

THE WASHINGTON UNIVERSITY V. CATALONA: DETERMINING OWNERSHIP OF GENETIC SAMPLES

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ABSTRACT: The ownership of tissue samples donated for medical research is an ongoing subject of dispute. Some advocates assert that patients have ongoing ownership rights in their tissues, including an unfettered right to determine what happens to their tissue sample. Researchers argue that giving patients property rights in their samples will turn the human body into a commodity and bring research to a screeching halt. One thing is certain: the creation of commercial products from human tissue has generated very difficult legal and ethical questions that have no clear, universally accepted answers. When those questions have come up in litigation, the courts have struggled to adapt the tradition and precedent of the law to the challenges arising from the biotech era. The case of *The Washington University v. Catalona* is the most recent instance of a court seeking to resolve this dilemma.

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Michael Crichton's novel *Next*¹ follows various legal, ethical, and moral dilemmas arising in the era of biotechnology and personalized medicine. One of the story lines follows Frank Burnet, a man with a rare genetic makeup that his treating physician had commercially exploited and sold to a biotech company. Burnet filed suit claiming that he had been duped into turning over the rights to his genetic information through ongoing testing, which he believed was a necessary part of his treatment. After losing all legal claims to an ownership interest in his tissue samples held by the biotech company, Burnet conspires to have the cell line destroyed and then disappears.

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1. MICHAEL CRICHTON, *NEXT* (HarperCollins Publishers 2006)

Outraged, the company files suit asserting that Burnet, his attorney daughter Alex, and eight-year-old grandson Jamie are in possession of stolen property—the genetic information within their own bodies—and engages the services of bounty hunters to return the “stolen” cells, by force if necessary.² The bounty hunters attempt to kidnap the boy from school by posing as an employee from his doctor’s office, but the effort fails when suspicious school officials contact Alex directly. When Alex unexpectedly arrives at the school, the bounty hunters attempt to kidnap her instead, but she escapes with the assistance of pepper spray and a well-placed high heel to the throat. Mother and son flee the bounty hunters while Alex’s law partners frantically contest the legal proceedings in court. Ultimately, Alex and her son are saved from the bounty hunters when, after considering the matter over night, the judge rules that the company’s ownership of Burnet’s tissue “does not entitle them to take these cells from any individual, living or dead, including Mr. Burnet himself.”³

2. The novel contains the following exchange of dubious legal advice between legal counsel and the head of the biotech company:

“Three courts have ruled that Burnet’s cells are your property. You therefore have a right to take them.”

“You mean, take them *again*.”

“Correct.”

“Except the guy has gone into hiding.”

“That is inconvenient. But it does not change the material facts of the situation. You are the owners of the Burnet cell line,” Rodriguez [the attorney] said. “Wherever those cells may occur.”

“Meaning . . .”

“His children. His grandchildren. They probably have the same cells.”

“You mean, I can take cells from the kids?”

“The cells are your property,” Rodriguez said.

“What if the kids don’t agree to let me take them?”

“They may very well not agree. But since the cells are your property, the children don’t have any say in the matter.”

“We’re talking punch biopsies of liver and spleen, here,” Diehl [the president of the company] said. “They’re not exactly minor procedures.”

“They’re not exactly major, either,” Rodriguez said. “I believe they are ordinary outpatient procedures. Of course, you would have a duty to make sure that the cell extractions were performed by a competent physician. I assume you would.”

Diehl frowned. “Let me see if I understand. You’re telling me I can just grab his kids off the street and haul them to a doctor and remove their cells? Whether they like it or not?”

“I am. Yes.”

“And how,” Rick Diehl said, “can that be legal?”

“Because they are walking around with cells that are legally yours, hence with stolen property. That’s felony two. Under the law, if you witness a felony being committed, you are entitled to perform a citizen’s arrest, and take the offender into custody. So if you were to see Burnet’s children walking on the street, you could legally arrest them.”

Id. at 251–52.

3. *Id.* at 393. After announcing his decision, the judge embarks on a diatribe against the private ownership of genetic material, arguing that “this situation has arisen out of confusion from prior court rulings as to what constitutes ownership in a biological context.” *Id.* The judge concludes his statement with an impassioned call for reversal of prior court decisions:

But in the end, the Burnet case has gone awry as it has because of a profound and fundamental error by the courts. Issues of ownership will always be clouded when individuals are able to manufacture

Determining Ownership of Genetic Samples

Though the scenario in the novel is, at best, far fetched, it highlights the concerns surrounding the ownership of genetic information and products derived from that information. It also accentuates the legitimate concerns raised by Crichton and others about the legal, ethical, and policy implications of allowing patents on human genetic material, as well as concerns about ownership of genetic samples and the commercial products flowing from those samples. “The creation of commercial products from human tissue has raised difficult questions about profit and property, consent and control, and ownership of the human body,”⁴ including, among others, the following:

- Should public policy restrict the commercialization and ownership of human genetic material in an effort to prevent the development of an “anticommons,” that is, knowledge that is “the antithesis of the traditional pool of common knowledge that all scientists freely share?”⁵
- In light of the substantial financial incentives for researchers who isolate, patent, and commercialize genetic information, can anything be done to keep researchers from hoarding tissue samples rather than sharing those samples with other scientists studying the same medical condition?⁶
- Is it possible to draft informed consent forms that adequately address the diverse cultural, religious, and personal values of the patients providing samples?

within their bodies what the court has ruled someone else owns. This is true of cell lines; it is true of genes, and of certain proteins. These things cannot reasonably be owned. It is a standing rule of law that our common heritage cannot be owned by any person. It is a standing rule that facts of nature cannot be owned. It is a standing rule of law that our common heritage cannot be owned by any person. It is a standing rule that facts of nature cannot be owned. Yet for more than two decades, legal rules have failed to affirm this concept. Patent court rulings have failed to affirm this concept. The resultant confusions will only increase with time, and with the advances of science. Private ownership of the genome or of facts of nature will become increasingly difficult, expensive, obstructive. What has been done by the courts is a mistake, and it must be undone. The sooner the better.

Id. at 395.

4. Lori Andrews, *The Battle Over the Body*, TRIAL, Oct. 2006, at 22, 28.

5. Gary Stix, *Owning the Stuff of Life*, SCI. AM., Feb. 2006, at 76, 80. The “tragedy of the anticommons” was identified as a concern in biomedical research in a 1998 article in *Science* written by two professors at the University of Michigan Law School. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998). They analogized their concerns to the “tragedy of the commons,” which holds that scarce resources held in common are overused because “too many owners each have a privilege to use a given resource and no one has a right to exclude another.” *Id.* at 698.

Anticommons property, they argued, is the mirror image of commons property. “[T]he recent proliferation of intellectual property rights in biomedical research suggests a different tragedy, an ‘anticommons’ in which people underuse scarce resources because too many owners can block each other.” *Id.* The development of the anticommons is “an unintended and paradoxical consequence of biomedical privatization.” *Id.* Once a body of anticommons develops in an area of biomedical research, “collecting rights into usable private property is often brutal and slow.” *Id.* Critics argue that if the body of “anticommons” is allowed to expand, exclusionary patent rights will deter discovery and innovation in biomedical research by increasing the cost and complexity of conducting research. *Id.* at 700.

6. Lori B. Andrews, *Harnessing the Benefits of Biobanks*, 33 J.L. MED. & ETHICS 22, 23 (2005).

- Because donors have diverse cultural, religious, and personal values, is it ethically permissible to use tissue samples in a manner that varies from the scope of the initial informed consent?
- What input, if any, should family or community members have in a donor's decision to provide tissue?
- "Is it appropriate to use stored biological materials in ways that originally were not contemplated either by the people from whom the materials came or by those who collected the materials?"⁷
- Can donors prohibit the "unauthorized and unwanted use of, or commercialization of, their tissue samples?"⁸
- What remedies, if any, should the law provide donors whose samples are used in unauthorized or unwanted ways?
- When and to what extent should donors be allowed to profit from the commercialization of their genetic information?
- Are researchers required to disclose their financial interests in the commercialization of tissue samples?
- Once patients voluntarily donate their tissue, when and to what extent should they be allowed to direct what happens to that tissue?
- Do tissue samples belong to the facility that maintains the biorepository, the researcher who directed the study where the tissue was collected, or to the participants who donated the tissue?

