Nos. 02-1052, 02-1065

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

INTEGRA LIFESCIENCES I, LTD., et al.

Plaintiffs-Appellees,

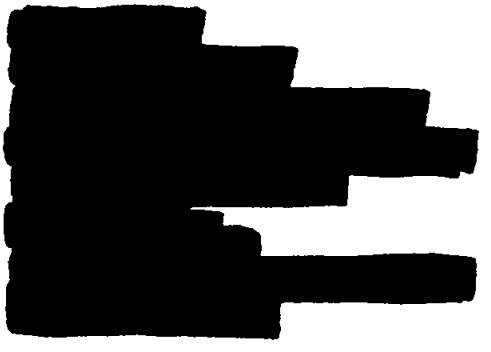
v.

MERCK KGaA,

Defendant- Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA IN NO. 96-CV-1307, SENIOR JUDGE JAMES M. FITZGERALD

BRIEF OF *AMICI CURIAE* CONSUMER PROJECT ON TECHNOLOGY, ELECTRONIC FRONTIER FOUNDATION, AND PUBLIC KNOWLEDGE IN SUPPORT OF DEFENDANT-APPELLANT



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October 17, 2005

CERTIFICATE OF INTEREST

Counsel for *Amici Curiae* Consumer Project on Technology, Electronic Frontier Foundation, and Public Knowledge certifies the following:

1. The full name of every party or *amicus curiae* represented by me is: Consumer Project on Technology; Electronic Frontier Foundation; and Public Knowledge.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: Consumer Project on Technology; Electronic Frontier Foundation; and Public Knowledge.

3. All parent corporations and any publicly held companies that own 10 percent of the stock of the party or *amicus curiae* represented by me are: None.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus curiae* now represented by me in the trial court or are expected to appear in this Court are:

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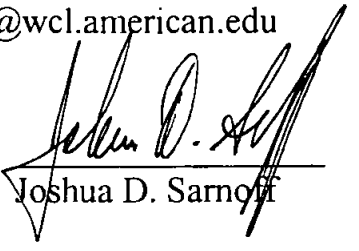
Signed: 
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Date: October 17, 2005

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutory Materials

Other Authorities

STATEMENT OF INTEREST OF *AMICI*

This brief is filed by the Consumer Project on Technology (CPTech), the Electronic Frontier Foundation (EFF), and Public Knowledge (PK).[1]

CPTech is a public interest non-profit organization founded by Ralph Nader in 1995. CPTech represents the public who are the ultimate beneficiaries of the invention of new technologies. CPTech is concerned that a mistaken understanding of experimental use, as a narrow exception to infringement rather than as a broad category of non-infringing conduct, will delay or impede scientific and technological developments that benefit the public.

EFF is a nonprofit, membership-supported civil liberties organization working to protect consumer interests, innovation and free expression in the digital world. EFF and its 15,000 dues-paying members are concerned to preserve the public benefits that result from research and innovative efforts unencumbered by patent litigation and licensing threats.

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[1] This Court *sua sponte* authorized the filing of briefs amicus curiae. Parties' Counsel have consented to the filing of this brief and a motion for leave to file has been submitted. No part of this brief was authored by counsel for any party and no party, person, or organization contributed besides *Amici* and their counsel. Gina Bassi, Guinevere Jobson, Rashmi Rangnath, and Alyssa Sandrowitz, students at the Washington College of Law, assisted in the preparation and filing of this brief.

PK is a public-interest advocacy organization dedicated to fortifying and defending a vibrant information commons. PK is concerned that information protected by patents should remain free for use in scientific research and technological innovation.

CPTech, EFF, and PK filed an amicus brief in support of Petitioner in the Supreme Court in this case, and CPTech and PK filed an amicus brief in support of the Petition for Certiorari in *Duke Univ. v. Madey*. No. 02-1007.

SUMMARY OF ARGUMENT

Defendant-Appellant Merck KGaA (Merck) correctly argues that the experiments at issue in this appeal cannot create liability as a matter of law. But while Merck focused its defense on Section 271(e)(1), this Court need not and should not reach out to address that section. Unless and until it is clear that the proven conduct could run afoul of Section 271(a), the conceptual predicate for consideration of Section 271(e)(1) is absent. The Court should apply the correct law – Section 271(a) – in this case. A challenge to the sufficiency of the evidence on which a jury rejected the application of Section 271(e)(1), moreover, should constitute a challenge to the sufficiency of the same evidence to find that Section 271(a) applies. No conduct that could infringe Section 271(a) was proved here, and the verdict of infringement thus cannot be sustained.

