AIPPI POSITION PAPER

in response to the

United Nations Secretary-General's High Level Panel Report of the United Nations Secretary-General's High Level Panel on Access to Medicines

In this position paper, the AIPPI, through its committees the Standing Committee on Pharma and Biotechnology and the TRIPS Committee, comments on the September 2016 report of the United Nations Secretary General's High-Level Panel on Access to Medicines. AIPPI acknowledges the importance of improving and enabling access to medicines around the world. However, AIPPI submits that the UN Report inappropriately targets intellectual property rights as a barrier to access to medicine, and ignores the many other factors that impact access to medicine. AIPPI submits that the Report does not propose realistic policy ideas that would improve access to medicine.

The High-Level Panel is aware that there are many other factors or aspects that impact on access to medicine (such as under-resourced health systems, inequalities between and within countries, among others). Nevertheless, the Panel chose to focus on perceived inconsistences between intellectual property practices and access to medicine. The Report is of concern to intellectual property professionals, in particular pharmaceutical patent professionals , as it presumes that intellectual property rights on pharmaceutical products can be an obstacle to the access to medicines, without considering that intellectual property rights foster research and ensure that new medicines are found and brought to the market.

Executive Summary

AIPPI acknowledges and supports the importance of improving access to medicines, but contends that the UN Report ignores the role of intellectual property in fostering innovation, thus improving health care. The Report also fails to recognize the strict standards of novelty and inventive step that ensure that only bona fide innovations are given patent protection, i.e. only innovations that satisfy the novelty and inventive step requirements. The Report also misstates the role of compulsory license provisions. The Report ignores the many other factors that impact access to medicine. Finally, the report fails to recognize that intellectual property is a human right.

AIPPI urges the UN leadership to consider the role of intellectual property in creating economic incentives for innovation, and thereby fostering new discoveries in pharmaceuticals and health care. The UN should also consider the ways in which intellectual property law has developed to guard against abuse of the IP laws. For example, laws on novelty and inventive step have developed, and patent offices have patent examination practices to ensure that patent applications are evaluated before grant.

1. Introduction to AIPPI

The International Association for the Protection of Intellectual Property, generally known under the abbreviated name AIPPI, is the world's leading international organization dedicated to the development and improvement of legal regimes for the protection of intellectual property (IP).

AIPPI is a politically neutral, non-profit organization, domiciled in Switzerland, which currently has over 9000 Members representing more than 100 countries.
The objective of AIPPI is to improve and promote the protection of intellectual property on both an international and national basis. It pursues this objective by working for the development, expansion and improvement of international and regional treaties and agreements and national laws relating to intellectual property.

AIPPI operates by conducting studies of existing national laws and proposes measures to achieve harmonization of these laws on an international basis. Where appropriate, AIPPI intervenes with submissions before major courts and legislative bodies to advocate for strengthened IP protection.

AIPPI is organized into Committees that specialize in areas of law or technology. Each Committee is composed of intellectual property professionals with expertise in the Committee subject. AIPPI strives to staff each Committee with representatives from many different countries.

The AIPPI Standing Committee on Pharma and Biotechnology (the 'Pharma Committee') was established to monitor, comment and advise the AIPPI on policy and legal issues related to intellectual property protection for pharmaceutical and biotechnology inventions. The Committee currently has 58 members, from over 27 countries. The AIPPI TRIPS Committee was established to advise the AIPPI on policy and legal issues relating to the WTO/TRIPS Agreement and its implementation, including monitoring activities of other international and regional bodies, both governmental and nongovernmental, in relation to WTO/TRIPS. The Committee currently has 17 members, from 14 countries.

AIPPI has acknowledged the importance of improving and enabling access to medicines around the world. AIPPI has issued a number of resolutions and summary reports assessing the relation between the intellectual property rights and public health issues.

Among the most relevant documents are the Question Q202[1] Resolution and Summary Report (2008) "The impact of public health issues on exclusive patent rights". The Q202 Summary Report analyses several limitations of exclusive patent rights in a wide variety of countries, such as:

- research and experimental use exception;
- Bolar exception;
- parallel import of patented medicines;

[1] The Q202 report can be found at http://aippi.org/wp-content/uploads/committees/202/RS202English.pdf

- individual prescriptions exception;
- medical treatment defence;
- compulsory licensing; and
- expropriation.