Like many questions arising in the era of biotechnology and personalized medicine, these questions have no clear, universally accepted answers. A recent article summarizes the ambivalence raised by these questions.

How you should feel about all this isn't obvious. Scientists aren't stealing your arm or some vital organ. They're just using tissue scraps you parted with voluntarily. But still, someone is taking part of you. And people often have a strong sense of ownership when it comes to their bodies. Even tiny scraps of it. Especially when they hear that someone else might be making money off those scraps. Or using them to uncover potentially damaging information about their genes and medical histories.⁹

Though these questions inspire varied answers, the law must resolve those diverse viewpoints into a thoughtful, coherent, and useful statement of public policy. Ownership and control of tissue samples are at the heart of this dispute, a dispute that surfaced again in *Washington University v. Catalona*,¹⁰ which

7. 1 NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE, at i (1999) [hereinafter RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS].

8. Andrews, *supra* note 6, at 24.

9. Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES MAG., April 16, 2006, at 38, 40.

10. 437 F. Supp. 2d 985 (E.D. Mo. 2006), *aff'd*, 490 F.3d 667 (8th Cir 2007), *cert. denied*, 128 S. Ct. 1122 (2008).

held that patients did not have continuing property rights in the research samples they had donated.¹¹ Resolving this dispute against the donors engenders the heartfelt emotional response articulated above; resolving the dispute in favor of the donors threatens to devastate the way in which medical research is conducted and turns the human body into a commodity.

This article considers the current state of the law regarding ownership of tissue samples. Part I addresses the massive number of tissue samples currently being stored in the United States. Part II reviews the three reported cases that have considered the ownership of genetic materials, with an emphasis on the recent *Catalona* decision. Part III raises additional considerations that may have contributed to the *Catalona* decision.

I. THE UBIQUITOUS NATURE OF TISSUE SAMPLES

Physicians and scientists have been storing human biological materials for more than a century.¹² As a result of that practice, a staggering number of tissue samples are being stored throughout the United States. A report issued in 1999 makes a “conservative estimate” that more than 307 million tissue samples from more than 178 million people were being stored in the United States, a number estimated to be increasing by some 20 million samples a year.¹³

“These tissue collections vary considerably, ranging from formal repositories to the informal storage of blood or tissue specimens in a researcher’s freezer.”¹⁴ “Individual collections of human biological materials range from fewer than 200 to more than 92 million individual quantities of material.”¹⁵ Those “samples come from routine medical tests, operations, clinical trials and

11. *Id.* at 997.

12. RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS, *supra* note 7, at 1; ELISA EISEMAN & SUSANNE B. HAGA, HANDBOOK OF HUMAN TISSUE SOURCES: A NATIONAL RESOURCE OF HUMAN TISSUE SAMPLES, at xvii (The Rand Corp. 1999).

13. EISEMAN & HAGA, *supra* note 12, at xvii.

14. *Id.* at xvii–xviii.

15. RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS, *supra* note 7, at 13. The individual collections of tissue samples are typically either

- large tissue banks, repositories, and core facilities
- materials collected as part of longitudinal studies
- tailored collections for research studies requiring unique tissue collections
- pathology specimens, initially collected for clinical purposes
- newborn screening tests accumulating in various laboratory sites
- forensic DNA banks
- umbilical cord blood banks
- organ banks
- blood banks
- sperm, ovum, and embryo banks, and
- individual investigators’ collections.

Id. (internal citation omitted).

research donations.”¹⁶ If the Rand Corporation’s “conservative estimate”¹⁷ is accurate, nearly half a billion tissue samples are currently being stored in the United States. “Some tissue samples are coded and not identified with specific individuals; others carry patient names or codes that allow personal identification. Virtually everyone has his or her tissue ‘on file.’”¹⁸

Additionally, that tissue “on file” may be extremely valuable. Ted Slavin was a hemophiliac who developed “extremely high concentrations of valuable hepatitis B antibodies in his blood” and, until his death in 1985, supported himself by providing those antibodies to pharmaceutical companies developing the hepatitis B vaccine.¹⁹ John Moore, the plaintiff in the seminal case of *Moore v. Regents of the University of California*,²⁰ alleged that his rare genetic makeup had a commercial value of \$3 billion. But most tissue samples, standing alone, are genetically unremarkable.²¹ Their value arises not from high concentrations of antibodies or rare genetic makeup, but from the fact that they enable researchers to piece together the jigsaw puzzle of information underlying genetic causes of disease. It is thus their similarity to samples from other sufferers, not their uniqueness, that gives them value.

With the mapping of the human genome now completed, the nearly half billion tissue samples contain a treasure trove of genetic information. That information not only is the key to unlocking the mysteries of personalized medicine; it is the characteristic that makes the accumulation of tissue samples so threatening to many.

16. Skloot, *supra* note 9, at 40.

17. EISEMAN & HAGA, *supra* note 12, at xvii.

18. *The Battle Over the Body*, *supra* note 4, at 26.

19. Skloot, *supra* note 9.

20. 51 Cal. 3d 120, 271 Cal. Rptr. 146, 793 P.2d 479 (1990).

21. The fact that those samples are genetically unremarkable does not mean they have no commercial value. “[T]he value of human tissue, from both living and dead donors, has increased dramatically in the biotech era.” *The Battle Over the Body*, *supra* note 4, at 22. “A human egg can be worth tens of thousands of dollars,” while a cadaver can be dissected and sold in parts—“its skin is worth \$36,522, its bones \$80,000, its tendons \$21,400, and so forth.” *Id.* In 2005, the University of California noted the black market value of body parts: “cornea, \$1,800 to \$2,800; heart valve, \$5,000 to \$7,000; patella tendon, \$1,800 to \$3,000; skin, \$1,000 per square foot.” Dan Majors, *You Can’t Have Too Many Eyes*, PITTSBURGH POST-GAZETTE, Feb. 10, 2005, at A-13. Other estimates place the value of a heart valve at \$9,120 and knee cartilage at \$14,000. Jeffrey Kluger, *The Body Snatchers*, TIME, Mar. 22, 2004, at 49, 49.

The commercial value of human bodies had led to some gruesome tales of illicit transactions in body parts. In 2004, for example, police arrested the director of the Willed Body Program at UCLA and a former mortuary worker on charges of grand theft. *Id.* “Using scalpels, scissors and electric saws, the former autopsy technician would expertly slice off hands, knees and other body parts and pack them in coolers for later shipment to one of 80 clients, including a subsidiary of medical giant Johnson & Johnson.” Andrew Murr, *Bad News for the Body Trade*, NEWSWEEK, Mar. 22, 2004, at 42, 42. According to his attorney, the mortuary worker gave the director cashier’s checks totaling \$704,600 for the right to harvest some 496 bodies donated to the program. *Id.*

II. LEGAL RESPONSES IN THE ERA OF PERSONALIZED MEDICINE

Personalized medicine is exciting and new. It sits on the cutting edge of scientific knowledge, promising cures for dreaded diseases and the ability to detect those diseases when prevention is still possible.

The law, on the other hand, operates on tradition and precedent. When new technologies present disputes that lie at the intersection of legal principles that suggest inconsistent results, the law must resolve those inconsistencies in ways that honor the traditions and precedent of the past, yet still incorporate sound public policy and a secure foundation for the future. For these reasons, the law has been slow to address the concerns raised by personalized medicine, with just three primary cases since 1990 addressing the question of ownership of genetic material donated for research purposes. Each of those cases contained compelling aspects in favor of granting the donors ownership rights in their tissue samples (or the products commercialized from those samples), yet in each case the courts declined to extend those ownership rights to the donors.

