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Access to medicines: Experiences with compulsory licenses and government use - The case of Hepatitis C

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ACCESS TO MEDICINES: EXPERIENCES WITH COMPULSORY LICENSES AND GOVERNMENT USE – THE CASE OF HEPATITIS C

Carlos M. Correa and Germán Velásquez



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SOUTH CENTRE

APRIL 2019

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ABSTRACT

This South Centre research paper discusses first, the limitations of the current research and development (R&D) model and its implications for access to medicines. Second, it considers the tension between intellectual property rights applied to medicines and States' observance of the fundamental right to health. Third, it examines the case of access to medicines for the treatment of Hepatitis C, illustrating the barriers to access created by intellectual property and the high prices normally associated with its exercise. Fourth, it presents the background, main aspects and obstacles to the achievement of the objectives of the Doha Declaration on the TRIPS Agreement and Public Health (2001). To conclude, this paper examines the experiences of compulsory licensing and government use of patents in Latin America (particularly in Ecuador, Peru and Colombia).

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INTRODUCTION¹

Access to medicines strongly relies on pricing and financing mechanisms that can be differently applied to each country. In developing countries, in the absence of broad health coverage systems, a large part of the expenditure comes from the patients' own pocket, provided, of course, that their level of income allows them to afford it. This does not happen, however, in many of the cases where medicine prices are inaccessible to various segments of the population. As medicines are financed by a third-party payer, high prices are the biggest source of pressure on the budget.

A determining factor regarding medicine pricing is the degree of competition in a particular therapeutic class, which in turn is influenced by the existence or nonexistence of intellectual property rights, such as invention patents. Patent rights grant exclusive rights over a medicine for at least twenty years, from the date that the patent application was filed. This allows the patent holder to act as a monopolist and to set the price that the market “can bear”.

The restriction of the competition generated by intellectual property rights affects mainly patients from developing countries, especially after the adoption in 1995 – and the entry into force in those countries in the year 2000 – of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) of the World Trade Organization (WTO). This agreement, actively promoted by the American and European pharmaceutical industry, forced all the member countries of this organization to grant patents on medicines. Consequently, for reasons of public health, many countries that excluded the patenting of pharmaceutical products had to adapt their legislation to this new international regulation. Failing to do so would expose themselves to commercial reprisals legitimized by the WTO dispute settlement mechanism.

First, this document discusses the limitations of the current research and development (R&D) model and its implications for access to medicines. Second, it considers the tension between intellectual property rights applied to medicines and the States' observance of the fundamental right to health. Third, it examines the case of access to medicines for the treatment of Hepatitis C, illustrating the barriers to access created by intellectual property and the high prices normally associated with its exercise. Fourth, it presents the background, main aspects and obstacles to the achievement of the objectives that led to the approval, in 2001, of the Doha Declaration on the TRIPS Agreement and Public Health. Having presented the above introductory sections, this document examines in three sections the concepts of compulsory licensing and government use of patents, experiences in Latin America (in particular, Ecuador, Peru and Colombia)² and in other countries, including the role of civil society and cases in which non-commercial government use was authorized in order to produce or import medicines and improve access for the population. Finally, the main conclusions of the document are drawn.

¹ Document prepared for the “International Congress on Policies and Strategies to Facilitate Access to Treatments for Hepatitis C”, held on 8-9 March 2018, in Bogotá, Colombia; organized by the Ministry of Health of Colombia, UNITAID, Coalition PLUS, and the South Centre. This paper was initially published by the South Centre in Spanish, in May 2018.

² The authors are grateful for the contribution of Francisco Rossi, Director of IFARMA, Colombia, to the analysis of the cases from Colombia and Peru.

I. HIGH PRICES, LOW PERFORMANCE OF RESEARCH AND DEVELOPMENT

A recent study in the United States found that many of their 71 cancer medicines registered by the Food and Drug Administration (FDA) between 2002 and 2014 cost more than \$ 100.00 per treatment/year.³ Another notable example of high prices, discussed below, is the treatment for hepatitis C based on sofosbuvir. The high price of such medicines – owing to the intellectual property system – is, as noted, especially burdensome for developing countries. It is estimated that one third of the world's population does not have regular access to medicines.⁴ However, this problem increasingly affects the developed countries themselves where, thanks to state (in Europe) or private (in USA) health insurance, patients used to afford to buy the medicines they needed. This is no longer the case, because these countries have also begun to have difficulties to ensure the supply of certain medicines, excessively expensive ones, to all their citizens.

The argument traditionally used by the pharmaceutical industry to justify the high prices of medicines⁵ has been high direct costs of R&D, as well as costs incurred in the development of products that, by not complying with health standards of efficacy or safety, never reach the market. In the last ten years, the estimates of R&D costs of the industry have increased dramatically. According to an estimate in November 2014 by the Tufts Medical Center in Boston, the development of a new molecule for medicinal use would require an investment of 2.5 billion US dollars.⁶

These estimates, which are based on data from the pharmaceutical industry, are not easily verifiable. In contrast, a study conducted in 2011 by independent researchers, published by the London School of Economics, estimated an average cost for the development of a new drug at only USD 43.4 million.⁷ For its part, the non-profit foundation Drugs for Neglected Diseases initiative (DNDi) disclosed in 2013 the R&D cost of the products it had worked on during its 10 years of existence, which amounted to USD 100-150 million per new chemical entity.⁸

While there is no transparency about what the real R&D costs are, the problem of pricing and, therefore, of access to medicines, will remain unresolved. Determining whether the cost of a new molecule is US\$ 40-150 million or US\$ 2,500 million is obviously critical to implement a medicines policy that ensures that therapeutic innovations reach those who need them and not only those who, by their own resources or the support of health systems, can

³ Ariadna Tibau, MD, Alberto Ocana, MD, PhD et al., "Oncologic Drugs Advisory Committee Recommendations and Approval of Cancer Drugs by the US Food and Drug Administration", *JAMA Oncol.* 2016; 2(6):744-750. doi:10.1001/jamaoncol.2015.6479.

⁴ OMS, *Accès équitable aux médicaments essentiels : cadre d'action collective*, (Genève, Mars 2004). Available at <http://apps.who.int/medicinedocs/pdf/s4963f/s4963f.pdf>.

⁵ More recently, some pharmaceutical companies have justified their high prices for the therapeutic benefit of the product and the cost of alternative treatments.

⁶ Tufts Center for the Study of Drug Development, *Cost of developing a new drug*, (Boston, November 2014).

⁷ Donald W. Light and Rebecca Warburton, "Demythologizing the high costs of pharmaceutical research" (2011), Available from http://www.pharmamyths.net/files/Biosocieties_2011_Myths_of_High_Drug_Research_Costs.pdf.

⁸ DNDi, "Research & Development for Diseases of the Poor: A 10-Year Analysis of Impact of the DNDi Model", (Geneva, 2013).

afford them at the prices, sometimes exorbitant ones, imposed by the so-called “innovative” industry.

Paradoxically, the alleged increase in pharmaceutical R&D costs does not correspond to a parallel increase in the R&D efficiency of the industry. On the contrary, the R&D performance has lowered significantly in the last twenty years, not only measured by the number of new medicinal chemical entities approved for commercialization, but by the therapeutic usefulness of the new products introduced to the market. For example, according to Prescrire’s⁹ ratings of new drugs and new indications introduced in the French market, only one out of ten years (2007 - 2016) was rated as “Excellent”, 10 rated as “Interesting” in that same period, and 14 rated as “Contributes something” in 2006 but only 5 in 2016. 524 products were rated as “Does not contribute anything new” in the ten years analyzed (see Table 1).

