

**United States Court of Appeals  
FOR THE EIGHTH CIRCUIT**

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No. 06-2286

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Washington University, \*  
\*  
Appellee, \*  
\*  
v. \*  
\*  
William J. Catalona, M.D., \*  
\*  
Appellant. \*

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No. 06-2301

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Appeals from the United States  
District Court for the  
Eastern District of Missouri.

Washington University, \*  
\*  
Appellee, \*  
\*  
v. \*  
\*  
Richard N. Ward; Thomas A. McGurk, \*  
Jr.; Luis Garcia; Antonio Castro; Philip \*  
Wilard; Ivan Parron; James D. Ellis; \*  
Mike Missios, \*  
\*  
Appellants. \*

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Us Too International; People's	*
Medical Society,	*
	*
Amici on Behalf of	*
Appellants,	*
	*
American Cancer Society; Cornell	*
University; Duke University; Emory	*
University; The George Washington	*
University; Johns Hopkins University;	*
Mayo Clinic; The Board of Trustees of	*
the Leland Stanford Junior University;	*
The University of Michigan; University	*
of Minnesota; The University of	*
Pittsburgh; The University of	*
Rochester; American Council on	*
Education; Association of American	*
Medical Colleges; Association of	*
American Universities,	*
	*
Amici on Behalf of	*
Appellee.	*

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Submitted: December 13, 2006  
 Filed: June 20, 2007

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Before WOLLMAN, RILEY, and SHEPHERD, Circuit Judges.

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RILEY, Circuit Judge.

We are asked to determine the ownership of biological materials contributed by individuals for the purpose of genetic cancer research and currently housed on the campus of Washington University (WU). WU brought a declaratory judgment action against Dr. William Catalona (Dr. Catalona), a former WU medical school faculty

member, seeking to establish WU's ownership of the research biological materials. Dr. Catalona counterclaimed, seeking a declaration the contributing individuals could direct the transfer of their biological materials to him. Dr. Catalona also moved for an order prohibiting WU from utilizing, disseminating, transferring, or destroying the biological materials at issue. The district court<sup>1</sup> concluded WU owns the biological materials and neither Dr. Catalona nor any contributing individual has any ownership or proprietary interest in the disputed biological materials. These appeals followed. We affirm.

## **I. BACKGROUND**

WU, a prominent private research university located in St. Louis, Missouri, houses its own medical school, including a Division of Urologic Surgery (Division). Within the Division, WU physicians treat patients, teach students and residents, and conduct medical research on urologic diseases such as prostate cancer. Dr. Catalona, a highly respected urologist and urologic surgeon and researcher, was employed by WU from 1976 to 2003, and he served as Division Chief from 1984 to 1998. During Dr. Catalona's tenure at WU, he performed thousands of surgeries, many involving prostate cancer. As a leading medical researcher for WU, one of Dr. Catalona's principal areas of research was the genetic basis of prostate cancer. In 1983, Dr. Catalona began collecting samples of biological materials, such as blood and tissue removed during surgery, to be used later for prostate cancer research. Dr. Catalona encouraged his colleagues to do the same.

Dr. Catalona was instrumental in establishing the GU<sup>2</sup> Biorepository (Biorepository), the world's largest storage facility for biological samples collected by Dr. Catalona and other WU physicians for prostate cancer research. The

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<sup>1</sup>The Honorable Stephen N. Limbaugh, United States District Judge for the Eastern District of Missouri.

<sup>2</sup>"GU" is an abbreviation for genito-urinary.

Biorepository is housed in one or more buildings owned by WU. WU provides the majority of funding necessary to support the maintenance and operation of the Biorepository. Additional funding is provided by public and private grants payable to and administered by WU as the “grantee.” While employed by WU, Dr. Catalona raised several million dollars in outside funding for the Biorepository. Other WU employees, including Dr. Catalona’s successor as Division Chief, also have raised a substantial amount of funds.

During the relevant time period, Dr. Catalona and other Division physicians performed many genetic cancer research studies, with each study naming a particular WU physician as the “principal investigator,” a term designating the person “in charge of conducting the research protocol.” Regardless of the physician designated as principal investigator on a particular research study, the named principal investigator generally collaborated with several other individuals in the research studies.

