

SEALING THE COFFIN ON THE EXPERIMENTAL USE EXCEPTION

In a petition for writ of certiorari, Duke University requests that the Supreme Court reverse a Federal Circuit holding that, in its view, “seals the coffin on the experimental use exception for private universities.”¹ This iBrief discusses the Federal Circuit’s decision in Madey v. Duke University² and its possible effects on the progress of science.

On October 3, 2002, the Court of Appeals for the Federal Circuit (“CAFC”) held that the district court improperly awarded Duke University (“Duke”) partial summary judgment in a patent infringement suit brought against Duke by John M.J. Madey (“Madey”), a former professor and head of the free electron laser (“FEL”) lab at Duke.³ In its finding, the district court relied on the experimental use defense to patent infringement.⁴ The CAFC held that “the district court [had] applied an overly broad version of the very narrow experimental use defense [that was] inconsistent with [the CAFC’s] precedent[.]”⁵ and remanded the case for application of the proper standard.⁶

The CAFC held that the “very narrow and strictly limited experimental use defense” applies only if use of the patented invention is “solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry,” and that the defense does not apply if the use is “in furtherance of the alleged infringer’s legitimate business[.]”⁷ This is true regardless of the “profit or non-profit” status of the user and “regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain[.]”⁸ This portion of the decision has caused numerous universities and non-profit organizations such as the Association of American Medical Colleges, the Association of American Universities, Consumer Project on Technology, a public interest non-profit organization founded by Ralph Nader, and Public Knowledge, a public interest advocacy organization, to seek Supreme Court intervention. They argue that the holding “erects a

¹ Petition for a Writ of Cert. at 14, *Madey v. Duke University*, 307 F. 3d 1351 (Fed. Cir. 2002) (No. 02-1007).

² *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002).

³ *Id.* at 1352-53.

⁴ *Madey v. Duke University*, No. 1:97CV1170, slip op. at 12-15, 18, 20 (M.D.N.C. June 15, 2001) (“Summary Judgment Opinion”).

⁵ *Madey*, 307 F.3d at 1360.

⁶ *Id.* at 1362-63.

⁷ *Id.* at 1362.

⁸ *Id.*

significant roadblock to the advancement of science” because of the “chilling effect [it will have] on all academic scientific research.”⁹

Background

Facts

In 1988, Madey left Stanford University to assume a position as professor in Duke’s physics department.¹⁰ Shortly thereafter, Duke built an addition to its physics building in order to house Madey’s FEL lab.¹¹ Contained in the lab are several pieces of equipment that practice the subject matter disclosed and claimed in two patents owned by Madey: U.S. Patent No. 4,641,103 (“the ‘103 patent”), which covers a “Microwave Electron Gun” and U.S. Patent No., 5,130,994 (“the ‘994 patent”) titled “Free-Electron Laser Oscillator For Simultaneous Narrow Spectral Resolution And Fast Time Resolution Spectroscopy.”¹²

Madey worked at Duke for nearly a decade but resigned in 1998 after being removed as lab director.¹³ Madey claims that his removal was predicated on his refusal to use the “lab’s equipment for research areas outside the allocated scope of certain government funding[.]”¹⁴ Despite Madey’s removal from the lab, Duke continued to use some of the lab’s equipment, including the equipment embodying Madey’s patents. Because of this unauthorized use of Madey’s patents, Madey sued Duke for patent infringement.¹⁵

District Court

The district court granted Duke’s motion to dismiss the infringement claims under Rule 12(b)(1) of the Federal Rules of Civil Procedure for lack of subject matter jurisdiction,¹⁶ but denied Duke’s motion under Rule 12(b)(6) for failure to state a claim upon which relief can be granted.¹⁷ In a motion for summary judgment, however, Duke claimed that its use of Madey’s patent was exempted from a claim of patent infringement based on the experimental nature of its

⁹ Brief of Amici Curiae Association of American Medical Colleges, et al. at 3-4, *Madey v. Duke University*, 307 F. 3d 1351 (Fed. Cir. 2002) (No. 02-1007).

¹⁰ *Madey*, 307 F.3d at 1352.

¹¹ *Id.*

¹² *Id.* at 1352-53.

¹³ *Id.*

¹⁴ *Id.* at 1352.

