

**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**

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

JIM J. SHOEMAKE
TROY A. DOLES
Guilfoil Petzall & Shoemake, LLC
100 S. Fourth Street, Suite 500
St. Louis, MO 63102

GENE C. SCHAERR
ANDREW C. NICHOLS
Winston & Strawn LLP
1700 K Street, N.W.
Washington, D.C. 20006
(314) 241-6890

(202) 282-5000

Counsel for Defendant-Appellant William J. Catalona

TABLE OF CONTENTS

TABLE OF AUTHORITIES	iv
INTRODUCTION	1
ARGUMENT.....	2
I. The University Has Offered No Persuasive Defense Of The District Court’s Ruling, Without A Jury Trial, That The University “Owns” The Tissues.....	3
A. <i>Moore</i> Is Not Controlling, And In Any Event Points Strongly In Appellants’ Favor.	3
B. The University’s Position That It Would Own The Tissues “Even If There Were No Evidence” That The Patients Donated Them Is A More Extreme Version Of The District Court’s Erroneous Holding That The University’s Informed Consent Forms Are “Inconsequential,” And Is Equally Incorrect.	5
C. The University’s Radical Theory Of “Donation” Ignores The Patients’ Reservation Of Essential Rights In Their Tissues, Rights Incompatible With An Outright Gift.	8
D. At A Minimum, The District Court Erred In Depriving The Defendants Of A Jury Trial On The Issue Of The Patients’ Donative Intent.	15
II. The University Has Offered No Persuasive Defense Of The District Court’s Ruling That The Patients Have No Rights With Respect To The Tissues, Either As Owners, Bailors, Or Mere Parties To A Contract.	18
A. The Patients’ Ownership Of Their Tissues Is Well Established In Both The Law And The Record.	19
B. Even If The Patients Do Not Own The Tissues, The Patients Are Bailors Under Settled Missouri Law Ignored By Both The District Court And The University And Are Entitled To The Rights Secured By Their Bailment Contract.	21

III.	Appellants Are Entitled To An Injunction Prohibiting The Use, Destruction Or Transfer Of The Tissues To Any Entity Other Than A Research Institution Chosen By The Patients.....	22
A.	Because The Patients And Dr. Catalona Face A Serious Risk Of Irreparable Harm, While The University Faces No Serious Risk, The Balance Of The Equities Favors Appellants.....	23
B.	The University’s Public Interest Argument Is Belied By Its Own Record Of Transferring Tissues Without The Patients’ Consent And Seeking To Profit From Patients’ Tissues.....	25
	CONCLUSION	29
	CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32(a)(7)	
	CERTIFICATE OF SERVICE	

TABLE OF AUTHORITIES

FEDERAL CASES

<i>Edson v. Lucas</i> , 40 F.2d 398 (8th Cir. 1930)	13
<i>Fields Engineering & Equipment, Inc., v. Cargill, Inc.</i> , 651 F.2d 589 (8th Cir. 1981)	18
<i>Hall Contr. Corp. v. Entergy Servs</i> , 309 F.3d 468 (8th Cir. 2002).....	16
<i>Gonzaga Univ. v. Doe</i> , 536 U.S. 273 (2002)	7

STATE CASES

<i>Bales v. Bales Chapel Baptist Church</i> , 101 S.W. 150 (Mo. App. 1950)	13
<i>Boyers v. Boyers</i> , 565 S.W.2d 658 (Mo. App. 1978).....	13
<i>Cochenour v. Cochenour</i> , 642 S.W.2d 402 (Mo. App. 1983).....	13
<i>Dunn Indus. Group v. City of Sugar Creek</i> , 112 S.W.3d 421 (Mo. 2003).....	10
<i>In re Estate of Hitchcock</i> , 483 S.W.2d 617 (Mo. 1972).....	13
<i>In re Estate of Wintermann</i> , 492 S.W.2d 763 (Mo. 1973)	6, 16
<i>In re Soulard's Estate</i> , 43 S.W. 617 (1897).....	13
<i>Gulf Ins. Co. v. Noble Broad.</i> , 936 S.W.2d 810 (Mo. 1997).....	9
<i>Krombach v. Mayflower Ins. Co.</i> , 827 S.W.2d 208 (Mo. 1992).....	11
<i>Moore v. Regents of the University of California</i> , 793 P.2d 479 (1990)	<i>passim</i>
<i>Ridenour v. Duncan</i> , 246 S.W.2d 765 (Mo. 1952)	10
<i>Schultz v. Schultz</i> , 637 S.W.2d 1 (Mo. 1982)	9
<i>State v. Betz</i> , 106 S.W. 64 (Mo. 1907)	21, 22
<i>State v. Edwards</i> , 137 S.W.2d 447 (Mo. 1940)	21

Weinberg v. Wayco Petroleum Co., 402 S.W.2d 597 (Mo. Ct. App. 1966)22

STATUTES AND RULES

46 C.F.R. § 116.....26

46 C.F.R. § 122.....7

MISCELLANEOUS

Samuel Epstein, *American Cancer Society: The World's Wealthiest “Non-Profit” Institution*, 29 Int'l J. Health Serv's (1999)27

Julia Liebeskind, *Risky Business: Universities & Intellectual Property*, Academe (2001) (<http://www.aaup.org/publications/Academe/2001/01SO/so01lie.htm>) (American Association of University Professors).....27

