*.

<sup>61</sup> *ILC Conclusions 2006. ILC, Report of the Study Group, Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law: Conclusions*, Doc. A/CN.4/L.702 of 18 July 2006.



hypothetical/*prima facie* or *actual* normative conflicts seek, first, to ascertain the common intention of States parties to the relevant regimes and include the principle of *harmonization-systemic integration* as a generally accepted principle: when several norms bear on a single issue, they should, to the extent possible, be interpreted in an integrated and harmonized way. In certain situations, generally accepted techniques of interpretation and conflict resolution consist in the priority of particular or special norms (*lex specialis*) over general norms and the priority of a subsequent rule (*lex posterior*) replacing an earlier conflicting rule. Another priority relates to “Relations of Importance”, based on the idea that while there is no formal constitution in international law and no general order of precedence between international legal rules, nevertheless some norms are more important than others because they secure important interests or protect fundamental values. Therefore in case of conflict they enjoy a superior position, including: *jus cogens* obligations, obligations *erga omnes* and Article 103 of the UN Charter. The well-known conclusions reached by the Report are the follows: International law is a legal system and its rules and principles should be interpreted against the background of other rules and principles; in applying international law, it is often necessary to determine the precise relationship between two or more rules and principles that are both valid and applicable in respect of a situation. For that purpose, the relevant relationships fall generally into two general types: a) “Relationships of interpretation”, which is the case where one norm assists in the interpretation of another as an application, clarification, updating or modification of the latter. In such a situation, both norms are applied in conjunction; b) “Relationships of conflict”, that is the case where two norms that are both valid and applicable point to incompatible decisions, so that a choice must be made between them (the basic rules concerning the resolution of normative conflicts are to be found in the 1969 Vienna Convention on the Law of Treaties, especially in the light of the provisions in Articles 31-33).

It is the Author’s opinion that the normative relationship between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies is not one of conflict; a conclusion this that seems valid even adopting a wide and loose understanding of notion of conflict, as “a situation where two rules or principles suggest different ways of dealing with a problem”, and not a narrow notion of conflict as *incompatibility* between the different sets of rules, so that it is impossible for a party to two or more treaties to comply



with one rule without failing to comply with another rule or obligation<sup>62</sup>. Many of the so-called actual or potential conflicts between different legislative policies can be resolved simply through a correct legal reasoning and interpretation of the rules in question (especially the TRIPS rules),

“by applying the general rules codified in the 1969 Vienna Convention, which mandate that treaty interpretation must be based on the text, context, object and purpose and good faith, to be used as one holistic rule of interpretation rather than a sequence of separate tests to be applied in a hierarchical order”<sup>63</sup>.

The starting point of the reasoning is that the WTO system is not a closed system, a position clearly rejected by the Appellate Body when it noted that WTO Agreements “should not be read in clinical isolation from public international law”<sup>64</sup>, referring further to “additional interpretative guidance, as general principles of international law”<sup>65</sup>, and that “such international law applies to the extent that the WTO treaty agreements do not ‘contract out’ from it”<sup>66</sup>. Contrary to the current assertions in many human rights discourses, the WTO system has not at all contracted out human rights concerns in respect of public health. Rather it has clearly *internalized* public health considerations into its TRIPS Agreement, and further enhanced them during the fourth Ministerial conference in Doha in 2001 *via* the *WTO Doha Declaration on TRIPS Agreement and Public Health*<sup>67</sup>.

In order to determine whether or not Section 5 of Part II of the TRIPS Agreement (which sets out the obligations of members with respect to standards concerning the availability, scope, use of patents) *really* prevents a sound balancing of incentives for R&D of new drugs with the interest of patients (making these medicines as widely accessible as possible), it is necessary to analyze very briefly the main features of the TRIPS provisions

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<sup>62</sup> Report of the Study Group of the ILC, finalized by M. KOSKENNIEMI, Doc. A/CN.4/L.682 of 13 April 2006, p.19. See also J. PAUWELYN, *Conflict of Norms in Public International Law. How WTO Relates to Other Rules of International Law*, Cambridge, 2003, pp.146-200.

<sup>63</sup> WTO, *United States-Sections 301-310 of the Trade Act of 1974*, Report of the Panel, Doc. WT/DS152/R of 22 December 1999, para. 7.22.

<sup>64</sup> WTO, *United States - Standards of Reformulated and Conventional Gasoline*, Report of the Appellate Body, Doc. WT/DS2/AB/R of 29 April 1996, p. 17.

<sup>65</sup> WTO Appellate Body, *United States - Import Prohibition of Certain Shrimp and Shrimp Products*, Doc. WT/DS58/AB/R of 12 October 1998, para. 158.

<sup>66</sup> WTO, *Korea - Measures Affecting Government Procurement*, Report of the Panel, Doc. WT/DS163/R of 1 May 2000, para. 7.96.