A. *Moore v. Regents of the University of California*

Any discussion of the property rights in genetic materials must begin with the seminal case of *Moore v. Regents of the University of California*,²² where the Supreme Court of California declined to give a patient property rights in his genes, despite outrageous behavior by his treating physician. John Moore had his spleen removed in October 1976 as part of his treatment for hairy cell leukemia under the direction of Dr. David W. Golde at the UCLA Medical Center.²³ Without telling Mr. Moore what he was doing, Dr. Golde conducted research using the spleen and, around August 1979, established a cell line from Mr. Moore's tissue.²⁴ Shortly afterwards, the Regents of the University of California applied for and received a patent on the cell line, which Mr. Moore asserted had a potential value of up to \$3 billion.²⁵ Dr. Golde negotiated for the commercial development of the cell line, became a paid consultant, and received stock in the company that acquired the development rights.²⁶

Mr. Moore returned to the UCLA Medical Center a number of times over a seven-year period after Dr. Golde told him that the visits were "necessary and required for his health and well-being" when, in reality, Dr. Golde used the visits as opportunities to take additional samples of "blood, blood serum, skin, bone marrow aspirate, and sperm" for use, at least in part, in his ongoing research.²⁷ Those visits continued after Mr. Moore moved to Seattle because

22. 793 P.2d 479 (1990).

23. *Id.* at 480–81.

24. *Id.* at 481.

25. *Id.* at 481–82.

26. *Id.* at 482.

27. *Id.* at 481.

Dr. Golde insisted that the procedures be done only in the Medical Center under his direction.²⁸

Mr. Moore became concerned when he was repeatedly asked to sign away any rights that he might have in “any cell line or any other potential product” that might be developed from his tissue samples.²⁹ On one visit, Mr. Moore checked that he did not consent; Dr. Golde frantically sought to have him sign the consent form.³⁰ Mr. Moore then retained an attorney who learned through a database search that “weeks before giving Moore the first consent form, Dr. Golde filed for a patent on Moore’s cells . . . and several valuable proteins those cells produced.”³¹

When Mr. Moore learned that his cells had been patented without his knowledge, he filed suit. He later described his feelings that he had been violated: “What the doctors had done . . . was to claim that my humanity, my genetic essence, was their invention and their property. They viewed me as a mine from which to extract biological material. I was harvested.”³²

Among other things, Mr. Moore asserted a claim for conversion, arguing that “he continued to own his cells following their removal from his body, at least for the purpose of directing their use.”³³ The court rejected those claims, holding that Mr. Moore had no property rights in his excised cells.³⁴ The court expressed concern that allowing a claim for conversion would “impose a tort duty on scientists to investigate the consensual pedigree of each human cell sample used in research.”³⁵ Allowing a claim for conversion would “destroy the economic incentive to conduct important medical research,” and would mean that “with every cell sample a researcher purchases a ticket in a litigation lottery.”³⁶

Though the court ruled that Mr. Moore lacked a property right in his excised cells, it did not leave him without a remedy, concluding that he could assert a claim based on his physicians’ failure to obtain informed consent and a claim for breach of fiduciary duty.³⁷

B. *Greenberg v. Miami Children’s Hospital Research Institute, Inc.*

Thirteen years later, a federal district court in Florida relied heavily on *Moore* to prevent patients from asserting a property interest in their excised cells in *Greenberg v. Miami Children’s Hospital Research Institute, Inc.*³⁸ The

28. *Id.* When Mr. Moore asked about having his follow up care provided in Seattle, Dr. Golde “offered to pay for the plane tickets and put him up in style at the ritzy Beverly Wilshire.” Skloot, *supra* note 9, at 41.

29. Skloot, *supra* note 9, at 41.

30. *Id.*

31. *Id.*

32. John Vidal & John Carvel, *Lambs to the Gene Market*, GUARDIAN, Nov. 12, 1994, at 25.

33. *Moore*, 793 P.2d at 487.

34. *Id.* at 497.

35. *Id.* at 487.

36. *Id.* at 495–96.

37. *Id.* at 483.

38. 264 F. Supp. 2d 1064, 1074–76 (S.D. Fla. 2003).

case involved the families of children who suffered from Canavan disease³⁹ in what the court described as “an unfortunate legal dilemma set against the backdrop of a historic breakthrough in the treatment of a previously intractable genetic disorder.”⁴⁰

In 1987, the families contacted Dr. Reuben Matalon, a research physician, seeking assistance in identifying the gene that causes Canavan disease and in developing tests to determine carriers and allow for prenatal testing for the disease.⁴¹ Working in conjunction with the Chicago Chapter of the National Tay-Sachs and Allied Disease Association, Inc., the families identified other Canavan families and convinced them to “provide tissues (such as blood, urine, and autopsy samples), financial support, and aid in identifying the location of Canavan families internationally.”⁴² The families and the association also created a confidential database and registry “with epidemiological, medical and other information about the families.”⁴³

Using the tissue, family histories, contacts, and financial support provided by the families and others, Dr. Matalon and his team isolated the gene responsible for Canavan disease in 1993.⁴⁴ Unknown to the families, Dr. Matalon applied for and received a patent for the genetic sequence.⁴⁵

The patent gave Dr. Matalon and his employer, Miami Children’s Hospital, the ability to prevent “carrier and prenatal testing, gene therapy and other treatments for Canavan disease and research involving the gene and its mutations.”⁴⁶ The Hospital began to exercise that right, announcing a campaign that would limit testing by licensing use of the patent for a fee.⁴⁷

The families filed suit, alleging that they had not been informed that Dr. Matalon and the Hospital intended to commercialize and restrict the use of the results of their research.⁴⁸ As part of their claims, they argued that they had a

39. Canavan disease is a “gene-linked, neurological birth disorder in which the white matter of the brain degenerates into spongy tissue riddled with microscopic fluid-filled spaces.” Medical College of Wisconsin, Canavan Disease, <http://healthlink.mcw.edu/article/921391101.html> (last visited Feb. 3, 2007). The degenerative disease is a cruel and relentless killer, with death often occurring “before age 4, although some children may survive into their teens and twenties.” *Id.*

Medical science has no known treatment or cure for Canavan disease, though genetic testing can identify persons at risk for transmitting the defective gene to their children. Though the defective gene can appear in any ethnic population, it occurs most frequently in Ashkenazi Jews and Saudi Arabians. *Id.* An estimated 1 in 40 Ashkenazi Jews is a carrier of the defective gene. Canavan Foundation, *What is Canavan Disease?*, available at <http://www.canavanfoundation.org/canavan.php> (last visited February 3, 2007). Afflicted children receive a copy of the defective gene from each parent, meaning that parents who carry the defective gene have a 25 percent chance of transmitting the disease to their child. Medical College of Wisconsin, *supra*.

40. *Greenberg*, 264 F. Supp. 2d at 1066.

41. *Id.*

42. *Id.* 264 F. Supp. 2d at 1067.

43. *Id.*

44. *Id.*

45. *Id.*

46. *Id.*

47. *Id.*

48. *Id.* at 1068. The Complaint asserted claims for lack of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment, conversion, and misappropriation of trade secrets. *Id.*

property interest in the tissue and genetic information that they had donated.⁴⁹ The court rejected that position. Citing to *Moore*, the court held that the families “have no cognizable property interest in body tissue and genetic matter donated for research.”⁵⁰ The families could not state a claim for conversion because they made “donations to research without any contemporaneous expectations of return of the body tissue and genetic samples.”⁵¹ Rather, the court held, any property right in blood and tissue samples “evaporates once the sample is voluntarily given to a third party.”⁵²

The court granted the Defendants’ motion to dismiss the claims for lack of informed consent, breach of fiduciary duty, fraudulent concealment, conversion, and misappropriation of trade secrets.⁵³ Nonetheless, the court denied the motion to dismiss the claim for unjust enrichment, holding that the issuance of the patent did not preclude a claim for unjust enrichment in light of the allegations that the parties had agreed to collaborate on the genetic research.⁵⁴ Shortly afterwards, the parties settled their dispute with an agreement that allowed for “continued royalty-based genetic testing by certain licensed laboratories and royalty-free research by institutions, doctors, and scientists searching for a cure.”⁵⁵

C. *The Washington University v. Catalona*

The most recent court decision concerning donated tissue ownership is *Washington University v. Catalona*,⁵⁶ a case involving an ownership dispute between a research university, a research scientist formerly associated with the University, and tissue donors. Both the federal district court and the Eighth Circuit Court of Appeals sided with the University, concluding that donors could not “direct the transfer of their biological materials” to the research scientist after he terminated his employment with the University.⁵⁷ As did the courts in *Moore* and in *Greenberg*, both the district court and the Eighth Circuit concluded that the donors had no property interests in their samples.⁵⁸

49. *Id.* at 1074.

50. *Id.*

51. *Id.*

52. *Id.* at 1075.