Victoria Saeland, *University Transfers Tech Into Commercial Dollars*, St. Louis Business Journal, August 25, 200526-27

Rebecca Skloot, *Taking the Least of You*, New York Times Magazine, Apr. 16, 200627-28

INTRODUCTION

As it did before the district court, Washington University seeks to force upon this Court a false choice between equally extreme positions. Claiming that the consent forms it drafted are irrelevant, the University argues that, as between its own total ownership of the tissues in dispute and the Patients' own "perpetual" ownership, it wins. But this totally ignores Appellants' core argument—that although the University may ordinarily use or even consume a patient's tissues (because those acts are within the scope of the forms), the University may not (again because of the forms) refuse a patient's request to stop all research on existing tissues and, if asked, destroy them. As Appellants explained in their opening briefs, that is the substance of the parties' agreement, and hence what Missouri law requires.

Because the University's own agreements so undermine its position under Missouri law, the University repairs to *Moore v. Regents of the University of California*, which of course is not binding because it involved California law. And in all events, *Moore* is powerful precedent in favor of Appellants, for it held that patients providing tissues for research are primarily protected, not by tort law, but by written informed consent agreements, which were absent there but present here.

The University's repeated attempts to characterize Appellants as seeking the Patients' "perpetual ownership" of their tissues, moreover, is pure sophistry. To be

sure, Appellants have observed that the University’s unfounded gift theory leaves the University no way to justify *its own* outright ownership of the tissues, and thus that the Patients must own them by default. But beyond that, Appellants have merely asked the Court to enforce the express promises—and the necessary implications of those promises—that the University made to the patients in its own written agreements.

By contrast, the University’s position is breathtaking in its implications. By asking this Court to rule that the University would own the Patients’ tissues “*even if there were no evidence*” of a donation (Opp’n 26)—a position that would justify outright theft—the University would make tissue research a matter of conscription.

From an institution that portrays itself as a disinterested guardian of medical research, this is a remarkable assertion of power. But it should not be entirely surprising, for genetic cancer research is lucrative business and the record here shows that the University seeks to use the Patients’ tissues for profit.

In reality, then, it is the University’s position—and especially its view that its promises to patients do not matter one whit—that is extreme, and that poses the real threat to medical research.

ARGUMENT

The University offers no explanation for how, under Missouri law, it came to own the Patients’ tissues outright given the crucial rights reserved to the Patients

in its own consent forms. Nor does the University provide any serious defense of the district court's conclusion that the Patients have no rights with respect to their tissues—including the rights expressly granted by the University's own forms—or the court's denial of the Appellants' request for injunctive relief.

I. The University Has Offered No Persuasive Defense Of The District Court's Ruling, Without A Jury Trial, That The University "Owns" The Tissues.

In their opening briefs, Appellants demonstrated that the district court erred in holding that the Patients' informed consent forms were "inconsequential" to whether the Patients made an *inter vivos* gift of their tissues under Missouri law. The University responds that this rule is required by *Moore v. Regents of the University of California*. But even if it controlled here (it does not), *Moore* said precisely the opposite. The University's fallback effort, to rewrite its consent forms after they have been signed by patients, fares no better.

A. Moore Is Not Controlling, And In Any Event Points Strongly In Appellants' Favor.

The University begins by mischaracterizing *Moore*. According to the University, *Moore* is "dispositive" because it "squarely" holds that research participants "do not retain ownership rights to biological materials they contribute for medical research." Opp'n 14. *Moore* holds no such thing. The plaintiff in *Moore* sued medical researchers who patented and profited from the plaintiff's cells without obtaining plaintiff's consent. The question for the court was

“whether plaintiff has stated a cause of action . . . for using his cells in potentially lucrative medical research without his permission.” 793 P.2d 479, 480 (1990). Interpreting California law, the court held that plaintiff did *not* state a cause of action for conversion, but did state a cause of action for failure to obtain informed consent. *Id.* at 497.

The University’s fundamental error is treating this case as if the Appellants seek to impose conversion liability on the University. Appellants do not seek to impose conversion liability, but instead seek to enforce the consent forms drafted by the University—precisely the approach endorsed in *Moore*. 793 P.2d at 493-97. For this reason, the University and its *amici* miss the mark badly by insisting that Appellants seek to create “novel” property rights. *See* Opp’n 2, 17, 21, 48; Br. for American Cancer Society (“ACS Br.”) 4, 12, 13, 21; Br. for Cornell Univ., et al. (“Univ. Br.”) 3, 4, 5, 18. That may have been a valid criticism of the plaintiff’s complaint in *Moore*, but it gets things backwards here, where Appellants rely on what the California Supreme Court termed the “well-established,” “well-recognized,” and “long-standing” principle of informed consent (793 P.2d at 483, 493).

The University’s reason for seeking to make this a conversion case is that it can then rely on *Moore*’s warning that creating a new tort of tissue conversion would endanger medical research. For example, the University and its *amici*

readily invoke *Moore*'s caution against subjecting researchers to a "litigation lottery." Opp'n 47; Univ. Am. Br. 15; *see* ACS Br. 16. But they fail to mention that, according to *Moore*, the source of that risk is conversion liability and its *solution* is the faithful and prudent use of informed consent forms. 793 P.2d at 494 ("Liability based upon existing disclosure obligations, rather than an unprecedented extension of the conversion theory, protects patients' rights of privacy and autonomy without unnecessarily hindering research."); *id.* ("In contrast to the conversion theory the fiduciary-duty and informed consent theories protect the patient directly, without punishing innocent parties or creating disincentives to the conduct of socially beneficial research."); *id.* at 497 (paraphrase of same).

