# 14. The Medicines Patent Pool: A Remedy for the Anti-Commons

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In 2002, at the International AIDS Conference in Barcelona, a group of people met in a small meeting room to discuss the high prices of antiretroviral medicines (ARVs) for the treatment of HIV/AIDS.

In those days, generic, non-patented ARVs were much lower priced and available from companies in India, as they were not barred from producing these medicines because India did not grant product patents for medicines. But this was going to change. The World Trade Organization's rules demanded that India be compliant with the global Agreement on Trade-Related Aspects of Intellectual Property Rights — the TRIPS Agreement. As a result, India would have to grant medicines patents from 2015 on. At the same time, newer and more robust medicines had started to become available in wealthier nations at high prices. Concerns were growing about how these new treatments could be made available in easy-to-use three-in-one pills in the absence of generic production.

To the surprise of the audience in Barcelona, Knowledge Ecology International's Director James Love put up a picture of the patent application for an early 20th century airplane1. The early developers of the airplane held patents on the technology. They were not keen to share their technology and took legal action whenever they suspected infringement of their patents. But these patent wars were really starting to hamper the United States' ability to develop and produce military airplanes. The government had to intervene and so established the first government mandated patent pool in which all airplane producers were required to collaborate2.

"If we can do this for reasons of war, why can't we do this to fight HIV/AIDS?" This was the question James Love put to the group at the AIDS conference. He outlined how the intellectual property needed for the production of low-cost AIDS/HIV medicines could be brought together in a patent pool for any eligible generic producer to use. This would not only guarantee the production of low cost medicines but also take away barriers to putting different compounds together in one pill and develop adapted formulations, such as those needed to treat children.

In such a pooling scheme, a generic producer would be allowed to make use of the patent in exchange for a royalty payment to the patent holder. This meant that patents would no longer pose a barrier to the production and supply of generic medicines, just like it was before the TRIPS Agreement. Just as the flying machine pool made large-scale production of military airplanes possible, so would a mandated medicines patent pool enable large-scale generic production of life-saving medicines. It was a brilliant idea. The question was how to implement it.

## The stars align

In 2006, a new global health financing mechanism, called UNITAID, had been established by a group of countries. Its mission was manifold: to scale up access to treatment for HIV/AIDS, tuberculosis, and malaria, achieve price reductions for medicines that meet international quality standards and diagnostics, and accelerate availability of medicines. What set UNITAID apart from other donors at that time was its clear mandate to work on intellectual property issues related to access to medicines.

UNITAID's constitution specifically demanded the organisation to support the World Trade Organization Doha Declaration on TRIPS and Public Health. The Doha Declaration was adopted in 2001 and stated that the TRIPS Agreement does not stand in the way of measures needed to protect public health, thereby introducing the primacy of health over trade considerations. The Declaration further outlined measures countries can take when patents form a barrier to ensure access to medicines for all, and suspended the obligation of least developed countries to provide or enforce medicines product patents3. Further, UNITAID was open to new and innovative ideas to tackle medicine access problems and showed leadership in taking on promising, yet controversial proposals.

The principle of a patent pool is to facilitate the availability of new technologies by making patents and other forms of intellectual property more readily available to entities other than the patent holder. The pool is intended to avert a "tragedy of the anti-commons" in which people are unable to make use of knowledge because of the entanglement of property rights that block them.

Also, in 2006, the World Health Organization Commission on Intellectual Property Rights, Innovation and Public health (CIPIH) recommended the establishment of a patent pool4. These developments strengthened the resolve of Knowledge Ecology International and Médecins sans Frontières in proposing to UNITAID to establish a medicines patent pool.

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Patent pools have been established in various fields related to public health — examples include the Golden Rice in agriculture, a vaccine for Severe Acute Respiratory Syndrome (SARS), as well as multiple areas of information technology. The aim of all of those initiatives was to overcome barriers to access and innovation that may arise when relevant patents are owned by many different entities6-7.

The UNITAID Patent Pool, as it was called in the early days, was a new idea. It focused on medicines and the collective management of pharmaceutical patents and other intellectual property for the purpose of accelerating access to medical innovations in low- and middle-income countries. The purpose of the UNITAID initiative was first and foremost to serve the public interest by creating the collective management of intellectual property related to important life-saving medicines. In essence, it transferred control over intellectual property from corporations to the larger community, making sure that all people had access to proper treatment.

After a feasibility study8 that concluded that the proposal was indeed desirable and doable, UNITAID formed an in-house team to develop an implementation plan for the Medicines Patent Pool (MPP) in 2009. A year later, in 2010, the Medicines Patent Pool was established as a separate legal entity and opened its doors in Geneva. UNITAID would remain its core funder until this day.

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In the early days, not all players in the global health arena were keen on the Medicines Patent Pool. Opposition came from unexpected corners such as the Bill and Melinda Gates Foundation, which was a member of the UNITAID board. They initially refused to support the establishment of the Medicines Patent Pool. The Gates' fortune mainly derived from Microsoft’s intellectual property, which is possibly why the Foundation was reluctant to support the idea.

The WHO leadership was also reluctant to embrace the initiative for fear it would fail. They insisted it be set up as a separate legal entity and not be housed at the WHO to avoid any potential liability issues. Certain factions of civil society saw the pool as not going far enough. Some claimed it would undermine other efforts to reform the system of intellectual property. Others expressed concern that the licenses from the pool might cover people in the poorest countries, but if they didn’t cover people in all middle-income countries, those patients would be out of options9.