53. *Id.* at 1077.

54. *Id.* at 1072.

55. Joint Press Release, http://www.canavanfoundation.org/news/09-03_miami.php (last visited Feb. 3, 2007).

56. 437 F. Supp. 2d 985 (E.D. Mo. 2006), *aff’d*, 490 F.3d 667 (8th Cir 2007), *cert. denied*, 128 S. Ct. 1122 (2008) [hereinafter *Catalona I*].

57. *Wash. Univ. v. Catalona*, 490 F.3d 667, 670 (8th Cir. 2007), *cert. denied*, 128 S. Ct. 1122 (2008) [hereinafter *Catalona II*].

58. *Id.*

1. *Background of the case*

The dispute involved two sophisticated, well-regarded players in the world of medical research. The Washington University (WU) in St. Louis, Missouri is “one of the leading private research universities in this country, if not in the world.”⁵⁹ Dr. William J. Catalona, a world-renowned urologist and urologic surgeon, “is about as close as one comes to medical celebrity (he’s been called ‘urologist to the stars’).”⁶⁰ Dr. Catalona worked as a full-time employee at WU from July 1976 until February 2003,⁶¹ serving as Chief of the Urology Division at WU from 1984 to 1998. Patients flocked from around the world seeking treatment for prostate cancer from Dr. Catalona who helped pioneer the PSA test used to detect prostate cancer.⁶²

While at WU, Dr. Catalona and “several other WU physicians” collected samples of “prostate tissue, blood, and DNA samples for prostate cancer research,”⁶³ the largest collection of its type in the world.⁶⁴ During the litigation, Dr. Catalona referred to the collection as the “Catalona Collection,” while WU referred to it as the “GU⁶⁵ Biorepository.”⁶⁶

The GU Biorepository is housed in buildings owned by WU, with the University providing “the majority of the funding necessary to operate and maintain the GU Biorepository.”⁶⁷ University employees, including Dr. Catalona, engaged in outside fund raising to support the Biorepository, with Dr. Catalona alone raising “several million dollars in outside funding.”⁶⁸

The tissue bank “is not used for clinical care or follow-up care; it is strictly used for research purposes.”⁶⁹ The samples were taken from more than 30,000 men who were enrolled in studies to research the genetic causes of prostate cancer; of these, some 2,500 to 3,000 had been patients of Dr. Catalona.⁷⁰ Dr. Catalona and other University physicians had gathered the samples while conducting numerous studies related to the genetic causes of prostate cancer.⁷¹ Each study identified a particular physician as the “‘principal investigator,’ a term designating the person ‘in charge of conducting [a] re-

59. *Catalona I*, 437 F. Supp. 2d at 988.

60. Kerry Howley, *Their Bodies, Our Selves*, Dec. 5, 2006, <http://reason.com/news/printer/117046.html> (last visited Feb. 3, 2007).

61. *Catalona I*, 437 F. Supp. 2d at 988.

62. Lori Andrews, *Who Owns Your Body? A Patient's Perspective on Washington University v. Catalona*, 34 J.L. MED. & ETHICS 398 (2006); Bruce Rushton, *Gland of Opportunity*, RIVERFRONT TIMES, Nov. 19, 2003, at 18, available at <http://www.riverfronttimes.com/2003-11-19/news/gland-of-opportunity>.

63. *Catalona I*, 437 F. Supp. 2d at 988.

64. *Catalona II*, 490 F.3d at 670.

65. “GU” is an abbreviation for “genito-urinary.” *Catalona I*, 437 F. Supp. 2d at 988. n.3.

66. Answer, Affirmative Defenses & Counterclaim of Defendant William J. Catalona, M.D. at 1, *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03CV01065SNL).

67. *Catalona I*, 437 F. Supp. 2d at 989.

68. *Id.*

69. *Id.*

70. *Id.* at 988–89.

71. *Id.* at 989.

search protocol.”⁷² Though one physician was identified as principal investigator in each study, “the named principal investigator generally collaborated with several other individuals in the research studies.”⁷³

The tissue samples in dispute include approximately 3,500 samples of prostate tissue, approximately 100,000 blood samples, and some 4,400 DNA samples.⁷⁴ The samples of prostate tissue were “taken from patients of Dr. Catalona and other WU physicians within the Urologic Surgery Division.”⁷⁵ Approximately 75% of the blood samples came from “research participants who were not patients of Dr. Catalona or any other WU physician.”⁷⁶ Likewise, some of the men who donated samples were patients of Dr. Catalona, while others were not.⁷⁷

In what appears to be a battle of egos, the seeds of the dispute were sown in 2002 “when the university changed how the tissue bank operated.”⁷⁸ According to Dr. Catalona, “It was just taken from me.”⁷⁹ Rather than allowing Dr. Catalona control over the samples, the University now required that he get approval from a Peer Review Board before using samples.⁸⁰ The change in policy led to a dispute about ownership and control over the collection and to increased tension between the parties.⁸¹ In a letter, an official at WU complained that Dr. Catalona gave free tissue samples to researchers at a biotech company in exchange for “the potential for [Dr.] Catalona to get a publication,” something the official determined to be “unacceptable.”⁸²

Dr. Catalona fought back against the restrictions. Beginning in 2001, he made a series of “telephone calls, e-mails, and letters” in which he threatened to take legal action against the University “to assert a purported claim of personal ownership over the GU Biorepository.”⁸³

72. *Id.* (quoting the trial testimony; alteration in original).

73. *Id.* at 990.

74. *Id.* at 989. Other estimates place the number of prostate samples at 4,000 and blood samples at 250,000. Skloot, *supra* note 9, at 75. Some 36,000 men donated samples. *Id.* “Some of these men came to [Dr. Catalona] through newspaper and radio ads he placed seeking donors. Some came from other doctors. But many were his patients.” *Id.*

75. *Catalona I*, 437 F. Supp. 2d at 989.

76. *Id.*

77. *Id.*

78. Jocelyn Kaiser, *Court Decides Tissue Samples Belong to University, Not Patients*, 312 SCIENCE 346, 346 (2006).

79. *Id.*

80. *Id.*

81. *Id.*

82. Skloot, *supra* note 9, at 75.

83. Complaint for Declaratory Judgment at 2, *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03CV01065SNL). Dr. Catalona denies both that he has “threatened legal action” against WU or asserted a personal ownership interest in the samples, arguing instead that “the Catalona Collection was entrusted to him and that the right to re-direct these materials remains with the patients/participants.” Answer, Affirmative Defenses & Counterclaim of Defendant William J. Catalona, M.D., *supra* note 66, at 2.

Determining Ownership of Genetic Samples

The University argued that Dr. Catalona was not denied access to the samples, but instead had to seek permission to use those samples by submitting an application to the Peer Review Panel, something that Dr. Catalona did successfully at least twice after he no longer served as Division Chief.⁸⁴ WU asserted that the dispute was not one over access, but rather control.

Catalona, however, is not satisfied with access. He demands control. He wants the ability to prevent other qualified researchers from using the materials, even though he himself has no open studies using those materials. Although no longer Chief of the Urology Division or even a WU employee, he wants to remain personally the gatekeeper over the GU Biorepository. He wants the unilateral and unfettered right to send GU Biorepository materials to other researchers across the country with whom he can collaborate and publish papers⁸⁵

Dr. Catalona ultimately decided to leave WU. He first sought to go to the University of Virginia, but that deal fell through when he failed to broker a deal to take the samples with him.⁸⁶ Later, he accepted a position at Northwestern University.

On February 18, 2003, just five days before his departure, Dr. Catalona sent a letter to 10,000 patients without telling the University that he was doing so.⁸⁷ The letter went not only to the patients whom Dr. Catalona had treated, but also to patients who had been treated by other physicians at the University and to men who had participated in research studies at the University.⁸⁸ In addition, Dr. Catalona published the letter in the newsletter distributed by the research foundation where he served as Medical Director, bringing the total circulation of the letter to approximately 60,000 people.⁸⁹ Dr. Catalona wrote of his desire to continue his research on prostate cancer and solicited the assistance from the recipients of his letter:

[T]o succeed in these goals, I need to have the tissue and blood samples that patients, their relatives, and other research volunteers have *contributed to me* over the years. You have entrusted me with samples, and I have used them for collaborative research that will help in your future medical care and in the care of others for years to come.⁹⁰

84. Plaintiff's Pre-Hearing Brief at 3, *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03CV01065SNL).

85. *Id.*

86. Kaiser, *supra* note 78, at 346.

87. Complaint for Declaratory Judgment, *supra* note 83, at 8.

88. *Id.*

89. *Catalona I*, 437 F. Supp. 2d at 993.

