H. R. 209

One Hundred Sixth Congress of the United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Monday, the twenty-fourth day of January, two thousand

An Act

To improve the ability of Federal agencies to license federally owned inventions.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Technology Transfer Commercialization Act of 2000".

SEC. 2. FINDINGS.

The Congress finds that—

(1) the importance of linking our unparalleled network of over 700 Federal laboratories and our Nation's universities with United States industry continues to hold great promise for our future economic prosperity;

(2) the enactment of the Bayh-Dole Act in 1980 was a landmark change in United States technology policy, and its success provides a framework for removing bureaucratic barriers and for simplifying the granting of licenses for inventions that are now in the Federal Government's patent portfolio;

(3) Congress has demonstrated a commitment over the past 2 decades to fostering technology transfer from our Federal laboratories and to promoting public/private sector partnerships to enhance our international competitiveness;

(4) Federal technology transfer activities have strengthened the ability of United States industry to compete in the global marketplace; developed a new paradigm for greater collaboration among the scientific enterprises that conduct our Nation's research and development—government, industry, and universities; and improved the quality of life for the American people, from medicine to materials;

(5) the technology transfer process must be made "industry friendly" for companies to be willing to invest the significant time and resources needed to develop new products, processes, and jobs using federally funded inventions; and

(6) Federal technology licensing procedures should balance the public policy needs of adequately protecting the rights of the public, encouraging companies to develop existing government inventions, and making the entire system of licensing government technologies more consistent and simple.

SEC. 3. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.

Section 12(b)(1) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(b)(1)) is amended by inserting "or, subject to section 209 of title 35, United States Code, may grant

a license to an invention which is federally owned, for which a patent application was filed before the signing of the agreement, and directly within the scope of the work under the agreement," after "under the agreement,".

SEC. 4. LICENSING FEDERALLY OWNED INVENTIONS.

(a) AMENDMENT.—Section 209 of title 35, United States Code, is amended to read as follows:

"§ 209. Licensing federally owned inventions

"(a) AUTHORITY.—A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under section 207(a)(2) only if—

"(1) granting the license is a reasonable and necessary incentive to—

"(A) call forth the investment capital and expenditures needed to bring the invention to practical application; or

"(B) otherwise promote the invention's utilization by the public;

"(2) the Federal agency finds that the public will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;

"(3) the applicant makes a commitment to achieve practical application of the invention within a reasonable time, which time may be extended by the agency upon the applicant's request and the applicant's demonstration that the refusal of such extension would be unreasonable;

"(4) granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws; and

"(5) in the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.

"(b) MANUFACTURE IN UNITED STATES.—A Federal agency shall normally grant a license under section 207(a)(2) to use or sell any federally owned invention in the United States only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

"(c) SMALL BUSINESS.—First preference for the granting of any exclusive or partially exclusive licenses under section 207(a)(2) shall be given to small business firms having equal or greater likelihood as other applicants to bring the invention to practical application within a reasonable time.

"(d) TERMS AND CONDITIONS.—Any licenses granted under section 207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions—

"(1) retaining a nontransferrable, irrevocable, paid-up license for any Federal agency to practice the invention or

have the invention practiced throughout the world by or on behalf of the Government of the United States;

"(2) requiring periodic reporting on utilization of the invention, and utilization efforts, by the licensee, but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with, except that any such report shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code; and

"(3) empowering the Federal agency to terminate the license in whole or in part if the agency determines that—

"(A) the licensee is not executing its commitment to achieve practical application of the invention, including commitments contained in any plan submitted in support of its request for a license, and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken, or can be expected to take within a reasonable time, effective steps to achieve practical application of the invention;

"(B) the licensee is in breach of an agreement described in subsection (b);

"(C) termination is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license, and such requirements are not reasonably satisfied by the licensee; or

"(D) the licensee has been found by a court of competent jurisdiction to have violated the Federal antitrust laws in connection with its performance under the license agreement.

"(e) PUBLIC NOTICE.—No exclusive or partially exclusive license may be granted under section 207(a)(2) unless public notice of the intention to grant an exclusive or partially exclusive license on a federally owned invention has been provided in an appropriate manner at least 15 days before the license is granted, and the Federal agency has considered all comments received before the end of the comment period in response to that public notice. This subsection shall not apply to the licensing of inventions made under a cooperative research and development agreement entered into under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a).

"(f) PLAN.—No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development or marketing of the invention, except that any such plan shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.".

(b) CONFORMING AMENDMENT.—The item relating to section 209 in the table of sections for chapter 18 of title 35, United States Code, is amended to read as follows:

"209. Licensing federally owned inventions.".

SEC. 5. MODIFICATION OF STATEMENT OF POLICY AND OBJECTIVES FOR CHAPTER 18 OF TITLE 35, UNITED STATES CODE.

Section 200 of title 35, United States Code, is amended by striking "enterprise;" and inserting "enterprise without unduly encumbering future research and discovery;".

SEC. 6. TECHNICAL AMENDMENTS TO BAYH-DOLE ACT.

Chapter 18 of title 35, United States Code (popularly known as the "Bayh-Dole Act"), is amended—

(1) by amending section 202(e) to read as follows:

"(e) In any case when a Federal employee is a coinventor of any invention made with a nonprofit organization, a small business firm, or a non-Federal inventor, the Federal agency employing such coinventor may, for the purpose of consolidating rights in the invention and if it finds that it would expedite the development of the invention—

"(1) license or assign whatever rights it may acquire in the subject invention to the nonprofit organization, small business firm, or non-Federal inventor in accordance with the provisions of this chapter; or

"(2) acquire any rights in the subject invention from the nonprofit organization, small business firm, or non-Federal inventor, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction and no other transaction under this chapter is conditioned on such acquisition."; and

(2) in section 207(a)—

(A) by striking "patent applications, patents, or other forms of protection obtained" and inserting "inventions" in paragraph (2); and

(B) by inserting ", including acquiring rights for and administering royalties to the Federal Government in any invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction, to facilitate the licensing of a federally owned invention" after "or through contract" in paragraph (3).

SEC. 7. TECHNICAL AMENDMENTS TO THE STEVENSON-WYDLER TECHNOLOGY INNOVATION ACT OF 1980.

