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A Comparative Analysis of the Impact of Experimental Use
Exemptions in Patent Law on Incentives to Innovate

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A COMPARATIVE ANALYSIS OF THE IMPACT OF EXPERIMENTAL USE EXEMPTIONS IN PATENT LAW ON INCENTIVES TO INNOVATE

KEVIN ILES*

I. INTRODUCTION

¶1 The patent laws of most leading pharmaceutical manufacturing nations contain provisions known colloquially as “research exemptions” or “experimental use exemptions.” The way in which the exemption is formulated has a direct bearing on research and development (R&D) in each nation and is intimately linked to one of the major jurisprudential rationales underpinning patent law, namely, the incentive to innovate theory.

¶2 In the absence of patent harmonization, different nations have divergent formulations of the research exemption based on their domestic policy decisions as to the best means of striking the balance between encouraging innovation and protecting patents.¹ Because of the close relationship between the research exemption and R&D, it can be anticipated that the formulation of a research exemption will determine a nation’s competitive advantage relative to other nations with respect to R&D. For example, assume that Ruritania (an imaginary country) has a narrow experimental use exemption. Because of the territorial character of intellectual property law, the Ruritanian inventor will receive patent protection only in the countries in which she filed for a patent. However, even when the Ruritanian inventor has secured patent protection abroad, if foreign countries have broader experimental use exemptions in their patent law than Ruritania does, foreign innovators will have greater scope to engage in innovative activity on Ruritanian goods under the protection of their countries’ research exemptions than Ruritanian innovators will be entitled to engage in on foreign patented goods in Ruritania. This would seem to place Ruritania at a competitive disadvantage relative to other nations.

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¹ See John A. Tessensohn, *Reversal of Fortune—Pharmaceutical Experimental Use and Patent Infringement in Japan*, 4 J. INT’L LEGAL STUD. 1, 50-51 (1998).

¶3 In addition, there is nothing to prevent an innovator from experimenting on or with a patented invention in a country with broad experimental use provisions and then patenting the resultant product in a country with narrow experimental use provisions, so as to maximise the profit of that invention. Thus, while a broad experimental use provision might affect the number of patents filed in a particular country, the effect on R&D may be more subtle.

¶4 Research exemption literature lacks any empirical assessments of the impact of research exemptions on domestic R&D. Given the intimate relationship between competitive advantage and the research exemption, it will be necessary to have a more detailed understanding of the relationship between price control, patent term extension schemes and the research exemption, and how these factors influence domestic R&D.

¶5 While comparative analyses of research exemptions have been undertaken,² there is little, if any, literature on the competitive effect of experimental use exemptions. Nor is there an examination of the rationales or jurisprudential bases that underlie the experimental use and research exemptions in national laws. For patent harmonization in the area of research exemptions to be achieved, it will be necessary to have an agreed upon understanding of the scope and operation of the exemption.

¶6 This paper undertakes a comparative analysis of the experimental use exemptions of four leading pharmaceutical manufacturing nations—the United States (US), the United Kingdom (UK), Germany and Japan³—with a view to understanding the jurisprudential rationales underlying each country’s formulation of the exemption. Some steps are also taken towards examining the empirical impact of each country’s research exemption on research and development in that nation.

¶7 The paper begins with an exploration of the “incentive to innovate” theory underlying patent law in Part I and examines the various hypotheses concerning the impact of experimental use exemptions on research and development. Special attention is given to pharmaceuticals and research tools. Parts II through V contain an analysis of the law in the US, Japan, the UK and Germany. In Part VI, the four formulations of the research exemption are analyzed in light of patent law jurisprudence and the jurisprudential rationales of research exemptions highlighted in Part I. Part VII contains a preliminary examination of the empirical impact of research exemptions on a nation’s research and development.

¶8 Finally, Part VIII shows that carving out limited and narrow exemptions does not necessarily curtail the research and development of a nation or hamper university research. It is also shown that research tools are distinguished from other inventions under the UK and German experimental use exemptions in a jurisprudentially sound way. The US alone bases its experimental use test on a commercial rationale. This test fails to sufficiently account for the economic and practical realities of modern research.

² See Natalie M. Derzko, *A Local and Comparative Analysis of the Experimental Use Exception – Is Harmonization Appropriate?*, 44 IDEA 1 (2003).