<sup>67</sup> *Declaration on the TRIPS Agreement and Public Health*. Ministerial Conference, Fourth Session (Doha, 9-14 November 2001), Doc. WT/MIN(01)/DEC/W/2 of 14 November 2001, available at: [www.wto.org/english/tratop\\_e/dda\\_e/dohaexplained\\_e.htm](http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm).



on patents, the *Doha Declaration*, as well as the patent system's primary regulatory purpose. The *rationale* 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. The patent system intends to correct the "market failure" by providing innovators with limited exclusive rights to prevent others from exploiting their invention, thereby enabling the innovators to appropriate returns on their innovation activities<sup>68</sup>. Absent patent protection, there may be insufficient incentives to invent (*i.e.* to invest in R&D) and to innovate, because others cannot be excluded from appropriating the benefits without sharing the costs. If it is true that the immediate goal is to incentivize and reward innovation, this is not the patent system's only goal. Patents have traditionally also been regarded as serving a number of other objectives, such as attracting foreign investment, facilitating technology transfer and dissemination, supporting domestic industries, generating trade gains or avoiding trade losses<sup>69</sup>. This is also the case of the TRIPS Agreement, where the patent system is aimed to contribute to the promotion of technological innovation and to the transfer and dissemination of technology as set out in the general provisions and basic principles of the TRIPS Agreement and its Preamble, which include reducing distortions and impediments to international trade, promoting effective and adequate protection of intellectual property rights, and ensuring that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade. These general goals must be read in conjunction with Article 7, entitled "Objectives", that reflects the search for a *balanced approach* to IP protection in the societal interest, taking into account the interests of both producers and users, since IP protection is expected to contribute not only to the promotion of technological innovation, but also to the transfer and dissemination of technology in a way that benefits *both* its producers and users and that respects a balance of rights and obligations, with the overall goal of promoting *social and economic welfare*. Article 8, entitled "Principles", recognizes the rights of members to adopt *measures for public health and other public interest reasons and to prevent the abuse of intellectual property rights*, provided that such measures are consistent with the provisions of the TRIPS

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<sup>68</sup> See WIPO *Guidelines and Manuals of National/Regional Patent Offices*, available at: [www.wipo.int/pct/en/texts/gdlines.html](http://www.wipo.int/pct/en/texts/gdlines.html).

<sup>69</sup> *Declaration on Patent Protection. Regulatory Sovereignty under TRIPS*, drafted under the auspices of the Max Planck Institute for Innovation and Competition in Munich, 15 April 2014, available at: [www.mpg.de/8132986/Patent-Declaration.pdf](http://www.mpg.de/8132986/Patent-Declaration.pdf).



Agreement<sup>70</sup>. Both the preamble and Articles 7 and 8, which express the general goals, objectives and principles of the TRIPS Agreement, are to be borne in mind when the substantive rules of the Agreement are being examined, as repeatedly recognized by WTO dispute settlement panels. The same conclusion is confirmed by the 2001 *Doha Declaration on the TRIPS Agreement and Public Health* that provides (in para. 5(a)) that

“[i]n applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles”.

However, the use of the exclusive right can itself contribute to a market distortion and can lead to a situation characterized by inefficiencies, high prices and the under-provision of goods. The establishment of *limitations* and *exceptions* to patent protection are integral elements of patent governance and *crucial* to the overall balance of the system of protection. As such, they need not to be interpreted in a *narrow* way; rather, Articles 7 and 8 of the TRIPS Agreement recognize that the patent system is embedded in a framework of *policy controls*. Article 1(1) of the TRIPS Agreement expressly grants WTO members the *freedom* to determine the appropriate method of implementing the provisions of the Agreement in their own legal systems and practice, allowing them to treat different situations differently. *Differentiation* may relate to the requirements of patentability, patent eligibility and disclosure to the exclusion of subject matter from patentability, as well as to the scope of protection<sup>71</sup>. Additionally, many key terms relating to TRIPS obligations are *not defined* in the Agreement itself, including essential patent law concepts such as “invention”, “new/novel” and “involve an inventive step/non-obvious”, which leaves considerable discretion to WTO members as to how to apply the three criteria of patentability - novelty, inventive step and industrial applicability - within their national laws. Further, a number of provisions agreement

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<sup>70</sup> According to F. M. ABBOTT, *WTO TRIPS Agreements and Its Implications for Access to Medicines in Developing Countries*, Commission on Intellectual Property Rights, UK, Study paper 2a, 2002, p. 46, “it is exceedingly difficult to explain why the WTO agreement most likely to impact on public health also most stringently restricts protecting public health”. GATT 1994 (Article XX (b)) and GATS (Article XIV (b)) allow that Members may adopt measures necessary to protect public human, animal or plant life or health that are otherwise inconsistent with those agreement. The Author, therefore, suggested to *amend* Article 8.1 of the TRIPS Agreement by conforming it with the comparable GATT 1994 and GATS language.

