Monopoly Patents on AZT Challenged

After more than a year of internal debate, the U.S. government last week publicly entered the patent fray surrounding the antiviral AIDS drug AZT. The government's attorneys took steps that could end the monopoly on AZT held by the Burroughs Wellcome Co. without taking on the pharmaceutical company directly.

At stake are scientific credit and hard cash. Burroughs Wellcome has made huge profits from its $287 million annual sales of AZT, based on the company's exclusive patents. But National Institutes of Health (NIH) director Bernadine P. Healy believes federal scientists should be named as coinventors on the patents. And NIH officials have said they plan to sign a nonexclusive license agreement with Barr Laboratories, a generic drug manufacturer, to market AZT in competition with Burroughs Wellcome. If such a license were granted, according to a statement by Healy, "competition would result in a lower price for the drug."

Impact Visuals

Expensive therapy. *AIDS activists protest the cost of AZT.*

For years, researchers at the National Cancer Institute (NCI), including its current director Samuel Broder, have argued that they played a crucial role in determining that AZT is an effective treatment for HIV infection and AIDS. Since last year, activist groups have been trying to pursuade the government to press the NCI scientists' claims as coinventor of AZT and enable other drug companies to cut the drug's $2000 to $3000 annual cost—a price well out of reach of many AIDS patients. Now the government seems ready to do exactly that.

Beginning in late 1989, lawyers at NIH began exploring the possibility of filing suit against Burroughs Wellcome and demanding coinventorship on the patents. A key question was whether the NCI scientists merely screened a compound on behalf of Burroughs Wellcome using routine testing procedures or made a unique contibution in identifying AZT as an effective tool in treating AIDS. Burroughs Wellcome has argued that its scientists had the "creative insight" that AZT could be used to treat AIDS, and that they therefore deserve exclusive claim on the six patents issued in 1988 that cover various formulations of AZT as an AIDS therapy. Yet the fact that Broder's assay system for testing AZT later was awarded its own patent suggests that he and his colleagues may have had more than a routine role in the discovery.

Although legal experts both within the government and outside suggested the government would have a strong case if it chose to act, U.S. officials have moved cautiously. At the end of 1990, NIH lawyers began meeting with Burroughs Wellcome to discuss the inventorship of the patents relating to AZT. The slow pace of negotiations drew fire from critics, such as Public Citizen, a public interest organization founded by Ralph Nader. In March 1991, Public Citizen filed suit against Burroughs Wellcome seeking to obtain coinventor status for Broder and his colleagues (*Science*, 29 March, p. 1554).

If the Burroughs Wellcome monopoly is broken, several companies might move into the commercial niche that opens up. In the United States, the first generic manufacturer to show an interest is Barr Laboratories of Pomona, New York. Apotex, a Canadian affiliate of Barr, is already making the drug and selling it in foreign markets. In April, Barr applied to the U.S. Food and Drug Administration for permission to sell a generic form of AZT in this country. Last month, Burroughs Wellcome filed suit in a North Carolina federal court seeking to block Barr from doing so (*Science*, 24 May, p. 1055). But if it is armed with a license from the government, Barr believes it will have a very strong defense. "Assuming that we get the license and we can establish that the government has an ownership interest in the patent, that's the end of the case," says Myron Cohen, attorney for Barr.

Why hasn't the government taken on Burroughs Wellcome directly? The answer, in part, is money. Patent suits can be quite complex and expensive to litigate. "It takes a level of expertise that we cannot get in the civil service," said a government lawyer who spoke on condition of anonymity. "So piggybacking on a private sector litigant's efforts has a lot of appeal." Preliminary motions in the case will be considered later this month. ■ JOSEPH PALCA

Gallo Concedes Contamination (Again)

Scientists could hardly be blamed if they got the impression that last week marked a dramatic turning point in the saga of the discovery of HIV. "Gallo admits French discovered AIDS virus," declared the 30 May *Chicago Tribune*. "American Drops Claim of Finding AIDS Virus," was the headline in *The New York Times* the next day.

But in reality, the news was merely a reiteration in a letter to the editor in the 30 May issue of *Nature* from National Cancer Institute scientist Robert C. Gallo of something that he had already publicly stated: that a viral isolate sent to him by Luc Montagnier of the Pasteur Institute in Paris in 1983 had apparently contaminated a viral culture that he was attempting to grow in his lab at that time (*Science*, 10 May, p. 771).

There have been important revelations in the HIV saga this year. No one had been able to explain why the first two viral strains that were intensively studied, dubbed HTLV-IIIB by Gallo and LAV by Montagnier, appeared to be genetically identical. Speculation ranged from inadvertent error to outright theft. Writing in the 28 February issue of *Nature*, Gallo and his colleagues made a startling claim: viral isolates from a French patient codenamed BRU could not have been the starting material for the virus called LAV, as scientists at the Pasteur Institute had claimed in the literature, because the BRU isolates and LAV differ in the details of their genetic makeup. After several weeks of feverish work, Pasteur scientists showed that Gallo was correct. Instead, a different isolate obtained by the Pasteur scientists in 1983, codenamed LAI, appeared to be the source of LAV (*Science*, 17 May, p. 961). LAI had apparently contaminated BRU samples in Paris, one of which was sent to Gallo's lab in 1983 where it got into Gallo's cultures.

The (possibly) final piece in the HIV saga should come shortly when the NIH Office of Scientific Integrity releases its final report on the affair. ■ JOSEPH PALCA