The Stevenson-Wydler Technology Innovation Act of 1980 is amended—

(1) in section 4(4) (15 U.S.C. 3703(4)), by striking "section 6 or section 8" and inserting "section 7 or 9";

(2) in section 4(6) (15 U.S.C. 3703(6)), by striking "section 6 or section 8" and inserting "section 7 or 9";

(3) in section 5(c)(11) (15 U.S.C. 3704(c)(11)), by striking "State of local governments" and inserting "State or local governments";

(4) in section 9 (15 U.S.C. 3707), by—

(A) striking "section 6(a)" and inserting "section 7(a)";

(B) striking "section 6(b)" and inserting "section 7(b)"; and

(C) striking "section 6(c)(3)" and inserting "section 7(c)(3)";

(5) in section 11(e)(1) (15 U.S.C. 3710(e)(1)), by striking "in cooperation with Federal Laboratories" and inserting "in cooperation with Federal laboratories";

(6) in section 11(i) (15 U.S.C. 3710(i)), by striking "a gift under the section" and inserting "a gift under this section";

(7) in section 14 (15 U.S.C. 3710c)—

(A) in subsection (a)(1)(A)(i), by inserting ", other than payments of patent costs as delineated by a license or assignment agreement," after "or other payments";

(B) in subsection (a)(1)(A)(i), by inserting ", if the inventor's or coinventor's rights are assigned to the United States" after "inventor or coinventors";

(C) in subsection (a)(1)(B), by striking "succeeding fiscal year" and inserting "2 succeeding fiscal years";

(D) in subsection (a)(2), by striking "Government-operated laboratories of the"; and

(E) in subsection (b)(2), by striking "inventon" and inserting "invention"; and

(8) in section 22 (15 U.S.C. 3714), by striking "sections 11, 12, and 13" and inserting "sections 12, 13, and 14".

SEC. 8. REVIEW OF COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT PROCEDURES.

(a) REVIEW.—Within 90 days after the date of the enactment of this Act, each Federal agency with a federally funded laboratory that has in effect on that date of the enactment one or more cooperative research and development agreements under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a) shall report to the Committee on National Security of the National Science and Technology Council and the Congress on the general policies and procedures used by that agency to gather and consider the views of other agencies on—

(1) joint work statements under section 12(c)(5)(C) or (D) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(c)(5)(C) or (D)); or

(2) in the case of laboratories described in section 12(d)(2)(A) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(d)(2)(A)), cooperative research and development agreements under such section 12,

with respect to major proposed cooperative research and development agreements that involve critical national security technology or may have a significant impact on domestic or international competitiveness.

(b) PROCEDURES.—Within 1 year after the date of the enactment of this Act, the Committee on National Security of the National Science and Technology Council, in conjunction with relevant Federal agencies and national laboratories, shall—

(1) determine the adequacy of existing procedures and methods for interagency coordination and awareness with respect to cooperative research and development agreements described in subsection (a); and

(2) establish and distribute to appropriate Federal agencies—

(A) specific criteria to indicate the necessity for gathering and considering the views of other agencies on joint work statements or cooperative research and development agreements as described in subsection (a); and

(B) additional procedures, if any, for carrying out such gathering and considering of agency views with respect

to cooperative research and development agreements described in subsection (a).

Procedures established under this subsection shall be designed to the extent possible to use or modify existing procedures, to minimize burdens on Federal agencies, to encourage industrial partnerships with national laboratories, and to minimize delay in the approval or disapproval of joint work statements and cooperative research and development agreements.

(c) LIMITATION.—Nothing in this Act, nor any procedures established under this section shall provide to the Office of Science and Technology Policy, the National Science and Technology Council, or any Federal agency the authority to disapprove a cooperative research and development agreement or joint work statement, under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a), of another Federal agency.

SEC. 9. INCREASED FLEXIBILITY FOR FEDERAL LABORATORY PARTNERSHIP INTERMEDIARIES.

Section 23 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3715) is amended—

(1) in subsection (a)(1) by inserting ", institutions of higher education as defined in section 1201(a) of the Higher Education Act of 1965 (20 U.S.C. 1141(a)), or educational institutions within the meaning of section 2194 of title 10, United States Code" after "small business firms"; and

(2) in subsection (c) by inserting ", institutions of higher education as defined in section 1201(a) of the Higher Education Act of 1965 (20 U.S.C. 1141(a)), or educational institutions within the meaning of section 2194 of title 10, United States Code," after "small business firms".

SEC. 10. REPORTS ON UTILIZATION OF FEDERAL TECHNOLOGY.

(a) AGENCY ACTIVITIES.—Section 11 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710) is amended—

(1) by striking the last sentence of subsection (b);

(2) by inserting after subsection (e) the following:

"(f) AGENCY REPORTS ON UTILIZATION.—

"(1) IN GENERAL.—Each Federal agency which operates or directs one or more Federal laboratories or which conducts activities under sections 207 and 209 of title 35, United States Code, shall report annually to the Office of Management and Budget, as part of the agency's annual budget submission, on the activities performed by that agency and its Federal laboratories under the provisions of this section and of sections 207 and 209 of title 35, United States Code.

"(2) CONTENTS.—The report shall include—

"(A) an explanation of the agency's technology transfer program for the preceding fiscal year and the agency's plans for conducting its technology transfer function, including its plans for securing intellectual property rights in laboratory innovations with commercial promise and plans for managing its intellectual property so as to advance the agency's mission and benefit the competitiveness of United States industry; and

"(B) information on technology transfer activities for the preceding fiscal year, including—

"(i) the number of patent applications filed;

"(ii) the number of patents received;

"(iii) the number of fully-executed licenses which received royalty income in the preceding fiscal year, categorized by whether they are exclusive, partially-exclusive, or non-exclusive, and the time elapsed from the date on which the license was requested by the licensee in writing to the date the license was executed;

"(iv) the total earned royalty income including such statistical information as the total earned royalty income, of the top 1 percent, 5 percent, and 20 percent of the licenses, the range of royalty income, and the median, except where disclosure of such information would reveal the amount of royalty income associated with an individual license or licensee;

"(v) what disposition was made of the income described in clause (iv);

"(vi) the number of licenses terminated for cause; and

"(vii) any other parameters or discussion that the agency deems relevant or unique to its practice of technology transfer.

"(3) COPY TO SECRETARY; ATTORNEY GENERAL; CONGRESS.—The agency shall transmit a copy of the report to the Secretary of Commerce and the Attorney General for inclusion in the annual report to Congress and the President required by subsection (g)(2).

"(4) PUBLIC AVAILABILITY.—Each Federal agency reporting under this subsection is also strongly encouraged to make the information contained in such report available to the public through Internet sites or other electronic means.";

(3) by striking subsection (g)(2) and inserting the following:

"(2) REPORTS.—

"(A) ANNUAL REPORT REQUIRED.—The Secretary, in consultation with the Attorney General and the Commissioner of Patents and Trademarks, shall submit each fiscal year, beginning 1 year after the enactment of the Technology Transfer Commercialization Act of 2000, a summary report to the President, the United States Trade Representative, and the Congress on the use by Federal agencies and the Secretary of the technology transfer authorities specified in this Act and in sections 207 and 209 of title 35, United States Code.