Since it was first articulated in 1803, the experimental use "exception" has been a judicial interpretation of the limits of infringing conduct under the Patent Act, and not a statutory exception or an affirmative defense. For claims of patent infringement, as for any other claim for a statutory violation, the burden is on the plaintiff to plead and prove the existence of prohibited conduct. Accordingly, the Court should address the interpretive

limits to Section 271(a) in regard to the proven scientific research experiments at issue here.

Congress never intended to prohibit as patent infringement under Section 271(a) any "making" and "use" in regard to scientific research. Because the proven experiments at issue do not constitute conduct within the scope of the statutory prohibition, there was no basis for a jury finding of liability under Section 271(a). As a result, regardless of the interpretation of Section 271(e)(1), Merck cannot be held liable.

This Court should act now to limit the harms caused by the earlier decision in *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002), which harms otherwise will continue to expand over time. It is important for this Court to clarify that the experimental use exception is an interpretive limit on conduct prohibited by Section 271(a), and that Section 271(a) simply does apply to making for and use of patented inventions in scientific research.

ARGUMENT

I. This Court Should Determine This Case Based on Experimental Use Limits to Section 271(a).

To avoid either a potential miscarriage of justice from upholding the infringement verdict, or an advisory opinion on the scope of Section 271(e)(1), this Court should reverse the judgment below based on the "experimental use exception."[2] Merck argued below and on appeal[3] that the proven scientific research experiments cannot impose liability, as a matter of law based on construction and application of Section 271(e)(1).[4] But because Section 271(e)(1) does not itself provide for liability, the conceptual predicate to its application is potentially infringing conduct under Section

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[2] Although this Court in this case and others has referred to the "common law experimental use exception," *Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 863 n.2 (Fed. Cir. 2003), experimental use is neither a statutory nor a common law exception to infringing conduct. Rather, it is conduct that is not prohibited in the first place. *See infra* sections II and III. Because the language of exception is so commonly employed, however, *Amici* also refer to the "experimental use exception" below.

[3] This case is pending on appeal from a motion for judgment as a matter of law (JMOL), in which Merck objected to the sufficiency of the evidence to support the jury finding of infringement in regard to specific experiments allegedly induced by Merck. *See Memorandum in Support of Motion of Merck KGaA for Judgment as a Matter of Law on the FDA Exemption 35 U.S.C. § 271(e)(1)*, at 50-51 (filed Oct. 16, 2000) (Merck Memorandum).

[4] In its motion, Merck stated that, "[e]ven viewing the facts in the light most favorable to Plaintiffs, no reasonable jury, applying the correct rule of law, could have concluded otherwise." Merck Memorandum at 1 (emphasis added). Merck pressed the same point on appeal. *See Brief for Defendant-Appellant Merck KGaA* (Feb. 13, 2002), at 41-52.

271(a). *See* 35 U.S.C. § 271(e)(1); *cf. Roche Prods. Inc. v. Bolar Pharms. Co.*, 733 F.2d 858, 862-65 (Fed. Cir. 1984) (finding liability under Section 271(a), following its broad construction in light the experimental use exception); *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1276 (N.D. Cal. 1991) ("Congress enacted § 271(e) in 1984 in order to reverse the experimental use exception holding of the United States Court of Appeals for the Federal Circuit in *Roche*."). Because Section 271(a) simply does not prohibit the experiments at issue, *see infra* section III, the conceptual predicate for a consideration of Section 271(e)(1) in this case is missing.[5] This Court need not and should not reach out to address the scope and application of Section 271(e)(1), but rather should address the predicate and actual issue in dispute – the scope of Section 271(a).

