AIDS PATENT DISPUTE

U.S. Officials Say *Non* on Royalties

After a year of behind-the-scenes dickering, the U.S. government last week rejected an attempt by France's Pasteur Institute to get more patent royalties from the AIDS blood test. At a 16 September meeting of the foundation that distributes the royalties, the four U.S. trustees voted against a French motion to reallocate the funds, now evenly split between France and the United States. Predictably, the four French trustees voted in favor, two short of the required six yes votes. "It's extreme shortsightedness on the part of the U.S. government," fumes Michael Epstein, an attorney for the Pasteur Institute—who says further legal action could follow.

One factor in the U.S. decision to stiff-arm the French publicly is a recent reorganization of the fraudbusting operation at the Department of Health and Human Services (HHS)—where a lengthy investigation of Robert Gallo and his isolation of the AIDS virus still has not been brought to a conclusion. Before that reorganization, HHS Secretary Louis Sullivan, who is the boss of all the American trustees, and assistant secretary for health James Mason—a trustee himself—had the last word on scientific misconduct investigations. But now, Sullivan and Mason are removed from the misconduct loop and this, says a Sullivan spokesman, frees them to reject the French claim "on its merits" without appearing to prejudge the Gallo investigation.

The current dispute stems from 1983, when the Pasteur's Luc Montagnier and NIH's Robert Gallo—both foundation trustees—were racing to find the virus that causes AIDS and develop a blood test. The Pasteur ended up suing HHS for patent royalties, charging that Gallo had made his blood test with a sample of HIV isolated by the French. A 1987 agreement settled a handful of lawsuits, forming the French and American AIDS Foundation to distribute royalties.

The settlement was dealt a blow in 1989 when *Chicago Tribune* reporter John Crewdson wrote an article implying that someone in Gallo's lab might have stolen the French virus (*Science*, 15 November 1991, p. 946). This triggered the HHS investigation. Since then, Gallo has reexamined the first AIDS virus he isolated and reported that his was contaminated by the French one.

To the French—who ironically found that the same contaminant had infiltrated their first isolate—Gallo was finally admitting defeat (Science, 14 February, p. 792). As attorney Epstein wrote in a 31 August letter to HHS general counsel Michael Astrue (another trustee), "Dr. Gallo's disclosure destroys the fundamental premise underlying the formula initially put in place to divide royalties..." In essence, the French want about $2.5 million that the U.S. earns each year.

Though HHS didn't officially explain why it voted against the French motion, Mason told Science that the 1987 agreement "took into consideration" the possibility of contamination in Gallo's lab. A law firm NIH recently hired to evaluate the dispute also concluded that the Pasteur did not have a strong legal argument against the patent.

The French aren't giving up. Alain Gallochat, Pasteur's general counsel, noted that the trustees could change if George Bush loses in November. Gallochat also says reallocation could occur if congressional hearings are held about the Gallo affair and surprises surface. Then there's the ultimate weapon: re-opening the lawsuits. Gallochat claims that's a last resort, saying it's "not the goal of Institute Pasteur to spend a lot of money in lawsuits. We'd rather preserve our money for research."

–Jon Cohen

GENE PATENTS

Rumors Fly Over Rejection of NIH Claim

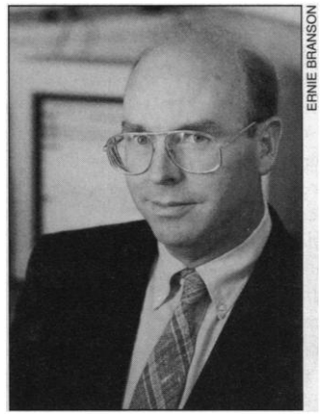
In an initial ruling, the Patent and Trademark Office has rebuffed the National Institutes of Health's (NIH) effort to secure patents on thousands of gene fragments of unknown function, as *Science* reported last week. But the exact grounds for the rejection remain unclear because NIH officials are steadfastly refusing to release the patent office report—which they have had since 20 August—despite calls from the scientific community and from within the Administration to make it public. Such secrecy has fueled rumors that the decision is a devastating setback for NIH and its director, Bernadine Healy, who has backed the patent strategy despite howls of protest from the scientific community.

Nonsense, says Healy. At a hearing of the Senate judiciary subcommittee on patents on 22 September, she portrayed the rejection as a routine action that was anticipated all along. Indeed, she said that the patent office rejects about 90% of all first-time applications; NIH now has 6 months to make its case once again.

Healy told the committee that the NIH application failed on three counts. The fragments—sequenced by former NIH researcher Craig Venter—lacked novelty because they were derived from a publicly available clone collection; they lacked utility because their value as probes was unclear; and they were obvious because 15-base stretches of the fragments had already appeared in the literature. Healy said the last point was particularly worrisome because it would prevent any gene from being patented if someone had already published a fragment of it. Despite the list of objections, Healy's spokeswoman, Johanna Schneider, says that the private patent attorneys advising NIH are "optimistic" that the patent will eventually be granted.

That's a far cry from word leaking out from other sources in the Administration, where a civil war seems to be waging over the patent issue. These sources describe the decision as a resounding rejection that goes far beyond the standard technical questions—and they are convinced that the patent is dead in the water. The discrepancy won't be resolved any time soon, as Schneider says NIH and the Department of Health and Human Services (HHS) do not intend to release the 30-page decision.

"They [NIH] are playing this completely wrong," says one official who hasn't seen the document but has heard the rumors. "They should make it public and put whatever spin they want on it." Even Venter, who kicked off the brouhaha by filing the application, is calling for openness. "NIH has nothing to gain or lose—except if they don't handle this in a forthright and open way."



ERNIE BRANSON

Patently obvious? Gene sequencer Craig Venter.

HHS has tentatively decided to respond to the patent office. If it does, a final ruling would not be expected for 6 months or a year. But in the interim, at the hearing both Healy and Venter called for action—either a legislative remedy or an international agreement to ensure that publishing sequences of gene fragments won't preclude obtaining patents once the full genes are characterized. (NIH has argued all along that if Venter published his gene fragments, researchers or companies that later characterized the full genes would be unable to get patent protection, to the detriment of the biotech industry.) Such legislation would remove any need or desire to seek patents on fragments of unknown function, says Venter, who has left NIH for a nonprofit research institute.

–Leslie Roberts