

FILED

AUG - 4 2003

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

U. S. DISTRICT COURT
EASTERN DISTRICT OF MO

THE WASHINGTON UNIVERSITY

Plaintiff,

-against-

WILLIAM J. CATALONA, M.D.

Defendant.

Case No. _____
4 : 03 CV 01065 SNL

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff, The Washington University (the "University"), for its causes of action against Defendant, William J. Catalona, M.D. ("Catalona"), avers as follows:

NATURE OF ACTION

1. This is an action for Declaratory Judgment and other relief to establish that the University is the owner of the "GU Biorepository." The GU Biorepository is a collection of specimens of prostate tissue and other materials, including serum and genetic material (collectively, the "Biological Material"), that was removed during surgery or otherwise collected from tens of thousands of patients and/or research participants at the Washington University School of Medicine. The collection of specimens began in or about 1989, continuing to the present, and has grown over many years to become one of the primary collections of tissue available for research into the treatment and prevention of prostate cancer and other urological disorders.

2. Upon removal or extraction, ownership of The Biological Material vests in the University, which is then responsible for the proper handling of the Biological Material, and for their

disposal or storage as necessary. For this and other reasons, the University is the sole owner of the GU Biorepository and the Biological Material it contains.

3. Declaratory relief is necessary because, since 2001, by and through a series of telephone calls, e-mails, and letters, Defendant William J. Catalona, M.D. ("Catalona") has threatened the University with legal action to assert a purported claim of personal ownership over the GU Biorepository.

4. Declaratory relief is further necessary because, among other reasons, by asserting his claim of ownership Catalona has unlawfully interfered with the University's relationship with its research collaborators by causing them to desist from legitimate and valuable medical research projects involving the GU Biorepository.

5. On information and belief, unless the declarations sought herein issue, or other equivalent injunctive relief is granted, Catalona will continue to engage in efforts to thwart the University's use of the GU Biorepository and its administration of that resource in response to medical research requests from others. The University will be irreparably harmed by such interference, for which there is no adequate remedy at law.

PARTIES

6. Plaintiff The Washington University is a Missouri corporation established by special act of the Missouri General Assembly approved on February 22, 1853, and acts amendatory thereto, with its principal place of business at One Brookings Drive, St. Louis, MO 63130. The University is home to the Washington University School of Medicine, one of the nation's foremost medical colleges and institutions for biomedical research.

7. Defendant William J. Catalona, M.D., is an individual who, on information and belief, is a citizen of the State of Illinois. At all times relevant to this action, until February 23, 2003, Catalona was an employee of the University.

JURISDICTION AND VENUE

8. Jurisdiction for this action is based on 28 U.S.C. §1331 as it involves a question of law arising under the Health Insurance Portability and Accountability Act, P.L. 104-191 ("HIPAA"), and its implementing regulations, 45 C.F.R. Part 160, et seq. Pursuant to §1367, all other claims are so related to claims in the action having jurisdiction under §1331 that they form part of the same case or controversy.

9. Jurisdiction for this action is also based on 28 U.S.C. §1332 as the amount in controversy is in excess of \$75,000 exclusive of interest and costs and this controversy is between citizens of different states.

10. Venue is proper in this district pursuant to 28 U.S.C. § 1391(a)(2), because the claims asserted in this complaint are based on events occurring in this district and the property at issue in this action is located in this district.

11. This is a proceeding for a declaratory judgment and further relief under 28 U.S.C. §§ 2201, 2202. This action presents an actual controversy within the Court's jurisdiction.

THE IMPORTANCE AND VALUE OF THE GU BIOREPOSITORY

12. The GU Biorepository was established in or about 1989. Over the life of the Biorepository, surgeons and staff in the Division of Urologic Surgery at the University's School of Medicine were expected as part of their duties at the University to cooperate in the preservation of extracted Biological Materials through the depositing of such material in the Biorepository. Most of the patients and research participants from whom such material was collected were under the care of University physicians other than Catalona.

13. The GU Biorepository is nationally and internationally known for its value to urological research. The University has invested hundreds of thousands of dollars to establish and maintain the GU Biorepository over the past 14 years. On information and belief, were the

University to surrender the GU Biorepository that is the subject of this Action to Catalonia, it would cost millions of dollars to replace, and it would take many years to do so.