³ See generally Kevin Sandstrom, *How Much Do We Value Research and Development?: Broadening the Experimental Use Exemption to Patent Infringement in Light of Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), 30 WM. MITCHELL L. REV. 1059 (2004); Tessensohn, *supra* note 1, at 50; Jennifer A. Johnson, *The Experimental Use Exception in Japan: A Model for US Patent Law?*, 12 PAC. RIM L. & POL’Y J. 499, 500 (2003).

A. Incentive to Innovate

¶9 Patent law is premised on the theory that conferring an artificial and limited monopoly on a patent holder benefits society in two ways: first, by requiring disclosure of the invention as a requirement for obtaining a patent, and second, by encouraging inventors to bring their inventions to the market because of the lead time the monopoly grants them in which to profit from their inventions.⁴ However, a free-rider problem arises when nations benefit from access to publicly disclosed patented inventions without protecting patentable subject matter themselves. Partially to combat this difficulty, the Trade Related Aspects of Intellectual Property Agreement (TRIPS) was passed and became a requirement for membership to the World Trade Organization.⁵ TRIPS requires member states to enact certain minimum standards of intellectual property protection. TRIPS also provides the patent holder with certain rights⁶ over her patented good for a period of twenty years in the territory in which the patent is granted.⁷ The rights granted to a patent holder under TRIPS include the exclusive rights to make, sell and import the manufactured invention.⁸ Unauthorized infringement of these is an actionable infringement of the patentee's rights in the country where the patent is held.⁹

¶10 The “incentive to innovate” theory of patent law is premised on the assumption that the grant of a patent monopoly is necessary to enable an inventor to recoup the costs of the R&D needed to bring the invention to market. Without an ability to recoup R&D costs, there would be no incentive to engage in R&D at all. Recouping R&D costs must, however, be distinguished from the control of follow-on innovation by a patent holder, which is an incidental effect of the patent system and which inhibits R&D.¹⁰

¶11 As part of the patent “bargain,” the patent holder must disclose the specifications of their work such that a person skilled in the art¹¹ can make and use the invention, and develop improvements and inventions based on, or emerging from, the technology employed in the patented invention.¹² Allowing experiments on patented inventions is important for further innovation and development.¹³ The degree and extent of disclosure required by the patent law, and the scope and duration of the exclusive rights granted to the patent holder, determines the degree to which follow-on innovation is stimulated or

⁴ See Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, Wis. L. REV. 81 (2004); Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 228-29 (2001); Advisory Council on Intellectual Property, Australia (ACIP), *Patents and Experimental Use Options Paper* 18 (Dec. 2004), <http://www.acip.gov.au/library/Experimental%20Use%20Options%20Paper%20A.pdf>; Johnson, *supra* note 3, at 500.

⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods (TRIPS), Apr. 15, 1994, Appendix 1C to the Agreement Amending the General Agreement on Tariffs and Trade and Creating the World Trade Organization, signed by GATT members.

⁶ *Id.*, § 5.

⁷ *Id.* art. 33.

⁸ *Id.* art. 26, 28.

⁹ *Id.* art. 41.

¹⁰ See Strandburg, *supra* note 4, at 88; ACIP, *supra* note 4, at 23.

¹¹ The phrase “skilled in the art” is a common technical phrase used in the patent laws of most nations to describe a person with knowledge, expertise and skill in the area of technology to which the patent refers.

¹² See Strandburg, *supra* note 4, at 100-04.

¹³ See *id.* at 101, 106.

inhibited.¹⁴ However, because patent-holders prefer to maximize their own economic returns, there is no incentive to license other innovators, to design around the invention or to develop follow-up inventions.¹⁵

¶12 For this reason, TRIPS provides certain exceptions to the exclusive rights of patent holders,¹⁶ and most leading statutory patent regimes contain comparable experimental use or research exemptions.¹⁷ The scope varies in each country, but essentially the exemption provides a limited defence for follow-on innovators who have engaged in certain permitted uses or experiments with patented goods.¹⁸ These provisions prevent patent-holders from blocking the introduction of follow-on innovations until the expiration of the patent (or unless compensation is paid to the patent-holder under a compulsory licence)¹⁹ and are thought to encourage domestic research and development.²⁰

¶13 Some commentators contend that narrow experimental use exemptions inhibit R&D by discouraging innovators from improving patented inventions and by restricting access to state-of-the-art technologies and research tools without the prior payment of a fee.²¹ On the other hand, a broad research exemption may discourage R&D by allowing innovators to design around inventions and develop competing technologies, thus reducing the ability of patent holders to recover returns on their investments.²²

¶14 Strandburg demonstrates that a distinction must be drawn between self-disclosing inventions (inventions which are easily reverse-engineered, such as pharmaceuticals and most product patents) and non-self-disclosing inventions (inventions where the R&D investment can be recouped through trade secret protection, such as many process

¹⁴ See *id.* at 119.