The Q202 Summary Report notes other ways to improve access to medicines, for instance by controlling (subsidizing) the prices of patented medicines, adopting information tools such as the US Orange Book, providing for incentives to encourage relevant R&D (e.g. innovation prize models), supporting relevant innovative activities (e.g. research on the basis of traditional remedies) and promoting effective and sustainable technology transfer. Also, incentives for development of new products, based on market exclusivity for a limited time should be considered, such as the orphan drug provisions and the pediatric exclusivity provisions.

AIPPI has also supported the principle that patent rights should be widely available for all technologies, and patent offices should be neutral in the evaluation of technology. Paragraph 1 of AIPPI's Resolution on "Gene patenting" (Sydney, 2017) states that "…patents should be granted for any inventions in all fields of technology including genes or parts thereof isolated from nature by a technical process or nucleic acid molecules artificially synthesized, provided an industrial, agricultural, diagnostic and/or therapeutic application is identified and other patentability criteria are met.

2. Report of the United Nations Secretary-General's High Level Panel on Access to Medicines to AIPPI and its membership

In November 2015, the United Nations Secretary General appointed a High-Level Panel on Innovation and Access to Health Technologies (hereinafter "High-Level Panel"), chaired by Ruth Dreifuss, former President of Switzerland, and Festus Mogae, former President of Botswana. The proposed objective of the High-Level Panel was to "review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."

The High Level Panel report was issued on September 14, 2016. The Report states that the imperative to respect patents on health technologies could, in certain instances, create obstacles to the public health objectives of World Trade Organization (WTO) Members, leading to the conclusion that the current business and governmental practices based on international intellectual property rules limit access to medicines. The Report focused its assessment and recommendations on perceived policy incoherencies between trade and intellectual property rules, public health objectives and international human rights.

The Report called for steps to be taken to ensure that "global intellectual property regimes and the application of the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are fully consistent with and contribute to the goals of suitable development". Amongst others, the following specific recommendations were cited:

- WTO members should adopt and apply rigorous definitions of invention and patentability for granting patents on health technologies.

- Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses.

- Governments and private sector must refrain from explicit or implicit threats, tactics or strategies that weaken the right of WTO members to use flexibilities.

- Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that exceed the minimum standards for intellectual property protection (TRIPS-plus provisions).

- Universities and research institutions that receive public funding must prioritize public health objectives over financial returns in their patenting and licensing practices.

- Governments should increase their current levels of investments in health technology innovation, and test and implement new models for financing and rewarding public health R&D, such as transaction taxes.

- Governments should establish national inter-ministerial bodies to coordinate laws, policies and practices that may impact on health technology innovation and access.

- Private sector companies should have a publicly available policy on their contribution to improving access to health technologies.

- Governments should require manufacturers and distributors of health technologies to disclose to drug regulatory and procurement authorities information about: (1) cost of R&D, production, marketing and distribution; and (2) any public funding received, including tax credits, subsidies and grants.

- WHO should establish and maintain an accessible international database of prices of patented and generic medicines and biosimilars in the private and public sectors of all countries where they are registered.

- Governments should require that the unidentified data on all completed and discontinued clinical trials be made publicly available in an easily searchable public register, regardless of whether their results are positive, negative, neutral or inconclusive.

- Governments should establish and maintain publicly accessible databases with patent information status and data on medicines and vaccines[2].

In sum, the Report recommends that WTO Members take advantage of the flexibilities and policy space available in the WTO intellectual property rules, invest more in health and make available the information about patented and generic medicines to promote access to medicines.

[2] AIPPI acknowledges the recent joint initiative of WIPO and IFPMA to establish a database of patents covering approved drug products.

3. AIPPI Response to Report Proposals

AIPPI is concerned that a number of aspects of the proposals do not recognize the value of intellectual property in providing access to medicine and creating improvements in health care. The Panel report does not seem to properly address the positive effects of intellectual property as an incentive to innovation.
AIPPI responds to the main proposals below.

a. Definitions of Invention and Patentability

The Panel urged governments to set "rigorous definitions of invention and patentability" for inventions in the health field. In response, AIPPI considers that there are already sufficient safeguards in the existing patent laws such that patents are granted only for legitimate inventions in the health field. Further, in many countries and regions, granted patents can be challenged in post-grant proceedings, such as opposition proceedings in the European Patent Office, and can be invalidated after grant.

