

**In the United States Court of Appeals
For the Eighth Circuit**

WASHINGTON UNIVERSITY, PLAINTIFF-APPELLEE,

v.

WILLIAM J. CATALONA, DEFENDANT-APPELLANT,

AND

RICHARD WARD, ET AL., DEFENDANTS-APPELLANTS.

**On Appeal from the United States District Court for the
Eastern District of Missouri, No. 4:03-CV-1065
The Honorable Stephen N. Limbaugh, Senior District Judge**

**OPENING BRIEF FOR DEFENDANT-APPELLANT,
WILLIAM J. CATALONA, M.D.**

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SUMMARY OF THE CASE

This case presents a dispute between Appellee Washington University, on the one hand, and Appellants Dr. William J. Catalona (“Dr. Catalona”) and eight of his patients (“the Patients”), on the other. The dispute centers on bodily materials that Dr. Catalona removed from the Patients and stored in his laboratory at Washington University pursuant to a written agreement. When Dr. Catalona left for another institution, the Patients requested that their materials be transferred, but the University refused and sued for a declaration that it owns the materials.

The district court held that the Patients had gifted their tissues to the University, which was therefore the owner. This was a clear legal error that, by itself, requires reversal of the decision below. Under Missouri law, an *inter vivos* gift must be unconditional to be effective. Here, the Patients’ written agreement imposed significant conditions. Moreover, because the University’s “gift” theory was its only basis for claiming ownership, Dr. Catalona and the Patients are entitled to a ruling that the Patients own the tissues at issue here. And if there were any doubt that the Patients own their tissues, they are entitled to control the tissues’ disposition under the settled law of bailment, which the district court also misstated, and under sound public policy codified in applicable federal regulations.

Oral argument is merited, as this important case requires reversal and should lead to a published opinion. Appellants seek thirty minutes per side.

JURISDICTION

The district court had jurisdiction over this case under 28 U.S.C. §§ 1331, 1332, and 1367. This court has jurisdiction over this appeal of the order of the district court entered on April 14, 2006, as it is a final order reviewable under 28 U.S.C. § 1291. Dr. Catalona's notice of appeal was timely filed on May 11, 2006.

STATEMENT OF THE CASE

In August 2003, Washington University filed this lawsuit against Dr. Catalona. The University sought a declaration that, among other things, (1) it owned the Patients' tissues and as such could use them for research and (2) it had not violated the federal Health Insurance Portability & Accountability Act (HIPAA) in making certain use of the tissues. Dr. Catalona answered in October 2003, demanding a jury trial and lodging affirmative defenses. Dr. Catalona also asserted counterclaims for, among other things, breach of contract and breach of bailment obligations, as well as declaratory relief that the patients had the right to control the disposition of their tissues. In January 2004, the University moved for summary judgment.

In early 2004, the parties awaited a discovery schedule and entered an agreement whereby Washington University would preserve the Patients' tissues pending the outcome of the district court litigation. (Washington University has agreed to continue this arrangement, promising to preserve all the tissues in its

possession until further notice.) In August 2004, the district court “converted” a motion Dr. Catalona filed to protect the Patients’ tissues pending disposition of the case into a motion for preliminary injunctive relief. Docket Entry No. 52.

In January 2005, the court asked the parties whether it should adjudicate Washington University’s summary judgment motion or the preliminary injunction motion. Docket Entry No. 82. The University said the court should adjudicate the latter motion. Dr. Catalona said the court should adjudicate the summary judgment motion first, but only after giving him an opportunity to take further discovery and then file a response to that motion. In February 2005, the court ordered that the hearing would be for a *permanent* injunction. Docket Entry No. 84. The court specified a “short” discovery schedule and “minimal live testimony.” *Id.* at 2. Further, the court denied Dr. Catalona’s request for six months to take discovery on the issues raised in the University’s summary judgment motion, so that it could prepare an adequate response. *Id.*

On February 22, 2005, eight of Dr. Catalona’s patients sought leave to intervene in the case. The court denied that request, but less than a month before the hearing held that the patients should be joined as necessary parties. The hearing was held from April 11-13, 2005. Nearly one year later, on April 14, 2006, the court entered its decision granting the University summary judgment,

denying Dr. Catalona's counterclaims, and granting the University a permanent injunction.

Although the court's opinion states that multiple "summary judgment motions" were pending, App. 1, in fact, there was only one—by Washington University. And because the court put the case on the injunctive relief track, set no schedule for a response, and refused Dr. Catalona's request for adequate discovery, that motion had never been fully briefed when the court granted it.

STATEMENT OF ISSUES

1. Did the district court err in concluding that, under Missouri's law of *inter vivos* gifts, transfer of personal property renders "inconsequential" a writing placing clear conditions on the recipient's use of that property, conditions that would ordinarily be sufficient to defeat an *inter vivos* gift?

In re Estate of Simms, 423 S.W.2d 758(Mo. 1968)

Cartall v. St. Louis Union Trust Co., 153 S.W.2d 370 (Mo. 1941)

In re Soulard's Estate, 43 S.W.617 (Mo. 1897)

2. Assuming the district court erred in holding that the University "owns" the tissues at issue here as a matter of law, did the district court also err in refusing to rule that the Patients retain ownership as a matter of law, given that Missouri law generally vests ownership of body tissues in the person from whom they are taken, and that the University offered no other theory on which it, rather than the Patients, was the rightful owner of the tissues?

Mo. Rev. Stat. §§ 194.210 - 194-307 (2006)

Mansaw v. Midwest Organ Bank, 1998 U.S. Dist. LEXIS 10307
(W.D. Mo. 1998)

3. Did the district court err in concluding that, under Missouri's law of bailments, there can be no bailment unless the putative bailor expects the bailed item to be returned, and on that basis rejecting the Appellants' argument that the agreements at issue here established a valid bailment?

State v. Edwards, 137 S.W.2d 447 (Mo. 1940)

Weinberg v. Wayco Petroleum Co., 402 S.W.2d 597 (Mo. Ct. App. 1966)

State v. Betz, 106 S.W. 64 (1907)

4. Did the district court err as a matter of Missouri contract and bailment law in interpreting an agreement requiring that individuals providing body tissues for research be allowed to "withdraw" their consent "at any time" and order their tissues to be "identified and destroyed" retained no rights in those tissues, including the right to specify that they remain with their doctor when he left the University?

Greenfield v. Purple Shoppe, Inc., 100 S.W.2d 345 (Mo. 1937)
Dunn Industries Group v. City of Sugar Creek, 112 S.W.3d 428
(Mo. 2003)
45 C.F.R. 46.116
Gulf Ins. Co. v. Noble Broadcasting, 936 S.W.2d 810 (Mo. 1997)

5. Did the district court err in awarding summary judgment without full briefing and (a) based on adverse credibility determinations made at a hearing for a permanent injunction; and (b) where there were disputed issues of material fact between the parties?

Fed. R. Civ. P. 56

In re Estate of Campbell, 939 S.W.2d 558 (Mo. App. 1997)
Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986)
Hall Contractors Corp. v. Entergy Services, 309 F.3d 468 (8th Cir. 2002)

FACTS

A proper understanding of the issues in the case requires some additional familiarity with (1) the parties; (2) the agreement pursuant to which the Patients entrusted their tissues to Dr. Catalona; (3) pertinent federal regulations; (4) Dr. Catalona's departure from Washington University; (5) the permanent injunction hearing in the district court; and (6) the district court's decision.

1. *The Parties.* Dr. Catalona is one of the leading urologists in the United States and for many years has conducted research on prostate cancer. App. 2. From 1976 to 2003, Dr. Catalona performed this research as a professor at Washington University. *Id.*

One of Dr. Catalona's principal areas of research is the genetic basis of prostate cancer. To perform this research, in the early 1980s Dr. Catalona began to collect samples of biological materials removed during surgery and to analyze the DNA stored in those materials. App. 36 (Tr.1:33-34). Later, as the value of such genetic research became clearer, patients of other doctors, including many not from Washington University, provided their tissues to Dr. Catalona. *See* Add. 3.¹

Washington University is a private research university in St. Louis, Missouri that houses the medical school where Dr. Catalona performed prostate cancer

¹ The Patients also provided Dr. Catalona with samples of the blood and serum. *See* App. 44 (Tr.1:65-66). For ease of reference, however, this brief will refer solely to "tissues."

surgeries, conducted his research, and stored his patients' samples. Add. 3.

Washington University employed Dr. Catalona as Chief of its Urology Division from 1984 to 1998. *Id.* at 2.

