

**INTELLECTUAL PROPERTY AND  
ACCESS TO MEDICINES:  
AN INTRODUCTION TO KEY ISSUES -  
SOME BASIC TERMS AND CONCEPTS**

Germán Velásquez





# **TRAINING PAPERS**

## **1**

### **INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES: AN INTRODUCTION TO KEY ISSUES – SOME BASIC TERMS AND CONCEPTS**

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## ABSTRACT

Intellectual property and patents in particular, have become one of the most debated issues on access to medicines, since the creation of the World Trade Organization (WTO) and the coming into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Patents are by no means the only barriers to access to life-saving medicines, but they can play a significant, or even determinant, role. During the term of patent protection, the patent holder's ability to determine prices, in the absence of competition, can result in the medicine being unaffordable to the majority of people living in developing countries. This first issue of the "South Centre Training Materials" aims, in its first part, to provide an introduction to key issues in the field of access to medicines and intellectual property. The second part describes and defines some basic terms and concepts of this relatively new area of pharmaceuticals policies which are the trade related aspects of intellectual property rights that regulate the research, development and supply of medicines and health technologies in general.

*La propiedad intelectual y las patentes en particular, se han convertido en uno de los temas más debatidos sobre el acceso a los medicamentos, desde la creación de la Organización Mundial del Comercio (OMC) y la entrada en vigor del Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC). Las patentes no son de ninguna manera las únicas barreras para el acceso a medicamentos que salvan vidas, pero pueden desempeñar un papel significativo, o incluso determinante. Durante el período de protección de la patente, la capacidad del titular de la patente para determinar los precios, en ausencia de competencia, puede hacer que el medicamento resulte inalcanzable para la mayoría de las personas que viven en los países en desarrollo. Este primer número del "South Centre Training Materials" pretende, en su primera parte, ofrecer una introducción a cuestiones clave en el ámbito del acceso a los medicamentos y la propiedad intelectual. La segunda parte describe y define algunos términos y conceptos básicos de esta área relativamente nueva de las políticas farmacéuticas, que son los aspectos comerciales de los derechos de propiedad intelectual que regulan la investigación, el desarrollo y el suministro de medicamentos y las tecnologías sanitarias en general.*

*La propriété intellectuelle et les brevets en particulier sont devenus l'une des questions les plus débattues sur l'accès aux médicaments, depuis la création de l'Organisation mondiale du commerce (OMC) et l'entrée en vigueur de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC). Les brevets ne sont nullement les seuls obstacles à l'accès aux médicaments qui sauvent des vies, mais ils peuvent jouer un rôle important, voire déterminant. Pendant la durée de protection d'un brevet, la capacité du titulaire du brevet à déterminer les prix, en l'absence de concurrence, peut faire en sorte que le médicament soit inabordable pour la majorité des personnes vivant dans les pays en développement. Ce premier numéro du "South Centre Training Materials" vise, dans sa première partie, à fournir une introduction aux questions clés dans le domaine de l'accès aux médicaments et de la propriété intellectuelle. La deuxième partie décrit et définit certains termes et concepts de base de ce domaine relativement nouveau des politiques*

*pharmaceutiques, qui sont les aspects liés au commerce des droits de propriété intellectuelle qui régissent la recherche, le développement et la fourniture de médicaments et les technologies de la santé en général.*

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## INTRODUCTION

The “South Centre Training Materials” is a new series of documents designed to support South Centre training workshops and seminars in developing countries to improve access to medicines. Improving equity in access to medicines is an essential part of the realization of government responsibilities with regard to the right to health, a fundamental human right legally recognized by many governments.

The South Centre offers diverse trainings and workshops to developing countries aimed at improving access to medicines by introducing a public health perspective in the management of intellectual property rights in the pharmaceutical sector.

The South Centre aims to support developing countries governments to be better equipped to adapt their IPR regimes –policies, laws, regulations and practices–, to improve the availability and affordability of essential medicines.

These training materials will be used by the South Centre in its project "A public health approach to intellectual property rights" but they will be available to governments, agencies and institutions carrying out training of various kinds, to improve access to medicines as a fundamental component of universal health coverage.

Intellectual property and patents in particular, have become one of the most debated issues on access to medicines, since the creation of the World Trade Organization (WTO) and the coming into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Patents are by no means the only barriers to access to life-saving medicines, but they can play a significant or even determining role. During the term of patent protection, the patent holder’s ability to decide on prices, in the absence of competition, can result in the medicine being unaffordable to the majority of people living in developing countries.

This first issue of the “South Centre Training Materials” aims, in its first part, to provide an introduction to key issues in the field of access to medicines and intellectual property. The second part describes and defines some basic terms and concepts of this relatively new area of pharmaceutical policies, the trade related aspects of intellectual property rights that regulate the research, development and supply of medicines and health technologies in general.

## **1. THE WTO TRIPS AGREEMENT**

The World Trade Organization (WTO) is an international organization of (currently) 164<sup>1</sup> Member States dealing with the rules of trade and providing the institutional framework for the conduct of trade relations among its Members. On joining the WTO, Members adhere to several agreements, and of these the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) certainly has the greatest impact on the pharmaceutical sector.

The TRIPS Agreement establishes minimum standards for the protection and enforcement of a set of intellectual property rights that WTO Members are required to implement through national legislation. The TRIPS Agreement was adopted and came into force in 1995, but countries could benefit from different transition periods according to their economic development and the protection that they had granted to intellectual property until then. Prior to the TRIPS Agreement, patent issues were treated differently in each country and countries had different approaches to patent (and other types of intellectual property) protection in order to cater for their different needs.

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<sup>1</sup> Cfr. Members and Observers, [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm).

## 2. WHAT IS A PATENT?

A patent is a title granted by the public authorities conferring temporary monopoly for the exploitation of an invention. It provides the patent holder a negative right; that is, the right to prevent others from using, making, selling, importing or marketing the patented invention during the term of the patent, without the permission or consent of the patent holder.

### 2.1 There is no Global or International Patent

An important concept related to patent rights is **territoriality**. What this means is that the rights over a patented invention have a limited geographic coverage. In many cases, patents are granted by **national patent offices**, governed by the patent legislation in force in the country. The territorial reach of the patent right in such cases is national; i.e. the patent-holder of a patent granted by the patent office of Country A, will not have patent rights in Country B, unless a patent has also been similarly granted in Country B.

In some cases, there may be a **regional patent office**; in which case, a patent granted by the regional patent office may be recognized in the countries that are members of the regional patent agreement, subject to different conditions and procedures. For example, the European Patent Office may grant an EPO patent, which is recognized by all parties of the European Patent Convention. In this case, such a patent is regarded as a “bundle of nationally-enforceable” rights; that is to say, the rights accruing to the patent will have to be individually enforced in each member country.

In Africa, the African Intellectual Property Organization, which is better known as OAPI (derived from the acronym of its name in French: *Organisation Africaine de la Propriété Intellectuelle*) is a regional patent organization, that acts as the common patent authority for the 16 OAPI Member States (i.e., Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Cote d’Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo). The unique feature of the OAPI patent regime is that a patent granted by OAPI will automatically apply in each of the OAPI Member States. OAPI thus functions as the national patent office for all its Member States, receiving applications and granting patents. While an application may be filed with the relevant national administration in a Member State, OAPI is the body responsible for the granting of the patent. Once granted, the rights accruing to a patent are independent of national rights, defined under the provisions of the Bangui Agreement but also subject to the national legislation, if any, of the Member States. In contrast, the African Regional Intellectual Property Organization (ARIPO) permits filing of one patent application (designating the countries in which protection is sought) at the Industrial Patent Office of any contracting State or directly with ARIPO, but does not have automatic national effect in its Member States. The 16 Member States of ARIPO (Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe) may reject patents granted by ARIPO within six months of receipt of the notification, on the basis that they are contrary to national legislation or that they do not comply with the provisions of the Harare Protocol on patents, marks, models and designs.<sup>2</sup>

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<sup>2</sup> Shashikant, Sangeeta, “The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents:

## 2.2 The Patent Cooperation Treaty

The Patent Cooperation Treaty (PCT) adopted in 1970 is one of the treaties administered by the World Intellectual Property Organization (WIPO) with more than 150 Contracting States. PCT makes it possible to seek patent protection for an invention simultaneously in a large number of countries by filing a single “international” patent application instead of filing several separate national or regional patent applications. The granting of patents remains under the control of the national or regional patent Offices in what is called the “national phase”.<sup>3</sup>

