

The Medicines Patent Pool

Since the 1994 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), patent-based pharmaceutical monopolies have increasingly hindered global access to medicines. The 2001 Doha Declaration affirmed flexibilities of the TRIPS Agreement, such as the rights to issue compulsory licenses and implement laws with strict patentability standards, which allow developing countries to protect public health. However, too often complexities and the political power of the pharmaceutical industry impede the use of these flexibilities to improve access to medicines.

One mechanism to overcome patent access barriers is the Medicines Patent Pool (MPP). In December 2009, UNITAID created the MPP as a separate entity to focus on increasing access to HIV medicines in developing countries. The Pool's objective is to facilitate licensing agreements with patent holders and generic pharmaceutical manufacturers. Unlike state-based compulsory licenses or patent oppositions, MPP licenses can reach many countries at once, potentially changing the global access picture for a given drug.

When a patent holder licenses to the MPP, other pharmaceutical manufacturers can use the license to supply markets which previously had to endure monopoly pricing. Generic competition drives down the costs of medicines. With reduced prices, the end product is far more affordable than a monopoly-priced brand name drug, even with a royalty payment to the patent holder.

The Medicines Patent Pool can also facilitate innovation by acting as a one-stop shop for licensing on drugs to be used in new treatment cocktails. For example, Chicago-based Abbott Laboratories holds patents on ritonavir, a booster used to enhance the efficacy of protease inhibitor HIV treatments. If Abbott's patents on ritonavir were licensed to the MPP, other pharmaceutical companies would be able to develop fixed-dose combinations using low-cost ritonavir as a booster.

Thus far, the Medicines Patent Pool has reached two licensing agreements. In the first, the United States licensed its patents on darunavir royalty free for all low- and middle-income countries. We applaud the U.S. for taking this first step, but this license cannot authorize use of darunavir until Johnson & Johnson licenses its patents as well.

Gilead then licensed its patents on tenofovir (TDF), cobicistat (COBI), elvitegravir (EVG) and the Quad, a fixed-dose combination of TDF-COBI-EVG-emtricitabine. There were shortcomings in these licenses, including the limited geographic scope of the licenses which excluded many middle-income countries. Despite the limitations of these licenses, they represent an important step and improvement to the status quo.

The deficiencies of the Gilead licenses can be largely attributed to the insufficient bargaining clout of the MPP. For the utility of the Medicines Patent Pool to reach its full potential, civil society groups must continue to encourage their governments to utilize compulsory licensing. Countries should make use of compulsory licensing, both for patents which have not been licensed to the Pool and for patents included in licensing agreements with geographic scopes that exclude their countries. If civil society groups and

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governments show patent holders that failure to license to the MPP, and license under terms which best facilitate generic competition, will lead to compulsory measures, then the effectiveness of the MPP will increase considerably.

Public Citizen sees the success of the MPP as an invaluable element in our fight to expand access to medicines. But for the Medicines Patent Pool to truly work, those of us in the global health community must continue to press for conditions which allow it to succeed. The MPP has the potential to be a gamechanger for global health which contributes to saving millions of lives, but it can't do it alone.

For more information, contact <u>medsaccess@citizen.org</u>.