

Standing Committee on the Law of Patents

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PATENTS AND HEALTH: PROPOSAL BY THE DELEGATION OF THE UNITED STATES OF AMERICA

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1. The Annex to this document contains a proposal submitted by the Delegation of the United States of America concerning patents and health, for consideration under item 7 of the revised draft agenda: Patents and Health.

2. *The members of the Standing Committee on the Law of Patents (SCP) are invited to consider the contents of the Annex.*

[Annex follows]

PROPOSAL OF THE UNITED STATES OF AMERICA ON THE TOPIC OF PATENTS AND HEALTH

BACKGROUND

In the 16th Session of the Standing Committee for the Law of Patents (SCP), South Africa on behalf of the African Group introduced a proposal on the topic of Patents and Health (SCP/16/7). This is a topic of great importance and interest to the USPTO, because the United States continues to be a global leader in promoting global availability of medicines. As part of this policy, President Obama announced the Administration's Global Health Initiative (GHI), in May 2009, which embodies the core tenets of the US development policy. In the spirit of these initiatives, the USPTO is pleased to contribute to the discussion.

Some of the public health issues facing developing and least developed countries (DC/LDCs) include neglected diseases, the spread of TB, malaria and HIV/AIDS, and availability of medicines to treat these and other ailments. None of these issues can be solved by IPR flexibilities alone and in particular cannot be solved by the wholesale use of compulsory licensing. To the contrary, the lack of effective patent protection is one factor which prevents the appropriate medicines from reaching the neediest patients in DC and LDCs.

Weakening the patent rights granted to pharmaceutical researchers and manufacturers in certain markets not only removes or reduces the incentive to develop new medicines, but also leads manufacturers to keep already developed medicines out of those markets. It has been shown that more goods become available in developing countries when IP rights are strengthened there¹. In the particular case of medicines, it has been shown that all else being equal, a new drug is more likely to be launched in a country where patent protection is strong, rather than one where such protection is lacking².

To successfully employ a technology such as manufacturing of medicines, know-how and specialized skills are often required in addition to the detailed disclosure found, for example, in a patent. Resorting to a compulsory license or other non-voluntary mechanism would not gain the cooperation of the patent owner, and the recipient of the compulsory license may not easily be able to successfully manufacture the medicine. The recipient would also not have access to other products such as medicines not yet approved, improvements, and other benefits that may be part of a negotiated license.

DISCUSSION

Weakening patent protection for innovative medicines is not a productive approach to improving availability of health care, because many other factors other than patents more directly affect the availability of medicines. It is known that patent protection has expired or was never sought for the vast majority of medicines on the WHO's List of Essential Medicines. As stated by the WHO³, in many countries, especially LDCs, there is no evidence of patent activity for medicines added to the EML, and for those countries where patents have been identified, the patents may not be valid, may be expired or may not be relevant. In fact, only about 4% of the medicines on the EML are presently protected by patents.

¹ "Intellectual Property Rights and Developing Countries: Theory and Evidence", Lee Branstetter, Carnegie Mellon University & NBER.

² "Diffusion of New Drugs in the Post-TRIPS Era", Ernst Berndt et al., *Int. J. of the Economics of Business*, Vol. 18, No. 2, July 2011, pp.203-224.

³ "The patent status of medicines on the WHO model list of essential medicines", Richard Laing, WHO/WTO/WIPO Technical Symposium, February 2011.

Many of the medicines on the EML once were protected by patents and were originally developed in large part due to the protection afforded to their developers by the patent system. This fact further highlights the large volume of important medicines that were developed under intellectual property protections and that subsequently became available from other manufacturers upon the expiration of the relevant patents.

Although most medicines on the EML are not protected by patents⁴, their availability in many markets is limited. This is particularly true in DC/LDCs. Therefore, it is apparent that other factors external to patent protection are at play in limiting the availability of these medicines. A complete assessment of the topic of patents and health must therefore also consider these other factors outside of the patent system that affect the availability of medicines. This is a necessary step which will help to properly quantify the impact of patents on the availability of medicines in specific DC/LDC markets.