The patient-defendants (“Patients”) were surgical patients of Dr. Catalona and participated in Dr. Catalona’s genetic cancer research.

2. *The Parties’ Agreement.* All of the Patients entered agreements establishing the terms by which they would provide their tissues for research. Printed on two documents delivered together—a consent form and a genetics brochure—the agreements also specified the responsibilities that Dr. Catalona and the University would assume in return. Add. 31-33 (form); Add. 34-36 (brochure).²

The Patients’ consent forms generally contained similar language. Add. 5. All bear the title “Informed Consent,” and refer to Dr. Catalona as the “Principal Investigator.” Add. 31. The purpose of the research, according to the forms, was to “investigate the genetic changes associated with prostate or bladder cancer.” *Id.* at 31. Potential benefits of the research, the forms stated, included: “[t]o possibly aid in the diagnosis and prevention of prostate and bladder cancer in future generations”; “[t]o add information which one-day may allow accurate prediction of the nature or course of the disease by you or others”; and “[t]o help in

² Because the Patients’ forms are substantially similar, for ease of reference we have placed a representative form (Tom McGurk’s) in the Addendum to this brief. *See* Local Rule 28A(b)(1)(iii). That form appears at pages 31-33 of the Addendum. The rest of the forms appear in the Joint Exhibit Appendix.

counseling your family members regarding cancer risks.” *Id.* at 32. On the other hand, the brochure stated that the Patients would “not receive any direct benefit from participating in this type of research.” *Id.* at 34.

The “typical” form also explains that the Patients’ participation is “voluntary” and that the Patients “may choose not to participate in this research *or* withdraw your consent at any time.” Add. 5 (emphasis added).

The genetics brochure, also to be signed, “generally addresses the issues of primary importance to the RPs [research participants].” Add. 6. Although the brochure states that the participant “make[s] a free and generous gift” of her tissues “that may benefit others” (*id.* at 5), the brochure (as well as the informed consent form) leaves significant rights with the patient. In a section entitled, “**What if you change your mind?**” the brochure states: “To request that your tissue no longer be used for research, you should call the investigator listed on the consent form. Your tissue will be identified and destroyed upon request.” *Id.* (bolding and underlining in original).

The documents also contain promises by Dr. Catalona and Washington University to diminish privacy and health risks to the Patients. “If this information were to become known outside of th[is] research,” the genetics brochure cautions, “you (and family members) may be unable to obtain health, life, or disability insurance. You might also be refused employment or terminated from your current

employment.” Add. 35. Accordingly, the brochure promises that “all reasonable measures will be taken to protect the confidentiality of your records” and “your identity will not be revealed in any publication that may result from this study.” *Id.* at 32. Further, the forms explain that patient information “will be securely maintained and no identifying details will be included in any report generated.” *Id.* The genetics brochure assures that the Patients’ tissue will be “stored in a freezer” and “coded to protect your confidentiality.” *Id.* at 34.

In addition, the forms promise that “Washington University and their staffs will make every effort to minimize, control, and treat any complications that may arise as the result of this research.” Add. 32. And, finally, they pledge that “you will be informed of any significant new findings developed during the course of participation in this research that may have a bearing on your willingness to continue in this study.” Add. 33

3. *Pertinent Regulations.* These provisions are consistent with, and no doubt driven by, regulations of the U.S. Department of Health and Human Services (“HHS”). Those regulations require institutions such as Washington University, that receive federal funding and conduct research using human subjects, to comply with a regulation known as “The Common Rule.” The Common Rule provides a minimum level of protection for subjects of human research, including stating what an informed consent document must contain. That Rule requires that:

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the researcher has obtained the legally effective consent of the subject No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases, or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

45 C.F.R. § 46.116.

To explain this requirement, HHS publishes a guidance document discussing prohibited exculpatory language in informed consent forms. *Catalona Ex. Q*. One example of forbidden exculpatory language states: “By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.” *Id.*

4. *Dr. Catalona's Departure From Washington University*. In 2003, Dr. Catalona left Washington University to join the faculty of Northwestern University's Feinberg School of Medicine in Chicago, Illinois. Add. 2-3, 10. In February 2003, Dr. Catalona wrote to patients who provided samples for his research at Washington University to inform them of his departure. Add. 10. The letter was also published in a quarterly newsletter (“Quest”) published by the non-profit Urological Research Foundation. *Id.*

In the letter, Dr. Catalona stated that “[y]ou 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.” Add. 11. Dr. Catalona offered to continue research on the patients’ tissues if they would request that the tissues be moved. *Id.* Approximately 6000 recipients responded to Dr. Catalona’s letter, authorizing their tissues to be moved to Northwestern. Add. 11.

5. *Permanent Injunction Hearing.* As noted above (*see* “Statement of the Case”), the University sued Dr. Catalona for declaratory relief in August 2003. The court converted a motion by Dr. Catalona for protective relief pending disposition of the case into a motion for preliminary injunction—and then, *sua sponte*, into a motion for a permanent injunction. A hearing on that motion and, apparently, on the University’s then-pending (but not fully briefed) summary judgment motion, was held for three days in April 2005.

At that hearing, several Patients testified to their intentions regarding their tissues. When James Ellis was asked whether he intended to make an “irrevocable gift to Washington University,” he answered, “No. . . . [W]hat I focused on was . . . the word withdraw . . . [A]nd you don’t have the right to withdraw if . . . you transferred ownership.” App. 69 (Tr.1:168). Tom McGurk testified he neither intended for WU to own his tissue, nor was he informed at any time that WU would claim ownership. *Id.* at 80 (Tr. 1:211). His stated intent was for Dr. Catalona to find a cure for prostate cancer. *Id.* And Richard Ward testified that he

“was simply contributing the tissue for Dr. Catalona’s research for his use in that program.” App. 101 (Tr. 2:72).

Numerous experts testified regarding the legal and ethical issues surrounding tissue-based research. *See, e.g.*, App. 54-65 (Tr. 1:106-152) (Dr. Ellen Wright-Clayton, Prof. of Genetics & Health Pol’y, Vanderbilt U.) (Defendants); *Id.* at 119-136 (Tr.2:143-211) (Dr. Philip A. Ludbook, Prof. of Medicine, Washington U.) (Plaintiffs). Dr. Gerald Andriole, the medical school’s new Chief of Urology, testified regarding the ongoing importance to patients of tissue-based research. Dr. Andriole explained that he “absolutely” and “wholeheartedly” agreed that the tissue samples were “very important” to the Patients’ “future health care.” App. 115 (Tr. 2:126). He also testified that genetic research on tissue samples could be used to alert “members of [a patient’s] family who are at high risk of developing prostate cancer.” *Id.* at 116 (Tr. 2:130). Further, Dr. Andriole agreed that the potential to notify patients’ families of such risks was “the benefit” of keeping tissue samples traceable to their source. *Id.*

In post-hearing briefs, the University argued that the Patients made *inter vivos* gifts of their tissues to Washington University, and did not bail their tissues to the University. Pl.’s Post-Trial Br. 3-10 (gift); *id.* at 11-13 (bailment). Dr. Catalona and the Patients countered that the Patients could not, as a matter of law, have made an *inter vivos* gift of their tissues because they retained the right to

withdraw their consent to research and order their tissues to be destroyed. Catalonia Post-Hrg. Br. 7-12; Patients' Post-Hrg. Br. at 13-19. Instead, they argued, the Patients entered a bailment contract with Dr. Catalonia and the University, the terms of which required the University to destroy the tissues at their request or, by implication, to transfer them to another facility. Patients' Post-Hrg. Br. at 21-22; Catalonia Post-Hrg. Br. at 13.

5. *The District Court's Decision.* Roughly a year after the hearing, on April 14, 2006, the court issued a decision. The court (1) granted Washington University's motion for summary judgment; (2) denied Dr. Catalonia's request for permanent injunctive relief; (3) denied Dr. Catalonia's counterclaims; and (4) declared Washington University to be the "true and rightful owner" of the Patients' tissues. Add. 29-30.

According to the court's memorandum, the "sole determinative issue" of this lawsuit is "ownership." Add. 12. Because the University had possession of the Patients' tissues, the court placed the burden on the Defendant-appellants to demonstrate the Patients' ownership by a preponderance of the evidence. *Id.* at 13. The court did so while acknowledging that a person claiming a gift bears the burden of proving it with "clear, cogent, and convincing evidence." *Id.* at 18 (citation omitted). The Defendant-appellants failed to carry their burden, the court ruled, because in light of the court's numerous factual findings (*see id.* at 2-11), the

Patients “had the present intent to make *inter vivos* gifts, i.e.[,] donations[,] of their biological materials to [the University] for medical research.” *Id.* at 19.

