MERCOSUR SEMINAR ON PATENTABILITY GUIDELINES FOR PHARMACEUTICALS
14 and 15 of june 2007

Organized by ICTSD, WHO, UBA, Ford Foundation and UNDP

Buenos Aires

FINAL NARRATIVE REPORT

I. The Context

Growing concerns over the way that international trade agreements and, particularly, the WTO TRIPS Agreement, can restrict access to medicines led to the adoption of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health. The Declaration marked an important milestone in the debate on intellectual property rights and access to medicines, in affirming that the TRIPS Agreement should be interpreted and implemented in a manner supportive of countries' right to take measures to protect public health and promote access to medicines. In this regard, the Declaration enshrines the principles that agencies, such as WHO and UNDP, have publicly advocated and advanced, namely, the re-affirmation of the right of WTO Members to make full use of the flexibilities of the TRIPS Agreement in order to protect public health and promote access to medicines. An important flexibility in this respect is the right of WTO Members to define patentability criteria in accordance with their particular national priorities. This may be an important tool for the promotion of genuinely new and inventive pharmaceutical products.

A common belief is that patents are normally granted to protect new medicines, but while the number of patents annually obtained to protect genuinely new pharmaceutical products is small and declining, thousands of patents are granted for pharmaceuticals. A large number of patents cover minor modifications of older existing drugs.[1] According to a report of the National Institute for Health Care Management in the United States, in the 12-years period 1989-2000, just 153 (15%) of all new drug approvals were medicines providing a significant clinical improvement[2].

The cumulative nature of innovation, as well as low standards of patentability and weaknesses in patent procedures has important repercussions on the patent system. That is, they limit the diffusion of innovations it is intended to promote and reduce access to vital medicines.

[1] See Correa (2004).
[2] National Institute for Health Care Management (2002).

"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[3]."

In order to develop normative frameworks for patent protection for pharmaceuticals that ensure a balance between the interests of the patent holders and the users of technology (as required by Articles 7 and 8 of the TRIPS Agreement) and to improve transparency, quality and efficiency of the patent examination process for pharmaceuticals, particularly for MERCOSUR countries, **ICTSD, WHO, UBA, Ford Foundation and UNDP** have joined efforts in the production of a set of draft patentability guidelines and the organization of joint seminar in Buenos Aires for local stakeholders in 2007.

This event was titled "***Mercosur Seminar on patentability guidelines***" and was held in Buenos Aires on the 14 and 15 of June 2007. The seminar gathered about 30 stakeholders from the region that activity engage and participate in the discussions.

This document seeks to provide a final narrative report for the activity mentioned above. For this purpose, it will introduce the main issued dealt and the main outcomes of the meeting. The agenda and list of participants can be found at:
http://www.iprsonline.org/ictsd/Dialogues/2007-06-14/2007-06-14_desc-es.htm

II. Discussions during the dialogue

The seminar was initiated with a general introduction on the current trends in the patenting of pharmaceutical products. It was mentioned that the pharmaceutical industry is one of the main users of the patent system today. One trend that called the participants attention, was the fact that while the there is a decreasing number of new chemical entities being approved each year, there is an increasing number of patent applications to protect small variations of existing chemical entities. Many of these variations are the consequence of changes in manufacturing practices, in the form of administration to patients or to second uses of existing drugs.

Patents grant exclusive rights over the production, sale, offer to sale, use of the patentable subject matter (invention). They can be used to limit competition and fix prices above the production costs. This situation is usually justified by the need to ensure sustainable investment in research and development for the production of new drugs. Nevertheless, in practice many markets were undersupplied and in many cases the prices were unaffordable for most of the population, especially in developing countries.

Due to the potential and actual negative effects that patents, especially low quality ones, can have over competition and prices, policies and criteria for the granting and examination of pharmaceutical patents are of extreme importance for public health policies.

At the beginning of the dialogue the document ***"Patentability Guidelines for the Examination for Pharmaceutical Patents"*** [4] **produced by WHO, ICTSD and UNCTAD** was presented to participants. The objective of the document was to provide a tool to improve the transparency, quality and efficiency of patent examinations in developing countries by intellectual property offices and sanitary authorities in developing countries. The guidelines presented constituted in the opinion of the organizers a "living document" that could be revised and adapted to the particular conditions of MERCOSUR countries.

