KEI submission to the WIPO Standing Committee on the Law of Patents (SCP) on Patents and Health

28 February 2012

During the 16th Session of the Standing Committee for the Law of Patents (SCP), South Africa, on behalf of the Africa Group and Development Agenda Group (DAG), introduced a proposal on the topic of Patents and Health (SCP/16/7). In response, the United States submitted its own proposal (SCP/17/11) during the 17th session which took place from 5-9 December 2011. KEI affirms our support for African Group/DAG proposal, which we have described in our submission to the SCP on 12 September 2011.[1] KEI also expresses concern regarding the attempts by the United States government to minimize the challenges and barriers for patient access created by patents on medical technologies.

Proposals before SCP should be placed in the context of existing international instruments that lay out commitments and obligations. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) set an important global norm for intellectual property protection. After the TRIPS came into effect, subsequent international commitments have been made with respect to public health that are also important.

The Doha Declaration on the TRIPS Agreement and Public Health (referred to here as the Doha Declaration) 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." Similarly, the World Health Organization Global Strategy and plan of action on public health, innovation and intellectual property, adopted in 2008, calls upon member states to promote access to medicines for all (para 15.e).

The United States proposal says that studies and presentations are needed with regard to non-patent barriers, and wants to document the positive impact of the patent system and the factors affecting access to medicines that are not related to patents to determine "the effect, if any, of patents on the availability of medicines." That the patent system provides for monopoly rights over life-saving medicines, and such monopolies lead to high prices is well-known and extensively documented. By calling on the SCP to focus only on exculpatory evidence that paints a rosy picture for a system of strong patent rights, the United States is seeking to undermine the attention given to implementing the changes that are necessary to achieve "access to medicine for all."

The World Health Organization Essential Medicine List (EML)

To support its proposal, the United States notes that only four percent of medicines on the WHO List of Essential Medicines (EML) are currently protected by patents, and implies that the paucity of patented drugs on the WHO list is evidence that patents on drugs are not important for patients. The comments on the EML illustrate at best that the U.S government is poorly informed about the access to medicines issue. Outside of drugs for HIV/AIDS, which were only added to the EML after extensive campaigning by AIDS activists, there are almost no patented drugs on the EML. But why is this? Does the U.S. Government claim that there are not patented medicines that poor

1 http://keionline.org/node/1260

people living in developing countries would use if they were affordable? Consider a few data points on cancer drugs.

In 2011, Paul Miano examined 100 cancer drugs considered important by the US NIH. *See* Cancer: Approval, ownership, market structure, and placement on WHO Model Essential Medicines List, for 100 new molecular entities (NMEs) on the NCI alpha list of cancer drugs and vaccines, KEI Research Note 2011:1.

According to Miano, of the 100 important cancer drugs, more than half were first registered for sale by the US FDA after January 2000, and about two thirds of the drugs were sole source products, suggesting they were protected from competition by patents or other intellectual property rights. If someone who worked on the United States submission was diagnosed with cancer, or one of their loved ones was diagnosed with cancer, would they want to have access to all of the drugs on that list, or only one third of the drugs?

In the 2011 WHO Model EML, there were zero cancer drugs on the main list, and 20 products on the complementary list. The newest product on the WHO EML that was among the NIH 100 most important products, was registered by the FDA in 1996, and all of the EML cancer products were off patent. To suggest that no patented cancer drugs are "essential" is to say either than the lives of poor people who have cancer are not essential, or that the products were just too expensive to justify their use in resource poor settings. But when the products go off patent, they often find themselves on the list. What the US is saying is that poor people can wait until patents expire before having access. For many patients with cancer, that means dying.

If the United States was more broadly consulting with health groups, it would never have made claims in the WIPO SCP submission that the paucity of patented drugs on the EML is evidence for anything other than the fact that patents make drugs too expensive. The fact that there are not patented cancer drugs on the EML does not mean that poor people do not get cancer or that the new drugs do not work. It means the patents drive the prices up so high that poor people do not get them.

In other parts of its filing, the United States compulsory licenses on patents will not "gain the cooperation of the patent owner" and the party receiving the compulsory license "may not be able to successfully manufacture the medicine." This is certainly true as stated, but everything in the statement also applies to the facts when patents expire. In both cases, there is the legal freedom to manufacture generic versions, and compete. There is certainly ample evidence that the elimination of legal barriers is an effective way to promote competition and lower prices. This is certainly true the United States where, according to the GphA, 10,072 of the 12,751 drugs listed in the FDA's Orange Book have generic counterparts, and generic medicines account for 69 percent of all prescriptions, but only 16 percent of outlays on prescription drugs. The United States might ask how many of the cancer drugs on the NIH list of 100 important cancer drugs are available from generic suppliers, and ask what needs to be done to expand that number, rather than to suggest that generic sources are impossible.