B. The University's Position That It Would Own The Tissues "Even If There Were No Evidence" That The Patients Donated Them Is A More Extreme Version Of The District Court's Erroneous Holding That The University's Consent Forms Are "Inconsequential," And Is Equally Incorrect.

Rather than contend with these statements, and the significant rights reserved to the Patients in the University's forms, the University and its *amici* endorse the district court's erroneous holding that the forms are "inconsequential." Indeed, the University takes an even more radical position, i.e., that it "would own the tissues even if there were *no* evidence that the [Patients] had donated them for medical research." Opp'n 26 (emphasis added). This is profoundly mistaken.

The University's position would abolish every one of Missouri's requirements for a gift. The parties do not dispute that a party seeking to establish a gift must demonstrate (1) an intent to part irrevocably and absolutely with all right in and control over the property, (2) delivery of the property, and (3) acceptance of the property. And each of these elements must be shown by clear and convincing evidence. *In re Estate of Wintermann*, 492 S.W.2d 763, 767 (Mo. 1973). Yet the University claims that it would own the tissues even if there were *no* evidence that the Patients had donated them. That circle cannot be squared.

A “no evidence” standard would also have disastrous practical implications. If the University could establish its ownership of patients' tissues with literally no evidence of a donation, the University could secure all the tissue samples it wanted without telling the patients anything. This would certainly make it easier to harvest patients' biological materials for research, or even transplantation. During prostate cancer surgery, for example, the University could preserve cancer tissue for research—or even take a spleen or a kidney—and automatically own it, by virtue of sheer possession.

The University counters that these are hypothetical dangers because the patients must consent to research under the Common Rule. Opp'n 19-20; Univ. Br. 17-25. But as the American Cancer Society acknowledges, the Common Rule provides no private right of action. ACS Br. 24. “And where Congress did not

intend to create rights enforceable in private actions, there is no basis for a judicial remedy.” *Id.* (citing *Gonzaga Univ. v. Doe*, 536 U.S. 273, 286 (2002)). Instead, the Common Rule “works” by an indirect time-lag mechanism: federal regulators who discern problems with compliance with consent requirements may eventually reduce university funding. 46 C.F.R. § 122. But this helps only future patients. It provides no relief for patients who already have had biological materials—or even entire organs—seized without their consent. With the University thus vested with outright ownership, and with the patients holding no private right of action, under the University’s “no evidence” theory the patients would be out of luck.

The University claims that this preposterous result is compelled by *Moore*. “Under *Moore* a defect in, or lack of, informed consent does not determine ownership rights,” the University declares. Opp’n 22. The University thus repeats the district court’s error—concluding that because an informed consent form was not required for the *Moore* plaintiff to transfer ownership of his tissues, the terms of a patient’s form are always irrelevant to whether ownership was transferred. Add. 19-20. But *Moore* did not say that. Rather, as we have explained, *Moore* said that the patient’s rights are defined, not by tort law, but by the terms of his informed consent form.

Even more importantly, the consent forms are dispositive under Missouri law. Missouri decisions teach that a putative donee’s statements, including those

made in writing, are *most* probative of his intent. *Catalona Br. 23-24*. It is therefore fallacious to say that, because a patient can transfer ownership of his tissues without a writing, if he does consent in writing, then the terms of that writing are inconsequential. Ultimately, the University cannot bring itself to dispute this. *See Opp'n 34-35* (claiming that Appellants' cases are factually dissimilar, but not disputing rule that alleged donor's statements are most probative of intent). So its last-ditch effort is to rewrite and reinterpret both its forms and Appellants' gift cases.

C. The University's Radical Theory Of "Donation" Ignores The Patients' Reservation Of Essential Rights In Their Tissues, Rights Incompatible With An Outright Gift.

The University's forms reserve such expansive rights to the Patients that, as with its characterization of *Moore*, the University is forced to hypothesize a new version of the forms. But the real forms show that the Patients made no outright gift.

The University omits or distorts three key provisions. *First*, the University ignores the district court's finding that the forms declare the Patients' right to direct that their tissues be destroyed. The district court's "Findings of Fact" declare that research participants, defined to include the eight Patients (Add. 4 n.5), had to sign a brochure that answered the question, "**What if you change your mind?**" (Add. 6 (emphases in original)). The University does not seriously dispute

this finding, and itself repeatedly relies on the brochures. Opp’n 9, 27, 39. Yet the University never explains how an *inter vivos* gift can occur under Missouri law where the putative donor retains the right to order the property destroyed. Indeed, neither of the terms “destroy” or “destruction” appears in the University’s discussion of the law of gifts. Nor does the phrase “**What if you change your mind?**”

Instead, the University boldly claims that the evidence that Patients donated their tissues is “much more compelling” here than in other cases where Missouri courts have found a gift (Opp’n 28). But the University manages to cite only two cases, neither of which has facts approaching those here.¹ The University is therefore left to recite the forms’ “gift-like” language, ignore the language that negates an *inter vivos* gift, and assert that there was a gift as a matter of law. Opp’n 27-28. This will not do. In Missouri, every word of an agreement is to be given meaning. *Gulf Ins. Co. v. Noble Broad.*, 936 S.W.2d 810, 814 (Mo. 1997). Hence, whatever the University’s forms mean by “free and generous gift,” “waive,” and “donate,” those terms cannot negate the University’s simultaneous

