Questions and Answers:
The US National Institutes of Health (NIH) License to the Medicines Patent Pool

1. Which patents did the NIH license to the Medicines Patent Pool?

United States	Application 09/720,226 – issued (7,470,506)
	Application 11/870,931 (pending)
Canada	Application 2336160 (pending)
Australia	Application 48280/99 – issued (7717880)
	Application 2004200629 (pending)
	Application 2007203321 (pending)
Japan	Application 556057/2000 (pending)
	Application 266865/2009 (pending)
European Patent Office	Application 99931861.1 (pending)

2. What are the patents about?

In 1998, scientists at the NIH National Cancer Institute and the University of Illinois at Chicago discovered that a class of compounds was particularly effective at treating people living with HIV/AIDS who had developed resistance to older drugs. One of these compounds was eventually developed into the drug darunavir. The patent covers methods of treating people with effective amounts of darunavir (and related compounds).

3. What are the key terms and conditions of the license?

Patents on the licensed technology are pending or have been granted in the US, Canada, Australia, Japan and 19 high-income member states[1] of the European Patent Office (EPO). The license stipulates that this technology is to be available for the benefit of all low- and middle-income countries, as defined by the World Bank. The license is royalty-free.

4. What is darunavir? Why is it important?

Darunavir is an antiretroviral (ARV) drug that was first approved by the US Food and Drug Administration (FDA) in 2006. It belongs to a class of ARVs called protease inhibitors, which are an important treatment option for people living with HIV/AIDS who have developed resistance to their older treatments. As more people in developing countries develop resistance to their first line treatments, there is a need to make newer, more widely-patented drugs such as darunavir available at affordable prices and in user-friendly formulations.

5. Does this license allow for the production of darunavir?

No. There are other patents relating to darunavir that are owned by different patent holders. Some of these patents are in force in both industrialized and developing

[1] Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, Great Britain, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, and Sweden.

countries. As a result, the patent holders and/or their licensees would have the right to prevent the manufacture or sale of darunavir in these countries. The Medicines Patent Pool has invited patent holders to license their ARV-related patents to the Pool.

6. What is the significance of this license?

The license is important for at least five reasons:

- First, it sets an important precedent by demonstrating support for the Pool from the NIH, the world's single largest funder of biomedical research and a significant patent-holder. This license is a first step in a longer process – NIH and the Pool are in dialogue regarding licenses to other NIH patents for technologies that have potential as new HIV medicines.
- Second, the terms of the license include all low and middle-income countries as intended beneficiaries, and the full text of the license is publicly available.
- Third, the license highlights the important role public funding plays in research for new medicines.
- Fourth, the license symbolizes the importance of making the fruits of publicly-funded research broadly available, especially to the poorest people in the world.
- Finally, as the source of billions of dollars in research funding, the leadership shown by NIH sets an example for universities, other publicly-funded research institutions, and other patent-holders to follow.

7. Since the patents only exist in high-income countries, what is the practical impact of the license?

The license agreement, which allows for the sub-licensee to make and use, but not sell the product in those territories where a patent exists, contributes to providing legal certainty for research and development (e.g. for product development) in countries where the patents are in force when the goal is to benefit developing countries.

a. Don't the Bolar-type exceptions allow for companies to engage in R&D anyway?

At the margins, there can be legal uncertainty about how extensive the scope of these exceptions are. A blanket license to "make and use" the patented technology provides further legal certainty.

8. Can the Medicines Patent Pool charge royalties when it sub-licenses the NIH patent?

No. The agreement between the NIH and the Medicines Patent Pool allows the sub-licensee to make and use, **but not sell**, the product in the countries where the patent is in force. As such, no sales of product are foreseen in those countries, and thus royalties will not be payable on any sub-licenses that the Medicines Patent Pool may issue for these patents.

9. When will the license agreement be made public?

The full text of the license has been made public with the announcement of the agreement. It is available at: www.medicinespatentpool.org