

EXPERIMENTAL USE EXCEPTION FOR RESEARCH TOOLS

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I. INTRODUCTION

An increasing number of patents on upstream discoveries have seemingly had a stifling effect on further beneficial investigation by limiting access to patented foundational discoveries.¹ In the past, upstream research results were disclosed to the public without seeking intellectual property rights, so they could be used by any investigator without restriction. The motives for innovation were usually based on the reputation and prestige resulting from successful work. Such upstream discoveries, however, are now being patented, probably due to “changes in the innovation system” and “the utilization of patents in new fields of technology.”²

Heller and Eisenberg discussed the “tragedy of the anticommons” where “people underuse scarce resources because too many owners can block each other.”³ They contended that if “[p]rivatization of biomedical research” is not “carefully deployed to sustain both upstream research and downstream product development,” more patent rights “may lead paradoxically to fewer useful products for improving human health.”⁴ Therefore, some commentators have proposed the introduction of compulsory licensing and broad experimental use exception schemes as approaches to prevent such an impeding effect on innovation.⁵

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¹ See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Sci. 698 (1998).

² See National Research Council of the National Academies, *A Patent System for the 21st Century* 39-41 (Stephen A. Merrill et al. eds., The Natl. Acad. Press 2004).

³ Heller & Eisenberg, *supra* n. 1, at 698.

⁴ *Id.*

⁵ See Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and*

Some other commentators, however, have stressed that the function of the patent system is to provide patentees with returns on their investment of resources.⁶ They argue that the broad experimental use exception would prevent inventors from disclosing their new inventions and reduce innovative activities in the biomedical industry that rely heavily on patent protection.⁷

Since United States patent law does not have a compulsory licensing doctrine, judicial disputes regarding research tool patents have relied on the experimental use doctrine.⁸ Therefore, this paper will focus on the experimental use exception to infringement of patented research tools. Specifically, Part II of this paper will review the definition of research tools. Part III will analyze how the experimental use exception has been applied and interpreted in terms of the common law experimental use doctrine and 35 U.S.C. § 271(e)(1) in the United States. Part IV focuses on the broad experimental use exception provisions in Germany and Japan. Finally, Part V will discuss preferable solutions to problems arising from patenting research tools.

II. DEFINITION OF RESEARCH TOOLS

It is difficult to precisely define research tools in biomedical science. The Working Group on Research Tools of the National Institutes of Health (NIH) defined “the term ‘research tool’ in its broadest sense to embrace the full range of resources that scientists use in the laboratory, while recognizing that from other perspectives the same resources may be viewed as ‘end products.’”⁹ This includes:

cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases and computer software.¹⁰

a Fair-Use Exemption, 76 N.Y.U. L. Rev. 1623 (2001); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1 (2001).

⁶ See Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 Yale L.J. 2169, 2181 (1991).

⁷ *Id.* at 2176.

⁸ See Natalie M. Derzko, *In Search of a Compromised Solution to the Problem Arising From Patenting Biomedical Research Tools*, 20 Santa Clara Computer & High Tech. L.J. 347 (2004).

⁹ *Report of the National Institutes of Health (NIH) Working Group on Research Tools*, <http://www.nih.gov/news/researchtools> (accessed May 13, 2005).

¹⁰ *Id.*

In her dissenting opinion in *Integra Lifesciences I, Ltd. v. Merck KGaA*,¹¹ Judge Newman defined the research tool more narrowly, excluding pharmaceutical candidate compounds.¹² By differentiating “research into the science and technology disclosed in patents” from “the use in research of patented products or methods, the so-called research tools,” Judge Newman considered the patented peptides at issue as “new compositions having certain biological properties,” and not as research tools.¹³

However, in the context of this paper, research tools are defined broadly as resources that provide the patentee with a position to dominate downstream research and development.¹⁴

III. EXPERIMENTAL USE EXCEPTION IN THE UNITED STATES

A. Common Law Experimental Use Exception

In the United States, the experimental use doctrine originated from an opinion by Justice Story in *Whittemore v. Cutter*.¹⁵ In *Whittemore*, Justice Story stated 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.¹⁶

Subsequent cases have limited the doctrine to very narrow grounds.¹⁷ The United States Court of Appeals for the Federal Circuit first considered the experimental use doctrine in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*¹⁸ In *Roche*, the Federal Circuit recognized the existence of a common law experimental use exception but construed its scope very

¹¹ 331 F.3d 860, 878 (Fed. Cir. 2003), *cert. granted*, 125 S.Ct. 823 (2005).