¹ *Schultz v. Schultz*, 637 S.W.2d 1, 6-7 (Mo. 1982), is particularly inapposite. According to the University, in *Schultz* a putative donor’s “throwing share certificates on [his] brother’s desk” and his “brother’s retention of them” was “sufficient to constitute a gift.” Opp’n 28 n.6. But the university fails to mention that there was “an argument between Sol and Jack which ended with Sol throwing the three remaining certificates on Jack’s desk with the instruction to ‘stick them . . .’” (637 S.W.2d at 6) or that “stick them . . .” was dispositive (*id.* at 7).

promise, in bold print, that the Patients could change their minds and order that their tissues be destroyed.

Nor does the University explain how the right to change one's mind and order property destroyed is compatible with Missouri's requirement that a gift be absolute, unconditional, and irrevocable. *Ridenour v. Duncan*, 246 S.W.2d 765, 769 (Mo. 1952). Of course, the two are not compatible, for there could be no qualification *greater* than the right to order property destroyed. Having reserved this ultimate right of control to the Patients, the University's forms and brochures render the Patients' tissues the quintessential non-gift. By failing even to mention (much less dispute) the Patients' reservation of this dispositive right, the University effectively concedes that here there was no valid *inter vivos* gift.

Second, the University sets aside its promise that the Patients could "choose not to participate in this research study" and "withdraw consent" at "any time," conditions that likewise negate an *inter vivos* gift. The forms provide: "Your participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time." Add. 5. The University does not dispute that this sentence must be read in context and given its "plain, ordinary, and usual" meaning. *Dunn Indus. Group v. City of Sugar Creek*, 112 S.W.3d 421, 428 (Mo. 2003). According to the University, however, the right to discontinue participation is merely the right "to refuse to submit to further procedures,

questions or other interactions with . . . researchers or . . . to refuse the continued use of one's identifiable private information." Opp'n 29, 32.

But the agreements themselves refute this convoluted definition. The forms and brochures repeatedly refer to ongoing participation in research, not merely in having tissues removed or in live interaction with researchers. Add. 31 ("Your participation will involve . . . [that] [y]our . . . specimen may be used for research . . ."); Add. 33 ("You will be informed of . . . findings developed during the course of participation in this research that may have a bearing on your willingness to continue in this study."); *id.* at 34 ("Before making a decision about participating in research involving genetic analysis . . ."); *id.* at 35 ("An insurance company might consider participation in a family study a high risk . . ."). Likewise, the ordinary meaning of "participation" in a "study" of one's tissues is having those tissues studied, not merely in having the tissues removed or in interacting with researchers.

Nor do the forms remotely equate "participation" with the mere use of identifiable private information. This is a classic example of one party, far better acquainted with an agreement's subject matter, "impos[ing] upon words of common speech an esoteric significance intelligible only to [its] craft." *Krombach v. Mayflower Ins. Co.*, 827 S.W.2d 208, 211 (Mo. 1992) (quoting Learned Hand, J.) (citation omitted). While the University's proposed definition might occur to a

lawyer or an academic, no ordinary, untrained person reading “participation” would think “that merely means using my identifiable private information.” Instead, they would think that “participation” in a study meant having their tissues used in the study. Under Missouri’s settled rule of construing agreements against the drafter, this Court therefore must reject the University’s labored reading of “participation.” *Id.*

To shore up its untenable position, the University argues that this Court should rely on the definition of “discontinue participation” in the Common Rule. Opp’n 32. Even if the Common Rule allowed stripping patients’ tissues of identifiable information and using them for research (it plainly does not; *see* Pat. Reply at 13-16), the Patients did not sign the Common Rule. The Patients signed an agreement written by the University that defined “choose not to participate” on the University’s own terms. And while the Rule establishes a minimum set of rights to be reserved to the Patients, it does not (and cannot) stop the University from making added promises. The Common Rule sets a floor, not a ceiling. Accordingly, the question for this Court is not what the Common Rule means by “discontinue participation,” but what the forms mean by promising that the Patients may “choose not to participate in this research study” at “any time.” Add. 32.

To the ordinary person, that meaning is crystal clear. At a minimum, the forms require that the Patients be allowed, upon request, to stop all research on their tissues.²

That promise is incompatible with an *inter vivos* gift. Cancer tissues are good only for research. And in Missouri, there can be no outright gift where the putative donor reserves the right to stop the property from affording the donee any benefit. *In re Soulard's Estate*, 43 S.W. 617, 622 (1897) (no gift where writing prohibited alleged donee from making “any disposition” of funds or receiving any income from funds).³ By reserving this ultimate right, the Patients did not part with all “dominion and control” over their tissues, as Missouri law requires. Like the Patients’ right to order their tissues destroyed, the University’s promise that Patients could choose not to participate in the proposed research study “at any time” shows that here there was no *inter vivos* gift.

² As Appellants have also explained, the forms necessarily also require allowing the Patients to order their tissues transferred to another institution. Catalona Br. 38-40; Pat. Br. 47-53.