"(B) CONTENT.—The report shall—

"(i) draw upon the reports prepared by the agencies under subsection (f);

"(ii) discuss technology transfer best practices and effective approaches in the licensing and transfer of technology in the context of the agencies' missions; and

"(iii) discuss the progress made toward development of additional useful measures of the outcomes of technology transfer programs of Federal agencies.

"(C) PUBLIC AVAILABILITY.—The Secretary shall make the report available to the public through Internet sites or other electronic means."; and

(4) by inserting after subsection (g) the following:

"(h) DUPLICATION OF REPORTING.—The reporting obligations imposed by this section—

"(1) are not intended to impose requirements that duplicate requirements imposed by the Government Performance and Results Act of 1993 (31 U.S.C. 1101 note);

"(2) are to be implemented in coordination with the implementation of that Act; and

"(3) are satisfied if an agency provided the information concerning technology transfer activities described in this section in its annual submission under the Government Performance and Results Act of 1993 (31 U.S.C. 1101 note).".

(b) ROYALTIES.—Section 14(c) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710c(c)) is amended to read as follows:

"(c) REPORTS.—The Comptroller General shall transmit a report to the appropriate committees of the Senate and House of Representatives on the effectiveness of Federal technology transfer programs, including findings, conclusions, and recommendations for improvements in such programs. The report shall be integrated with, and submitted at the same time as, the report required by section 202(b)(3) of title 35, United States Code.".

SEC. 11. TECHNOLOGY PARTNERSHIPS OMBUDSMAN.

(a) APPOINTMENT OF OMBUDSMAN.—The Secretary of Energy shall direct the director of each national laboratory of the Department of Energy, and may direct the director of each facility under the jurisdiction of the Department of Energy, to appoint a technology partnership ombudsman to hear and help resolve complaints from outside organizations regarding the policies and actions of each such laboratory or facility with respect to technology partnerships (including cooperative research and development agreements), patents, and technology licensing.

(b) QUALIFICATIONS.—An ombudsman appointed under subsection (a) shall be a senior official of the national laboratory or facility who is not involved in day-to-day technology partnerships, patents, or technology licensing, or, if appointed from outside the laboratory or facility, function as such a senior official.

(c) DUTIES.—Each ombudsman appointed under subsection (a) shall—

(1) serve as the focal point for assisting the public and industry in resolving complaints and disputes with the national laboratory or facility regarding technology partnerships, patents, and technology licensing;

(2) promote the use of collaborative alternative dispute resolution techniques such as mediation to facilitate the speedy and low-cost resolution of complaints and disputes, when appropriate; and

(3) report quarterly on the number and nature of complaints and disputes raised, along with the ombudsman's assessment of their resolution, consistent with the protection of confidential and sensitive information, to—

(A) the Secretary;

(B) the Administrator for Nuclear Security;

(C) the Director of the Office of Dispute Resolution of the Department of Energy; and

(D) the employees of the Department responsible for the administration of the contract for the operation of each national laboratory or facility that is a subject of

report, for consideration in the administration and view of that contract.

Speaker of the House of Representatives.

Vice President of the United States and
President of the Senate.

NL - Interesting case involving Bayh-Dole

United States Court of Appeals for the Federal Circuit

01-1567

JOHN M.J. MADEY,

Plaintiff-Appellant,

v.

DUKE UNIVERSITY,

Defendant-Appellee.

Randall M. Roden, Tharrington Smith, L.L.P., of Raleigh, North Carolina, argued for plaintiff-appellant. Of counsel on the brief was James L. Lester, MacCord Mason PLLC, of Greensboro, North Carolina.

John A. Bauer, Fulbright & Jaworski LLP, of New York, New York, argued for defendant-appellee. Of counsel on the brief were John M. Simpson, John E. Lynch, and Caroline M. Mew, of Fulbright & Jaworski LLP, of Washington, DC. Also of counsel on the brief was Jeffrey L. Wilson, of Durham, North Carolina.

Appealed from: United States District Court for the Middle District of North Carolina

Judge James A. Beaty, Jr.

United States Court of Appeals for the Federal Circuit

01-1567

JOHN M.J. MADEY,

Plaintiff-Appellant,

v.

DUKE UNIVERSITY,

Defendant-Appellee.

DECIDED: October 3, 2002

Before BRYSON, GAJARSA, and LINN, Circuit Judges.

GAJARSA, Circuit Judge.

Dr. John M.J. Madey ("Madey") appeals from a judgment of the United States District Court for the Middle District of North Carolina. Madey sued Duke University ("Duke"), bringing claims of patent infringement and various other federal and state law claims. Pursuant to a motion filed by Duke under Federal Rule of Civil Procedure ("FRCP") 12(b)(1), the district court dismissed-in-part certain patent infringement claims and dismissed certain other claims. Madey v. Duke Univ., No. 1:97CV1170, slip op. at 12-14, 38-40 (M.D.N.C. Dec. 1, 1999) ("Dismissal Opinion"). After discovery, the district court granted summary judgment in favor of Duke on the remaining claims. For a first set of alleged infringing acts, it held that the experimental use defense applied to Duke's use of Madey's patented laser technology. For a second set of alleged infringing acts, it held that Duke was not the infringing party because a third-party owned and controlled the

allegedly infringing laser equipment. Madey v. Duke Univ., No. 1:97CV1170, slip op. at 12-15, 18, 20 (M.D.N.C. June 15, 2001) ("Summary Judgment Opinion"). The district court erred in its partial dismissal, erred in applying the experimental use defense, but, for the second set of alleged infringing acts, correctly determined that Duke did not infringe because it did not own or control the equipment. Accordingly, we reverse-in-part, affirm-in-part, and remand.

BACKGROUND

In the mid-1980s Madey was a tenured research professor at Stanford University. At Stanford, he had an innovative laser research program, which was highly regarded in the scientific community. An opportunity arose for Madey to consider leaving Stanford and take a tenured position at Duke. Duke recruited Madey, and in 1988 he left Stanford for a position in Duke's physics department. In 1989 Madey moved his free electron laser ("FEL") research lab from Stanford to Duke. The FEL lab contained substantial equipment, requiring Duke to build an addition to its physics building to house the lab. In addition, during his time at Stanford, Madey had obtained sole ownership of two patents practiced by some of the equipment in the FEL lab.