90. *Id.* (quoting Dr. Catalona's letter) (alteration in original; emphasis added).

To continue that research, he wrote, "I need your assistance and your permission."⁹¹ The letter asked the men to sign and return a "Medical Consent and Authorization" form instructing WU to release the samples to Dr. Catalona.⁹² Within a few weeks, some 6,000 men had returned the forms directing WU to release the samples to Dr. Catalona.⁹³

2. The district court's decision

After Dr. Catalona left the University, WU filed a declaratory judgment action in federal district court seeking to establish its ownership of the samples.⁹⁴ Dr. Catalona filed a counterclaim asserting that the men who donated samples retained the right to direct the use of their samples and raising six claims against the University: (1) violation of patient-participants' rights to revoke consent; (2) failure to comply with informed consents; (3) interference with patient relationship; (4) violation of free speech; (5) breach of implied bailment; and (6) defense and indemnity.⁹⁵

Shortly afterwards, eight men who had donated tissue samples to the biorepository (Donors) were allowed to intervene as defendants in the case.⁹⁶ Ultimately, the district court held a three-day hearing on the defendants' request for a permanent injunction, a hearing in which the University, Dr. Catalona, and the Donors participated.⁹⁷ After that hearing, the district court granted the University's motion for summary judgment and denied Dr. Catalona's request that the University be enjoined from using the samples.

In what the Eighth Circuit later called a "well-reasoned opinion,"⁹⁸ the district court succinctly characterized the nature of the dispute: "once having made voluntary donations of biological materials for medical research to a research institution, do the research participants retain ownership rights in such materials in that they can direct said materials' use and transfer to third

91. Skloot, *supra* note 9, at 75 (quoting Dr. Catalona's letter).

92. *Catalona I*, 437 F. Supp. 2d at 993. In pertinent part, that form reads as follows:

I have donated a tissue and/or blood sample to Dr. William J. Catalona's Research studies. Please release all of my samples to Dr. Catalona at Northwestern University upon his request. I have entrusted these samples to be used only at his direction and with his express consent for research projects.

Id.

93. Dr. Catalona has repeatedly asserted that he received some 6,000 requests from patients instructing WU to transfer their samples. Nonetheless, as of November 24, 2003, the University maintained that "[Dr.] Catalona has never provided such purported consents to the University." Answer to Counterclaim at 1, *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03CV01065SNL).

94. *Catalona I*, 437 F. Supp. 2d at 987.

95. Answer, Affirmative Defenses & Counterclaim of Defendant William J. Catalona, M.D., *supra* note 66, at 26-37.

96. The parties disagreed on the title that should be used to describe the men. WU referred to them as "Research Participants," while Dr. Catalona and the men called them "Patients." This article will refer to them as "Donors."

97. *Catalona I*, 437 F. Supp. 2d at 988.

98. *Catalona II*, 490 F.3d at 677.

parties.”⁹⁹ The district court held that the research participants did not retain those ownership rights,¹⁰⁰ relying on three principal grounds.

First, WU exhibited all indicia of ownership required under Missouri law.¹⁰¹ WU had continuously held “exclusive possession” of and “exclusive control over” the samples.¹⁰² It had supplied the facilities and incurred the costs of housing the specimens; access to the specimens came only through the Institutional Review Board (“IRB”) and Human Studies Committee (“HSC”) at the University.¹⁰³ Though Dr. Catalona had done much of the work on the GU Biorepository, “any decisions made by Dr. Catalona were made as a WU employee.”¹⁰⁴ Moreover, the University “alone bears all legal, regulatory, and compliance risks with respect to all research done in connection with the GU Biorepository.”¹⁰⁵

Second, the district court held that the Donors made an *inter vivos* gift of their samples.¹⁰⁶ The patients voluntarily agreed to participate in medical research studies at WU.¹⁰⁷ The Principal Investigator for many of those studies was someone other than Dr. Catalona; many of the Donors were patients of WU physicians other than Dr. Catalona.¹⁰⁸ The informed consent forms typically bore the logo of WU Medical Center and stated that they were not valid until approved by the University’s HSC.¹⁰⁹ The forms directed the Donors to contact WU staff if they had concerns about the investigation and advised that WU would take steps to “protect their privacy and minimize the burdens of participating in the study.”¹¹⁰

As a theme in the litigation, Dr. Catalona and the Donors asserted that the Donors had entrusted their samples to Dr. Catalona. If the Donors had specifically intended that result at the time of their donation, the argument would have some significance. Yet, as the district court noted, “[n]owhere in the forms were [the Donors] advised that they were entrusting their samples to Dr. Catalona only.”¹¹¹ The statements of “intent” advanced in litigation were not statements of contemporaneous intent, but rather positions advanced for the purpose of litigation. The district court acknowledged that the Donors had a “deep personal connection to Dr. Catalona” and that they “believed that they owed their lives to him.”¹¹² Nonetheless, the district court held that “their

99. *Catalona I*, 437 F. Supp. 2d at 994.

100. *Id.* at 1002-03.

101. *Id.* at 994.

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.* 437 F. Supp. 2d at 997.

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.* 437 F. Supp. 2d at 999.

testimony regarding intent, especially now after getting Dr. Catalona's letter, is suspect or at least, shows nothing more than an 'afterthought of regret'.¹¹³

Dr. Catalona and the Donors argued that the tissue samples were not gifts, but rather constituted a bailment. As the district court noted, "however, when a 'bailment' is made, the bailor has every expectation of receiving back the subject of the bailment."¹¹⁴ None of the parties presented any evidence that at the time of the donation, any of the Donors intended to receive back their tissue samples.¹¹⁵ Moreover, "the medical research community itself has never considered the relationship between [a research participant] and a medical research institution to be one of bailment."¹¹⁶

Third, the district court considered "the possible (if not probable) public policy ramifications" of the position advanced by Dr. Catalona and the Donors.¹¹⁷ Under that position,

these highly-prized biological materials would become nothing more than chattel going to the highest bidder. It would no longer be a question of the importance of the research protocol to public health, but rather who can pay the most. Selling excised tissue or DNA on E-Bay would become as commonplace as selling your old television on E-Bay. The integrity and utility of all biorepositories would be seriously threatened if [research participants] could move their samples from institution to institution at any time they wanted.¹¹⁸

Moreover, the district court held that allowing the Donors to "choose who can have the sample, where the sample will be stored, or how the sample can be used is tantamount to a blood donor's being able to dictate that her blood can only be transfused into a person of a certain ethnic background, or a donated kidney being transplanted only into a woman or man."¹¹⁹

Summarizing these positions, the district court held that (1) defendants were not entitled to injunctive relief; (2) WU owns the tissue samples in the GU Biorepository; (3) Dr. Catalona and the Donors do not have "any ownership or proprietary interest" in the tissue samples; and (4) the signed "Medical Consent & Authorization" forms that Dr. Catalona solicited from the Donors

113. *Id.* The district court's conclusion is consistent with the Corbin approach of interpreting contracts "'in light of the parties' intentions as reflected by the language and in view of all the circumstances.'" *Darner Motor Sales, Inc. v. Universal Underwriters Ins. Co.*, 682 P.2d 388, 398 (Ariz. 1984) quoting *Smith v. Melson*, 659 P.2d 1264, 1266 (Ariz. 1983). "All of the circumstances" include the actions of the parties before a dispute arose. *See id.* As one court has stated,

[t]he construction or interpretation given to the agreement as evidenced by the acts and conduct of the parties with knowledge of the terms and prior to any controversy as to meaning arises is entitled to great weight and when reasonable will be adopted and enforced by the court. The acts of the parties themselves, before disputes arise, are the best evidence of the meaning of doubtful contractual terms.

United Cal. Bank v. Prudential Ins. Co., 681 P.2d 390, 418 (Ariz. Ct. App. 1983).

114. *Catalona I*, 437 F. Supp. 2d at 1001.

