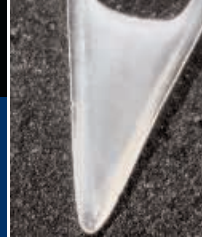


The proteins behind "stemness"

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Round the horn for the first time

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BIOMEDICAL RESEARCH

Court Decides Tissue Samples Belong to University, Not Patients

A high-stakes battle pitting a top prostate cancer researcher and his patients against a major research university over who owns the patients' tissue samples was decided last week in a Missouri federal court. The ruling gives Washington University (WU) in St. Louis ownership of tissue samples that urologist William Catalona began collecting 2 decades ago when he was a faculty member at WU. Catalona, who is now at Northwestern University Feinberg School of Medicine in Chicago, Illinois, had sought to establish unprecedented rights for patients by arguing that those who donated to the collection retained control of their tissues.

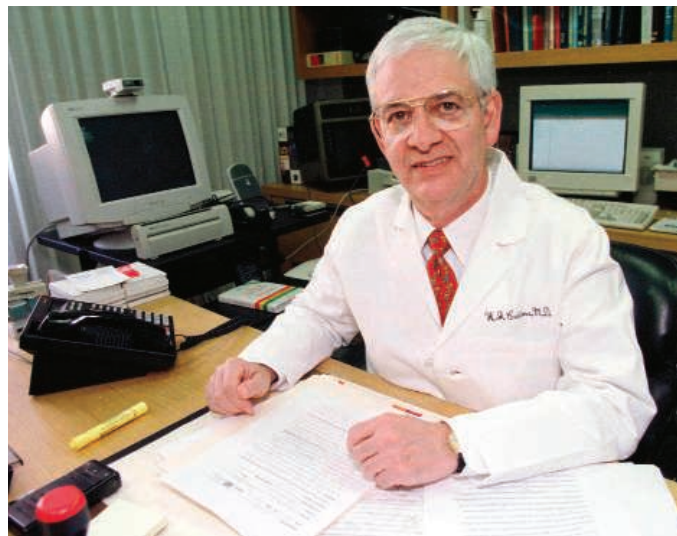
"The opposite decision would have been disastrous for tissue banks and tissue research," says David Korn, a senior vice president of the Association of American Medical Colleges, which filed an amicus brief supporting WU's position. But some ethicists and legal experts suggest the result could dissuade people from donating tissue samples. "It's a poor precedent for academic researchers and research subjects alike," says Lori Andrews, a professor at the Chicago-Kent College of Law, who advised the patients' attorneys.

Catalona, who has a roster of high-profile patients, is credited with developing the prostate-specific antigen (PSA) test for prostate cancer. He says he began the WU tissue collection in the 1980s with blood and tissue samples from 3000 patients from his private practice, mostly using his own grant funds and departmental money he raised. Other surgeons at WU have since added to the collection, which now has 100,000 serum samples, 3500 prostate tissue samples, and 4400 DNA samples.

The problem began in 2002, Catalona says, when the university changed how the tissue bank operated. "It was just taken from me," he says. The university set up a peer-review panel to decide who could use the samples. When Catalona applied to use samples to test a new PSA assay with a biotech

company, the university, he says, "stalled," although the request was granted. Catalona tried to broker a deal to take the tissue collection to the University of Virginia but that fell through, and he eventually decided to leave for Northwestern.

The week before he left, he wrote to all participants in his studies, asking them to send in an enclosed form requesting that WU "release" their samples to him at Northwestern. About 6000 patients signed it. WU refused to transfer the samples, however, and filed a lawsuit in 2003 to resolve the



Tissue tussle. Prostate cancer researcher William Catalona is considering whether to appeal the recent court decision that his former university maintains ownership of a tissue collection he established.

ownership issue. Eight patients later petitioned to join Catalona as defendants.

In the case, Catalona and the patients argued that the patients' original "intent" was to give their tissue samples to Catalona. The suit also claimed that the patients retained ownership over their tissue because their consent forms said they could ask to withdraw from any WU research.

Judge Stephen Limbaugh of U.S. District Court, Eastern District of Missouri, Eastern Division, showed little sympathy for these arguments. He noted that the tissue donations were a "gift" to WU under Missouri law,

which meant the university owned the samples. The judge concluded that the patient consent forms, which typically bore the WU logo, gave the samples to the university. He also noted that many samples didn't come from Catalona's patients and that WU funds had been used to maintain the repository. The decision also cites precedents in two earlier court cases finding that patients do not own biological samples they have donated for research—one involving spleen tissue from a leukemia patient, the other, a study that patented the gene for Canavan disease (*Science*, 10 November 2000, p. 1062).

The court rejected arguments that the patients' request to withdraw consent meant they could get their tissue back. Federal and state regulations simply require that the university had to choose between destroying it, storing it indefinitely without use, or anonymizing the data, Limbaugh noted.

Officials at other universities are relieved by the ruling. Says Ernest Prentice, associate vice chancellor of regulatory and academic affairs at the University of Nebraska Medical Center in Omaha and chair of a federal human research protections advisory board, who testified for WU, "[If] anytime a patient donates tissue ... they could say 'I want my tissue back,' that would tie the hands of biomedical research."

Some experts, although sympathizing with the patients, say it should have been no surprise to Catalona that his university owned the samples. "That was the deal. Most researchers realize that," says George Annas, who teaches health law at Boston University. Catalona expects he and the patients will appeal, however. "I don't think this

is really informed consent. ... A very large number of these patients felt they were giving [tissue] for my research projects," he says.

The decision, say WU officials, should finally allow researchers, even Catalona, to again conduct studies on the tissue samples, which have sat unused since the university filed suit. "We will use the repository for its intended purpose, which is to pursue new information about the development of, and potentially a cure for, prostate cancer," WU said in a prepared statement.

—JOCELYN KAISER

With reporting by Eli Kintisch.