14. The divestiture of the University's ownership interest in the GU Biorepository would injure the University's existing research involving the GU Biorepository, restrict its ability to initiate new health care research projects involving such important fields as prostate cancer, hinder its ability to secure research grants and other external support for such research, impair its ability to recruit and retain leaders in the field of urological research and care, and would injure its reputation in such field. Moreover, replacement of the GU Biorepository would require not only financial outlays well in excess of \$1 million, but also many years of work to build up an equivalent inventory of Biological Materials. For these reasons, the injury that the University would suffer would be immediate, irreparable, and not adequately compensable in money damages.

15. The creation and maintenance of the GU Biorepository was and continues to be funded by the University. Similarly, the University has funded much of the medical research involving the GU Biorepository.

16. The GU Biorepository is a valuable asset, belonging to the University, which it considers vital to its continued medical research and education activities. However, the University, like many such institutions maintaining tissue banks, allows other researchers and institutions to have access to the GU Biorepository to pursue promising medical research projects either in collaboration with the University or independently. In 2001, the University established a peer review panel (the "Peer Review Panel") to field requests for access to specimens from the GU Biorepository. The University established the panel in order to allocate the valuable resources of the GU Biorepository so as to maximize its value to scientific research.

**THE COLLECTION OF BIOLOGICAL MATERIALS
FOR THE GU BIOREPOSITORY**

17. Biological Materials for the GU Biorepository were and are collected incident to surgery, approved research protocols, or in the course of patient treatment.

18. All Biological Materials collected and made a part of the GU Biorepository were and are the property of the University, which became responsible for their disposal and/or storage upon collection. The University is subject to federal and state laws and regulations governing the disposal and storage of human biological material, and is responsible for compliance with such laws and regulations. *See, e.g.*, 29 C.F.R.1910.1030 (“Bloodborne Pathogens”); 10 C.S.R. 80-7.010 (“Infectious Waste Management”). The University further bears responsibility for any liability for the mishandling of such material.

19. Furthermore, Biological Materials for the GU Biorepository were collected from the University’s patients and research participants with their informed consent.

20. It is the University’s practice to obtain from patients undergoing surgery or otherwise receiving treatment a consent form stating that the patient “consent[s] to the disposal, use or examination of any bones, organs, tissues, fluids or parts which it may be necessary to remove,” or words to that effect.

21. Where the patient was a participant in a research study, the University obtained a separate informed consent. The forms for such research consents varied over the years, but frequently contained the following language: “By agreeing to participate in this study, you agree to waive any claim you might have to the body tissues that you donate. Participation in this research means you waive the right to any new material or process developed through research involving your tissues.”

CATALONA’S RELATIONSHIP WITH THE UNIVERSITY

22. Catalona’s attempt to claim ownership of the GU Biorepository violates the covenants and contractual relationship existing between the University and Catalona.

23. Throughout the time of Catalona’s employment and continuing through to the present, the University has maintained a staff of clinical physicians who are all faculty members.

These specialist physicians engage in research while also serving the community through substantial clinical work with patients. All of this work is performed in their capacity as faculty at the University. Faculty at the University's School of Medicine are not permitted to engage in the private practice of medicine. All patients who see doctors at the School of Medicine are patients of the School of Medicine and thus of the University.

24. Catalona is a urological surgeon and was employed full time at the School of Medicine from 1976 until February 23, 2003. Catalona was employed first as an Associate Professor of Surgery (Urologic Surgery) from July 1, 1976 through June 30, 1982. Dr. Catalona was awarded tenure on July 1, 1978 and was promoted to Professor of Surgery (Urologic Surgery) on July 1, 1982 and retained that title and position until his retirement from the University on February 23, 2003. From 1984 to 1998, Catalona was Chief of Urologic Surgery at the School of Medicine.

25. During the time Catalona was a professor at the School of Medicine, Catalona practiced medicine as a Washington University Physician and also engaged in research, specializing in prostate surgery and diseases of the prostate. Catalona received a regular salary from the University. Catalona also received supplemental and bonus income as a part of his salary package. The University also provided Catalona with malpractice insurance, office and laboratory facilities as well as clinical and research assistance and secretarial services.