¹² *Id.*

¹³ *Id.*

¹⁴ See Hans-Rainer Jaenichen & Friederike Stolzenburg, *The Patenting and Enforcement of Inventions Relating to Research Tools in Europe: Chances and Problems* § 2.1, <http://www.vossiusandpartner.com/eng/publication/research-tools.html> (accessed May 13, 2005).

¹⁵ Donald S. Chisum, *Chisum on Patents: A Treatise on the Law of Patentability, Validity, and Infringement* vol. 5 § 16.03[1][a] (Matthew Bender & Co. 2004).

¹⁶ *Whittemore v. Cutter*, 29 F.Cas. 1120, 1121 (D. Mass. 1813).

¹⁷ See Chisum, *supra* n. 15, at § 16.03[1][b].

¹⁸ 733 F.2d 858 (Fed. Cir. 1984).

narrowly.¹⁹ The court held that the use of a patented active ingredient by the competitor to perform tests necessary to obtain approval of the Food and Drug Administration (FDA) for a generic drug did not fall within the experimental use exception to the patent right.²⁰ The court opined that the competitor's experimental use was "solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."²¹ In particular, the court stated that the competitor could 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.²²

The holding in *Roche*, however, was partially overruled by Congress's enactment of the Hatch-Waxman Act, which provided a safe harbor for experimentation solely for the purpose of generating FDA regulated data.²³

Thereafter, the Federal Circuit re-confirmed the existence of the common law experimental use doctrine in *Embrex, Inc. v. Service Engineering Corp.*²⁴ but, citing *Roche*, the court did not exempt experiments that were conducted in order to design around the patented subject matter.²⁵ The patented subject matter was related to "methods [of] inoculating birds against disease by injecting vaccines into a specified region of the egg before" it hatched.²⁶ The court held that tests performed by the competitor to investigate the possibility of injecting chicken embryos outside the region covered by the patent was neither experimental use nor *de minimis*, as tests were performed for commercial purposes and therefore infringed the patent.²⁷

Despite the court's narrow interpretation of the experimental use exception, academic researchers believe that the scope of the experimental use exception should extend to at least experimentation performed at universities or non-profit institutions.²⁸ This belief, however, was broken

¹⁹ *Id.* at 863.

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ *See infra* pt. III(2) (discussing statutory experimental use exception).

²⁴ 216 F.3d 1343 (Fed. Cir. 2000).

²⁵ *Id.* at 1349.

²⁶ *Id.* at 1346.

²⁷ *Id.* at 1349.

²⁸ *See* Michelle Cai, *Madey v. Duke University: Shattering the Myth of Universities' Experimental Use Defense*, 19 Berkeley Tech. L.J. 175, 178 (2004).

down by a recent Federal Circuit decision in *Madey v. Duke University*.²⁹ The Federal Circuit held that Duke University was not immunized from patent infringement when it used the patented research equipment for experimental purposes.³⁰ The court reasoned that:

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.³¹

Furthermore, the court included as the university's "legitimate business objectives . . . [the] educati[o]n and enlighten[ment of] students and faculty."³² This Federal Circuit decision seems to reflect the current status of research universities in pursuing aggressive patent policies and obtaining substantial revenue from the patents.³³ The decision, however, provoked outcries among universities and non-profit research institutions that feared the decision would significantly impede the nation's scientific advancement.³⁴

B. Statutory Experimental Use Exception

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, popularly known as the Hatch-Waxman Act.³⁵ The Hatch-Waxman Act had two purposes: first, the Act sought to reduce health care costs by expediting generic drug manufactures to manufacture and sell low price generic drugs; second, the Act sought to protect the profit incentives that encourage innovative pharmaceutical companies to develop pioneer drugs.³⁶ The first purpose of the Act was partially addressed by creating 35 U.S.C. § 271(e)(1) which allows generic drug manufacturers to use a patented invention prior to the expiration of its patent term if the use is

²⁹ 307 F.3d 1351 (Fed. Cir. 2002).