While Missouri law governs the issue of ownership at stake in this case (Add. 12), the court stated that because of a “scarcity of legal precedent” “the most guidance” comes from cases from California and Florida (*id.* at 14). Both cases, *Greenberg v. Miami Children’s Hospital Research Institute, Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003) and *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990), involved patients suing doctors for converting donated tissues into patented products. Add. 15, 16. Under these decisions, and in light of its review of Missouri law, the court concluded that the University “met its burden” of showing its ownership of the Patients’ tissues. *Id.*

The court rejected the Defendant-appellants’ argument that, unlike *Moore* and *Greenberg*, the Patients’ consent forms—by allowing the Patients to “withdraw” from research and have their tissues “destroyed upon [their] request”—reserved rights to the Patients incompatible with an *inter vivos* gift. According to the court, a gift “only” requires donative intent, delivery, and acceptance. Add. 18. Accordingly, the court concluded that, “since delivery of the subject biological materials was made and accepted by [the University] the existence of the informed consent forms is inconsequential.” *Id.* at 19-20.

The court also rejected patients' testimony as to their intentions, on credibility grounds. According to the court, "it was clear that these gentlemen all had a deep personal connection to Dr. Catalona and believed that they owed their lives to him." Add. 21. While the court "understands and appreciates these feelings," "their testimony regarding intent, especially now after getting Dr. Catalona's letter is suspect or[,] at least, shows nothing more than an afterthought of regret." *Id.* (quotation marks omitted).

The court also concluded that the federal regulations did not undermine the University's ownership claims because the regulations did not expressly equate the "right to discontinue participation" in research with a right to control disposition of the tissues. Add. 22.

In conclusion, the court found, "*the right to discontinue participation in a research project means nothing more than [sic] the [patient] has chosen not to provide any more biological materials . . . , i.e., not to make any more inter vivos gifts of donated biological materials.* Nothing more can or should be read into this right possessed by the [patients] at all times," it concluded. Add. 23 (emphasis added).

The court also rejected the proposition that Washington University was a bailee of the Patients' tissues. Add. 24. According to the court, "[t]his argument fails for the simple reason that when a 'gift' is made, the gift or/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.” *Id.* at 24-25. Because the Patients had no expectation of receiving their tissues again, the court concluded that there could be no bailment. *Id.* at 25.

The court also articulated what it apparently viewed as the policy rationale for its decision: “Medical research,” the court said, “can only advance if access to these materials to the scientific community is not thwarted by private agendas. If left unregulated and to the whims of a [patient], these highly prized biological materials would become nothing more than chattel going to the highest bidder.” App. 27.

For these reasons, the court held that the Defendant-appellants were entitled to no injunctive relief, and that as a matter of law the University was the “true and rightful owner” of the Patients’ tissues. Add. 29. Conversely, the court held that as a matter of law no “research participant in connection with *any* research protocol conducted under the auspices of Washington University has *any* ownership or proprietary interest in the biological samples housed” at the University.” *Id.* at 28 (emphasis added).

SUMMARY OF ARGUMENT

In declaring Washington University the “true and rightful owner” of the Patients’ tissues, the district court violated settled principles of Missouri property

and contract law as well as Federal Rule of Civil Procedure 56. It is undisputed that the Patients entered an agreement reserving the Patients' right to "withdraw" from research at "any time" and to require that their tissues to be "identified and destroyed." By repeated substantive and procedural missteps, the district court read this agreement out of existence.

1. The court began by misinterpreting Missouri gift law. According to the district court, the Patients made an *inter vivos* gift of their tissues to Washington University, and therefore the University owns the tissues. The court properly stated that an *inter vivos* gift requires "donative intent" as well as "unconditional delivery" and "acceptance." Yet the court concluded that, where any kind of delivery and acceptance occur, a writing conditioning the gift is "inconsequential."

The Missouri Supreme Court, however, has said the opposite. *See In re Estate of Simms*, 423 S.W.2d 758, 763 (Mo. 1968); *Cartall v. St. Louis Union Trust Co.*, 153 S.W.2d 370, 384 (Mo. 1941); *In re Souldard's Estate*, 43 S.W.617, 620-21 (Mo. 1897). The district court ignored these authorities, and thus discounted the parties' agreement, which placed express conditions on the transfer of the tissues. Those conditions show that the Patients did not "unconditional[ly] deliver" their tissues to the University—and hence the University does *not* own them.

2. To the contrary, under the undisputed facts, the Patients own the tissues that they provided to Dr. Catalona. Missouri law makes clear that an individual generally owns her own body tissues. *See, e.g.*, Mo. Rev. Stat. §§ 194.210-194-307 (2006). Because the University offered no theory of ownership other than its meritless “gift” theory, Dr. Catalona and the Patients are entitled to a ruling that the Patients own their excised tissues, and the district court erred in denying them that ruling.

3. The district court also erred in refusing to recognize that the Patients’ agreement constituted a bailment contract. The district court rejected this conclusion on the *sole* ground that, in its view, bailments always require return of the property to the bailor. But the Missouri Supreme Court has squarely held that bailments do not always require return of the property to the bailor. *State v. Edwards*, 137 S.W.2d 447, 451 (Mo. 1940). Rather, a bailment is simply delivery of property for a specific purpose, with at least an implied contract that the property will be accounted for according to the purpose of the delivery. *Weinberg v. Wayco Petroleum Co.*, 402 S.W.2d 597, 599 (Mo. Ct. App. 1966). That is precisely the nature of the parties’ arrangement here.

4. However one characterizes the agreements, moreover, the district court erroneously set aside standard principles of contract interpretation in concluding that the Patients’ right to “withdraw” from research “means nothing

more than that [sic] the [Patient] has chosen not to provide any more biological materials” to the University. And the court simply ignored the contractual promise that the Patients’ tissues would be “identified and destroyed” upon request. Under Missouri law, *e.g.*, *Triarch Indus. v. Crabtree*, 158 S.W.3d 772, 775 (Mo. 2005), which parallels federally established public policy, *see* 45 C.F.R. § 46.116, the plain language of the parties’ contract requires that the Patients be allowed to control disposition of their tissues.

5. Finally, even if the court’s analysis of the law were correct (and it is not), summary judgment was inappropriate. First, besides its failure to give Dr. Catalona an adequate opportunity to respond to the University’s summary judgment motion, the district court ignored numerous disputed issues of material fact regarding what the Patients intended when they transferred their tissues to Dr. Catalona and the University. Second, the district court relied on credibility determinations that are the proper province of the jury. Under Rule 56, both actions are plainly reversible error.

ARGUMENT

The district court’s errors fall into two main categories. First, as we explain in Section I, the Court erred as a matter of law in concluding that the Patients gifted rather than bailed their tissues to the University, and therefore erred in refusing to hold that the Patients retain the legal right to control the disposition of

their tissues. Second, as we explain in Section II, at a minimum the Court erred as a matter of law in granting summary judgment to the University based on the foregoing errant legal conclusions and despite a host of disputed issues of material fact.

I. On The Record Before The District Court, Appellants Are Entitled To A Determination That The Patients Have A Legal Right To Control Disposition Of The Tissues, And An Injunction Prohibiting Their Use, Destruction, Or Transfer To Anyone Other Than Dr. Catalona.

Based on several serious misunderstandings of Missouri common law, the district court erred in holding that Washington University owns Appellants' tissues, and in rejecting the Appellants' arguments that the Patients own them or, at a minimum, are entitled to control their disposition.

A. Appellants Are Entitled To A Ruling That Washington University Is Not The "Owner" Of The Tissues.

While the district court correctly determined that this case turns in part on whether the Patients made an *inter vivos* gift of their tissues to Washington University, it answered that question incorrectly. As shown below, the district court's opinion omits any discussion of a critical requirement in Missouri for all valid *inter vivos* gifts—that they be unconditional and irrevocable. As the very agreements quoted by the district court demonstrate, the Patients' transfer of their tissues to Washington University was neither. And of course, the district court's

interpretation of this pure issue of Missouri law is reviewed *de novo*. *Baum v. Helget Gas Prods., Inc.*, 440 F.3d 1019, 1020-22 (8th Cir. 2006).