26. Catalona received substantial funding directly from the University for research in his capacity as a University faculty member. University funds supported research studies that resulted in the collection of Biological Material for the GU Biorepository as well as studies that involved the use of Biological Material in the GU Biorepository.

27. Catalona's relationship with the University was governed by a set of policies, practices, procedures, and regulations that together constituted an express or implied contract with the University, supported by substantial consideration including Catalona's salary, bonuses, the provision of facilities and the support of Catalona's research activities by the University.

28. In particular, Catalona was subject to the University's Intellectual Property Policy, which provides in part:

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

29. In or around January 2001, the University discovered that Catalona was planning to resign from his position at the University. Catalona was negotiating to relocate to the University of Virginia, and take the GU Biorepository with him. At that time, the Chairman of the Department of Surgery informed him that the equipment being used by Catalona, his study data and the GU Biorepository were all property of the University and not to be removed in the event that Catalona left the University.

30. Catalona was, however, permitted to have continued access to the GU Biorepository by applying to the Peer Review Panel, on the same basis as other researchers at the University and other institutions. Since the creation of the Peer Review Panel, Catalona has utilized this process to access the GU Biorepository on multiple occasions.

31. Catalona subsequently left the University in February 2003, and joined Northwestern University. Since prior to his departure, and continuing to the present, Catalona has claimed personal ownership of the GU Biorepository that is inconsistent with the University's ownership, and has threatened the University with legal action for use of the GU Biorepository without his permission, and has committed other tortious and wrongful acts as set forth herein.

CATALONA'S ACTIONS WITH RESPECT TO THE GU BIOREPOSITORY

32. As set forth above, the GU Biorepository was created and maintained with University funds, was involved in multiple research projects directly funded by the University, was maintained at University facilities, and comprises Biological Materials collected from patients and

research participants of the University and its School of Medicine (from surgeries or other procedures performed at and using University facilities), most of whom were under the care of University physicians other than Catalona.

33. Notwithstanding these facts, from at least 2001 to the present Catalona has, among other actions, (a) asserted and published an unsupported claim of personal ownership and/or control over the GU Biorepository, (b) interfered with the use of the GU Biorepository by University researchers, (c) threatened the University with legal action if it refuses to cede possession and control of the Biorepository to Catalona, (d) interfered with the use of Biological Materials from the GU Biorepository by researchers given such material by the University, and (e) for a purpose unrelated to their clinical care or participation in any particular research study, improperly accessed the University's patient lists to contact patients or research participants from whom Biological Material had previously been collected for the GU Biorepository.

34. Catalona began final preparations to leave the University on or around February 2003. Catalona engaged in these preparations without providing notice to the relevant Department and Division at the University. Catalona departed the University to take a position at Northwestern University in Chicago on February 23, 2003.

35. On February 18, 2003, a few days before Catalona's departure from the University, Catalona sent a letter announcing his departure to an unknown number of University patients (including patients of other University faculty or physicians) and research participants who had been involved in research, undergone prostate surgery, and/or had been diagnosed or treated at the University. A copy of this letter is attached hereto as Exhibit A. In the letter, Catalona requests that the patients submit revised consent forms (the "New Consents") with respect to the Biological Materials deposited in the GU Biorepository. The New Consents state in relevant part:

"I have donated a tissue and / or blood sample for Dr. William J. Catalona's Research studies. Please release all of my samples to Dr. Catalona at Northwestern University upon his request. I have

entrusted these samples to be used only at his direction and with his express consent for research projects.”

36. The correspondence to the patients contained several misstatements and/or omissions of fact. For example, it failed to disclose, among other things, that the University repeatedly and consistently asserted ownership over the Biological Materials, that Catalonia would continue to be eligible for access to the GU Biorepository under established University procedures, that the recipients of the letter had signed pre-existing consents that were inconsistent with the New Consents, and that such recipients had no continuing right to the Biological Materials upon removal. Furthermore, the letter misleadingly conveyed to the patients that the Biological Materials were necessary for use in their personal medical care.

37. Catalonia knew of the patients' prior consents to surgery, research, or treatment, knowingly failed to mention such consents in his correspondence, and without justification intended to interfere with such consents and with the patients' relationship with the University.

