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Research Paper 61
March 2015

GUIDELINES ON PATENTABILITY AND ACCESS TO MEDICINES

Germán Velásquez

RESEARCH PAPERS

61

GUIDELINES ON PATENTABILITY AND ACCESS TO MEDICINES

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SOUTH CENTRE

MARCH 2015

[1] Special Adviser for Health and Development, South Centre, Geneva. I am grateful to Carlos Correa and Viviana Muñoz Tellez for their comments and suggestions.

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INTRODUCTION

Until recently, the link between the examination of patents carried out by national patent offices and the right of citizens to access to medicines was not at all clear. They were two functions or responsibilities of the State that apparently had nothing to do with each other. Examining the growing literature on intellectual property and access to medicines, it seems that the analysis of one actor has been left out: the patent offices. And the reason is clear: patent offices are administrative institutions. Patentability requirements are not defined by patent offices, but frequently by the courts, tribunals, legislation or treaty negotiators.[2] There is now greater understanding that the examination of patents and the role played by patent examiners are key elements that could contribute to or obstruct access to medicines. Given the impact of pharmaceutical patents on access to medicines, patent offices should draw up public policies and strategies that respond to national health and medicine policies.

In 1994, the creation of the World Trade Organization (WTO) resulted in the establishment of a new treaty, the broadest on intellectual property rights: the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). This Agreement links issues of intellectual property and trade for the first time and provides a multilateral mechanism to resolve disputes between States. The TRIPS Agreement requires all WTO Member States to incorporate into their legislation universal minimum standards for almost all rights in this domain: copyright, patents and trademarks.[3] In addition, the Agreement has considerably limited the freedom previously enjoyed by countries to develop and apply their own intellectual property systems.[4] Such an obligation did not exist within the framework of previous international agreements. In the past, it was considered that each nation had the right to legislate in this respect. International agreements prior to the TRIPS Agreement did not specify minimum standards on intellectual property. Before the TRIPS Agreement, over 50 countries did not provide patent protection for pharmaceutical products; many provided patent protection for the processes but not the products and in a large number of countries, the duration was less than 20 years.[5]

A patent is "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."[6] Monopolies generally lead to high prices that, in many cases, restrict access. The structure, patent – monopoly – high price – restricted access, does not present a problem when related to a patent for simple merchandise, such as a perfume or musical equipment. The problem arises when monopolies are granted for public goods or essential products used to prevent illness, improve health or prevent death.

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[2] Cf. Drahos, Peter "Trust me: Patent offices in developing countries", Centre for governance of knowledge and development, working paper, November 2007.

[3] See Velásquez Boulet, Bulletin of WHO 1999, vol. 77, no. 3 "Essential drugs in the new international environment".

[4] See Correa C, Bulletin of WHO 2001, vol. 79, no. 5 "Health and Intellectual Property rights".

[5] See Correa C. "Guidelines for the examination of pharmaceutical patents: Developing a public health perspective" WHO-ICTSD-UNCTAD, January 2007.

[6] Velasquez, G. and Boulet P. Globalization and Access to Drugs. Perspectives on the WTO/TRIPS Agreement, WHO/DAP/98.9, Geneva 1998.

According to the TRIPS Agreement, the patentability requirements used by national intellectual property offices require a product or manufacturing process to meet the conditions necessary to grant patent protection, namely: novelty, inventive step and industrial applicability (utility). These three elements, however, are not defined in the TRIPS Agreement and WTO Member States are free to define these three criteria in a manner consistent with the public health objectives defined by each country.

According to the report of the United Nations High Commissioner for Human Rights "The requirements under the TRIPS Agreement for the grant of patents – novelty, inventive step and industrial applicability – are open to interpretation under national legislation and each country can decide according to local conditions. Consequently, the High Commissioner encourages interpretations of these requirements that do not lose sight of the public interest in the wide dissemination of knowledge…"[7]

The world has never had at its disposal such a wide arsenal of treatments to fight the diseases that afflict humanity. At the same time, many people die owing to a lack of certain medicines and/or vaccines. This applies to illnesses such as AIDS, malaria, tuberculosis, cancer, diabetes, hepatitis C, bacterial meningitis and pneumonia, among many others.

The growing concerns about the way international trade agreements, and particularly the TRIPS Agreement, could limit access to medicines led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health in 2001 (Doha Declaration). The Doha Declaration marked an important milestone in the discussions on intellectual property rights and access to medicines by affirming that the TRIPS Agreement should be interpreted and applied in a way that supports the right of WTO Member States to protect public health and, in particular, promote access to medicines for all. In this respect, the Doha Declaration contains the principles that the World Health Organization (WHO) has defended and promoted since the end of the 1990s, namely the reaffirmation of the rights of Members of WTO to fully apply the safeguarding provisions contained in the TRIPS Agreement in order to protect public health and promote access to medicines.

It is generally believed that patents are normally granted to protect new medications, but the number of patents obtained annually to protect truly new pharmaceutical products is very small and is decreasing. Each year, thousands of patents are granted for pharmaceutical products, however only a few are for new molecular entities (NMEs)

In a well-known and quoted article from 2002, P. Trouiller et al. found that of all of the pharmaceutical products developed in the world between 1975 and 1999, only 1.1 per cent were for neglected diseases, which should really be called ignored diseases. The same study was repeated recently[8] and the results were not significantly better. Of the 850 products brought to market around the world between 2000 and 2011, only 4 per cent (exactly 37) were related to neglected diseases, which mainly exist in developing countries and include malaria, tuberculosis, Chagas' disease, leishmaniasis and diarrhoeal diseases.

[7] The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights: Report of the High Commissioner, E/CN.4/Sub.2/2001/13, 27 June 2001, para 62.

[8] Dr Belen Pedrique, Nathalie Strub-Wourgaft, Claudette Some, Piero Olliaro, Patrice Trouiller, Nathan Ford, Bernard Pécoul, Jean-Hervé Bradol, "The drug and vaccine landscape for neglected diseases (2000-11): a systematic assessment", Lancet, 24 October 2013.

The cumulative nature of innovations owing to low patentability standards and weaknesses in the patent granting procedure has significant repercussions on patent systems, limiting the diffusion of the innovations that the system seeks to promote and hindering access to vital medicines. "Patents on broad scientific principles are generally bad, because in the words of the United States Supreme Court, they may confer power to block off whole areas of scientific development, without compensating benefit to the public"[9]

All of the above led WHO, in collaboration with the United Nations Conference on Trade and Development (UNCTAD), the United Nations Development Programme (UNDP) and the International Centre for Trade and Sustainable Development (ICTSD), to develop, in 2007, guidelines for the examination of pharmaceutical patents from a public health perspective.

These guidelines or directives were intended to contribute to improving the transparency and efficacy of the patent system for pharmaceutical products, so that countries could pay more attention to patent examination and granting procedures in order to avoid the negative effects of non-inventive developments on access to medicines.[10]

The exercise to draft guidelines for patent examination sought a way to manage the pharmaceutical product patent system and, more specifically, the "strengthened patent system" arising from the TRIPS Agreement and current regional and bilateral trade and investment agreements. Patents are a social contract between the patent holder and society; therefore it is necessary to explore, identify and implement mechanisms to improve the functioning and transparency of the patent system in the interest of public health.

In order to develop a legal and normative framework to grant pharmaceutical products patent protection that ensures a balance between the producers and the users of technological knowledge (as required by Article 7 of the TRIPS Agreement), several issues need to be carefully examined at the national level so as to ensure access to medicines. In this context, the guidelines for the examination of patents are a contribution to tackle this significant challenge.

Three key questions that this document could address: 1) how to relate intellectual property and public health and what are the implications, particularly in terms of access to medicines; 2) how much room for manoeuvre and flexibility is permitted by new international trade rules, particularly the TRIPS Agreement; 3) third and central point of this reflection, what is the role of and, above all, the contribution that national patent offices could make to improving access to medicines, through guidelines for the examination of patents.

[9] John H. Barton, Bulletin of WHO, October 2004, vol. 82 number 10.
[10] C. Correa Op. cit.