1. *Under Missouri Law, There Can Be No Valid Inter Vivos Gift Where The Alleged Donor Retains Rights In The Property.*

It is hornbook law in Missouri that there can be no valid *inter vivos* gift where the donor places conditions on the gift or makes any part of the gift revocable. The district correctly stated that “the elements of an *inter vivos* gift are: 1) present intention of the donor to make a gift; 2) delivery of property by donor to donee; and 3) acceptance by donee whose ownership takes effect immediately and absolutely.” Add. 17-18. Yet the Court failed to acknowledge the significance of the first of those elements—that “[t]here must be . . . an intention on the part of the donor 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). That is, a putative donor must relinquish all “dominion *and* control” over the gift. *Id.* at 770 (emphasis added); *Smith v. Smith*, 313 S.W.2d 753, 756 (Mo. Ct. App. 1958).

According to the Missouri Supreme Court, an *inter vivos* gift is not valid unless it is unconditional. “Language, written or spoken, expressing an intention to give does not constitute a gift unless the intention is executed by a complete and unconditional delivery of the subject matter or a delivery of a proper written instrument evidencing the gift.” *Ridenour*, 246 S.W.2d at 769. The district court recited this proposition, Add. 20, but misunderstood its significance. While the

Court correctly noted that “[t]here is no requirement that the gift be made pursuant to any written document,” it erred in holding that mere delivery and acceptance render all writings accompanying a transfer “inconsequential.” *Id.* at 19-20.

The district court cited no authority for this proposition, which is flatly contradicted by the settled rule that “statements of the [putative] donor are *most* probative of his intent.” 5A MO. PRAC., PROBATE LAW & PRAC. § 820 (3d ed. 2006) (emphasis added); accord *In re Estate of Simms*, 423 S.W.2d 758, 763 (Mo. 1968) (“[T]hese oral statements attributed to [the alleged donor] not only do not indicate, but they refute, an intention on the part of Mr. Simms . . . to make an irrevocable gift of the trust account to claimant.”); *Cartall v. St. Louis Union Trust Co.*, 153 S.W.2d 370, 384 (Mo. 1941). And such statements may be either oral or written. See, e.g., *Ridenour*, 246 S.W.2d at 770 (incomplete deed); *Smith*, 313 S.W.2d at 756 (letter).

Moreover, and more specifically, because “[t]here must be . . . an intention on the part of the donor to part with his right in and dominion over the property immediately and irrevocably” (*Ridenour*, 246 S.W.2d at 769), a writing showing that the putative donor did *not* intend to surrender irrevocably all rights in the property refutes any putative *inter vivos* gift. *In re Estate of Simms*, 423 S.W.2d at 762; *In re Soulard’s Estate*, 43 S.W. 617, 620-21 (Mo. 1897). This is made clear in *Soulard’s Estate*, in which the Missouri Supreme Court held that “[t]hough the

evidence shows a delivery of the notes and bonds to [the putative donee],” the “transaction does not amount to an executed gift.” 43 S.W. at 621. The reason was that, under the controlling document, the transfer to the donees was not “absolute and unqualified.” *Id.* Specifically, “[t]he right of control reserved by the donor [was] inconsistent with absolute ownership by the donees.” *Id.* As we now show, under the undisputed facts, that is what occurred here.

2. *The Undisputed Evidence Demonstrates That The Patients Retained Significant Rights In Their Tissues.*

The district court’s undisputed factual findings demonstrate that the Patients’ transfer of their “right in” their tissues was anything but irrevocable. According to the court’s findings, when the Patients transferred their tissues to Dr. Catalona they entered agreements expressly reserving their right to revoke his right to use the tissues. The first document the Patients “had to sign” was an “informed consent form[]” stating that “[y]our participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time.” Add. 5. The genetics brochure, “to also sign,” was given “[a]long with the informed consent forms . . . [and] generally address[ed] issues of primary importance to the [Patients].” Add. 6. Under a section entitled “**What if you change your mind,**” the brochure stated: “To request that your tissue no longer be used for research, you should call the investigator listed on the consent form. *Your tissue will be identified and destroyed upon request.*” Add. 6 (emphasis added).

The court disregarded these conditions on the ground that “[s]ince delivery of the subject biological materials was made and accepted by [Washington University], the existence of the informed consent forms i[s] inconsequential.” Add. 20. As noted above, this conclusion was an error of law. In Missouri, a statement showing that the putative donor placed significant conditions on the transfer negates any *inter vivos* gift. See, e.g., *In re Estate of Simms*, 423 S.W.2d at 763; *Cartall*, 153 S.W.2d at 384; *In re Soulard’s Estate*, 43 S.W. at 620-21.

Moreover, having discounted this language negating any gift, the court compounded its error by erroneously relying upon the agreements to deflect the Patients’ insistence that they did not intend to make a gift. According to the Court, the informed consent forms “repeatedly asserted [Washington University’s] ownership of the donated materials” and in some cases spoke of “donation” and purported to “waive[]” the Patients’ “claim to the excised body tissues.” Add. 21-22. But the first part of this statement is incorrect, and the remainder is irrelevant. Neither the word “own” nor any of its variants appears in any of the forms in the record; nor is Washington University’s ownership even intimated. Moreover, while some of the forms speak of “donat[ion]” and “waiv[er]” of claims to the tissues, as the district court itself acknowledged, “language written or spoken, expressing an intention to give, does not constitute a gift, unless the intention is executed by a complete and *unconditional* delivery of the subject matter, or

delivery of a proper written instrument evidencing the gift.” Add. 20 (quoting *Ridenour*, 246 S.W.2d at 769) (emphasis added).

Thus, notwithstanding the language cited by the court, as a matter of Missouri law the Patients manifestly did not gift their tissues to Washington University because they placed express conditions on the tissues’ transfer. And because the Patients did not gift their tissues to the University, the University does not—and cannot—“own” them outright. Under the undisputed facts, the appellants are entitled to a ruling to that effect.³

B. Based On The Record, Appellants Are Entitled To A Ruling That The Patients Own The Tissues.

On the undisputed facts, the Appellants are also entitled to a ruling that the Patients, and they alone, retained legal title to the tissues removed from them by Dr. Catalona. The district court relied on one, and only one, theory by which Washington University owns the Patients’ tissues: that the Patients made an *inter*

³ As we have shown, the best reading of Missouri case law is that the Patients made no gift at all. However, there is also authority in Missouri for the proposition “that, if a gift is made upon a condition, a failure of, a violation of, or refusal to perform such condition by the donee constitutes good ground for *revocation* by the don[o]r.” *Franklin v. Moss*, 101 S.W.2d 711, 714 (Mo. 1937) (emphasis added); *Clippard v. Pfefferkorn*, 168 S.W.3d 616, 619 (Mo. Ct. App. 2005) (citing *Franklin*). “In other words, the donor retains the right to revoke the gift unless or until the condition is satisfied.” *Clippard*, 168 S.W.3d at 619. These “conditional gift” cases demonstrate that the Patients *at most* made a conditional gift—requiring the University to stop research and destroy the tissues upon the Patients’ request. Add. 32, 36.

vivos gift of the tissues. *See* Add. 17. Because, as we have shown, the Patients did not make such a gift, it is axiomatic that they must retain title to the tissues—for no one else *could* hold that title.

Because Missouri law expressly recognizes a right in body tissues, this is an unremarkable conclusion. Missouri’s Uniform Anatomical Gift Act (UAGA), for example, establishes that an individual has the right to control disposition of his organs, tissues, and body parts *after* his death. Mo. Rev. Stat. §§ 194.210-194.307 (2006). The Act recognizes and gives legal effect to the right of the individual to dispose of his own body, without subsequent veto by others. Surely the living have no fewer rights over their bodies under Missouri law than the dead.

Further, in *Mansaw v. Midwest Organ Bank*, 1998 U.S. Dist. LEXIS 10307, at * 16 (W.D. Mo. 1998), the court recognized that a *father* held a property interest in the body of his deceased son, including “the right to possess the body for burial . . . the right to control the disposal of the body . . . and a right to maintain a claim for disturbance of the body.” *Id.* at *16 (citing *Lanigan v. Snowden*, 938 S.W.2d 330, 332 (Mo. Ct. App. 1997); *Galvin v. McGilley Mem’l Chapels*, 746 S.W.2d 588, 591 (Mo. Ct. App. 1987)). Accordingly, the court held that the father and his ex-wife both retained a property interest in the dead body of their son. *Id.* Under these authorities, there is no disputing that, absent a valid *inter vivos* gift, the Patients retained title in the tissues.