¹⁵ *Id.* at 1353.

¹⁶ *Id.* at 1354. (dismissing claim with respect to Duke’s unauthorized use of Madey’s patent in furtherance of an Office of Naval Research grant relying on 28 U.S.C. §1498(a), which states that a patentee’s remedy for unauthorized use of his/her patent for the United States is an action against the United States in the US Court of Federal Claims).

use, and the district court agreed. Duke's motion for summary judgment based on the defense of experimental use was granted.¹⁸ The court held that "the defense was viable for experimental, non-profit purposes" and placed the burden on Madey to "establish that [Duke's] use of the patent had 'definite, cognizable, and not insubstantial commercial purposes.'"¹⁹

The district court rejected Madey's evidence of commercial use as "mere speculation" and held that Madey "failed to meet his burden of proof to create a genuine issue of material fact."²⁰ The holding was in reliance on Duke's patent policy which states that Duke is "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."²¹ The court found that these statements refuted any contention that Duke was in the business of developing technology for commercial applications.²²

Experimental Use

Article I, Section 8, Clause 8 of the United States Constitution provides that:

The Congress shall have the Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

In order to secure this limited but exclusive right to inventors, Congress enacted the Patent Act, which provides, in part, that:

[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States during the term of the patent thereof, infringes the patent.²³

In recognition of the desire to protect a patentee's interests while avoiding the enactment of laws that would stifle the progress of science, an exception to liability for patent infringement was created for use that is for mere experimentation. The origin of the experimental use defense is linked to an opinion by Supreme Court Justice Story; in *Whittemore v. Cutter*²⁴ he stated:

[I]t could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments,

¹⁷ *Id.* at 1353 (citing *Dismissal Opinion* at 9 n. 2).

¹⁸ *Id.* at 1355 (citing *Summary Judgment* at 9).

¹⁹ *Id.* (citing *Summary Judgment* at 9-10 (citing *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984)).

²⁰ *Id.* (citing *Summary Judgment* at 12).

²¹ *Id.* (citing *Summary Judgment* at 11).

²² *Id.* (citing *Summary Judgment* at 12).

²³ 35 U.S.C. § 271(a).

²⁴ *Whittemore v. Cutter*, 29 Fed. Cas. 1120, 1121 (C.C.D. Mass. 1813).

or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.

By 1861 it was well accepted that “an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement of the rights of the patentee.”²⁵ When an invention is “made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized[.]”²⁶

The exception was held to be “truly narrow” by the CAFC in *Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc.*²⁷ In *Roche*, the court held that the experimental use rule could not be construed 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.”²⁸ The defense is also limited to “tests, demonstrations, and experiments” *not* “in keeping with the legitimate business” of the alleged infringer.²⁹

The only case to address the experimental use of a patented invention by a non-profit educational institution is *Ruth v. Stearns-Rogers Mfg. Co.*³⁰ In *Ruth*, a Colorado district court held that the experimental use defense was available to manufacturers of mining and milling machinery against a claim of contributory infringement since the end-user/purchaser was the Colorado School of Mines.³¹ It held that “[t]he making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement.”³²

CAFC’s Decision

The CAFC held that the district court had applied an overly broad version of the experimental use defense and remanded for application of the narrower version set out in its opinion. However, it is arguable whether there is anything for the district court to do on remand other than to find the defense unavailable to Duke, since, according to the Court, “*Duke’s acts*

²⁵ *Peppenhause v. Falke*, 19 Fed. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

²⁶ W. Robinson, *The Law of Patents for Useful Inventions* § 898 (1890).

²⁷ *Roche Prods., Inc. v. Bolar Pharm. Co., Inc.*, 733 F.2d 858, 863 (Fed. Cir. 1984).

²⁸ *Id.* (holding that conducting tests on a patented drug in order to get FDA approval did not fall within the experimental use exemption).

²⁹ *Pitcairn v. United States*, 547 F.2d 1106, 1125-26 (Fed. Cir. 1977).

³⁰ *Ruth v. Stearns-Rogers Mfg. Co.*, 13 F. Supp. 697 (D. Colo. 1935).

³¹ *Id.* at 713.

