



Patents and Health: Submission by the Medicines Patent Pool to the Standing Committee on the Law of Patents

At the Sixteenth Session of the Standing Committee on the Law of Patents, under the Agenda item on "Patents and Health", it was agreed that Member States and Observers would be invited to submit any comments to the Committee by February 28, 2012.¹ The present submission responds to that invitation and provides the perspective of the Medicines Patent Pool ("The Pool") on the issues being discussed under that agenda item, with a specific focus on HIV/AIDS.

Patenting of HIV Medicines in Developing Countries

One of the issues raised by WIPO Member States during the discussion on "Patents and Health" is the extent to which needed medicines are patented in developing countries and the impact of such patents on access to medicines. Since its establishment in 2010, the Pool has made considerable efforts to collect up-to-date patent information on HIV medicines to have a clear picture of what is patented where.

The data gathered by the Pool, with the collaboration of WIPO and many national and regional patent offices, has been published in the Patent Status Database on Selected HIV Medicines, available on the Pool's website.² The data shows that many HIV medicines have been widely patented in developing countries. Patents have been granted on the drug compounds, on new forms of drug compounds, on new formulations (such as formulations appropriate for children), on manufacturing processes and on combinations of several drugs into one pill.³ Many patent applications are also pending in many developing country jurisdictions and may be granted sometime in the future.

Data gathered by the Pool also shows an increase in the number of developing countries in which newer medicines for the treatment of HIV are patented. While patents for many of the older compounds have expired in many jurisdictions, or were never filed or granted, newer HIV medicines are more widely patented, including in countries where generic manufacturers for HIV medicines are based. Examples of such medicines are etravirine, raltegravir, rilpivirine and several investigational drugs. This is likely due to changes in national patent laws in many countries following the entry into force of the TRIPS Agreement, as well as to changing patenting practices of applicants.⁴

¹ See document SCP/16/7

² <http://www.medicinespatentpool.org/LICENSING/Patent-Status-of-ARVs>

³ It is important to note that combinations of various products into a single pill (known as "fixed dose combinations" or FDCs) are particularly important for the treatment of HIV and a large number of patents on FDCs have been granted or are pending in many developing countries.

⁴ A detailed analysis of the patent status of different HIV medicines in developing countries is available in the working paper "ARV Priority List for the Medicines Patent Pool" available at <http://www.medicinespatentpool.org/WHAT-WE-DO/Target-Medicines>

Among the medicines for HIV that are included in the WHO Model List of Essential Medicines (widely referred to as the EML)¹, some are patented in several developing country jurisdictions.² In addition, there are medicines that have so far not been included in the EML that are also patented or for which patent applications are pending, including those currently recommended by the WHO as part of a third-line regimen for the treatment of HIV.³

The patent landscape report undertaken by WIPO on key HIV medicine ritonavir confirms the trend of widespread patenting of ARVs in developing countries.⁴ It identified 805 patent families claiming ritonavir, many of which are either pending or granted in some developing countries. The landscape also noted that at least 400 such patents were on combinations of ritonavir with other compounds.

The changing patent landscape for HIV medicines is at the heart of the decision taken by UNITAID to support the establishment of the Medicines Patent Pool in 2010, an initiative mentioned by a number of delegations during the discussions on "Patents and Health" in the Committee. The Pool's mandate is to negotiate public-health-oriented voluntary licences with a view to enhancing access to patented HIV medicines and promoting the development of fixed-dose combinations and adapted formulations for the treatment of HIV.⁵ As a mechanism to enhance innovation and access, it must be seen as complementary to other mechanisms and initiatives that are being discussed by the Committee, including the use of flexibilities available under international agreements on intellectual property. Its success depends on the voluntary participation of patent holders that need to be willing to agree to licences that meet the public health needs of developing countries.

Patent Status Databases

One of the proposals being discussed

by the Committee concerns the development of patent status databases for diagnostic tools and medicines in relation to ten diseases.⁶ This is an area in which the Pool has some experience that may be of interest to the Committee.

In April 2011, the Pool published its patent status database on HIV medicines. It covers 24 compounds and approximately 69 developing countries. Obtaining accurate, up-to-date patent status data in many developing countries is often a difficult task as such information is not readily available from public databases. The Pool, therefore, initially worked on identifying the most important patents relating to 23 antiretroviral products (subsequently expanded to 24) and then

¹ According to the WHO, "Essential medicines are those that satisfy the priority health needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness"

² Examples include atazanavir, efavirenz, lopinavir, ritonavir and tenofovir disoproxil fumarate.

³ These include darunavir, etravirine and raltegravir.

⁴ See WIPO, *Patent Landscape Report on Ritonavir*, 2011.

⁵ Since its establishment in 2010, the Pool has signed agreements with two patent holders and is currently in negotiations with five others. The agreements have been published on the website of the Medicines Patent Pool.

⁶ Paragraph 10, document SCP/16/7

collaborated with WIPO and national and regional patent offices to obtain patent status information on those patents. The database is periodically updated with information obtained from the relevant patent offices. Also, as new HIV medicines are developed, they too are added to the database.

The Pool's database is limited to one disease: HIV; and to one type of medical technology: antiretroviral medicines. It only includes those patents considered to be most important in relation to each medicine. Its geographical coverage is gradually expanding, as data is obtained from more patent offices or other sources.⁷ But despite its limitations, it has proven that with the collaboration of patent offices, this kind of database is not only feasible, but also extremely useful. The database is being used today by a wide range of actors in the public health field including UN agencies, donor agencies, civil society institutions and many others. Initiatives of this kind can play an important role in enhancing the transparency of the patent system and are of great importance for public health actors around the world.

Geneva, 28 February 2012.

⁷ The most recent additions to the database are Mongolia and Pakistan.