Patents not key barrier to AIDS therapy

As *Nature Medicine* went to press, delegates to the World Trade Organization (WTO) were meeting in Doha, Qatar to discuss a range of trade issues, including the ability of nations to compel the licensing of patents on lifesaving drugs when faced with a public health crisis. Activists have argued that the issue highlights the stark hypocrisy of developed countries, but closer analysis reveals a more complex situation.

Around 25 million people in sub-Saharan Africa are infected with HIV but only 25,000 of them receive any drug therapy for the disease. According to non-governmental organizations such as *Médecins sans Frontières* (MSF), patents on the most effective antiretroviral drugs have kept the price of treatment out of reach for most Africans. MSF has campaigned vigorously to alter international trade rules to allow countries to bypass these patents. "The cheapest generic offer today for triple combination therapy is around \$250–300 per year per patient, and the cheapest triple combination therapy by a brand-name manufacturer is probably between \$800 and \$1000," says Anne-Valerie Kaninda, medical advisor for MSF.

The United States has opposed changes in the trade rules, but after the death of four Americans from anthrax, the US government subtly threatened compulsory licensing of the Cipro (ciprofloxacin) patent in order to extract a lower price from the antibiotic's manufacturer, Bayer.

Activists claim that the US government is maintaining a double standard, but others contend that groups like MSF have misunderstood the problem. The US threat against Bayer was permitted under current international trade rules, and was no different in principle from earlier negotiations Brazil conducted with drug manufacturers to get AIDS drugs at lower prices. "That is the TRIPS agreement and international law working exactly as it should," says Amir Attaran, director of international health research at Harvard University, referring to the WTO's Trade-Related Intellectual

Property Rights agreement.

Attaran is co-author of a new study that surveyed patent coverage for AIDS drugs in Africa (*JAMA* 286, 1886; 2001). His findings cast further doubt on the idea that patents are the key barrier to stopping the African AIDS epidemic, as Africa has only 22% of the possible patent coverage for AIDS drugs. Moreover, according to Attaran, "even in the cases where there are patents on drugs ... in every single one of those cases there is a discount or donation offer in force [from the manufacturer]."

In the paper, Attaran writes, "...geographic patent coverage does not appear to correlate with antiretroviral treatment access in Africa, suggesting

GSK's combined lamivudine and zidovudine anti-AIDS drug

Bob Briggs/Glauco F. F. F.

that patents and patent law are not a major barrier to treatment access in and of themselves."

Broken down by country, the data strongly suggest that poverty, rather than patent protection, is the primary barrier to AIDS treatment. "\$350 a year is better than \$1,000 a year ... but \$350 a year is no more affordable to public health systems in Africa than \$1,000 a year," says Attaran. Indeed, the average per capita gross domestic product in sub-Saharan Africa currently stands at about \$350 per year, and per capita health expenditures hover around \$10.

Meanwhile, the US government has offered a compromise on patents: the Bush administration says that for the next five years, it will not pursue legal action against South Africa if that country violates AIDS drug patents held by US companies. But it is unclear what effect this measure will ultimately have, as South African president Thabo Mbeki has consistently refused to endorse anti-HIV drugs (*Nature Med.* 7, 1170; 2001).

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NIH posts online ES-cell registry

Last month, the United States National Institutes of Health (NIH) posted its long-awaited online embryonic stem (ES) cell registry (see <http://escr.nih.gov/>). It comprises the addresses and contact names for 11 institutions with 72 ES-cell lines that meet the narrow criteria for NIH funding set by President George W. Bush this past summer (*Nature Med.* 7, 981; 2001). However, only three of the institutions offer detailed technical information about the cell lines. Most only state, "This cell line meets the criteria for the use of human embryonic stem cells by federally funded researchers."

One institution that provides more detail is the Wisconsin Alumni Research Fund (WARF), which reports that cells from one of its lines "give rise to teratomas containing derivatives of three germ layers in SCID mice" and differentiate *in vitro*.

WARF also states that only one of their five lines is currently available to investigators. On the same day the registry was posted, the NIH extended its deadline for ES-cell research proposals to 27 November and officially withdrew the more liberal ES-cell guidelines from the Clinton era.

The registry was created to help researchers locate the federally approved cells. NIH originally stated that it might include information about the derivation of cells, the number of passages, culture conditions and growth characteristics. But midway through the project, NIH decided it would be more efficient to direct investigators to cell line providers for such information. Wendy Baldwin, deputy director of the NIH's Office of Extramural Research told *Nature Medicine*. This way, the providers will not have to constantly notify NIH of changes, she says. "It's their data. It gives them better control over it. We didn't want to interject the government into the process."

But as Mark Frankel, director of the Scientific Freedom, Responsibility and Law Program at the American Association for the Advancement of Science points out, the NIH may have had an easier time gathering and confirming this information: "NIH has leverage that no individual researcher has. If NIH had done this it would have made it much less burdensome for researchers."

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