

Pasteur Wants More HIV Blood Test Royalties

Why? Because, their lawyer now argues in a 19-page memo, Robert Gallo merely "rediscovered" Luc Montagnier's virus

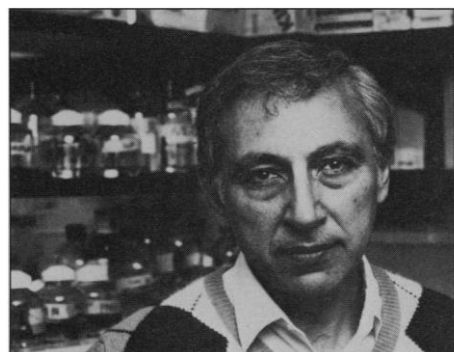
JUST AS THE NATIONAL INSTITUTES OF Health's bruising investigation of AIDS researcher Robert Gallo seems to be drawing to a close, France's Pasteur Institute is climbing back into the ring to wrestle Gallo and the U.S. government for patent royalties from the AIDS blood test.

A draft of the final report on Gallo's search for the AIDS virus, carried out by NIH's Office of Scientific Integrity, is circulating among the principals and may be issued soon, sources close to the investigation say. The draft recommends that Gallo associate Mikulas Popovic be found guilty of scientific misconduct as a result of inaccuracies in a paper published in *Science* in May 1984 reporting the Gallo lab's isolation of the AIDS virus. The same sources say that though the report is critical of Gallo in places, it does not find him guilty of scientific misconduct or formally censure him.

Although the issuing of the report could close one chapter in the long-running controversy that has surrounded Gallo, the dispute about the patent for the blood test is simmering anew. The immediate cause is a 19-page memo dated 24 January from Pasteur attorney Michael Epstein to U.S. Department of Health and Human Services (HHS) general counsel Michael Astrue. The memo argues that a 1987 formula for dividing patent royalties from the blood test between Pasteur and HHS "must be completely restructured to redress the inequities of the present situation."

At issue is the portion of the annual revenue from the French and American blood tests for HIV—several million dollars' worth—that Pasteur and HHS now split evenly. Epstein's memo argues that Pasteur should get more than half. Why? Because, the memo says, in 1991 Gallo "admitted" that the AIDS virus he used to make his blood test apparently was contaminated by samples of an AIDS virus given to his lab by Pasteur's Luc Montagnier. Hence, the memo says, "Dr. Gallo merely 'rediscovered' the original French virus sent to him by Pasteur." This information "changes the fundamental premise underlying the formula initially put in place to divide the royalties received by Pasteur and HHS on the sale of AIDS diagnostic tests."

Epstein's memo is merely the latest plot twist in a patent dispute stretching back to 1983, when the Pasteur first filed U.S. and European patent applications for the work done in Montagnier's lab. Though the U.S. government did not file a patent application for Gallo's blood test until 1984, the U.S. Patent and Trademark Office granted the Gallo patent application in 1985 without ruling on the French application. A few



Good news/bad news. Robert Gallo may soon be cleared of scientific misconduct, but the French want his royalties.

months later, officials from Pasteur and HHS met to discuss Pasteur's assertion that its patent deserved priority. Pasteur attorneys maintained Montagnier had been the first to isolate the AIDS virus, which he dubbed LAV. What's more, they said, the viral sample Gallo used to make his blood test—called HTLV-IIIB—seemed remarkably similar to a sample of LAV that Montagnier had sent Gallo.

At the behest of HHS, the National Cancer Institute (NCI) conducted its own review of the Gallo lab's work to determine whether the French and Americans should share patent royalties. But in a 27 August 1985 memo, NCI associate director Peter Fischinger concluded that "no base of information exists for us to seek a reissue or reexamination of the issued patent or any pending patent."

Pasteur responded by filing four claims and lawsuits in various U.S. courts. With legal costs mounting on both sides and the Gallo-Montagnier brawl making headlines, Pasteur and the U.S. government signed a settlement in March 1987 dismissing all pending legal matters, putting Gallo and Montagnier on each other's patents, and

mandating that HHS and Pasteur divide the royalties equally. The settlement also stipulated that both HHS and Pasteur would shunt 80% of their royalties into a newly established foundation dedicated to funding AIDS research in developing countries.

The settlement agreement led to the creation of the French and American AIDS Foundation, which passed a 1987 resolution specifying how its 80% would be divided: 25% to the World AIDS Foundation, an organization dedicated to supporting AIDS research in developing countries with Pasteur and HHS splitting the balance. The 80% was pooled because the U.S. test kit sold better—and pooling redistributed the wealth evenly. But now that Gallo has agreed that HTLV-III and LAV are in fact one and the same, Pasteur wants an even larger share.

Their latest request carefully avoids the idea of overturning the entire 1987 settlement agreement. "A decision to reallocate royalties to Pasteur, both prospectively and retroactively, does not require legislation, a rulemaking, or even that the 1987 settlement agreement be modified," reads Epstein's memo. Pasteur is merely asking that the 1987 foundation resolution be changed.

Joseph Onek, Gallo's attorney, believes the Pasteur's argument doesn't hold up. "The new information is not new," says Onek. "They don't have a case." Onek says the similarity between the Gallo isolate, HTLV-IIIB, and the Montagnier isolate, LAV-BRU, was known well before the 1987 agreement. In spite of the contaminations that occurred in both laboratories, he says, Gallo's patent application was based on independent work and not on misappropriation of the French virus. Therefore, he argues, there is no reason to reopen the discussions of royalties. An HHS spokesman said the department was reviewing Epstein's memo to decide what action to take on it.

Epstein concedes that HHS isn't legally bound to reopen the discussion of patent royalties, but says "you do the right thing because you're compelled to, not simply as a matter of law." He adds: "The United States government could stand fast and say you signed the [settlement agreement], you live with it." And what would the French response be if that's what the United States did? "I don't want to go into that," says Epstein. "I would hope that the U.S. government reads the memo and comes back with some kind of offer." Whatever the result, the final bell may never ring in the Gallo-Montagnier match, for it seems nothing having to do with this affair is ever finished once and for all. ■ JON COHEN

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