³ None of the University’s cases allegedly to the contrary involved such a serious condition, which amounts to a right of revocation. *In re Estate of Hitchcock*, 483 S.W.2d 617 (Mo. 1972) (condition allowed donee some use of property); *Edson v. Lucas*, 40 F.2d 398 (8th Cir. 1930) (same) (not construing Missouri law); *Cochenour v. Cochenour*, 642 S.W.2d 402 (Mo. App. 1983) (same); *Boyers v. Boyers*, 565 S.W.2d 658 (Mo. App. 1978) (same); *Bales v. Bales*, 101 S.W. 150 (Mo. App. 1950) (same).

Third, the University ignores its promise to notify Patients of research findings that might persuade them to drop out of research, a pledge also inconsistent with an outright gift. The forms promise that “[y]ou 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.” Add. 33. The University never mentions this commitment, which undermines its argument that medical research would be ruined if Patients could control the use of their tissues. Nor does the University acknowledge that if it “anonymizes” the tissues, as it claims is its right, it cannot keep this promise.

The biggest problem with this promise for the University, however, is that it makes no sense if the Patients intended to make an irrevocable gift. After all, a person trying to make an unconditional donation does not reserve the right to receive updates that might cause him to render the gift useless. Nor does the University cite a case where a donor reserved such a telling right. *See* note 3, *supra*. That Patients here reserved such a right is yet one more clear indicator that they made no outright gift.

The district court’s decision obliterates all three of these major promises. Ruling that such promises are “inconsequential,” it concluded that “the subject biological materials constitute an *inter vivos* gift.” Add. 17, 23. That means, the court declared, that no research participant “in connection with any past, present or

future protocol conducted under the auspices of Washington University has any ownership *or* proprietary interest in the said biological materials housed in the . . . biorepository.” Add. 2 (emphasis added).

Now shown the court’s error, the University’s response is to continue to ignore the restrictions and ask this Court to bless the district court’s “thoughtful, well-reasoned” decision (Opp’n 14). But the error remains. Under *Moore*, the University’s informed consent forms are *not* inconsequential, for they protect patient autonomy without endangering medical research. And under Missouri law, these ultimate restrictions show there was no *inter vivos* gift.

D. At A Minimum, The District Court Erred In Depriving The Defendants Of A Jury Trial On The Issue Of The Patients’ Donative Intent.

Even if the evidence of the Patients’ donative intent does not dictate outright reversal of the district court’s order (it does), it surely merits the jury trial that Dr. Catalona demanded. The University responds that (1) there is no disputed issue of material fact here; (2) Dr. Catalona defaulted on the University’s motion for summary judgment and waived his right to a jury trial; and (3) that in any event Dr. Catalona got the trial he sought. The University is incorrect on all three counts.

1. The University is incorrect that there is no disputed issue of material fact here. According to the University, “intent at the time of delivery and acceptance is the only intent that counts.” Opp’n 50. As we will explain,

Appellants do not concede this point. But even if true, this assertion begs the question whether the University established by “clear, cogent, convincing evidence” that the Patients intended to make an *inter vivos* gift. *In re Estate of Wintermann*, 492 S.W.2d at 767. At a *minimum*, the evidence creates a sharp dispute of fact on that point. *See* Catalonia Br. at 46-50. The University does not dispute that “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). That is the situation here.

Moreover, the University is wrong that “intent at the time of delivery and acceptance is the only intent that counts.” It is true that evidence of intent created before delivery is powerful, as Appellants have shown in discussing the University’s forms. But the University’s own Missouri cases show that later evidence of intent (or lack thereof) can be essential. *See, e.g., In re Estate of Wintermann*, 492 S.W.2d at 767 (determining intent, in part, by considering statements by decedent’s relatives after her death). Under these authorities, the Patients’ testimony about their lack of intent was highly relevant. Yet the district court rejected this testimony by making adverse credibility determinations. Catalonia Br. 48. This was error, and the University has no answer for it.

2. The University is also incorrect that Dr. Catalona defaulted on his motion for summary judgment and waived his demand for a jury trial. He did neither.

The University asserts that the Court gave Dr. Catalona an extension until January 28, 2004, but that Dr. Catalona missed that deadline. That is false. The University moved for summary judgment on January 7, 2004. On January 16, Dr. Catalona moved for a continuance so he could conduct discovery. App. 5:1109. On January 22, the district court granted that motion. App. at 5:1113. On January 30, the district court orally ordered the parties to state their positions about a summary judgment discovery schedule. On February 6, the University asked the district court to “*set a briefing schedule requiring Catalona to respond to WU’s motion for Summary Judgment by April 9, 2004.*” App. 5:1155 (emphasis added). The court never set that briefing schedule. App. 5:1251.

In January 2005 the district court ordered the parties to tell the court whether to adjudicate the pending summary judgment motion (which obviously had not been defaulted) or the preliminary injunction motion. App. 6:1333. In February, the court set the matter for a *permanent* injunction hearing, leaving the summary judgment motion permanently on hold. Dr. Catalona never defaulted.

Nor did he waive his right to a jury trial. Dr. Catalona requested that the district court rule on summary judgment after full discovery. The court instead

took up the motion for a preliminary injunction, converted that to a permanent injunction motion, and in its final decision granted summary judgment without warning. Until the court issued that decision in 2006, Dr. Catalona had no way to know that summary judgment was on the table. He waived nothing.⁴

3. Contrary to the University's argument, moreover, Dr. Catalona *did* seek money damages. Count VI of Dr. Catalona's counterclaim was for defense and indemnity and expressly sought money damages. App. 5:1053-55. That is why Dr. Catalona's counterclaim alleged an amount in controversy over \$75,000. App. 5:1034. Dr. Catalona thus did not get a jury trial as required by the Sixth Amendment. And it was error for the district court to resolve disputed factual issues rather than saving those issues for a jury.