1. INTELLECTUAL PROPERTY, WHO AND MEDICINES

1.1 The Mandate of the WHO

The issue of intellectual property first arose at the WHO in 1996 and practically coincided with the end of the Uruguay Round and the creation of the WTO. In 1995, the Charles III University of Madrid, together with the WHO Essential Medicines Programme, organized a conference at which Professor Carlos Correa[11] presented a piece of work entitled "The Uruguay Round and Drugs".[12] The 40-odd page article analyses the possible implications of the TRIPS Agreement for access to medicines and describes the "room for manoeuvre" provided in the Agreement to protect public health. The article is the first document that specifically alerts the health sector to the possible implications of the TRIPS Agreement for public health and, more specifically, for access to medicines.

Even during the negotiations of the Uruguay Round (1986-1994) several negotiators from developing countries saw that the TRIPS Agreement would have significant implications for the pharmaceutical and health sectors. Shortly after its adoption, UNCTAD published a study on the TRIPS Agreement and developing countries.[13]

At the World Health Assembly (WHA) in 1996, a resolution was adopted on medicines,[14] which was the first mandate given by Member States to the WHO Secretariat to work on the issue of intellectual property with regard to health (Resolution WHA 49.14).

The request made to the Director-General of WHO through resolution WHA 49.14 of 1996 to produce a study on the implications of the TRIPS Agreement was entrusted to the Action Programme on Essential Drugs, which would publish in November 1997 a document entitled "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement".[15]

The executive summary of the document clearly states its objective: "The aim of this document is to inform people in the health sector with no particular legal background about the impact of globalization on access to drugs, and especially about the TRIPS Agreement that may have repercussions in the pharmaceutical field." Further on, the document affirms that "The TRIPS standards derive from those of industrialized countries and are not necessarily appropriate for all countries' level of development. Public health concerns should therefore be considered when implementing the Agreement."[16]

This publication on globalization and access to drugs "anticipated what the Doha Declaration would eventually recognize: the right of the WTO Members to exploit as far as possible the flexibilities incorporated into the Agreement in order to protect public health".[17]

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[11] Negotiator of the TRIPS Agreement during the Uruguay Round, as Secretary of Industry of the Government of Argentina.
[12] Correa C., "The Uruguay Round and drugs" WHO/TFHE/97.1 Distr: General, Original: English, 1997, 40 pg.
[13] United Nations Conference on Trade and Development (UNCTAD), The TRIPS Agreement and Developing Countries U.N. Pub. 96.II.D.10 (1996) (prepared for the UNCTAD secretariat by Carlos Correa, Keith Maskus, J. H. Reichman, and Hanns Ullrich).
[14] WHA 49.14 "Revised drug strategy", WHO, Geneva 1996.
[15] Velásquez, G. Boulet P., "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement", WHO/DAP/98.9, Geneva, 1998, 58 pg.
[16] Ibid p. 3 and 4.
[17] Op. cit. p. 44.

In the aforementioned UNCTAD document[18] C. Correa et al. refer to the **"room for manoeuvre"** in the TRIPS Agreement for the formulation of national public policies. According to one opinion, the expression "room for manoeuvre" was too harsh for the diplomatic environment of the United Nations and for this reason, WHO talked of **"margins of freedom"**[19] (1997). Subsequently, in March 2001, WHO adopted the term **"safeguards"** in a document widely distributed in the six official languages of WHO. [20]

In June 2001, the European Commission mentioned "a sufficiently wide margin of discretion"[21], referring to the implementation of the TRIPS Agreement. Some months later, in November 2001, the WTO Doha Declaration on the TRIPS Agreement and Public Health refers to "the provisions of the TRIPS Agreement, which provide flexibility."[22] It was only in June 2002 that WHO, in a document analysing the implications of the Doha Declaration, authored by Carlos Correa, referred to the "flexibilities" of the Agreement.[23]

Currently, there is broad consensus on the use of the term "flexibilities" to refer to the mechanisms and provisions of the TRIPS Agreement aimed at protecting public health. Flexibilities that are not, as some people try to suggest, exceptions for developing countries, but rather a right obtained through the negotiations that led to the adoption of the TRIPS Agreement.

Since 1999, in successive resolutions of the World Health Assembly, WHO has been requested to ensure that its pharmaceutical strategy addressed the important question of the effects of international trade agreements on public health and access to medicines. The World Health Assembly requested WHO to cooperate with Member States and international organizations to monitor and analyse the pharmaceutical and health consequences of international trade agreements, in order to help Member States to assess and develop policies and measures on health and pharmaceutical regulation that maximize the positive effects of these agreements and mitigate the negative effects. Overall, these resolutions have provided WHO with a mandate that can be broadly summarized as follows: 1) analyse and monitor the effects on public health caused by globalization, intellectual property rights and trade agreements and report on the issue; 2) assist Member States in the strengthening of their pharmaceutical practices and policies; and 3) provide support and technical assistance to Member States to fully apply the safeguards and flexibilities related to public health provided in the TRIPS Agreement.

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[18] United Nations Conference on Trade and Development (UNCTAD), The TRIPS Agreement and Developing Countries U.N. Pub. 96.II.D.10 (1996) (prepared for the UNCTAD secretariat by Carlos Correa, Keith Maskus, J. H. Reichman and Hanns Ullrich).

[19] Velásquez, G. Boulet P., "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement", WHO/DAP/98.9, Geneva, 1998, p. 34.

[20] WHO Policy Perspectives on Medicines, "Globalization, TRIPS and access to pharmaceuticals" No. 3 WHO, Geneva March 2001, p. 5.

[21] Submission 0f 12 June of the European Commission: "a sufficiently wide margin of discretion", (IP/C/W/280), 12 June 2001.

[22] WTO "Doha declaration on the TRIPS Agreement and Public health, WT/MIN(01)/DEC/W/2, p. 1.

[23] C. Correa "Implications of the Doha Declaration on the TRIPS Agreement and Public Health", WHO/EDM/PAR/2002.3, Geneva, 2012, see chapter entitled TRIPS Flexibilities, p. 13.

1.2 Commission on Intellectual Property Rights, Innovation and Public Health

In 2003 via a World Health Assembly resolution,[24] the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was established. WHO Member States requested the WHO Secretariat to produce a report by independent experts on the subject of intellectual property, innovation and public health, an exercise that would continue and go into further detail on aspects already addressed in the report of the British Commission on Intellectual Property Rights[25] in 2002 on the same issue.

In 2006, the report of the CIPIH on "Public Health, innovation and intellectual property rights" stated that "The TRIPS Agreement allows countries a considerable degree of freedom in how they implement their patent laws, (…) Thus developing countries may determine in their own ways the definition of an invention, patentability requirements, the rights conferred on patent owners and what exceptions to patentability are permitted (…)".[26]

The report of the CIPIH also suggests that the problem of access to medicines is not limited to developing countries. "This issue is important because even in developed countries, the rapidly rising costs of health care, including supplies of medicines, are a matter of intense public concern. In developing countries, and even in some developed countries, the cost of medicines, often not available through public health- care systems, can be a matter of life and death."[27]

The CIPIH report contains 60 recommendations. The majority refer to issues related to intellectual property, which were taken up by the Global strategy and plan of action on public health, innovation and intellectual property, resolution WHA 61.21 approved in 2009. It is in the context of the CIPIH recommendations and the mandate given by the World Health Assembly since 1999 that WHO drafted the "guidelines for examination of pharmaceutical patents", which are referred to specifically in chapter III of this document.

In the WHO guidelines, several mechanisms that could be adopted are suggested in order to incorporate a public health perspective into the procedures for granting patents for pharmaceutical products. The guidelines also propose a series of general measures to assess some of the common methods of granting pharmaceutical patents and suggest elements for the drafting of guidelines that take into account public health in the assessment and examination of patents for pharmaceutical products at the national level in developing countries.