At Duke, Madey served for almost a decade as director of the FEL lab. During that time the lab continued to achieve success in both research funding and scientific breakthroughs. However, a dispute arose between Madey and Duke. Duke contends that, despite his scientific prowess, Madey ineffectively managed the lab. Madey contends that Duke sought to use the lab's equipment for research areas outside the allocated scope of certain government funding, and that when he objected, Duke sought to remove him as lab director. Duke eventually did remove Madey as director of the lab in 1997. The removal is not at issue in this appeal, however, it is the genesis of this unique patent infringement case. As a result of the removal, Madey resigned from Duke in 1998.

Duke, however, continued to operate some of the equipment in the lab. Madey then sued Duke for patent infringement of his two patents, and brought a variety of other claims.

The Patents and Infringing Equipment

One of Madey's patents, U.S. Patent No. 4,641,103 ("the '103 patent"), covers a "Microwave Electron Gun" used in connection with free electron lasers. The other patent, U.S. Patent No. 5,130,994 ("the '994 patent"), is titled "Free-Electron Laser Oscillator For Simultaneous Narrow Spectral Resolution And Fast Time Resolution Spectroscopy." The details of these two patents are not material to the issues on appeal. Their use in the lab, however, as embodied in certain equipment, is central to this appeal.

The equipment at the Duke FEL lab that practices the subject matter disclosed and claimed in the patents is set forth in the list below, which first lists the equipment and then the patent(s) it embodies.

- An infrared FEL called the "Mark III FEL," embodying the '994 patent and the '103 patent (by incorporating the microwave electron gun in the infrared FEL).
- A "Storage Ring FEL," embodying the same patents as the Mark III FEL because it incorporates a Mark III FEL.
- A "Microwave Gun Test Stand," embodying the '103 patent (by incorporating the microwave electron gun).

The three alleged infringing devices are the Mark III FEL, the Storage Ring FEL, and the Microwave Gun Test Stand. Although it is not clear from the record, perhaps because Duke defended by asserting experimental use and government license defenses, Duke seems to concede that the alleged infringing devices and methods read on the claims of the patents. Although the three devices were housed in Duke's physics facilities, the Microwave Gun Test Stand was not Duke's asset, but rather belonged to North Carolina Central University ("NCCU").

Duke's Relationship with NCCU

Madey and Duke built the Microwave Gun Test Stand as a subcontractor to NCCU after the government awarded NCCU a contract to study microwave guns (the "AFOSR Contract"). Professor Jones of NCCU was the principal investigator under this government project. The Microwave Gun Test Stand was built and housed in the Duke FEL lab. The AFOSR Contract listed the Microwave Gun Test Stand as NCCU's asset.

The District Court's Dismissal Opinion

Duke moved to dismiss the infringement claims under the '103 patent under both FRCP 12(b)(1) for lack of subject matter jurisdiction, and under FRCP 12(b)(6) for failure to state a claim upon which relief can be granted. Dismissal Opinion at 9 n.2. The district court granted the first motion in part, but denied the second motion. Madey alleges on appeal that the district court erred in its FRCP 12(b)(1) partial dismissal.

Motion to Dismiss under FRCP 12(b)(1)

The district court reasoned that Duke's alleged unauthorized use of the '103 patent fell into two categories: (i) use in furtherance of an Office of Naval Research ("ONR") grant; and (ii) use that exceeds the authorized scope of the ONR grant. The district court determined that if all the unauthorized use fell in the first category, jurisdiction would lie in the Court of Federal Claims. On the other hand, if all of the unauthorized use fell in the second category, jurisdiction would lie in federal district court. In all probability, however, the use spanned both categories.

To make the determination as to whether dismissal under FRCP 12(b)(1) was proper, the district court relied on 28 U.S.C. § 1498(a), set forth below.

> (a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . .
>
> For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States. . . .

28 U.S.C. § 1498(a) (2000) (emphasis added).

The district court reasoned that under § 1498(a) Madey must sue in the Court of Federal Claims for any use in furtherance of the ONR grant. Dismissal Opinion at 10-11. This reasoning assumes that the ONR grant provides the "authorization or consent" of the government to be sued, and designates Duke's use as "by or for" the United States. The district court did not, however, discuss or analyze the particular statements or aspects of the ONR grant that provided the government's authorization or consent to be sued. Nor did the court discuss or characterize Duke's use or manufacture as "by or for the United States."

The district court acknowledged that the use at issue was potentially mixed between the two categories, within the scope of the ONR grant, and without. The district court applied Fourth Circuit law, under which the burden of proving subject matter jurisdiction is with the plaintiff. Id. at 11 (quoting Richmond, Fredericksburg & Potomac R.R. Co. v. United States, 945 F.2d 765, 768 (4th Cir. 1991)). Thus, even at the pleading stage, according to the district court, the nonmoving party must set forth evidence of specific "jurisdictional" facts to show that a genuine issue of material fact exists; the

moving party prevails only if the material jurisdictional facts are not in dispute. Id. (citing Trentacosta v. Frontier Pac. Aircraft Indus., 813 F.2d 1553, 1558 (9th Cir. 1987)).

The district court rejected Duke's contention that even if only some use is for the government, the claim should be dismissed. The court noted that the extent of Duke's "use of the '103 patent for private purposes is unclear." Id. at 13. The court acknowledged that discovery would be necessary to determine the nature and extent of Duke's private use. However, for Duke's use of the patents "under the authority of the government research grant," the district court dismissed Madey's claim without prejudice.[1]

The District Court's Summary Judgment Opinion

Among Duke's motions for summary judgment, two are relevant on appeal, entitled by the district court as: (i) the "Patent Motion;" and (ii) the "Test Stand Gun Motion."

The Patent Motion and the Experimental Use Defense

The district court acknowledged a common law "exception" for patent infringement liability for uses that, in the district court's words, are "solely for research, academic or experimental purposes." Summary Judgment Opinion at 9 (citing Deuterium Corp. v. United States, 19 Cl. Ct. 624, 631, 14 USPQ2d 1636, 1642 (1990); Whittemore v. Cutter,

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[1] The district court also ruled on various other motions to dismiss. First, it granted a motion by a number of individual defendants named with Duke to dismiss Madey's claims against them pursuant to FRCP 8, 9(b) and 12(b)(6). Dismissal Opinion at 6. Specifically, without reaching the merits of Rule 9(b) or Rule 12(b)(6), the district court dismissed Madey's claims against the individual defendants under Rule 8 because the claims did not provide sufficient notice to the individual defendants. Id. at 7-8. Madey has not appealed this dismissal.

Second, the district court denied Duke's motions to dismiss Madey's claims for conversion of property, id. at 16, misappropriation of business opportunities, id. at 21, constructive fraud, id. at 33, and breach of contract, id. at 38. However, the court granted Duke's motions to dismiss Madey's age discrimination claims, id. at 27, and civil rights claims, id. at 30. Madey has not appealed the district court's grant of these last two motions.