As this Court stated in *Markman v. Westview Instruments, Inc.*, "on review of a motion for JMOL the court retains the power and duty to say what the correct law is, and then to examine the factual issues submitted to

[5] Other cases may arise that will raise the scope and application of Section 271(e)(1), for conduct that otherwise would clearly violate Section 271(a). For example, Section 271(e)(1) applies to sales and offers for sale of the patented invention for the requisite types of experiments, which conduct is prohibited by Section 271(a). *See, e.g., Brief of* Amici Curiae *Consumer Project on Technology, Electronic Frontier Foundation, and Public Knowledge in Support of Petitioner* (S.Ct. No. 03-1237, Feb. 22, 2005), at 11 (hereinafter *Amici's* Supreme Court Brief). A motion for leave to file *Amici's* Supreme Court Brief as a separate Appendix for the convenience of this Court has been submitted.

the jury and determine whether findings thereon are supported by substantial evidence and support the verdict under the law." 52 F.3d 967, 975 (Fed. Cir. 1995) (emphasis added).[6] To perform its duty, this Court must articulate and apply the correct law[7] – Section 271(a) – which here prevents the Court from upholding the verdict. Given the lack of proof of an underlying violation of Section 271(a), no reasonable jury could have found for Plaintiffs-Appellees.

This Court has previously shown no reluctance to rule on appeal on legal issues that were not raised by either party, so as to clarify the proper scope of the statute and to apply the correct law. *See, e.g., Fuji Photo Film Co., Ltd. v. Jazz Photo Corp.*, 394 F.3d 1368, 1377 (Fed. Cir. 2005) (noting that the Court's prior ruling in the same case addressed a legal issue that had not been raised by the parties below or on appeal). As cogently stated in *SmithKline Beecham Corp. v. Apotex Corp.*, "where the legal implication of the[] facts is clear," this Court should raise issues *sua sponte* rather than "try to contort the aspects of patent law raised by the parties in order to avoid ...

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[6] The issues involved in this appeal are questions unique to patent law and therefore Federal Circuit law applies. But even if 9th Circuit law were to apply, the Court should apply *de novo* review to these questions of law. *See Markman*, 52 F.3d at 975; *Monroe v. City of Phoenix, Arizona*, 248 F.3d 851, 861 (9th Cir. 2001).

[7] For somewhat different policy reasons, this Court must address issues of validity even when they are not raised by the defendant. *See, e.g., Slawson v. Grand St. R.R.*, 107 U.S. 649, 652 (1883); *Cardinal Chem. Co. v. Morton Int'l. Inc.*, 508 U.S. 83, 100 (1993).

anomalies." 403 F.3d 1331, 1355 & n.5 (Fed. Cir. 2005) (Gajarsa, J., concurring).

A challenge to the sufficiency of the evidence for the jury to reject the application of Section 271(e)(1), moreover, should be deemed to preserve a challenge to the sufficiency of the same evidence for the jury to find that Section 271(a) applies. The scope of Section 271(e)(1) is historically and integrally related to the scope of application of Section 271(a) and the experimental use exception. *See Integra LifeSciences I, Ltd.*, 331 F.3d at 875-77 (Newman, J., dissenting); *Amici's* Supreme Court Brief at 4-11. In its earlier opinion in this case, however, this Court refused to reach the issue of experimental use under Section 271(a) because the trial court did not provide the jury with instructions on that issue and Merck does not press the issue in its current arguments. *See* 331 F.3d at 863 n.2. But as this Court recently stated:

> An appellate court retains case-by-case discretion over whether to apply waiver. *Singleton v. Wulff*, 428 U.S. 106, 120 ... (1976).... The test is whether there is a legally sufficient basis for a reasonable jury to find for the nonmoving party "under the controlling law[.]" Fed.R.Civ.P. 50(a)(1). The longstanding test for appeals of the denial of JMOL ... is whether the evidence presented can suffice, as a matter of law, to support a jury verdict, and "review of [a] JMOL-denial is not restricted to the law as stated in the jury instructions."

Harris Corp. v. Ericsson Inc., 417 F.3d 1241, 1251-52 (Fed. Cir. 2005) (citations omitted) (emphasis added).

The Supreme Court in *Singleton* was even more forceful that appellate courts may review judgments on any relevant grounds.

> The matter of what questions may be taken up and resolved for the first time on appeal is one left primarily to the discretion of the courts of appeals, to be exercised on the facts of individual cases. We announce no general rule. Certainly there are circumstances in which a federal appellate court is justified in resolving an issue not passed on below, as where the proper resolution is beyond any doubt ... or where "injustice might otherwise result."