In order to conduct these studies, individuals were invited to participate in genetic research. Individuals who chose to donate excised prostate tissue or a blood sample to medical research and to become a research participant (RP) were required to complete an informed consent form.<sup>3</sup> Although the language of the consent forms differs, depending upon the nature of the particular study or the study’s principal investigator, generally all of the forms contain similar provisions, such as the WU Medical Center or WU School of Medicine logo, the principal investigator, the purpose of the research, and the nature of the RP’s participation.

The consent forms often used the term “donation” to describe the biological sample’s transfer from the RP to a WU physician or medical technician. The forms also noted biological samples “may be used for research with our collaborators at [WU], other institutions, or companies.” The consent forms typically provided that

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<sup>3</sup>Fifteen versions of the consent forms, used for six different research studies, were admitted into evidence before the district court.

by participating in the study, the RP “agree[s] to waive any claim [he] might have to the body tissues that [he] donate[s]” and also “waive[s] the right to any new material or process developed through research involving [his] tissues.” RPs also were informed by the consent forms, “Your participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time.” Some consent forms indicated RPs could request destruction of their biological materials if they changed their minds about participating in the study, but noted it would not be possible to destroy or recall any research results already obtained. Other consent forms made no mention about an RP’s right to request destruction of materials donated to research.<sup>4</sup>

In addition to the consent form, RPs received a genetic research information brochure (brochure) to review and sign. The brochure provided RPs’ tissue samples (1) will be used by “[WU] Medical Center researchers,” (2) “may be shared with other authorized researchers doing research in similar fields at [WU] and other research centers,” and (3) “may be used for studies currently in progress or studies conducted 10 or 20 years from now.” Similar to the consent forms, the brochure used the term “donation” to describe the RP’s participation, noting, “By agreeing to participate, you are making a free and generous gift of your tissue to research that may benefit society.” The brochure advised RPs, “You will receive no monetary payment for your tissue nor can you claim ownership rights to any medical or scientific product that results from research with your tissue.” The brochure also informed RPs of their right to have their biological materials destroyed upon request should they change their minds about participating in the research study.

At the time of the district court’s permanent injunction hearing in this case, more than 30,000 RPs were enrolled in WU prostate cancer research studies. About 2,500 to 3,000 RPs had been patients of Dr. Catalona. The Biorepository contains: (1) approximately 3,500 prostate tissue samples taken from patients of Dr. Catalona

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<sup>4</sup>Forms signed by seven of the eight defendant-patients fall within this category.

and other WU physicians within the Division; (2) about 100,000 blood or serum samples donated by over 28,000 men, 75% of whom were not patients of any WU physician, but rather were volunteers recruited through the media; and (3) DNA samples provided by approximately 4,400 men, which included patients of different WU physicians and relatives of those patients.

Over the years, other research institutions requested and received biological samples from the Biorepository to conduct genetic cancer research projects either in partnership with or independent of WU. While at WU, Dr. Catalona repeatedly transferred Biorepository materials to other research institutions pursuant to material transfer agreements (MTAs). The MTAs typically were signed by an authorized WU official as well as a providing investigator. Several MTAs personally signed by Dr. Catalona, as the principal or providing investigator, acknowledge WU as the owner of the biological samples.

In early 2003, Dr. Catalona accepted a faculty position at Northwestern University in Chicago, Illinois. Given his plan to continue genetic research in the area of prostate cancer, Dr. Catalona sent a letter in February 2003 to his patients, their relatives, and other individuals who had served as RPs informing them of his departure from WU and requesting transfer of biological materials. Attached to the letter was a “Medical Consent & Authorization” form (release form). In addition, both the letter and release form were printed in a newsletter from the Urological Research Foundation, for which Dr. Catalona served as the medical director. Dr. Catalona estimated between 50,000 and 60,000 individuals received the letter and release form. Although Dr. Catalona was still a WU employee at the time he sent the letter and release form, Dr. Catalona was no longer the principal investigator on any of the research protocols involving biological samples he sought to have transferred to Northwestern University. Neither the letter nor the release form were approved by any WU administrators or WU’s institutional review board. The letter discussed, among other things, Dr. Catalona’s availability for treatment, his continuation of prostate cancer research, and his need for the tissue and blood samples “contributed

to [him] over the years.” In connection with Dr. Catalona’s stated necessity, the letter requested the recipient sign and return to Dr. Catalona the attached release form, which set forth the following language:

I have donated a tissue and/or blood sample for 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 Dr. Catalona to be used only at his direction and with his express consent for research projects.