29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600); and citing two commentators[2]). The district court recognized the debate over the scope of the experimental use defense, but cited this court's opinion in Embrex, Inc. v. Service Engineering Corp., 216 F.3d 1343, 1349, 55 USPQ2d 1161, 1163 (Fed. Cir. 2000) to hold that the defense was viable for experimental, non-profit purposes. Summary Judgment Opinion at 9 (citing Embrex, 216 F.3d at 1349, 55 USPQ2d at 1163 (noting that courts should not "construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes" (quoting Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863, 221 USPQ 937, 940 (Fed. Cir. 1984))[3])).

After having recognized the experimental use defense, the district court then fashioned the defense for application to Madey in the passage set forth below.

> Given this standard [for experimental use], for [Madey] to overcome his burden of establishing actionable infringement in this case, he must establish that [Duke] has not used the equipment at issue "solely for an experimental or other non-profit purpose." 5 Donald S. Chisum, Chisum on Patents § 16.03[1] (2000). More specifically, [Madey] must sufficiently establish that [Duke's] use of the patent had "definite, cognizable, and not insubstantial commercial purposes." Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984), cert. denied, 469 U.S. 856, 863 (1984).

Summary Judgment Opinion at 10.

On appeal, Madey attacks this passage as improperly shifting the burden to the plaintiff to allege and prove that the defendant's use was not experimental.

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[2] Janice M. Mueller, No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools, 76 Wash. L. Rev. 1, 17 (2001); 5 Chisum on Patents § 16.03[1] (2000).

[3] The accused infringer in Roche sought to assert the experimental use defense to allow early development of a generic drug. After the Roche decision, however, Congress changed the law, overruling Roche in part, but without impacting the experimental use doctrine. Congress provided limited ability for a company to practice a

Before the district court, Madey argued that Duke's research in its FEL lab was commercial in character and intent. Id. Madey relied on Pitcairn v. United States, 547 F.2d 1106, 192 USPQ 612 (Ct. Cl. 1976), where the government used patented rotor structures and control systems for a helicopter to test the "lifting ability" and other attributes of the patented technology. Pitcairn, 547 F.2d at 1125-26, 192 USPQ at 625. The Pitcairn court held that the helicopters were not built solely for experimental purposes because they were also built to benefit the government in its legitimate business. Id. Based on language in Duke's patent policy, Madey argues that Duke is in the business of "obtaining grants and developing possible commercial applications for the fruits of its 'academic research.'" Summary Judgment Opinion at 11.

The district court rejected Madey's argument, relying on another statement in the preamble of the Duke patent policy which stated that Duke was "dedicated to teaching, research, and the expansion of knowledge . . . [and] does not undertake research or development work principally for the purpose of developing patents and commercial applications." Id. The district court reasoned that these statements from the patent policy refute any contention that Duke is "in the business" of developing technology for commercial applications. Id. at 12. According to the district court, Madey's "evidence" was mere speculation,[4] and thus Madey did not meet his burden of proof to create a

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patent in furtherance of a drug approval application. See Deuterium, 19 Cl. Ct. at 632 n.14, 14 USPQ2d at 1642 n.14.

[4] Madey also argued that Duke's acceptance of funding from the government and private foundations was evidence of developing patented devices with commercial intent. The district court also rejected this proposition. Summary Judgment Opinion at 13 (citing Ruth v. Stearns-Roger Mfg. Co., 13 F. Supp. 697, 713 (D. Colo. 1935) (concluding that the experimental use defense applies when a university uses a patented device in furtherance of its educational purpose); Ronald D. Hartman, Experimental Use as an Exception to Patent Infringement, 67 J. Pat. Off. Soc'y 617, 633 (1985) (concluding that Ruth supports application of the experimental use defense to a university's operations in furtherance of its educational function)).

genuine issue of material fact.[5] Id. The court went on to state that "[w]ithout more concrete evidence to rebut [Duke's] stated purpose with respect to its research in the FEL lab, Plaintiff has failed to meet its burden of establishing patent infringement by a preponderance of the evidence." Id. at 13.

Finally, under its discussion of the Patent Motion, the district court reasoned that Duke's argument that "essentially all" uses of the patents were covered by a license to the government was moot given the experimental use holding. Despite its mootness determination, the district court went on to partially analyze the government license issue as set forth in the passage below.[6] Id. at 16.

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[5] The district court discussed and dismissed in a footnote other evidence suggested by Madey, including the fact that Duke had established (but not yet applied) an hourly fee for industrial users wishing to use the FEL lab's resources, and statements from Duke's website for the FEL lab indicating an interest in corporate partnerships. Id. at 15 n.2.

[6] In a footnote, the district court cites to a section from the Bayh-Dole Act to support its reasoning that the government has a license to have patents practiced on its behalf when the government contributed to the funding of such patents. Id. at 16 n.3 (citing 35 U.S.C. § 202(c)(4) (2000)). The relevant section is set forth below.

> (c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:
>
> . . .
>
> (4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world . . . .

35 U.S.C. § 202(c)(4) (2000).

The district court stated that the "funding agreements for the inventions created under the '994 and '103 patents expressly provide that the Government retained rights in those inventions." Id. Thus, the district court reasoned, in light of the Bayh-Dole Act, Duke's use of the patents that has been authorized by the government does not constitute patent infringement. Finally, the district court noted that:

> [a]lthough the parties have presented conflicting evidence as to the extent to which the patented devices have been used for a purpose consented to by the Government, because [Madey] has failed to create a genuine issue of material fact as to whether [Duke] has commercially benefited or intends to do so with respect to the patents at issue, the uses that have been made to date with respect to both patents are, at this point, exempt from infringement liability.

> The Court does note, however, as it did previously when ruling upon [Duke's] Motion to Dismiss, that all uses that have been made of the patented devices that are covered by such a license are not subject to infringement liability.

Id.

The Test Stand Gun Motion

Under the Test Stand Gun Motion, Duke argued that any use of the patented equipment before June 1997 is not infringement because Madey consented to the manufacture and use of the Microwave Gun Test Stand by Duke and NCCU before this date. The district court agreed, concluding that there was no infringement before such date because Madey approved of such use via his direct involvement. Summary Judgment Opinion at 17. Madey does not appeal this issue.

After June 1997, however, Duke's defense is that no one affiliated with Duke used the Microwave Gun Test Stand. Duke relied on attestations by Dr. Jones, the NCCU professor who was the principal investigator for the AFOSR contract. The district court determined that Dr. Jones was not an agent of Duke. Id. at 19-20. It also determined that Dr. Jones controlled physical access to the Microwave Gun Test Stand because he had the key switch to operate the device. Id. at 18. The district court held any contrary assertions by Madey to be "bald allegations and mere speculation." Id. at 19.