<sup>71</sup> See the *Declaration on Patent Protection* and its critic on what the WTO’s DSB panel mistakenly assumed in Doc. WT/DS114/R of 17 March 2000.



have been included in the TRIPS Agreement in order to prevent and correct IP undesired effects: the provision that patent rights only last for a limited period of time (usually 20 years); exclusions from patentable subject matter; patent application, examination and grant procedures, as well as opposition, appeal, and other review procedures that allow courts and other review bodies to correct erroneous decisions and give relief where necessary, in order to ensure that the patent system as a whole functions as a public interest policy tool. Thirdly, general exceptions and limitations to patent rights are permitted under TRIPS Agreement in order to ensure harmony with broader public policy goals, such as *ordre public* or morality. The TRIPS Agreement also recognizes: a) *limited exceptions* regulated in Article 30, to provide certain uses by third parties for private, non-commercial uses; research or experimental purposes; early working of patented pharmaceuticals for the purposes of obtaining approval (the so-called *Bolar provision*); and b) *compulsory licenses* (actually the TRIPS Agreement does use rather the term “use without authorization of the right holder”) covered by Article 31, which regulates both compulsory licenses granted to third parties for their own use and the use by or on behalf of governments without the authorizations of the right holder. This norm does not limit the grounds or underlying reasons that might be used to justify the grant of compulsory licenses, mentioning - among other circumstances - national emergencies, other circumstances of extreme urgency and anti-competitive practices only as grounds when there is not the need to try for a voluntary license first<sup>72</sup>. In addition to the already mentioned flexibilities in the process of acquisition of the right and flexibilities related to the scope of the patent right, the TRIPS Agreement provides member States also with flexibilities related to the use and enforcement of patent right. In this regard, they are entitled - in addressing public health concerns - to take necessary steps to prevent abusive and anti-competitive practices (including the preventive control of such practices in contractual licenses). Competition law helps in correcting and preventing anti-competitive behaviours such as: (i) abuses of IPRs because of refusal to deal with or imposition of overly restrictive conditions in medical technology licensing; (ii) preventing generic competition through anti-competitive patent settlement agreements; (iii) mergers between pharmaceutical companies that lead to undesirable concentration of R&D and IPRs; (iv) cartel agreements between pharmaceutical companies, including between manufacturers of generics; (v) anti-competitive behaviour in the medical retail and other related

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<sup>72</sup> See WTO, *Module V, Patents*, available at: [www.wto.org/english/tratop\\_e/trips\\_e/ta\\_docs\\_e/modules5\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/modules5_e.pdf), pp. 1-15.





sectors. Article 8.2 and Article 40.1 of the TRIPS Agreement stipulate the appropriate measures that may be used to prevent any abuse of IPRs<sup>73</sup>.

Many of these policy options are often referred to as “TRIPS flexibilities”, a term, by the way, that the TRIPS Agreement only limits in relation to the special requirements of least developed countries (LDCs) members in order to explain the motivation for the additional transition period accorded to LDCs<sup>74</sup>. The expression “flexibility” only became part of the wider IP community’s glossary<sup>75</sup> at the time of the adoption, in 2001, of *Doha Declaration on TRIPS Agreement and Public Health*<sup>76</sup> that clarified the term, by referring to flexibilities in a much broader way. Following multiple actions by the US and others that had challenged low- and middle-income countries’ right to adopt and utilize flexibilities set forth in the TRIPS Agreement<sup>77</sup>, the Africa Group demanded a clarification of those

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<sup>73</sup> *The Trilateral Study*, pp.77-79.

<sup>74</sup> LDCs are given an extended transition period under Article 66.1 of the TRIPS Agreement to protect intellectual property under the TRIPS Agreement, in recognition of their special requirements, their economic, financial and administrative constraints, and the need for flexibility so that they can create a viable technological base. On 3 November 2015, WTO members reached an agreement to extend the pharmaceutical waiver for LDCs until 2033. In December 2015, the WTO General Council also decided that the obligations of least developed country members under paras 8 and 9 of Article 70 of the TRIPS Agreement shall be waived with respect to pharmaceutical products until 1 January 2033, or until such a date on which they cease to be a least developed country member, whichever date is earlier.

<sup>75</sup> WIPO’s expert view on classification and flexibilities provided by the TRIPS Agreement concluded that they could be classified in just two categories: those regarding *transition periods* and those regarding *substantive flexibilities* in the TRIPS Agreement. A more detailed classification distinguishes among *subject matters* which qualifies for protection: *scope of protection*, *mode of IP enforcement* and *matters of administration*. See WIPO document CDIP/5/4 REV., 18 August 2010, *Patent Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels*, Document prepared by the Secretariat., available at: [www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=142068](http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=142068), pp. 1- 28. See also M. A. OLIVEIRA, J. A. ZEPEDA BERMUDEZ, G. C. CHAVES, G. VELÁSQUEZ, *Has the Implementation of the TRIPS Agreement in Latin America and the Caribbean Produced Intellectual Property Legislation that Favours Public Health?*, in BWHO, 2004, pp. 815-821; UNAIDS, WHO, UNDP, *Policy Brief, Using TRIPS Flexibilities to Improve Access to HIV Treatment*, 5 March 2011, available at: [www.unaids.org/en/resources/documents/2011/20110315\\_JC2049\\_PolicyBrief\\_TRIPS](http://www.unaids.org/en/resources/documents/2011/20110315_JC2049_PolicyBrief_TRIPS).