By analyzing the reasons why unpatented, medicines do not reach the intended patients, it is possible to determine what are the factors not related to patents that impede their availability. These factors would naturally affect the availability of all medicines.

In view of the limited impact of patent protection on the availability of essential medicines in DC and LDCs, and of the crucial role that patent protection has been shown to play in the development of new medicines and in fostering the availability of medicines in DC and LDCs, measures that weaken patent protection systems through greater use of flexibilities are not useful in securing better availability of medicines. Instead, the following approaches are preferable and more effective in providing better availability of medicines to those that desperately need them. These alternative approaches have been more successful in fostering the development of new medicines and delivering them to those in need.

EXAMPLES OF SUCH ALTERNATIVE APPROACHES

Voluntary licensing and funding schemes:

There have been several programs to develop voluntary licensing concepts to foster the development and distribution of medicines to the population of DC/LDCs. Examples of these programs include:

Patent Pools

An independent agency is formed to hold voluntary licenses on patents for drugs provided by pharmaceutical companies. It then sub-licenses the IP rights to low cost manufacturers for low or no royalties, as agreed, as long as they supply the drugs to LDCs and in some cases to DCs. The sub licensees may specify where the medicines are sold, and the prices being charged.

One of these agencies is the Medicines Patent Pool (MPP), established by the global health financing initiative UNITAID to stimulate innovation and improve availability of HIV medicines. It works by facilitating the voluntary sharing of IP by patent holders through the negotiation of voluntary licenses. The US National Institutes of Health (NIH) and Gilead Sciences are the first participants that have agreed to license some of their patents. Under this program, Gilead Sciences has granted licenses to generic manufacturers to make medicines for the treatment of HIV and Hepatitis B. Additional companies interested in producing generic versions of Gilead Sciences' medicines can contact MPP for licensing information.

⁴ "How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries? Poverty, not patent policies, more often inhibits access to essential medicines in the developing world", Attaran Amir, Health Affairs, Volume 23, Number 3 (2004).

Re:search consortium at WIPO for neglected diseases

Provides a platform where access to medicines and associated intellectual property is offered on a royalty-free basis for the purpose of developing treatments for neglected tropical diseases. So far the consortium includes universities, governmental bodies including the USPTO and several private companies, such as Alnylam, AstraZeneca, Eisai, GSK, Merck, Novartis and Pfizer.

Global Funding

These are pools of money contributed by private donors and by national governments targeted to specific diseases. The funds are not only used for disease prevention and treatment, but also to provide incentives for the creation of new drugs and vaccines to treat neglected diseases. These have been used, for example, to fight AIDS, malaria and TB in DC/LDCs.

Advanced Market Commitments

These are promises by donors, given in advance of a medicine development process, to purchase a particular quantity of drugs or vaccines at a particular price. The donors may include governments, private interests, non-profit organizations and the pharmaceutical industry. One example includes the development of a new pneumococcal vaccine that was successfully developed as a result of an AMC co-led by the World Bank and the Global Alliance for Vaccine and Immunization.

Glaxco Smithkline malaria vaccine partnership

Anti-malaria medicines are offered at no-profit prices in 63 of the poorest countries. Working with the PATH Malaria Vaccine Initiative (funded by the Bill & Melinda Gates Foundation) to develop a new malaria vaccine, together with NYU, Walter Reed and University of Barcelona Medical Center.

Access Program

Gilead Sciences operates the Access Program, which provides non-exclusive license agreements with several Indian manufacturers to produce and sell high quality, low cost versions of Gilead's medicines. The agreement covers also pipeline products, which have not yet received product approval. In addition to the license to the patents, under the Access Program Gilead Sciences provides a complete technology transfer of the manufacturing process.

Tiered Pricing

This system has been in place for some time, and has been successful in providing lower cost medicines to the poorest countries. Under the system, the price charged for medicines relates to the ability of the patients in those countries to pay. Prices for the wealthiest nations are based on the product's full value, while substantial discounts are voluntarily offered to low-income and lower middle-income nations, as determined from the country's economic status.