38. Furthermore, in transmitting his letter and the enclosed consent form, Catalonia violated Federal Law and University procedures relating to privacy and informed consent. The University maintains policies and procedures designed to ensure its compliance with federal rules respecting the proper conduct of research involving human subjects, promulgated by the Office of Human Research Protection (“OHRP”) of the U.S. Department of Health and Human Services (“DHHS”). *See, e.g.*, 45 C.F.R. Part 46 (“Protection of Human Subjects”). The University's policies are also designed to comply with HIPAA, the federal law regarding the assurance of privacy for patient-identifiable information.

39. Under the University's procedures, Catalonia was required to submit his correspondence and his New Consent form to the University's Institutional Review Board (“IRB”), which was established and governed by DHHS regulations. On information and belief, Catalonia

knowingly disregarded his obligation to submit his correspondence and his New Consent to the University IRB.

40. After his departure, Catalona would not have had lawful access to the lists of addresses of the University's patients used to send these letters. On information and belief, Catalona further knew or had reason to know that his use of such data was in contravention of the University's procedures and relevant federal rules, and in violation of Catalona's duties to the University.

41. Catalona misused University proprietary information and private patient-identifiable information to prepare and send his letter and the enclosed New Consent forms. Catalona's misuse is ongoing, as he has continued to use patient identifying information for purposes other than research or treatment; that is, to advance his claim of ownership to the GU Biorepository.

42. Catalona's New Consents are invalid, because, among other reasons, they constitute an intentional interference with the University's pre-existing consents and waivers, they were sent in violation of federally mandated procedures, they misused the University's proprietary information, and they were legally ineffective to alter the pre-existing consents or other disclaimers of rights to the Biological Materials.

43. Catalona knowingly induced the patients to attempt to change or revoke their existing consents to the University's use of the Biological Material in the GU Biorepository with the intention to benefit Catalona and to harm the University beginning at a time when Catalona was still employed by the University. Furthermore, Catalona's interference was a breach of Catalona's employment contract with the University and a breach of his confidential relationship and/or fiduciary duty to the University.

44. On April 8, 2003, the University received a letter from attorneys representing Catalona demanding that the University transfer the GU Biorepository to Catalona. A copy of the

letter is attached hereto as Exhibit B. In the letter, Catalona's counsel states that the University's possession of the Biological Materials in the GU Biorepository was "in derogation of Dr. Catalona's rights, interests and responsibilities regarding the samples." In the letter, Catalona's counsel states that Catalona has received approximately 3,200 consent forms (which forms had been drafted by Catalona and sent to the recipients without the required IRB review) that allegedly consented "to his control over the samples and the removal of the samples to Northwestern University's Medical School, where he is now on the faculty." The letter further accuses the University of conversion as well as violation of HIPAA and demands that the University not make use of the Biological Material in such samples.

45. On or about June 5-6, 2003, Catalona contacted the National Cancer Institute of the National Institutes of Health ("NCI") regarding "approximately 400 serum samples Washington University recently shipped" to NCI for research purposes. Such materials had previously been provided to NCI by the University in accordance with a request approved by the University's Peer Review Panel. Catalona informed NCI "that the right to possession and use of these samples is being contested and that the university may be proceeding in contravention of the express wishes of some or all of the donors." On information and belief, Catalona further suggested to an NCI researcher that the publication of scholarly articles involving the use of such materials would constitute professional misconduct.

46. Thereafter, on June 22, 2003, counsel for Catalona again wrote NCI regarding the Biological Material. This letter stated that "[t]he recently implemented regulations of the Healthcare Insurance Portability and Accountability Act of 1986 [sic] underscore the ongoing viability of these patient's interest and ability to direct and control the use of their body tissue and serum" and that "given the fiduciary relationship between Dr. Catalona and these patients and the clear direction of the informed consents that Dr. Catalona direct and control the use of these samples the claim of the University to 'ownership' of the samples is apocryphal."

47. Both the June 6 and June 22 letters requested that the NCI refrain from the use of the Biological Materials and return them to the University, despite the fact that they had been provided to the NCI by the University according to its properly adopted procedures. On information and belief, Catalona knew that the University's transmission of Biological Material to the GU Biorepository was proper and consistent with the University's and its Peer Review Panel's procedures.