International norms of patent law provide that patents protect only inventions having novelty, inventive step and that are industrially applicable. These concepts have been accepted around the world, and are supported by international treaties.

The Patent Cooperation Treaty (PCT), originally signed in 1970, recognizes that member states have the authority to establish their own definitions of patentability. There are currently more than 150 PCT signatory states. However, the PCT recognizes the concepts of novelty, inventive step and industrial applicability. In Article 33, the PCT calls for examination on the basis of whether an invention is "novel", whether it has "inventive step" and whether it is "industrially applicable." Article 33 states that a claimed invention "shall be considered to involve an inventive step if, having regard to the prior art as defined in the Regulations, it is not, at the prescribed relevant date, obvious to a person skilled in the art."

AIPPI supports rigorous examination of patent applications, and a strict interpretation of patent laws so that patents are granted only for qualifying inventions. AIPPI urges countries to support strong intellectual property systems, with the quality of examination that is necessary in order to have high quality assessment of novelty and inventive step, thus leading to stronger patents. Finally, AIPPI strongly believes that the patent offices must be allowed to use and invest resources in better training, databases and infrastructure in order to secure patent quality.

AIPPI considers that any law or rule that limits patentability for a particular field of technology violates TRIPS. TRIPS Article 27 states that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." This provision requires that member states apply the patent laws consistently across technologies, and do not set barriers to patentability that apply to one technology but not to others. As a result, it would be a violation of TRIPS Article 27 to establish separate rules for patentability for inventions in the field of pharmaceutical development.

b. Economic Incentives and Importance of Innovation

The Panel asks universities and publicly-financed research institutions to "prioritize public health objectives over financial returns in their patenting and licensing practices." The Panel also calls for increased government investments in innovations in health technology.

The Panel does not recognize that a strong patent law acts as an incentive to innovation, and thus leads to the developments of improvements in health care. Intellectual property enters into the public policy arena as a tool for incentivizing innovation. The innovator knows that through a patent the investment made in developing a new product will be secured in the sense that competitors, during a limited time period, will not be able to copy the innovations and launch an identical product. The exclusivity provided by patents allows the innovator to set a price that can provide a return in the investment and a reasonable profit.

This is the basic rationale behind the incentive of patents. Society at large benefits immediately by the availability of a solution to a need and also by the disclosure of the invention that is mandatory in order to be granted a patent. In return, society has to pay, for a limited time, a price that is higher than would occur with competition, for a technology that might otherwise not have been available.

The Panel also did not consider the high rate of failure of products in the early research and regulatory processes, and the cost that such failures imply for those who invested in such failed products. Public institutions, who must account to governments or the public for their budget, are unlikely to authorize investments in high risk medical research. Only private investors, who would benefit from successful research, would be able to fund the scientific research. The high risk of failure during development supports the grant of exclusivity for those who achieve a successful product, and also support the need for protection from unfair competition.

AIPPI acknowledges the Panel's concern that many people cannot afford available health care solutions. The real challenge is to introduce ways to make such access possible, while minimizing unfair competition. Weakening or nullifying the necessary intellectual property protections would yield an even higher cost to society, for example, in the form of a decrease in drug development.

Another barrier to achieving health care innovations is the public policy level itself in the regulatory arena. Health Authorities worldwide seek to ensure the procurement of safe and effective drugs to people. Medical products that have not yet been proven safe and effective require the active intervention of health authorities and rigorous ethical standards for the scientific information presented for the regulatory process in order to allow the selling of the medicament to the public. This has a great impact in innovation in the pharmaceutical industry, and is not discussed in the Report. This is without taking into account the need of regulatory authorities to ensure quality of the drugs produced by any manufacturer through good manufacturing practices, pharmacopeia standards and other regulatory requirements related to the production of specific drugs. The generation of such evidence, plus the evidence related to the quality in the production of the drugs imply a higher cost than the cost of

development, production and launch of products that are not as regulated as pharmaceuticals, and it is unrealistic to think that these quality requirements will not impact the cost and price of drugs on a case-by-case basis.