II. The University Has Offered No Persuasive Defense Of The District Court's Ruling That The Patients Have No Rights With Respect To The Tissues, Either As Owners, Bailors, Or Mere Parties To A Contract.

The University does not merely fail to defend its outright ownership of the Patients' tissues. It also fails to explain why, if there was no gift, ownership does

⁴ The University claims that Dr. Catalona somehow waived his jury trial right when he said that the district court's hearing would address "a primary determinative" question of law, the Patients' ownership of their tissues. Opp'n 49. That statement meant nothing more than that, for practical reasons, the litigation would likely come to an end if the court ruled, as a result of the injunction hearing, that the Patients retained ownership of their tissues. The statement says nothing about what would happen if the Court ruled *against* the Patients. In any event, in this Circuit a waiver must be clear. *See, e.g., Fields Engineering & Equipment, Inc., v. Cargill, Inc.*, 651 F.2d 589, 592 (8th Cir. 1981). And Dr. Catalona's statement cannot be considered a clear waiver of his earlier demand for jury trial.

not vest in the Patients. And it embraces the district court's obviously mistaken holding that the parties here had no bailment contract.

A. The Patients' Ownership Of Their Tissues Is Well Established In Both The Law And The Record.

The University's all-or-nothing theory of this case leaves it in a bind. For the University, everything hinges on whether there was an *inter vivos* gift, and the University claims that its consent forms are irrelevant to this question. But as we have shown, the forms establish that there was no *inter vivos* gift. It is axiomatic that the Patients therefore must own the tissues. The University cannot explain why this is not so.

Contrary to the University's assertion, Missouri's law of medical waste does not divest the Patients of their ownership rights. First, by its terms, Missouri's law of medical waste does not apply to valuable biological tissues that are not discarded. *See* Pat. Br. 50-51. The University has no reasoned response to this dispositive point. Opp'n 24. Second, even if Missouri's law of medical waste did apply here, Northwestern University, to which Patients seek to transfer their tissues, is perfectly capable of complying with it. The University has no reasoned response to this dispositive point, either. *Id.*

Nor does the Common Rule establish that the Patients are non-owners. According to the University, the Common Rule "assumes" that the Patients do not own the samples. Opp'n 24. Even if that were true (it is not), it would be

irrelevant. An institution can induce patients to participate in research with any number of promises not required by the Common Rule. Again, the Rule sets a floor, not a ceiling. Thus, even assuming that the Rule “permits” the University to waive the informed consent requirement (in other words, it allows the *University* to waive the *Patients*’ rights; Opp’n 24) it cannot prevent the University from promising not to do that. Similarly, even assuming that the Rule provides that the University “may” use anonymized samples without Patient approval (Opp’n 24), it cannot prevent the University from promising not to do *that*.⁵

The University, moreover, has failed to rebut the Appellants’ showing that Missouri’s Uniform Anatomical Gift Act (UAGA) and *Mansaw v. Midwest Organ Bank* establish the Patients’ residual ownership of their tissues. Both the UAGA and *Mansaw* demonstrate that, even after death, Missouri law affords individuals a baseline property right in their bodies. The University counters that neither authority addresses the rights of living people who have consented to the use of their body tissues for research. But Appellants did not argue that either authority directly controls here; they argued that the UAGA and *Mansaw* apply by inference. *Catalona Br. 27. That* argument remains unimpeached. And, as shown above, the University has no directly controlling authority of its own.

⁵ While this Court need not reach this question, the Patients clearly show that the Common Rule makes neither allowance. Pat. Reply 13-16, 14 n.8.

B. Even If The Patients Do Not Own The Tissues, The Patients Are Bailors Under Settled Missouri Law Ignored By Both The District Court And The University And Are Entitled To The Rights Secured By Their Bailment Contract.

Nor can the University explain why, if the Patients do not own their tissues outright, this was not a simple bailment. Instead, the University merely reasserts the district court's erroneous holding that a bailment requires return of the bailed item. Appellants have cited two square holdings of the Missouri Supreme Court declaring that a bailment does *not* require return of the property: *State v. Edwards*, 137 S.W.2d 447, 451 (Mo. 1940) *State v. Betz*, 106 S.W. 64, 66 (Mo. 1907). Appellants have also cited numerous consignment cases demonstrating beyond dispute that return is not a requirement. Catalona Br. 32-33. And Appellants have cited one of this Court's own cases showing the same thing. Pat. Br. 44. Nevertheless, without mentioning these authorities, the University simply asserts, with no case-law support, that "[t]here was no bailment [here] since there was no expectation of return." Opp'n 16; *accord* 38.