48. As a result of Catalona's interference NCI has suspended its use of GU Biorepository Biological Material in its research.

49. On July 8, Catalona's counsel wrote the University to provide a list of those patients from whom Catalona has received his New Consents. Catalona's counsel demanded "that no further wasting, use or assignment of these Samples be made by [the University] and that these Samples and all future Samples provided by these donors be immediately returned to the possession of Dr. Catalona at Northwestern University."

50. Counsel further "advised that any additional use or transfer of the Samples identified above shall be considered to be a conversion, and Dr. Catalona and a number of his patients are prepared to take whatever forthwith action is necessary to preserve the Samples."

FIRST CAUSE OF ACTION
FOR DECLARATORY JUDGMENT OF OWNERSHIP OF THE BIOREPOSITORY

51. The averments of paragraphs 1 through 50 of this Complaint are hereby incorporated by reference herein.

52. An actual case and controversy exists between the University and Catalona with respect to the ownership of the GU Biorepository.

53. The University is entitled to a declaratory judgment that:

- a. It is the true and legal owner of the GU Biorepository, including all Biological Material contained therein, that it is not liable for conversion of said Biorepository, and that Catalonia has no ownership or other rights therein;
- b. The University is entitled to use, consume and/or transfer Biological Material from the GU Biorepository in its sole discretion; and
- c. Catalonia's efforts to frustrate the University's and/or others' use of the Biological Materials in the GU Biorepository constitute an unlawful interference with the University's contractual relations, business relations, and prospective economic advantage.

54. Absent the declarations recited herein, which are alleged to be true, the University and its research collaborators will face the continuing threat of legal action from Catalonia, continued interference with their business relations, and irreparable harm to their research interests.

**SECOND CAUSE OF ACTION
FOR DECLARATORY JUDGMENT THAT NEW CONSENTS
CONFER NO RIGHTS IN THE GU BIOREPOSITORY ON CATALONA**

55. The averments of paragraphs 1 through 50 of this Complaint are hereby incorporated by reference herein.

56. An actual case and controversy exists between the University and Catalonia with respect to whether the New Consents confer any rights in the GU Biorepository on Catalonia.

57. The University is entitled to a declaratory judgment that:

- a. The New Consents confer no rights on Catalonia because they were not properly issued upon review by the University's IRB;

- b. The New Consents confer no rights on Catalonia because they were procured through the use of fraudulent or misleading statements or omissions;
- c. The New Consents confer no rights on Catalonia because they were procured through Catalonia's breach of his employment contract with the University.
- d. The New Consents confer no rights on Catalonia because they were procured in violation of the confidential relationship and/or fiduciary duty owed by Catalonia to the University;
- e. The New Consents confer no rights on Catalonia because they were obtained through the misuse of proprietary information belonging to the University;
- f. The New Consents confer no rights on Catalonia because they were obtained through the use of patient medical information in violation of the University's IRB procedures, HIPAA and its implementing regulations, and/or OHRP regulations;
- g. The New Consents confer no rights on Catalonia because they are an ineffective attempt to rewrite or reconstrue the patients' and research participants' pre-existing consents; and
- h. The New Consents confer no rights on Catalonia because they were obtained through Catalonia's interference with the University's preexisting contractual and/or business relationship with the patients providing such consents.

58. Absent the declarations recited herein, which are alleged to be true, the University and its research collaborators will face the continuing threat of legal action from Catalonia, continued interference with their business relations, and irreparable harm to their research interests.

THIRD CAUSE OF ACTION
FOR DECLARATORY JUDGMENT OF NO LIABILITY UNDER HIPAA

59. The averments of paragraphs 1 through 50 of this Complaint are hereby incorporated by reference herein.

60. An actual case and controversy exists between the University and Catalona with respect to Catalona's assertion that the University has violated HIPAA.

61. The University is entitled to a declaratory judgment that:

- a. The Biological Materials are not "identifiable health information" within the meaning of HIPAA;
- b. With respect to the GU Biorepository and any "identifiable health information" associated therewith, the University has acted in accordance with all applicable regulations and procedures and has fully complied with all requirements of HIPAA; and
- c. In the alternative and hypothetically, if a violation of HIPAA had occurred, Catalona would not have standing to seek redress for such violation, or would otherwise be unable to assert a private right of action.