³² *Id.*

appear to be in accordance with any reasonable interpretation of Duke’s legitimate business objectives.”³³

The CAFC further held that no “conduct that is in keeping with the alleged infringer’s legitimate business, regardless of commercial implications[,]” is immunized from a claim of patent infringement.³⁴ It went on to state that the sanctioning and funding of research projects with arguably no commercial application whatsoever by institutions such as Duke “unmistakably further the institution’s business objectives, including educating and enlightening students and faculty participating in these projects.”³⁵ In the view of the CAFC, “the district court attached too great a weight to the non-profit, educational status of Duke.”³⁶

The CAFC dismissed *Ruth*’s reliance on the combination of “apparent lack of commerciality, with the non-profit status of the educational institution” as “not consistent with the binding precedent or [its] case law[.]” The Court thereby held that such reliance cannot serve as the sole basis for holding that the experimental use defense applied “without any detailed analysis of the character, nature and effect of the use[.]”³⁷

The basic rule established by the Court was that:

[R]egardless 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.³⁸

In this holding, therefore, the Court shifted the focus of the experimental use defense from the commercial versus noncommercial nature of the experimentation and the profit versus non-profit status of the alleged infringer to merely a question of whether the use was in furtherance of the alleged infringer’s legitimate business.

Arguments for Broader Version of Exemption

Chilling Effect on Academic Scientific Research

Duke argues that the CAFC’s decision “effectively eliminate[s] the experimental use exception for research institutions” since “[n]o research institution will be able to demonstrate

³³ *Madey v. Duke University*, 307 F3d 1351, 1362. (Fed. Cir. 2002) (*Emphasis added*).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

that its experimental use of any patent fails to further the institution's 'legitimate business.'"³⁹ In so doing, the holding disrupts the "balance between the need to promote innovation and the recognition that imitation and refinement through imitation are necessary to invention itself" which is embodied in the federal patent laws⁴⁰ and overrides "Congress' legislative judgment" turning "the experimental use exception on its head."⁴¹

Without the experimental exemption, research institutions like Duke will be at the mercy of patent holders. "This 'proliferation of intellectual property rights' now allows each individual patent holder 'to set up another tollbooth' delaying or even blocking further research innovation."⁴² These "tollbooths" consist of license agreements that will have to be agreed upon for each of the patents underlying a contemplated research project. This increases both the cost and duration of valuable research. A significant threat is that "uncooperative patent holder[s] will demand[] unreasonable returns in exchange for the right to use a particular patent."⁴³ Experiments may be precluded altogether if the patentee refuses to license use of his or her patented invention. Researchers may be forced to stop in the middle of a project upon the realization that a new patent has been implicated in the course of their experimentation. Other concerns for research institutions include "administrative and financial costs to cover patent searches, infringement opinions, ... and the inevitable litigation."⁴⁴

This result "threatens to delay or stymie research"⁴⁵ conducted by such institutions, inevitably affecting scientific progress in general. Non-profit educational institutions like Duke conduct a significant portion of the research and development crucial to scientific progress. Approximately 43% of all basic research is conducted in universities.⁴⁶ It is this basic research, as opposed to more targeted and focused research, that contributes to important discoveries and inventions. For example, in its *Amici Curiae* submitted to the Supreme Court in support of Duke, Consumer Project on Technology (CPT) and Public Knowledge (PK) cited a brochure entitled *Why Do Basic Research?* published by the National Institute General Medical Sciences, National

³⁹ Petition for a Writ of Cert. at 13-14.

⁴⁰ *Bonito Boats, Inc v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

⁴¹ Petition for a Writ of Cert. at 14.

⁴² *Id.* at 18 (citing Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *Science* 698, 698-99 (1998)).

⁴³ *Id.* at 21.

⁴⁴ Brief of Amici Curiae Association of American Medical Colleges at 3, Madey (No. 02-1007).

⁴⁵ Petition for a Writ of Cert. at 16.

⁴⁶ See National Science Foundation, *Science and Engineering Indicators 2002, Academic Research and Development, Highlights, Financial Resources for Academic R&D*, at www.nsf.gov.

