## U.S. PATENT ON TRIBESMAN'S BLOOD RAISES ETHICAL QUESTIONS CAN A GOVERNMENT CLAIM RIGHTS OVER PARTS OF YOUR BODY?

## April 20, 1996 GOROKA, Papua New Guinea (AP)

He's out there somewhere in the wild gorges of the Yuat River, hunting pig, harvesting yam, a young tribesman whose heart belongs to the jungle -- but whose blood belongs to the <u>U.S. government</u>. Or so says Patent No. 5,397,696. The story of the Hagahai tribesman, of how the United States of America patented the blood cells of one of Earth's most primitive citizens, could only be a tale from the bioengineered '90s, a time when the prehistoric can still come face to face with the futuristic, and the technology of tomorrow often outwits the society of today.

The story has emerged only slowly in recent months, but the rhetoric has begun to sharpen over what some call "genetic colonialism." It could become a test case for the bio-age. In March, the government of this poor western Pacific nation angrily summoned the U.S. ambassador for a full explanation, as it began to build a possible case against Washington to take to the World Court. Even the American anthropologist who helped obtain the patent, Carol Jenkins, believes the growing furor may do some good.

"We have to come to grips with this issue of biological patents," she said. Coming to grips would mean answering some fundamental questions: Should life forms be patentable? Is it ethical to assign commercial rights for human genes, or blood cells, or viruses? Can a govern ment 16,000 miles away claim some right over bits of your body it finds interesting?

In a way, the Hagahai saga begins only in 1983, when a few tribesmen first ventured out of the forest. Before then, the 300 or so Hagahai, one of 1,000 language groups on this huge Melanesian island, were unknown to outsiders. But the tale really goes back through uncounted centuries of Hagahai life in the Shrader mountains, where tiny bands of the hunter-gatherers lived off the land, in a remote region of rushing rivers and jungle rich in wild pig, birds of paradise -- and mosquitoes.

The mosquitoes and the malaria they carry had been killing more and more Hagahai children in recent decades. Hearing from other tribes about the outside world, a few

Hagahai went looking for help. One who responded was Jenkins, a medical anthropologist at Papua New Guinea's Institute of Medical Research, in this rugged highlands town 100 miles southeast of the Hagahai rainforest. Flying out by helicopter, the American scientist began a long-term study of this isolated people, work that won her international attention and eventually a call from the U.S. National Institutes of Health. Its virologists, engaged in pure research on retroviruses, the family that includes the AIDS virus, were surveying remote populations for variants of the microbes. They asked to check the Hagahai. Subsequent blood tests found that many Hagahai carried a human T-cell leukemia virus, although they were not afflicted with the disease.

"I told them we wanted to see a `binitang' -- an insect -- in their blood," Jenkins recalled. She said she assured them it would not make them sick, but could help others. In Washington, NIH researchers laboriously analyzed the blood, intrigued with what appeared to be a benign variant virus that might help them better understand its deadlier relatives. Using a sample from an unidentified 21-year-old Hagahai male, they established a "cell line" -- a self-perpetuating culture of virus-infected white blood cells. And in 1991 they quietly applied for a patent. In March 1995, it was issued. United States Patent 5,397,696 applies to "a human T-cell line (PNG-1) ... and to the infecting virus." It lists Jenkins and four U.S. government researchers as "inventors" and the U.S. Department of Health and Human Services as "assignee." The tribesman is not named or listed as a beneficiary.

The document suggests the "invention" may be useful in developing a vaccine, or in devising screening techniques for T-cell leukemia. It means that for 17 years the U.S. government -- or a company that buys rights to the patent -- will have the sole right to use that individual's virus-infected cells for commercial purposes. Such patents' international standing remains shaky. But U.S. court decisions have cleared the way for the patenting of dozens of human genes, DNA sequences and cell lines in America to "protect" them for product development, generally disease diagnostic tests or treatments.

"A company is going to need exclusivity to be able to invest the money and go to the marketplace and get a return," NIH patent lawyer Barbara McGarey said in a Washington interview. Business, in other words, is business, even when it's biology. Not everyone accepts that. Almost 200 U.S. religious leaders have called for a moratorium on gene patenting, saying life is not a "product of human invention." The

European Parliament is working to ban patents on life forms. The U.S. National Breast Cancer Coalition protested the way a biotech firm patented a breast cancer gene, saying women subjects in that research "didn't give blood so some company could make millions of dollars." And the NIH has retreated on one front, ending efforts to obtain patents for gene fragments even before their functions were determined. Mark Sagoff, an ethicist at the University of Maryland who is a close student of these issues, believes legal theory will eventually swing against patenting cell lines.

"This is not an invention," he said. "If you lose the distinction between what is an object of nature and what is human design and invention, any sort of absurdity follows." Now the Hagahai patent adds an international dimension to the debate. The Canadian-based advocacy group Rural Advancement Foundation International, which first publicized the patent, contends it is part of a pattern of unfair exploitation by wealthier nations of seed, medicinal plants and other genetic resources developed by indigenous peoples.

At the NIH, biodiversity specialist Josh Rosenthal disdains that argument, calling it a "destructive" approach. "It's NIH's feeling that the good of humankind is at stake, that this can be useful in saving human lives," he said of the Hagahai patent. But, of the activists, he also added, "I think they ask important questions." One of those questions: Will governments establish some international standards on patenting life? The 1994 global trade pact, which seeks to standardize patents and other intellectual property rights worldwide, is silent on human genetic material. Another treaty, the 1992 Biodiversity Convention, set principles for sharing benefits of genetic resources. But a review conference last November -- a month after the Hagahai patent was disclosed -- declared that human genetic resources are not covered. "It was too hot a subject," acknowledged a key official in those discussions, speaking on condition of anonymity. "It was felt it would be better to deal with areas where solutions were possible ."

Too hot or not, the Papua New Guinea government may raise the subject before the World Court. "Can this cell line truly be the intellectual property of the U. S. government and the scientists, when the property was derived, alienated from a citizen of PNG?" asked Dominic Sengi of the Foreign Affairs Department in Port Moresby, the capital. Here in Goroka, in tropical highlands lush with unique life forms -- plant, animal, human -- the director of the Institute of Medical Research is clearly pained by the patent dilemma. "I don't think there should be patents on any biological material," said Dr. Michael Alpers, who has spent a career trying to alleviate the plagues of New

Guineans. "But there should be a way for the information to be exploited and the original owners, in the broadest sense, to benefit." Still, Alpers stands by the Hagahai patent. "We couldn't say it would be dealt with by international agreements reached over the next 10 years. We had to deal with the issue immediately."

That's the irony: The patent was viewed here as protection for the Hagahai. Any financial return would go to the U.S. government and independent "inventor" Jenkins. But the anthropologist has declared she'll devote any royalties to benefiting the Hagahai. When U.S. scientists, wary of controversy, suggested dropping the application in early 1995, Jenkins objected. "I said, `That's the Hagahais' protection.' "

A year later, however, royalties look less and less likely. Biotech firms show little interest in PNG-1, the human T-cell line that waits in readiness, with its virus, in storage at Rockville, Maryland. And while the world gathers nerve for the debates to come, a tribesman roams among the orchids and birds of the Shrader Range, either a footnote at the dawn of the bio-business age, or a name less character in some final act.

http://coombs.anu.edu.au/SpecialProj/PNG/htmls/AP.html