After “international” patent application is filed in the patent office of a PCT member State or in the International Bureau of WIPO, a search and examination is then conducted on that application by a patent office of a PCT member State that is recognised as a PCT International Search and Examination Authority. The “international” patent application can be filed within a period of 12 months from the first filing of the corresponding patent application in any State that is party to the Paris Convention. The International Search Authority to which the application is transmitted then conducts a prior art search based on published documents and issues a written opinion and an international search report on whether the application meets generally the criteria of patentability based on the prior art search, without any assessment of the application against national legal standards on the thresholds of patentability criteria. The application and the written opinion and the search report are then published within a period of 18 months from the first filing of the application in any country. The applicant then has the option to request a supplementary search by another patent office recognised as an International Search Authority. The applicant also the option to request a supplementary international examination to analyse the patentability of the application, usually based on an amended version of the application. These requests can be made within a period of 22 months from the initial application. The International Preliminary Report on Patentability or the Supplementary International Search Report is issued within 22 months. Following this, the applicant can decide on whether to pursue national phase prosecution of the patent application and the request the same to the respective national offices within a period of 30 months from the initial application.

“The national patent offices are not bound by the international search and examination report, but may rely on it in course of their own search and examination. However, this also allows patent offices that produce the international search and examination report in their capacity as International Search Authority (ISA) to influence the national examination of that application in a developing country. Indeed, as explained by the WIPO Secretariat, one advantage of the PCT system is that “... the search and examination work of patent offices can be considerably reduced or virtually eliminated ....”<sup>4</sup>

The bilateral and regional free trade agreements promoted by the United States and the European Union (EU), typically introduce an obligation for developing countries to join PCT. According to Syam, “while a large number of developing countries have acceded to the PCT, the system is predominantly used by applicants from a few countries. Many developing countries that have joined the PCT system lack

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Implications for Access to Medicines”, Research Paper No. 56, South Centre, November 2014.

<sup>3</sup> WIPO, PCT FAQs, <https://www.wipo.int/pct/en/faqs/faqs.html>.

<sup>4</sup> Syam, Nirmalya, “Mainstreaming or Dilution? Intellectual Property and Development in WIPO”. Research Paper 95, South Centre, July 2019.

capacity in conducting substantive examination, though they have witnessed significant increase in the number of patent applications filed in their countries through the PCT route.”<sup>5</sup>

### **2.3 Validity of Patents**

The fact that a patent has been granted by a patent office does not mean that this is the final say on the matter. A granted patent can sometimes be partly or completely invalidated, for a number of reasons. For example, if on closer scrutiny, it is found that the patent does not meet one or more of the patentability criteria (as set out in the national patent law); it may be possible to challenge its validity.

Patent laws may also have provisions that exclude certain kinds of inventions: common examples are therapeutic or surgical methods. Patent laws may also exclude the patenting of inventions when their commercialisation is prohibited because the invention would be contrary to *ordre public* or morality. Patents granted in the excluded fields would also be invalid.

Even where a patent has been properly granted, the patent holder must maintain the patent by paying the required maintenance fees to the patent office. When the fees are not paid, the patent will lapse and therefore will no longer be valid.

### **2.4 Minimum Standards of Patent Protection**

The minimum standards that the TRIPS Agreement requires for the protection of patent rights include the following:

- All WTO Members have to provide patent protection for *inventions*, in all fields of technology. In the case of pharmaceuticals, WTO Members have to grant patents to any invention of pharmaceutical product or process.
- WTO Members shall apply the patentability criteria of novelty, inventive step (non-obviousness), and industrial application (utility). However, there is room for individual countries to determine the actual definition and application of these criteria.

The fact that the TRIPS Agreement does not define novelty, inventive step and industrial applicability leaves countries significant room for manoeuvre; therefore patentability requirements represent the principal and most important flexibility allowed by the Agreement to protect public health and access to medicines.<sup>6</sup> “Politicians and legislators have broad room for manoeuvre to give legal effect to those flexibilities.”<sup>7</sup>

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<sup>5</sup>Ibid.

<sup>6</sup> Velasquez, G. “Guidelines on Patentability and Access to Medicines.” Research Paper 61, p. 22, South Centre, March 2015.

<sup>7</sup> Arias Eduardo, PPT on Guidelines for the examination of Patentability of Chemical-Pharmaceutical Inventions, INPI, Argentina, 2014.

- The TRIPS Agreement also requires a minimum term of protection for patent rights of 20 years from the date of filing the application. Thus, WTO Members cannot now have a shorter duration of patent protection than the minimum required 20 years.

Even though the minimum duration required by the TRIPS Agreement is 20 years, a recent report from I-MAK, analyzes the twelve best-selling drugs in the United States and reveals that drug makers file a large number of patent applications to extend their monopolies far beyond the twenty years of protection intended under patent law. Some examples:<sup>8</sup>

PRODUCT	COMPANY	CONDITIONS TREATED	NO. PATENTS GRANTED	YEARS OF PROTECTION
Humira	ABBVIE	Arthritis	132	39
Rituxan	BIOGEN	Cancer	94	47
Revlimid	CELGENE	M. Myeloma	96	40
Enbrel	AMGEN	Arthritis	41	39
Herceptin	ROCHE	Cancer	108	48

Source: I.MAK “Overpatented, Overpriced, Nov. 2018

However, the TRIPS Agreement did not impose a uniform international law or uniform legal requirements. It contains provisions that allow for a degree of flexibility and some room for countries to accommodate their own patent and intellectual property systems according to their developmental needs. Thus, WTO Members are still able to determine how certain aspects of patent protection may be applied or implemented at the national level, in accordance with the social and economic welfare of the country.

**Article 7 of the TRIPS Agreement**, which spells out the **objectives** of the Agreement, provides that protection of intellectual property rights: “should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare”. In addition, WTO Members are allowed to “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development ...”, as stated in **Article 8**, which lays down the **principles** of the TRIPS Agreement.

These two provisions, together with the Preamble of the TRIPS Agreement, reflect the fundamental tenet that intellectual property rights protection should be regarded as a public policy tool; that is to say, the protection of such rights should be balanced against other public interests, in order to achieve public policy goals

## 2.5 Patents on Pharmaceutical Products

The conventional rationale for patent protection can be explained as follows: by conferring a temporary or time-limited monopoly, patents allow the inventor/producer to recover the costs of investment in research and development, and also to earn a profit in the production and sale of the invention. This is in return for making publicly available the knowledge about the

<sup>8</sup> I.MAK “Overpatented, Overpriced, Nov. 2018, <https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>.

invention, so that further research and development, and subsequent innovations, can be stimulated. Therefore, patent protection can be seen as a bargain struck by society with the patent holder, based on the premise that without patent protection there would be insufficient incentive for innovation. It is also based on the assumption that consumers would be better off in the long term because the short-term cost of having to pay higher prices will be offset by the creation of new inventions thanks to additional research and development.

However, questions arise as to whether these assumptions are always borne out in practice. In the area of public health and patents on pharmaceuticals, these questions have been particularly persistent.

In the case of pharmaceuticals, it is argued that patents are crucial for pharmaceutical innovation, and that without patent protection, there would be no financial incentive to fund the costs of discovery and development of new medicines. It is true that patent protection has provided an important incentive mechanism to drive research and development in the pharmaceutical industry. Yet it is also true that patented medicines are normally priced well above production costs so as to obtain significant profits after paying marketing costs that frequently surpass those of research and development.<sup>9</sup> In some developing countries, the high price of certain medicines means that patients in these countries will not have access to treatment.

Developing countries account for a very small fraction of the global pharmaceutical market (USA, EU and Japan accounted in 2018, for 89.3 per cent of world pharmaceutical sales)<sup>10</sup> and the generation of income to fund more research and development is not dependent on the profits derived from their markets. Indeed, the patent protection system has provided little incentive for research and development of new medicines needed for diseases afflicting developing countries.<sup>11</sup> This highlights some of the difficulties in relying solely on patent protection as the incentive system and on the private sector to develop essential medicines. The WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was tasked with analysing these issues, amongst others. In its Report, CIPIH stated that “because market demand for diagnostics, vaccines and medicines needed to address health problems mainly affecting developing countries is small and uncertain, the incentive effect of IPRs may be limited or non-existent”.<sup>12</sup> Thus, there is a need for other incentives and financial mechanisms to be put in place, which is what the WHO Global Strategy and plan of action (GSPOA) on Public Health, Innovation and Intellectual Property refers to in the WHA Resolution 61.21 (see Selected Bibliography).