Table 1
Therapeutic value of medicines introduced in the market in 2007-2016

YEARS	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Excellent	1	0	0	0	0	0	0	1	0	0
Interesting	2	0	0	1	0	1	0	2	3	1
Contributes something	14	6	3	3	3	3	6	5	5	5
Occasionally useful	27	25	14	22	13	14	12	15	15	9
Does not contribute anything new	79	57	62	49	53	42	48	35	43	56
Objected by the Journal	15	23	19	19	16	15	15	19	15	16
Without sufficient elements for evaluation by the Journal	3	9	6	3	7	7	9	10	6	5
Total	141	120	104	97	92	82	90	87	87	92

Source: Prescrire, “L’année 2016 du médicament : un système qui favorise l’imitation plutôt que la recherche de réels progrès”, Tome 37 No. 400 (Paris, février 2017), p. 136

Given the importance of the French pharmaceutical market, one can assume that the vast majority of medicines that came onto the world market between 2007 and 2016 were the same ones introduced in the French market. In other words, the limitations in the innovation of new pharmaceutical products found in France is a good indicator of the world’s actual situation.

The opacity of R&D costs, the declining productivity in R&D activities of the “innovative” industry, and high prices are three aspects that characterize the current R&D model.

⁹ Rev. Prescrire, “L’année 2016 du médicament : un système qui favorise l’imitation plutôt que la recherche de réels progrès”. Tome 37 No. 400 (Paris, février 2017), p. 136.

This has led civil society and groups of experts¹⁰ to vast academic discussions and various initiatives pointing to a change in the R&D model that would allow generating more genuinely useful innovation from the point of view of public health, which would culminate in products accessible to those who need them, especially segments of society with fewer resources. These initiatives have included, in particular, the establishment of reward systems, advance purchase contracts, and the negotiation in the scope of the World Health Organization (WHO) of a binding instrument on R&D related to medicines.¹¹

¹⁰ See Velásquez, G., “Access to Hepatitis C Treatment: A Global Problem”, South Centre Research Paper No. 77 (Geneva, May 2017), p. 4. In fact, 180 proposals were submitted to the United Nations Secretary General’s High Level Panel on Access to Medicines, 46 of which were proposals for a substantive modification of the current R & D model.

¹¹ WHO, “Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG)”, 2012. Available from http://www.who.int/phi/cewg_report/en/.

II. INTELLECTUAL PROPERTY AND HUMAN RIGHTS

The discussion of a new R&D model has faced the expected resistance of developed countries and the industry that benefits from the current model based on the scheme: R&D (private and public) – patent (monopoly)¹² – high price – high profitability – restricted access.

The application of the current R&D model leads, as discussed at the High Level Panel convened by the United Nations (UN) Secretary-General (SG) in late 2015,¹³ to incoherence between the intellectual property system and the realization of human rights to health. The terms of reference set for the expert group called for a study on “The incoherence between the rights of inventors, international human rights legislation, trade rules and public health”.¹⁴ Among the main recommendations in the Report¹⁵ of the Panel, the following stand out:

- Make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability.
- Adopt and implement legislation that facilitates the issuance of compulsory licenses (CL).
- Revise the paragraph 6 decision of the Doha Declaration on the TRIPS Agreement and Public Health (hereinafter “Doha Declaration”¹⁶).
- Refrain (governments and the private sector) from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities.
- Initiate a process (led by the Secretary-General of the United Nations) for governments to negotiate a mandatory convention for R&D in the pharmaceutical area.

The aforementioned report suggests that although a change in the current R&D model is necessary, there are immediate measures that governments can adopt in order to mitigate the effect of intellectual property on access to medicines, within the framework of the TRIPS Agreement, in order to comply with human rights obligations and achieve the sustainable development goals set for the year 2030.¹⁷ In particular, it is about the use of the so-called “flexibilities” that were confirmed in that agreement in 2001 by the Declaration discussed below.

Significantly, the Human Rights Council (HRC) of the United Nations considered, in its deliberations in 2015-2016, that barriers to access to medicines can be deemed as a violation

¹² In some countries, test data exclusivity is added to patent protection. See, e.g. Cortes M., et al., “Impacto de diez años de protección de datos para medicamentos en Colombia”, IFARMA, Serie Buscando Remedio, No. 2 (Bogotá, 2014). Available from http://web.ifarma.org/images/files/buscandoremedio/BuscandoRemedio_2.pdf.

¹³ The United Nations Secretary-General’s High-Level Panel on Access to Medicines, “The Panel”. Available from <http://www.unsgaccessmeds.org/new-page/>.

¹⁴ In less than three months, more than 180 proposals were received from countries, institutions, United Nations agencies, non-governmental organizations (NGOs), universities, the pharmaceutical industry, individuals.

¹⁵ Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines (2016). Available from <http://www.unsgaccessmeds.org/final-report>.

¹⁶ Declaration on the TRIPS Agreement and Public Health adopted on November 14, 2001, WT/MIN/(01)/DEC/2.

¹⁷ Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines (2016), p. 12. Available from <http://www.unsgaccessmeds.org/final-report>.

of human rights.¹⁸ The Council approved in 2016 a resolution that reaffirms that access to medicines is a fundamental element for the full exercise of the right to health.¹⁹

Resolution 32/L.23 entitled “Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health”, supported by 72 co-sponsors, was presented by Brazil, China, Egypt, Haiti, India, Indonesia, Paraguay, Peru, Senegal, Sri Lanka, South Africa and Thailand.

Many resolutions have been approved in the last 15 years in the context of the WHO. The debate was held fundamentally between health and trade. What comes first, health or trade? What were the possible contradictions and what were the mechanisms to protect health from the possible negative effects of the new rules governing international trade? On several occasions, developing countries attempted to introduce into these resolutions, and to approve by consensus, a reference to human rights as a basis to ensure access to medicines. Unfortunately, all the attempts were frustrated by opposition from some developed countries, particularly the USA.²⁰

The importance of the aforementioned resolution 32/L.23 is mainly that the HRC confirmed the primacy of human rights, such as the right to health, over intellectual property rights and those derived from other investment or trade agreements. Equally important, the resolution reaffirms the ability of countries to take advantage of the flexibilities provided by the TRIPS Agreement to promote access to medicines, recognizing that patents can be used to set high prices to medicines.²¹

The resolution reiterates the importance of access to medicines for all as one of the fundamental human rights and emphasizes that the improvement of that access could save millions of lives each year. The resolution also refers to the Doha Declaration, which, as discussed below, confirms that the abovementioned Agreement does not and should not prevent WTO members from taking measures to protect public health.

The approval by consensus of the resolution coincided with the celebrations of the 30th anniversary of the Declaration on the Right to Development in which both the right to health and access to medicines and public health are recognized as fundamental elements for the exercise of the right to development.²²

¹⁸ HRC Resolution 32/L.23 on “Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health”, Geneva, 2016.

¹⁹ Viviana Muñoz Tellez and Adriano José Timossi, “Human Rights Council adopts historic resolutions on access to medicines”, South Bulletin No. 92 (4 August 2016).

²⁰ During the negotiations of the Global Strategy on Public Health, Innovation and Intellectual Property in the WHO in 2006-2008, some developed countries, mainly the United States, refused to include the expression “human rights” in the text of the Strategy.

²¹ HRC Resolution 32/L.23 on “Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health”, Geneva, 2016.

²² HRC Resolution 32/L.23 on “Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health”, Geneva, 2016.

III. THE CASE OF HEPATITIS C – TOWARDS A PARADIGM SHIFT?

A paradigmatic case evincing the incoherence between the exercise of intellectual property rights and the realization of the fundamental right to health is that which concerns the treatment against the hepatitis C virus.

Until late 2013, the standard treatment for hepatitis C consisted of injections of pegylated interferon for 24 to 48 weeks accompanied by ribavirin tablets. This treatment was expensive, toxic, poorly tolerated, complicated to administer and with cure rates of less than 50 per cent.²³

At the end of 2013, a new type of treatment based on direct-acting antivirals (DAAs) was introduced into the market. With eight to twelve weeks of treatment, these medicines can cure more than 90 per cent of patients with chronic Hepatitis C infection.

