The Medicines Patent Pool

Ellen 't Hoen

Author's biography

Ellen F.M. 't Hoen is a lawyer and an expert in intellectual property and medicines policy. From 1999 until 2009 she was Director of Policy and Advocacy of the Campaign for Access to Essential Medicines of Médecins Sans Frontières (MSF). She is currently the Senior Adviser Intellectual Property and Medicines Patent Pool at UNITAID.

She is the author of the book "The Global Politics of Pharmaceutical Monopoly Power. Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health," published in 2009.

Essay

The idea of a Medicines Patent Pool was born out of the need to formulate an effective response to a changed intellectual property (IP) environment and the crisis with respect to access to medicines in developing countries. Medicines are increasingly patented across the globe, including in developing countries, following the implementation of the 1994 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). In general, patented medicines are much more expensive than those that are not. Generic competition, the most effective means of lowering medicine prices, is not authorized while patents are in effect unless licenses can be obtained ('t Hoen, 2009).

Patent pools are collective management structures for patents and other forms of intellectual property to facilitate the availability of new technologies. The principle is to make IP more readily available to entities other than the patent holder through licenses that authorizes them to use the technology. Patent pools are intended to avert a "tragedy of the anti-commons" (Heller, 1998) in which people are unable to make use of knowledge because of the tangle of

property rights that block them. By making medicines patents more readily available to other manufacturers, a medicines patent pool should, among other benefits, enhance generic competition and bring the prices of medicines down.

UNITAID is establishing the first patent pool for HIV/AIDS medicines. GlaxoSmithKline (GSK) and Alnylam Pharmaceuticals have announced a patent pool for some neglected diseases. Patent pools have been successfully established in many fields of technology, including for Golden Rice in agriculture, for aircraft to facilitate US military efforts in the First World War, and multiple areas of information technology (Serafino, 2007). This essay explores the UNITAID-sponsored Medicines Patent Pool.

The History of Medicine Patent Pools

The idea of a patent pool for medicines is relatively new. It was discussed for the first time in 2002 during a presentation at the XIV International AIDS Conference in Barcelona by James Love of Knowledge Ecology International (KEI), then known as the Consumer Project on Technology. He proposed a non-voluntary patent pool for essential health technologies modeled after the US government effort in 1917 to create a pool for essential aircraft patents (Consumer Project on Technology, 2002).

In 2006, KEI and Médecins sans Frontières (MSF) approached the international medicine financing agency UNITAID, proposing that it introduce a patent pool for medicines to overcome patent barriers to access to and development of new AIDS medicines. While some older antiretroviral medicines (ARVs) have become increasingly affordable, newer, less toxic products are still too expensive to be made available in developing countries on a widespread basis. In addition key formulations and adapted treatments do not exist. UNITAID was seen as the appropriate actor to undertake this initiative as a patent pool would complement the other market-based mechanisms UNITAID uses to stimulate the availability of more appropriate and affordable AIDS, TB and malaria medicines, such as reliable financing and bulk purchasing power.

Since then patent pools have been recognized as an important tool to promote innovation and access to medicines by the broader global public health community. In May 2008, the World Health Organization (WHO) adopted a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property which mandated an examination of patent pools as possible new mechanisms to promote transfer of and access to key health-related technologies (World Health Organization, 2008).

The UNITAID board decided to work towards the establishment of a voluntary Medicines Patent Pool initially targeting ARVs in 2008. (UNITAID, 2008) The agency is scheduled to launch an independent Medicines Patent Pool Foundation in the second half of 2010 in Geneva, Switzerland (UNITAID, 2010).

How would the UNITAID Medicines Patent Pool work?

The idea behind the Medicines Patent Pool is that ARV patent holders - companies, governments, researchers or universities - voluntarily offer, under certain conditions, licenses to the patents related to their inventions to the patent pool. Any party that wants to use the technology to produce or develop medicines for use in developing countries could seek a license from the Pool against the payment of royalties to the patent holder. Producers that make use of the patents in the pool would need to meet agreed quality standards. The Pool will focus on HIV medicines initially, but in the future could expand to serve other diseases. The Medicines Patent Pool is designed to complement other access to medicines mechanisms, including TRIPS flexibilities like the compulsory licensing of patents and other tools available within national patent law regimes (UNITAID, November 2009).