The Panel recommends "delinkage" of development costs from price, but it does not address the incentive that any person, company, R&D center or even government will have to invest in starting the regulatory process of a new drug candidate that may very likely fail. The Panel limits the analysis to point partially towards patents as the cause of access limitation and recommends limiting intellectual property rights.

The Report asserts that pharmaceutical innovators engage in "evergreening,[3]" defined pejoratively in the Report as "minor and insignificant variants or indications". However, AIPPI responds that many of the inventions characterized as "evergreening" may be key improvements, which can be of value to patients. In any event, so-called "evergreening" patents will not affect the ability to market, make, use or sell the existing product without such "insignificant variant" once the patent on the existing product has expired.

AIPPI also contends that development of innovations and the marketing of that innovation should not, by itself, be anticompetitive. There are legal frameworks in most countries that can judge whether an activity is anti-competitive.

c. Support for Compulsory License Provisions and TRIPS Flexibilities

AIPPI acknowledges that compulsory licenses are recognized by international agreements. However, AIPPI does not favor a loose interpretation of TRIPS provisions, particularly those related to the so-called "TRIPS flexibilities", in order to justify the violation of the TRIPS principle of non-discrimination of patent availability by field of technology. The Paris Convention also provides that *"grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law"*.

Both TRIPS and the Paris Convention have regulated compulsory licensing. The Paris Convention, which currently has 195 member states, recognized the compulsory license provision, but added significant limitations to a country's ability to issue the license. Article 5(A) stated that a government cannot impose compulsory licenses on the grounds of failure to work less than four years from the filing date, or three years from grant, whichever is longer. Article 5 also states that a compulsory license "shall be refused if the patentee justifies his inaction by legitimate reasons." Article 5 also states that compulsory licenses will be nonexclusive, and cannot be transferred. In this regard, Article 27.1 of TRIPS states that compulsory licenses should not be accepted for lack of local manufacturing by stipulating "...patents shall be available and patent rights enjoyable without discrimination as to...whether products are imported or locally produced."

[3] The Report defines "evergreening" as "patenting or marketing strategies to extend the period of patent protection or effective period of market exclusivity, which are considered to be unjustifiable and therefor abusive." The Report states that evergreening "might involve the filing of multiple, often successive, patent applications on minor and insignificant variants or indications of the same compound."

Additionally, Article 30 and 31 of TRIPS strictly regulate exceptions to patent rights.

The TRIPS Agreement (effective January 1, 1995), recognizes the importance of Access to Medicines. Section 8 acknowledges that member states may "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."

Article 31 of TRIPS also puts limits on compulsory licenses, in section 31(a) to (l). The limitations include that the user make "efforts to obtain authorization from the right holder on reasonable commercial terms and conditions, for a reasonable period of time." The duration of the compulsory licenses will be limited to the purpose for which it was authorized, and must be non-exclusive and non-assignable. Article 31 also states that the authorization should be terminated "if and when the circumstances which led to it cease to exist and are unlikely to recur."

The Doha Declaration, a Declaration on the TRIPS Agreement and Public Health, was issued in November 2001, as part of the Doha World Trade Organization ministerial conference. In the Declaration, the signatories recognized public health issues in developing and least developed countries, and the role of WTO. In the Declaration, the signatories recognized that IP protection is important in developing new medicines, but stated that TRIPS "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." The Declaration stated that "[e]ach member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency." The WTO General Council adopted the Article 31 bis protocol in December 2005. Nevertheless, it was not until January 2017 that two thirds of WTO members had ratified TRIPS Article 31 bis, making it part of the TRIPS Agreement.

Accordingly, some countries have enacted specific legislation to remove any patent barriers to export of medicines to the developing world. For example, Canada's "Use of Patent for International Humanitarian Purposes to Address Public Health Problems" facilitates availability of medicines in the developing world, by permitting companies to override any Canadian patent rights in exporting certain medicines to WTO recognized least developed countries.

It is noted that the transition period under Article 66.1 for Least Developed Countries with regard to patenting of pharmaceutical products has been extended to 2033.

AIPPI recognizes the compulsory licensing provisions in TRIPS, but maintains that compulsory licenses should only be granted in exceptional and strictly defined circumstances, and should generally be narrowly construed.