In little more than 10 years, WHO has produced significant material in the area of public health and intellectual property, whether in the 17 resolutions[28] of the World Health Assembly, or in the numerous publications[29] providing analysis and guidance with the aim of protecting access to health in light of new international trade regulations required within the framework of WTO, and recently the free trade agreements (FTAs) and bilateral investment treaties (BITs) that contain more demanding clauses and conditions than the standards set by the TRIPS Agreement. The publication on "guidelines for the examination of pharmaceutical

[24] WHA Resolution, WHA56.26 Intellectual Property Rights, Innovation and Public Health.
[25] "Integrating intellectual property rights and development policy" Report of the Commission on Intellectual Property Rights, London, September 2002.
[26] WHO, "Public Health, innovation and intellectual property" Geneva 2006, Op. cit. p. 21.
[27] Ibid. p. 177.
[28] See list in Annex I.
[29] See list in Annex II.

patents" is perhaps the most important guidance documents drafted by WHO to fulfil the mandate set by various resolutions of the World Health Assembly and the Doha Declaration to provide a public health perspective to the use of the patent system in the pharmaceutical sector.

1.3 Strategy on Intellectual Property and Public Health

During the WHO World Health Assembly in May 2008, the "Global Strategy and Plan of action on Public Health, Innovation and Intellectual Property" (hereafter, the Global Strategy) was approved. The Strategy was drafted by the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG). The Global Strategy gives WHO the mandate to "Provide (…), in collaboration with other competent international organizations, technical support (…) to countries that intend to make use of the provisions of the TRIPS Agreement, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health (…)."[30]

Resolution WHA 61.21 on the Global Strategy recognized that intellectual property incentives did not respond to the needs of the majority of people living in developing countries. The Global Strategy declared that it is necessary: "to encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights and other WTO instruments related to that agreement and meets the specific research and development needs of developing countries."[31]

The focus of a strategy on intellectual property for health, and for medicines in particular, should be centred on access to essential medicines and technologies for all persons that need them.

The principles on which the strategy should be based upon are as follows:

- The right to health protection is a universal and inalienable right and it is the duty of governments to ensure ways to fulfil that right.
- The right to health takes precedence over commercial interests.
- The right to health means equitable access to medicines.
- The promotion of innovation and technology transfer is the right of all States and should not be restricted by intellectual property rights.
- Intellectual property rights should not become an obstacle to access to medicines or to the formulation of policies to ensure and protect public health. Intellectual property rights should guarantee economic and social well-being in a balanced manner.
- Countries have the right to apply all of the flexibilities contained in the TRIPS Agreement, which were reaffirmed in the Doha Declaration and other international resolutions in order to safeguard access to technology and medicines.

[30] WHO resolution 61.21 paragraph 5.2 p. 17.
[31] WHA 61.21 "Global strategy and plan of action on public health, innovation and intellectual property" May 2008.

- International negotiations related to intellectual property and public health carried out in different organizations should be consistent with public health priorities.
- Strengthening innovative capacity is essential to respond to health problems.
- Developing countries should have the capacity to cooperate on the basis of their common interests and economic and social needs if they want to benefit from global markets.

The components of this strategy on intellectual property for health and medicines, which should be well-defined in national intellectual property laws and regulations, will be the so-called TRIPS flexibilities, namely:

- o Pre- and post-grant patent opposition
- o Definition of patentability requirements from a public health perspective
- o Research exception and "early working" exception (Bolar exception)
- o Parallel imports
- o Use of compulsory licenses
- o Test data protection
- o No to exclusive data protection as a way to extend monopolies
- o Prior patent consent for the grant of the patent by health authorities (as in the case of Brazil and other countries).

1.4 Pharmaceutical Policies and TRIPS Agreement

National pharmaceutical policies have drawn on political perspectives on trade agreements, public health and access to essential medicines. Political perspectives guide and ensure the coherence of national programmes to guarantee access to medicines for the entire population. However, implementation of these policies at the national level is often hindered by tensions between the different actors: health, trade, industry.

Political perspectives on issues related to the TRIPS Agreement, intellectual property rights and access to medicines can be summarized as follows:

- Essential medicines are a public good.
- Access to essential medicines is a human right and, as a result, a public health priority.
- Patents should be managed impartially, protecting the interests of the patent holder and preserving the principles of public health, meaning that it is essential to make appropriate use of the flexibilities and safeguards contained in the TRIPS Agreement.[32] WHO has been updating a guide for the development and implementation of national drugs policies.[33]

[32] Owing to tensions between different national actors, the use of the flexibilities permitted by the TRIPS Agreement is not always found appropriately in drug legislation and policies.
[33] "How to develop and implement a national drug policy", WHO 2001.

1.5 Examination of Patents and Access to Medicines

The development of a public health perspective for the examination of pharmaceutical patent applications is one of the key elements of the work on access to medicines. In this context, WHO considered it important to train patent examiners of patent offices from developing countries. Therefore, between 2006 and 2010, workshops for national patent offices were carried out in more than 40 countries.

This technical assistance for patent offices was resumed by the South Centre, an intergovernmental organization, which is also continuing to analyse trends in the granting of patents for pharmaceutical products in order to respond to the growing concerns at the increase in the number of patents that protect variants of existing medicines or procedures while, as mentioned earlier, the number of patents for new molecular entities is limited and decreasing. Patent examiners and those responsible for health policy development should be aware that decisions relating to the granting of a patent (which is generally considered to be valid until otherwise demonstrated) can directly affect the health and life of the people in the country in which the patent is granted and used.

2. THE PATENT SYSTEM APPLIED TO MEDICINES

One third of the global population does not have regular access to essential medicines, and this proportion can reach more than half of the population in some developing countries. Of the 34 million people estimated by WHO, the Children's Rights and Emergency Relief Organization (UNICEF) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) in their report from 2012[34] to be living with the human immunodeficiency virus (HIV) and who should have been receiving treatment, only 8 million had access to treatment at the end of 2012.[35]

This situation, as stated by Eric Goemaere, is largely due to the high costs of medicines protected by patents. "How shocked am I to hear that patent rights do not constitute a barrier to treatment here in South Africa. I have seen young men and women die after experiencing unbearable headaches, victims of AIDS-related brain tumours. I have seen children covered in scars caused by AIDS-related dermatitis, unable to sleep because of the pain. I knew that antiretroviral therapy could help them, and that the only barrier that prevented this was the cost of patented medicine." [36]

The subject of patents for pharmaceutical products has been one of the most-debated issues related to access to essential medicines since the creation of WTO in 1995 and the signing of the TRIPS Agreement.

[34] UNAIDS World AIDS day Report 2012.
[35] Velásquez, G. in "Public Health and pharmaceutical patents" collection coordinated by Seuba, X. p. 24, Barcelona, 2008.
[36] Goemaere, E. "Medicines patents in the spotlight. Sharing practical knowledge about pharmaceutical patents, MSF, Madrid, May 2003.

Patents are not the only barrier to access to medicines, but increasingly they can be a determining factor since patents grant a monopoly for a medication to the patent holder, who is then free to fix prices. This freedom to fix the prices of patented products has led to a large number of medicines not being available for the majority of the global population, that live in developing countries.

It is important to remember that a patent is a territorial right and that it is therefore possible to grant a patent for an invention in one country but that this can be legally rejected in another. At the same time, a patent that has been issued in one country can be revoked if it is demonstrated that the patent office ought not to have granted it.

It is also important to highlight that in the pharmaceutical sphere, the situation is not ONE product, ONE patent. An invention can be protected by numerous patents, the production process for the product can also be protected by one or numerous patents, and in many countries a combination or new clinical indication can be patented. As a result of this, a single medicine can be protected by a large number of patents.

The TRIPS Agreement contains provisions that require the amendment of patent legislation in the vast majority of developing countries in order to introduce, widen and strengthen intellectual property protection of pharmaceutical products.

It is important that in the adaptation of intellectual property legislation all of the provisions for protecting public health are included. In cases where the room for manoeuvre allowed by the TRIPS Agreement were not used, national legislation can always be revised, as done by countries such as China and India.

In principle, the patent system was conceived to ensure that the public benefited from inventions. Currently, not only do a large number of people that live in developing countries not benefit from inventions, but in many countries, patents represent a barrier to access to life-saving medicines simply because business logic overcomes the right to access to health care.