Another concern relates to the subject matter and number of patents that are granted to provide protection for pharmaceutical products. While only a small number of new chemical entities are approved annually, a large number of patent applications for the protection of pharmaceutical products are submitted. For example, the number of new molecular entities

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<sup>9</sup> The Washington post, “Big pharmaceutical companies are spending far more on marketing than research”, 11 February 2015, <https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?noredirect=on>.

<sup>10</sup> EFPIA, “The pharmaceutical industry figures”, Key Data, 2018 [https://www.efpia.eu/media/361960/efpia-pharmafigures2018\\_v07-hq.pdf](https://www.efpia.eu/media/361960/efpia-pharmafigures2018_v07-hq.pdf).

<sup>11</sup> Pedric, B., Strub-wourgaft, N., Some C., Oloaro, P., Pecoul B., et al., “The drug vaccine landscape for neglected diseases (2000-11): a systematic assessment”, *The Lancet*, vol. 1, No. 6 (2003). DOI: [https://doi.org/10.1016/S2214-109X\(13\)70078-0](https://doi.org/10.1016/S2214-109X(13)70078-0).

<sup>12</sup> WHO, Commission on Intellectual Property Rights, Innovation, and Public Health. *Public Health, Innovation and Intellectual Property Rights*. Geneva: WHO, 2006.

(NMEs) approved by the US Food and Drug Administration has drastically declined since the mid-1990s (from 53 in 1996 to 22 in 2016).<sup>13</sup> Patent applications for pharmaceuticals are not filed merely on the newly-discovered chemical molecule or compound. Patents have increasingly been filed and often granted on variants of a pharmaceutical product, such as salts and other derivatives of the molecule and the specific formulation or dosage form of the medicine. Even so-called “incremental” modifications of existing products, including slight modifications or trivial features such as the form, colour and inert ingredients, have been claimed and obtained patent protection in some countries. Patents have also been granted on the combinations of a known medicine with other known medicines. The granting of these various patents means that a particular pharmaceutical product may be protected during many years even though the patent on the chemical molecule on which it is based has expired.

In these circumstances, the criteria applied to examine and grant pharmaceutical patents are extremely relevant for public health policies and not only a matter of concern for patent and industrial policy. Policy makers in the public health area, as well as patent examiners, should be aware that decisions relating to the granting of a patent can directly and unduly affect the health and lives of people.

## **2.6 Patents and Access to Essential Medicines**

The HIV/AIDS pandemic and the urgent need to make treatment available for the 14.6 million people in need of treatment (at the end of 2018)<sup>14</sup> continue to bring the question of the affordability of antiretroviral (ARV) medicines to the forefront of international attention.

When ARVs were first introduced, the cost of treatment per person was over US\$ 10,000 a year (about US\$ 30 a day). This cost put ARVs out of reach for the vast majority of HIV patients in developing countries, where more than 3 billion people live on less than US\$ 2 a day.<sup>15</sup> Introduction of competition has resulted in significant reductions in the prices of ARVs. Since then, there has been an increasing reliance on low-cost generic ARV therapy as a strategy for treating more patients; today the annual first line treatment per person is available at less than 100 US\$.

HIV/AIDS was one of the detonating factors of the controversy on patents and access to medicines. Affordability of treatment for other diseases affecting millions of people, such as hepatitis C, malaria, diabetes, cancer, tuberculosis or cardiovascular diseases is also now part of the debate.

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<sup>13</sup> In 2017/2018 the number increased due to the approval of 34 orphan drugs. Cfr. Nature Review Drug Discovery, 15 January 2019, “The FDA drug approvals” <https://www.nature.com/articles/d41573-019-00014-x>.

<sup>14</sup> UNAIDS DATA 2019 <https://www.unaids.org/en/resources/documents/2019/2019-UNAIDS-data>.

<sup>15</sup> DO Something.org “11 Facts About Global Poverty”, <https://www.dosomething.org/us/facts/11-facts-about-global-poverty>.

### **3. THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH**

Although the TRIPS Agreement has introduced a multilateral framework with minimum binding standards for the protection of intellectual property rights, there still exists flexibility within the provisions of the Agreement that permits countries to determine how intellectual property rules should be interpreted and applied, in order to make them more consistent with their national public interest and priorities. However, some governments have been unsure of how that flexibility would be interpreted and how far their rights to use it would be respected.

Although TRIPS affords some discretion about how its obligations are interpreted and implemented by national governments, developing countries have faced obstacles when they sought to use measures to promote access to affordable medicines. For example, when the South African Medicines and Related Substances Act was amended in 1997 to enable parallel importation, the provision was challenged by 39 pharmaceutical companies and the South African Pharmaceutical Manufacturers' Association (PMA) before the Supreme Court of South Africa. The pharmaceutical companies eventually withdrew their legal suit as a result of a strong reaction from international organizations (notably WHO) and civil society. In another case, the United States challenged the legality of the Brazilian legislation that authorises the grant of compulsory licences in cases where the patent holder has not "worked" their invention locally (i.e. to manufacture the patented product in the country). The US Government initiated a complaint under the WTO dispute settlement system against Brazil but later withdrew its complaint in 2001.

Other examples are referred to in the report of the United Nations Secretary-General's (UN SG) High-Level Panel on Access to Medicines such as Thailand's 2006 decision to import generic versions of the antiretroviral medicine efavirenz from India under compulsory licence.<sup>16</sup> This decision was met with hostility from the manufacturer, Merck, and the United States Government, which questioned the legality of the compulsory licence and pressed Thailand to rescind its decision. Thailand's subsequent decision to issue two further compulsory licences in 2007 for lopinavir/ritonavir and clopidogrel also resulted in retaliatory measures. Abbott withdrew from the Thai market all medicines awaiting registration in the country. The European Trade Commissioner wrote to the Thai government criticizing its use of compulsory licences as "detrimental" to medical innovation, noting that such approaches could lead to Thailand's isolation from the global biotechnology investment community and urging negotiations.<sup>17</sup>

In early 2016, the Ministry of Health of Colombia adopted resolution 2475, declaring that access to imatinib, a medicine that appears on the WHO Essential Medicines List, was of "public interest" for the treatment of leukaemia. The resolution was a legal step necessary for the subsequent issuance of a compulsory licence. Letters sent to the co-chair of the UN SG report on Access to Medicines chronicle attempts by various domestic and foreign parties to dissuade the Colombian government from issuing a compulsory licence as allowed by the TRIPS Agreement and the Doha Declaration.

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<sup>16</sup> Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies: Promoting Innovation and Access to Health Technologies, September 2016.

<sup>17</sup> *Ibid.*

Paragraph 4 of the Doha Declaration provides important guidance on the interpretation and implementation of the TRIPS Agreement, setting out the basic principle as follows:

**We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and 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. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions of the TRIPS Agreement, which provide flexibility for this purpose. (Emphasis added.)**

## 4. WHAT ARE THE TRIPS FLEXIBILITIES?

The resolution (WHA49.14) on “Revised Drug Strategy” requested the WHO Director-General to undertake a study on the impact of the WTO, and particularly the TRIPS agreement, on access to health. This study was entrusted to the WHO Drugs Action Programme -DAP- In November 1997, the DAP published the study “Globalization and Access to Drugs: Perspectives on the WTO TRIPS Agreement,”<sup>18</sup> commonly known in the WHO as the “red book” on the TRIPS Agreement.