Questions that could be asked about the EML

If the WIPO SCP examines the WHO EML, there are many different directions that are possible for such a review. For example, one could ask these questions:

1. How many persons living with HIV/AIDS died in developing countries before the WHO agreed to put patented AIDS drugs on the EML?

2. What would the WHO EML look like if there was a new category for for "product that are cost effective if available from generic suppliers?"

3. What percent of women with HER2+ breast cancer have access to Herceptin in developing countries?

4. What percent of women with HER2+ breast cancer have access to Herceptin in high income countries?

5. How many developing countries have sufficient medical infrastructure to provide Herceptin to women with HER2+ breast cancer, if the product was available at lower biogeneric prices?

6. Would Herceptin be on a WHO EML if the price was much lower?

7. Should the WHO provide pre-qualification for generic and biosimiliar cancer drugs?

Additional Issues

Countries have the sovereign right to grant TRIPS-compliant compulsory licenses and the Doha Declaration on TRIPS and Public Health explicitly affirmed that member states have the "right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[2]

It should be noted that the United States has issued several judicial compulsory licenses in the years since the Supreme Court held in *eBay v. MercExchange*, 547 U.S. 388 (2006) that permanent injunctions do not automatically issue in cases where patent infringement occurs. In subsequent case law with respect to patent infringement of medical devices or inventions, courts have denied injunctive relief and granted monetary damages and royalties instead.

Judicially imposed compulsory licenses issued in the United States concern the denial of injunctions as a remedy to patent infringement. In 2011 these cases have included denials of injunctions on a patent used for manufacturing and exporting a medical device to treat aortic stenosis[3] and for contact lenses.[4] Several other cases following the *eBay v. MercExchange* case have also resulted in the denial of a permanent injunction of medical patents including for an angioplasty guide catheter,

2 WT/MIN(01)/DEC/2, Declaration on the TRIPS agreement and public health (Nov. 14, 2001), http://www.wto.org/english/thewto_e/minist_e/min01_e/mindeel_trips_e.htm

3 James Love, The CoreValve compulsory license on patent to treat aortic stenosis, (Sept. 1, 2011), http://keionline.org/node/1218

4 Anne Mira Guha, *The Johnson & Johnson Acuvue Compulsory License* (Sept. 1, 2011), http://keionline.org/node/1219

method of genotyping the hepatitis C virus, a prosthetic vascular graft, and patents related to devices and methods used by spinal surgeons.[5] Although the United States has issued its own compulsory licenses, it appears to discourage other countries considering such options.

We refer back to our comments on the African Group/DAG proposal and reaffirm our support for the request to organize a technical workshop on the practices of issuing compulsory licensing of medical technologies:

> We note that technical assistance experts often fail to distinguish between compulsory licenses that are granted under the procedures of Part II of the TRIPS, concerning patent rights, and those granted under Part III of the TRIPS, concerning the remedies for infringement of those rights. For example, the most commonly used mechanisms for obtaining a compulsory license in the United States are those associated with Part III of the TRIPS, including in particular Article 44 of the TRIPS. Under the structure of the TRIPS agreement, Article 44 compulsory licenses are not subject to the restrictions that exist for Article 30 and 31 of the TRIPS, an issue not explored in the experts reports. Consequently, we support the African Group/DAG request for the International Bureau of the World Intellectual Property Organization (WIPO) to "Organize a technical workshop on state practice involving the compulsory licensing of medical technologies, including the application of TRIPS Articles 30, 31 and 44.

The United States proposal appears to minimize the barriers created by patents, and presents a variety of humanitarian AIDS programs and voluntary actions as a substitute for government policies that guarantee access. The US proposal echoes the views of the large pharmaceutical companies and ignores the views of the public health, development and consumer groups working on the access to medicines issues. KEI is extremely disappointed that the United States government would make such a submission to the SCP.

Additionally, although the United States notes its concern regarding non-patent barriers to access to medicines, it ignores those non-patent mechanisms that give additional rights to right-holders. For example, the United States proposal does not take into account exclusive rights over test data, a practice that effectively extends monopoly power over medicines.

The United States proposal does not address the justification for or consequences of its efforts to change global norms on intellectual property outside of multilateral institutions such as WIPO and the WTO. The United States has asked smaller market country to trade preferential market access for higher levels of patent protection and enforcement than are required under international obligations. The most recent example is the secret negotiation for a Trans-Pacific Partnership Agreement (TPPA). The United States also has an annual unilateral rating of countries for its annual Special 301 Report, often for not implementing intellectual property standards on pharmaceutical test data and patentability of medicines that go beyond the requirements of international agreements such as TRIPS, and which violate medical ethics and increase prices for medicines.

5 Anne Mira Guha, *U.S. Compulsory licensing of medical inventions as a limit on remdies under eBay v. MercExchange*, (June 7, 2010), http://keionline.org/node/862