¹⁵ See *id.* at 102.

¹⁶ TRIPS art. 31.

¹⁷ See Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917, 918 (2004). For some justifications for experimental use not constituting infringement, see ACIP, *supra* note 4, at 24.

¹⁸ See ACIP, *supra* note 4, at 24.

¹⁹ See Strandburg, *supra* note 4, at 82. The economic reality is such that a practical research exemption probably operates in most nations which is broader than any legal exemption. This results from the fact that an infringement action is not likely to be brought against the non-commercial user of a patented invention. See ACIP, *supra* note 4, at 36.

²⁰ Strandburg, *supra* note 4, at 83.

²¹ See Mueller, *supra* note 17, at 919. See generally Sandstrom, *supra* note 3; David C. Hoffman, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing a Broad Experimental Use Exception*, 89 CORNELL L. REV. 993 (2004); David Cyranoski, *This Protein Belongs To. . .*, 426 NATURE 10 (Nov. 6, 2003); Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989). For a summary of the experimental use debate, see John R. Thomas, *Scientific Research and the Experimental Use Privilege in Patent Law*, Congressional Research Service Report for Congress, Library of Congress, Order Code RL 32651, at 9-13 (2004).

²² See Strandburg, *supra* note 4, at 82; Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991) (advocating the use of compulsory licensing which will allow the researcher or inventor to still claim a royalty for their research efforts while not hindering future innovation.). For a similar proposal relating to research tools, see Strandburg, *supra* note 4, at 82.

patents).²³ Patenting a non-self-disclosing invention is a public good as the disclosure requirement gives the public technological know-how.²⁴ But, because non-self-disclosing inventions can be protected through trade secret protection, they will only be patented (and therefore also disclosed) where the economic returns from the patent monopoly are greater than the gains provided by trade secret protection alone.²⁵ If trade secret protection alone would enable the inventor to recoup their R&D costs, patenting in these circumstances would give the patent holder an economic gain beyond the mere recouping of R&D costs.²⁶

¶15 If the patent system is designed to benefit society as a whole through the fuelling of R&D and technological development rather than the individual patent-holder,²⁷ it is fair to ask what benefit society gains in exchange for the economic boon gained by the patent-holder of a non-self-disclosing invention. The benefit in this situation is the opportunity to compete with the patentee in a follow-on innovation contest on an invention that otherwise would not have been disclosed. In effect, experimental use amounts to a broadened disclosure requirement on the patentee in exchange for a patent monopoly.

¶16 For self-disclosing inventions, disclosure is implicit in bringing the product to market.²⁸ The public good lies in the fact that without the benefit of patent protection the inventor has no incentive to bring the product to market at all. Self-disclosing products can be instantly copied because they carry their inventiveness on their face. Without the benefit of the lead time that a patent grants, inventors would not be able to recover R&D costs.²⁹

¶17 Strandburg's distinction between self-disclosing and non-self-disclosing inventions demonstrates that the research exemption is necessary for non-self-disclosing inventions, such as process patents, in order to compensate society for the patentee's extra economic gain.³⁰ However, in the case of product and pharmaceutical patents, Strandburg's analysis shows that the public has already received its benefit in being granted market access to the invention.³¹

B. *The special case of pharmaceuticals*

¶18 Given Strandburg's analysis, it is interesting that research exemptions have primarily been implemented to benefit the generic pharmaceutical industry. Pharmaceuticals, in Strandburg's analysis, are self-disclosing inventions.³² They are only brought to market because of the patent regime, and the public benefit gained from the patent is market access to the product. No additional public benefit is therefore required.

²³ Strandburg, *supra* note 4, at 83.

²⁴ *Id.* at 105-106.

²⁵ *Id.* at 111.

²⁶ *Id.* at 112-113.

²⁷ *Id.* at 90-91.

²⁸ Strandburg, *supra* note 4, at 105-07.

²⁹ *Id.* at 104-05.

³⁰ *Id.* at 104-08.

³¹ *Id.* at 104-05.

³² *Id.* at 105.

Narrowing the patentee's rights by the creation of a research exemption in the field of pharmaceuticals therefore would appear to tip the balance unevenly in the public's favor.

¶19 The R&D costs for pharmaceuticals are exceptionally high.³³ However, because medicines are necessary for public health, a balance needs to be struck between maintaining the revenue stream of pharmaceutical companies to ensure further R&D and providing medicines to the public at an affordable price.