The WHO “red book” speaks about “**margins of freedom.**”(1997).<sup>19</sup> Subsequently, in March 2001, the WHO adopted the term “**safeguards**” in a widely distributed document available in the six WHO official languages.<sup>20</sup> In June 2001, the European Commission talks about “**a sufficiently wide margin of discretion**” regarding the implementation of the TRIPS Agreement.<sup>21</sup> A few months later, in November 2001, the Doha Declaration on the TRIPS Agreement and Public Health refers to “**the provisions of the TRIPS Agreement that provide flexibility.**”<sup>22</sup> It is only in June 2002 that the WHO referred to TRIPS “**flexibilities**”, in a paper analyzing the implications of the Doha declaration, authored by Carlos Correa.<sup>23</sup>

The Doha Declaration confirmed that the TRIPS Agreement permits governments to consider and implement a range of options that take public health into account, when formulating intellectual property laws and policy, at national and regional levels. It specifically referred to several aspects of flexibility within the TRIPS Agreement, including the right to grant compulsory licences and to permit parallel importation. This means that countries cannot be prevented from taking certain measures that limit exclusive patent rights, where the interests of public health and the need to ensure access to affordable medicines so require.

The main public health-related flexibilities available under the TRIPS Agreement are briefly described below.

### 4.1 Criteria for Patentability

A patent is granted when the application satisfies the criteria for patentability, as laid down in the national (or regional) patent legislation. According to article 27 of the TRIPs Agreement all national legislations must require a patent application to satisfy the three-fold criteria of:

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<sup>18</sup> Velásquez, G. Boulet P., “Globalization and Access to Drugs: Perspectives on the WTO TRIPS Agreement”, WHO/DAP/98.9, Geneva, November 1997, p. 58.

<sup>19</sup> Velásquez, G. Boulet P., “Globalization and Access to Drugs: Perspectives on the WTO TRIPS Agreement”, WHO/DAP/98.9, Geneva, November 1997, p. 34. Emphasis added.

<sup>20</sup> WHO Policy Perspectives on Medicines, « Globalization, TRIPS and access to pharmaceuticals » No. 3 WHO, Geneva March 2001, p. 5. Emphasis added.

<sup>21</sup> European Commission’s submission on the 12th of June: “a sufficiently wide margin of discretion”, (IP/C/W/280), June 12th, 2001. Emphasis added.

<sup>22</sup> WTO “Doha declaration on the TRIPS Agreement and Public health, WT/MIN(01)/DEC/W/2, p. 1. Emphasis added.

<sup>23</sup> C. Correa « Implications of the Doha Declaration on the TRIPS Agreement and Public Health», WHO/EDM/PAR/2002.3, Geneva, 20012, see chapter titles “TRIPS flexibilities”, p. 13. Emphasis added.

- **novelty** – the invention must be new, in that it does not form part of the current state of the art in the particular technical field or technology; the state of the art comprises everything that prior to the application date has been available to the public, nationally or internationally, through its description, utilization or any other way.
- **inventive step (non-obviousness)** – the invention must not be evident for a “person skilled in the art” (a person trained and experienced in the particular field or technology) in the light of the current state of art; and
- **industrial applicability (utility)** – the invention must be capable of being manufactured or otherwise industrially used, since the aim of the patent law is to protect technical solutions to a given problem, not abstract knowledge.

The way in which the patentability criteria are applied has changed over time and across countries, depending on how governments have determined the appropriate balance of public and private interests. Although the WTO TRIPS Agreement sets out the patentability criteria, it does not provide specific directions or definitions for how these criteria should be interpreted or applied at national level. Hence WTO members retain the ability to define and apply the criteria, as it best suits the public interest. In this context the definition and interpretation of the three criteria for patentability are probably the most important flexibility contained in the TRIPS Agreement.<sup>24</sup>

## 4.2 Compulsory Licences

The patent holder is free to exploit the patent-protected invention or to authorize another person to exploit it. However, when reasons of public interest or the need to correct anticompetitive practices justify it, the government may allow a third party to use the invention, without the patent holder’s consent, under a compulsory licence. The patent holder is therefore forced to tolerate the exploitation of his invention by a third person or by the government itself. In these cases, the public interest in ensuring broader access to the patented invention is deemed more important than the private interest of the patent holder in fully exploiting his exclusive rights. Compulsory licences thus permit third parties to use an invention, without the patent holder's consent. For example, where particular medicines are patent protected and priced out of reach of the local population, local pharmaceutical companies may obtain compulsory licences to produce generic versions of patented medicines, or to import generic versions of medicines from foreign manufacturers. There have been 108 attempts to issue compulsory licensing for 40 pharmaceuticals in 27 countries since 1995.<sup>25</sup>

Compulsory licenses have been issued in developing as well as developed countries. For instance, in July 2017, the **German** Federal Court announced that it had affirmed the decision of the Federal Patent Court last year to issue a compulsory license for the HIV drug

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<sup>24</sup> See Correa C. “Guidelines for examination of pharmaceutical patents: Developing a public health perspective”, WHO, ICTSD, UNCTAD, Geneva 2007, Velásquez, G., “Guidelines on Patentability and Access to Medicines” South Centre, Research Paper 61, 2015.

<sup>25</sup> Kyung-Bok Son & Tae-Jin Lee “Compulsory licensing of pharmaceuticals reconsidered: Current situation and implications for access to medicines” *Journal Global Public Health An International Journal for Research, Policy and Practice* Volume 13, 2018 - Issue 10.

raltegravir (marketed as Isentress),<sup>26</sup> **Thailand** issued a compulsory licence for Efavirenz, an HIV/AIDS drug, and in January 2007 issued another two compulsory licences for a heart-disease medicine and for another HIV/AIDS medicine. In May 2007, **Brazil** also issued a compulsory licence for Efavirenz.

### 4.3 Government Use

Most patent laws allow the government (or authorized agents of the government) to use privately-owned patents for public, non-commercial purposes, without the consent of the patent holder. The right of the government to use a patent for public and non-commercial use is often framed in broad terms in national laws and very often the process is procedurally much simpler. In other words, it allows for the government use of patents to be “fast-tracked”, which is of importance when life-saving medicines are required urgently. There is only an obligation to inform the patent holder of the proposed use of the patent, or promptly after such use. Government use permits the public sector’s production or the importation of generics, for instance, for use in public hospitals. (see Box 1)

#### Box 1

##### Examples of government use

In October 2003, **Malaysia** allowed the import of generic didanosine, zidovudine and the lamivudine+zidovudine combination from India, to supply its public hospitals, under the government use provision in its Patent Law. In 2004, **Indonesia** authorized government use of patents to enable local production of nevirapine and lamivudine. In September 2017 Malaysia issued a “government use” licence for Sofosbuvir to treat hepatitis C. (2012)

### 4.4 Parallel Imports

Patented products that have been legitimately put on the market of the exporting country may be imported into a country without the consent of the patent holder under the principle of exhaustion of rights. This principle means that the rights-holder’s control over the pharmaceutical product ceases when the said product is placed in the market for the first time. Since some patented products are sold at different prices in different markets, the rationale for parallel importation is to enable the import of patented products from countries where they are sold at lower prices. For example, where the national law provides for it, there can be export of a patented medicine from Country A (where it is sold at a lower price) for sale in Country B, subject to the drug regulatory requirements of Country B. “Developing countries were keen to clarify in the Doha Declaration, the Members’ right to adopt an international principle of exhaustion of rights”.<sup>27</sup>

<sup>26</sup> Teschemacher R., “German Federal Court Of Justice Confirms The Compulsory License Granted By Way Of A Preliminary Injunction For The AIDS Drug Isentress” Pagenberg, Bardehle, January 2018, <http://www.mondaq.com/germany/x/667848/Patent/German+Federal+Court+of+Justice+confirms+the+compulsory+license+granted+by+way+of+a+preliminary+injunction+for+the+AIDS+drug+Isentress+the+EPO+Board+of+Appeal+then+revokes+the+European+patent>.

<sup>27</sup> Correa, Carlos M., “Public Health Perspective on Intellectual Property and Access to Medicines – A Compilation of Studies prepared for WHO”, p. 110 (Geneva, South Centre, 2016).

#### **4.5 Exceptions to Patent Rights**

All national patent laws have provisions relating to exceptions to the exclusive rights granted by a patent (not to be confused with the exceptions to patentability), although the scope and content of these provisions vary from country to country. Exceptions to the exclusive rights granted by patents are justified on the grounds that in certain circumstances limited exercise of the patent rights is required to achieve public policy purposes of encouraging innovation, promoting education and protecting other public interests. In the context of public health, exceptions to patent rights may be extremely important in facilitating the transfer and diffusion of technologies and in facilitating the production of generic medicines. National legislation may include different types of exceptions to patent rights; the most important among them being exceptions granted for research and the so called “early working” exception. The “early working” exception (also known as the “Bolar” exception) permits the production of samples of a patented medicine for the purposes of testing and approval before the end of the patent term, to enable speedy introduction of a generic product once a patent expires.