Almost 20 years after the adoption of the TRIPS Agreement, its impact, at least in terms of public health, raises more unanswered questions than solutions.

A few months after the creation of the WTO and the entry into force of the TRIPS Agreement, Carlos Correa stated that "The adoption of the Agreement has undoubtedly involved a major concession on the part of those countries which refused to grant patents for drugs in order to avoid the effects of market monopolies derived from exclusive rights. The information available (…) shows that the universalization of pharmaceutical patents will not lead to increased R&D on new drugs by large companies nor to the possibility that this will be carried out to any significant degree in developing countries. Neither will developing countries receive increased flows of direct foreign investment or transfer of technology." [37] Fifteen years later, as we will see later, it was found that neither R&D nor technology transfer have increased and instead, the trend has been to decrease.

[37] C. Correa, «The Uruguay Round and Drugs » in Medicines and the new economic environment, edited by F. Lobo and G: Velasquez, Ed. Civitas, Madrid 1998.

2.1 The Problem

Four major problems can be identified in the current patent system used for medicines: reduction in pharmaceutical innovation, high prices of medicines, lack of transparency in research and development costs, and proliferation of patents.

2.1.1 Reduction in pharmaceutical innovation

A study carried out by the journal *Prescrire* analysed the medicines that were introduced to the French market between 2006 and 2011 (six years), arriving at the conclusion that the number of molecules that produced significant therapeutic progress reduced drastically: 22 in 2006; 15, 10, 7, 4 in the following years up to 2011, which was a year in which *Prescrire* declared that only one medicine of significant therapeutic interest was brought to the market.[38] Given that France is one of the largest pharmaceutical markets in the world, where the State also pays the bills for medicines, it can be supposed that the large majority of medicines that were released in the world between 2006 and 2011 were introduced into the French market. In other words, the reduction in innovation confirmed in France is a good indicator of the global situation.

2.1.2 High prices of medicines

Another recent study demonstrated that, on average, medicines cost three times more in France than the same drugs in Italy.[39] It should be remembered that the medicines on the market are quite similar in both countries: the same laboratories, the same medicines and, most of the time, the same doses.

Oncologists from fifteen or so countries recently denounced the excessive prices of cancer treatments, which are necessary to save the lives of the patients, and urged that "moral implications" should prevail.[40] According to this group of oncologists, of the 12 cancer treatments approved in 2012 by the United States Food and Drug Administration (FDA), 11 cost more than US$ 100,000 per patient per year.

In 2010, a group of English academics analysed the most prescribed drugs in the National Health Service (NHS) and calculated that approximately GBP 1 billion is wasted each year due to the prescription of patented "me too drugs", for which there is an equally effective out of patent equivalent.[41] What is considered to be a waste of State funds resulting from the use of patented medicines in the English system is the reality in developing countries simply because of the impossibility of accessing the medicine for the majority of the population.

During the summer of 2014, a number of European countries, including France and Spain, spent many months negotiating with the company Gilead on the price of a new medicine for hepatitis C (known as brand name "Sovaldi"). The price fixed by Gilead was EUR 56,000 per patient for a twelve-week treatment, that is to say EUR 666 per tablet.

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[38] Philippe EVEN, Bernard DEBRE, "Guide to the 4000 useful, useless and dangerous medicines" Ed. Cherche Midi, Paris, September 2012, p. 82.

[39] *Le Monde* from 11 November 2013, http://www.lemonde.fr/culture/article/2013/11/13/le-scandale-du-prix-des-medicaments_3510819_3246.html.

[40] American journal *Blood*, publication of the American Society of Hematology (ASH) April, 2013.

[41] B. Goldacre, Op. cit. p. 243.

According the newspaper *Le Monde* the price of each tablet was 280 times more than the production cost.[42] In France, it is calculated that 250,000 patients should receive this medicine, the cost of which would represent 7 per cent of the annual State medicine budget.

2.1.3 Lack of transparency in R&D costs

Since the 1950s, there have been some references to the costs of R&D for pharmaceutical products. According to some sources (see box below) these figures have increased from US$ 1 million to US$ 1.3 billion for the development of a single product. While there continues to be no clarity and transparency in this sphere, the difficulty that can lead to the high prices of medicines continues to be unresolved.

The granting of patents, based on which the inventor should recover the costs of their invention, when there is no clarity about the actual costs is something that States and society in general should examine. The duration of patents, for example, for a period of 20 years as arbitrarily required by the TRIPS Agreement, should be dependent on the R&D costs of the products.

Average cost of research for a new pharmaceutical product*

1950:	US$ 1 million
1970 & 1980:	Between US$ 48 million and US$ 54 million
1991:	Tufts Center (Boston): US$ 231 million
2000:	Tufts Center: US$ 473 million
2002:	US$ 802 million (double the cost in two years!)
2008:	IFPMA: US$ 900 million
2012:	IFPMA: US$ 1.3 billion
2014:	Tufts Center (Boston): US$ 2.56 billion

*Prepared using diverse sources

An article from the journal *BioSocieties*[43] a publication of the London School of Economics, argues that the real cost of R&D is, in fact, a fraction of the commonly quoted estimates. According to the authors Light and Warburton, the average cost of R&D to develop a medicine varies between US$13 million and US$ 204 million depending on the type of product. The authors estimate an average cost of US$ 43.4 million for R&D for each drug. And they conclude: "This is very far from the US$ 802 million or US$ 1.3 billion claimed by the industry."

The Drugs for Neglected Diseases initiative (DNDi), founded by the non-governmental organization Médecins Sans Frontières (MSF) in 2004, recently published its research costs after 10 years of experience.[44] Its figures are as follows:

- From EUR 6 million to 20 million to improve a treatment.
- From EUR 30 million to 40 million for a new chemical entity.

[42] Santi, P. "Hépatite C: le nouveau hold-up des labos", in *Le Monde* 8 July 2014.
[43] Donald W. Light and Rebecca Warburton, Demythologizing the high costs of pharmaceutical research" 2011 The London School of Economics and Political Science 1745-8552 *BioSocieties* 1-17. www.palgrave-journals.com/biosoc/.
[44] DNDi, "An Innovative Approach to R&D for Neglected Patients: Ten Years of Experience and Lessons Learned by DNDi", Geneva 2013.

If this figure were to be adjusted as usually done for pharmaceutical R&D for infectious diseases to cover the risk of failure, the figures would be as follows:

- From EUR 10 million to 40 million to improve a treatment.
- From EUR 100 million to 150 million for a new chemical entity.

It is unfathomable that after 15 or more years of debate, there is still no consensus about the real costs of R&D for medicines. Until this issue is resolved, it will be difficult to advance constructive thinking that could determine the future of access to medicines. The differences in data between academia or non-profit initiatives, such as DNDi, and industry are between ONE and TEN. WHO has been silent on this issue, probably as a result of the growing influence of the pharmaceutical industry on policy development and decision-making within this Organization.

This is how monopolies granted by patents will enable the obtaining of disproportionate benefits on the one hand, and on the other will block a large number of peoples' access to medicines, which in many cases are vital.

The problem with R&D costs is that there is no transparency about the real costs of R&D, as there is no pricing logic for medicines, rather the prices correspond to the maximum that each market can accept or pay.

2.1.4 Proliferation of patents

An investigation carried out by the European Union (EU) about the conduct and practices of the pharmaceutical industry between 2000 and 2007 found that a single medicine can be protected by up to 1300 patents or pending patent applications.[45] The number of lawsuits between originator companies and generic companies has increased four-fold in the EU. These lawsuits delay the entry of the generic product by between six months and six years. The study estimates that the savings resulting from the entry of generics could have been approximately EUR 3 billion, if the entry had occurred immediately after the loss of exclusivity.[46]

A policy and strategy change at the patent office level could lead to significant changes. In Argentina, for example, after the introduction of new guidelines for the examination of pharmaceutical patents in 2012, the number of patents granted was 54, while in Mexico, a similar-sized market to Argentina, the number of patents granted in 2012 for pharmaceutical products was 2500.