³⁰ *Id.* at 1361-62.

³¹ *Id.* at 1362.

³² *Id.*

³³ *See id.* at 1363 n. 7. The Bayh-Dole Act of 1980, which allows universities to patent federally funded inventions and thereby encourage them to commercialize their research results, blurred the distinction between pure scientific research and commercial research.

³⁴ *See Derzko, supra* n. 8, at 365-66.

³⁵ *Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

³⁶ H.R. Rpt. 98-857 at 14-15, 17 (June 21, 1984).

solely for the purpose of obtaining FDA approval.³⁷ The second purpose was achieved by establishing 35 U.S.C. § 156, which provides a patent term extension to compensate for the decrease in patent term resulting from the time-consuming FDA approval process.³⁸ In particular, 35 U.S.C. § 271(e)(1) provides a safe harbor for experimentation stating:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Although this safe harbor provision was introduced to overrule the holding of *Roche*, thereby protecting generic drug manufacturers, the courts have broadly interpreted the provision. In *Eli Lilly & Co. v. Medtronic, Inc.*,³⁹ the United States Supreme Court affirmed that 35 U.S.C. § 271(e)(1) exempts from patent infringement liability the use of a patented invention to develop and submit information for marketing approval of a medical device under the Federal Food, Drug and Cosmetic Act.⁴⁰ Justice Scalia, focusing on the legislative history, stated that the broad interpretation of including medical devices appears to create a “perfect product fit” between 35 U.S.C. § 156 and 35 U.S.C. § 271(e)(1).⁴¹

A broader interpretation of the safe harbor provision, however, was made in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*⁴² The district court held that the competitor’s use of patented intermediates during its research and development activities for new drugs was not infringement pursuant to 35 U.S.C. § 271(e)(1).⁴³ Judge Patterson construed that “the term ‘patented invention’ means all patented inventions or discoveries, and not merely those that are covered by [35 U.S.C. §] 156.”⁴⁴ Moreover, applying the *Intermedics* test,⁴⁵ Judge Patterson stated that the inquiry would be

³⁷ 35 U.S.C. § 271(e)(1) (2000).

³⁸ *Id.* at § 156.

³⁹ 496 U.S. 661 (1990), *vacated*, 915 F.2d 670 (Fed. Cir. 1990) (vacating the decision consistent with the opinion by the Supreme Court).

⁴⁰ *Id.* at 664, 679.

⁴¹ *Id.* at 674.

⁴² 2001 WL 1512597 (S.D.N.Y. Nov. 28, 2001).

⁴³ *Id.* at **3-4.

⁴⁴ *Id.* at **2-3 (citing *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997), *amend. by*, 131 F.3d 1009 (Fed. Cir. 1997) (holding that the § 271(e)(1) exemption for testing a patented device applied even though the alleged infringing Class II device “was not eligible for patent” extension under § 156)).

⁴⁵ This test was originally suggested in *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp.

whether it was “reasonable, objectively, for a party in the [competitor’s] situation to believe that there was a decent prospect that” its use of the patented intermediates in experiments:

would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant in the process by which the FDA would decide whether to approve the product.⁴⁶

The Federal Circuit, however, recently diverged from the broad interpretation of the safe harbor provision in *Integra Lifesciences I*.⁴⁷ The court affirmed that the competitor’s use of a patented peptide in experiments to develop and identify new drugs that will, in turn, be subject to FDA approval was not embraced by the safe harbor provision.⁴⁸ Judge Rader stated that the exemption did “not endorse an interpretation of section 271(e)(1) that would encompass drug development activities far beyond those necessary to acquire information for FDA approval of a patented pioneer drug already on the market.”⁴⁹ Moreover, he indicated that the expanded interpretation of the safe harbor provision would deprive patentees owning biomedical research tool patents of their exclusive patent rights.⁵⁰

As discussed above, recent Federal Circuit decisions show that there is little, if any, leeway to use the experimental use defense against the alleged infringement of research tool patents in the United States, whether under common law or 35 U.S.C. § 271(e)(1). Many countries other than the United States, however, have generally accepted the concept of an exemption from patent infringement for experimental or research use of a patented invention.