Approximately 6,000 RPs returned completed release forms to Dr. Catalona.

**A. Procedural Background**

On August 4, 2003, WU filed a declaratory judgment action against Dr. Catalona, seeking to establish WU’s ownership of the Biorepository and the biological materials contained therein. Dr. Catalona counterclaimed and sought a declaration that the RPs have the right to direct the transfer of their biological samples to him. In January 2004, WU moved for summary judgment. On June 8, 2004, after filing several extensions to respond to WU’s summary judgment motion, Dr. Catalona moved for an order prohibiting WU from utilizing, disseminating, transferring, or destroying the genetic material at issue. The following day—and before WU could respond—the district court temporarily granted the motion. WU then moved to set aside the district court’s order, arguing Dr. Catalona was truly seeking a preliminary injunction. The district court agreed, withdrew its June 9, 2004, order, converted Dr. Catalona’s motion to a motion for a preliminary injunction, and set the motion for hearing.

On February 11, 2005, in an effort to resolve continuing disputes between the parties on the priority of the pending motions, the district court, sua sponte, ordered a permanent injunction hearing for April 11, 2005. On February 22, 2005, eight of Dr.

Catalona's patients who served as RPs,<sup>5</sup> sought to intervene in support of Dr. Catalona. Upon finding the eight men were necessary parties to the litigation, the district court ordered they be joined as defendants.

Following a three-day hearing on the permanent injunction, the district court found (1) WU was the owner of the biological samples housed in the Biorepository, (2) neither Dr. Catalona nor any RP in connection with any research protocols conducted under the auspices of WU had any ownership or proprietary interest in the biological samples in question, and (3) none of the release forms authored by Dr. Catalona and signed by any RP were effective to transfer ownership or possession of the biological samples to Dr. Catalona or to any other research facility or individual. Wash. Univ. v. Catalona, 437 F. Supp. 2d 985, 1002 (E.D. Mo. 2006). Therefore, the district court granted WU's motion for summary judgment and denied Dr. Catalona's motion to enjoin WU's use of the biological samples. This appeal followed.

## **II. DISCUSSION**

### **A. Standards of Review**

Because the district court's finding that WU owns the biological samples resolved all issues in the case, we have jurisdiction under 28 U.S.C. § 1291 to review the defendants' appeal from a final decision of the district court. We review de novo the district court's grant of summary judgment. See Burlington N. & Santa Fe Ry. Co. v. State Tax Comm'n, 188 F.3d 1039, 1041 (8th Cir. 1999). We may affirm a grant of summary judgment on any ground supported by the record. See P & O Nedlloyd, Ltd. v. Sanderson Farms, Inc., 462 F.3d 1015, 1018 (8th Cir. 2006). We review the district court's denial of injunctive relief for an abuse of discretion. See Int'l Ass'n of Machinists & Aerospace Workers, Dist. Lodge No. 19 v. Soo Line R. Co., 850 F.2d 368, 374 (8th Cir. 1988) (en banc). An abuse of discretion occurs if the district court bases its decision on an erroneous application of the law or a clearly erroneous factual

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<sup>5</sup>The men included Richard N. Ward; Thomas A. McGurk, Jr.; Luis Garcia; Antonio Castro; Phillip Wilard; Ivan Parron; James D. Ellis; and Michael Missios.

finding. See Taylor Corp. v. Four Seasons Greetings, LLC, 403 F.3d 958, 967 (8th Cir. 2005).

## **B. Ownership of the Biological Materials**

We now turn our attention to the pivotal inquiry in this 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. Under the facts of this case, the answer is no.