428 U.S. at 121 (emphasis added).

An injustice clearly would result if this Court were to uphold a jury verdict in which infringement was found in regard to conduct that Congress had never intended to prohibit under Scction 271(a). Moreover, to do so would usurp a power that the legislature has not delegated. *Cf. Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 195 (1978) ("[T]he commitment to the separation of powers is too fundamental for [courts] to pre-empt congressional action by judicially decreeing what accords with common sense and the public weal.") (internal quotation marks and citation omitted). The proper resolution here is beyond any doubt, that Section 271(a) does not apply to making or using a patented invention for or in scientific

experimentation. This resolution prevents any finding of infringement here, and avoids any need to construe Section 271(e)(1).

II. The Experimental Use "Exception" Is a Statutory Interpretation of the Limits of Section 271(a).

In Article I, Section 8, clause 8, the U.S. Constitution authorizes Congress alone to enact patent legislation providing limited exclusive rights, which rights convey the power to exclude only to the extent specified by legislation. Like copyright law, patent liability is purely statutory. *Cf. Wheaton v. Peters*, 33 U.S. (8 Pet.) 591, 661 (1834) ("Congress, then, by this act, instead of sanctioning an existing right, as contended for, created it."). Since 1790, Congress has legislated under the Patent Act to provide rights that prohibit only specific forms of conduct. *See, e.g.*, Act of Apr. 10, 1790, ch. 7, § 1, 1 Stat. 109 ("exclusive right and liberty of making, constructing, using and vending to others to be used") (currently codified as subsequently amended at 35 U.S.C. §§ 154(a), 271(a)).

The experimental use "exception" is neither a statutory nor a common law exception to infringement liability. It is an integral limit of the scope of the exclusive patent right that has been codified by Congress. The so-called exception is nothing more – nor less – than a statutory interpretation of Section 271(a)'s (and its predecessors') prohibitions of specified conduct.

Not long after the enactment of the Patent Act, in *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600), Justice Story first articulated the reason why the patent laws circumscribe infringement to exclude experimental uses of patented inventions, and unauthorized making of patented inventions for such uses:

> [a]nother objection is to the direction, that the making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right, for which an action was given by the statute. This limitation ... was adopted by the court from the consideration, that it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.

Id. at 1121 (emphasis added).[8] Such language clearly indicates that Justice Story was engaged in statutory interpretation to elaborate what conduct Congress prohibited, and was not engaged in creating affirmative defenses to prohibited conduct through its common law or equitable rulemaking powers.

[8] The term "philosophical experiments" was understood to refer to scientific research in general, and research on physical principles in particular. *See Amici's* Supreme Court Brief at 13 & n.10 (citing sources). Although it does not affect the outcome of this case, "philosophic experiments" were not limited to research on the patented invention – as was the alternative clause referring to "ascertaining the sufficiency" – but encompassed research with the patented invention.

After *Whittemore*, Justice Story and other judges understood that the experimental use exception articulated the statutory limits of the Patent Act's exclusive rights. In *Sawin v. Guild*, Justice Story held that:

> [i]t is a sound rule of law, that every statute is to have a reasonable construction; and its language is not to be interpreted so as to introduce public mischiefs, or manifest incongruities, unless the conclusion be unavoidable.... We should not incline to adopt such a construction, unless we could give no other reasonable meaning to the statute.... This court has already had occasion to consider the clause in question, and upon mature deliberation, it has held that the making of a patented machine to be an offence within the purview of it, must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification. *Whittemore v. Cutter* [Case No. 17,600]. In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.

21 F. Cas. 554, 554-55 (C.C.D. Mass. 1813) (No. 12,391) (emphasis added). When disagreeing in dicta with the scope of the experimental use exception adopted by Justice Story, Justice Curtis made clear that the Court was engaged in interpreting the limits to what Congress had prohibited. *See Byam v. Bullard*, 4 F. Cas. 934, 935 (C.C.D. Mass. 1852) (No. 2,262). Justice Curtis thus interpreted the related statutory term "vend to others" to exclude certain sales from being considered an infringement.

> But the law now in force contains no such provision; and if it did, I should still be of the opinion, that a sale to the patentee himself was not such a sale as was intended by the statute; that no sale was within its meaning, except one which would be

> within the terms of the grant contained in the letters-patent, which is a grant of an exclusive right to make, use, and vend to others to be used. In this case, I am of opinion that the sale to the plaintiffs' agent was a sale to them, and that such a sale is not, per se, an infringement.