#### **4.6 Flexibility in Test Data Protection**

The TRIPS Agreement (Article 39.3) requires WTO Members to protect test data against unfair competition, which does not create exclusive rights. A correct interpretation and implementation of that provision avoids the burden of creating a “data exclusivity” problematic layer of protection in addition to patent rights on pharmaceuticals. In effect, WTO Members are not obligated under article 39.3 to confer exclusive rights on the originator marketing approval data.<sup>28</sup>

#### **4.7 Avoidance of TRIPS-plus Provisions and Policies, including Extension of Patent Term, Data Exclusivity, Second Use Patents, Border Measures**

TRIPS-plus provisions in free trade agreements (FTAs) (or resulting from accession to WTO) may negatively affect access to medicines. Negotiators of these agreements need timely and evidence-based information to avoid, as far as possible, provisions of this kind that may reduce the accessibility and affordability of medicines through the extension (beyond 20 years) of the term of a patent, exclusive rights in respect of the results of clinical trials (data exclusivity), overbroad border measures (e.g. covering medicines in transit) and other measures affecting market dynamics (See Section 6 below).

#### **4.8 Mitigating Implementation or Effects of TRIPS-plus Provisions**

If TRIPS-plus provisions have been accepted, however, there is a range of conditions and safeguards that may be introduced to limit the possible negative impact of such provisions, such as exceptions to data exclusivity (for instance, when a compulsory license has been granted) and limitations to the scope and length of patent term extensions.

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<sup>28</sup> Correa, Carlos M., “*Public Health Perspective on Intellectual Property and Access to Medicines – A Compilation of Studies prepared for WHO*”, p. 62 (Geneva, South Centre, 2016).

#### **4.9 Exemption for LDCs**

Least developed countries (LDCs) need not grant patents for pharmaceuticals at least until 2033.<sup>29</sup> In order to use this policy space, some LDCs that provide for the grant of such patents would need to review their legislation or to adopt other measures to protect the government and private parties from infringement claims. They should also preserve that policy space in negotiations of free trade and other international agreements.

#### **4.10 Pre and Post Patent Grant Opposition<sup>30</sup>**

Procedures before many patent offices, including the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO), provide for the possibility for third parties to contribute to the examination process through “observations” or “oppositions” whether before or after the grant of a patent, or both. The correct implementation of these procedures helps to improve the quality of patents granted and to avoid the creation of unjustified market barriers.

#### **4.11 Use of Competition Law to Address the Misuse of Patents**

Competition law may be applied to correct market distortions created through the abuse of intellectual property rights. There are national precedents that may provide useful examples of best practices.<sup>31</sup> Guidelines for the competent authorities on intellectual property and competition law may be developed to facilitate the intervention of such authorities when needed to address anti-competitive practices.

#### **4.12 Disclosure Requirement, Particularly for Biologics**

The full and precise disclosure of an invention is crucial for the patent system to perform its informational function. Deficient disclosure may unjustifiably extend the coverage of a patent and prevent legitimate acts by third parties. This is particularly relevant for biologicals, which cannot be described in the same way as medicines produced by chemical synthesis.

#### **4.13 Flexibilities in Enforcement of IP**

Measures to enforce IP – such as reversal of the burden of proof, determination of damages, border measures – if overly broad, may distort competition by discouraging or preventing market entry and the availability of generic medicines. However, there is room to design such measures in a manner that is fair and equitable to all parties engaged in administrative or judicial procedures regarding IP.

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<sup>29</sup> WTO “TRIPS Agreement: Transitional period for implementing the Agreement (Article 66.1)

<sup>30</sup> For 9.5 to 9.12 see SC WEB, Training and other tools offered by the South Centre on IP and Health”, <https://www.un.org/ldcportal/trips-agreement-transitional-period-for-implementing-the-agreement-article-66-1/> <https://ipaccessmeds.southcentre.int/wp-content/uploads/2018/12/Public-Health-Related-Flexibilities-in-the-TRIPS-Agreement.pdf>.

<sup>31</sup> UNDP “Using competition law to promote access to health technologies, N.Y. 2014, <https://hivlawcommission.org/wp-content/uploads/2017/06/UNDP-Using-Competition-Law-to-Promote-Access-to-Medicine-05-14-2014-1.pdf>.

## 5. THE PARAGRAPH 6 PROBLEM AND ITS SOLUTION

The so-called “Paragraph 6” mechanism of the Doha Declaration, as implemented by the WTO Decision of 30 August 2003, was a mandate of the WTO Ministerial Conference in Doha (2001) to solve, in an “ad hoc” manner, a problem that affected the poorest countries.

What was (is) the problem? In paragraph f) of article 31 of the TRIPS Agreement, it is stated that a compulsory license “shall be authorized predominantly to meet the supply of the domestic market”. This limits the volume of medicines that can be exported when their production has been enabled by a compulsory license. Such provisions affect mainly those countries that lack the manufacturing capacity to produce medicines, such as the least developed countries. This is the reason why Paragraph 6 of the Doha Declaration gives a mandate to find an “expeditious solution” to this problem.<sup>32</sup>

The WTO Members first agreed on a temporary solution with the General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003. On 6 December 2005, WTO Members agreed to convert the waiver into a permanent solution, which would take the form of an amendment to the TRIPS Agreement. The amendment only came into force on 23 January 2017, when two-thirds of the WTO Members ratified it, although the scheduled deadline to formally accept the amendment was originally fixed for 1 December 2007. The “solution” requested by the Doha Declaration took more than 10 years to be incorporated into the WTO rules.

The decision on Paragraph 6 contains a number of cumbersome conditions, to ensure that beneficiary countries can import generic medicines. In 15 years only one country, Rwanda has used it once, with an importation of antiretroviral medicines from Canada. The manager of the Canadian generic firm stated after the exportation that the system was so complicated that his firm had no intention of using it again.<sup>33</sup>

One of the recommendations of the UN Secretary-General’s High Level Panel on Access to Medicines state that “WTO Member States should review the decision in Paragraph 6 to find a solution that would allow for a quick and convenient export of pharmaceutical products produced under a compulsory license. WTO Member States should, as appropriate, adopt an exception and a permanent reform of the TRIPS Agreement”.<sup>34</sup>

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<sup>32</sup> Velasquez, G. “Intellectual Property, Public Health and Access to Medicines in International Organizations” Research Paper 78 p. 7, South Centre, July 2017.

<sup>33</sup> South Centre Policy Brief No. 7, “The Doha Declaration on TRIPS and Public Health: Ten years later – the state of implementation”, Nov. 2011.

<sup>34</sup> United Nations Secretary-General’s High Level Panel on Access to Medicines, p. 27, <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/147389003132/0/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>.

## **6. IMPACT OF "TRIPS-PLUS" AND "TRIPS EXTRA" PROVISIONS**

A number of bilateral and multilateral international trade and investment agreements require countries to adopt TRIPS-plus or TRIPS extra measures. Such provisions are known as "TRIPS-plus".

While TRIPS-plus and TRIPS extra provisions that have been enacted unilaterally (i.e. where a country has adopted TRIPS-plus or TRIPS extra provisions on its own) may be changed where they are deemed to be inconsistent with the national public health interest, TRIPS-plus obligations entered into under bilateral and other agreements are not as easily reversed without costs. In exchange for the promise of greater access to developed country markets, a number of developing countries have accepted such TRIPS-plus or TRIPS extra obligations. These provisions have raised questions regarding their potential to compromise the use of the TRIPS flexibilities for public health purposes and for promoting innovation with respect to diseases that disproportionately affect developing country populations. The proliferation of bilateral and regional free trade agreements has increased concerns about the impact of trade agreements on access to medicines.