Institute of Health.⁴⁷ The brochure documents the results of a study in which 90 physicians were asked to “list the top 10 developments in cardiovascular-pulmonary medicine.”⁴⁸ The roots of the medical breakthroughs were then traced, and it was found that “42 percent of the conceptual steps in the development of the 10 most important medical treatments” came from basic researchers.⁴⁹

“This nation has benefited enormously in the past from noncommercial academic scientific research, as more discoveries and greater understanding of the unknown have facilitated commercial research leading to new and socially beneficial products and applications.”⁵⁰ “The [CAFC’s] decision ... threatens to stifle that research and thereby endanger this nation’s continued leadership in science and technology.”⁵¹

CAFC Ignores History of Experimental Use Exemption as Applied to Non-Profit Researchers Conducting Non-Commercial Experiments

The Association of American Medical Colleges, the American Council on Education, various individual colleges, universities and medical schools, and several other organizations argue that the CAFC’s decision is in contrast to the historical exemption that non-profit educational institutions enjoyed when their research was *noncommercial*.⁵² They claim that “[i]n determining the type of ‘experimental use’ entitled to exemption, courts historically drew the line between commercial and noncommercial research.”⁵³ In their *Amici Curiae* in support of Duke, these various organizations cite a study “based upon ‘70 interviews with personnel at biotechnology and pharmaceutical firms and universities’” that, to them

confirms that ‘university researchers, to the extent that they are doing noncommercial work, are largely left alone’ and that in those rare instances when universities received letters alleging infringement ‘the typical response was effectively to ignore such letters and inform the [patent] holder that the university was engaged in research, did not intend to threaten the firm’s commercial interests, and would not cease its research.’⁵⁴

⁴⁷ Brief of Amici Curiae Consumer Project on Technology and Public Knowledge at 6, *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002) (No. 02-1007).

⁴⁸ National Institute General Medical Sciences, National Institutes of Health, *Why Do Basic Research?*, at http://www.nigms.nih.gov/news/science_ed/whydo.html.

⁴⁹ *Id.*

⁵⁰ Brief of Amici Curiae Association of American Medical Colleges at 16.

⁵¹ *Id.* at 3.

⁵² *Id.* at 5.

⁵³ *Id.* at 6.

⁵⁴ *Id.* at 8 (citing J. Walsh, A. Arora, and W. Cohen, “The Patenting and Licensing of Research Tools and Biomedical Innovation,” 2, 35, in National Academy of Sciences, *Patents in the Knowledge-Based Economy* (2003)).

Duke also argues that it was the “long-settled expectations of the scientific community ... that non-profit research institutions may make experimental use of patented inventions without running afoul of the patent law”⁵⁵ and that a “universal assumption among universities and academic researchers was that the experimental use exception permitted non-profit researchers to conduct non-commercial experiments without regard to possible patent infringement.”⁵⁶ The Supreme Court, in *Festo Corporation. v. Skoketsu Kinzoku Kogyo Kabushki Co. Ltd.*, held that Congress alone has the responsibility for making fundamental changes to settled law, since such changes “risk destroying the legitimate expectations” of the investing community.⁵⁷ Arguable, the CAFC ignored this proscription with regards to the scope of the experimental use defense, thus warranting Supreme Court intervention.

Conclusion

In recognition of the goal of promoting the progress of science, it has been well settled that individuals who use a patented invention without authorization will be able to escape liability for infringement if that use is merely for experiment and produces no pecuniary result. The exception has been held to be quite narrow, but prior to the CAFC’s decision, has been based primarily on the commercial versus noncommercial implications of the research and the profit versus non-profit status of the alleged infringer.

Arguably, the CAFC has deviated from the history of the experimental use exception disrupting the “settled expectations of the inventing community[.]”⁵⁸ The impact that this decision will have on basic research, and in turn scientific progress, is yet to be determined. However, it is clear that, under the CAFC’s new test, universities and non-profit organizations now face numerous additional obstacles to their performance of basic research, and it is this result and the fear that such a result will inevitably stifle the progress of science that has incited much outcry from the scientific community.

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⁵⁵ Petition for a Writ of Cert. at 16.

⁵⁶ *Id.* at 18 (citing John P. Walsh et al., *Research Tool Patenting and Licensing and Biomedical Innovation* 44 (Dec. 11, 2002); Rubenstein, *Promega Wins Round in European Patent Office*, *Legal Times*, Aug. 2001, at 26).

⁵⁷ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushki Co.*, 122 S. Ct. 1831, 1841 (2002) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997)).

⁵⁸ *Id.*