62. Absent the declarations recited herein, which are alleged to be true, the University and its research collaborators will face the continuing threat of legal action from Catalona, continued interference with their business relations, and irreparable harm to their research interests.

FOURTH CAUSE OF ACTION
MISUSE OF PROPRIETARY INFORMATION

63. The averments of paragraphs 1 through 50 of this Complaint are hereby incorporated by reference herein.

64. The identities of some or all of the individuals from whom Biological Material for the GU Biorepository had been collected was confidential and proprietary information belonging to the University. Catalonia's access to such information was permitted only in his capacity as an employee of the University. Catalonia knew, or had reason to know, that use of such confidential and proprietary information was permitted only in the context of authorized medical research activities.

65. Catalonia's use of the confidential and proprietary information to solicit the New Consents was for the purpose of advancing his claim of ownership to the GU Biorepository. This use was without the express or implied consent of the University. Such use was improper, and Catalonia knew or should have known that such use was improper.

66. Catalonia's use of the confidential and proprietary information constitutes a misappropriation of a trade secret by and through the improper use of information acquired under circumstances giving rise to a duty to limit its use, and is in violation of Missouri common law and the Missouri Uniform Trade Secrets Act.

PRAYER FOR RELIEF

WHEREFORE, the University prays that the Court:

- A. Declare that the University has all ownership rights over the GU Biorepository;
- B. Declare that the New Consents do not create any ownership or other rights to the GU Biorepository in Catalonia.
- C. Declare that the University has not acted in violation of any standards set forth by HIPAA;
- D. Enjoin Catalonia from further interference with the use of the GU Biorepository;
- E. Enjoin Catalonia from further interference with the relationships between the University and its patients, research participants, and research collaborators;

- F. Enjoin Catalona from further misuse of proprietary information he received while employed by the University;
- G. Order Catalona to pay attorneys fees, costs and expenses incurred by the University in connection with this action; and
- H. Award the University such other and further relief as the Court deems just and proper, or which is otherwise available at law, equity or under any applicable rule or regulation.

Dated: August 4, 2003

By:



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**UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF MISSOURI
CIVIL TRACK INFORMATION STATEMENT (TIS)**

The Civil Track Information Statement is for internal management purposes only. This form is not required for Prisoner cases (see reverse). Plaintiff(s) shall file and serve a TIS with the complaint or within 10 days of a notice of removal. Defendant(s) shall file and serve a TIS with the removal petition, first responsive pleading or motion. Track assignment will be based upon information contained in the case file together with information provided below. The information below shall not be binding upon the party and shall not be admissible into evidence.

PLEASE PRINT AND ANSWER ALL ITEMS

AUG - 4 2003

CAPTION The Washington University v. William J. Catalona, M.D.	4109CV00103 NL U.S. DISTRICT COURT Case No. _____ including judge _____ in the EASTERN DISTRICT OF MO
	Identification of Party(ies) Submitting this Form <input checked="" type="checkbox"/> Plaintiff <input type="checkbox"/> Defendant <input type="checkbox"/> Other Name <u>The Washington University</u>
Name of Primary Attorney Representing Party(ies) submitting this form <u>Thomas A. Schweich</u> Name of Secondary Attorney (if any) _____	

Track Assignment preferred: (SEE REVERSE SIDE OF FORM FOR TRACK DESCRIPTIONS)

Track 1 (Expedited) <input type="checkbox"/>	Track 2 (Standard) <input checked="" type="checkbox"/>	Track 3 (Complex) <input type="checkbox"/>	Track 4 (Administrative) <input type="checkbox"/>
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Please answer the following:

- Estimated time needed for discovery One Year
- Estimated number of days needed for trial Seven Days
- Does this case require accelerated disposition (TRO, Injunctive Relief)? _____
- Other factors or circumstances considered relevant to track assignment This is a request for declaratory judgment

ALTERNATIVE DISPUTE RESOLUTION (ADR):

The Court currently offers two alternative dispute resolution processes:

- **MEDIATION** - a process in which an impartial neutral (mediator) facilitates negotiations among the parties in litigation to help them reach a settlement.
- **EARLY NEUTRAL EVALUATION (ENE)** - a process in which an experienced neutral evaluator offers pre-trial planning assistance to parties together with a reasoned, non-binding assessment of their case at an early stage of the litigation process.