Benefits of the Medicines Patent Pool

Without the Medicines Patent Pool, a generic drug manufacturer might need to obtain licenses from several different patent holders to be able to develop, produce, export and sell a fixed-dose combination (FDC), AIDS treatments that combine several pharmaceutical compounds into a single pill. A concrete example is an FDC of the new WHO-recommended first-line ARV for HIV/AIDS, which consists of tenofovir (Gilead), lamivudine (GlaxoSmithKline) and either

nevirapine (Boehringer-Ingelheim) or efavirenz (Merck). An FDC containing either one of these triple combinations currently does not exist or is in limited supply. Today, a generic manufacturer seeking voluntary licenses to produce both of these FDCs may have to obtain licenses from four different patent-holders. However, if all of the patents for these products are put into the Medicines Patent Pool, qualified generic manufacturers will only have to negotiate with a single entity, considerably decreasing transaction costs and risk. Thus, the Medicines Patent Pool will be a one-stop-shop for all parties involved – facilitating the legal and bureaucratic processes involved in obtaining voluntary licenses, reducing transaction costs and increasing access to the patent licences needed to make important medicines.

The Medicines Patent Pool will also help to speed up the availability of lower-priced, newer medicines because there will be no need to wait out the patent term (usually about 20 years), before price-lowering generic production can begin. For example, with increasing numbers of AIDS patients becoming resistant to first-line therapy, there is an urgent need to make the much-more expensive second-and third-line treatments they must switch to more affordable. Second-line regimens are priced between seven and seventeen times more, and possible third-line regimens costing 13 to 30 times more than the most affordable first-line regimen, which stands at about US$80 annually. (Médecins sans Frontières (MSF), 2010). If the relevant patents for these or other new products are put in the Pool, any qualified producer could obtain a license to manufacture and sell them in developing countries before the expiration of the patent term, in exchange for the payment of royalties. With licenses covering both low and middle-income countries, the geographical scope of the market would be attractively large, thereby encouraging multiple generic producers to come forward and obtain licenses. The greater the competition between producers, the more the price of ARVs should fall.

Another advantage of the Medicines Patent Pool is that it could stimulate the development of adapted products and formulations that target unmet needs of people in developing countries. Pharmaceutical research often does not deliver products adapted to meet these needs because of insufficient market incentives. (Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), 2006) Paediatric AIDS formulations are a particularly disturbing

example; of the 22 antiretroviral AIDS medicines approved by the US Food and Drug Administration and currently available, six are not approved for paediatric use and seven are not available in pediatric formulations. There are currently relatively few paediatric AIDS formulations because there are low numbers of HIV-positive children in high-income countries (MSF, 2010).

The central challenges facing the Medicines Patent Pool are connected to the voluntary nature of the initiative. Its success will largely depend on the willingness of patent holders to license their patents to the Pool, and generic pharmaceutical manufacturers to make use of the licenses. To date, several key patent holders and generic manufacturers have expressed interest in participating in the patent pool (UNITAID, November 2009). Formal negotiations on specific terms and conditions of the licenses will begin once the patent pool becomes operational.

Conclusion

The Medicines Patent Pool is a promising new approach to managing IP that can assist with the challenge of developing and delivering appropriate, affordable, well-adapted medicines to people in developing countries. If all concerned parties are willing to work with the Pool and make it a success, all stand to benefit. Patent holders will be compensated for the use of their technologies. Drugmakers will be able to obtain licenses more easily to produce and sell medicines at lower cost. Global public health providers, including donors and developing country governments, will be able to treat more people for the same amount of money. And, most important of all, patients in developing countries will get faster access to better, more affordable essential treatments.

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