Given Dr. Jones' attestation that he was unaware of any Duke faculty members or employees using the Microwave Gun Test Stand after June 1997, the district court determined that there was no genuine issue of material fact and awarded summary judgment of no infringement to Duke on this issue. Id. at 20.

Id.

Supplemental Jurisdiction of Madey's State Law Claims

At the conclusion of its Summary Judgment Opinion, the district court noted that four state law claims remained in the case: conversion of property, misappropriation of business opportunities, constructive fraud, and breach of contract. Id. at 20 n.6. Given its determination on the two patent infringement motions, the district court declined to exercise supplemental jurisdiction over the outstanding state law claims and dismissed them without prejudice. Id. at 21.

DISCUSSION

Standard of Review

We review a district court's grant of summary judgment without deference. Atmel Corp. v. Info. Storage Devices, Inc., 198 F.3d 1374, 1378, 53 USPQ2d 1225, 1227 (Fed. Cir. 1999). Summary judgment is appropriate when the moving party demonstrates that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FRCP 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). On summary judgment, the evidence must be viewed in the light most favorable to the party opposing the motion, Poller v. Columbia Broad. Sys., Inc., 368 U.S. 464, 473 (1962), with doubts resolved in favor of the nonmovant, Cantor v. Detroit Edison Co., 428 U.S. 579 (1976); Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1274, 35 USPQ2d 1035, 1038 (Fed. Cir. 1995). Once the moving party has satisfied its initial burden, the opposing party must establish a genuine issue of material fact and cannot rest on mere allegations, but must present actual evidence. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Issues of fact are genuine only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Id. A disputed fact is material to the outcome of the suit if a finding of that fact is necessary and relevant to the proceeding.

Id.; General Mills, Inc. v. Hunt-Wesson, Inc., 103 F.3d 978, 980, 41 USPQ2d 1440, 1442 (Fed. Cir. 1997).

We review questions of patent law de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1172 (Fed. Cir. 1998) (en banc). The determination of infringement, whether literal or under the doctrine of equivalents, is a question of fact. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353, 48 USPQ2d 1674, 1676 (Fed. Cir. 1998). On procedural issues, this Court follows the rule of the regional circuit, unless the issue is unique to patent law and therefore exclusively assigned to the Federal Circuit. See Nat'l Presto v. W. Bend Co., 76 F.3d 1185, 1188 n.2, 37 USPQ2d 1685, 1686 n.2 (Fed. Cir. 1996). Accordingly:

> [w]e apply regional circuit law to procedural issues that are not themselves substantive patent law issues so long as they do not (1) pertain to patent law, Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1365, 57 USPQ2d 1635, 1637 (Fed. Cir. 2001) ("We will apply our own law to both substantive and procedural issues 'intimately involved in the substance of enforcement of the patent right'" (citation omitted)), (2) bear an essential relationship to matters committed to our exclusive control by statute, or (3) clearly implicate the jurisprudential responsibilities of this court in a field within its exclusive jurisdiction. Midwest Indus., Inc. v. Karavan Trailers, Inc., 175 F.3d 1356, 1359, 50 USPQ2d 1672, 1675 (Fed. Cir. 1999) (en banc in relevant part).

Int'l Nutrition Co. v. Horphag Research Ltd., 257 F.3d 1324, 1328, 59 USPQ2d 1532, 1535 (Fed. Cir. 2001).

Review of the district court's interpretation of the experimental use defense and its proper scope are questions of law and statutory interpretation that are reviewed de novo. Vectra Fitness, Inc. v. TNWK Corp., 162 F.3d 1379, 1381, 49 USPQ2d 1144, 1146 (Fed. Cir. 1998). A dismissal for lack of subject matter jurisdiction is a procedural question not unique to patent law, therefore we follow the law of the regional circuit. Molins PLC v. Quigg, 837 F.2d 1064, 1066, 5 USPQ2d 1526, 1527 (Fed. Cir. 1988) (explaining that justiciability in the district court does not pertain to patent law and thus follows regional

circuit law). The United States Court of Appeals for the Fourth Circuit reviews de novo a dismissal under FRCP 12(b)(1). Evans v. B.F. Perkins Co., 166 F.3d 642, 647 (4th Cir. 1999).

The District Court's Dismissal Opinion

On appeal, Madey argues that the district court improperly applied 28 U.S.C § 1498(a) by failing to make sufficient supporting determinations. As a result, according to Madey, partial dismissal of the '103 patent infringement claim for Duke's use under the ONR grant was improper. Specifically, Madey argues that the court did not find that Duke's use was "by or for the United States," and that the use was with the "authorization or consent" of the United States. Madey makes the distinction that a research grant is different from a contract to acquire property or services for the government. Duke, on the other hand, attacks Madey's distinction as meaningless, arguing that either a grant or a contract can meet the prerequisites of § 1498(a).

Based on the district court's findings, we agree with Madey that the district court erred in granting the partial dismissal. Madey, however, also asserts that a research grant can never meet the requirements of § 1498(a). We disagree with this proposition.

The district court did not clearly identify, discuss or analyze the particular statements or aspects of the ONR grant that may have provided the government's authorization or consent to be sued. The court seems to have assumed that a research grant by a federal agency to a university for financial support of scientific research proposed by the university constitutes activity "for the United States" and provides authorization or consent by the United States for patent infringement liability for any patents used in the course of the research. In addition, the court did not discuss or

characterize Duke's use or manufacture of the '103 patent embodiments as "by or for the United States."

In general, there are two important features of § 1498(a). It relieves a third party from patent infringement liability, and it acts as a waiver of sovereign immunity and consent to liability by the United States. See Crater Corp. v. Lucent Tech., Inc., 255 F.3d 1361, 1364, 59 USPQ2d 1044, 1045 (Fed. Cir. 2001) ("If a patented invention is used or manufactured for the government by a private party, that private party cannot be held liable for patent infringement."); Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 554-55 & n.6, 16 USPQ2d 1587, 1595-96 & n.6 (Fed. Cir. 1990) (discussing § 1498(a) in two contexts, when raised by a private party as a defense, in which case it is not jurisdictional, and when invoked in a suit against the United States, in which case it is jurisdictional) (citing for support and discussing Sperry Gyroscope Co. v. Arma Eng'g Co., 271 U.S. 232, 235-36 (1926)). Waivers of sovereign immunity are to be strictly construed. See, e.g., Irwin v. Dep't of Veterans Affairs, 498 U.S. 89, 94 (1990); Library of Congress v. Shaw, 478 U.S. 310, 318 (1986). This general mantra influences the application of § 1498(a) between private parties because in such a situation § 1498(a) is an affirmative defense. Manville, 917 F.2d at 555 & n.6, 16 USPQ2d at 1595-96 & n.6. As a result, one possible consequence of dismissal based on this defense is a suit against the government in the Court of Federal Claims. Id. at 555 & n.8, 16 USPQ2d at 1596 & n.8. In the sphere of this sovereign immunity influence on the defense, the teachings of Crater and Manville illustrate two errors by the district court in dismissing the claims for Duke's use of the '103 patent under the ONR grant.

