

# Medicines patent pool

## Questions & answers

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### What is a patent?

A patent is a form of intellectual property (IP) that is granted to an inventor by a State or by a regional office acting for several States. A patent allows the inventor to exclude anyone else from commercially exploiting an invention for a limited period, generally set at 20 years. To be patentable, an invention has to be novel, non-obvious and 'useful' – meaning that it has an application for industry, for example.

In the field of medicines, pharmaceutical patents can be

given both for products (e.g. chemical compounds) and for processes (e.g. the process or method used for producing the chemical compound).

The idea behind the patent system is to give inventors the exclusive right to exploit the invention, so that they can recoup their investments in developing the new product. This will then stimulate innovation and thus the development of new products – in other words, the inventor benefits but so does society.

### If everyone benefits, why are pharmaceutical patents thought to hamper access to medicines?

The patent holder of an existing medicine – often the company that has developed the medicine – can exclude other companies from marketing the product. With no competitors to threaten its sales, the patent-holding company can thus determine the price. A company with a patented product is likely to market its product in a profit-maximizing way. If the price of a drug is set too high, this will come at the expense of poorer patients' access to medicines, and their health.

Once the patent expires and the product comes "off patent", other manufacturers can start to market the medicine

and compete with the originator company. Competition between different manufacturers invariably brings the price of medicines to more affordable levels.

Patents can also create barriers in terms of follow-on innovation. Take the development of fixed dose combinations (FDCs) such as the three-drugs-in-one-pill formulations that are used to treat AIDS, for example. FDCs are simple, patient-friendly, and boost treatment outcomes. But when the patents on the individual drugs are held by different patent owners, anyone seeking to make a fixed-dose combination would need to seek permission from at least three different companies before developing the product.

### But aren't there companies – like the generic companies in India – who produce medicines at reduced prices?

Indian generic manufacturers could produce medicines at reduced prices, because until 2005 the country did not grant pharmaceutical product patents. This also explains why the most affordable triple fixed-dose combination antiretrovirals (ARVs) used to treat AIDS are available from Indian producers.

But the situation for newer drugs is very different. Intellectual property protection is increasingly tighter across the globe. Since India began granting pharmaceutical patents in 2005, the newer ARVs, like all new medicines, are likely to be patented there and in other countries. As a result, generic competition - and the spontaneous development of FDCs - will only be possible if an international solution is found to ensure greater access to intellectual property.



## Are patents global? For instance, if a company patents its medicine in the United States, is that patent valid in other countries?

No, patents are national in scope and each country takes its own decision on the granting of patents. In the past, countries could also exclude entire areas of technology from patentability. For example, many countries did not allow patents on medicines or food. Since the adoption of the World Trade Organization (WTO) TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement, this is no longer possible. All WTO member countries now have to grant patents for pharmaceutical products and processes. Since the adoption of the Doha Declaration on TRIPS and Public Health the 32 least developed country members of the WTO are excluded from the obligation to provide

product patents until 2016. On the other hand, WTO rules and in particular the Doha Declaration on TRIPS and Public Health also allow countries to take action when a patent represents an obstacle to public health, such as when a medicine is priced too high for a population to afford. For example, any government can issue a compulsory license allowing an entity other than the patent holder to produce or import cheaper versions of the product, without the consent of the patent owner. However, a compulsory license in general only serves the country it has been issued for, so we still need additional solutions that are truly international in scope.

## What is a patent pool?

UNITAID believes that a patent pool could well be that solution. Issuing licenses – be they compulsory (i.e. without the patent holder's consent) voluntary (i.e. through a negotiated agreement with the patent holder) - to produce a patented medicine at a reduced price is one way of addressing the impact of patents on access to medicines. It is also possible to manage IP collectively and make it more accessible through various mechanisms. One of these mechanisms is called a "patent pool". A patent pool is created when a number of patent rights, held by different owners (companies, universities, government institutions),

are brought together (or pooled) and made available on a non-exclusive basis. Third parties (e.g. generic manufacturers of medicines) can then make use of the patents against the payment of a royalty. Such a scheme allows easier access to many patents at once as it serves as a "one-stop-shop" for all involved. As well as increasing access to IP and reducing risks and costs to companies, a patent pool would have the added benefit of making life saving medicines more widely available and affordable. The UNITAID initiative aims to establish a voluntary medicines patent pool, constituted for the public good.

## How exactly would the Medicines Patent Pool improve the situation?

The Medicines Patent Pool will function on a voluntary basis – it relies on the patent owners will to participate in the mechanism. Drug companies and others who own patents can choose to place them in the pool. If they do, they will then be rewarded through the payment of royalties, for example a percentage over the sale, when a third party, such as a generic manufacturer, makes use of the patents. A company wishing to gain access to the IP in order to produce and sell the medicines may then do so, in exchange for paying the royalties. The effects will be to boost access to medicines: with more companies producing the medicine, the tried

and tested effects of competition should take hold, and the price of the medicine should fall. In addition, the patent pool will help spur medical innovation, in particular with the development and production of fixed-dose combinations, including formulations for children. Indeed, the pool will make it possible for companies to access in a single body all the patents needed to combine products into a three- in-one pill, even if they are held by different companies. This will greatly benefit children and people who have grown resistant to conventional AIDS therapy, for whom few fixed-dose combination options currently exist.

## How will UNITAID choose the medicines for which licenses will be issued by the patent pool?

UNITAID will initially target HIV medicines. It will work with global health authorities, such as the World Health Organization (WHO), to establish the best possible

treatment regimens needed for different segments of populations according to scientific and clinical evidence.

## How will UNITAID ensure that those medicines will be of good quality and safe?

It is the responsibility of the companies that produce and market the medicines to ensure that their products meet quality standards. However it will likely be a condition for obtaining a license that companies are prepared to submit

their product dossiers to the WHO prequalification process – a scheme established to assess the quality, safety and efficacy of medicines procured – or any other stringent drug regulatory agency before they are sold.