Patent Pools: *Assessing Their Value-Added to Global Health*

Policy Brief

Today, infectious diseases such as HIV/AIDS, tuberculosis, malaria, and other highly neglected illnesses pose a huge public health problem globally. To combat these diseases, we need new and better drugs, and we need to make them more accessible to people in low and middle income countries. Currently, only a third of the people requiring treatment for HIV/AIDS are on anti-retroviral therapy. Malaria drugs are rapidly becoming ineffective because of resistance, and current TB treatments are slow, cumbersome to use, and often fail to cure the disease. For many of the most neglected tropical diseases like lymphatic filariasis and Chagas Disease, which cause poor people to lose millions of years to illness and premature deaths each year, there is still no drug available to fight the pathogens that cause these diseases.[1]

To help address this challenge, some policy researchers and global health advocates have argued that the existing intellectual property (IP) system is part of the problem, inhibiting innovation and reducing access to drugs for these diseases.

In response, several groups have proposed changes in IP rules and institutions, including the creation of various forms of joint IP management, known as ***patent pools***, to address these purported IP barriers. Two initiatives are now under way—the **Medicines Patent Pool (MPP)** and the **Pool for Open Innovation against Neglected Tropical Diseases (Pool for Open Innovation)**.

At the Center for Global Health R&D Policy Assessment, we have reviewed both patent pools and sought to answer the following question:

The Question

Do these patent pools actually address a serious barrier, and, as designed, are they likely to work in speeding the development of and access to new and affordable medicines in low and middle income countries?

Our Overall Answer

Yes, where the drug in question has a large market potential in rich countries and in high income segments of middle income countries; provided that the patent pool sponsors can induce a critical mass of patent holders and generic manufacturers to join.

No, where there is only a small market for the drug in question and most would-be product developers are fairly savvy about the landscape of existing patents and how to approach the companies holding the patents they need.

About the Medicines Patent Pool

The Medicines Patent Pool is an independent organization created in 2010 by UNITAID (an international facility that purchases drugs against HIV/AIDS, malaria, and tuberculosis) to negotiate the terms under which branded, and typically costly, HIV/AIDS medicines could be licensed to generic manufacturing companies and sold at lower cost in the developing world.

The MPP was established to address concerns that, without a patent pool, some existing and new AIDS drugs would begin to be patented in developing countries, making them too expensive for poor patients. This is because, starting in 2005, the current global accord on IP requires countries like India, which previously allowed its generic companies to copy drugs that were patented abroad, to begin to grant exclusive patents for medicines, including AIDS medicines. These patents can block generic production, leaving the multinational companies that hold the patents as the only sellers in the market and allowing them to charge higher prices for their products.

Although most of the AIDS drugs (anti-retrovirals or ARVs) in widespread use in low- and middle-income countries now are already off-patent, newer patented drugs will be needed as patients develop resistance to first-line drugs and as treatment programs move to newer, more effective products. High prices for these newer drugs would put a big strain on treatment resources.

[1] http://www.plosntds.org/article/info%3Adoi%2F10.1371%2Fjournal.pntd.0000114

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Furthermore, patents could inhibit the development of new formulations suited to conditions in low- and middle-income countries such as generic versions of fixed-dose combinations (FDCs), which combine several medicines in one pill and thus make it easier for patients to take their drugs, and ARVs for children.

As a mission-oriented third party, the plan behind the Medicines Patent Pool is to negotiate with pharma companies the licenses for a wide range of ARVs and then sub-license to generic manufacturers the right to make and market the ARVs in return for modest royalties to the patent holder. In theory, the MPP's advantage over the status quo would be its ability to:

- Obtain better terms from the patent holders (lower royalties, wider geographic scope of countries where the generic firms can sell the ARVs);
- Reduce transaction costs and increase transparency by acting as a one-stop licensing shop where generic firms can access sub-licenses to multiple drugs;
- Foster wider competition and lower prices by increasing the number of generic manufacturing companies having access to the sub-licenses; and
- Encourage the faster development of FDCs and pediatric formulations.

Our Findings on the MPP

The rationale for establishing the MPP is strong, since IP constitutes a significant barrier to access for some ARVs. More time is needed to judge whether the MPP is more effective and efficient than the status quo of direct voluntary licensing currently practiced by Gilead Sciences, Pfizer, GSK, and some other ARV makers. Recent MPP agreements with Gilead and three Indian generic manufacturing firms may suggest that momentum is building, but other pharma companies have said they will not join the patent pool or are still in extended discussions with the MPP. One strategy for the pool would be to focus on enlisting a critical mass of companies needed to make new FDCs for a select number of the most critically needed HIV/AIDS treatments currently recommended by the World Health Organization. Overall, we think the MPP is an idea that has merit and should be fully tested. We would like to see more companies join the pool, as Gilead has done.

About the Pool for Open Innovation against Neglected Tropical Diseases

The Pool for Open Innovation was established by GlaxoSmithKline (GSK) in February 2009 to motivate the discovery of novel drugs for neglected tropical diseases (NTD), by expanding access to IP. The pool targets the 16 NTDs identified by the U.S. Food and Drug Administration (FDA), such as African sleeping sickness and visceral leishmaniasis, which disproportionately affect low-income countries. In 2011, the Pool for Open Innovation was recast as WIPO Re:Search, led by several leading pharmaceutical companies, the World Intellectual Property Organization (WIPO), and BIO Ventures for Global Health.[2]

WIPO Re:Search is a searchable, open database of IP assets and resources intended to facilitate collaborations among organizations conducting research on treatments for NTDs. These organizations can be involved as a provider of knowledge, services, or patents, or as a user of these resources.

Our Findings on the Pool for Open Innovation

The Pool for Open Innovation (now WIPO Re:Search) is still in its early stages. For this reason, it is hard to evaluate its impact on drug discovery because the process normally takes several years or more. Based on extensive interviews and a review of other evidence, however, our analysis suggests that IP for NTDs, most of which have weak commercial markets, is not a serious barrier to the development of new drugs, vaccines, and other health technologies. Thus, the value-added of this patent pool in breaking down IP barriers may not be substantial.

The most useful purpose for the pool may instead be to aid in building partnerships between large and small companies and non-profit health technology organizations that might not occur otherwise. In order to better evaluate the pool, WIPO managers must set performance targets that can be monitored in the coming years, not only in terms of how many organizations participate or how many R&D collaborations are formed, but also by measuring whether meaningful exchanges of IP result in the development of new drugs, vaccines, and diagnostics against NTDs.

[2] http://www.wipo.int/pressroom/en/articles/2011/articles_0026.html

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