Please answer the following:

Is this case suitable for ADR? Yes No

If no, why not? _____

If yes, indicate the type of ADR preferred - Mediation Early Neutral Evaluation

Signature of Litigant/Attorney of Record: Thomas A. Schweich

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI

**NOTICE TO FILE
TRACK INFORMATION STATEMENT**

RE:

4:03CV01065SNL

Pursuant to the Administrative Order dated December 20, 1994 adopting the Differentiated Case Management System (see General Order Pertaining to Differentiated Case Management in Civil Actions, Sec. III listed below),

*You are hereby notified that all civil cases filed on or after January 1, 1995 shall be accompanied by a completed track information statement from all parties. **FAILURE TO FILE A TRACK INFORMATION STATEMENT MAY WAIVE A PARTY'S RIGHT TO STATE A TRACK PREFERENCE TO THE COURT.***

General Order Pertaining To Differentiated Case Management (Sec. III):

III. Track Information Statement.

- A. Filing Requirement. Every plaintiff's complaint or other document initiating a civil action, and every removal petition, first responsive pleading or motion filed by each defendant shall be accompanied by a completed track information statement, on a form provided by the Clerk of the Court. Leave of court shall be required for a later filing. The track information statement shall not be required in cases assigned to Track 5.
- B. Failure to File. If any document described in paragraph III(A) is filed without a completed track information statement, the Clerk shall mark the document with the date filed and promptly give notice of the omission to the party filing the document. Failure to file a track information statement may waive a party's right to state a track preference to the court.
- C. Use of Information. The track information statement shall be used for internal management purposes, and for making an appropriate assignment to a case processing track. Matters appearing on the track information statement shall not be binding on the party. The form shall contain general descriptions of track characteristics to assist parties in selecting a track preference.

**UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF MISSOURI
CIVIL TRACK INFORMATION STATEMENT (TIS)**

The Civil Track Information Statement is for internal management purposes only. This form is not required for prisoner cases (see reverse). Plaintiff(s) shall file and serve a TIS with the complaint or within 10 days of a notice of removal. Defendant(s) shall file and serve a TIS with the removal petition, first responsive pleading or motion. Track assignment will be based upon information contained in the case file together with information provided below. The information below shall not be binding upon the party and shall not be admissible into evidence.

PLEASE PRINT AND ANSWER ALL ITEMS

CAPTION	4-03 CV 01065 SNL <small>Case (include judge's initials)</small>
	Identification of Party(ies) Submitting this Form <input type="checkbox"/> Plaintiff <input type="checkbox"/> Defendant <input type="checkbox"/> Other Name _____

Name of Primary Attorney Representing Party(ies) submitting this form _____
Name of Secondary Attorney (if any) _____

Track Assignment preferred: (SEE REVERSE SIDE OF FORM FOR TRACK DESCRIPTIONS)

Track 1 (Expedited) Track 2 (Standard) Track 3 (Complex) Track 4 (Administrative)

Please answer the following:

- Estimated time needed for discovery _____
- Estimated number of days needed for trial _____
- Does this case require accelerated disposition (TRO, Injunctive Relief)? _____
- Other factors or circumstances considered relevant to track assignment _____

ALTERNATIVE DISPUTE RESOLUTION (ADR):

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- **EARLY NEUTRAL EVALUATION (ENE)** - a process in which an experienced neutral evaluator offers pre-trial planning assistance to parties together with a reasoned, non-binding assessment of their case at an early stage of the litigation process.

Please answer the following:

Is this case suitable for ADR? Yes No

If no, why not? _____

If yes, indicate the type of ADR preferred - Mediation Early Neutral Evaluation

Signature of Litigant/Attorney of Record: _____



United States District Court
EASTERN DISTRICT OF MISSOURI
NOTICE OF LAWSUIT AND
REQUEST FOR WAIVER OF SERVICE OF SUMMONS

** Plaintiff to Complete Gray Area **

TO: William J. Catalano, M.D.