IV. INTERNATIONAL EXPERIMENTAL USE EXCEPTION

The patent laws of most European countries provide an experimental use exception. Each provision largely corresponds to the wording of Article 27(b) of the Community Patent Convention, which exempts from infringement “acts done for experimental purposes relating to the subject

1269, 1280 (N.D. Cal. 1991), *aff’d*, 991 F.2d 808 (Fed. Cir. 1993). While *Intermedics* is an unpublished disposition that is not to be employed or cited as precedent, it was cited with approval by the Federal Circuit in *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1525 n. 5 (Fed. Cir. 1992).

⁴⁶ *Bristol-Myers Squibb*, 2001 WL 1512597 at *3.

⁴⁷ 331 F.3d 860.

⁴⁸ *Id.* at 867-68.

⁴⁹ *Id.* at 867.

⁵⁰ *Id.*

matter of the patented invention.”⁵¹

In particular, Section 11, Paragraph 2 of the German Patent Act provides that “[t]he effects of the patent shall not extend to . . . acts done for experimental purposes which are related to the subject matter of the patented invention.”⁵² Moreover, the German Federal Supreme Court recently had opportunities to apply the provision in “‘Clinical tests’ (GRUR 1996, 109) and ‘Clinical tests II’ (Mitt. 1997, 253) which overruled the former decision ‘Ethofumesate’ (GRUR 1990, 997).”⁵³ The German Federal Supreme Court held that research with a patented pharmaceutical compound to identify and establish a new medical use was exempted, although the research was “for commercial purposes.”⁵⁴ In particular, the Court indicated that the research had to pursue new knowledge about the subject matter of the patented invention but must not use the patented invention “only as a tool.”⁵⁵ This position seems to be in accord with Judge Newman’s perspective in *Integra Lifesciences I*, which was discussed in Part II.⁵⁶ The reasoning of the German Federal Supreme Court, however, is based on the belief that such interpretation of the research exemption:

would not be disadvantageous for patentee, since any improvement obtained from the research tool could only lead to a dependent patent (compound patent v. medicinal use patent), which could not be used without the patentee’s consent.⁵⁷

Therefore, the scope of the research exemption is unclear in spite of the German “Federal Supreme Court decisions”⁵⁸

Meanwhile, Article 69, Paragraph 1 of the Japanese Patent Act provides that “the effects of the patent right shall not extend to the working of the patented invention for the purposes of experiment or research.”⁵⁹ With regard to the scope of this provision, the Japanese Supreme Court recently held that the statutory exemption applies to the testing of a patented drug for

⁵¹ See Hans-Rainer Jaenichen & Friederike Stolzenburg, *Patent Infringement by Clinical Trials in EPC Contracting States* § 19, <http://www.vossiusandpartner.com/eng/publication/pub-epc.html> (accessed May 13, 2005).

⁵² *Id.* at § 1.1.

⁵³ *Id.*

⁵⁴ *Id.* at § 1.3.

⁵⁵ *Id.*

⁵⁶ See text accompanying *supra* n. 11.

⁵⁷ Jaenichen & Stolzenburg, *supra* n. 51, at § 1.3.

⁵⁸ *Id.* at § 1.1.

⁵⁹ Jennifer A. Johnson, *The Experimental Use Exception in Japan: A Model for U.S. Patent Law*, 12 P. Rim L. & Policy J. 499, 510 (2003).

obtaining regulatory approval to manufacture and sell a generic equivalent.⁶⁰

Although the scope of the experimental use exception is unclear regarding research tool patents, the broad experimental use provisions in many countries suggest the possibility of broader interpretation compared to the common law experimental use exception or safe harbor provision of the United States.⁶¹ This difference may cause problems if downstream product development using patented research tools is made offshore to avoid patent infringement.