Other countries, as in the recent case of Ecuador, decided to raise rates for registering a new patent to more than US$ 100,000 (with exceptions for example in the case of small companies and universities).

[45] Investigation by the European Union:
http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.
[46] Investigation by the European Union, Op. cit.

2.2 The International Context

In general, it is currently recognized that the existing protection regime using patents "globalized" by the TRIPS Agreement has significant repercussions on the pharmaceutical sector. In addition, there is a concern that the standards specified in the TRIPS Agreement are not necessarily suitable for countries fighting to meet their health and development needs. Since 2002, the Commission on Intellectual Property Rights (CIPR) of the United Kingdom published a report recommending that countries ensure their intellectual property protection systems do not impact on their public health policies and are consistent with those policies.

Pharmaceutical R&D using the patent system as the main source of financing has not enabled the medicines to be accessible to the vast majority of people, especially those living in developing countries. On the one hand, there is limited investment in R&D for diseases prevalent in those countries, as large companies concentrate on the development of products to satisfy the demands of rich markets. On the other, products subject to patents and other methods of exclusive rights are usually marketed at unreachable prices for the majority of the population. Various reports and studies, together with the Global strategy and plan of action on public health, innovation and intellectual-property adopted by Member States of WHO (2003-2008),[47] have recognized these issues.

In April 2012, the WHO Consultative Expert Working Group on Research and Development (CEWG) recommended the start of international negotiations for a treaty on R&D for pharmaceutical products, within the scope of article 19 of the WHO Constitution, which states:

> "The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes."

The only precedent in the history of WHO of the use of this article in a substantive area was the Framework Convention on Tobacco Control (FCTC). New, effective and simultaneous mechanisms[48] that promote innovation and access to medicines are needed, particularly for diseases that chiefly affect developing countries. A binding international instrument or international treaty on R&D, negotiated under the auspices of WHO could provide an adequate framework to guarantee the establishment of priorities, coordination and sustainable financing for medicines at affordable prices for developing countries.

Recently, in October 2014 in her speech opening the Sixth Conference of the Parties to the Framework Convention on Tobacco Control (COP6 of the FCTC) held in Moscow, the Director General of WHO said that: "We have abundant evidence from multiple sources that implementation of the Framework Convention brings both immediate and long-term improvements for health. (…) As time has shown, the tobacco treaty is important for a second reason. It is a model of how multiple sectors of government, and multiple UN agencies, can work together seamlessly and in tandem, united by a most worthy shared goal. The

[47]World Health Organization, Global strategy and plan of action on public health, innovation and intellectual-property.WHA Resolution 61.21, (May 24, 2008).
[48]World Health Assembly Global strategy and plan of action on public health, innovation and intellectual-property point 13.

importance of this model continues to grow as more and more of the century's biggest threats to health (…)"[49]

2.3 Human Rights and Intellectual Property

When discussing international trade rules or questions related to public health, we are talking about two different regimes that are not at the same level. In the first case, it is a matter of trade and economic standards and regulations, and in the second case, we are referring to the right to health as part of human rights.

Medicines are a fundamental tool for society to prevent, treat and cure diseases and access to them is a fundamental right of citizens, an integral part of the right to health care as established in some international treaties and the constitutions of many countries.[50]

Access to medicines has to be considered as a fundamental human right, with full international and constitutional recognition. The Universal Declaration of Human Rights (1948) refers to this in article 25:*"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services (...)"*

"The areas of interaction between the patenting process for pharmaceutical products and human rights are numerous, given that the standards that a country adopts on patenting of inventions is linked to regulatory regimes that particularly protect legal rights. In reality, the impact on life, on science, on access to vital products that results from the application of standards in the patent process, including patentability requirements, leads to their interaction with a wide range of fundamental rights, such as the right of access to scientific and technological advances, the right to health care and the right to life itself. This is precisely the reason why courts, administrative bodies and ministries of health, among others, are paying increasing attention to the relationship between the patentability requirements that a country adopts and its human rights protection regime, particularly with regard to the right to health care."[51]

While, as stated by P. Drahos, the challenge is that patent offices have functioned, and many continue to function, as administrative institutions, the examination of patent applications "is much more than an administrative task. The basis on which such activity is carried out, and the activity itself, are closely related to the protection of the public domain and fundamental rights."[52]

In the context of the United Nations, the vast majority of countries have adopted international treaties, such as the International Covenant on Economic, Social and Cultural Rights (ICESCR), the Convention on the Rights of the Child or the Convention for the Elimination of All Forms of Racial Discrimination, which ratify, in different ways, the right

[49] Speech of Margaret Chan, Director-General of WHO, opening of COP6 of the FCTC, Moscow, October 13 2014. FCTC/COP6/DIV/4.
[50] Seuba, X. "The protection of health in light of international regulation of pharmaceutical products" Doctoral thesis p. 92 onwards, Barcelona 2008.
[51] X. Seuba, "The right to health care, national pharmaceutical policy and patentability guidelines", 2012 (unpublished work).
[52] X. Seuba Op. cit.

to health care. The Committee on Economic, Social and Cultural Rights stated that "the right to health embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life".[53] It is within this "wide range of socio-economic factors" that are linked to health that patentability requirements can be linked to the right to access to health care.

In its General Comment No. 14 of May 2000,[54] the Committee on Economic, Social and Cultural Rights declared that the medical services referred to in Article 12.2.(d) of the Covenant include access to the essential medicines as defined by WHO. This is how the Committee on Economic, Social and Cultural Rights of the United Nations has included access to essential medicines among the key components of the right to health care.

The understanding that access to medicines is a right of citizens would change the debate and clarify the primacy of health over international trade regulations. This perspective of rights, as stated by Seuba, "simultaneously offers the tools to report violations and a framework to guide national drugs policies in this direction."[55]

3. GUIDELINES FOR THE EXAMINATION OF PHARMACEUTICAL PATENTS: A PUBLIC HEALTH PERSPECTIVE[56]

3.1 A History of the Guidelines

As already mentioned, the fact that the TRIPS Agreement does not define novelty, inventive step and industrial applicability (utility) 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. "Politicians and legislators have broad room for manoeuvre to give legal effect to those flexibilities."[57]

Articles 7 and 8 of the TRIPS Agreement (1995) clearly stipulate that **all** of the provisions should be interpreted in light of their objectives and principles, which establish:

> *"Article 7. Objectives. The protection and enforcement 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, and to a balance of rights and obligations.*

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[53] Committee on Economic, Social and Cultural Rights, *General Comment no. 14, The right to the highest attainable standard of health* 2000, E/C.12/2000/4, paras. 4 and 9.

[54] Committee on Economic, Social and Cultural Rights. The right to the highest attainable standard of health. 11/08/2000. E/.12/2000/4, CESCR General Comment 14, para 12(a).

[55] Seuba X,. "A human rights approach to the WHO Model List of Essential Medicines", in World Health Organization Bulletin, vol. 84 no.5 Geneva May 2006

[56] Correa C. "Guidelines for the examination of pharmaceutical patents: a public health perspective". WHO – ICTSD, UNCTAD, Geneva, March 2008.

[57] Arias Eduardo, PPT on "Guidelines for the examination of patentability of chemical-pharmaceutical inventions, INPI, Argentina, 2014.