TRIPS Article 39.3 also provides for test data protection for pharmaceutical products. Although this is separate from IP rights, it acknowledges the right of the developer of the drug product to maintain its intellectual property in its test data.

d. Intellectual Property as a Human Right

The Universal Declaration of Human Rights states that a person has the right to benefit from his or her own innovations or creations. Intellectual property rights recognize the contribution of the person to humanity (moral rights), and incentivize the disclosure of innovations by providing a right to benefit from such contribution. Article 17 of the Universal Declaration expressly reads that "Everyone has the right to own property alone as well as in association with others," and "No one shall be arbitrarily deprived of his property." Article 27 (2) provides "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author".

Box 3 of the report implies that health is a human right above the supposed contrary interests of multinational companies. However, the conclusion does not correlate with the analysis of the UN Economic and Social Council in their comments to Art. 15 of the International Covenant on Economic, Social and Cultural Rights (ICESC)[4], which are cited and referred to in Box 3.[5] The Council clearly states that the protection should not limit other rights under the Covenant. The comments of the Council also state in paragraph 16 that:

*16. [T]**he purpose of enabling authors to enjoy an adequate standard of living can also be achieved through one-time payments or by vesting an author, for a limited period of time, with the exclusive right to exploit his scientific, literary or artistic production**."*

Further, the UN Economic and Social Council states that:

*"27. As in the case of all other rights contained in the Covenant, **there is a strong presumption that retrogressive measures taken in relation to the right to the protection of the moral and material interests of authors are not permissible**. If any deliberately retrogressive measures are taken, the State party has the burden of proving that they have been introduced after careful consideration of all alternatives and that they are duly justified in the light of the totality of the rights recognized in the Covenant.[20]"*

These principles illustrate that the value of intellectual property has been recognized by United Nations institutions.

e. Role of Intellectual Property in Fostering Innovation in Developing Countries

[4] United Nations Economic and Social Council. Document E/C.12/GC/17 (12/Jan/2006). Available from: http://www.refworld.org/docid/441543594.html Consulted 8/Feb/2017

[5] Item 14 of the comments of the Council referring to Article 15 of the ICESC as follows:

"The Committee observes that, by recognizing the right of everyone to "benefit from the protection" of the moral and material interests resulting from one's scientific, literary or artistic productions, article 15, paragraph 1 (c), by no means prevents State parties from adopting higher protection standards in international treaties on the protection of the moral and material interests of authors or in their domestic laws,[11] provided that these standards do not unjustifiably limit the enjoyment by others of their rights under the Covenant.[12]"

The Panel also ignores the role that intellectual property rights can play in encouraging investments and innovation in health technologies in developing countries**.** In the last 10 years, countries that have entered free trade agreements, have generated a significant number of patents related to medical technology, biotechnology and pharmaceuticals.

Mexico is one of the most active countries regarding commercial treaties under WTO, and has implemented some of the "TRIPS-plus" provisions criticized in the Report.

Patents covering marketed drugs in Mexico are published in the Special Gazette for Drug Patents issued by the Mexican Institute of Industrial Property. The Gazette currently lists 724 granted patents, or which 24 patents are owned by Mexican entities. All of the Mexican owned patents correspond to incremental innovation. Locally, this means that Mexican citizens have access to formulations of drugs that have been developed by local companies. Furthermore, the mere existence of the patents from R&D centers in Mexico gives the possibility of reaching out to companies that, through licensing, might be able to introduce these innovations into the national market.

Finally, the Report assumes that health care innovation is always pursued by big corporations. No references are made as to how independent or smaller inventors and institutions can benefit from the patent system, and how patents can in fact empower governments and weaker institutions such as universities, R&D centers and small companies in developing countries to improve quality and access to health to their own population.

f. Conclusion

AIPPI considers that patents have shown to be a tool for fostering innovation, precisely because they are an incentive to develop new treatments and drugs. As outlined in this Position Paper, a strategy of fair use of intellectual property rights can also solve some of the issues identified in the report of the High Level Panel. AIPPI urges UN policy makers and the UN leadership to better take into account the role of intellectual property in encouraging innovation in medicine, and to consider the findings of other international organizations, such as the World Intellectual Property Organization (WIPO), which is the UN agency with intellectual property expertise, and the World Trade Organization.

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