¶20 Price regulation, compulsory licensing and research exemptions have been used to foster this balance and encourage generic competition. Generic drugs have an enormous impact on the price of brand name medicines.³⁴ In many countries, generic manufacturers are permitted to conduct certain preparatory work on patented drugs so as to obtain market approval for the generic medicines prior to the expiration of the patent on the brand name drug. This ensures that once the patent on the brand name drug expires, there is no undue delay and de facto extension of the brand name drug's monopoly while the generic drug manufacturer goes through the regulatory approval process. This exemption for generic drug manufacturers can either form a part of a broader experimental use exemption or can be contained in an industry specific experimental use exemption.³⁵

C. *The special case of the research tool*

¶21 The research tool is an invention primarily intended to be used as a tool in performing research.³⁶ Some commentators have expressed concern that patents on research tools, especially biotechnology research tools, can impede future research by creating "patent-thickets" and preventing researchers from performing experiments that rely on patented tools without authorization and royalty payments.³⁷ However, it is rational for the patent-holder of a research tool to encourage researchers to use that tool since that is where the patent holder's profit is to be made.³⁸ She is therefore unlikely to make the use of that tool burdensome through high prices or the withholding of authorization.³⁹

¶22 Patents on research tools have a direct effect on universities and other primary research institutions.⁴⁰ Mueller cites studies that show that in order to navigate through

³³ See Glasgow, *supra* note 4, at 231; Tessensohn, *supra* note 1, at 22-23.

³⁴ See Glasgow, *supra* note 4, at 232.

³⁵ Drug compounds are typically patented fairly early in the drug development process. Because of the length of time taken to obtain marketing approval for a new drug, the effective patent term on a patented brand name drug is typically substantially shorter than the minimum 20 years given to all patented products. To compensate for this time loss, nations that have generic drug exemptions typically also provide for patent term extensions on the brand name drug to partially compensate for the time lost to regulatory approval.

³⁶ See Strandburg, *supra* note 4, at 121.

³⁷ See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (May 1, 1998); Strandburg, *supra* note 4, at 124-30.

³⁸ Strandburg, *supra* note 4, at 124-30.

³⁹ See Heather Hamme Ramirez, *Defending the Privatization of Research Tools: An Examination of the 'Tragedy of the Anticommons' in Biotechnology Research and Development*, 53 EMORY L.J. 359, 362 (2004); F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science – A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691 (2001).

⁴⁰ E.g., Mueller, *supra* note 17, at 944-45.

growing patent thickets and obtain licenses to use research tools covered by corporate-owned patents, universities are required to divert limited resources and sign contracts mandating reporting requirements, improvement assignments and the payment of reach-through royalties.⁴¹ However, other studies report that while the preconditions for a breakdown of downstream research are present, there remains no detectable anti-commons effect.⁴² Some commentators also argue that because university-based researchers typically do not harness the patent system as private sector researchers do, a research exemption should be crafted to cover them.⁴³ However, university research is not isolated from private sector commercial implications and is increasingly benefiting from the patent system.⁴⁴

II. THE EXPERIMENTAL USE EXEMPTION IN U.S. LAW

A. Common law exemption

¶23 The US has no general statutory research exemption, only a narrow judicially crafted common law exemption⁴⁵ which dates back to 1813.⁴⁶ In stating the exemption, Justice Story held that to infringe a patent holder's exclusive right of use, the alleged infringer had to intend to profit from that use. Justice Story held that the legislature could never have intended to include within the meaning of the word "use" in the patent law those persons who used the invention "merely for philosophical experiments" or to ascertain "the sufficiency of the machine to produce its described effects."⁴⁷ By 1861 it was "well-settled 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."⁴⁸

¶24 In *Roche Products Inc. v. Bolar Pharmaceutical Co.*⁴⁹ the appellant (Roche) sought to enjoin the appellee (Bolar) from taking, during the life of the appellant's patent, the statutory and regulatory steps necessary to market a generic drug equivalent to the appellant's patented drug after the expiration of the appellant's patent.⁵⁰ The appellee conceded that its use of the appellant's patented chemical did not fall within the

⁴¹ *Id.*

⁴² See ACIP, *supra* note 4, at 37.

⁴³ E.g., John P. Walsh, Ashish Arora, & Wesley M. Cohen, *Working Through the Patent Problem*, 299 SCI. 1021, 1021 (Feb. 14, 2003).