Greenberg and *Moore*, which the district court cited as favoring the University, actually support this conclusion. In those cases, research participants sought rights in intellectual property developed from their tissues. The courts held that the research participants could claim no right in intellectual property developed by someone else. *Greenberg*, 264 F. Supp. 2d at 1076, *Moore*, 793 P.2d at 492. But neither court suggested that the participants lacked a property interest in their *tissues*. To the contrary, the *Moore* Court emphasized that “we do not purport to hold that excised cells can never be property for any purpose whatsoever.” 793 P.2d 480-81. And *Greenberg* stated that under Florida law “the property right in blood and tissue samples . . . evaporates *once the sample is voluntarily given to a third party.*” 264 F. Supp. 2d at 1075 (emphasis added). Thus, while not binding here, neither decision suggested that body tissues are *not* property—and indeed *Greenberg* expressly affirmed as much.⁴

In short, the district court, like the University, put all its eggs in one basket—that the Patients made a gift of their tissues. Because the Patients manifestly did not do so, by operation of law they must retain title to those tissues.

⁴ As this discussion shows, the district court erred in assuming that *Moore* and *Greenberg* had relevance to this case. They do not. Not only do those cases emphasize that “the patented result of research is ‘both factually and legally distinct’ from excised material used in the research” (*Greenberg*, 264 F. Supp. 2d at 1074-75 (quoting *Moore*, 793 P.2d at 492)), both cases involved straightforward donations with no strings attached. As we have explained, that is *not* the situation here.

C. Alternatively, Appellants Are Entitled To A Ruling That The Patients Are Bailors Of The Tissues And May Control The Tissues' Disposition Under The Plain Terms Of Their Bailment Contract.

Even if the Patients did not retain clear legal title to their tissues as a matter of law, the terms of their agreements still must be enforced under Missouri's law of bailments. Here again, the district court failed to grasp settled property law—and contract interpretation principles. This Court reviews the district court's interpretation and application of Missouri law *de novo*. See *Baum*, 440 F.3d at 1020-22 (interpretation); *Lindsay v. Safeco Ins. Co. of Am.*, 447 F.3d 615, 617 (8th Cir. 2006) (application).

1. Under Settled Missouri Law, The Patients Bailed Their Tissues to the University.

The district court erred first in assuming that the Patients could not have bailed their tissues because they did not expect to get them back. Even if the Patients did not expect to get the tissues back (a point Appellants do not concede), they could and did enter a bailment contract.

The parties' arrangement exceeds the requirements for a bailment contract in Missouri. For a bailment to exist there need only be: (1) delivery of the property; (2) for a specific purpose; (3) with at least an implied contract that the trust will be faithfully executed and the property duly accounted for when the specific purpose is accomplished. *Weinberg v. Wayco Petroleum Co.*, 402 S.W.2d 597, 599 (Mo.

Ct. App. 1966). In making that determination, “matters of form are of slight significance insofar as the validity of the bailment contract is concerned.” 8 C.J.S., *Bailments* § 27 (2006). Indeed, a bailment may be either express or implied.⁵

Here, the undisputed evidence shows that here there was a bailment contract. It is undisputed (1) that the Patients physically delivered their tissues through Dr. Catalona to storage facilities at Washington University (Add. 2-3); (2) that they did so for a specifically stated purpose, genetic cancer research (Add. 31); and (3) that by written agreement, the University pledged to use the tissues for that research and account for the tissues, acknowledging that the Patients retained significant rights in the tissues (*id.* at 31-33, 34-36).⁶ This clearly constitutes a bailment

⁵ While a bailment contract may be written or oral, *D.S. Sifers Corp. v. Hallak*, 46 S.W.3d 11, 16 (Mo. Ct. App. 2001), “[w]here one knowingly comes into possession of a chattel and exercises physical control over it, or where possession has been acquired accidentally, or for some purpose other than bailment, the *law* imposes on the recipient the duties and obligations of a bailee.” *Stone v. Crown Divers. Indus. Corp.*, 9 S.W.3d 659, 669 (Mo. Ct. App. 1999) (emphasis added); *D.S. Sifers Corp.*, 46 S.W.3d at 16.

⁶ In addition to destroying the tissues upon the Patient’s request (Add. 36), the University agreed to account for the tissues by promising (1) to take “all reasonable measures to protect the confidentiality of [the Patients’] records,” including keeping all information “securely maintained” (*id.* at 32); (2) that in any research publication, the Patients’ “identity will not be revealed” (*id.*); (3) to inform the patients “of any significant (major) new findings developed during the course of [their] participation in this research which may have a bearing on [their] willingness to continue in [the] study” (*id.* at 33); (4) to “code[]” the tissues “to protect your confidentiality” (*id.* at 34); and (5) that the Patients could “choose not to participate in this research study or withdraw [their] consent at any time,” and the University would stop research (*id.* at 32).

contract in Missouri. *Compare, e.g., Temple v. McCaughen & Burr, Inc.*, 839 S.W.2d 322, 326 (Mo. Ct. App. 1992 (sufficient evidence of bailment where property was delivered with written agreement requiring that property either be returned or sold and proceeds paid to plaintiff)).

The district court committed a clear error of law when it nevertheless held that there was no bailment here “for the simple reason” that “when a bailment is made, the bailor has every expectation of receiving back the subject of the bailment.” Add. 24, 25. The Missouri Supreme Court has squarely held that, “even where there is no unconditional requirement that the thing delivered be restored, the transaction may sometimes be a bailment.” *State v. Edwards*, 137 S.W.2d 447, 451 (Mo. 1940). The reason is plain. A bailment is simply “a delivery of personal property in trust.” *Scherrer v. Plaza Bowl Inv. Co.*, 277 S.W.2d 695, 698 (Mo. Ct. App. 1955). Or, as Justice Story stated in his seminal treatise, a bailment is “[t]he delivery of a thing in trust for some special object or purpose, and upon a contract, express or implied, to conform to the object or purpose of the trust.” *State v. Betz*, 106 S.W. 64, 66 (Mo. 1907) (quoting STORY, J., COMMENTARIES ON THE LAW OF BAILMENTS, 9th ed.).

It is therefore well settled that, “[w]hen property is entrusted to another for some purpose or consigned to another, a type of bailment is created.” 35 MO. PRAC., CONTR., EQUITY, & STAT. ACTIONS HAND., § 7:1 (2006 ed.) (emphasis

added). Because property may be entrusted for “some purpose” not requiring return to the bailor, a bailment “*need not always contemplate a redelivery of the goods to the bailor.*” *Betz*, 106 S.W. at 66 (emphasis added); *accord Weinberg*, 402 S.W.2d at 599 (property must be “returned *or* duly accounted for”) (emphasis added).

A classic example of a non-returnable bailment is a consignment. “A consignment is a type of bailment where the goods are entrusted for sale.” *Eagle Boats, Ltd. v. Continental Ins. Co. Marine Office of Am., Corp.*, 968 S.W.2d 734, 737 (Mo. Ct. App. 1998). By definition, of course, parties to consignments hope that the goods will *not* be returned to the bailor—but instead will be sold to someone else.

Eagle Boats demonstrates this principle. There, a corporation sought to recover from its insurance company for a stolen boat. The policy covered boats “entrusted to the insured for sale.” *Id.* at 736. The Missouri Court of Appeals concluded that this phrase covered “property consigned to the insured, where the purpose of the bailment is the sale of the property.” *Id.* at 737. The problem for the corporation was that the stolen boat was not for sale; it had been borrowed for a photo-shoot and was to be returned to its owner. The court held that precisely because the boat was returnable bailed property—rather than a non-returnable consignment—coverage was properly denied. *Id.* See also *Temple v. McCaughen*

& Burr, Inc., 839 S.W.2d 322, 326 (Mo. Ct. App. 1992) (plaintiff established “a specific kind of bailment contract, a consignment agreement” in which bailee would either return property or pay bailor \$10,000 for it).

In light of these Missouri authorities, the district court’s holding that a bailment cannot exist without an expectation of return to the bailor—the linchpin of the court’s analysis—is simply untenable.