> *Article 8. Principles.1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."*

The perspective of articles 7 and 8 of the TRIPS Agreement were ratified again by the Doha Declaration (2001), which:

1. *recognizes "the gravity of the public health problems afflicting many developing and least-developed countries…"*
2. *stresses "the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems"*
3. (…)
4. *agrees "that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health (...) 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. (...) we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose".*

In 2005, with the mandate already granted by the World Health Assembly in different resolutions, the WHO Essential Medicines Programme decided to develop draft guidelines for the examination of pharmaceutical patents from a public health perspective. Based on the first working document drafted by Professor Carlos Correa, a series of international, regional and national consultations were started, the following of which are worth highlighting:

1) October 2005, in Bangkok, Thailand: consultations organized by Thailand's Food and Drug Administration and WHO and included: representatives of drug regulatory authorities and national patent offices of China, India, Malaysia and Thailand, representatives of schools of law, medicine and pharmacy in Thailand and representatives of the pharmaceutical industry.
2) In June 2006, comments and contributions were requested from experts in public health and patents from Australia, United Kingdom and WHO.
3) July 2006, in Buenos Aires, Argentina. This consultation included representatives of Argentina, Paraguay and Brazil from patent offices, Ministries of Health and schools of law and pharmacy from the three countries.
4) 14 September 2006, Geneva. This consultation included representatives of the Swiss patent office, the South Centre, WHO, UNCTAD, ICTSD, the Lausanne Polytechnic School, WIPO, WTO, MSF and Third World Network.
5) December 2006, in Beijing, China: the draft guidelines were discussed and analysed with 50 patent examiners from the China national patent office.
6) July 2007, Panama. This consultation included representatives of Costa Rica, Colombia, Cuba, Nicaragua, El Salvador, Guatemala, Honduras and Panama.
7) October 2007, Cairo, Egypt: consultation with patent examiners from the national intellectual property office of Egypt.
8) December 2007, New Delhi, India: review and discussion with the Indian patent office with the participation of representatives of Thailand and Indian NGOs working on the issue.

In addition to the consultations mentioned, numerous comments were sent to the Director-General of WHO and the WHO Essential Medicines Programme. One example of this is the letter from the Minister of Health of Argentina dated 25 October 2007, which said: "To DR MARGARET CHAN, DIRECTOR-GENERAL OF THE WORLD HEALTH ORGANIZATION. By means of this letter, I wish to express my gratitude and appreciation for the document entitled "*Guidelines for the examination of pharmaceutical patents: developing a public health perspective"*, recently published by WHO, ICTSD and UNCTAD. I consider the document to be of crucial importance for developing countries which, like Argentina, are compelled to ensure that the implementation of intellectual property rights related to medicines does not have a negative impact on the health of our society. In my position as health authority of Argentina, I recognize the hard work of WHO to follow up on and strengthen measures adopted by countries to protect public health, such as those established in the Doha Declaration, and I feel that the document is highly consistent with the timely recommendations made by the CIPIH."

Or the letter from the Secretary-General of Thailand's Food and Drug Administration on 10 September 2007: "Your Excellency, Dr. Margaret Chan: The Food and Drug Administration, Thailand (FDA), has the honour of writing this letter to congratulate WHO for its successful contribution and commitment shown by the recent drafting and publication of a very useful document entitled, Guidelines for the examination of pharmaceutical patents: developing a public health perspective. (…)

The document addresses the vital need to take into account public health aspects in the examination of pharmaceutical patents in order to ensure that only high quality patents are granted to reward genuinely creative inventions. (…). The granting of low quality patents exacerbates the problem of people's access to essential medicines in developing countries. Therefore, the Guidelines have arrived at an opportune moment to help develop a public health perspective in the examination of pharmaceutical patents. (…). The publication of this document by WHO shows true and visionary leadership".

The letter from the Minister of Health of Brazil, dated 27 October of the same year, also sent to the Director-General of WHO, can be seen below:

"In the name of the Brazilian Government, I would like to congratulate you for the initiative of WHO to publish the document entitled "Guidelines for the examination of pharmaceutical patents: developing a public health perspective" written by Professor Carlos Correa.

The Brazilian Government believes (…) that the document is an indispensable tool to prevent abuse related to intellectual property rights, ensuring that only pharmaceutical products of processes that meet the criteria of novelty, inventive step and utility will have their patent applications granted."

In the comments made by the Swiss patent office, transmitted by the representative of Switzerland to WTO on 14 September 2006, the first paragraph included the following: "I think, the guidelines are carefully drawn up, very comprehensive and well-balanced in a lot of their points".

Lastly, it should be noted that approximately ten years after the publication of the document, no in-depth examination of the issue has taken place in the WTO.[58]

3.2 What are the Guidelines for the Examination of Pharmaceutical Patents?

The Guidelines for the examination of pharmaceutical patents developed by WHO are a guide for the drafting of internal procedure manuals of national intellectual property offices for the examination of patentability of chemical-pharmaceutical inventions.

"It is the habitual practice of all patent offices in the world to instruct their examiners on the way to carry out the patentability assessment through so-called patentability guidelines that describe in detail the implementation of patent law in specific circumstances. (…). These guidelines generally include a chapter about patents in the chemical-pharmaceutical sector."[59]

It is also a habitual practice of all patent offices around the world to set the level of patentability requirements that the examiners use for the examination of patents through patentability instructions or guidelines, which describe in detail the implementation of patent rights in specific circumstances.

In the introduction of the guidelines it is stated that the pharmaceutical sector is a user of fundamental importance within the patent system. While each year only a small – and decreasing – number of new chemical entities are approved, thousands of requests are submitted to protect variations of existing products, manufacturing processes or, when permitted, second indications for known pharmaceutical products.

Given that patents grant exclusive rights for the production, sale and use of the patented material, they can be used to limit competition and fix higher prices than would have existed with competitive products and generic medicines.

Taking into account the underlying effects that patents can have on competition and, as a result, on prices and access to medicines, the criteria used to examine and grant pharmaceutical patents are of significant importance for public health policies.

The purpose of the guidelines for the examination of pharmaceutical patents is to provide a series of general guidelines for the examination of some common types of pharmaceutical patents granted. They respond to the growing concerns emerging in different circles[60] about the proliferation of patents that protect minor variants, and in some obvious cases, existing medicines and processes (for example, changes to drug formulations and to salts, esters, ethers, isomers, polymorphs of existing molecules, and to combinations of known drugs with other known drugs), while the number of new chemical entities for pharmaceutical use is low and decreasing.[61] While those patents may be weak, or, if subjected

[58] The questions of some countries when the intellectual property legislation of Argentina was reviewed by WTO (March 2013) requested information but did not question the consistency of the legislation with the TRIPS Agreement.
[59] Arias, E. Op. cit.
[60] See, for example, Federal Trade Commission (FTC) (2003); Jaffe and Lerner (2004); Correa, 2001a.
[61] The number of new molecular entities approved by the United States Food and Drug Administration of the (FDA) has fallen drastically since the mid-1990s (from 53 in 1996 to a low of 17 in 2002). See "*CDER, NDAs approved in calendar years 1990-2004 by therapeutic potential and chemical type*". United States Food and

to strict scrutiny, invalid, in many cases they can be used to prevent generic competition and, therefore, to reduce access to medicines.

While these guidelines recognize the importance of subsequent pharmaceutical innovations in certain cases,[62] their aim is to increase the capacity of patent offices, regulatory authorities for medicines and public health, and civil society to assess and adopt necessary measures, in accordance with national legislation, to protect public health in those cases in which patent requests and claims cover a material that does not merit the monopolistic reward that a patent grants. The purpose of the guidelines is to provide support to national patent offices and to try to contribute a rational analysis of pharmaceutical patents based on the rational implementation of patentability requirements.

The guidelines do not suggest the implementation of a new condition for patentability, but the taking into account of specific considerations related to innovation in pharmaceutical products when the common requirements of novelty, inventive step and industrial applicability (utility) are applied.

3.3 Content of the Guidelines

The guidelines for the examination of patents analyse and discuss the most common claims in the pharmaceutical sector. They include observations on practices in a number of countries and analyses of 41 examples of individual cases of different claims considered. Transcribed below, for illustrative purposes, are the recommendations for each type of claim from a public health perspective that promote access to medicines.

3.3.1 Formulations and compositions

Recommendation: New formulations and compositions, as well as processes for their preparation, should generally be deemed obvious in the light of the prior art, particularly when a single active ingredient is claimed in association with known or unspecified carriers or excipients. Exceptionally, claims of this type could be patentable if a truly unexpected or surprising effect is obtained, for instance, when a really difficult problem or a long standing need, such as a noticeable reduction in side effects, is solved in a non-obvious way, or when the solution found leads to a tremendous advantage compared to the state of the art.

3.3.2 Combinations

Recommendation: Combinations of known active ingredients should be deemed non inventive. If, however, a new and non-obvious synergistic effect is considered a basis for patentability, it should be properly demonstrated by biological tests and appropriately disclosed in the patent specifications.