<sup>76</sup> See *supra*, note 67.

<sup>77</sup> In 1998 a group of 39 pharmaceutical companies along with the Pharmaceutical Manufacturers Association of South Africa sued the South African government over its medicines act, which included provisions to increase access to lower-priced medicines. One of their arguments was that the act was not in accordance with the TRIPS Agreement. A massive public outcry against this abusive conduct (at the time, nearly a fifth of the South African population was living with HIV) induced the Big Pharma companies to withdraw



flexibilities from the TRIPS Council<sup>78</sup>. The result was the Doha Declaration adopted at the Doha Ministerial Conference in November 2001, when the WTO members struck a pivotal deal which clarified the TRIPS Agreement and provided governments in the developing world with greater clarity and certainty that protection of patents does not and should not prevent members from taking measures to protect public health<sup>79</sup>. In its seven paragraphs the Doha Declaration clarified some of the flexibilities contained in the TRIPS Agreement. It recognized: the growing concerns over HIV and other diseases; firmly established the primacy of public health concerns over IP; firmly supported interpretations of the TRIPS Agreement allowing governments to take action necessary to protect the health of their populations; and set out plans to cope with the particular need of LDCs and countries lacking the capacity to make their own medicines. Paragraph 6 deals with production for export under a compulsory licence. According to Article 31 (f) of the TRIPS Agreement, the use of compulsory licensing is authorized “predominantly for the supply of the domestic market of the Member authorizing such use”. Member States recognised in Doha that this restriction causes problems for countries without local production capacity and that rely on importation for their supply of medicines in a world where medicines are patented almost everywhere. The Doha Declaration promised to find an “expeditious solution” to this problem in Paragraph 6. However, it took two years of difficult negotiations at the WTO to arrive in 2003 at the “August 30” decision, which established a process to allow such export on a case-by-case basis<sup>80</sup>. The System - informally dubbed the “Paragraph 6 System” - that initially took the form of a waiver of certain conditions regarding compulsory licences, has been transformed in 2005 in a Protocol Amending the TRIPS Agreement. This Amendment has now become a permanent feature of the TRIPS Agreement and has entered into force on 23 January 2017<sup>81</sup>.

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the law suit in 2001.

<sup>78</sup> See Doc. IP/C/W/296 of 19 June 2001.

<sup>79</sup> C.M. CORREA, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO publication, 2002, pp.1-55; F. M. ABBOTT (2002), *supra*, note 70, p.8 ff.; E. ‘T HOEN (2009) *supra*, note 41, pp.19-39.

<sup>80</sup> C.M. CORREA, *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO publication, 2004, pp.1-29.

<sup>81</sup> Many commentators have noted that the Paragraph 6 system has serious flaws, being too many cumbersome and not at all conducive to the economic realities on the production and supply of generic medicines, as evidenced by the very limited experience: by 2012 it has been used only once to supply a triple combination of ARVs from Canada to Rwanda. *The Trilateral Study, The Paragraph 6 System: Special Export Licences for Medicines*, available at: [www.wto.org/trilateralstudy](http://www.wto.org/trilateralstudy). See also the *Submissions of Contributions to the United Nation*



To sum up, the analysis of the relevant provisions of the TRIPS Agreement and the Doha Declaration reveals the total absence of a *genuine normative conflict* between the IP /patent system codified in the WTO TRIPS Agreement and the States' human rights law obligations not only to respect, but also to protect and fulfil the right to health. Rather, the current TRIPS IP norms can and should, to the maximum extent possible, be interpreted as to give rise to a single set of *compatible international obligations* based on a *human rights approach* in policies and programmes. This conclusion is especially commanded in the light of the Doha Declaration on TRIPS Agreement and Public Health that, without being a formal amendment of the TRIPS Agreement, and thus having no specific legal *status* within the WTO law<sup>82</sup>, could be certainly construed both as: a) a subsequent agreement under Article 31. 3(a) of the Vienna Convention; or, b) as evidence of subsequent practice established the understanding of the WTO members regarding interpretation of the TRIPS Agreement<sup>83</sup>.

#### 4 - Conclusions

The above considerations bring us directly to the main point of this study: the policy incoherencies between the today pharmaceutical innovation system, firmly rooted in the patent system, and the fundamental right to health, largely *lie outside the IP TRIPS System*. Essentially they lie in the defective States' *implementation* of the TRIPS Agreement: too many countries still lack sufficient awareness about the use of TRIPS flexibilities and/or have limited capacity to implement them; these flexibilities are not *self-executing* and require a lot of attention and actions at the national level in order to tailor each nation

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Secretary-General's HLP on Access to Medicines of SOUTH CENTRE\_B, 28 February 2016, and of KAJAL BHARDWAJ. The WHO Commission on Intellectual Property recommended to keep under review the system and to consider appropriate changes to achieve a more workable solution. In a 2013 TRIPS Council meeting, India, Brazil and Cuba, also questioned the effectiveness of the System, supporting the position that a revision is needed (Doc. IP/C/69, pp.8-9).