2. *Under Their Bailment Contract With The University, The Patients Have The Right To Direct The Disposition Of Their Tissues.*

Under the plain terms of the bailment at issue here, the Patients have an undeniable right to direct their tissues’ disposition—including ordering their destruction or transfer to another facility. The starting point, of course, is that the terms of a bailment contract control the behavior of the parties. That is, “the parties to a bailment relationship may abrogate the law of bailment by making their own express contract that may enlarge, abridge, qualify or supercede the obligations which otherwise would arise.” 8 C.J.S. *Bailments* § 28. *See, e.g., Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 713 (8th Cir. 2001) (holding that written bailment contract did not change the underlying standard of care under Missouri’s common law of bailment, which is ordinary care). *Id.* at 713. Thus, the liability of the parties “is subject to the express terms of the contract,” *Greenfield v. Purple Shoppe, Inc.*, 100 S.W.2d 345,

346 (Mo. 1937), which must be given its “plain, ordinary, and usual meaning” *Dunn Indus. Group v. City of Sugar Creek*, 112 S.W.3d 421, 428 (Mo. 2003).⁷

Moreover, any ambiguities in the contract must be construed against the drafter (here, the University), which wrote the agreement and was in the better position to remove ambiguities from it. *Triarch Indus. v. Crabtree*, 158 S.W.3d 772, 776 (Mo. 2005). Indeed, “in recognition of the difference between the parties in their acquaintance with the subject matter,” drafters “who seek to impose upon words of common speech an esoteric significance intelligible only to their craft, must bear the burden of any resulting confusion.” *Krombach v. Mayflower Ins. Co.*, 827 S.W.2d 208, 211 (Mo. 1992) (quoting *Gaunt v. John Hancock Mut. Life Ins. Co.*, 160 F.2d 599, 602 (2d Cir. 1947) (Learned Hand, J.)).

The district court ignored all of this teaching. As the court itself noted, the consent forms promised that the patients could “*withdraw [their] consent at any time,*” and “*request that their tissues no longer be used for research,*” and that their “*tissue, will be identified and destroyed upon request.*” Add. 5, 6 (emphasis added). There is no a hint of ambiguity in any of these phrases, yet the court lent force to none of them. The court did not even discuss the University’s express

⁷ Of course, “[t]he cardinal rule in the interpretation of a contract is to ascertain the intention of the parties and to give effect to that intention.” *Peterson v. Continental Boiler Works, Inc.*, 783 S.W.2d 896, 901 (Mo. 1990). Only where language is ambiguous may courts resort to extrinsic evidence to resolve the ambiguity. *Modine Mfg. Co. v. Carlock*, 510 S.W.2d 462, 467 (Mo. 1974).

promise to destroy the patients' tissues upon their request. *Compare* Pl.'s Post-Trial Brief 8 (“Of course, if an informed consent form expressly provides that a sample will be destroyed when a participant discontinues participation and so requests, [the University] would be required to abide by that provision of the agreement.”). And the court inexplicably concluded that the “withdraw consent” language meant “nothing more” than that the patients retained the right “not to provide any more biological materials” to Washington University. Add. 23. The court did not even mention that the forms assure the patients that, in addition to withdrawing from research, they could “choose not to participate in this research.” Add. 32.

The court thus flouted the “plain, ordinary, and usual meaning” of the contract, *Dunn Indus. Group*, 112 S.W.3d at 428, transforming a right to “withdraw” from research and order the tissues destroyed into a mere right not to provide any more tissues. And in the end, the Court declared the University to be the “true and rightful owner” of the tissues, to do with the tissues whatever it likes (Add. at 29-30)—a conclusion flatly incompatible with the Patients reservation of significant rights in their tissues. *See* note 6, *supra*. This simply cannot be what the parties intended. *Contra Peterson v. Continental Boiler Works, Inc.*, 783 S.W.2d 896, 901 (Mo. 1990).

To support its remarkable reading of the parties' agreement, the Court relied on two sources of authority. First, the court noted that "[t]here is nothing stated in the governing federal regulations which equates a right to discontinue participation with a right to control the disposition and use of the excised biological materials." Add. 22. Yet the court never explained how the *absence* of language in federal regulations transforms the Patients' express contractual right to "withdraw" into a right merely not to provide anymore tissue. Nor did the court explain how Washington University's contractual promise to "identify and destroy" the patients' tissues undergoes a similar metamorphosis. The answer, of course, is that the lack of language in federal regulations can have no such effect.

Second, the Court pointed to expert testimony indicating "that only three (3) things happen when a [Patient] chooses to 'discontinue participation': (1) [the University] may destroy the sample; (2) [the University] may store the sample indefinitely without any further use; or (3) [the University] may remove all identifying markers and use the sample in exempt 'anonymized' research." Add. 22. As a threshold matter, this description of the expert testimony was incorrect. Dr. Ellen Wright-Clayton testified that withdrawal *precludes* de-identification, because a patient's right to withdraw includes stopping all research on his tissues. App. 58-59 (Tr.1:124-125). And Dr. Goodman testified that it would violate

disclosure rules to allow samples to be de-identified and subsequently used. App. 71 (Tr.1:175)

More importantly, expert testimony about present practices (or even testimony as to the expert’s understanding of general law) cannot override the plain language of the contract between the patients and Washington University. And that contract gives the Patients the right among others, to have their tissues “identified and destroyed upon request,” not just “anonymized.” *Modine Manu. Co.*, 510 S.W.2d at 467 (external evidence admissible only where contractual language is subject to ambiguity).⁸

In sum, by failing to employ standard principles of contract interpretation, the district ignored critical phrases in the parties’ agreement and produced a result the parties cannot possibly have intended. Yet determining and enforcing their intent was the court’s task. *Peterson*, 783 S.W.2d at 901.

⁸ There were at least two other problems with the court’s use of expert testimony here. *First*, the district court relied on the expert for an essentially judicial task: interpreting the law. *See* Fed. R. Evid. 702 (permitting expert testimony to “assist the trier of fact *to understand the evidence or to determine a fact in issue*”) (emphasis added); *Kostelecky v. NL Acme Tool/NL Indus., Inc.*, 837 F.2d 828, 830 (8th Cir. 1998). *Second*, the testimony is indicative rather than prescriptive, suggesting merely what the parties *are* doing, rather than under the contract what they should be doing. *See* Add. 22 (The relevant testimony at the hearing indicated that only three things happen when a [patient] chooses to discontinue participation”); *id.* (No one questioned [the University’s] ability to simply store the samples indefinitely”); *id.* (Drs. Ludbrook and Prentice both testified that anonymization is a response available to [the University].”). Thus, even if the court could have relied upon such testimony, it would be irrelevant.

3. *The Contracts' Plain Language Shows That The Patients Provided Their Tissues For Treatment As Well As Research; Hence The Contracts Must Be Read To Allow Transfer Of The Tissues To Another Treating Facility Rather Than Allowing The University To Use, Destroy, Or De-Identify Them.*

The district court's reading of the parties' agreement suffers still another fatal infirmity. A basic axiom of Missouri contract law is that, if possible, "every word in a contract is to be given meaning." *Gulf Ins. Co. v. Noble Broad.*, 936 S.W.2d 810, 814 (Mo. 1997); *Armstrong Bus. Servs. v. H&R Block*, 96 S.W.3d 867, 878 (Mo. Ct. App. 2002). By allowing the University to do whatever it likes with the tissues (including performing unconsented research, as well as destroying, transferring, or de-identifying them) the court's decision renders meaningless whole provisions in the agreement that require the University to maintain contact with the patients. Instead, for these provisions to retain any vitality, the right to "withdraw" in the contract must encompass the Patients' right to order their tissues transferred to another facility.

For example, in its agreement with the Patients, the University promised to maintain contact with the Patients to provide cancer-related therapy. Dr. Catalona's research, the forms state, could "aid in the diagnosis and prevention of prostate and bladder cancer in future generations," could "add information which one day may allow accurate prediction of the nature or course of the disease in you or others," and could even "help in counseling [the Patients'] family members

regarding cancer risks.” Add. 32. Accordingly, the University promised to “make every effort to minimize, control, and treat any complications that may arise as a result of this research.” Additionally, the University promised that the Patients “will be informed of any significant new findings developed during the course of participation in this research that may have a bearing on your willingness to continue in the study.” *Id.* at 33.

The district court’s order negates both of these commitments. Under that order, the University essentially holds the tissues in fee simple. There is no restriction on how the University may use them. Before the court’s order, the University’s expert testified that the University could either destroy tissues of a withdrawing Patient or de-identify the tissues and use them for further research. Add. 22. Now, as the adjudged true and rightful owner of the tissues, the University may also sell the tissues to another institution without telling the Patients. Any of these actions would make it impossible for the University to keep its promise to treat the patients and inform them of research developments.