The new treatments based on DAAs were introduced by the pharmaceutical companies Gilead Sciences and Bristol-Myers Squibb (BMS). Gilead has patented or applied for patents for sofosbuvir, ledipasvir and velpatasvir.²⁴ BMS has patented or applied for patents for daclatasvir.²⁵ As the treatment in many cases should include sofosbuvir and daclatasvir, a double barrier is generated when patents belong to different companies. Other transnational companies such as AbbVie, Merck and Janssen have put other DAAs on the market, as new products are found in the pipeline of these and other firms. Gilead Sciences introduced sofosbuvir at the exorbitant price of US\$ 84,000 for a twelve-week treatment in the US.

According to a WHO²⁶ fact sheet published in 2015 (two years after the appearance of the first treatments), of the estimated 130-150²⁷ million people living with Hepatitis C, only 275,000 received the new treatment with DAAs, of which 170,000 lived in Egypt, the country with highest incidence of hepatitis C in the world. This was possible thanks to the dramatic drop in the treatment cost to US\$ 153 for 3 months (a product made by the Egyptian company PHARCO). The explanation for this situation is simple: Gilead could not obtain a patent on sofosbuvir in Egypt as the country's patent office applies strict patentability criteria.²⁸

English scholars²⁹ have determined that the production cost for the twelve-week treatment with sofosbuvir is US\$ 62 (including a 50 per cent profit margin), but Gilead Sciences has managed to negotiate, with several governments, prices – with large differences from one country to another – completely unrelated to the probable costs of R&D and

²³ Manns MP, Wedemeyer H, Cornberg M., “Treating viral hepatitis C: efficacy, side effects, and complications”. *Gut* 2006; 55(9):1350-9.

²⁴ Gilead Sciences, 2016. Available from <http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-irhome>.

²⁵ Médecins Sans Frontières (MSF) Briefing Document, May 2015. Available from http://hepcasia.com/wp-content/uploads/2015/05/hcv_overcomingbarrierstoaccess_en_may2015.pdf.

²⁶ Available from [https://www.who.int/en/news-room/fact-sheets/detail/hepatitis-c; https://apps.who.int/iris/bitstream/handle/10665/250625/WHO-HIV-2016.20-eng.pdf](https://www.who.int/en/news-room/fact-sheets/detail/hepatitis-c;https://apps.who.int/iris/bitstream/handle/10665/250625/WHO-HIV-2016.20-eng.pdf).

²⁷ Figure recently reviewed by the WHO that now reports 70 million in the world.

²⁸ Gilead offered Egypt a price of US \$ 900 per each 12-week treatment, an offer that was not put forward since the patent was not obtained, and a local firm offered a significantly better price.

²⁹ Gotham D, Barber M, Fortunak J, Pozniak A, Hill A, Abstract number A-792-0516-01639, presented at AIDS 2016, Durban.

production: 50,426 euros in Germany, 41,680 euros in France,³⁰ 13,000 euros in Spain, 6,000 euros in Brazil, 3,465 euros in Australia.³¹

Why 41,000 euros in France and 13,000 euros in Spain? This seems to depend on the negotiating capacity of each country. Gilead's business strategy, in its new business model, is to obtain the maximum profits without any relation to the R&D costs – with the aim of setting the highest price that governments agree to pay (so in the end they realize that universal access will not be possible at the prices that were negotiated, as is the case of France or Spain).

This case brings forward three interesting elements that mark a change in the debate on access to medicines. First, they are medicines that heal, unlike the vast majority of drugs put on the market in the last 20 years that allow controlling a disease as chronic, without curing it. Second, unaffordable prices were set for both developed and developing countries. It is now a global problem. Third, the pharmaceutical industry de-links R&D costs from the final price, and argues that it must be related to the country's ability to pay³² or to the “value” of the medicine compared to a possible cost of a liver transplant. With this approach, it is clear that the pharmaceutical industry's main objective is to remunerate its shareholders as much as possible, rather than as an instrument to serve public health. This industry has also achieved what academics and civil society organizations claimed several years ago: de-link the R&D costs from the final price of the product. However, as stated by Ruth Dreifuss (former president of Switzerland) at the Graduate Institute³³ in Geneva, on 23 February 2017, it is a “malefic de-linkage” because the cost of R&D and production has nothing to do with the final price of the medicine.

³⁰ On March 17, 2017, the French Government announced a new reduction to 28,700 euros for the 12-week treatment, a price that is still more than double what Spain pays. “Soins: le prix des médicaments contre l'hépatite C va baisser”. Available from <http://www.leparisien.fr/laparisienne/sante/soins-le-prix-des-medicaments-contre-l-hepatite-c-va-baisser-31-03-2017-6812619.php>.

³¹ Price of the 12-week treatment.

³² Pratap Chatterjee, “Gilead Sciences Under Investigation for Over Charging for Hepatitis C Pill”, July 21, 2014. Available from <http://www.corpwatch.org/article.php?id=15964>.

³³ Seminar about the High Level Panel on Access to Medicines.

IV. THE USE OF THE TRIPS AGREEMENT'S FLEXIBILITIES AND THE DOHA DECLARATION

As aforementioned, to the same extent that a new R&D model has not been installed to simultaneously promote innovation and access to new medicines, governments must rely on the flexibilities of the TRIPS Agreement to favour such access. The Doha Declaration – adopted on 14 November 2001 by the Fourth WTO Ministerial Conference – played a key role in confirming these flexibilities.

IV.1 Background

In 1996, the World Health Assembly adopted Resolution WHA 49.14 regarding the Revised Drug Strategy in which it requested the World Health Organization (WHO) “to report on the impact of the work of the WTO with respect to national medicine policies and essential medicines, including making recommendations for collaboration with the WTO”. With this resolution, the WHO was entrusted with the task of examining the new architecture of the multilateral trading system established by the WTO system in relation to public health.

In compliance with such a mandate, in 1998 the WHO Action Programme on Essential Drugs published a monograph entitled *Globalization and Access to Drugs – Perspectives on the WTO/TRIPS Agreement*.³⁴ This guide was made with the objective of informing professionals responsible for health policies, those who lack specific legal training, of the effect that the TRIPS Agreement could have on public health and pharmaceutical policies. Although the authors noted that the TRIPS Agreement imposed standards historically derived from industrialized countries, they also asserted that the Agreement provided considerable discretion to protect public health, now generally known as “the TRIPS flexibilities”. The Agreement, in effect, gives countries the possibility of implementing measures such as granting compulsory licenses, admitting parallel imports, considering exceptions to patent rights, as well as rigorously defining patentability criteria. These flexibilities can be used with a view to striking a balance between patent rights and public health needs.³⁵

However, in practice, the multinational pharmaceutical companies and the governments of some developed countries questioned, both legally and especially in the political sphere, the right of developing countries to make use of the aforementioned flexibilities.

In 1998, a lawsuit filed by 39 pharmaceutical companies against the South African Government to challenge the use of flexibilities (parallel imports, compulsory licenses), provided for in the TRIPS Agreement³⁶ in line with a correct interpretation of this Agreement and the recommendations of the WHO, provoked massive public protests. After an intense

³⁴ Velásquez, Germán y Boulet, Pascale, “Globalización y acceso a los medicamentos: Implicaciones del Acuerdo de la OMC sobre los ADPIC”, Serie: Economía de la salud y medicamentos, Serie del DAP Núm. 7 (WHO/DAP/98.9, Noviembre de 2007, Programa de Acción sobre Medicamentos Esenciales, Organización Mundial de la Salud, Ginebra).

³⁵ In 1999, the 52nd World Health Assembly adopted resolution WHA 52.38 on the Revised Drug Strategy urging member countries to “ensure that the interests of public health be a priority in pharmaceutical and health policies”.

³⁶ In 1997, South Africa introduced several amendments to its Medicines and Related Substances Control Act with a view, among other objectives, to authorizing “parallel imports” (i.e. imports without authorization from the patent holder) of pharmaceutical products.

international campaign in support of the South African Government, the pharmaceutical industry was forced to withdraw the demand. As a result of this episode, the African Group proposed and obtained the necessary consensus to discuss the topic of intellectual property and access to medicines in special sessions of the WTO TRIPS Council. These discussions showed the need to confirm the legitimacy of the flexibilities allowed by the TRIPS Agreement, and ultimately led to the adoption of the Doha Declaration.