<sup>82</sup> L. FORMAN, *An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law*, in *JWIP*, 2011, pp. 155-175, at p. 166; R. BEALL, R. KUHN, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 12 January 2012, available at: <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001154>.

<sup>83</sup> See, J. THUO GATHIL, *The Legal Status of the Doha Declaration on the TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, in *HJLT*, 2002, pp. 292-317, at p. 299.



IP regime to respond to each country's individual needs and policy objectives<sup>84</sup>. Additionally, policies incoherencies lie, essentially, in the *changed role* of patents in corporate management: as clearly pointed in a recent seminal Max Planck study, patents are increasingly used as "strategic assets to influence the conditions of competition rather than as a defensive means to protect research and development outcomes". The *shift* of the patent from a right of defence to a *commercial tool* greatly affects the manner in which the right to exclude operates in practice. More importantly, in many industrialized States with highly developed economies and advanced technological infrastructures, there has been another gradual *shift of balance* in the patent regime towards right holders, both by reducing the burdens for patent applicants and by extending the rights of patent holders. In turn, over the past decades, the governmental autonomy to countervail these proprietary rights with the aim to protect the public interest in free competition and third parties' freedom to operate have been progressively eroded due to an increasingly complex legal and institutional regime consisting of multilateral, regional and bilateral agreements<sup>85</sup>. As a result, the ability of States to maintain a proper balance between the need for IP protection and the policy space for pursuing diverse public interest goals "has been unduly constrained"<sup>86</sup>. This also as a result of too many intimidations, or worst, threats of retaliation from governments and corporations against the sovereign right to issue compulsory licences, in order to "dissuade" governments from using all the various forms and procedures that could protect public health<sup>87</sup>. Finally, policies incoherencies arise when legitimate economic, societal and political interests and priorities are misaligned: that is what currently occurs in respect of the global "narrative" about the trade liberalization, frequently

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<sup>84</sup> CIPIH, *Study 4C, The Use of Flexibilities in TRIPS by Developing Countries. Can they Promote Access to Medicines?* 2005, pp.1-15.

<sup>85</sup> P.K. YU, *TRIPS and Its Discontents*, in *MIPLR*, 2006, pp.384-386; H. GROSSE RUSE-KHAN, *A Trade Agreement Creating Barriers to International Trade? Acta Border Measures and Good in Transit*, in *AUILR*, 2011, pp. 645-726; A. DI BLASE, *Intellectual Property Protection in Investment Agreements and Public Concerns*, in G. SACERDOTI, P. ACCONCI, M. VALENTI, A. DE LUCA (eds.) *General Interests of Host States in International Law*, Cambridge, 2014, pp. 194-217.

<sup>86</sup> See *Declaration on Patent Protection*, *supra*, note 69.

<sup>87</sup> See WTO, *Report of the Panel*, *supra*, note 63, paras 7.88-7.90; S. K. SELL, *Trips Was Never Enough: vertical Forum Shifting, FTAS, ACTA, and TPP*, in *JIPL*, 2011, pp. 468-478 (on the pharmaceutical firms' bullying both governments, NGOs and even *particular patients*); OXFAM, HAI EUROPE, *Trading Away Access to Medicines-Revisited. How European Trade Agenda Continues to Undermine Access to Medicines*, 29 September 2014, pp.1-39; EUROPEAN COMMISSION, *Report on the Protection and Enforcement of Intellectual Property Rights in Third Countries*, Doc. SWD(2015) 132 final of 1 July 2015.



associated with jobs, capital flows and generation of wealth; while, public health objectives, such as access to medicines and universal health care, are normally and simply presented to the citizens as an increase in public expenditure, difficult to justify in the current wage of global economic crisis<sup>88</sup>.

In the light of the above considerations, several comments submitted to the UN HLP on access to medicines asserted that the tensions and policy incoherencies between patents, health technologies innovation and access to medicines and treatments, should be solved by resorting to a *hierarchical relationship* and by reference to the “Relations of Importance” mentioned in the ILC Report, that derive from Article 103 of the UN Charter, the notions of *jus cogens* and obligations *erga omnes*<sup>89</sup>. All these proposals, despite their different recommendations, are based on the same premises: the assumption of *primacy of the right to health* enshrined into the UN Charter, its (uncertain) constitutional nature, and the combination of Article 103 of the UN Charter with the treaty obligations assumed by member States under Articles 2, 55 and 56 of the Charter. The conclusion is that the UN human rights obligations on access to medicines *must take priority over any conflicting* (trade treaty) obligation<sup>90</sup>. As already argued above, the relationships between human rights obligations in respect to the right to health and the IP TRIPS system is not a conflict one, but a simple relationship of interpretation. As such, it could and should be resolved by a systemic and harmonized interpretation through the norms of the Vienna Convention on the Law of Treaties<sup>91</sup>. The qualification, by the UN human rights bodies, of access to essential medicines as a *core obligation* under the right to health, therefore not subject to progressive realization within available maximum resources, a sort of an “underogable” obligation in respect of which a State party to ICESCR “cannot under any circumstances whatsoever, justify its non-compliance”, does not change this reality. Yet, the right to health is *not* generally recognized as a *superior norm* under international law, falling into the three

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<sup>88</sup> A clear example of the difficulties related to these costs is the recent Donald Trump’s executive order to repeal the Obama care healthcare reform platform. More details at: <http://obamacarefacts.com/trumpcare-explained/>.