115. *Id.*

116. *Id.*

117. *Id.* 437 F. Supp.2d at 1002.

118. *Id.*

119. *Id.*

are “void and ineffective to transfer ownership and/or possession” of any of the samples.¹²⁰

3. The Eighth Circuit Affirms the District Court

Dr. Catalona and the Donors appealed the decision to the Eighth Circuit Court of Appeals, which affirmed the decision of the district court.¹²¹ Like the district court, the Eighth Circuit succinctly characterized the “pivotal inquiry” of the dispute:

whether individuals who make an informed decision to contribute their biological materials voluntarily to a particular research institution for the purpose of medical research retain an ownership interest allowing the individuals to direct or authorize the transfer of such materials to a third party.¹²²

Like the district court, the Eighth Circuit held that under the facts of this case, the Donors had no remaining ownership interest in their genetic material.¹²³

The Eighth Circuit based its decision on the district court’s finding that the Donors voluntarily donated their tissue samples to the University as *inter vivos* gifts. The court held that WU showed clear and convincing evidence of each of the three elements of a claim of an *inter vivos* gift under Missouri law: “(1) present intent of the donor to make a gift, (2) delivery of the property by the donor to the donee, and (3) acceptance of the gift by the donee, whose ownership takes effect immediately and absolutely.”¹²⁴ Finding that the Donors “unquestionably delivered their biological materials to WU at the time of their donation,” the court addressed only the first and third requirements for an *inter vivos* gift in detail.¹²⁵

120. *Id.* at 1002–03.

121. *Catalona II*, 490 F.3d 667, 677 (8th Cir. 2007).

122. *Id.* at 673.

123. *Id.* The Eighth Circuit’s decision is legally sound, and the court properly affirmed on that basis. Nonetheless, as is the case with virtually all appellate cases, the standard of review on appeal largely dictated the result of the *Catalona* case. Dr. Catalona and the Donors sought to reverse the district court’s decision granting the motion for summary judgment against them and denying their request for injunctive relief. While an appellate court reviews the granting of summary judgment *de novo*, see, e.g., *Burlington N. & Santa Fe Ry. Co. v. State Tax Comm’n*, 188 F.3d 1039, 1041 (8th Cir. 1999), the denial of injunctive relief is reviewed for an abuse of discretion, see, e.g., *id.*, a standard that is very difficult to meet on appeal. The abuse of discretion standard required the appellants to show that the district court “base[d] its decision on an erroneous application of the law or a *clearly erroneous factual finding*.” *Catalona II*, 490 F.3d at 673, (emphasis added).

As is noted below, the Eighth Circuit’s decision is based on the district court’s factual finding that the Donors had donated their samples as *inter vivos* gifts to the University. Dr. Catalona and the Donors could not prevail on appeal unless they could show that the district court’s finding was clearly erroneous. The clearly erroneous standard is extremely difficult to overcome in a case where the evidence equally supports either party’s interpretation. Where the evidence overwhelmingly favors the district court’s factual finding (as in this case), the standard of review dictates that the factual finding be sustained on appeal.

124. *Catalona*, 490 F.3d at 674, 676–77.

125. *Id.* at 674.

With regard to the first element, the language of the informed consent forms and the brochure given to the Donors supported the conclusion that the Donors intended to make a gift at the time the samples were taken.¹²⁶ Each Donor had signed a consent form bearing the WU logo.¹²⁷ The consent forms identified the Donor's participation in the studies as "a 'donation' of bodily tissues or blood;" the forms "emphasized the voluntariness of the [Donor's] participation and discussed the [Donor's] right to decline participation in the study or to withdraw consent at any time."¹²⁸ Moreover, many consent forms did not identify Dr. Catalona as the person to whom the Donors were entrusting their samples. Instead, those of the consent forms identified "someone other than Dr. Catalona as the principal investigator."¹²⁹ Even when the consent form identified Dr. Catalona as the principal investigator, the form referenced "a research study conducted by Dr. William J. Catalona *and/or colleagues*."¹³⁰ The consent forms further advised the Donors that their biological samples "may be used for research with our collaborators at [WU], other institutions, or companies."¹³¹

In addition, the brochures given to the Donors "characterized [their] donations as 'a free and generous gift of [biological materials] to research that may benefit society.'"¹³² The language of the brochure, "considered together with the consent form, cannot reasonably be characterized as reflecting the [Donor's] intention either to entrust their samples solely to Dr. Catalona or to transfer the samples in some legal form other than a gift."¹³³

Turning to the third element of a claim for an *inter vivos* gift—acceptance of the gift by the donee—the court rejected the contention that the Donors retained rights in the tissue samples and that the transfer to WU was not absolute. The court noted that the University immediately "accepted and retained absolute possession of the biological materials upon donation."¹³⁴ That fact did not change simply because the Donors had the right to revoke their donation and withdraw from the studies in the future. "The attachment of a condition to a charitable donation of property does not negate or void an otherwise valid *inter vivos* gift."¹³⁵ Any rule to the contrary "would make charitable donations wholly impossible or ineffectual."¹³⁶

The Donors' right to withdraw from participating in future studies did not give them "the right to revoke and physically repossess the donated biological materials," nor did they "retain the right to direct or authorized the use, trans-

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.*

130. *Id.* (emphasis in original).

131. *Id.* (first alteration added; second alteration in original).

132. *Id.*

133. *Id.* at 675.

134. *Id.*

135. *Id.*

136. *Id.*

fer, or destination of the biological materials after their donation.”¹³⁷ Rather, the Donors’ future rights “were expressly limited to the option to discontinue participation in the study to avoid answering additional questions, donating more biological materials, or allowing their biological materials to be used for further research.”¹³⁸

The court found further support for its holding in “Dr. Catalona’s past conduct, as well as the practical consequences of the research process itself.”¹³⁹ Before the dispute arose, Dr. Catalona repeatedly acknowledged that WU owned the genetic materials and took actions consistent with the Donors’ no longer having any residual ownership interest in the samples.¹⁴⁰

4. *The Aftermath of the Decision*

As is the case with *Moore* and *Greenberg*, reaction to the *Catalona* decision has been controversial. After the district court’s decision, Dr. Catalona argued that the ruling “runs roughshod on patients’ rights,”¹⁴¹ and likened the university to Adolph Hitler. “You can’t start infringing on the rights of research subjects,” he said. “You can say it’s for the good of society, but that’s what Hitler said when they started throwing people in ice water and seeing how long it took them to die.”¹⁴²

Lori Andrews, an ethicist at the Illinois Institute of Technology and a law professor at the Chicago-Kent College of Law, called the decision “a big setback for patients’ rights.”¹⁴³ The decision, she said “is going to turn patients into treasure-troves rather than partners in research.”¹⁴⁴

Not surprisingly, the University praised the decision. In a letter published in the *St. Louis Post-Dispatch*, Larry J. Shapiro, Executive Vice Chancellor and Dean of the Medical School at WU, asserted that the decision “is important to science and protects research participants’ rights.”¹⁴⁵ Actions like those taken by Dr. Catalona, he maintained, “can allow a researcher’s personal agenda to supersede donors’ interests.”¹⁴⁶ After the Eighth Circuit’s decision, Dr. Shapiro reiterated that the ruling would “allow important research into the causes of prostate cancer to continue, with the goal of developing new

137. *Id.*

138. *Id.*

139. *Id.* at 676.

140. *See infra* text accompanying notes 150–59.

141. Tina Hesman Saey, *WU gains rights to tissue samples*, ST. LOUIS POST-DISPATCH, Apr. 18, 2006, at A1.

142. *Id.*

143. *Id.*

144. *Id.*

145. Larry J. Shapiro, Letter to the Editor, *Research Must Put Science above Agenda*, ST. LOUIS POST-DISPATCH, Apr. 21, 2006, at C12.

146. *Id.*

cures.”¹⁴⁷ The ruling, he said, “creates the best opportunity for this extensive collection of tissues to be used to advance understanding of the disease.”¹⁴⁸

III. OBSERVATIONS ON THE CATALONA DECISION

Catalona addresses the difficult questions of ownership in a thoughtful manner that looks to the precedent of the past while maintaining an open eye toward the emerging technologies of the future. While the decision raises many important issues for consideration, at least three important points merit special attention.