The World Health Assembly, in 2004, passed a resolution urging Member States to “encourage that bilateral trade agreements take into account the flexibilities contained in the WTO TRIPS Agreement and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health”.<sup>35</sup> The need to take into account the Doha Declaration and the public health oriented flexibilities while subscribing trade agreements has been further reiterated by World Health Assembly resolutions. Similarly, the United Nations Secretary-General’s High-Level Panel on Access to Medicines (2016) recommended that: “Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health. As a first step, they must undertake public health impact assessments. These impact assessments should verify that the increased trade and economic benefits are not endangering or impeding the human rights and public health obligations of the nation and its people before entering into commitments. Such assessments should inform negotiations, be conducted transparently and made publicly available.”<sup>36</sup>

Some key examples of TRIPS-plus and TRIPS extra provisions are described below.

### **6.1 Extension of Patent Protection beyond the TRIPS Minimum**

The TRIPS Agreement requires a minimum patent term of 20 years from the date of filing. This patent term has been extended by provisions in certain bilateral trade agreements to compensate patent holders for any “unreasonable delays” in the granting of the patent or unreasonable curtailment of the patent term as a result of the marketing approval process. No such requirement exists under the TRIPS Agreement.

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<sup>35</sup> WHA Resolution 57.14 “Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS”, 2004.

<sup>36</sup> United Nations Secretary General High Level Panel on Access to Medicines, p. 28 <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>.

## **6.2 Restrictions on the Use of Compulsory Licences**

A few free trade agreements include provisions that restrict use of compulsory licences to cases of emergencies, public non-commercial use or to remedy anti-competitive practices. Such limitations are contrary to the broad discretion governments have in the granting of compulsory licences, as affirmed by the Doha Declaration.

## **6.3 Data Exclusivity**

Provisions in a number of bilateral agreements prohibit the use of test data submitted by originator companies for obtaining marketing approval of a product to facilitate the marketing approval of the generic versions of the originator product for a certain period. A number of bilateral trade agreements require a 5-year period during which such data exclusivity will prevent drug regulatory authorities from relying on submitted test data to approve generic entrants. Data exclusivity is not a requirement of the TRIPS Agreement and creates a potential barrier for generic entrants, even when there is no patent on the product. Data exclusivity may also prevent effective use of a compulsory license, in that it may not be possible to obtain marketing approval for a medicine produced or imported under compulsory licence. Furthermore, should generic manufacturers decide to produce such data, it would result in economic waste and in unethical repetition of tests for which the outcomes are already known.

## **6.4 Marketing Approval and Patent Term Linkage**

A number of bilateral trade agreements have included provisions that prevent national drug regulatory authorities from granting marketing approval for generic pharmaceutical products without “consent or acquiescence” of the patent holder, when there is a relevant??? patent in force???. This “linkage” between the patent protection and marketing approval may prevent approvals for generic products during the lifetime of a patent, whereas the TRIPS Agreement permits generic producers to seek regulatory approval during the life of a patent without conditions. Additionally, it obliges an already overloaded national drug authority to undertake a job beyond its field of expertise and competence. In addition, commonly there are many “secondary” patents in relation to a single drug, which may be unduly used to prevent generic competition, even when the patent on the active ingredient has expired.

## CONCLUSIONS

Notwithstanding the Doha Declaration and article 31bis of the TRIPS Agreement, there remain major challenges in the future scenario for access to medicines. Their success in securing effective access to medicines in developing countries – depends on how countries will implement intellectual property rules in order to optimize the TRIPS flexibilities in their national laws and whether or not the necessary policy decisions and measures will be taken. Major challenges for access to medicines in the context of intellectual property rights and trade agreements still exist.

Many developing countries have yet to incorporate the full range of the TRIPS flexibilities within their national laws. There may be several reasons for this delay. Firstly, there may be a need for specific legal expertise to craft and formulate patent laws and regulations that can take into account developing countries' needs and concerns. Secondly, governments may be subject to pressure from the industry or other governments not to incorporate such flexibilities.

## **GLOSSARY/TERMS AND CONCEPTS<sup>37</sup>**

### **Biologic**

Any medical product produced from living organisms or components of living organisms such as virus, therapeutic serum, toxin, antitoxin, hormone or protein, including monoclonal antibodies or similar products used to diagnose, prevent, treat or cure a disease or condition.

### **Biomedical**

The field of science, industry and research that applies the natural sciences, especially the biological and physiological sciences, to clinical medicine to better understand disease processes and develop therapies for the prevention and treatment of diseases and conditions that cause illness.

### **Biosimilar – Bioequivalent – Biogeneric**

A biologic product sufficiently similar in quality, safety and efficacy to an already licensed and market-approved biologic product that is shown to have no clinically meaningful differences from the original biologic product.

### **Biotechnology**

The use of biological processes, organisms or systems to manufacture treatments intended to improve the quality of human life. Biotechnology is an interdisciplinary science-based technology that combines knowledge from various fields, such as microbiology, biochemistry, genetics, process technology and chemical engineering.

### **Bolar exemption**

A legal exception that permits the use of a patented invention before the patent expires for the purposes of obtaining marketing approval of a generic product for commercialization once the patent expires.

### **Brand name**

A brand name is the name given to a drug by the manufacturer. The use of this name is reserved exclusively to its owner.

### **Clinical trial**

A research study in which candidate therapies are tested on human subjects to identify their clinical, pharmacological or other effects, adverse reactions and absorption, distribution, metabolism and excretion in the human body in order to ascertain their safety and efficacy. There are four phases of clinical trials: Phase I (a candidate therapy is given to a small group of people for the first time); Phase II (the candidate therapy is given to a larger group of people to further evaluate its safety and efficacy); Phase III (the candidate therapy is given to larger groups of people to confirm its efficacy, monitor side effects, compare it to commonly used treatments and collect safety information); and Phase IV (post-marketing studies gather

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<sup>37</sup> This Glossary/Terms and concepts is based on the Glossary/Terms and concepts of the following documents: WHO, “Globalisation and Access to drugs: Perspectives on the WTO TRIPS Agreement”, EDM series No. 7 (WHO/DAP/98.9) <http://www.who.int/medicines/areas/policy/who-dap-98-9rev.pdf> and the Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines, 2016, <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>.

information on the health technology's efficacy in various populations and side-effects associated with long-term use).

### **Compulsory licence**

This term is used when the judicial or administrative authority is allowed by law to grant a licence, without permission from the patent holder, on various grounds of general interest (absence of working, public health, economic development, and national defence).

### **Counterfeit goods**

Counterfeiting is a form of trademark infringing activity. Counterfeit goods are generally defined as goods involving wilful copying of trademarks on a commercial scale.

### **Data exclusivity**

A legal regime in which, for a specified period of time, national regulatory authorities are barred from the use of clinical studies and data developed by an originator company to register the generic equivalent of a medicine. Generic manufacturers seeking regulatory approval within a period of data exclusivity must conduct new clinical trials to prove the safety and efficacy of their equivalent products.

### **Delinkage**

A term used to describe a key characteristic of any financing model of innovation characterized by the uncoupling of R&D costs and consumer prices for health technologies. Examples of delinkage models include grants, prizes and advance market commitments, among others.

### **Dependent patent**

A patent that cannot be exploited without using another patent. When the use of compulsory licences is necessary, it is subject to certain conditions in the TRIPS Agreement:

- a) *“the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;*
- b) *the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and*
- c) *the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.”*

### **Doha Declaration on the TRIPS Agreement and Public Health**

The World Trade Organization (WTO) Declaration on the TRIPS Agreement and Public Health (2001), which affirmed, inter alia, that the TRIPS Agreement "can and 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"

### **Drug Regulatory Authority**

A Drug Regulatory Authority is designated by the State to ensure compliance with regulations applicable to drugs: issuing of marketing authorizations, authorizations of dispensaries, etc.

### **Essential drugs**

Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate

dosage form. The WHO Model List of Essential Medicines is intended to be flexible and adaptable to many different situations; exactly which drugs are regarded as essential remains a national responsibility. Revised every 2 years. Last revision contains 433 products.

### **Evergreening**

A term used to describe patenting or marketing strategies to extend the period of patent protection or effective period of market exclusivity, which are considered to be unjustifiable and therefore abusive. In some cases, for example, this might involve the filing of multiple, often successive, patent applications on minor and insignificant variants or indications of the same compound

### **Exhaustion of intellectual property rights (see parallel imports)**

This is a partial extinction of the right of the patentee (holder of the patent) consisting of the termination of certain of his prerogatives, due to exhaustion of rights. According to this theory, the patentee's right is exhausted when the product covered by it is put into circulation for the first time, if this has been done with the consent of that right holder. It follows that once the product has been put on the market, the patentee may no longer exercise control over the subsequent circulation of that product.