Undisputed testimony by Washington University’s own Head of Urology, Dr. Gerald Andriole, demonstrates this danger. Dr. Andriole “absolutely” and “wholeheartedly” agreed that the tissue samples were “very important” to the Patients’ “future health care.” App. 115 (Tr. 2:126). Further, Dr. Andriole testified that genetic research on tissue samples could be used to alert “members of

[a patient's] family who are at high risk of developing prostate cancer." App. 116 (Tr. 2:130). Indeed, Dr. Andriole agreed that the potential to notify patients' families of such risks was "*the* benefit" of keeping tissue samples traceable to their source. *Id.* (emphasis added).

If the Patients' tissues are destroyed, sold, or de-identified, however, they will no longer be available to contribute to the Patients' "future health care." Nor will they be available to alert Patients' family members at high risk of developing prostate cancer. Nor will the University have any means for contacting the Patients to inform them of research results. Yet these are precisely the benefits for which the Patients contracted.

Accordingly, in addition to allowing the Patients to order their tissues to be destroyed, the Patients' right to withdraw from research, combined with the other provisions discussed above, must encompass the right to transfer their tissues to Dr. Catalona at another facility. *Compare York v. Jones*, 717 F. Supp. 421, 427 (E.D. Va. 1989) (right to withdraw pre-zygote from research encompassed right to transfer to another facility to fulfill purpose of bailment contract).

4. *The Contractual "Waivers" On Which The District Court Relied Are Irrelevant To The Issues And, If They Are Relevant, Are Void As Against Public Policy.*

Lastly, the district court erred in concluding that the patients could not have expected to retain rights in their tissues because two forms expressly waived any

claim to the excised tissues. Add. 22. This was misguided for at least three reasons.

First, in context, the waiver language is plainly meant to apply to rights to intellectual property in those tissues. The sentences before the waiver explain that the study's purpose was to determine whether a "valuable material or process (such as a new drug or new cell line)" could be developed. Add. 31. They then define "cell line." And then they explain that cell lines can result in the development of "new chemical products." *Then* comes the waiver: "By agreeing to participate in this study, you agree to waive any claim you might have to the body tissues you donate." *Id.* Contracts in Missouri must of course be read in context. *See, e.g., Lacey v. State Bd. of Registration for the Healing Arts*, 131 S.W.3d 831, 838 (Mo. Ct. App. 2004). Thus read, the "rights" waived here plainly are intellectual property-related claims.

Any other reading would fly in the face of the "meaning to every word" rule. As noted earlier, the consent forms expressly gave patients the right to "withdraw" from research, to decide "not to participate in this research study," and to have their tissues destroyed. And the contracts reserved the Patients' right to receive tissue-based medical treatment, to be informed regarding research results that might cause them to withdraw from research, and to have their tissues transferred to another medical facility. *See generally* note 6, *supra*. If the patients literally

waived “any claim” with respect to the tissues, all of these rights would evaporate. So the “waive any *claim*” language cannot possibly mean (as the district court said) that patients are waiving any and all *rights* with respect to the tissues. That would violate the settled Missouri rule that every word must be given meaning. *See, e.g., Gulf Ins. Co.*, 936 S.W.2d at 814.

Third, the district court’s interpretation of the “waive any claim” language would render the provision void as against public policy. In Missouri, “[a] contract is most often found to be against public policy when its enforcement would defeat or impede statutory regulation of a particular subject matter.” 35 MO. PRAC., CONT., EQ. & STAT. ACT. HAND. § 12:8 (2006 ed.); *Barnes v. Boatmen’s Nat’l Bank*, 156 S.W.2d 597, 602 (1941). Yet here the district court’s reading of the “waive any claim” language runs headlong into the Common Rule, which binds research institutions—including Washington University—that receive federal funding. The Common Rule declares that “[n]o informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.” 45 C.F.R. § 46.116.

The U.S. Department of Health and Human Service (“HHS”) is actively enforcing the Common Rule right now. For example, HHS sent a letter on January

25, 2006 to Louisiana State University Health Science Center Shreveport directing it to remove the following exculpatory language from its informed consent agreements: “By your consent to participation in this research study, you give up your property rights that you may have in your bodily fluids, substances or tissues.” HHS determined this language was exculpatory in violation of 45 C.F.R. § 46.116 because it made a subject waive or appear to waive his or her legal rights.⁹

As interpreted by the district court, the “waive any claim” language would likewise defeat the Common Rule’s prohibition on research subjects’ waivers of their legal rights. The language thus would be void as against public policy.¹⁰

⁹ Letter from Carol J. Weil, Compliance Oversight Coordinator, Division of Human Subject Protections, Office of Human Research Protections, to John C. McDonald, Chancellor/Dean, Louisiana State University Health Science Center Shreveport (Jan. 25, 2006) (On file with the PHS FOIA Office) *available at* http://www.hhs.gov/ohrp/detrm_lettrs/YR06/jan06a.pdf. *See also* Letter from Patrick J. McNeilly, Compliance Oversight Coordinator, Division of Compliance Oversight, Office of Human Research Protections, to Fawwaz T. Ulaby, Vice President for Research, University of Michigan (June 29, 2004) (On file with the PHS FOIA Office) *available at* http://www.hhs.gov/ohrp/detrm_lettrs/YR04/jun04c.pdf.

¹⁰ The district court also avoided the force of the regulation by glaringly misreading it. To be sure, the court started out on the right foot: “It is clear,” the court began, “that [under this language] the only legal obligation [Washington University] had was not to include exculpatory language in its informed consent forms which waived any legal rights the [patients] may have *or* relieve any party from its liability for negligence.” Add. 20 (emphasis added). But then the Court asserted—without basis—that “[h]earing testimony from all experts indicated that the research community consistently understood [this regulation] to bar exculpatory language involving releases from malpractice or other negligence.” And, without explanation, the district court adopted this reading. Add. 20-21.

In sum, the district court read the contract's waiver provision for far more than it was worth. That provision's plain language, its potential (under the district court's reading) to wipe out critical clauses in the contract, and its tension with express public policy, demonstrate that a narrower reading is required. At most, the provision waives the patients' rights to have the tissues physically returned to *them*. But it does not negate the bailment created by the University-drafted agreements, or deprive the Patients of their right to determine which researcher may use those tissues.

II. The District Court Erred In Granting Summary Judgment To The University On The Critical Issue Of The Patients' Intent To Grant Ownership Of Their Tissues To The University.

Even if Appellants were not entitled to a declaration and permanent injunction in *their* favor, the district court surely erred in holding that the record shows no genuine issue as to the facts underlying Washington University's right to judgment. Specifically, in addition to granting a summary judgment without

This reading, however, cannot be squared with the regulation's plain language. The regulation forbids exculpatory clauses that waive patient rights "or" relieve a party for its negligence. In this Circuit, the disjunctive matters. *See, e.g., Mages v. Johanns*, 431 F.3d 1132, 1140 (8th Cir. 2005) ("The USDA's decision is flawed because it required Mages to show a separate and distinct interest in his land *and* crops, notwithstanding the disjunctive nature of the regulation.") (emphasis in original). Here again, the district court mistakenly relied on expert testimony to interpret a regulation it should have interpreted itself. *See* note 8, *supra*.

adequate opportunity for a response,¹¹ the district court erred in its interpretation of Missouri law and in its remarkable decision to reject critical testimony on the basis of the court's own credibility determination.

A. The District Court Fundamentally Misunderstood Missouri's Law Of Gifts And Bailments, Leading It To Conclude Erroneously That The Patients Made An *Inter Vivos* Gift Of Their Tissues And Could Not Have Bailed Them.

As a threshold matter, summary judgment is inappropriate where a district court grants relief based on a misinterpretation of state law. *See Myers v. Richland County*, 429 F.3d 740, 749 (8th Cir. 2005). As noted, the Court reviews the district court's interpretation of Missouri law *de novo*. *Baum*, 440 F.3d at 1020-22 (interpretation); *Lindsay*, 447 F.3d at 617 (application).

Here, the district court made at least three errors of law rendering summary judgment inappropriate. *First*, as we explained in Section I.A., the district court mistakenly concluded that the parties' written contract was "inconsequential" to whether the Patients gifted their tissues. *Second*, as we explained in Section I.C., the district court mistakenly concluded that the parties could not have entered a

¹¹ As noted earlier, the parties were not even notified before the hearing that the court would *decide* summary judgment. To the contrary, the court instructed the parties to put on a permanent injunction hearing, and therefore denied as moot Dr. Catalona's request for discovery on Washington University's motion for summary judgment. Docket Entry No. 84. Of course, given the very different standards for permanent injunctive relief and summary judgment, the permanent injunction hearing required a far different set of witnesses and evidence than a summary judgment hearing.

bailment contract because (according to the Court) the Patients did not expect to have their tissues returned to them. *Third*, as also explained in Section I.C., the district court misread the plain language of the Patients' agreement in violation of settled principles of Missouri contract law.