In fact, as Appellants have shown, there was a bailment agreement here. Catalona Br. 29-33; Pat. Br. 43-46. That agreement's plain terms explain why the Patients' tissues could be consumed or transferred and why Dr. Catalona could

discard extra blood samples—because those uses were within the bailment’s “special object or purpose” *Betz*, 106 S.W. at 66.⁶

Like the district court, the University assumes that bailments can only resemble the coat-check bailment covered in law school. But as Justice Story explained, bailments are much more flexible than that; after all, they are *contracts*. *Betz*, 106 S.W. at 66. Having acted within the purpose of the bailment, the University surely may, if asked, “duly account[]” for the tissues (*Weinberg v. Wayco Petroleum Co.*, 402 S.W.2d 597, 599 (Mo. Ct. App. 1966)). And as we explained in our opening brief, there are numerous other ways that the University may account for the tissues. *Catalona Br.* 30 n.6.

Thus, rather than seeking “perpetual ownership,” the Patients merely ask that this Court require the University to live up to the basic terms of its bailment contract.

III. Appellants Are Entitled To An Injunction Prohibiting The Use, Destruction Or Transfer Of The Tissues To Any Entity Other Than A Research Institution Chosen By The Patients.

As we have shown, Appellants must prevail on the merits of this case. They are therefore entitled to reversal of the district court’s declaratory judgment. As we now show, they are also entitled to permanent injunctive relief.

⁶ The University claims that Dr. Catalona “regularly destroyed blood samples” (Opp’n 25), but fails to mention that he discarded only *duplicative* quantities (App. 1:89).

A. Because The Patients And Dr. Catalona Face A Serious Risk Of Irreparable Harm, While The University Faces No Serious Risk, The Balance Of The Equities Favors Appellants.

There can be no question that Appellants face a serious risk of irreparable injury. The district court's order places no meaningful restriction on how Washington University may use the Patients' tissues, which contain their genes. As the adjudged "true and rightful owner" of the tissues, the University can: destroy the tissues; use the tissues with or without de-identifying them; sell the tissues to another institution without telling the Patients; use the tissues in studies the patients would find objectionable; or publish research results directly identifiable to the Patients. Any of these dispositions would constitute irreparable harm for the Patients, their families, and (in some cases) generations to follow.

The University does not claim that these harms are not irreparable, but promises that they would never occur. That promise is empty for three reasons. First, the University's core inducement to the Patients was that, with a phone call, they could withdraw from research at any time and order their tissues to be destroyed. Add. 32, 36. Now that the Patients have withdrawn consent in writing, the University already has ignored their wishes and shipped their blood samples off for research. Opp'n 11. Second, if the Patients are thus injured, they will have no recourse, for the Common Rule provides no private right of action. ACS Br. 24-26. Third, the record shows that the University wishes, not merely to advance

medical science, but to profit from the patients' tissues. In view of these considerations, it is insufficient for the University merely to say "trust us." Opp'n 19-20.

Without an injunction, Dr. Catalona also will be irreparably harmed. Among the 6,000 research participants who asked to transfer their biological materials, 4,000 donated tissues. App. 1:62-63. Such tissues are taken from tumors, and thus can be obtained only once. *Id.* at 63. Yet, as the University's Head of Urology testified, these tissues are very important to the Patients' future health care. App. 2:347. If Dr. Catalona cannot perform research on these tissues, he will be hampered in providing follow-up care to patients whose tissues remain at Washington University.

Destruction or de-identification would also irreparably harm Dr. Catalona's research. Dr. Catalona performs 300 prostate cancer surgeries per year. Thus, to obtain 4,000 more tissue samples—the number now housed at Washington University—would take at least twelve years. App. 1:63. Such substantial lost opportunity constitutes irreparable harm.⁷

⁷ While the district court declared that nothing in its decision "shall be construed to prohibit [Dr. Catalona] from *seeking* access to said biological materials," Add. 30 (emphasis added), the decision does not require the University even to *keep* the tissues. And even if the University decides to keep the tissues, the University's Vice Chancellor for Research *already* has told the Head of Urology (and conceded in the hearing) that he was "stalling" approval of Dr. Catalona's research. App.

While Appellants’ hardships could be incalculable without an injunction, the University would hardly notice it. The University concedes that the number of patients seeking transfer is a “small band.” Opp’n 18. And the University’s biorepository contains more than 250,000 samples from some 35,000 research participants. App 1:66; App. 2:311-312. Approximately 6,000 patients—or 17% of the total—have declared their wish to transfer. App. 1:66. If Appellants are successful, the University will still have access to samples from 29,000 patients, or approximately 200,000 samples.

Given the direct, irreparable harm to the Patients, and that the small reduction in the University’s reserves would be quickly overcome, the balance of the hardships clearly favors the Appellants.

B. The University’s Public Interest Argument Is Belied By Its Own Record Of Transferring Tissues Without The Patients’ Consent And Seeking To Profit From Patients’ Tissues.

The public interest also favors Appellants. The University goes to great lengths to portray itself as a protector of medical research and Dr. Catalana as a hindrance to new discoveries.⁸ But the record shows that the University is

2:512-13. The record thus undermines the University’s assurances that it is prepared to grant Dr. Catalana meaningful access to the tissues.

⁸ The University contends that Dr. Catalana sent his patients and research participants flawed informed consent forms. The district court never ruled on this issue (because the University did not and could not sue Dr. Catalana under the Common Rule), so it is not properly before this Court. But in all events, the letter was valid under the Common Rule, because it did not, and was never intended to,

interested in profiting from the Patients' tissues. By ensuring that the University keeps its express commitments, an injunction would both advance prostate cancer research and preserve patient autonomy.