IV.2 Reaffirmation of the TRIPS Agreement's flexibilities

The Doha Declaration recognized existing concerns about the effect of intellectual property rights on medicine prices (paragraph 3), which represented one of the greatest political achievements for developing countries in this area.

In addition, paragraph 4 of the Declaration provides a rule of interpretation to judge whether measures necessary to protect public health violate the provisions of the TRIPS Agreement. It declares that the Agreement “does not and should not prevent members from taking measures to protect public health” and that it “should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all”.

The Declaration reaffirmed the right of WTO members to make maximum use of the flexibilities provided for in the TRIPS Agreement to protect public health and promote access to medicines. In paragraph 5, it confirms that its provisions must be interpreted in the light of its object and purpose, as expressed, especially in its objectives and principles (Articles 7 and 8 of the TRIPS Agreement). In the same paragraph, the Declaration identifies some of the flexibilities provided in the Agreement for public health and mentions, in particular, the right of Members to grant compulsory licenses and to determine the reasons why such licenses should be granted. These may include the lack of or insufficient exploitation of a patent, anti-competitive practices, exorbitant prices and, more generally, the public interest.

The Declaration also recognizes the right to determine what constitutes a national emergency, or other circumstances of extreme urgency, on the basis that public health crises, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics, can create those situations. This is a crucial element of the Declaration because, as discussed below, WTO Members can grant a compulsory license/government use without the obligation to previously negotiate a voluntary license with the patent holder (Article 31, subparagraph b, TRIPS Agreement). These measures can continue to be applied as long as the situation of national emergency or extreme urgency persists.³⁷

Additionally, the Declaration confirms that members are free to apply the principle of international exhaustion of rights to allow parallel importation of a product protected by intellectual property rights legitimately marketed in any other country.

³⁷ 36 Carlos M. Correa, “Implications of the Doha Declaration on the TRIPS Agreement and Public Health”, (World Health Organization, June 2002), Available from http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf.

IV.3 Obstacles to the implementation of the Doha Declaration

Even after sixteen years of the Doha Declaration adoption on TRIPS and Public Health, it still remains a historic achievement in terms of clarifying the relationship between intellectual property and public health. However, several developing countries have faced obstacles to implement it.

One of the biggest stumbling blocks that has been observed, after 16 years of the Declaration, is the lack of adequacy of national legislations. The use of flexibilities requires, in many cases, that national legislations be amended. The lack of appropriate national legislation for the full implementation of such flexibilities remains one of the greatest difficulties for some developing countries. At the international level, there is a need to improve the legal and technical assistance offered to these countries with respect to intellectual property and public health. In the 16 years since the Doha Declaration, technical assistance has been insufficient or inappropriate.

Although since the adoption of the Doha Declaration, the use of the TRIPS Agreement's flexibilities has been challenged on only two occasions in the face of the WTO Dispute Settlement Body (DSB). None of these cases resulted in a panel or report stating a violation of the Agreement. This situation is, perhaps, in itself a proof of the importance of the legitimation of these flexibilities to the developing countries by means of the Doha Declaration.

V. USES WITHOUT AUTHORIZATION FROM THE PATENT HOLDER

The possibility of authorizing the use of a patent without the consent of its holder is one of the main flexibilities of the TRIPS Agreement – confirmed, as could be seen, by the Doha Declaration – and a crucial element in a patent law that considers public health needs. These authorizations can serve to mitigate the monopoly rights conferred by a patent and, therefore, promote competition without denying the right of the patent holder to continue the exploitation of the invention (through importation or local production) or to receive remuneration for the use of the invention patented by third parties.

Two types of authorizations can be distinguished according to who their beneficiary is. On the one hand, “compulsory licenses” or “non-voluntary licenses” are granted by the State (administratively or judicially) in favour of a natural or legal person that complies with the procedural and substantive requirements established by the applicable national legislation. The beneficiary is a person other than the State itself. On the other hand, the “authorization of government use”, also called “non-commercial public use”, can be dictated by the State for the use, by the very State, of a patented invention. In this case, unlike in compulsory licenses, the direct beneficiary is not a third party, although State contractors may intervene.

WTO Member countries can establish compulsory licenses for various reasons and arrange government use for non-commercial purposes in accordance with Article 31 of the TRIPS Agreement. Article 31 does not limit the reasons why compulsory licenses can be granted or non-commercial government use can be adopted. It leaves, in this sense, ample room for manoeuvre for countries to legislate and decide on the matter. This provision only establishes the conditions under which such authorizations may be issued, such as dictated on a case-by-case basis, prior negotiation with the patent holder (in some cases), payment of an adequate remuneration, and non-exclusivity of the licenses granted. In most countries, including developed countries, some form of compulsory licensing or government use is provided by law.³⁸ These instruments have been widely used, for example, in the USA in order to correct anti-competitive practices and as a part of the government’s pre-eminent right to exploit any patented invention.³⁹ In that country, compulsory licenses can be articulated by the administration or by the judicial courts, through the file of authorizing a party in violation of a patent to continue with the use of the invention for reasons of “equity” against the payment of a royalty.⁴⁰

³⁸ According to a World Intellectual Property Organization (WIPO) study, the laws of at least 84 countries contain provisions for the use of patents without the authorization from the holder. See WIPO Secretariat Report on Compulsory Licensing: SCP/21/4 REV., Nov. 3, 2014.

³⁹ See JH Reichman, “Non-Voluntary Licensing of Patented Inventions: The Law and Practice of the United States” (UNCTAD-ICTSD, 2006).

⁴⁰ See Supreme Court of the United States on *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) and the decisions issued under the doctrine of this case, e.g. in *Sue Ann Mota*, “*eBay v. MercExchange*: Traditional Four-Factor Test for Injunctive Relief Applies to Patent Cases, According to the Supreme Court”, *Akron Law Review*: Vol. 40: Iss. 3, Article 4, available at <http://ideaexchange.uakron.edu/akronlawreview/vol40/iss3/4>; Ryan T. Holte & Christopher B. Seaman, “Patent injunctions on appeal: An empirical study of the federal circuit’s application of *eBay*”, *Washington Law Review*, Vol. 92: 145, 2017, available at <https://digital.law.washington.edu/dspace-law/bitstream/handle/1773.1/1669/92WLR0145.pdf?sequence=1&isAllowed=y>.

Compulsory licenses have also been granted on patents in Italy and, more recently, Germany, specifically in relation to pharmaceutical products. In the latter country, for example, the court of appeal confirmed in July 2017 a compulsory license granted by a lower court for reasons of ‘public interest’ in relation to an antiretroviral drug.⁴¹

Some developing countries have begun to make a more efficient use⁴² of compulsory licenses/government use (see Table 2), despite the obstacles and pressures (from governments and the multinational pharmaceutical industry) that they have had to face. For example, in 1997, the USA threatened to impose sanctions on Thai exports if Thailand did not abandon its plan to use compulsory licenses. As mentioned, 39 pharmaceutical manufacturers filed in 1998 a lawsuit against the South African legislation on parallel imports, in which the legitimacy of compulsory licenses was also questioned.⁴³ The most recent case of Colombia referring to imatinib (discussed below) points out that the same obstacles persist twenty years later.