Drug Administration, 22 March 2005 (http://www.fda.gov/cder/rdmt/pstable.htm, accessed on 14 November 2005).

[62] CIPIH, p. 17. However, in some cases, patents can hinder subsequent innovations, in particular when material from basic science is patented. See, for example, Commission on Intellectual Property Rights, 2002; Sampath, 2005, p. 29.

3.3.3 Dosage/dose

Recommendation: New doses of known products for the same or a different indication do not constitute inventions, particularly (but not only) in countries where methods of medical treatment are not patentable as such.

3.3.4 Salts, ethers and esters

Recommendation: New salts, ethers, esters and other forms (e.g. amides) of existing pharmaceutical products should not be deemed patentable. This may not apply, exceptionally, when tests, appropriately conducted and described in the specifications, demonstrate unexpected advantages in properties such as an important difference in efficacy or side effects as compared to what was in the prior art. Processes for obtaining salts, ethers, esters and other forms should be deemed as non-patentable.

3.3.5 Polymorphs

Recommendation: Polymorphism is an intrinsic property of matter in its solid state. Polymorphs are not created, but found. Patent offices should be aware of the possible unjustified extension of the term of protection arising from the successive patenting of the active ingredient and its polymorphs, including hydrates/solvates. Processes to obtain polymorphs may be patentable in some cases if they are novel and meet the inventive step standard.

3.3.6 Markush claims

Recommendation: Claims covering a large range of compounds should not be allowed. Patent offices should generally require patent applicants to provide sufficient information, such as fusion point, Infrared Absorption Spectrum (IR) or Nuclear Magnetic Resonance (NMR), obtained through true testing and experimentation to enable the reproduction by the disclosed method of each embodiment of the invention for which protection is sought. However, claims of limited scope could be granted if evidence is provided at least that, with the substitution of any member within the same family class, the same disclosed result would be obtained. The coverage of the patent should be limited to what is actually enabled by the disclosure in the specification.

3.3.7 Selection patents

Recommendation: As a general rule, selection patents should not be granted if the selected components have already been disclosed or claimed and, hence, lack novelty. If an existing product were deemed patentable due to its unexpected advantages under the applicable law, the patentability of a selection could be considered when an inventive step is clearly present.

3.3.8 Analogy processes

Recommendation: Non-novel or obvious pharmaceutical processes, regardless of whether the starting materials, intermediaries or the end product are novel or inventive, should be considered not patentable as such.

3.3.9 Enantiomers

Recommendation: Single enantiomers should generally not be deemed patentable when the racemic mixture was known. However, processes for the obtention of enantiomers, if novel and inventive, may be patentable.

3.3.10 Active metabolites and prodrugs

Recommendation: a) Active metabolites of drugs should generally not be deemed patentable separately from the active ingredient from which they are derived.

b) Patents over prodrugs, if granted, should disclaim the active ingredient as such, if previously disclosed or otherwise non-patentable. They should only be granted if the prodrug is specifically described and an unusual, non-predictable, effect was found. Like other subject matter claimed in a patent, a prodrug should be sufficiently supported by the information provided in the specifications. In addition, evidence may be required that the prodrug is inactive or less active than the compound to be released, that the generation of the active compound ensures an effective level of the drug and that it minimizes the direct metabolism of the prodrug as well as the gradual inactivity of the drug.

3.3.11 Method of treatment

Recommendation: Methods of treatment, including for prevention, diagnosis or prophylaxis should be deemed non patentable where industrial applicability is required as a condition for patentability (including in cases where the patentability of such methods is not expressly excluded).

3.3.12 Use claims, including second indications

Recommendation: Claims relating to the use, including the second indication, of a known pharmaceutical product can be refused, inter alia, on grounds of lack of novelty and industrial applicability.

WHO has suspended the workshops for patent examiners, most likely because many countries have formally adopted the guidelines, as is the case for Mercosur countries, or informally, as is the case for Egypt, or the guidelines have inspired the development of their own guidelines, as in the case of India, Ecuador and a few others. Currently, the South Centre is continuing to provide this type of support to countries; most recently through seminars held in August 2014 in the four patent offices in India, in Mumbai, Chennai, Kolkata and New Delhi.

3.4 The Case of India

On 4 April 2005, the President of India gave his consent to the amendment of the patent law. This brought into force a law that should bring India into compliance with the TRIPS Agreement. India was one of the few developing countries that are members of WTO that had opted to use a transition period of ten years (1995-2005), pursuant to the TRIPS Agreement, in order to delay the introduction of patents for pharmaceutical products.

As the TRIPS Agreement does not define the three patentability requirements – novelty, inventive step and industrial applicability – leaving a margin of flexibility for countries to define and interpret the meaning of these requirements, the new Indian Patent Act contains a series of provisions that try to define the patentability requirements, as follows:

Firstly, a definition of "inventive step" is provided as something that "involves technical advance compared to the existing knowledge or having economic significant, or both, and that makes the invention not obvious to a person skilled in the art." Secondly, there is a provision intended to hinder the "evergreening" of patents, by not allowing the simple discoveries of the following to be patentable: a new form of a known substance that does not improve the known efficacy of the substance; the mere discovery of a new property or new use of a known substance; or the mere use of a known process.

"India, considered the "pharmacy of the Third World", has since 2005 a legislation on Intellectual Property that from the public health standpoint can be considered as a model for other developing countries. For the first time ever, on 12 March 2012, the Indian Patent Office issued a compulsory license to the local company Natco Pharma for an anti-cancer medicine: "sorafenibtosylate" (trade name "Nexavar") patented by Bayer, thus creating the possibility to obtain this product at a lower cost so as to increase access to persons that need this medicine. In order to justify the high price of this medicine (USD 5,600 per patient, per month) Bayer attempted to put forward the high R&D cost involved in the creation of the medicine although it refused to present figures of the R&D for this product".[63]

After seven years of litigation, the Swiss pharmaceutical giant, Novartis, lost its case before the Supreme Court of India. On Monday, 1 April 2013, the Supreme Court rejected the patent application for a costly anti-cancer product with the Brand name Gleevec (or Glivec, depending on the country). Since 2006, Novartis has been fighting in different legal institutions in India to obtain a patent for Gleevec. In 2006 and then in 2009, India had rejected the patent on the basis that it was not, according to the Indian Patent Act, related to a new medicine, and was rather a simple amendment of a known molecule. This medicine simply did not meet one of the requirements for patentability, that of novelty. Unhappy with the verdict, Novartis took the case to the Supreme Court to contest the article of Indian intellectual property law known as section 3(d), an article that was perfectly consistent with the requirements of the TRIPS Agreement of WTO.

With a certain amount of cynicism, when the law of India did not suit it, the Swiss company tried to change the law. According to MSF, quoted by *Le Monde* on 1 April 2013, the price of Glivec in India is US$ 4000 per person per month (EUR 3122), while the generic version, Imantinib, is US$ 73 per person per month (EUR 57). This, in a country where 40 per cent of the population live on less than US$ 1.25 (EUR 0.97) per day.

When the case entered the Supreme Court to denounce the intellectual property law, it stopped being a case of Glivec versus India, and became a case of public health against the big pharmaceutical industry. India will continue to refuse to patent small changes (known as evergreening) and many countries may follow their example to enable low-resource populations to access medicines. Novartis' Glivec is patented in more than 40 countries, including the United States of America, Russia and China. The aforementioned article in *Le*

[63] Velasquez, G. India Compulsory license for anti-cancer medicine, in South Bulletin No. 62, May 2012.

Monde mentions that it is Novartis' most sold medicine, with sales in 2012 amounting to US$ 4.6 billion (EUR 3.59 billion).

The generics industry of India could continue to produce and export this and many other medicines at prices at which people and health systems in many countries could access.[64]

Currently, in September 2014, the Indian Patent Office is completing the process of revising the guidelines for the examination of pharmaceutical products, which it is hoped will be approved at the end of 2014. As previously mentioned, in the guidelines currently being finalized by India, there are numerous elements in common with or similar to the guidelines proposed by WHO.