Efficient Regulatory Review

Determination that a medicine is safe and effective, and manufactured according to good manufacturing practice is an important public service to ensure that the medicines available within a market are safe and effective. This review process, however, can delay the availability of safe and effective public health products.

Enforcement

The US supports efforts to curb trade in falsified and other substandard medicines. Available evidence suggests that falsified and other substandard medicines, meaning those that are not approved under a regulatory system as being safe and effective, are most prevalent in countries which have weak regulatory and enforcement frameworks.

Falsified and other substandard medicines are a dangerous public health risk because these products may have no active ingredients or the wrong dosage of active ingredients and very often include contaminants. Falsified and other substandard medicines are ineffective in treating a patient's disease and may in fact make the patient sicker. In addition, in reaction to medicines that contains too little active ingredient, pathogens causing some diseases, such as tuberculosis, may mutate and become drug resistant resulting in widespread public health risks.

The proliferation of falsified and other substandard medicines interferes with availability of genuine medicines (both patented and generic) because a patient is very often fooled into taking the fake medicine. Some sellers pretend that the medicines they sell have been approved by a local regulatory agency as being safe and effective. In reality, they have not. There is no way to know whether these products are adequate or not. This problem applies to generic as well as branded medicines.

The U.S. supports measures to strengthen regulatory and enforcement frameworks around the world to combat this growing problem that disproportionately impacts patients in DCs and LDCs. The proposed SCP work program should therefore address to what extent the presence in a market of falsified medicines hinders the availability of genuine medicines, both generic and patented.

STUDIES

A comprehensive study on the impact of patent protection in promoting the development of lifesaving medicines would be helpful in understanding the causes of the problem. This study would look at the role of patent protection in providing incentives for research and development required to produce innovative medicines and to make them available to patients.

Another study to inform the decision making of the SCP, would consider the many factors affecting availability of medicines that are not related to the patent system. These factors may include a lack of basic infrastructure, trade barriers such as taxes and tariffs on medicines, discriminatory and non-transparent regulatory regimes, procurement inefficiencies, and the proliferation of falsified and substandard medicines. By studying the availability of unpatented medicines, and by analyzing the reasons why they do not reach the intended patients, it will be possible to determine what are the factors not related to patents that impede the availability of medicines, and thus estimate the potential effect of licensing practices, including compulsory licensing.

PROPOSAL

The United States considers global availability of medicines an extremely important topic. To contribute to the discussion initiated by the paper on Patents and Health, the United States proposes the following elements of a work program for consideration by the member states of the SCP.

- (1) Inviting the WHO to make a presentation to the SCP on the availability of generic medicines in DC/LDCs, on the non-patent barriers to availability of safe and effective medicines that are encountered in many countries, and on the effect of falsified medicines,

both generic and patented, on the availability of proper medicines. This presentation would help to put in context the potential effect of patents, as compared to the effect of other factors, on the availability of medicines.

- (2) Conducting a comprehensive study on the positive impact of patent systems in providing lifesaving medicines to developing countries. The study would evaluate the role of patent protection in providing incentives for research and development leading to innovative medicines, and in fostering the technology transfer necessary to make generic and patented medicines available in DC/LDCs.
- (3) Conducting a comprehensive study to examine the availability of lifesaving medicines that are not protected by patents, and the reasons for their lack of availability. Determining what are the many factors affecting availability of medicines that are unrelated to patents will help to distill the effect, if any, of patents on the availability of medicines. An important factor to be reviewed in this element of the study is the effect of falsified medicines, which circumvent any regulatory and enforcement regime set up to ensure the safety of those medicines. The availability of safe and effective medicines is a multifaceted problem, which impinges on many areas of law, national policy, physical infrastructure, social, education and economic factors, to name only a few. Informed analysis on how the patent system may or may not affect the availability of medicines is only possible with an understanding of these additional factors that affect the problem. The SCP would not be expected to take action on these non-patent issues, which are not within its mandate, but would benefit from an understanding of where its action fits within the broader range of factors influencing access to medicines.

[End of Annex and of document]