Id. *See also Poppenhusen v. Falke,* 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279) ("I do not think the facts disclosed warrant the conclusion that these were within that class of experiments protected by law."). As recognized by Judge Giles Rich after passage of the 1952 Patent Act, Congress simply has not prohibited experimental uses of patented inventions. *See In re Kirk,* 376 F.2d 936, 965 (C.C.P.A. 1967) (Rich, J., dissenting) ("experimental use is not infringement").

The Supreme Court has similarly held that "public use" under Section 102(b) (and its predecessors) was not intended to and did not include experimentation within its ambit.

> That the use of the invention in question was public in one sense cannot be disputed. But can it be said that the invention was in public use? The use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as such a use.

City of Eliabeth v. American Nicholson Pavement Co., 97 U.S. 126, 134 (1877) (emphasis added).

When articulating the "fair use" doctrine in copyright law thirty years after the experimental use doctrine in patent law, Justice Story also

interpreted the Copyright Act's limits to prohibited conduct. *See Folsom v. Marsh,* 9 F. Cas. 342, 348 (C.C.D. Mass. 1841) (No. 4901) ("The question, then, is, whether this is a justifiable use of the original materials, such as the law recognizes as no infringement of the copyright of the plaintiffs.") (emphasis added). Subsequently, Justice Clifford – relying on Justice Story – and later Judge Learned Hand, "seemed also to speak of fair use as merely the contrary of infringement." Benjamin Kaplan, *An Unhurried View of Copyright* 67 (Columbia U. Press 1967) (*citing Lawrence v. Dana,* 15 F. Cas. 26, 60 (C.C.D. Mass. 1869) (No. 8163); *Nichols v. Universal Pictures Corp.*, 45 F.2d 119, 121 (2d Cir. 1930); and *Sheldon v. Metro-Goldwyn Pictures Corp.*, 81 F.2d 49, 54 (2d Cir. 1936)).[9] Whether or not Congress subsequently altered the shape of copyright law in 1976 when codifying the fair use doctrine, *see* 17 U.S.C. § 107,[10] Congress has not similarly codified

[9] *See also Sony Corp. of America, Inc. v. Universal City Studios, Inc.*, 464 U.S. 417, 434, 451, 454-55 (1984) ("To prevail, [plaintiffs-respondents] have the burden of proving that users of the Betamax have infringed their copyrights and that Sony should be held responsible for that infringement.... In this case, respondents failed to carry their burden with regard to home time-shifting.... [W]e must conclude that this record amply supports the District Court's conclusion that home time-shifting is fair use.") (emphasis added).

[10] *See Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 590 & n.20 (1994) (suggesting that Congress made fair use an affirmative defense in 1976).

experimental use as an "exception" or "affirmative defense" to the limits of infringement under the Patent Act.[11]

To demonstrate infringing conduct, the plaintiff must prove an act that is prohibited and (if required) conducted with the requisite intent. *General Electric Co. v. United States*, 572 F.2d 745, 783 n.17 (Ct. Cl. 1978) ("Plaintiff, of course, has the burden of proof on issues relating to infringement."). It is axiomatic that this Court cannot shift the Plaintiffs-Appellees' burden to Defendant-Appellant, nor uphold a challenged verdict of patent infringement without proof of conduct that is prohibited by Section 271(a). "It would make no sense to give the defendant a defense of showing

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[11] Even when codifying contributory liability under Section 271(c), Congress did not impose on defendants the burden of proving their lack of infringing intent or a "staple article or commodity of commerce." 35 U.S.C. § 271(c). Rather, Congress required plaintiffs to prove that the defendant intended to infringe and that the article was not a staple. *See, e.g., Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 491 (1964) ("Aro cannot be held liable in the absence of a showing that at that time it had already acquired the requisite knowledge that the Ford car tops were patented and infringing") (emphasis added); *United States Surgical Corp. v. Hospital Prods. Int'l Pty. Ltd.*, 701 F. Supp. 314, 350 (D. Conn. 1988) ("In order to state a claim under § 271(c), the plaintiff must establish: ... (c) that the thing sold is not a staple article or commodity of commerce suitable for substantial noninfringing use") (emphasis added). Similarly, the plaintiff must prove the relevant intent before liability can be found for active inducement under Section 271(b). *See, e.g., Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990) ("The plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements.").