Table 2

Compulsory licenses/authorizations for government use in developing countries

Zimbabwe, May 2002, compulsory license to produce seven generic versions of antiretroviral drugs (ARVs)
Malaysia, November 2003, compulsory license to import ARVs from India for 2 years from November 1, 2003
Mozambique, April 2004, compulsory license for the local manufacture of ARVs
Zambia, September 2004, compulsory license for the local manufacture of ARVs
Indonesia, October 2004, compulsory license for ARVs
Eritrea, June 2005, compulsory license to import generic ARVs
Ghana, October 2005, government use to import generic ARVs
Thailand, November 2006, government authorization for local production of efavirenz and importation of the same medication from India
Thailand, January 2007, government authorization for the cardiovascular drug Plavix (clopidogrel)
Thailand, January 2007, government authorization for ARV Kaletra (lopinavir+ ritonavir)
Brazil, May 2007, government authorization for the importation of generic efavirenz from India
Thailand, 2008, government authorization for four anti-cancer drugs
India, 2012, license due to lack of Sorafenib (medicine for liver cancer) exploitation
Ecuador, 10 compulsory licenses between 2013 and 2014
Malaysia, 2017, government use for sofosbuvir

Source: Based on Carlos M. Correa, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing*, South Centre, Geneva, 2011.

⁴¹ See <http://ipkitten.blogspot.co.za/2017/07/bgh-grants-compulsory-license-in.html>.

⁴² See, for example, C. Oh, “Compulsory licenses: Recent experiences in developing countries”, 1 Intl J of Intellectual Property Management no. 1-2 (2006): pp. 22-36.

⁴³ J-F Morin, “Tripping Up: TRIPS Debates, IP and Health in Bilateral Agreements”, International Journal of Intellectual Property Management 1, no. 1-2 (October 3, 2006): pp. 37-53; JC Nwobike, “Pharmaceutical corporations and access to drugs in developing countries: The way forward”, Sur-Intl Journal on Human Rights 3, no. 4 (2006): pp. 126-143.

While the majority of compulsory licenses/government use have referred to medicines for HIV/AIDS, the Doha Declaration confirmed that these measures can be adopted without being limited to particular ailments, such as HIV/AIDS, tuberculosis, and malaria. Thus, in 2008 Thailand authorized government use for four anti-cancer drugs. The same country had already granted in 2007 a compulsory license for a medicine for cardiac use (clopidogrel). India granted a compulsory license in relation to a medicine for liver cancer (“sorafenib”) in 2012. These are compelling (albeit sparse) examples of the possible use of the flexibilities provided for in the TRIPS Agreement.

Some free trade agreements restrict the freedom of WTO members to determine the grounds for compulsory licensing, contrary to what was confirmed by the Doha Declaration on the TRIPS Agreement and Public Health. Thus, in free trade agreements of the United States with Jordan, Australia and Singapore, these causes are limited to cases of anti-competitive practices, non-commercial public use, national emergency or other circumstances of extreme urgency. This limitation, however, does not appear in other free trade agreements signed with developing countries (including those in Latin America) after the adoption of the aforementioned Doha Declaration. However, some provisions of free trade agreements, namely, data exclusivity and the patent protection/medicine registration link,⁴⁴ may in practice limit the use of patented inventions under compulsory licenses and for non-commercial governmental purposes.⁴⁵

Finally, it should be noted that although from a public health perspective it is necessary that national legislation should provide for a system of compulsory licensing and governmental use, these instruments do not solve by themselves the problems that may arise from the granting of patents related to medicines, especially if lax or inappropriate examination standards are applied, which allow obtaining patents when the requirements of novelty, inventive step or industrial application have not been rigorously observed.

It is, therefore, crucial to ensure that patentability criteria be rigorously defined for the patent examination and the granting procedure, as is the case in a growing number of countries (Argentina, India, Egypt, Ecuador, Indonesia) and is what the European Parliament⁴⁶ has recently claimed.

⁴⁴ The free trade agreements negotiated by the United States require a link between the registration of medicines and the protection of patents – not provided for in the TRIPS Agreement. As a result of this linkage, the national health authority may be required to refuse marketing approval of a generic version of a product if a patent on it is in force, unless it has the consent or acquiescence of the patent holder. In addition, such authority must inform the patent holder about the applications for approval of generic products. See, for example JR Sanjuan, “Patent-Registration Linkage” (Discussion Paper No. 2, Consumer Project on Technology, 3 April 2006), available at <http://www.cptech.org/publications/CPTEchDPNo2Linkage.pdf>.

⁴⁵ See C. M. Correa, “Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines”, *Case Western Reserve J of Intl L* 36, no. 1 (Winter, 2004).

⁴⁶ European Parliament resolution of 2 March 2017 on European Union options for improving access to medicines (2016/2057(INI)), para. 48. ‘...emphasises that the European Patent Office (EPO) and the Member States should only grant patents on medicinal products that strictly fulfill the patentability requirements of novelty, inventive step and industrial applicability, as enshrined in the European Patent Convention’.

VI. COMPULSORY LICENSES/GOVERNMENT USE IN LATIN AMERICA

The legislations of the Latin American countries provide for different foundations for the granting of compulsory licenses (see Table3).

Table 3
Compulsory licenses in Latin American legislation

<i>Reasons for the issuance of a compulsory license</i>	<i>Countries</i>
Lack of exploitation	Andean Community, Argentina, Brazil, Dominican Republic, Honduras, Mexico
Public interest	Andean Community, Brazil, Dominican, Republic, Honduras, Mexico
National emergency	Andean Community, Argentina, Brazil, Dominican Republic, Honduras, Mexico
To correct anti-competitive practices	Andean Community, Argentina, Brazil,
Unfair competition	Dominican Republic
Reasonable conditions	Dominican Republic, Honduras
If they are not produced locally	Brazil
Dependent patents	Andean Community, Argentina, Brazil, Dominican Republic, Honduras
Refusal to treat	Argentina, Dominican Republic
No provision on compulsory licenses	Panama

Source: Prepared based on Oliveira et al., “Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced industrial property legislation that favours public health policy?” *Bull World Health Organ.* 2004 Nov; 82 (11): 815-821.

In several Latin American countries, the lack of exploitation of a patent can be a valid reason for the granting of a compulsory license, but the importation of protected products is deemed as exploitation. Only Brazil has expressly provided for the possibility of granting compulsory licenses in cases of lack of local industrial use of the patent (Article 68 of the Industrial Property Code).⁴⁷

Argentina and the Dominican Republic explicitly allow the granting of compulsory licenses in cases of “refusal to treat”, that is, when the patent holder refuses to grant a voluntary license that has been requested under reasonable commercial terms.⁴⁸

Brazil granted a compulsory license (in May 2007) after a failed agreement with the patent holder to reduce the price of an antiretroviral (efavirenz). Brazil had also announced

⁴⁷ USA requested the constitution of a panel against Brazil in the WTO Dispute Settlement Understanding framework in relation to this provision, arguing that it was inconsistent with Article 27.1 of the TRIPS Agreement. The complaint was, however, withdrawn by the Government of the United States before the creation of the panel, upon reaching an agreement with the Government of Brazil according to which, before granting a compulsory license, the latter will report the alleged causes. See *Brazil - Measures Affecting Patent Protection, Request for the Establishment of a Panel by the United States* (WTO, WT/DS199/3, 9 January 2001).

⁴⁸ See C. Correa, “Refusal to deal and access to an essential facility: balancing private and public interests in intellectual property law”, in *Mélanges Victor Nabhan*, edited by Y Blais (Série Les cahiers de Propriété Intellectuelle, 2004).

the possible use of these licenses in 2001, but without granting them, since the prices of the patented medicines were considerably reduced as a consequence of the government threat.⁴⁹

It should be noted that no country in Latin America has introduced changes to its legislation in order to implement the WTO Decision of August 30, 2003 (incorporated in January 2017 into the TRIPS Agreement as new Article 31bis), which establishes exemptions for the supply of pharmaceutical products to countries that do not have or have insufficient manufacturing capacity for pharmaceutical products. However, several countries in Latin America ratified the aforementioned amendment.

VI.1 The Case of Ecuador

From 2013 to 2017, the Ecuadorian Institute of Intellectual Property (IEPI) processed 33 applications for compulsory licenses,⁵⁰ some of which were denied, others were abandoned and ten of them were issued in relation to medicines.