In deeming WU the owner of the biological samples, the district court found all RPs donated their biological materials to WU as inter vivos gifts.<sup>6</sup> Wash. Univ., 437 F. Supp. 2d at 999. In addressing this issue, we look to the substantive law of Missouri, which defines an inter vivos gift as “a voluntary transfer of property by the owner to another, without any consideration or compensation as an incentive or motive for the transaction.” Pilkington v. Wheat, 51 S.W.2d 42, 44 (Mo. 1932); see, e.g., Wills v. Whitlock, 139 S.W.3d 643, 653 (Mo. Ct. App. 2004). As the party claiming the existence of an inter vivos gift, WU bears the burden to prove by clear and convincing evidence there was (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. See Clippard v. Pfefferkorn, 168 S.W.3d 616, 618 (Mo. Ct. App. 2005). The RPs unquestionably delivered their biological materials to WU at the time of their donation; thus, we focus our inquiry on the first and third elements.

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<sup>6</sup>Whether the RPs made inter vivos gifts is a state law question of fact. See Estate of Thompson v. Hicks, 148 S.W.3d 32, 36 (Mo. Ct. App. 2004). We review de novo the district court’s interpretation of state law. See Protective Life Ins. Co. v. Jim Orr & Assoc., Inc., 384 F.3d 949, 950 (8th Cir. 2004).

With regard to the first element, we assess the donor's intent by examining whether a gift was intended at the time of the transaction. No specific language is required to reflect the donor's present intent to make a gift; in fact, the circumstances surrounding the contribution may create an inference the donor intended to make a valid *inter vivos* gift. See Duvall v. Henke, 749 S.W.2d 714, 716 (Mo. Ct. App. 1988). However, the donor must intend "to part with his right in and dominion over the property immediately and irrevocably." Ridenour v. Duncan, 246 S.W.2d 765, 769 (Mo. 1952). Here, the circumstances surrounding the RPs' decisions to participate in genetic cancer research demonstrate the status of the RPs as donors and their intent to make gifts of their biological materials to WU's medical research activities. Before participating in WU's research activities, each RP was required to read and sign the consent form, which bore WU's logo and characterized the RP's participation as a "donation" of bodily tissues or blood. The consent form emphasized the voluntariness of the RP's participation and discussed the RP's right to decline participation in the study or to withdraw consent at any time. Although some RPs were Dr. Catalona's patients, many other RPs were patients of different WU doctors and participated in research studies designating someone other than Dr. Catalona as the principal investigator. Even the consent forms designating Dr. Catalona as the study's principal investigator invited RPs "to participate in a research study conducted by Dr. William J. Catalona *and/or colleagues*." (emphasis added). The consent forms also advised RPs their biological samples "may be used for research with our collaborators at [WU], other institutions, or companies."

Our conclusion the RPs intended to make gifts of their biological samples at the time of their donation is bolstered further by the language of the brochure, which characterized the RPs' donations as "a free and generous gift of [biological materials] to research that may benefit society." The brochure's acknowledgment that donated materials may be shared with non-WU researchers, without any further authorization needed from the RPs, informed the RPs they would relinquish or abandon the right to designate the particular destination of their biological materials upon agreeing to

participate in a medical research study. Such language, considered together with the consent form, cannot reasonably be characterized as reflecting the RPs' intention either to entrust their samples solely to Dr. Catalona or to transfer the samples in some legal form other than a gift.

With regard to the third element—acceptance of the gift by the donee—the defendants contend the RPs retained significant rights in the donated materials, and thus the transfer of materials to WU could not have been absolute. We disagree. WU accepted and retained absolute possession of the biological materials immediately upon donation. Although Missouri law generally prohibits a donor from revoking a completed inter vivos gift once the gift is delivered to and accepted by the donee, an inter vivos gift nevertheless may be subject to a condition allowing the donor to exercise a particular revocation right in the future. See Clippard, 168 S.W.3d at 619; see, e.g., Franklin v. Moss, 101 S.W.2d 711, 714 (Mo. 1937). The attachment of a condition to a charitable donation of property does not negate or void an otherwise valid inter vivos gift. See 14 C.J.S. Charities § 34 (2006) (recognizing “the disposition of property for charitable purposes . . . can be in the form of an absolute transfer subject to conditions”). Indeed, as WU points out, a contrary rule would make many charitable donations wholly impossible or ineffectual. In this case, the signed consent forms and the brochure delineate the specific and limited recourse placed upon each RP's donation of biological materials should an RP change his mind about participating in the medical research: namely, the right to revoke voluntary participation in or consent to the research study, and, in some of the consent forms, the right to request destruction of the donated biological materials.