<sup>89</sup> See the Contributions of R. ELLIOTT, *supra*, note 32; SOUTH CENTRE A, February 26, 2106; X. SEUBA, Global Health Law Committee of the International Law Association, 22 February 2016; E. ‘T HOEN, Global Health Law Committee of the International Law Association, 22 February 2016; BROOK BAKER, Health GAP\_A, 26 February 2016; CHANDNI RAINA, Centre for WTO Studies, Indian Institute of Foreign Trade\_B, 25 February, 2016; all available at: [www.unsgaccessmeds.org/new-page/](http://www.unsgaccessmeds.org/new-page/).

<sup>90</sup> R. ELLIOTT, *supra*, note 32, pp. 20-22.

<sup>91</sup> L. FORMAN, *supra*, note 82, pp. 162-165.



primary sources of hierarchically superior norms, such as a peremptory (*jus cogens*) norms, *erga omnes* obligations, and Article 103 of the UN Charter<sup>92</sup>.

So said, in respect of the many difficulties faced by developing countries to take fully advantage of the TRIPS Agreement flexibilities, 15 years after the Doha Declaration, one might rightly questioned the usefulness of the many recommendations made in both the HRC resolutions and the HLP, that *again* called for WTO members to commit themselves to respect the WTO Doha Declaration on the TRIPS Agreement and refrain from any action that would limit its implementation and that countries should make *full use* of the flexibilities enshrined in this Agreement. Unsurprisingly, many NGOs regretted that the UN bodies were unable to reach consensus on *bolder* recommendations towards more *progressive* and *visionary* proposals concerning the actual limits of the WTO's Agreement on TRIPS framework to protect access to medicines, strongly rejecting the HLP's premise that the right of access to medicines and other health technologies could be resolved *within the existing framework of TRIPS flexibilities*. Some radical proposals have been advanced, directly challenging the inclusion of pharmaceutical products and life-saving medicines in the same regime as movies and software, based on incentives deemed to mobilize maximal profits for pharmaceutical monopolies rather than the unmet health needs of million people. Some submissions to the HLP made detailed proposals from *full exemption* for patenting *for all or some medicines*: in the light of the political pressure exerted by western governments and the current litigations brought by big pharma companies against countries exercising their right issue compulsory licenses, it has been recommended to exempt from IP protection *all the medicines on national essential medicines lists* or on the *WHO Model list for essential medicines*<sup>93</sup>. This

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<sup>92</sup> For a recent reconstruction of the notion of *jus cogens* norms in international law see the Judgment of the UK Supreme Court in the case *Bellhaj & Anor v. Straw & Ors* of 17 January 2017, available at: <http://www.bailii.org/uk/cases/UKSC/2017/3.html>.

<sup>93</sup> The WHO defines *essential medicines* as "those drugs that satisfy the healthcare needs of majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford". The WHO published the first *Model List of Essential Drugs* in 1977 and identified 208 individual medicines which together could provide safe, effective treatment for the majority of communicable and non-communicable diseases. The WHO Model Lists are now seen as equally relevant to high-, middle- and low-income countries, particularly due to the inclusion of new, highly effective and very expensive medicines in more recent years. The current Model List of Essential Medicines has been prepared by the WHO Expert Committee in April 2015. See WHO, *Essential Medicines*, available at: [www.who.int/medicines/services/essmedicines\\_def/en/](http://www.who.int/medicines/services/essmedicines_def/en/).



is particularly important especially now, since in May 2015 the WHO added several important medicines, including very high price drugs for the treatment of cancer, tuberculosis and hepatitis C to its Essential Model List (EML)<sup>94</sup>.

It is the Author's personal belief that the TRIPS Agreement is here to stay and that any proposed additional formal amendment to the text is simply unrealistic. In this respect, it is important to note that the HLP did not reach a *consensus* on the necessity to *renegotiate the TRIPS Agreement* or to *amend* it. According to the final HLP's Report "to revise or update these existing rights would be to concede ground to any argument of their derogability"<sup>95</sup>. A conclusion, this, objected by three members of the HLP who recommended, in their commentary to the Report, that this proposal should be pursued in *other UN forums*<sup>96</sup>. Neither, did the HLP uphold the proposal, requested in a number of calls, for a new *United Nations Instrument* to uphold universal human rights in laws, policies and actions that affect health technology innovation and access, that expressly recognizes the *primacy of human rights*. The HLP, rightly, concluded in this respect that human rights and other obligations related to access to essential medicines *already exist* and are embedded in United Nations instruments, guidance and decisions of human rights bodies and in a number of national and regional legal instruments. As to the current IP system, if given proper effect and properly observed, the provisions of the TRIPS Agreement and the Doha Declaration would give rise to the necessary protections and required balances to protect the human right to health in trade and intellectual property matters<sup>97</sup>.