The first three licenses were issued for antiretroviral drugs: Ritonavir+Lopinavir and Lamivudine+Abacavir, medicines that the Ministry of Public Health provides free of charge for the treatment of HIV/AIDS.⁵¹

In addition to the licenses issued for antiretroviral drugs, licenses were issued for Etoricoxib (Arcoxia® for the treatment of diseases with acute pains); Mycophenolate Sodium (MYFORTIC) used in the treatment of rejection of kidney transplants; sunitinib, an anticancer drug used for the treatment of carcinoma renal cells (CRC) and gastrointestinal stromal tumours (GISTs); and finally Certolizumab, used to counteract rheumatoid arthritis.⁵²

According to Hernán Núñez Rocha, former president of the Ecuadorian Institute of Intellectual Property (IEPI), “with the compulsory licensing policy, prices can be reduced from 30 per cent and up to 90 per cent”.⁵³

The legal framework for compulsory licenses in Ecuador is composed of:

- **Republic Constitution, Article 3.1:** “It is the primary duty of the State to guarantee, without any discrimination, the effective enjoyment of the rights established in the Constitution and in international instruments, in particular, constitutionally recognized rights, such as health”;

⁴⁹ See “Public Health, Innovation and Intellectual Property Rights” (Report of the Commission on Intellectual Property Rights, Innovation and Public Health, World Health Organization, 2006), p. 135, available at <http://www.who.int>.

⁵⁰ “Ecuador: Las 10 licencias obligatorias en el país bajarían el costo de medicinas hasta el 90%”, Interview with Andres Icaza, Arsenal Terapéutico, 6 June 2015. Available from <http://www.arsenalterapeutico.com/2015/06/06/las-10-licencias-obligatorias-en-el-pais-bajarian-el-costo-de-medicinas-hasta-el-90/>.

⁵¹ Ketty Véliz, “Licencias obligatorias, mayor acceso a medicamentos en el Ecuador”, 29 de septiembre de 2014.

⁵² Ibid.

⁵³ “Ecuador: Las 10 licencias obligatorias en el país bajarían el costo de medicinas hasta el 90%”, Interview with Andres Icaza, Arsenal Terapéutico, 6 June 2015. Available from <http://www.arsenalterapeutico.com/2015/06/06/las-10-licencias-obligatorias-en-el-pais-bajarian-el-costo-de-medicinas-hasta-el-90/>.

- **Andean Decision 486, Article 65:** “Prior to the declaration of a member country on the existence of reasons of public interest, emergency, or national security, and only while these reasons remain, at any time, the patent may be subject to compulsory license. In such case, the national office in charge will grant the licenses requested. The patent holder subject to the license will be notified when reasonably possible.”

The national office in charge shall establish the scope or extension of the compulsory license, specifying in particular the period for which it is granted, the object of the compulsory license, the financial compensation amount and conditions.

The granting of a compulsory license for reasons of public interest does not diminish the right of the patent holder to continue to exploit it.⁵⁴

- **Ecuador’s Intellectual Property Law of 1998, Article 154:** requires the Republic President’s Declaration of Public Interest to grant a compulsory license.
- **Executive Decree 118 in October 2009, Article 1:** “Declare of public interest access to medicines used for the treatment of diseases that affect the Ecuadorian population and that are priorities for public health, for which compulsory licenses may be granted on the patents of medicines for human use that are necessary for their treatments. Cosmetic, aesthetic, hygiene and, in general, those medicines that are not for the treatment of diseases will not be considered a priority for public health”.⁵⁵
- **Resolution 10-4-P-IEPI – 2010:** regulates the procedures for granting a compulsory license, including the following steps:
 - Interested Party Request (form).
 - Application Review.
 - Evidence that a voluntary license has been attempted with the holder and has not been achieved.
 - Notification to the patent holder.
 - Consultation with the Health Authority (Ministerio de Salud Pública – MSP) in order to indicate if the requested matter is considered as “of public interest” and if it is a medicine used in the treatment of diseases that affect the Ecuadorian population.
 - Determine the amount of royalties and the duration of the compulsory license.
 - Resolution for granting or denying.
 - According to Ycaza Mantilla, the results of the compulsory licenses granted in Ecuador can be summarized as follows:
 - Generation of competition with generic medicines
 - Improvements in the public procurement system
 - Reduction of medicine prices for reverse auctions.⁵⁶

⁵⁴ Andean Decision 486, Art. 65 of the year 2000, <http://www.wipo.int/edocs/lexdocs/laws/en/can/can012en.pdf>.

⁵⁵ Ycaza Mantilla, A., “LICENCIAS OBLIGATORIAS, EN ECUADOR”, PPT presented in Havana, Cuba, 2017.

⁵⁶ “Ecuador: Las 10 licencias obligatorias en el país bajarían el costo de medicinas hasta el 90%”, Interview with Andres Icaza, Arsenal Terapéutico, 6 June 2015. Available from <http://www.arsenalterapeutico.com/2015/06/06/las-10-licencias-obligatorias-en-el-pais-bajarian-el-costo-de-medicinas-hasta-el-90/->

At a press conference in July 2014 in Quito, the Minister of Health of Ecuador, Carina Vance, referring to the compulsory licenses granted between 2013 and 2014, stated that: “In these nine processes, we have generated the potential for savings of 23 per cent to 99 per cent.” As an example, she mentioned the case of Etoricoxib, a drug that could cost \$0.84 per tablet on the market, but with the license a saving of 99 per cent can be achieved, thus costing \$ 0.0084.⁵⁷

A recent review by Ooms et al. evaluated the impacts of compulsory licenses granted in Ecuador.⁵⁸ The review noted that the procedure requires the participation of an applicant, which has been interpreted as a potential producer or importer. Although compulsory licenses have been granted for reasons of “public interest” supported by the aforementioned presidential statement, the government has in no case been directly the applicant and receiver of those, nor have civil society organizations been so. It is not entirely clear if the requests could have been submitted by the Ministry of Health or an NGO, which may explain the difficulties in implementing some compulsory licenses, as happened to the one related to Kaletra.

Any compulsory license beneficiary must obtain the sanitary registration to enter the market; in addition, given that in the Ecuadorian case the main (if not only) buyer of medicines for HIV/AIDS is the Ministry of Health, the licensee must be part of the registered and qualified providers, which implies time and costs. For these reasons, according to WHO, the impact of compulsory licenses in Ecuador has been limited in certain cases in order to achieve price reductions and improvements in access with relevant and sustainable dimensions over time.⁵⁹ This situation may reflect a certain tension between the objectives of industrial policy (favouring the local production of medicines) and public health (obtaining medicines at the lowest possible price, whether by local production or importation) that governments must make compatible in the definition of their strategies in this matter.

The case of Etoricoxib in which, as mentioned above, the price reduction was over 90 per cent, is illustrative of that tension. Etoricoxib is a “close relative” (a “me-too”) of Rofecoxib (Vioxx® by Merck), a product that has gone down in history as one of the biggest scandals in the pharmaceutical industry.⁶⁰ Vioxx® was withdrawn from the market worldwide, but the large promotional investments that had been made benefited Etoricoxib, arguing that it was a product with the benefits of rofecoxib but without its cardiac risks. However, etoricoxib has been little used in the vast majority of countries, precisely because of its proximity to rofecoxib, except in Ecuador, where the product opportunely patented by Merck became the best-selling anti-inflammatory in a few years, thanks to a very effective promotional campaign with doctors. It was precisely because of this commercial success that a competing company decided to apply for a compulsory license. The Ministry of Health opposed this license because it was considered a product of little or no interest from a public health perspective.

⁵⁷ Ministry of Public Health, “Ecuador concedió nueve licencias obligatorias para medicamentos estratégicos”. Available from <http://www.salud.gob.ec/ecuador-concedio-nueve-licencias-obligatorias-para-medicamentos-estrategicos/>.

⁵⁸ G., Ooms, C.M. Vargas-Peláez, H. van den Bosch, “A situation analysis of compulsory licensing in Colombia and Ecuador”, Master Thesis, UV University, 2017.