### **Falsified medical products<sup>38</sup>**

Medical products that deliberately/fraudulently misrepresent their identity, composition or source. Any consideration related to intellectual property rights does not fall within this definition.

### **GATS**

The General Agreement on Trade in Services constitutes one of the new domains of competence assigned to the WTO. It is compulsory for all Member States and is aimed at liberalizing trade in services. It is likely to have consequences in the field of public health in that it may provide for Member States to open their domestic market to foreign suppliers of hospital and medical services.

### **GATT/WTO**

The World Trade Organization is the institutional successor to the General Agreement on Tariffs and Trade (GATT). The latter was a very particular institution: the GATT was, in fact, simply a treaty signed in 1947 by 23 nations and not an organization such as the International Monetary Fund or the World Bank, which were established at the same time. The GATT was thus a multilateral instrument whose objective was to promote and regulate the liberalization of international trade through "rounds" of trade negotiations. In 45 years, there have been eight rounds of negotiation under the auspices of the GATT. The first rounds were only concerned with sectoral reductions of customs duties. In the Kennedy Round (1964-1967) and the Tokyo Round (1973-1979), the scope of the negotiations was enlarged to include global reduction of customs duties and non-tariff measures constituting a barrier to trade (dumping, subsidies and government procurement). The last round of negotiations opened in Uruguay in 1986 and ended with the signature of the Final Act in Marrakech in 1994, establishing the new WTO. This Organization has international legal status and henceforth all matters relating to international trade will fall within its jurisdiction. The WTO agreements consist of multilateral agreements that become binding upon Member States when they join the WTO, and plurilateral agreements that are optional.

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<sup>38</sup> Ibid.

## **GATT 1947/GATT 1994**

The General Agreement on Tariffs and Trade of 1994 is one of the WTO multilateral agreements. It consists of the original text of the GATT of 1947 as revised and modified during the various rounds of negotiations, including the concessions agreed during the Uruguay Round.

## **Generic drug**

A pharmaceutical product usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after the expiry of patent or other exclusivity rights. Generic drugs are marketed either under a non-proprietary or approved name rather than a proprietary or brand name.

## **Good manufacturing practice for pharmaceutical products**

Good manufacturing practice (GMP) is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization (product licence).

## **Intellectual property rights**

Intellectual property rights (IPRs) are exclusive rights, often temporary, granted by the State for the exploitation of intellectual creations. Intellectual property rights fall into two categories: the rights relating to industrial property (invention patents, industrial designs and models, trademarks, and geographical indications) and those relating to literary and artistic property (copyright). The Agreement on Trade-Related Aspects of Intellectual Property Rights covers the main categories of intellectual property law.

## **International non-proprietary name or generic name (INN)**

Common, generic names selected by designated experts to identify new pharmaceutical substances unambiguously. The selection process is based on a procedure and guiding principles adopted by WHA. They are recommended for worldwide use, destined to be unique and public property (non-proprietary).

## **Licence**

A contract whereby the holder of an industrial property right (patent, trademark, design or model) cedes to a third party, in whole or in part, the enjoyment of the right to its working, free of charge or in return for payment of fees or royalties.

## **Marketing authorization**

An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality.

## **Most-favoured-nation (MFN)**

Article 1 of the GATT of 1947 requires Member States to comply with a general obligation to apply most-favoured-nation treatment. According to this Article, "Any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country, shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties". In other words, it is prohibited to treat products differently on account of their origin. In order to avoid any discrimination, any advantage accorded to one country must also be accorded to all other Members of the GATT.

### **Multilateral/plurilateral agreements**

The new agreement instituting the WTO consists of multilateral trade agreements that are binding on all WTO Member States and plurilateral trade agreements whose acceptance by Members is optional.

The Multilateral Agreements include the multilateral agreements on trade in goods, the General Agreement on Trade in Services (GATS) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The agreements on trade in goods comprise the GATT of 1994, the Agreement on Agriculture, the Agreement on the Application of Sanitary and Phytosanitary Measures, the Agreement on Textiles and Clothing, the Agreement on Technical Barriers to Trade, the Agreement on Trade-Related Investment Measures (TRIMs), the Anti-dumping Agreement, the Agreement on Customs Valuation, the Agreement on Pre-shipment Inspection, the Agreement on Rules of Origin, the Agreement on Import Licensing Procedures, the Agreement on Subsidies and Countervailing Measures and the Agreement on Safeguards.

The plurilateral agreements are the Agreement on Trade in Civil Aircraft and the Agreement on Government Procurement.

### **Neglected diseases**

Diseases for which there is a lack of sufficient medical innovation, resulting in inadequate, ineffective or non-existent means to prevent, diagnose and treat them. The lack of sufficient medical innovation is often rooted in an absence of market incentives owing to the low purchasing power of the populations disproportionately affected by such conditions.

### **Originator**

A term that generally refers to the product that was first authorized worldwide for marketing (normally as a patented product). The term also refers to the company that commercialized the originator product.

### **Orphan disease**

A disease that affects only small numbers of individuals. The threshold number varies from country to country. An orphan disease may affect fewer than 200,000 individuals (United States), fewer than 50,000 (Japan) or less than 2,000 (Australia). Definitions vary from diseases affecting about 1 to 8 in 10,000 individuals.

### **Paragraph 6 decision**

An agreement reached by WTO Members on 30 August 2003 in response to paragraph 6 of the Doha Declaration. The paragraph 6 decision grants waivers of the TRIPS Agreement Article 31 (f) and (h) to permit the manufacture of pharmaceutical products under a compulsory licence within the territory of a WTO Member predominantly for export to another WTO Member that lacks the requisite domestic manufacturing capacity. With this solution, subject to a number of conditions, the predominant or total consignment of pharmaceutical products manufactured under compulsory licence may be exported to another country.

### **Parallel imports**

Products imported into a country without the authorization of the right holder in that country and have been legally put on the market in another country.

### **Parallel patent**

This term is used when an invention is covered by more than one national patent registered by the same person in different countries.

### **Patent**

A title granted by the public authorities conferring a temporary monopoly for the exploitation of an invention upon the person who reveals it, furnishes a sufficiently clear and full description of it, and claims this monopoly.

### **Patentability criteria**

Requirements that must be satisfied before a patent is awarded. These are (1) subject matter for eligibility, (2) novelty, (3) an inventive step (non-obviousness) and (4) industrial application (utility). The precise interpretation of these requirements is not defined in the TRIPS Agreement and it is up to countries to define these in their laws and policies.

### **“Pipeline” protection**

It is a kind of retroactive protection, to the effect that pharmaceuticals already patented in other countries but not yet patented in the "pipeline" country (because its legislation did not grant patents for pharmaceuticals), nor marketed in that country, may be claimed for protection as such as soon as the law regarding patentability of pharmaceuticals comes into force.

### **Piracy**

Pirated goods are goods that violate copyright and related rights. Publishers and producers of records, films and recorded tapes are often the victims of breaches of copyright. The computer software industry is particularly affected.

### **Research & Development**

The activity of devoting money and energy to researching a new technology in any field, and then developing the product or process obtained. In the pharmaceutical field, the costs of research and development are particularly high. The invention and development of a new drug requires considerable investment, hence the demand from the pharmaceutical industry for patents to be issued for all new inventions, with a view to recovery of the funds invested in research and development.

### **Reverse engineering**

A practice for discovering the manufacturing process of a product starting from the finished product. This practice has often been used to copy original drugs in countries that do not grant patents for pharmaceutical products.

### **Settlement of international trade disputes**

The dispute settlement mechanism allows countries to challenge the measures taken by their trading partners and obtain a ruling on the compatibility of these measures with the provisions of the WTO agreements. The "*Understanding on Rules and Procedures Governing the Settlement of Disputes*", that is part of the Agreement establishing the WTO, instituted the Dispute Settlement Body, which is competent to deal with any dispute arising in regard to any of the multilateral or plurilateral WTO agreements.