[3] See Barton (2004).
[4] The guidelines can be found at:
http://www.iprsonline.org/resources/docs/Correa_Patentability%20Guidelines.pdf

The agenda of the event followed the content of the guidelines. The main issues discussed included the following:

- Built-in flexibilities in the TRIPS Agreement on patentability criteria
- The particularities of pharmaceutical innovation and patentability
- Cases where other authorities different that the IP offices have competence in patentability examination
- Particular cases where the patentability criteria can or cannot be fulfilled from a public health perspective

Most of participants understood the wide scope that the TRIPS Agreement gives in relation to the definition of patentability criteria. Nevertheless, participants acknowledge that in certain cases the application of the patentability criteria was too loose and too generous toward very small or inexistent innovations. It was mentioned that national legislation, along with administrative guidelines and examination practices, were the main sources for defining novelty, inventive step and industrial application. In many cases such administrative guidelines and principles followed the experience of industrialized countries and not the local conditions and lacked of a public health perspective

With regard to novelty criterion, cases of previously disclosed inventions in the pharmaceutical field were discussed. In the case of the inventive steps, it was critical to determine whether the level of technical contribution by a particular "pharmaceutical innovation" was such that it would deserve patentability and offset the potential negative effects that particular patents could produce over competition. When discussing the industrial application criteria, it was underlined that the existence of a "viable technical solution" was the most adequate standard due to the empirical nature of chemistry and biosciences.

It was mention that the most of the research today focuses more on variations and not on the development of new chemical entities. Currently, most patents are protecting minor variations, in many cases obvious derivations of existing active ingredients. These variations presented a challenge for patent offices in determining when exactly a particular variation fulfilled the patentability criteria and deserved patent protection.

The level of participation and role of the sanitary authorities in patentability examination has increased in the last years as a consequence of the IP and public health debate locally and internationally. In the experience of some particular countries in Latin America and more precisely, the case of Brazil, Bolivia and Paraguay, the patentability examination was not only left to patent offices, but sanitary authorities have a bearing on the determination of the patentability. Coordination among different authorities during patent examination processes has proven to occur with a high extent of consensus and fluidity. Nevertheless it was pointed out that in some cases divergent views where held and mechanisms to determine the final practice in such cases still was in the process of adjustment. In some cases where no consensus was reach, some delays in patent granting could take place.

After these initial items for discussion were addressed, the participants approached specific cases where the patentability determination of minor variations was controversial. They included the following:

- Formulations and compositions
- Combinations
- Dosage /dose
- The case of salts, ethers and esters
- Polymorphs
- Complex and multiple claims

- Patent selection
- Analogy processes
- Active metabolites and pro drugs
- Second indications

The debate over these variations was technical and supported by pharmaceutical and scientific experts. It was considered that in most cases these variations did not fulfill the patentability criteria unless, and depending on the particular case, exceptional situations occurred, such as truly unexpected or surprising effect (for instance, when a difficult problem has been solved or a noticeable reduction of side effects has been achieved), a significant improvement in the production process, a high cost reduction, or a tremendous advantage for the state of the art is achieved.

Finally, the participants discussed possible administrative mechanisms to improve patent quality including pre and post granting opposition, the relationship with sanitary authorities, and clear examination rules as to provide certainty for examiners, applicants, sanitary authorities and other interested stakeholders. While some of these mechanism existed in the national and sub regional legislation, experience on their use is still incipient. Some participants expressed the need for capacity building to facilitate their use by stakeholders in the region.

III. Outcomes of the seminar

The main outcomes of the seminar were the following:

1. It established a platform for a regional discussion over the particularities of the examination of pharmaceutical patents under a public health perspective;
2. It facilitated comments to the patentability guidelines by relevant authorities in the region. This will facilitate their review and adaptation to the regional context and potential for the preparation of national and regional guidelines;
3. It generated better understanding on possible options for national implementation, especially for MERCOSUR countries and national examiners and sanitary authorities;
4. Participant considered the seminar a very timely and useful exercise and recommended its replication in the context of other countries in the continent such as in Central America and the Caribbean.