⁵⁹ *Ibid.*

⁶⁰ The company received a heavy fine not so much for having caused serious side effects including deaths from cardiac causes, but because it was heavily promoted even though its risks were known. See Stéphane Horel, “Intoxication: Perturbateurs endocriniens, lobbyistes et eurocrates: une bataille d'influence contre la santé” (Ed. La Découverte, Paris, 2015).

VI.2 Experiences from Colombia and Peru

In the countries of the Andean Community, a compulsory license may be requested and obtained for reasons of public interest. An analysis of the concept of public interest made by the Ministry of Health of Colombia⁶¹ comparing the decisions on compulsory licenses in 10 countries highlights that it is up to each country to define what is the public interest, according to its own criteria. The TRIPS Agreement, as mentioned, is limited to formulating flexibilities, but it gives a certain margin (certainly not unlimited) for different countries to adjust the relevant provisions, including compulsory licenses, to their needs. Additionally, the study notes that the concept is often associated with the social function of property and represents a means to address the tensions between human rights and commercial rights that have recently been examined by the High-Level Panel of the Secretary General of the United Nations.⁶²

In cases where the public interest has been invoked for the granting of a compulsory license, it has been associated with epidemiological (Cancer, HIV), economic criteria (excessive prices derived from the existence of intellectual property protection), and budgetary restrictions (all applications have been filed in low- or middle-income countries). These three considerations are repeated, to a greater or lesser degree, in all the administrative acts of granting such licenses.⁶³

In contrast to the Ecuadorian case, in which compulsory license applications were submitted by entities with the capacity to produce or distribute medicines, in Peru and Colombia (and more recently in Guatemala),⁶⁴ the applicants have been civil society organizations, which have formulated these requests based on the following considerations:

- existence of a problem that is considered “of public interest”
- derived from an abusive exercise of a patent right expressed at an excessive price
- in relation to medicines of high sanitary relevance (HIV, Cancer)
- in a context of budgetary limitations for health

The first application for a compulsory license was filed in Colombia in 2008 for the combination lopinavir+ritonavir, Kaletra® by Abbott Laboratories. It was presented by four civil society organizations: The Colombian Network of People Living with HIV (RECOLVIH), the NGO Working Group on HIV, the Misión Salud Foundation, and the IFARMA Foundation. The license request was based on “public interest” reasons. The request was rejected by the Ministry of Health based on the argument that, while the product was included in the Compulsory Health Plan, there were no access problems even though its price was very high as a result of a patent (the first granted to a combination of drugs in the history

⁶¹ Available from: <https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/interes-publico-otorgamiento-licencias-medicamentos.pdf>.

⁶² *Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines* (2016). Available from <http://www.unsgaccessmeds.org/final-report>.

⁶³ Ministry of Health of Colombia, *Análisis del concepto de interés público para el otorgamiento de licencias en medicamentos* (see citation 61).

⁶⁴ In Guatemala, a compulsory license application has been submitted for the thermo-stable version of Kaletra®, a secondary patent of lopinavir-ritonavir. Kaletra® represents more than half of total HIV spending in that country. In Peru, a group of NGOs has requested compulsory licensing for atazanavir, which thanks to a patent is responsible for half of all HIV spending. The request is pending a decision, as is a compulsory license application for Antivirals of Direct Action for hepatitis C in Colombia.

of the country's patent office).⁶⁵ The organizations involved appealed the decision of the Ministry before the judiciary and obtained a decision in their favour. After almost three years, access to that medicine was declared of public interest, and the judge in charge ordered a strong price control on the product, which resulted in a reduction of the final price of more than 90 per cent, an important result even when the compulsory license has not been granted.

In Peru, a request was submitted by a coalition of civil society organizations led by International Action for Health (*Acción Internacional por la Salud – AIS*) to grant a compulsory license on atazanavir, patented in Peru as sulphate by BMS. Atazanavir came to represent more than half of the total cost of the Ministry of Health to treat HIV, with the highest prices in the region, precisely because a patent on a salt was obtained.⁶⁶ This request generated a national debate on prices and access to medicines that, although it did not result in a compulsory license, resulted in a price reduction of 30 per cent.⁶⁷

In the cases of Peru and Colombia, strong disagreements between the Ministries of Health, on the one hand, and the trade sectors and the patent office, on the other, transpired to the public and the media. The latter managed to influence the procedure for processing compulsory license applications, turning these requests into a bilateral procedure in practice.

In Colombia, the procedure has been modified three times: by Decree 4302 of 2008, Decree 4966 of 2009, and, more recently, Decree 670 of 2016.

To understand the above most recent Decree, it is necessary to know in some detail what happened in the case of Imatinib. Novartis applied for a patent in 1998 for the beta crystal of imatinib mesylate salt (a typical “secondary” patent intended to extend the period of patent protection (a strategy commonly known as “evergreening”). This was how it was understood by the patent office of Colombia (the Superintendency of Industry and Commerce – SIC), which rejected the request arguing that it was the result of crystallization of the molecule and a particular salt of a product already known.

The response from the patent office was so strong that several companies registered and sold generic formulations of imatinib for many years, on the grounds that the denial of the application was *res judicata* (i.e., “a matter [already] judged”). In 2012, more than 60 per cent of the imatinib market was covered by a generic that had a price below 20 per cent of that of Novartis' Glivec®. However, Novartis successfully appealed to the State Council against the patent office's decision. In 2012, the State Council ordered the SIC to revoke its refusal and grant Novartis the requested patent.⁶⁸

In 2014, Novartis asserted its intellectual property rights, excluding the main competitors of the market. The Ministry of Health, therefore, had to face a dramatic increase in spending on this product. Three civil society organizations – IFARMA, Misión Salud and the Drug Information Center of the National University of Colombia (CIMUN) – requested a declaration of public interest on this product, so that a compulsory license was granted. The

⁶⁵ This is an example of the granting of a “secondary” patent in the absence of a genuine invention, which would probably not have been granted if rigorous patentability criteria had been applied.

⁶⁶ Another example of a “secondary” patent, granted for lack of rigorous application of patentability criteria.

⁶⁷ *Acción Internacional para la Salud (AIS Peru)*. Available from <http://aisperu.org.pe/nuestro-trabajo/noticias/item/8-peru-continua-el-debate-sobre-la-licencia-obligatoria-para-atazanavir>.

⁶⁸ This precedent compels us to insist once again on the need to apply rigorous criteria when examining patent applications. Many problems could have been avoided if patents had not been granted to combinations, salts or crystals of molecules that were already in the state of the art.

announced intention of the Ministry of Health to move towards the granting of a compulsory license unleashed strong commercial and political pressures (on the part of Novartis, the Swiss government, and the US government),⁶⁹ observed in the aforementioned High-Level Panel Report as an example of the unacceptable situation in which developing countries are often placed trying to legitimately use some of the TRIPS flexibilities.⁷⁰ The process, which ultimately led to a declaration of public interest that recommended the Minister of Health to carry out a price negotiation before resorting to a compulsory license, can be followed in detail on the website of the Ministry of Health.⁷¹

Consequently, the aforementioned Ministry requested the National Price Commission of Medicines and Medical Devices (CNPMDM)⁷² to apply a novel method for “competition simulation”,⁷³ which resulted in the setting of a substantially lower price (a 44 per cent reduction) for the patented product.⁷⁴

The industry’s reaction to this decision led to the issuance of Decree 670 of 2016 which, in essence, requires that any sectorial technical committee in charge of determining if there are reasons to declare a “public interest” include a representative of the Ministry of Commerce and of the National Planning Department, and prohibits future pricing controls of products declared “of public interest”.

⁶⁹ G. Ooms, C.M. Vargas-Peláez, H van den Bosch, “A situation analysis of compulsory licensing in Colombia and Ecuador”, Master Thesis, UV University, 2017.

⁷⁰ *Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines* (2016). Available from <http://www.unsgaccessmeds.org/final-report>.