If this Court concludes that the district court erred on *any* of these points, that conclusion will require, at a minimum, that the district court's grant of summary judgment be reversed. Because the district court was wrong on all three points, there can be no doubt that Washington University was not entitled to judgment as a matter of law.

B. The Evidence Creates, At The Least, A Jury Issue As To Whether The Patients Intended To Create A Bailment Rather Than An *Inter Vivos* Gift, And Whether They Intended To Retain A Right To Transfer Samples To Another Medical Facility.¹²

¹² In this section, we assume that the district court decided fact issues only for summary judgment purposes and under summary judgment standards. An alternative reading of the court's opinion is that it *sua sponte* conducted a bench trial on factual issues that should have gone to a jury. *See* Add. 1, 12. That would have been plainly incorrect as well. In actions (such as this one) involving both equitable and legal claims, legal claims must be decided first, and their factual predicates decided by a jury. *Dairy Queen, Inc. v. Wood*, 369 U.S. 469, 479 (1962) (“[L]egal claims . . . must be determined prior to any final court determination of [] equitable claims.”); *Johnson v. Fidelity & Cas. Co.*, 238 F.2d 322, 326 (8th Cir. 1956) (“The factual issues presented were jury issues and the trial court was in error in undertaking to serve as the trier of the facts and in denying the jury trial demanded.”). This rule applies to actions for declaratory relief. *Simler v. Conner*, 372 U.S. 221, 223 (1963) (“The fact that the action is in form a declaratory judgment case should not obscure the essentially legal nature of the action. The questions involved are traditional common-law issues which can be and should have been submitted to a jury under appropriate instructions as petitioner requested.”).

Moreover, if the record does not *compel* permanent declaratory and injunctive relief for Appellants (which it does, for reasons explained earlier), it at least presents numerous issues of material fact. *See* Fed. R. Civ. P. 56(c). Here, too, the Court “review[s] the district court's grant of summary judgment *de novo*,” and views the facts in the light most favorable to the Appellants, who were the non-moving parties. *Grabovac v. Allstate Ins. Co.*, 426 F.3d 951, 955 (8th Cir. 2005).

Here, the required *de novo* review means that Washington University, which claims that a gift exists, must carry the burden of proving the gift by clear, cogent, and convincing evidence. *See In re Estate of Campbell*, 939 S.W.2d 558, 562 (Mo. App. 1997); *Duvall v. Henke*, 749 S.W.2d 714, 716 (Mo. App. 1988). The record demonstrates that Washington University has not come close to making such a showing.

1. By itself, the written agreement between the Patients and Washington University shows that the existence of a gift *inter vivos* is anything but clear. As we have noted, a valid *inter vivos* gift requires an “intention on the part of the donor to part with his right in and dominion over the property immediately and irrevocably.” *Ridenour*, 246 S.W.2d at 769.

Here, the consent forms promised that the patients could “withdraw [their] consent at any time,” and “request that their tissues no longer be used for

research,” and ask that their tissues be “identified and destroyed upon request.” Add. 5, 6 (emphasis added). This is valid evidence showing a lack of donative intent in Missouri, and at a minimum it seriously clouds the picture the University seeks to paint of a clear, irrevocable gift. It is sufficient to preclude summary judgment in the University’s favor.

2. The Patients’ testimony at the hearing likewise precludes summary judgment in the University’s favor. The Patients’ testimony consistently verified that they did not intend to make a gift at all. *See* p. 10, *supra*. Indeed, the district court *acknowledged* their statements that they did not intend to make a gift. Add. 21. Thus, even assuming the University presented some legitimate evidence of donative intent, the Patients’ statements were sufficient, at a minimum, to create a jury issue on that question.

How did the district court deal with what it obviously viewed as a conflict in the evidence? It made a *credibility* determination: that the witnesses had a deep personal connection to Dr. Catalona and their testimony showed “nothing more than an after thought of regret.” Add. 21 (citation omitted).

This was a plain and egregious error. If the Supreme Court’s decisions construing the summary judgment procedures in Rule 56 are clear about anything, it is that a district court cannot make credibility determinations in resolving a motion for summary judgment. *See, e.g., Anderson v. Liberty Lobby*, 477 U.S.

242, 255 (1986) (“Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whether he is ruling on a motion for summary judgment or for a directed verdict.”). Accordingly, in this Circuit, “[i]n ruling on a motion for summary judgment, a court must not weigh evidence or make credibility determinations.” *Kenney v. Swift Transp., Inc.*, 347 F.3d 1041, 1044 (8th Cir. 2004).

Such intrusion into the jury’s role is particularly inappropriate where, as here, the underlying issue is one of intent. The Missouri courts have “consistently held that cases in which the underlying issue is one of motivation, intent, or some other subjective fact are particularly inappropriate for summary judgment.” *Ganaway v. Shelter Mut. Ins. Co.*, 795 S.W.2d 554, 562 (Mo. App. 1990); *see also In re Estate of Heidt*, 785 S.W.2d 668, 670 (Mo. App. 1990) (observing that summary judgment is “rarely appropriate in cases involving proof of such elusive facts as intent, motive, fraud, duress, undue influence, mental capacity, and the like—which must in nearly every case be proved by circumstantial evidence.”). And this Court agrees. *United States v. Taber Extrusions LP*, 341 F.3d 843, 846 (8th Cir. 2003) (“Particularly when the issue turns on the defendant’s intent, or scienter, summary judgment for the plaintiff is inappropriate.”) (Loken, C.J.); *Pfizer, Inc. v. Int’l Rectifier Corp.*, 538 F.2d 180 (8th Cir. 1976). Indeed, “*when the intent of the parties as to the meaning of a contract is in issue, summary*

judgment is particularly inappropriate.” Hall Contr. Corp. v. Entergy Serv’s, 309 F.3d 468, 472 (8th Cir. 2002) (emphasis added) (quotation omitted).

Here, at *most* the Patients’ intent remains unclear. Consequently, the record fails to establish by “clear, cogent, and convincing evidence” that the Patients made a gift. *See In re Estate of Campbell, 939 S.W.2d at 562; Duvall, 749 S.W.2d at 716.* The district court’s grant of summary judgment, if not reversed outright, must be vacated and the case be remanded for trial to determine whether the Patients intended to make any gift of their tissues.

* * * * *

As explained above, the district court was plainly wrong on the law, and in numerous ways. It was also profoundly mistaken in concluding that adherence to settled legal rules in this case would somehow threaten the advancement of medical research by allowing “access to these materials to [be] thwarted by private agendas.” Add. 27. To the contrary, as the University’s forms recognize, if genetic information such as that at issue here “were to become known outside of th[is] research, you (and family members) may be unable to obtain health, life, or disability insurance. You might also be refused employment or terminated from your current employment.” Add. 35. Because of such risks, a refusal to enforce settled legal rules and contract terms securing a patients’ right to control the disposition of bodily tissues will, in the words of one expert witness at the hearing,

“radically *undermine* the research enterprise.” App. 58 (Tr.1:122) (emphasis added). It is therefore the district court’s decision—not the Appellants’ position—that poses the real risk to medical research.

CONCLUSION

For the foregoing reasons, Appellants are entitled to (1) a declaration that Washington University is not the true and rightful owner of their tissues, that the Patients themselves are the owners, and or that they bailed their tissues to Dr. Catalona and Washington University and may order their tissues to be destroyed or transferred to Dr. Catalona; and (2) a permanent injunction forbidding the University from using, transferring, de-identifying, or destroying the Patients’ tissues.

Respectfully submitted,

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**CERTIFICATE OF COMPLIANCE
WITH FED. R. APP. P. 32(a)(7)**

Pursuant to Fed. R. App. P. 32(a)(7), counsel for Defendant-Appellant hereby certifies that this brief conforms to the rules contained in Fed. R. App. P. 32(a)(7) for an opening brief produced with proportionally spaced font. Created in Microsoft Word 2000, the length of this brief is 12,655 words.

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Counsel for Defendant-Appellant hereby certifies that on July 12, 2006, two copies of Defendant-Appellant William J. Catalona's Opening Brief, as well as a digital version of the brief, were delivered by U.S. Mail to

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