affirmatively that the plaintiff cannot succeed in proving some element (like confusion)." *KP Permanent Make-Up, Inc. v. Lasting Impression I, Inc.*, 125 S. Ct. 542, 549 (2004) (rejecting the argument that a trademark "fair use" defendant under 15 U.S.C. § 1115(b)(4) must "show confusion unlikely," as the burden of proving likelihood of confusion under 15 U.S.C. § 1114 "rests with the plaintiff"). Accordingly, this Court must determine whether the proven experiments were prohibited under Section 271(a).[12]

III. Section 271(a) Does Not Prohibit The Scientific Experiments At Issue.

As explained in detail in *Amici's* Supreme Court Brief at 4-11, Congress intended in Section 271(e)(1) to correct – in regard to specific types of research leading to regulatory approval by the Food and Drug Administration (FDA) – this Court's unwarranted extension of infringement liability under by Section 271(a), which resulted from its erroneous restriction of the experimental use exception. The experimental use limits to

[12] Although this Court recognized in *Madey v. Duke Univ.*, that experimental use is not an affirmative defense and correctly held that the plaintiff has the burden of proving infringing conduct, this Court improperly held that the plaintiff is not required to prove "as part of his initial claim that [the defendant's] use was not experimental. The defense, if available at all, must be established by [the defendant]." 307 F.3d 1351, 1361 (Fed. Cir. 2002). Whatever motivations may have existed for placing the burden of proof on the defendant, there is no warrant for this Court to rewrite the statute and create liability for conduct (or intentions) that Congress did not prohibit.

Section 271(a) and the express protection from infringement liability of Section 271(e)(1) thus overlap. Both rationales prevent the conduct at issue here – legitimate *in vitro* and animal experiments performed to develop information for FDA approval – from being considered infringement under Section 271(a). For the reasons stated above and in section IV below, this Court should address Section 271(a), which (properly understood) will make it unnecessary to reach Section 271(e)(1).

Section 271(a) was never intended to prohibit "making" or "using" for legitimate scientific research of any kind, or even for use in evaluations of patented inventions by the patent holder's competitors. *See Amici's* Supreme Court Brief at 12-16. Congress intended to prohibit only the making of an invention "with an intent to use for profit," which could deprive the owner of a relevant commercial market (that did not include use for research, including competitive research). *Sawin*, 29 F. Cas. at 555; *Amici's* Supreme Court Brief at 13-14. Thus, infringement could be found only for scientific research or competitive evaluations that were proved to be a sham for actual commercial activity, or for commercial sales of the invention during the patent term that followed legitimate research or competitive evaluations. *See Amici's* Supreme Court Brief at 17-19. There is no suggestion here that the experiments at issue were not legitimate, or

that the patented materials were used in a commercial manner rather than in scientific research leading to the submission of data to the National Cancer Institute. *See Merck KGaA v. Integra LifeSciences I, Ltd.*, 125 S.Ct. 2372, 2378-80 (2005). Thus, there is no conduct at issue here that could infringe the patent under Section 271(a).

IV. This Court Should Limit the Harms Being Caused By *Madey*, By Confirming That Congress Did Not Prohibit Experimental Uses.

This Court should act now to limit the harms being caused by the earlier decision in *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002). The proliferation of patents on biotechnology and in other fields combined with this Court's earlier broad construction of Section 271(a), *i.e.*, its narrow construction of the experimental use exception, threatens the ability of scientists to perform research having great importance to society. *See Amici's* Supreme Court Brief at 21-27. *Amici* raised in the Supreme Court substantial concerns that this Court's decisions have changed the public's understanding of the scope of the experimental use exception, and that the correspondingly expanded scope of liability under Section 271(a) is exerting a social-welfare-decreasing chill on the progress of science and technological development. *See id.* at 26-28 (also discussing the potential for off-shoring of research given the broader scope of foreign experimental

use exceptions). Empirical research proves that *Amici's* concerns are valid and that the problem is expanding.