⁷¹ See www.minsalud.gov.co/propiedadintelectual.

⁷² Composed of the Minister of Health, the Minister of Commerce, and a President of the Republic’s delegate.

⁷³ Circular 03 of 2016 of the CNPM.

⁷⁴ Circular 04 of the CNPM of 2016.

VII. EXPERIENCES OF GOVERNMENT USE

Government use for non-commercial purposes of a patent, as noted, takes place when the government itself is the beneficiary of the authorization. This modality has two clear advantages, as regulated by the TRIPS Agreement, with respect to compulsory licenses.

On the one hand, it is not necessary to negotiate with the patent holder prior to government use. Moreover, one can start the use and then communicate to the patent holder (Article 31 (b) of the TRIPS Agreement). On the other hand, national laws may establish that governments may not be subject to an interdiction to use a patented invention; the only possible claim for a patent holder is a remuneration based on the “economic value” of the authorization (Article 44.2 of the Agreement).

In addition, the governmental and non-commercial nature of the authorization does not prevent the government from allowing a third party, including a commercial entity, to use the invention (for example, as a contractor) to satisfy the government’s needs. This extends the possible use of this type of authorizations because – at least under the TRIPS Agreement – it is not necessary for the government itself to import or produce the product or use the patented process. As noted above, the United States has intensively used this modality;⁷⁵ any ministry can decide on the use of a patented invention, at any time since its granting, even without previously communicating it to the patent holder, whose only recourse is to request judicial tribunals to determine the remuneration (28 USC section 1498).

The advantages of government use may explain why some of the so-called “compulsory licenses” granted in developing countries in the last two decades constitute, in fact, cases of government use.⁷⁶

For example, in 2004 the Indonesian government authorized the Minister of Health to designate a “pharmaceutical manufacturer” to exploit a patent on behalf of the government. The authorization was based on Presidential Decree No. 83 of 2004 “Regarding Exploitation of Patent by the Government on Anti-retroviral Drugs”.⁷⁷ According to the available literature; the government achieved substantial savings with such authorization.⁷⁸

In 2005, the Government of Ghana issued a government use measure that allowed the importation of HIV/AIDS generic medicines from India. With this measure, costs were reduced by more than 50 per cent, from US\$ 495 to US\$ 235 per year/patient.⁷⁹

⁷⁵ See, for example, e.g., John R. Thomas, “Compulsory Licensing of Patented Inventions, Cong. Res. Serv., R43266, January 14, 2014; Colleen Chien, “Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?”, 18 Berkeley Tech. L. J. 853 (2003).

⁷⁶ See Martin Khor, *Compulsory License and “Government Use” to Promote Access to Medicines: Some Examples* (TWN, Penang, 2014).

⁷⁷ Ministry of Commerce, Trade and Industry letter, Compulsory Licence No.01/2004, signed by Minister Patel, 21 September 2004 and please see TWN website: <http://www.twinside.org.sg/title2/par/TRIPS.flexibilities.30jan07>.

⁷⁸ See Padmashree Gehl Sampath, “Promoting Local Pharmaceutical Capacity in Developing Countries: A Discussion on Inventive Step and Compulsory Licensing”, in Carlos Correa (editor), *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* (South Centre, Geneva, 2013).

⁷⁹ See Martin Khor, *Compulsory License and “Government Use” to Promote Access to Medicines: Some Examples* (TWN, Penang, 2014).

Thailand decided in 2006 on the government use of an efavirenz patent until December 31, 2011 to import products from India and produce them locally. The amount should not exceed 200,000 patients per year covered under the National Health Security System Law. Merck marketed the product at 1,500 baht per month (USD\$ 41), while the government imported a generic version of the medicine from India at an estimated cost of 800 baht.⁸⁰ In January 2007, Thailand decided on a new government use until the patent expires or there is no essential need, in relation to a medicine for cardiac treatment, “Plavix®” (clopidogrel bisulphate). The authorization allowed the supply of generic medicines for patients covered by the National Health Security Law B.E.2545, the Social Security Law B.E.2533, and the Medical Benefits Plan of Public Servants and Government Employees, subject to doctors’ criteria. The cost of Plavix® was expected to decrease from 120 baht per pill to 6-12 baht per pill. On the same date, Thailand also decided on the government use until January 31, 2012 of the patent on the medicine against AIDS Kaletra® (LPV + RTV). The use of patent rights was limited to the provision of the medicines to no more than 50,000 patients per year, for those covered by the National Health Security System Law B.E. 2545, Social Security Law B.E. 2533, and the Medical Benefits Plan of Public Servants and Government Employees. In the face of 6000 baht per month or 72,000 baht per year per patient charged by Abbott, the government estimated to save 20 per cent with the generic version.

In May 2007, Brazil decided on government use after the negotiations with efavirenz’s patent holder failed, in order to import the product from India at a cost of US \$ 0.46 per pill instead of purchasing Stocrin® – the patented product from its US manufacturer Merck & Co.

Malaysia’s recent intervention on the patent that protects sofosbuvir (for the treatment of hepatitis C) was also implemented through government use,⁸¹ with the main intention of supplying the network of public hospitals.

⁸⁰ See CP Tech website: <http://www.cptech.org/ip/health/c/thailand/>.

⁸¹ <https://www.ip-watch.org/2017/09/15/malaysia-grants-compulsory-licence-generic-sofosbuvir-despite-gilead-licence/>.

VIII. MAIN CONCLUSIONS

The current R&D model for pharmaceutical products (characterized by a lack of transparency in R&D costs and high medicine prices) does not ensure desirable levels of innovation of genuine therapeutic value, nor universal accessibility to the new products that are introduced to the market. The implementation of this model (mainly through patents and other forms of exclusivity) generates inconsistencies in health policies and tensions with the States' obligations towards the realization of the fundamental right to health.

This situation seems to be aggravated by the new pricing policy of some companies, explicitly based on the use **value** of the medicine (and the cost of alternative treatments), without connection to R&D costs. Significantly, as indicated in the High-Level Panel Report of the Secretary General of the United Nations, the problem of access to medicines has acquired a global dimension as it affects both developing countries and developed countries. Illustrative in this regard are the cases of new medicines for Hepatitis C and cancer, which even in industrialized countries are inaccessible to patients who need them. From a public health perspective, it is essential to continue with the search for global R&D models that guarantee, simultaneously, innovation and access.

In the current context, the use of the so-called flexibilities of the TRIPS Agreement, confirmed by the Doha Declaration, is one of the available ways to reconcile public and commercial health interests at stake. This Declaration, sixteen years after its adoption, remains a historic achievement in terms of clarifying the relationship between intellectual property and public health.

The analysis of compulsory licenses in Ecuador and requests in Colombia and Peru suggests that the feasibility of obtaining these licenses and their impact on access to medicines depend strongly on the applicable legal framework, including the possibility that these licenses are requested by non-governmental organizations (those that have had a leading role in the case of Colombia and Peru). There is a tension between the objectives of industrial policy and public health in the use of compulsory licenses. The extent to which these objectives are made compatible will depend on the extent to which a sustainable supply is ensured over time, price reductions and improvements in access to medicines with relevant dimensions.

Given the requirements that must be observed to obtain a compulsory license, to opt for government use may be a more direct and appropriate way (in particular, no prior negotiation with the patent holder is necessary) than the compulsory licenses requested by a third party. In fact, as the examples mentioned above have shown, in several cases governments have chosen the alternative of government use, which does not prevent them from subcontracting an entity (including commercial ones) for the non-commercial supply of the patented product. The precedent set by the Malaysian government is of particular interest as regards government use for sofosbuvir in response to the patent holder's high price and marketing strategy.

Finally, it should be noted that despite the unquestionable legitimacy of compulsory licenses/ government use, the case of imatinib in Colombia demonstrates the persistence of political and commercial pressures to avoid the use of these instruments. It also points to the

need to more effectively neutralize those practices that erode the national sovereignty and the right of every government to take the necessary measures to protect public health.














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