First, although neither the district court nor the Eighth Circuit explicitly said as much, Dr. Catalona and the Donors harmed their position by taking prelitigation positions that were inconsistent with their positions in the litigation. In the litigation, Dr. Catalona officially maintained that neither he nor WU owned the samples;¹⁴⁹ his prelitigation actions and statements were, however, inconsistent with this position.¹⁵⁰ The Eighth Circuit specifically referenced Dr. Catalona’s actions that were inconsistent with the position that the Donors retained an ownership interest in the samples.¹⁵¹

For example, Dr. Catalona previously acknowledged that the University owned the samples. On a number of occasions, the University made samples from the collection available to collaborating companies and academic researchers at other institutions, authorizing that use through a material transfer agreement (MTA).¹⁵² “Several MTAs personally signed by Dr. Catalona, as

147. Washington University at St. Louis, U.S. 8th Circuit Court of Appeals rules in Favor of Washington University in Case Involving Ownership of Tissues Donated for Research, <http://prostatecure.wustl.edu/> (last visited June 23, 2007).

148. *Id.*

149. See Answer, Affirmative Defenses & Counterclaim of Defendant William J. Catalona, M.D., *supra* note 66, at 2, 4..

150. See *infra* text accompanying notes 151–59. Dr. Catalona is not the only one exhibiting this schizophrenic attitude toward the samples. An article sympathetic to Dr. Catalona begins, “Dr. William Catalona just wants *his blood and tissue* back.” Howley, *supra* note 60 (emphasis added). Nonetheless, the article notes that Dr. Catalona sought approval from his patients to move the samples, “*which he considers theirs, not his.*” *Id.* (emphasis added).

151. The Court excoriated Dr. Catalona for the inconsistencies in his positions:

Dr. Catalona’s past conduct, as well as the practical consequences of the research process itself, also refutes the defendants’ position. While at WU, Dr. Catalona signed numerous MTAs and research agreements acknowledging WU’s ownership of the biological materials. Moreover, during Dr. Catalona’s tenure, he routinely ordered the destruction or “purging” of Biorepository samples in order to create more storage space, and did so without obtaining any additional consent from [the research participants]. Dr. Catalona’s habitual destruction of samples, in a manner consistent with apparent indifference to any proprietary interest of the donors, is at odds with his later assertion the [Donors] own the biological materials. Furthermore, during research involving the use of prostate tissue and blood samples, the research process might consume an entire particular biological specimen, leaving behind no tangible material in which a donor could assert a potential proprietary interest. It is difficult to reconcile the use, consumption, and destruction of biological materials by Dr. Catalona and the events that occurred during the research process with the assertion the [Donors] retained an ownership interest in the donated materials.

Catalona II, 490 F.3d at 676.

152. Memorandum of Points and Authorities in Support of Motion for Summary Judgment at 3, Wash. Univ. v. Catalona, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03CV01065SNL). WU uses MTAs providing that the material supplied “shall remain the property of the Provider,” and

the principal or providing investigator, acknowledge WU as the owner of the biological samples.”¹⁵³

Dr. Catalona did not dispute that WU owned the collection until around the time he decided to leave the University.¹⁵⁴ The first time Dr. Catalona attempted to dispute WU’s ownership in an MTA came a year after he left the University. At that time, Dr. Catalona did not claim that the Donors retained property rights in their samples, as he did in the litigation, but rather attempted to redraft an MTA to reflect that he was a joint owner of the biological samples being transferred.¹⁵⁵ When WU refused to accept his amended MTA, Dr. Catalona relented and signed the original draft of the agreement, asserting that he was doing so on the advice of his counsel but that he personally believed that he had “proprietary rights” in the samples.¹⁵⁶

At trial, Dr. Catalona denied that he received the samples as unconditional gifts.¹⁵⁷ He refused to state who owned the samples, but asserted that he had “a strong proprietary interest in the broad sense of the word.”¹⁵⁸ Though he advocated that the research participants should be able to direct samples to another prostate surgeon, “he was unwilling to say that those same participants could direct their tissues to third parties who are *not* renowned prostate surgeons.”¹⁵⁹

Moreover, the Donors’ position was also inconsistent with their prelitigation position. While the Donors claimed in litigation that they merely had entrusted their samples to Dr. Catalona and still retained the right to control the use of those samples, their prior conduct instead reflected that the samples were gifts. For example, the consent form signed by two of the three Donors who testified at trial stated, “By agreeing to participate in this study, you agree to waive any claim you might have to the body tissues [that] you *donate*.”¹⁶⁰ Another consent form referenced the patient’s “*donation*” of blood.¹⁶¹

identify WU as the “Provider.” *Id.* at 9–10. Those agreements also expressly distinguish the “Provider” from the “Provider Scientist.” *Id.* at 10.

Dr. Catalona was the Provider Scientist on 15 MTAs involving the transfer of samples from the repository. *Id.* Each of those agreements specifically affirms that WU owned the biological materials being transferred. *Id.* Dr. Catalona signed nine of the 15 MTAs; he received and reviewed the other six MTAs in question. *Id.*; *Catalona I*, 437 F. Supp.2d at 995 (“in all MTAs concerning these materials, including those wherein Dr. Catalona was the ‘Provider’s Scientist’, WU clearly exerted its ownership interest without objection by Dr. Catalona”).

153. *Catalona II*, 490 F.3d at 672.

154. Memorandum of Points and Authorities in Support of Motion for Summary Judgment, *supra* note 152, at 10.

155. *Catalona I*, 437 F. Supp.2d at 995. The court discounted Dr. Catalona’s testimony that “he felt he had no choice but to sign” the MTA but still maintained that he had a “proprietary interest in the subject biological materials,” holding that “the document speaks for itself.” *Id.* at 995, n.14.

156. Memorandum of Points and Authorities in Support of Motion for Summary Judgment, *supra* note 152, at 10, n.3.

157. Plaintiff’s Pre-Hearing Brief, *supra* note 84, at 9.

158. Plaintiff’s Post-Trial Brief at 15–16, *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03CV01065SNL).

159. *Id.* at 16 (emphasis in the original).

160. *Id.* at 7 (emphasis added).

161. *Id.* (emphasis added).

Furthermore, if the Donors entrusted their samples to Dr. Catalona at the time they made their donation—as they claimed during litigation—they entrusted him with the authority to deal with their samples in the manner he deemed most appropriate. The best way to determine what Dr. Catalona deemed to be most appropriate at the time is to look at his actions. Those actions reflect that he understood that WU owned the tissue samples, as he repeatedly affirmed in the MTAs he signed. That understanding is consistent with the practice in the research community. Although the Donors and Dr. Catalona argued that “the right to discontinue participation includes the right to control over the use and location of [the Donor’s] excised biological materials,”¹⁶² they advanced no examples supporting their contention. Rather, the testimony identified only three possible results when a research participant chooses to discontinue participation in a study: “1) WU may destroy the sample; 2) WU may store the sample indefinitely without any further use; or 3) WU may remove all identifying markers and use the sample in exempt ‘anonymized’ research.”¹⁶³ The evidence did not show any instances where a research participant had required that his samples be transferred to another facility for research purposes.

Second, as is noted above, when Dr. Catalona first contested WU’s ownership of the samples, he claimed that he *personally* owned the so-called Catalona Collection. Indeed, when he contacted the Donors, he asserted that they had contributed their samples to him.¹⁶⁴ While neither the opinions of the district court or the Eighth Circuit nor the pleadings disclose why Dr. Catalona abandoned this position, he may have done so because, as an employee of the University, he could not acquire a personal interest in the samples.¹⁶⁵ As the Restatement (Second) of Agency makes clear, “[u]nless otherwise agreed, an agent is subject to a duty to his principal to act solely for the benefit of the principal in all matters connected with his agency.”¹⁶⁶ Dr. Catalona’s responsi-

162. *Catalona I*, 437 F.Supp.2d at 999.

163. *Id.* at 999. Indeed, that is the practice that Dr. Catalona continues to use after leaving WU. As the district court noted, “even Dr. Catalona, as a researcher at Northwestern University, testified that he is using informed consent forms which only state two (2) options upon a RP’s decision to withdraw participation: 1) destruction of the sample or 2) anonymization of the sample. Northwestern University’s consent form interestingly does not provide the third option advocated by Dr. Catalona and the RPs; i.e., return of the sample to the RP or transfer of the sample to a location chosen by the RP.” *Id.*, at 999–1000 n. 17.