First, the district court relied on the doctrine of jurisdictional facts when, as between private parties, § 1498(a) is not jurisdictional. Id. at 555 & n.6, 16 USPQ2d at

1595-96 & n.6. The district court applied the Fourth Circuit's general jurisdictional facts doctrine. This is error because Federal Circuit law provides the applicable interpretation of § 1498(a). Section 1498(a) applies exclusively to patent law, meaning that Federal Circuit law applies. Nat'l Presto, 76 F.3d at 1188 n.2, 37 USPQ2d at 1686 n.2. One might counter-argue that § 1498(a) is procedural. However, to the extent that § 1498(a) is procedural, it is unique to patent law, which also indicates that Federal Circuit law applies. Id. Federal Circuit law, under Crater and Manville, teaches that § 1498(a) is an affirmative defense and is not jurisdictional. Crater, 255 F.3d at 1364, 59 USPQ2d at 1045; Manville, 917 F.2d at 555 & n.6, 16 USPQ2d at 1595-96 & n.6. Because § 1498(a) is not jurisdictional, the jurisdictional facts doctrine does not apply. Therefore, the basis for the district court's partial dismissal was improper.

Second, by failing to explain or demonstrate precisely how the ONR grant authorizes the government's consent to suit or authorizes Duke to use or manufacture the patented articles for the government, the district court has provided no findings or analysis upon which we can base our review of the issue appealed from the court's Dismissal Opinion. Although a research grant may not meet the requirements of § 1498(a), from the limited record presented by the parties, it cannot be determined whether the ONR grant may authorize the necessary predicates for § 1498(a). However, even if Duke ultimately prevails on its assertion of § 1498(a) as an affirmative defense for its use of the '103 patent under the ONR grant, that does not mean that the district court's dismissal of the claim was without error. The ultimate factual and liability determinations are issues for the district court to determine initially on remand because in addition to evaluating the ONR grant and making the requisite findings, as it noted in its Dismissal Opinion, it has not yet determined which uses fall within the scope of the ONR

grant and which uses are outside that scope. See Dismissal Opinion at 13. This determination, as well, seems necessary to support the dismissal in-part.

The District Court's Application of Experimental Use

On appeal, Madey asserts three primary errors related to experimental use. First, Madey claims that the district court improperly shifted the burden to Madey to prove that Duke's use was not experimental. Second, Madey argues that the district court applied an overly broad version of the very narrow experimental use defense inconsistent with our precedent. Third, Madey attacks the supporting evidence relied on by the district court as overly general and not indicative of the specific propositions and findings required by the experimental use defense, and further argues that there is no support in the record before us to allow any court to apply the very narrow experimental use defense to Duke's ongoing FEL lab operation. We substantially agree with Madey on all three points. In addition, Madey makes a threshold argument concerning the continued existence of the experimental use doctrine in any form, which we turn to first. Our precedent, to which we are bound, continues to recognize the judicially created experimental use defense, however, in a very limited form.

The Experimental Use Defense

Citing the concurring opinion in Embrex, Madey contends that the Supreme Court's opinion in Warner-Jenkinson Co. v. Hilton-Davis Chem. Co., 520 U.S. 17 (1997) eliminates the experimental use defense. Embrex, 216 F.3d at 1352-53, 55 USPQ2d at 1166-67 (Rader, J., concurring). The Supreme Court held in Warner-Jenkinson that intent plays no role in the application of the doctrine of equivalents. Warner-Jenkinson, 520 U.S. at 36. Madey implicitly argues that the experimental use defense necessarily incorporates an intent inquiry, and thus is inconsistent with Warner-Jenkinson. Like the majority in

Embrex, we do not view such an inconsistency as inescapable, and conclude the experimental use defense persists albeit in the very narrow form articulated by this court in Embrex, 216 F.3d at 1349, 55 USPQ2d at 1163, and in Roche, 733 F.2d at 863, 221 USPQ at 940.

The District Court Improperly Shifted the Burden to Madey

As a precursor to the burden-shifting issue, Madey argues that the experimental use defense is an affirmative defense that Duke must plead or lose. We disagree. Madey points to no source of authority for its assertion that experimental use is an affirmative defense. Indeed, we have referred to the defense in a variety of ways. See Roche, 733 F.2d at 862, 221 USPQ at 939-40 (referring to experimental use as both an exception and a defense). Given this lack of precise treatment in the precedent, Madey has no basis to support its affirmative defense argument. The district court and the parties in the present case joined the issue during the summary judgment briefing. We see no mandate from our precedent, nor any compelling reason from other considerations, why the opportunity to raise the defense if not raised in the responsive pleading should not also be available at the later stages of a case, within the procedural discretion typically afforded the trial court judge.

The district court held that in order for Madey to overcome his burden to establish actionable infringement, he must establish that Duke did not use the patent-covered free electron laser equipment solely for experimental or other non-profit purposes. Summary Judgment Opinion at 10. Madey argues that this improperly shifts the burden to the patentee and conflates the experimental use defense with the initial infringement inquiry.

We agree with Madey that the district court improperly shifted the burden to him. The district court folded the experimental use defense into the baseline assessment as to

whether Duke infringed the patents. Duke characterizes the district court's holding as expressing the following sequence: first, the court recognized that Madey carried his burden of proof on infringement; second, the court held that Duke carried its burden of proof on the experimental use defense; and third, the court held that Madey was unable to marshal sufficient evidence to rebut Duke's shifting of the burden. We disagree with Duke's reading of the district court's opinion. See Summary Judgment Opinion at 8-14. The district court explicitly contradicts Duke's argument by stating that Madey failed to "meet its burden to establish patent infringement by a preponderance of the evidence." Id. at 13. This statement is an assessment of whether Madey supported his initial infringement claim. It is not an assessment of which party carried or shifted the burden of evidence related to the experimental use defense. Thus, the district court did not conclude that Madey failed to rebut Duke's assertion of the experimental use defense. Instead, it erroneously required Madey to show as a part of his initial claim that Duke's use was not experimental. The defense, if available at all, must be established by Duke.