Under the terms of the consent forms and brochures, the RP's participation in genetic cancer research includes answering questions about the RP's family history of cancer, having blood drawn, and allowing excised tissue and blood samples to be sent to a laboratory and used for research at WU or other institutions. Additionally, should an RP experience a change of heart about participating in genetic cancer

research, the RP is entitled to request his biological materials no longer be used, and under the terms of the brochures (and some of the consent forms as well), the materials would be identified and destroyed upon request. Viewing these provisions in their entirety, it is evident the RPs did not retain the right to revoke and physically repossess the donated biological materials. Nor did the RPs retain the right to direct or authorize the use, transfer, or destination of the biological materials after their donation. The RPs' subsequent rights to their biological materials 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. Beyond these particular and limited rights, the RPs retained no greater interest with regard to their biological materials. Such rights cannot be equated with or interpreted to include the broad privileges or proprietary interests advocated by the defendants.<sup>7</sup>

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 RPs. 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

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<sup>7</sup>Because the specific language contained in the consent forms and brochures, as well as the circumstances surrounding the RPs' voluntary decision to donate their biological materials, convinces us the RPs intended to make inter vivos gifts of their materials, we find it unnecessary to address the effect or validity of the consent forms' waiver language ("By agreeing to participate in this study, you agree to waive any claim you might have to the body tissues that you donate.").

assertion the RPs own the biological materials.<sup>8</sup> 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 RPs retained an ownership interest in the donated materials.

Noticeably absent from the record is any mention the RPs ever were informed they could physically withdraw or request the return of their biological samples. Indeed, in no event *could* the samples physically be returned to their donors. Federal and state regulations prohibit such a result by defining excised body tissue and blood as hazardous substances or infectious waste, and by articulating the proper disposal method. See 29 C.F.R. § 1910.1030; Mo. Rev. Stat. §§ 260.200.1(17), 260.203. Nor could RPs who were surgical patients reasonably have anticipated they had any right to have excised materials returned to them following surgery, because before undergoing surgical procedures, patients were required to sign standard surgical consent forms acknowledging that tissues removed during surgery and not used for clinical purposes would be destroyed as hazardous medical waste. Also absent from the record is any indication the RPs ever were informed they had the ability to direct the transfer of their samples to another entity for research purposes. Based on the record before us, we conclude WU's acceptance of the donated biological materials was absolute.

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<sup>8</sup>Dr. Catalona's privileges to and treatment of biological samples while at WU comports with the terms of WU's Intellectual Property Policy, which provides "all intellectual property (including . . . 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." (emphasis added).

Thus, the district court properly concluded the RPs made informed and voluntary decisions to participate in genetic cancer research, and thereby donated their biological materials to WU as valid inter vivos gifts.<sup>9</sup> This voluntary transfer of tissue and blood samples to WU—without any consideration or compensation as an incentive for doing so—demonstrates WU owns the biological samples currently housed in the Biorepository. Whatever rights or interests the RPs retained following their donation of biological materials, the right to direct or authorize the transfer of their biological materials from WU to another entity was not one of them. Thus, the release forms authored by Dr. Catalona and signed by approximately 6,000 RPs are ineffective to transfer possession of biological samples housed in the Biorepository to another entity. Given WU’s ownership of the biological materials, the district court neither abused its discretion in denying Dr. Catalona’s motion for injunctive relief, nor erred in granting summary judgment in WU’s favor.

### **III. CONCLUSION**

For the foregoing reasons, we affirm the well-reasoned opinion and judgment of the district court.

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<sup>9</sup>Given our conclusion the RPs made inter vivos gifts to WU, it is unnecessary for us to address, in detail, whether the RPs are entitled to control the disposition of their biological materials under the law of implied bailments. However, in our view, the district court correctly rejected this argument as unavailing.