

Report prompts US to enter talks on new split of AIDS patent royalties

Washington and Paris. The United States this week opened talks with France aimed at ending a long-running battle over the joint US-French AIDS blood test patent. The move follows the completion of a two-year US inquiry which questions the claim of Robert Gallo of the National Institutes of Health (NIH) to have invented the US test.

Lawyers from the US administration and the Pasteur Institute were scheduled to start talks this week in preparation for a meeting of the foundation that administers the royalties on 11 July. Maxine Schwartz, director general of the Pasteur Institute, says he will seek an increased share of the royalties for his institute at the meeting.

For over two years, the US has been rejecting French pressure to re-negotiate an agreement that all royalties arising from the patent should be shared equally between the two countries.

But last week Harold Varmus, director of NIH, wrote to Schwartz agreeing that their lawyers should discuss the wording of "an acknowledgement from me appropriate to the current state of knowledge: that the French virus was used by NIH scientists in developing the American test kit".

Varmus did not concede that the Pasteur should get a bigger share of the royalties from the patent agreement. But he agreed with Schwartz that this would be straightforward. "Were I to be persuaded that a change in our current arrangement... is warranted, I would surely take steps to see that a change is made," the letter says.

A senior NIH official confirms that Varmus has shifted his position markedly since 8 June, when he wrote to Schwartz that "no alteration to our shared royalty arrangement is warranted", and asked him to "put the matter behind us". Varmus declined to comment on his correspondence with Schwartz, which NIH released in response to a Freedom of Information Act request.

The 1987 settlement confirmed that Gallo and Luc Montagnier of Pasteur had 'co-discovered' the virus. Under its terms the US Department of Health and Social Services (HHS) and Pasteur agreed to each donate four-fifths of the royalties from sales of tests to a French and American AIDS Foundation. A quarter of this pool then went to the World AIDS Foundation, while the remaining three-quarters was split equally between HHS and Pasteur.

Pasteur has fought for a bigger share on the basis that Gallo acknowledged in 1991 that the HTLV-III virus which he used to make the US test was in fact a virus isolated

previously by French researchers, including a group at Pasteur. Schwartz emphasizes that Pasteur explicitly stated that Gallo could not use the samples it sent to him for commercial purposes.

Varmus's change of position appears to have been prompted by conversations with Schwartz and by the completion earlier this month of a two-year inquiry into the Gallo affair by the inspector general of the HHS.

The inquiry, which covers the period 1983 to 1994, is broader in scope than one carried out previously by HHS's Office of Research Integrity (ORI). ORI dropped its efforts to convict Gallo of misconduct last year, after its case against his co-worker Mikulas Popovic collapsed on the grounds that it did not constitute legal proof of intent to falsify data, or that anyone had been defrauded (see *Nature* 366, 191; 1993).

Extracts of the summary of the new inquiry — which were first published in the *Chicago Tribune* — criticize Gallo's role in developing the AIDS test. It cites the patent examiner who granted the patent on Gallo's test in 1985 as saying she would not have done so had she known that the French also had a patent application in hand.

The summary claims that Gallo failed to disclose to the patent office that the French had performed "extensive work" on the virus, and that his laboratory had cultured it "for an extensive period and used it for



Gallo: claims no new allegations.

many of their experiments". NIH is taking the findings of the inquiry "extremely seriously" says the NIH official. Schwartz describes its conclusions as "damning".

Gallo says that it contains no new allegations against him, adding that, under an agreement with his employer, the National Cancer Institute, he cannot comment further in public. But his lawyer, Joseph Onek, has written to the inspector general rejecting the 10 June summary. He says it is "is filled with an extraordinary number of errors reflecting deliberate factual distortions, scientific illiteracy and obvious bias".

Renegotiating Pasteur's share of the royalties would not require rewriting the 1987 settlement, which does not mention how royalties should be distributed. A motion from the board of the French and American AIDS Foundation would be sufficient. Schwartz told Varmus this would be "a workable, simple solution that does no injustice to Dr Gallo, deprives him of no rights, but still rights a wrong".

HHS has received over US\$ 20 million in royalties since 1987, and Pasteur US\$14 million. Schwartz says he will seek changes in the distribution that would double the FF5 million (US\$850,000) royalties that Pasteur now receives annually. If he does not obtain a satisfactory solution, "then all options will be open" — including going to court.

But if Varmus makes concessions on the distribution of royalties this will inevitably re-open one of the most celebrated recent instances of alleged scientific misconduct in the United States, and raise new questions about the failure of either NIH or the wider scientific community to resolve it satisfactorily. **Colin Macilwain and Declan Butler**

Television appeal funds genetics institute

Munich. Money raised through a charity drive on Italian television is being used to build a new institute for human genetics in Milan. The institute, due to open next January, will be paid for entirely by Telethon, a charity supporting research into genetic disorders.

The new institute will be headed by Andrea Ballabio, currently at the Institute for Molecular Genetics, Baylor College of Medicine in Houston, Texas. Known as TIGEM (Telethon Institute of Genetics and Medicine), the new institute will be housed in laboratory space donated by the San Raffaele Biomedical Science Park, where the biomedical research centre Dibit is already located

(see *Nature* 360, 7; 1992).

In line with Telethon's new policy of concentrating its research funding on large-scale projects, TIGEM will eventually have a staff of 35. Telethon will pay all administrative costs, as well as salaries, estimated at about IL1.8 billion (US\$11.5 million) a year. The laboratory will be set up with two grants of IL4.5 billion and IL3.5 billion for 1995 and 1996 respectively.

Research activities at the institute will include the positional cloning of genes, and identification of gene mutations leading to genetic diseases such as Kallmann's syndrome and ocular albinism.

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