A recent study demonstrates that the number of scientific researchers who are being subjected to threatening "notification letters" has increased since the *Madey* decision. *See* John P. Walsh, Charlene Cho & Wesley M. Cohen, *View from the Bench: Patents and Material Transfers*, 309 Science 2002 (2005) (increase from 3% to 5%); *see also id.* (notification by scientists' own institutions to respect patent rights has increased from 15% to 22%). Worse yet, scientists are foregoing or delaying their research as a result of patents, although still at relatively low levels. *See id.* (of those aware of potentially applicable patents, 4 of 32 – 12.5% – changed their research approach, and 5 of 32 – 15.6% – were delayed by at least a month). Significantly, as the authors' acknowledge, the relatively low current levels of harm to research depend on researchers continuing to flout the implications of the *Madey* decision and on the continued forbearance of patent holders from suing them.

> Our research thus suggests that "law on the books" need not be the same as "law in action" if the law on the books contravenes a community's norms and interests.... [W]hen research is itself also a commercial activity, patent holders are much more likely to assert and clinical researchers more likely to abandon infringing activity.

Id. As recognition and understanding of the *Madey* decision continues to expand and as patent holders increasingly make use of all opportunities to obtain licensing revenue, the willingness of scientists and their institutions to ignore patents will continue to deteriorate. The predictable result will be more foregone research, more delays, and decreased innovation for public benefit.

This Court should act now to protect the progress of Science and useful Arts, before this unstable situation is pushed past the tipping point and scientific research is much more substantially impeded. By holding clearly in this case that Congress did not prohibit scientific research using patented inventions under Section 271(a), but rather has protected such research from infringement, this Court will bring the social-welfare-enhancing conduct of the overwhelming majority of scientists and other researchers back under the protection of the law.[13] As evidenced by the facts of this case, where the researchers sought to test and obtain FDA approval for a potential cure for

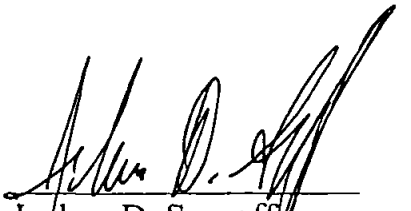
[13] This Court should make clear that such research with patented inventions is protected from infringement even if it may lead the scientists to potentially lucrative new products. If such products also infringe the patent and are sold during the patent term, the patent holder will have its remedy. If the products do not infringe or are not sold during the patent term, the patent holder should not be able to hold up such innovation, which would effectively extend the patent right or the patent term. *See Amici's* Supreme Court Brief, at 14-15.

cancer, the potential benefits to society of a clear and protective rule are immense.

CONCLUSION

For the foregoing reasons, the Court should vacate the judgment and hold that Section 271(a) does not prohibit the experiments at issue.

Respectfully submitted,



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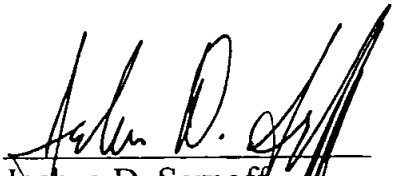
CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure, I certify that the foregoing Brief of *Amici Curiae* Consumer Project on Technology, Electronic Frontier Foundation, and Public Knowledge is double-spaced (except headings, block quotations, and footnotes) and complies with the type volume limitations of Rule 29(d) of the U.S. Court of Appeals for the Federal Circuit and this Court's August 17, 2005 Order. I further certify that the body of this brief – not including the cover page, table of contents, table of authorities, and certificates – contains 4943 words as determined by Microsoft Word, including the statement of interest, headings, footnotes, quotations, signature lines, and date.



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October 17, 2005

CERTIFICATE OF SERVICE

I, Joshua D. Sarnoff, hereby certify that I caused two copies of the foregoing Brief of *Amici Curiae* Consumer Project on Technology, Electronic Frontier Foundation, and Public Knowledge to be served this seventeenth (17th) day of October 2005, by first class mail, postage prepaid, upon each of the following Counsel of Record:

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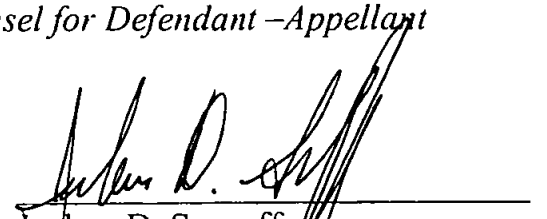

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