1. According to the University, it has not "sought to profit from or sell any tissues from the Biorepository." Opp'n 20. The facts suggest otherwise. Recently, the University's business development director wrote to a vice chancellor: "Bill Catalona wants to send nearly 2,000 documented samples to Hybertech for free. Just from a cost recovery scenario, this should be worth nearly \$100,000 to the University. . . . It is my opinion this is an unacceptable proposal." App. 2:511.

The University's profit-seeking is not new,⁹ and it is not slowing. In 2004, the University brought in more than \$8 million in licensing revenue and spun off four companies. Yet the director of the University's technology transfer office stressed that "[w]e should spin off five to six companies every year," based on the amount of research funding the university receives." Victoria Saeland, *University*

function as an informed consent form. *Compare* 46 C.F.R. § 116 (informed consent requirements apply when involving a patient in covered research). Before Dr. Catalona can undertake additional research on his patients' tissues, Northwestern University must obtain their informed consent.

⁹ In the early 1980s, the University's medical school sold a right of first refusal on all of its patents to Monsanto Corporation. Julia Liebeskind, *Risky Business: Universities & Intellectual Property*, Academe (2001) (available at: <http://www.aaup.org/publications/Academe/2001/01SO/so01lie.htm>) (published by the American Association of University Professors).

Transfers Tech Into Commercial Dollars, St. Louis Business Journal, August 25, 2005.¹⁰

Dr. Catalona, by contrast, is not patent- or profit-driven. This is shown by the business development manager's complaint that "Bill Catalona wants to send nearly 2,000 documented samples to Hybertech for free." It is even more dramatically illustrated in Dr. Catalona's decision not to patent his discovery that an established blood test could be used to predict most prostate cancers. Rebecca Skloot, *Taking the Least of You*, New York Times Magazine, Apr. 16, 2006. That choice likely cost Dr. Catalona millions of dollars. *Id.*

2. An injunction would protect the Patients from more than profiteering. It would also ensure that their express wishes are followed, which is squarely in the public interest according to *Moore*.

The University's view of its obligations here is well summed up by David Korn, senior vice president of the Association of American Medical Colleges (an *amicus* in this case): "Sure, consent feels nice. Letting people decide what's going to happen with their tissue seems like the right thing to do. But consent diminishes the value of tissue." Skloot, *Taking the Least of You*, *supra*. Because tissue is so

¹⁰ Even cancer advocacy is a profit center. Serious questions have long been raised, for example, about whether the *amicus* American Cancer Society should remain a non-profit institution. See generally Samuel Epstein, *American Cancer Society: The World's Wealthiest "Non-Profit" Institution*, 29 Int'l J. Health Serv's (1999).

valuable, Korn concludes that “people are *morally obligated* to allow their bits and pieces to be used to advance knowledge to help others.” *Id.* (emphasis added).

But consent does not just “feel[] nice,” and Patients are not the only ones with obligations. Moreover, as *amici* supporting Appellants have explained, obtaining and keeping consent is essential to convince people to part with genes showing their propensity to deadly disease: “If affirmed, the district court’s judgment will inhibit future medical research because patients will not agree to participate in studies when they learn that promises made to them in informed consent documents can be disregarded.” People’s Med. Soc. Br. 29; *accord* Us Too, Int’l Br. 4. That is why *Moore* placed such a premium on informed consent. And that is why (among many reasons) the University should be held to its promises.

As a leading researcher and prostate cancer surgeon, Dr. Catalona understands this. He stands ready to conduct cancer research on his patients’ tissues. That is what the patients here seek. By ignoring the Patients’ contractual right to withdraw consent, and threatening to transfer their tissues for unconsented use by others, it is the University that is interfering with legitimate medical research. It is time for *that* interference to stop, and for the University to honor its commitment to permit withdrawal “without penalty” and “upon request” (Add. 32, 36).

This is required by the University's own forms. As *Moore* teaches, it is also required by sound public policy. And, as we have shown, it is required by Missouri law. Given the University's disregard for the Patients' wishes, and its track record of profit-seeking, an injunction is needed to ensure the University finally keeps its promises.

CONCLUSION

For the foregoing reasons, Appellants are entitled to the relief requested in their opening briefs.

Respectfully submitted,

GENE C. SCHAERR

ANDREW C. NICHOLS

Winston & Strawn LLP

1700 K Street, N.W.

Washington, D.C. 20006

(202) 282-5000

Counsel for Defendant-Appellant

William J. Catalona

**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 a reply brief produced with proportionally spaced font. Created in Microsoft Word 2000, the length of this brief is 6,952 words.

Dated: September 21, 2006

GENE C. SCHAERR
Winston & Strawn LLP
1700 K Street, N.W.
Washington, D.C. 20006
(202) 282-5000

Counsel for Defendant-Appellant
William J. Catalona

CERTIFICATE OF SERVICE

Counsel for Defendant-Appellant hereby certifies that on September 21, 2006, two copies of Defendant-Appellant William J. Catalona's Reply Brief, as well as a digital version of the brief, were delivered by U.S. Mail to:

Thomas E. Wack
BRYAN CAVE LLP
211 N. Broadway, Ste. 3600
St. Louis, MO 63102-2750
(314) 259-2000

GENE C. SCHAERR
Winston & Strawn LLP
1700 K Street, N.W.
Washington, D.C. 20006
(202) 282-5000

Counsel for Defendant-Appellant
William J. Catalona