(Name of defendant)

(as

of

(Title)

(Name of business)

A lawsuit has been commenced against you (or the entity on whose behalf you are addressed). A copy of the complaint is attached to this notice. It has been filed in the United States District Court for the Eastern District

of Missouri and has been assigned docket number

4:03CV01045-CM

This is not a formal summons or notification from the court but rather my request that you sign and return the enclosed waiver of service in order to save the cost of serving you with a judicial summons and an additional copy of the complaint. The cost of service will be avoided if I receive a signed copy of the waiver within 30 days after the date designated below as the date on which this Notice and Request is sent. I enclose a stamped and addressed envelope (or other means of cost-free return) for your use. An extra copy of the waiver is also attached for your records.

If you comply with this request and return the signed waiver to the undersigned, it will be filed with the court and no summons will be served on you. The action will then proceed as if you had been served on the date the waiver is filed, except you will not be obligated to answer the complaint before 60 days from the date designated below as the date on which this notice is sent (or before 90 days from that date if your address is not in any judicial district of the United States).

If you do not return the signed waiver within the time indicated, I will take appropriate steps to effect formal service in a manner authorized by the Federal Rules of Civil Procedure and will then, to the extent authorized by those Rules, ask the court to require you (or the party on whose behalf you are addressed) to pay the full costs of such service. In that connection, please read the statement concerning the duty of parties to waive the service of the summons, which is set forth on the foot of the waiver form.

I affirm that this request is being sent to you on behalf of the plaintiff this 11th day of August, 2002.

Signature of Plaintiff's Attorney or Unrepresented Plaintiff

DUTY TO AVOID UNNECESSARY COSTS OF SERVICE OF SUMMONS

Rule 4 of the Federal Rules of Civil Procedure requires certain parties to cooperate in saving unnecessary costs of service of the summons and complaint. A defendant located in the United States who, after being notified of an action and asked by a plaintiff located in the United States to waive service of summons, fails to do so will be required to bear the cost of such service unless good cause be shown for its failure to sign and return the waiver.

It is not good cause for a failure to waive service that a party believes that the complaint is unfounded, or that the action has been brought in an improper place or in a court that lacks jurisdiction over the subject matter of the action or over its person or property. A party who waives service of the summons retains all defenses and objections (except any relating to the summons or to the service of summons), and may later object to the jurisdiction of the court or to the place where the action has been brought.

A defendant who waives service must within the time specified on the waiver form serve on the plaintiff's attorney (or unrepresented plaintiff) a response to the complaint and must also file a signed copy of the response with the court. If the answer or motion is not served within this time, a default judgment may be taken against that defendant. By waiving service, a defendant is allowed more time to answer, than if the summons had actually served, when the request for waiver of service was received.



United States District Court

EASTERN DISTRICT OF MISSOURI

WAIVER OF SERVICE OF SUMMONS

NOTICE TO DEFENDANT(S)

** Plaintiff To Complete Gray Area **

To Thomas A. Schweich, BRYAN CAVE LLP, 211 N. Broadway, Suite 3600, St. Louis, MO 63102
(Name of plaintiff's attorney or unrepresented plaintiff)

I acknowledge receipt of your request that I waive service of a summons in the action of

Case Caption: The Washington University v. Catalena

Case Number: 4:03cv01065-SW

in the United States District Court for the Eastern District of Missouri. I have also received a copy of the complaint in this action, two copies of this instrument, and a means by which I can return the signed waiver to you without cost to me.

I agree to save the cost of service of a summons and an additional copy of the complaint in this lawsuit by not requiring that I (or the entity on whose behalf I am acting) be served with judicial process in the manner provided by Rule 4.

I (or the entity on whose behalf I am acting) will retain all defenses or objections to the lawsuit or to the jurisdiction or venue of the court except for objections based on a defect in the summons or in the service of the summons.

I understand that a judgment may be entered against me (or the party on whose behalf I am acting) if an answer or motion under Rule 12 is not served upon you within 60 days after 8/10/03

(Date Waiver sent) 8-4-03

or within 90 days after date if the request was sent outside the United States.

DEFENDANT'S ACKNOWLEDGMENT OF WAIVER OF SERVICE

Date _____

Print name _____

Signature _____

as _____
(Officer or Agent)

of _____
(Corporation or Association)

Address _____

City, State, Zip Code _____