164. *See supra* note 83 and accompanying text.

165. Among other things, the University’s Intellectual Property Policy made clear that the University owned the fruits of Dr. Catalona’s labors:

General Statement of Ownership. Except as is noted below, all intellectual property (including lab notebooks, cell lines and other tangible research property) shall be owned by the University if significant University resources were used or if it is created pursuant to a research project funded through corporate, federal or other external sponsors administered by the University.

Complaint for Declaratory Judgment, *supra* note 83, at 7. Moreover, an employee’s duty of loyalty prohibits him from competing with his principal “concerning the subject matter of his agency” unless the principal and agent agreed otherwise. RESTATEMENT (SECOND) OF AGENCY, § 393 (1958) Indeed, “it is the agent’s duty to further his principal’s interests even at the expense of his own in matters connected with the agency.” *Id.*, cmt. b.

166. RESTATEMENT (SECOND) OF AGENCY, § 387 (1958).

bilities with WU—that is, his employment as a medical researcher¹⁶⁷—define the scope of the “matters connected with his agency.” The so-called Catalona Collection “is not used for clinical care or follow-up care” but is, instead, “strictly used for research purposes.”¹⁶⁸ For that reason, Dr. Catalona was acting in connection with his agency as a medical researcher when he gathered the samples. As a matter of law, the fruits of his labors—in this case, any property rights in the tissue samples—belonged to the University, particularly because the University incurred all expenses associated with gathering and maintaining the samples.¹⁶⁹

Similarly, Dr. Catalona cannot claim the right to own or control the samples simply because he raised funds that were used to develop or maintain the Biorepository. Even if Dr. Catalona “raised virtually all of the money for the direct support of the biorepository,”¹⁷⁰ as he claims on his Web site, he did so in his capacity as an employee acting on behalf of his employer.¹⁷¹ Absent an employment agreement that specifically allowed him to do so (and no such agreement was present in this case), Dr. Catalona cannot claim both the right to be paid for his work and the right to own or control the the samples in the biorepository developed as a result of his employment with WU.

Third, Dr. Catalona and the Donors hurt their credibility by overreaching. Lori Andrews, an ethicist at the Illinois Institute of Technology and a law professor at the Chicago-Kent College of Law, frequently argues that donors have an ongoing ownership interest in their samples under a bailment theory.¹⁷² The Donors advanced this legal argument as part of their case.¹⁷³ While the bailment theory has, appropriately, succeeded in other litigation involving human organisms, it is not persuasive in the context of donations of tissue samples for research.¹⁷⁴

167. *Catalona I*, 437 F.Supp. 2d at 988.

168. *Id.* at 989.

169. *Id.* at 994.

170. Dr. Catalona’s Response to Washington University Statements About Tissue Samples, <http://www.drcatalona.com/qanda.html> (last visited Jan. 28, 2008).

171. *See Catalona I*, 437 F.Supp.2d at 989.

172. *See, e.g., Andrews, supra* note 62, at 403 (“The fact that the patients cared about what was done with their tissue – and might wish to provide samples only for certain purposes – is consistent with other legal concepts, such as bailment”); Andrews, *supra* note 4, at 22 (cases involving ownership of human tissues might cross “many areas of law: tort, property, gift, bailment, constitutional rights, and federal regulation”).

173. Answer, Affirmative Defenses & Counterclaim of Defendant William J. Catalona, M.D., *supra* note 66, at 12.

174. In *York v. Jones*, for example, a couple went to a fertility clinic to seek assistance in conceiving a child through *in vitro* fertilization (IVF). *York v. Jones*, 717 F. Supp. 421, 423 (E.D. Va. 1989). At the end of the IVF process, the couple had one remaining cryogenically preserved prezygote remaining. *Id.* at 424. They sought to have the prezygote transferred to another facility for IVF implantation in the wife. *Id.* The facility argued that transfer was not possible because the informed consent the couple signed limited the couple to one of three possibilities: (1) donating the prezygote to another infertile couple, (2) donating the prezygote to an approved research facility, and (3) having the prezygote “thawed but not allowed to undergo further development.” *Id.*

The district court found that a bailment existed, even though no specific language in the informed consent created that bailment. *Id.* at 425. Under Virginia law, “all that is needed [to

Moreover, the Donors and Dr. Catalona could not legitimately claim that the right to withdraw their tissue samples from the research studies also gave them the right to transfer their samples to a new institution. The withdrawal and destruction of a tissue sample cannot reasonably be equated to the transfer of that sample to another facility, particularly when no one was able to cite a single instance where a research facility had transferred a sample to another research facility at the request of the donor.

Not only did Dr. Catalona and the Donors overreach by advancing inapplicable legal theories, they also engaged in revisionist history. While they argued passionately at trial and on appeal that the Donors intended to entrust Dr. Catalona alone with their tissue samples, they could point to no credible evidence that supported their position. Rather, their litigation position was inconsistent with the underlying documents and their actions, which are the best indications of what the parties intended at the time of the donations. Undoubtedly, as is true in most cases, the parties did not consider what would happen in the event of a change of circumstances, for example, if Dr. Catalona leaves WU and wants to take the samples with him. Future researchers, especially prominent researchers, are well advised to negotiate their rights to tissues donated for research purposes prior to any dispute or impending departure.



Many people understandably feel a strong emotional connection with their excised genetic material, particularly if they believe that someone else is making money on that sample or the sample is being used in a manner contrary to their wishes. Nonetheless, as the *Catalona* decision emphasizes, current practices for the taking and using of samples do not give donors an ongoing ownership interest in excised tissues that they have clearly donated for research purposes.

create a bailment] 'is the element of lawful possession however created, and duty to account for the thing *as the property of another.*' *Id.* (quoting *Crandall v. Woodard*, 143 S.E.2d 923, 927 (1965)) (emphasis added). Further, as the court noted, "[t]he essential nature of a bailment relationship imposes on the bailee, when the purpose of the bailment has terminated, *an absolute obligation to return the subject matter of the bailment to the bailor.*" *Id.* (emphasis added).

When a couple entrusts their sperm and eggs to a fertility clinic, they do so with the express understanding and expectation that, through IVF, embryos will be developed that can be implanted, leading to the expected birth of a child. The clinic specifically assumes the duty to account for the prezygotes; it has an absolute duty to return the property to the couple.

The recipient of a donation of tissue assumes none of these obligations. As contrasted with an embryo that an infertile couple hopes will develop into a child, no one gives a sample of a cancerous prostate tissue or a vial of blood with the understanding that the sample will be returned. Indeed, the donor more likely understands that the tissue ultimately will be consumed during the research. Moreover, a researcher does not have a duty to account to the donor for how his sample is used. A theory of bailment makes sense in the context of IVF; it is inapplicable in the context of a donation of research samples. As the court held in *Catalona*, "[t]his argument fails for the simple reason that when a 'gift' is made, the giftor/donor has no expectation of getting the 'gift' back; however, when a 'bailment' is made, the bailor has every expectation of receiving back the subject of the bailment." *Catalona I*, 437 F. Supp. 2d at 1001.

Determining Ownership of Genetic Samples

A different fact pattern might dictate a different result, but that different result would raise additional legal challenges. For example, if the consent forms had specifically stated that the Donors were entrusting their samples to Dr. Catalona and not to the University, the Donors might have been able to persuade the court that they could require the samples to follow Dr. Catalona to his new employment. In such a case, however, Dr. Catalona might have had the financial, legal, and regulatory responsibilities of storing the samples, a burden that he did not accept and might be unwilling to accept.

If Dr. Catalona initially accepted the responsibilities for the samples and later changed his mind, Donors might feel deceived or offended if he sought to have the samples destroyed or transferred to another researcher. The same circumstances would arise upon the death or retirement of Dr. Catalona. Giving patients control over their samples in perpetuity would increase the cost of research, require cumbersome monitoring systems and processes, and delay life-saving research studies.

Catalona recognizes the only practical method for addressing these critical issues. A tissue donation is a gift. By the specific terms of that gift, donors retain a limited right to withdraw their participation in the study. Otherwise, their donation is an unqualified gift over which they have no control.