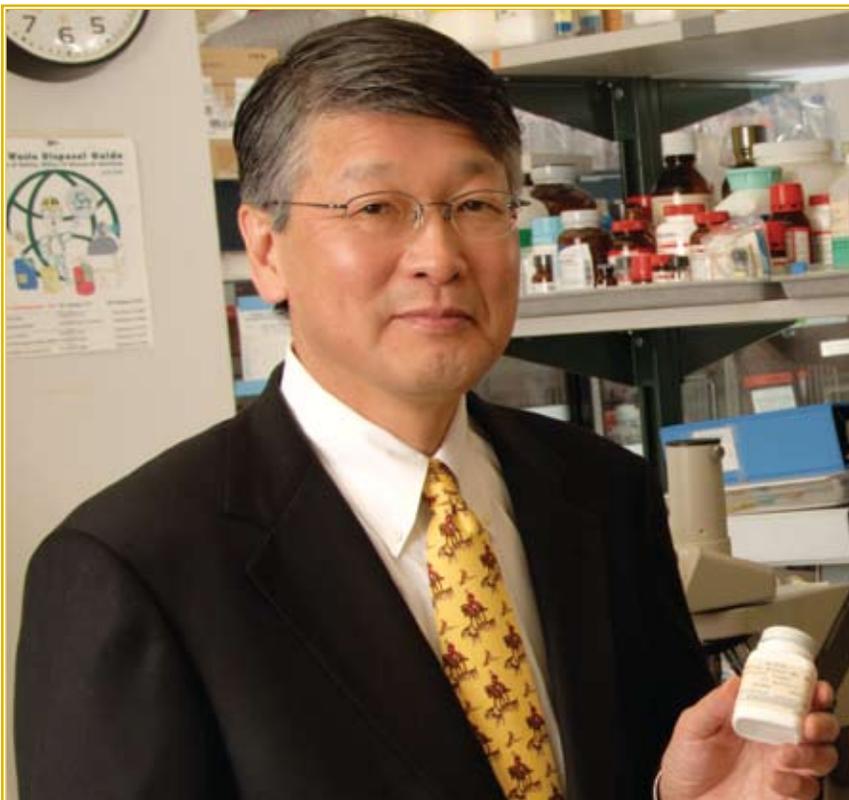


# Patent Pool Goes Global

*CCR-developed HIV drug darunavir is the first patent licensed to the Medicines Patent Pool.*

(Photo: E. Branson)



Hiroaki Mitsuya, M.D., Ph.D.

In recent years, there have been heated debates on how to ensure that patents do not stand in the way of access to medicines—especially for the world's poorest nations. According to UNITAID, an independent global health financing agency founded by the United Nations in 2006, treating a patient for one year with today's recommended first-line AIDS treatment costs between \$151 and \$1,033—in part because certain products are patented in some countries. This, according to the agency, is an almost two- to 13-fold increase from the price of the most affordable and widely used older regimens.

Enter the Medicines Patent Pool, a newly established UNITAID initiative that aims to find a route for expensive drugs to reach developing countries. By streamlining licensing processes for the production of generic versions of patented HIV/AIDS medicines, the

Pool serves as a one-stop shop that will accelerate the pace at which newer medicines reach patients and will help drive down prices to low, sustainable levels by encouraging competition among multiple generic producers.

The Pool received its first, high-profile member when the NIH licensed a patent for the new AIDS drug darunavir in September 2010. The royalty-free 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. Darunavir (Prezista™) is a novel protease inhibitor developed by Hiroaki Mitsuya, M.D., Ph.D., Head of CCR's Experimental Retrovirology Section, HIV and AIDS Malignancy Branch, in a 13-year collaboration with Purdue University Professor Arun K. Ghosh, Ph.D.

"Darunavir embodies a breakthrough in the struggle against the notorious

obstacle of current AIDS therapy: multidrug-resistant HIV variants," said Dr. Mitsuya. "The drug is active and has been proven clinically efficacious against multi-protease inhibitor-resistant HIV. More notably, darunavir effectively keeps HIV from becoming drug-resistant."

HIV rapidly mutates to resist new drugs, and many patients on first-line regimens will soon need to switch to second-line therapies that are more effective against drug-resistant HIV. And just as there is a need to continually develop new drugs, there is also a need to develop new approaches for improving drug access globally. With this first license in hand, the Pool is one critical step closer to achieving its goal of making life-saving medicines, like darunavir, more affordable and accessible to people in developing countries.

The Medicines Patent Pool provides a valuable model for attacking a longstanding problem: how to get patented products, developed through public and private investment, to developing countries today without having to wait many years for patents to expire in high-income markets. With darunavir, the NIH demonstrates its commitment to creative approaches to conducting research and development that meet global health needs. Dr. Mitsuya noted, "I am so pleased and honored that darunavir became the first drug to be licensed to the Pool." Although this is a significant step towards open access to patents for life-saving drugs, this alone will not transform the system unless the pharmaceutical industry follows suit. "The NIH's move is a good start," added Dr. Mitsuya, "but this should be only the beginning."

*To learn more about Dr. Mitsuya's research, please visit his CCR Web site at <http://ccr.cancer.gov/staff/staff.asp?Name=mitsuya>.*