In this respect it is the Author's opinion that a more promising avenue would consist in profiting of the "asymmetries" of *implementation power* in respect of the competing obligations in order to take advantage of the much stronger WTO accountability system, which - by the way - would require collaboration by the WTO. A sound proposal in this respect has been advanced by the HLP Report: countries that threaten and retaliate against others for using their entitlement under the TRIPS Agreement should be forced to face significant *serious sanctions*, According to the Panel, instances of undue political and commercial pressure should be reported to by the WTO Secretariat during the Trade Policy Review of members and WTO

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<sup>94</sup> WHO, MEDIA CENTRE, *WHO moves to improve access to lifesaving medicines for hepatitis C, drug-resistant TB and cancers*, 8 May 2015, available at: <http://who.int/mediacentre/news/releases/2015/new-essential-medicines-list/en/>.

<sup>95</sup> HLP Report, p. 19.

<sup>96</sup> HLP Report, J. BERMUDEZ, W. BYANYIMA and S. PHURAILATPAM's *Commentary*, p. 53.

<sup>97</sup> HLP Report, p. 19.



members must register complaints against such pressure, which include taking *punitive measures* against offending WTO Members. This proposal could be reinforced by the proposed creation of an *additional mechanism* to be established at the UN HRC, able to receive and investigate complaints (by UN member States, civil society, any other stakeholder or even by the HRC on its own accord) relating to the violation of human rights treaties as a result of trade retaliation (actual or threatened) where countries seek to use TRIPS flexibilities.

In addition, developing countries should start thinking seriously to lodge complaints at the WTO dispute settlement units, resorting to an increased use of the multilateral dispute settlement mechanism of the WTO. In the light of the Doha Declaration (a landmark political event) and the subsequent legal developments that have shown a growing acceptance in State practice of the use of various forms of TRIPS flexibilities in the area of public health<sup>98</sup>, it is probable that the WTO Dispute Settlement Body's approach and jurisprudence on the TRIPS Agreement would be, nowadays, necessarily quite different from the largely criticized cases settled since 1995, four of which directly addressed pharmaceutical patents, as having largely interpreted the object, purpose and context of the TRIPS Agreement in favor of protecting IPRs and having given very little weight to arguments about public health<sup>99</sup>. This conclusion is particularly important in respect of two complaints lodged at the WTO by two developing countries, India and Brazil, against the EU and the Netherlands for seizure of generic drugs in transit, claiming that this seizure violated *inter alia*, Articles 2, 28, 31, 41 and 42 of the TRIPS Agreement, arguing that the measures at issue have an adverse impact on the ability of developing and least-developed countries members of the WTO "to protect public health and provide access to medicines for all"<sup>100</sup>. At the moment India settled with the EU, but the dispute between Brazil and the EU still remains<sup>101</sup>. Should this complaint

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<sup>98</sup> E. 'T HOEN, (2016) *supra*, note 10, pp. 49-63 (on the practical use of the Doha Declaration since 2001 and trends in the use of the TRIPS Agreement flexibilities).

<sup>99</sup> See L. FORMAN *supra*, note 82, at pp. 165- 167.

<sup>100</sup> WTO (2010a), *European Union and a Member State — Seizure of Generic Drugs in Transit: Request for Consultations by India*, Doc. WT/DS408/1, G/L/921, IP/D/28 of 19 May 2010; WTO (2010b), *European Union and a Member State — Seizure of Generic Drugs in Transit: Request for Consultations by Brazil*, Doc. WT/DS409/1, G/L/922, IP/D/29 of 19 May 2010.

<sup>101</sup> See *India EU Reach an Understanding on Issue of Seizure of Indian Generic Drugs in Transit*, Press Information Bureau Government of INDIA, Ministry of Commerce & Industry, 28 July 2011; *EU guidelines No 1383/2003 and Its Implementing Regulation No 1891/2004 with Regard to Goods in Transit on the Territory of EU*, that address the specific concerns raised by India and Brazil on medicines in genuine transit through the territory of the EU; see also Regulation No 608/2013 of the European Parliament and of the Council of 12 June 2013





proceed, it would be a great opportunity for the WTO panel to provide an “authoritative” interpretation of the TRIPS provisions in the context of the Agreement as a whole and in respect of the various HRs agreements, beyond the context of HIV/AIDS pandemic. This interpretation, while only binding with respect of the particular dispute between the parties, would nevertheless provide useful guidance to the WTO in approaching questions of innovation and access to medicines for other diseases, not confined to HIV as a mean to realize the fundamental *right to health*.