3.5 Experiences in the Implementation of Guidelines for the Examination of Pharmaceutical Patents

3.5.1 Argentina

Making use of the room for manoeuvre in the TRIPS Agreement regarding the definition of patentability requirements, the Ministry of Health, Ministry of Industry and the President of the INPI issued on 2 May 2012, joint resolution MI118/2012, MS 546/2012, and INPI 107/2012, through which the *Guidelines for the examination of patentability of patent applications for chemical-pharmaceutical inventions* were approved. The Guidelines have been applied to all pending patents since the date it entered into force.

"The Guidelines do not add new conditions for patentability. Patents are granted or denied on the basis of the consideration for each application of the conditions for patentability contained in patent legislation: novelty, inventive step and industrial applicability, as well as the rules pertaining to what are considered to be inventions and which inventions are excluded from patentability in accordance with that legislation."[65]

3.5.2 Mercosur

In the same vein, the Ministers of Health of the Common Market of the South (MERCOSUR) noted, on the occasion of the XXVII Meeting of Ministers in Montevideo on 2 December 2009, that the coincidence of objectives between public policies and the intellectual property system, particularly compliance with and implementation of patentability requirements in the region, raises concerns about the proliferation of patent applications for materials that do not constitute an invention or marginal developments in their own right.

As a result, the Ministers took the opportunity to promote within MERCOSUR the adoption of criteria that protect public health in guidelines or guides on patentability.

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[64] Velasquez, G. "David against Goliath" in *El País*, Spain. http://sociedad.elpais.com/sociedad/2013/04/01/actualidad/1364824227_627519.html.
[65] Arias E. Op. cit.

3.6 Compatibility with the TRIPS Agreement of WTO

During the fourth review of the trade policies of Argentina by WTO covering the period 2006-2011, carried out in 2013, a number of countries asked questions about the guidelines for the examination of pharmaceutical patents adopted by Argentina in 2012.

During the aforementioned review of trade policies, Japan, United States of America, Switzerland, Canada and the European Union asked very detailed questions about whether the new guidelines permitted the patenting of compositions, doses, esters and ethers, polymorphs, analogy processes, active metabolites and prodrugs, enantiomers, selection patents and Markush claims. The United States specifically asked if the new regulations added new patentability requirements other than novelty, inventive step and industrial applicability.

It is clear that the guidelines do not add new patentability requirements and only make use of the leeway allowed by the TRIPS Agreement in the definition and interpretation of patentability requirements.

Two developing countries, Chile and Costa Rica, expressed interest in the establishment by Argentina of guidelines on this issue.

Based on the provisions of the TRIPS Agreement, the response of Argentina to the long and detailed questions from the above-mentioned countries, limited itself to asserting that questions related to the guidelines for the examination of pharmaceutical products were not the subject of the review of the trade policies of Argentina as they are not a requirement of the TRIPS Agreement.

CONCLUSION

National drugs policies, including matters related to intellectual property, are fundamental elements of a national health policy that endeavours to protect the right of all citizens to access to health care.

In order to develop new medicines, mechanisms promoting innovation and product development should be established, while at the same time it should be ensured that patients are able to quickly access the fruits of this research. In the context of essential medicines, innovation should be structurally linked to access. This means that the research costs and final product price should be separate.

The effect of the introduction of pharmaceutical patents on access to medicines largely depends on the way in which the TRIPS Agreement is interpreted and implemented. This is why it is particularly important that when incorporating the provisions of the TRIPS Agreement, countries consider, inter alia, the following measures:

a) The incorporation of the requirements of the TRIPS Agreement into national intellectual property legislation should take into account the principles of articles 7 and 8 in order to regulate intellectual property in a manner consistent with

public health interests and minimize the economic and social costs that the changes can have on production, trade and access to medicines. These principles were ratified by the Doha Declaration (2001) on the TRIPS Agreement and public health;

b) Defining the three patentability requirements – novelty, inventive step and industrial applicability (utility) – in a manner consistent with public health objectives;
c) Integrating a mechanism to grant the compulsory licenses permitted by the Agreement into national legislation;
d) Ensuring the import of products that have been legitimately placed on the market, under the principle of international exhaustion;
e) Excluding naturally occurring substances from patentability (for not meeting the requirements for an "invention")
f) Limiting reversal of the burden of proof for process patents related to new chemical entities.

National intellectual property offices, through the examination of patents, play an important role in the access to medicines. The patentability requirements for public goods should be different from those for simple merchandise or luxury items. Therefore, the first and most important step is to use the freedom permitted by the TRIPS Agreement to define the patentability requirements: novelty, inventive step and industrial applicability (utility) in a way "that do[es] not lose sight of public interest in the wide dissemination of knowledge (…)"[66]

Countries can interpret the criteria to assess patent applications in a manner consistent with their public policies. Patent regimes are generally part of national technological and industrial strategies, but it is also vital that they are designed in a manner consistent with public health strategies. In particular, it is important that the scope of patentability is consistent with public health policies, and that governments are aware that the undue expansion of patentability can distort competition and reduce access to medicines. Patents for minor developments can be used to effectively discourage and block competition, given that producers of generics, buying agents and consumers, particularly in developing countries, generally lack the essential financial and technical resources to oppose incorrectly granted patents or to defend themselves from infringement claims.

The purpose of the analysis and criteria contained in the guidelines for the examination of patents[67] is to provide general guidance to patent offices and other bodies that participate in the examination of pharmaceutical patents, so that such examinations are consistent with patent legislation and also with public health objectives, in particular with the right of all to access medicines. These guidelines can be perfected and adjusted to national legislation at a later date, where applicable.

As previously analysed, if these guidelines are implemented, it is unlikely that the following types of patent applications for pharmaceutical products will be admissible by a national patent office:

[66] Op. cit. The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights: Report of the High Commissioner, E/CN.4/Sub.2/2001/13, 27 June 2001, para 62.
[67] Correa C. "Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective". WHO – ICTSD, UNCTAD, Geneva, January 2007.

- A new salt, ester, ether or polymorph, including hydrates and solvates, of an existing chemical entity;
- A single enantiomer of an existing chemical entity;
- A new combination of two or more active ingredients that are already available as individual entities;
- A new form of administration that enables a new administration route (for example, an injectable form when an oral tablet already exists);
- A new form of controlled release administration which already exists in uncontrolled release form;
- A new route for an existing form of administration (for example intravenous administration of a drug when subcutaneous administration has already been approved);
- A change in formulation.

An indispensable requirement when addressing the issue of patent applications from a public health perspective is, necessarily, to adequately train and retain qualified examiners in the patent offices. The training provided by patent offices from developed countries could increase the technical knowledge of the examiners, but can also pass on assessment standards that could lead to an undue expansion in the scope of patentability for pharmaceutical products.

Lastly, patent examiners should be aware that the decisions that they take, although they can seem of a technical nature, can have definite consequences on people's lives and health, since incorrectly granted patents can be used to unduly limit competition and restrict access to essential medicines.

ANNEX I

World Health Assembly Resolutions on Intellectual Property

1996 WHA49.14: Revised drug strategy

1999 WHA52.19: Revised drug strategy

2000 WHA53.14: HIV/AIDS: confronting the epidemic

2001 WHA54.10: Scaling up the response to HIV/AIDS

2001 WHA54.11: WHO medicines strategy

2002 WHA55.14: Ensuring accessibility of essential medicines

2003 WHA56.27: Intellectual property rights, innovation and public health

2003 WHA56.30: Global health sector strategy for HIV/AIDS

2004 WHA57.14: Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS

2006 WHA59.24: Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action

2006 WHA59.26: International trade and health

2007 WHA60.30: Public health, innovation and intellectual property

2008 WHA61.21: Global strategy and plan of action on public health, innovation and intellectual property

2009 WHA62.16: Global strategy and plan of action on public health, innovation and intellectual property

2011 WHA64.5: Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits

2011 WHA64.14: Global health sector strategy on HIV/AIDS, 2011-2015

2012 WHA65.22: Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

ANNEX II

WHO Publications on Intellectual Property and Public Health

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