The key to the pool's success would be the willingness of patent holders, mostly pharmaceutical corporations, to engage and license their intellectual property. This was no small order considering that medicines patents are the crown jewels of the industry. It would not be easy to persuade them to part with them. Some in the industry responded to the establishment of the patent pool idea with resistance. For example, one company told the Financial Times10 that they could better accelerate access themselves and that ‘’The pool’s key focus has been political in getting access to IP without explaining how it will work. [...] The €4.7m they will spend could save thousands of lives [by buying drugs.]"

Other companies were more forthcoming in the early days. Gilead was notable in that it publicly declared at the 2008 AIDS conference to be open to licensing its intellectual property to the Medicines Patent Pool.

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A first breakthrough for the Pool came when the US National Institutes for Health (NIH) approached UNITAID and offered to license its patents related to HIV medications. In 2010, the Medicines Patent Pool signed its first agreement with NIH11. It became apparent that this move had support from the highest political levels when the White House’s blog12 encouraged companies to follow suit and congratulated those13 that14 did15. Gilead, an important holder of patents on essential and new medicines for the treatment of HIV, followed soon after. The company signed16 its first license agreement with the Medicines Patent Pool in 2011. That same year, the first generic companies joined the initiative17, which was crucial because generic companies are the ones that actually produce and sell low-priced medicines.

## Core features of the Medicines Patent Pool

The Medicines Patent Pool is "public health driven", not driven by the commercial needs of the companies with which it works. It focuses on essential products and areas of greatest health need. Its country scope is low- and middle-income countries, which means that it seeks to include as many countries as possible in the scope of the licenses. The country scope is one of the great challenges for the Medicines Patent Pool because pharmaceutical companies do not like to give up large emerging markets such as Brazil, China, and Russia to their competitors.

Contrary to the airplane patent pool, which was a non-voluntary mechanism mandated by the government, the MPP was set up as a voluntary mechanism. This means that its success depended on the willingness of companies to part with full control over their intellectual property. A key feature of the Pool is that the licenses allow for multiple non-exclusive sub-licenses. This enables competition between generic manufactures which helps to drive down the price. The licenses also facilitate further innovation by allowing the development of new "three-in-one pills" or fixed-dose combinations (FDCs) and other products to treat children.

Another important feature of the MPP is that its work has to be consistent with the WTO Doha Declaration on TRIPS and Public Health. This means that the Pool cannot enter into agreements containing terms and conditions that limit the policy space countries have under international law, such as using compulsory licensing of medicines patents. As a result, the Medicines Patent Pool licenses allow the generic companies to supply generic medicines to countries that are not listed in the agreement when such countries make use of TRIPS flexibilities such as compulsory licensing18. If the Pool’s licenses would not allow the generic companies they work with to supply to countries that have issued a compulsory license, the Pool could potentially paralyse the effectiveness of such measures.

The Pool's license agreements also include waivers for data exclusivity and require quality assurances of the medicines. When needed, the agreements can also provide for technology transfer. A significant and unique feature is the transparency of the MPP's licenses. They all are available, in full text, on the MPP’s website19.

## State of play today

Today, the Medicines Patent Pool has licenses from nine companies related to 18 products. All of the standard first- and second- line treatments for HIV/AIDS, as recommended by the WHO, are covered by licenses in the MPP. The MPP includes licenses needed to produce a medicine for the treatment of hepatitis C and also one for tuberculosis.

A total of 24 generic companies and drug developers have licensed from the Patent Pool. As a result, there are over 130 drug development projects that are ongoing. The Pool licenses for HIV/AIDS drugs cover between 92 and 131 countries. This means that between 87% and 91% of adults with HIV/AIDS, and 100% of children, can benefit from the MPP.

The new first-line HIV treatment, TLD (tenofovir/lamivudine/dolutegravir), was first developed by licensees of the MPP20. The generic company, Mylan, was the first to obtain marketing approval for the product in 2017, bringing a truly innovative product to market as a generic from the first day of sale.

The MPP also has three hepatitis C related licenses. The product licenses’ territory ranges from 95 to 112 countries representing 47.5% to 65.4 % of people with hepatitis C. From 2012 to 2017, the Pool has created US $553 million in savings. In 2018, the board of the MPP expanded its mandate to all patented essential medicines.

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## Conclusion

The Patent Pool’s achievements are significant for an initiative that, only nine years ago, was regarded by many in the global health and trade arena as high risk and likely to fail. Of course, an element of self-interest of donor countries contributed to its success. Those countries wanted to make sure that finite global health financing for medicines was not spent on high-priced branded medicines which would have severely restricted the number of people that could be treated with the same amount of money.

It is therefore uncertain whether there will be enough political support for a similar voluntary licensing schemes for non-communicable diseases like cancer, diabetes, and asthma. Currently, national governments pay most of the costs of treatment for such diseases. It is therefore important that those governments become more vocal on the need for MPP licenses for medicines for non-communicable diseases. It is encouraging that some companies have signalled to be willing to work with the Patent Pool on cancer medication21.

The Pool has successfully pried some of the hold over medicines intellectual property, mostly related to HIV and hepatitis C products, away from the industry and put it to work for the public interest. However, the work of the Patent Pool did not stretch out to all middle-income countries, and is so far limited to a set of communicable diseases. Today’s global struggle to lower prices for other medicines shows that it is vital that governments retain the right and ability to make corrections in the management of intellectual property of companies. This is especially true when such management leads to undesirable societal effects and does not serve the public interest.