### **Substandard medical products<sup>39</sup>**

Also called “out of specification” these are authorized medical products that fail to meet either “their quality standards or their specifications, or both.

### **Tariff/non-tariff barriers to trade**

The tariff measures constituting a barrier to trade are customs duties, taxes imposed on goods entering a territory other than their territory of origin. The non-tariff measures constituting a barrier to trade are all the other regulatory or legislative measures that result in the distortion of competition in international trade. These include: commercial dumping, technical barriers to trade, government procurement, subsidies or customs valuations.

### **Technical barriers to trade**

The Agreement on Technical Barriers to Trade is one of the multilateral agreements on trade in goods and therefore binding on all Members. It expands and spells out the TBT Agreement concluded at the Tokyo Round. It aims to ensure that technical regulations and standards, and testing and certification procedures, do not create unnecessary barriers to trade. Nevertheless, it recognizes that a country has the right to take measures, for example, to protect the health and life of humans and animals and for the preservation of plant life or protection of the environment, at the levels it deems appropriate, and that nothing can prevent it from taking the necessary measures to ensure respect for these levels of protection. Countries are thus encouraged to have recourse to international standards where they are appropriate, and in particular to the WHO standards of quality applicable to pharmaceutical, biological and food products; but they are not required to modify their levels of protection following standardization.

### **Term of protection**

This is the duration of the lifetime of a patent, in other words, the time during which the title holder of the invention may enjoy a monopoly for its exploitation. The TRIPS Agreement imposes a minimum term of 20 years for all product and process patents, measured from the date on which the patent application was filed.

### **Test data protection**

A legal obligation imposed by the TRIPS Agreement on WTO Members to protect undisclosed test data from unfair commercial use. Such data is required to be submitted as a condition of approving the marketing of a pharmaceutical or agricultural chemical product. (Contrast to data exclusivity above).

### **Trademark (Article 15 of the TRIPS Agreement)**

*Any sign or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark. Such signs, in particular words including personal names, letters, numerals, figurative elements and combination of colours as well as any combination of such signs, shall be eligible for registration as trademarks. Where signs are not inherently capable of distinguishing the relevant goods or services, Members may make registrability depend on distinctiveness acquired through use. Members may require, as a condition of registration, that signs be visually perceptible.*

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<sup>39</sup> WHO MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT (SSFFC) MEDICAL PRODUCTS, WORKING DEFINITIONS, [https://www.who.int/medicines/regulation/ssffc/A70\\_23-en1.pdf?ua=1](https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1).

### **Transition period**

In the TRIPS Agreement, certain countries are granted periods of transition, adapted to their levels of development, constituting waivers to the time limits normally stipulated for compliance with the Agreement. Whereas all WTO Members are entitled to a one-year transition period, developing countries and, subject to certain conditions, the former Socialist Republics are granted four extra years to bring their legislation into conformity with the Agreement. Likewise, the least-developed countries are accorded an extra ten years to start applying the provisions of the Agreement, with a possibility of extension. Extension until 2033 was approved in 2017.

### **TRIMs**

The Agreement on Trade-Related Investment Measures recognizes that certain measures may have the effect of restricting or distorting trade. It provides that no Contracting Party may apply trade-related investment measures (TRIMs) that are not compatible with Article III (national treatment) and Article XI (general elimination of quantitative restrictions) of the General Agreement. To this end, an indicative list of TRIMs agreed to be incompatible with these Articles is annexed to the Agreement. This list includes measures requiring an enterprise to buy a certain volume or a certain value of locally produced goods (provisions relating to the content of elements of local origin) or which limit the volume or value of the imports this enterprise may purchase or use to an amount linked with the volume or value of the local products it exports (prescriptions relating to the balance of trade). The Agreement provides for compulsory notification of all TRIMs that do not comply and their elimination within two years for developed countries, five years for developing countries and seven years for the least-developed countries.

### **TRIPS**

The Agreement on Trade-Related Aspects of Intellectual Property Rights covers a new field in multilateral international trade law. It was proposed that this subject should be included in the multilateral trade negotiations of the Uruguay Round in an attempt to remedy problems of international piracy and infringement of intellectual property rights. The Agreement establishes minimum standards of protection for each category of rights. These standards should be integrated into the national legislation of all WTO Members, and should be applied in accordance with the principles of most-favoured-nation treatment and national treatment. They subsume and extend to all WTO Members the substantive obligations of the main treaties administered by WIPO, i.e. the Bern Convention for the Protection of Copyright and the Paris Convention for the Protection of Intellectual Property, with the addition of other obligations when necessary to complement the scope of these Conventions. The TRIPS Agreement, as an entity in the block of multilateral agreements, binds the obtaining and maintenance of customs benefits in the framework of WTO to respect for intellectual property rights by the State in question. It is the agreement in the Final Act of the Uruguay Round that could have the most implications for the production of and access to drugs, particularly in developing countries.

### **TRIPS flexibilities**

A term used broadly to describe a set of norms, rules and standards that allow variations in the implementation of the TRIPS Agreement obligations, including limits on the exercise of intellectual property rights.

### **Unfair competition**

This is defined in the TRIPS Agreement as any act of competition contrary to honest trade

practices, leaving it to the authorities in each country to define the concept of commercial honesty. More generally, it is defined as wrongful actions committed in professional practice, of a nature such as to incur the civil liability of those committing them. Such actions would be likely to attract clients or turn them away from a competitor in a wrongful manner.

### **Unregistered/unlicensed medical products<sup>40</sup>**

Medical products that have not undergone evaluation and/or approval by the national and/or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation. These medical products may or may not have obtained the relevant authorization from the national/regional regulatory authority of its geographical origin.

### **Uruguay Round**

“Rounds” of negotiation were instituted when GATT was established. The GATT agreement itself results from the first round of negotiations, since the objective in 1947 was to get States to negotiate in the domain of international trade with a view to granting mutual trade concessions. When the GATT became institutionalized, it was decided to keep the idea of rounds of multilateral trade negotiations (MTN). Thus there have been in succession the Geneva, Annecy and Torquay Rounds, followed by the better known Dillon Round, Kennedy Round, Tokyo Round and Uruguay Round. It was the round that lasted longest (1986-1994) and also the most ambitious, being the origin of the establishment of the WTO and a string of multilateral agreements.

### **Voluntary licence**

A licence granted by a patent holder to a third party to produce and/or market and distribute a patented product, usually in exchange for a royalty on net sales and certain other conditions (for example, geographical restrictions on where the product can be sold).

### **WHO Certification Scheme**

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce guarantees, through the issue of a WHO certificate, the quality of pharmaceutical products entering international commerce. It is a simple administrative procedure that enables importing countries to obtain information on whether a product has been authorized to be placed on the market in the exporting country, and assurance that the manufacturer has been found to comply with WHO standards of good manufacturing practice. This system is particularly useful for countries with limited capacity for quality control of drugs.

### **WHO Essential Medicines List**

The World Health Organization (WHO) Essential Medicines List (EML) contains therapeutic medicines that satisfy the priority healthcare needs of the global population. Medicines are deemed “essential” by WHO following an evaluation of disease prevalence, public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness. The WHO EML is often used as a guide in the development of national essential medicines lists.

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<sup>40</sup> Ibid.

## **WIPO**

The World Intellectual Property Organization was set up in 1970 to manage the protection and regulation of intellectual property rights. It replaced the Union for the Protection of Intellectual Property, an association of States with permanent independent bodies established by the Paris and Bern Conventions. In 1996, WIPO had 140 Member States and was administering 18 international conventions, the most important of which are the Paris Convention on intellectual property (1883 – 114 Members), the Bern Convention on copyright (1886 – 102 Members), the Madrid Agreement on the international registration of marks (1891 – 37 Members), the Patent Cooperation Treaty (1970 – 68 Members), the Budapest Treaty on the international recognition of the deposit of micro-organisms (1977 – 26 Members) and the International Union for the Protection of New Plant Varieties (UPOV 1961 – 24 Members). Since the existing conventions in the field of intellectual property do not provide for any system of sanctions for non-compliance, it was proposed in the WTO negotiations to introduce the obligation to ensure minimal protection of intellectual property rights, and to make compliance a condition for the granting of customs concessions. The TRIPS Agreement will coexist with the earlier conventions administered by WIPO, without replacing them.

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