Developing countries could also lodge complaints particularly in respect of the governments’ rights to address access barriers *within* the current IP system through “automatic licensing” for essential medicines. It is not by chance that one of the major specific issues of concerns of pharma industries and western developed countries was exactly on the UN call on governments to make liberal use of compulsory licenses to override patents. The recommendation for effectively automatic compulsory licensing has been eliminated by the HLP Report at the very last minute because of lack of consensus: some members of the HLP were concerned over the potential incompatibility of such measures with the TRIPS Agreement and the unintended consequences that may result from such an approach<sup>102</sup>. Two-third of the HLP members, on the contrary, along with several members of the HLP’s Expert Advisory Group, were of the opinion that automatic compulsory licences (CLs) are fully compatible with the letter and the spirit of the TRIPS Agreement as long as an “effectively automatic” CL met and adhered to the recommendation specified in Article 31 of the TRIPS Agreement. It would be interesting to know how WTO dispute settlement body would treat CLs, in the light of the supposed “unintended” long-term consequences of such use (or abuse). In addition, a future WTO panel could also consider the compatibility between demands for higher standards than the TRIPS Agreement requires and pronounces itself on the very lasting academic debate about TRIPS provisions as a “ceiling” and not a “floor”, by interpreting the second sentence of the TRIPS Agreement Article 1.1 that stipulates:

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concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003, in *OJEU* L 181 of 29 June 2013, p. 15 ff.; in literature see K. BAKER, *Settlement of Regulation Isn’t Good Enough*, available at: *Digital Commons @ American University Washington College of Law*.

<sup>102</sup> The counter-argument is that companies would be much less willing to invest the significant levels of funding required to discover, research and develop new medicines due to the significant uncertainty about returns being available for successful, value-adding products at the end of the journey from concept to finished medicine. See *HLP Report*, M.C. FREIRE’s Commentary, p. 57.



“Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement”<sup>103</sup>.

As the Indian delegation has noted in its intervention in the TRIPS Council, TRIPS-plus measures cannot be justified under Article 1.1; enforcement levels cannot be raised to the extent that they contravene the TRIPS Agreement<sup>104</sup>. Finally, the task to harmonize the core human rights obligations with other (WTO) legal duties to provide essential medicines access and respect of inventor’s rights could be certainly fulfilled by domestic courts, that could easily provide consistent implementation of different policy oriented obligations<sup>105</sup>.

As to the current innovation system, something that the TRIPS Agreement does not regulate, there is clearly the need of change to become less costly and more responsive to health needs, especially to develop missing essential medicines needed to respond to global health problems. New R&D models are needed: they should provide for transparent sharing of the results of research, ensure transparency of clinical trial results to enable independent assessment of the value of a product and include new models of financing drug development.

The idea of an international agreement on R&D (debated since the initial proposal in 2004 and continuously supported from a number of governments, scientists, Nobel laureates, civil society organisations, and other experts) could be crafted under the auspices of the WHO. It should be

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<sup>103</sup> C. CORREA, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, 2007, p. 25; A. KUR, H. GROSSE RUSE-KHAN, *Enough is Enough. The Notion of Binding Ceilings in International Intellectual Property Protection*, in A. KUR, M LEVIN (eds.), *Intellectual Property Rights in a Fair World Trade System*, Cheltenham, 2011, pp. 359-407.

<sup>104</sup> TRIPS Council Minutes of June 8-9 2010, Doc. IP/C/M/63 of 4 October, 2010, available at: [www.org/english/traop\\_e/trips](http://www.org/english/traop_e/trips).

<sup>105</sup> See, H.V Hogerzeil, M. SAMSON, J. VIDAL CASANOVAS, L. RAHMANI-OCORA, *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable through the Courts?*, in *The Lancet*, 22 July 2006, pp. 305-311; JUSTICE S. MURALIDHAR DELHI HIGH COURT, *The Expectations and Challenges of Judicial Enforcement of Social Rights*, available at: [http://delhicourts.nic.in/ejournals/social\\_rights\\_jurisprudence.pdf](http://delhicourts.nic.in/ejournals/social_rights_jurisprudence.pdf); The High Court of Delhi (*Mohd Ahmed (Minor) v. Union of India*, et al, W.P.(C) 7279/2013, judgment of 12 February 2014) is the only national court to our knowledge that has judged in favour of a child born to an economically disadvantaged part of society, who has a rare genetic disorder, and who would be entitled to free medical treatment, by referring to Indian Constitution, to Article 12 of ICCPR and to the General Comment No. 14 of the CESCR, as well as to other Conventions and regional human rights instruments. See A. DIVER, J. MILLER (eds.), *Justiciability of Human Rights in Domestic Jurisdiction*, New York-Dordrecht-London, 2015, pp.105-108.



based on the *delinkage* of the cost of R&D from the price of the end product (examples include prize funds, patent buy-outs, open source innovation and other new financing mechanisms) and, as a new binding international agreement, it would offer several potential advantages in bringing down the price of new, patented essential medicines, so they become affordable to the communities that need them. Same as happened with the Framework Convention on Tobacco Control, entered into force on 27 February 2005, the first public health treaty negotiated within the WHO, which has significantly contributed to global tobacco control efforts<sup>106</sup>.

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<sup>106</sup> See B. BAKER, *Background Paper: Existing and prior work, initiatives and proposal to improve innovation and access to health technologies*, available at: [www.unsgaccessmeds.org/new-page/](http://www.unsgaccessmeds.org/new-page/); HLP Report, 29-32.