A recent Federal Circuit decision regarding a patent claiming a screening method provides an example of the problems that might result from the difference in the scope of the experimental use exception. In *Bayer AG v. Housey Pharmaceuticals, Inc.*,⁶² the Federal Circuit held that infringement under 35 U.S.C § 271(g) prohibiting importation or sale of a product made by a patented process is limited to physical goods that were manufactured and does not include information generated by the patented process.⁶³ In addition, the court held that a drug identified as useful by the use of a patented process is not a product made by the patent process.⁶⁴ The court stated that “the process must be used directly in the manufacture of the product, and not merely as a predicate process to identify the product to be manufactured.”⁶⁵

In the light of the *Bayer* decision and the broad experimental use provisions in many other countries, the patent rights of research tools will be likely evaded by doing research and development in countries where the use of the research tools for experimental purposes is generally allowed and by importing the resulting information and products. The Federal Circuit, however, seems to leave the solutions to any possible problems up to Congress.⁶⁶

V. CONCLUSION

Noting the issues arising from patenting research tools and discussing whether to resolve those issues with a broad interpretation of the experimental use exception, the recent Federal Circuit decisions in effect

⁶⁰ *Id.* at 516-18.

⁶¹ *Id.* at 518-19; Mueller, *supra* n. 5, at 38-39.

⁶² 340 F.3d 1367 (Fed. Cir. 2003).

⁶³ *Id.* at 1377.

⁶⁴ *Id.* at 1377-78.

⁶⁵ *Id.* at 1378.

⁶⁶ *See id.* at 1376-77.

eviscerated the experimental use exception in the United States. Therefore, commercial companies must pursue costly licensing ventures whenever they need to use patented research tools, stop research if they cannot obtain authorization from the patentees, or move their research base from the United States to foreign countries who allow a broad interpretation of the experimental use exception.⁶⁷ Furthermore, academic researchers who cannot afford expensive licensing costs must discontinue research activities using patented research tools or continue to research hoping that patent holders will not sue them for patent infringement.⁶⁸ However, these results can never be sustained in terms of a desirable patent policy. It now appears that the United States Congress should step in to resolve these issues.

As a solution, Mueller proposed:

a “liability rule” model that would permit the non-consensual “development use” of patented research tools that are not readily available for licensing or purchase, while providing an ex post royalty payment to the owner of the patented research tool of sufficient amount to maintain adequate incentives for innovation in new tools.⁶⁹

The royalty payment would be computed “based on the marketplace value of the new products or diagnostics developed through use of the patented research tool.”⁷⁰ This approach seems to provide both the provider and user of research tools with seemingly similar compromises, but it is still problematic. First of all, the “reach-through” royalty approach may impose an unreasonable financial burden on “future biomedical research products”⁷¹ Moreover, if the owner of the patented research tool is a small start-up without assets except for the research tool patent, the company cannot survive without royalty revenues until new products or diagnostics are developed.

Therefore, a more preferable solution seems to follow international trends allowing a broad interpretation of the experimental use exception as well as compulsory licensing. Most of all, Congress should introduce a broad experimental use provision to the patent law to allow, at a minimum, for the use of research tools by non-profit research performers for non-commercial purposes. Moreover, Congress should enact a compulsory licensing system, which grants a license from the government to use a patent

⁶⁷ John P. Walsh, Ashish Arora & Wesley M. Cohen, *Working Through the Patent Problem*, 299 *Sci.* 1021, 1021 (2003).

⁶⁸ *Id.*

⁶⁹ Mueller, *supra* n. 5, at 54-55.

⁷⁰ *Id.*

⁷¹ Derzko, *supra* n. 8, at 393 (arguing that reach-through license agreements on research tools should be unenforceable under the patent misuse doctrine).