The District Court's Overly Broad Conception of Experimental Use

Madey argues, and we agree, that the district court had an overly broad conception of the very narrow and strictly limited experimental use defense. The district court stated that the experimental use defense inoculated uses that "were solely for research, academic, or experimental purposes," and that the defense covered use that "is made for experimental, non-profit purposes only." Id. at 9. Both formulations are too broad and stand in sharp contrast to our admonitions in Embrex and Roche that the experimental use defense is very narrow and strictly limited. In Embrex, we followed the teachings of Roche and Pitcairn to hold that the defense was very narrow and limited to actions performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." Embrex, 216 F.3d

at 1349, 55 USPQ2d at 1163. Further, use does not qualify for the experimental use defense when it is undertaken in the "guise of scientific inquiry" but has "definite, cognizable, and not insubstantial commercial purposes." Id. (quoting Roche, 733 F.2d at 863, 221 USPQ2d at 941). The concurring opinion in Embrex expresses a similar view: use is disqualified from the defense if it has the "slightest commercial implication." Id. at 1353, 55 USPQ2d at 1166. Moreover, use in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defense. See Pitcairn, 547 F.2d at 1125-26, 192 USPQ at 625. The district court supported its conclusion with a citation to Ruth v. Stearns-Roger Mfg. Co., 12 F. Supp. 697, 713 (D. Colo. 1935), a case that is not binding precedent for this court.

The Ruth case represents the conceptual dilemma that may have led the district court astray. Cases evaluating the experimental use defense are few, and those involving non-profit, educational alleged infringers are even fewer. In Ruth, the court concluded that a manufacturer of equipment covered by patents was not liable for contributory infringement because the end-user purchaser was the Colorado School of Mines, which used the equipment in furtherance of its educational purpose. Id. Thus, the combination of apparent lack of commerciality, with the non-profit status of an educational institution, prompted the court in Ruth, without any detailed analysis of the character, nature and effect of the use, to hold that the experimental use defense applied. Id. This is not consistent with the binding precedent of our case law postulated by Embrex, Roche and Pitcairn.

Our precedent clearly does not immunize use that is in any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For

example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.

In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.

In the present case, the district court attached too great a weight to the non-profit, educational status of Duke, effectively suppressing the fact that Duke's acts appear to be in accordance with any reasonable interpretation of Duke's legitimate business objectives.[7] On remand, the district court will have to significantly narrow and limit its conception of the experimental use defense. The correct focus should not be on the non-profit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.

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[7] Duke's patent and licensing policy may support its primary function as an educational institution. See Duke University Policy on Inventions, Patents, and Technology Transfer (1996), available at http://www.ors.duke.edu/policies/patpol.htm (last visited Oct. 3, 2002). Duke, however, like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream. See id.

The District Court's Analysis of the Test Stand Gun Motion

In contrast to our conclusion that the district court erred in its dismissal-in-part of the alleged '103 patent infringement and its application of the experimental use defense, we find no error in the court's summary judgment conclusion that there is no genuine issue of material fact concerning Duke's non-use of the NCCU Microwave Gun Test Stand during the relevant time period.

Specifically, the district court found that NCCU, through the subcontractor agreement it had with Duke, owned the Microwave Gun Test Stand, and that Dr. Jones of NCCU controlled the gun with a key switch. Even though the gun was located on Duke's premises, Dr. Jones stated that no Duke faculty member or employee had used the gun during the relevant time period. This evidence of ownership, control, and no known Duke use, is sufficient to shift the summary judgment burden to Madey, who, in the district court's words, offers in response only bare allegations and speculation. Most of the response is testimony by Madey himself.

Madey contends that Duke and Dr. Jones have tacitly admitted to disputed questions of fact concerning whether Duke had any control or benefit over the Microwave Gun Test Stand. In addition, Madey contends that joint publications by Dr. Jones and Duke faculty, as well as research interests held by Duke faculty in areas potentially implicated by the Microwave Gun Test Stand, demonstrate disputed material facts about Duke's benefit and influence over the gun. Like the district court, we do not find that the record supports Madey's contentions, nor do we concur in the inferences in which Madey would have us draw. See Anderson, 477 U.S. at 248 (explaining that a party cannot create a genuine issue of material fact based on mere allegations, but must present actual evidence); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206-07, 18 USPQ2d 1016,

1021 (Fed. Cir. 1991) (explaining that the patent-holder's alleged inferences were mere speculation and thus not supportable).

In addition, we note that the record does not indicate that Madey plead any vicarious liability claims, such as alleging that Duke induced NCCU's infringement, or contributory infringement claims. To the extent that this was a strategic decision or tactical choice on Madey's part, he should not be allowed to overcome this choice now by acceptance of allegations and speculation as genuine issues of material fact.

Additional Matters

Finally, we note two additional matters in response to the parties' arguments before us and for the district court's attention on remand.

Duke's Assertion of a Government License Defense

Before this court, Duke argued vehemently that even if we did not agree with the district court's application of the experimental use defense that we could affirm the district court's judgment on alternate grounds: that the government had a license to have the patents at issue practiced on its behalf. We disagree with Duke's assertion because it overstates the information contained in the record on appeal. The only concrete evidence Duke cites is the statements on each of the patents noting that the government has rights in the patents. This, however, is insufficient because these short notations on the patents do not define the scope of the government's rights. None of the controlling contracts that would define the scope of such rights are provided in the record nor discussed by Duke in its arguments.

In addition, Duke discusses at length the Bayh-Dole Act, urging that this provides a basis to conclude that the scope of the rights granted to the government encompass Duke's use. Madey, however, notes that the provisions cited by Duke were enacted into

law after Madey's two patents issued. Thus, some other provision may have generated the "government rights" notation on the two patents. In sum, this discussion serves to illustrate that the government license issue needs further development before the district court if it is to ultimately provide Duke the defense it seeks.

The District Court's Supplemental Jurisdiction Determination

At the end of its Summary Judgment Opinion, the district court declined to exercise supplemental jurisdiction over four state law claims remaining in the case: conversion of property, misappropriation of business opportunities, constructive fraud, and breach of contract. Summary Judgment Opinion at 20 n.6. On remand, given our reversal of the district court's application of the experimental use defense, these claims are still initially available to Madey.

III. CONCLUSION

The district court erred in its application of the common law experimental use defense, and, consequently, incorrectly found that there was no genuine issue of material fact upon which Madey could prevail. In addition, the court's dismissal-in-part of Duke's use of the '103 patent embodiments under the government ONR grant was in error. Due to these errors, further proceedings are necessary. This includes the opportunity for the district court to reevaluate the issues we remand in light of this opinion, for the parties to litigate Duke's asserted government license defense, and for the court to potentially consider the state law claims in accordance with the case's progression. Accordingly, we affirm-in-part and reverse-in-part the district court's decision and remand for additional proceedings consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED.

COSTS

No costs.