⁴⁴ See Thomas, *supra* note 21, at 10; Traci Dreher Quigley, *Commercialization of the State University: Why the Intellectual Property Restoration Act of 2003 is Necessary*, 152 U. PA. L. REV. 2001 (2004); ACIP, *supra* note 4, at 19; Mueller, *supra* note 17, at 946.

⁴⁵ See Janice M. Mueller, *No 'Dilettante Affair': Rethinking the Experimental Use Exemption to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001); Mueller, *supra* note 17, at 927-30.

⁴⁶ See Thomas, *supra* note 21, at 1; Mueller, *supra* note 17, at 926-32; Strandburg, *supra* note 4, at 93-100.

⁴⁷ See Strandburg, *supra* note 4, at 93-100

⁴⁸ *Roche Prod. Inc. v. Bolar Pharm.*, 733 F.2d 858, 862 (Fed. Cir. 1984) (quoting *Peppenhause v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1862) (No. 11,279)), *superseded by statute on other grounds*, *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 404-05 (Fed. Cir. 1989).

⁴⁹ *Id.*; Mueller, *supra* note 17, at 932-34; Derzko, *supra* note 2, at 5-6.

⁵⁰ *Roche*, 733 F.2d at 860.

“traditional limits” of the common law experimental use doctrine.⁵¹ However, appellee argued that the experiments were true scientific enquiries in the literal sense to which the exception should logically extend.⁵² Still, the court found that Bolar’s use was solely for business reasons.⁵³ The court held that the experimental use in this case had definite, cognizable, and not insubstantial commercial purposes.⁵⁴

¶25 In *Embrex Inc. v. Service Engineering Corp.*,⁵⁵ the defendant had attempted to design around an existing patent.⁵⁶ In doing so the defendant had used the patented invention in the course of its experiments.⁵⁷ On a suit for infringement the court relied on *Roche v. Bolar* and held that the defendant’s use of the invention did not fall within the experimental use exception.⁵⁸ The court held that the tests were being performed expressly for commercial purposes and were merely disguised as scientific inquiries, even though the defendant did not end up selling any of its intended machines.⁵⁹

¶26 In the most recent case, *Madey v. Duke University*,⁶⁰ Duke University continued to use various items of research equipment owned and patented by the plaintiff after the plaintiff terminated his employment with the University.⁶¹ The University filed a motion for summary judgment on the infringement claim, arguing that its use of the patented inventions constituted non-commercial academic research and was therefore exempted from infringement liability by the experimental use exemption.⁶² Even though Duke University’s only purpose in continuing to use the patented equipment at issue was for educational purposes under government grants at a privately funded institution,⁶³ the Court held that the exemption did not apply because Duke’s use of the equipment had “definite, cognizable, and not insubstantial commercial purposes.”⁶⁴ After the holding in *Madey*, some commentators have argued that the exemption has become so narrow in scope⁶⁵ as to only allow “uses done for amusement, to satisfy the idle curiosity or for strictly philosophical inquiry.”⁶⁶

⁵¹ *Id.* at 863.

⁵² *Id.* at 862.

⁵³ *Id.* at 863.

⁵⁴ *Id.*

⁵⁵ 216 F.3d 1343 (Fed. Cir. 2000); see Mueller, *supra* note 17, at 934-35.

⁵⁶ See *Embrex*, 216 F.3d at 1346.

⁵⁷ *Id.*

⁵⁸ *Id.* at 1349.

⁵⁹ *Id.*

⁶⁰ 266 F.2d 420 (M.D.N.C. 2001), *reversed by* *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002); see Mueller, *supra* note 17, at 936-47; Strandburg, *supra* note 4, at 81-100.

⁶¹ See *Madey*, 266 F.2d at 422-23.

⁶² *Id.* at 424.

⁶³ *Id.* at 427.

⁶⁴ *Id.* at 425 (quoting *Roche*, 733 F.2d at 863).

⁶⁵ See Michelle Cai, *Madey v. Duke University: Shattering the Myth of Universities’ Experimental Use Defense*, 19 BERKELEY TECH. L.J. 175 (2004).

⁶⁶ Mueller, *supra* note 17, at 942, 944.

B. Statutory exemption

¶27 In response to the *Roche v. Bolar* decision⁶⁷ Congress passed the Hatch-Waxman Act in 1984.⁶⁸ Section 202 of that Act created an industry-specific research exemption known as the FDA exemption⁶⁹ (or the “Bolar exemption”) for biomedical research undertaken to obtain governmental regulatory approval under the Federal Food, Drug and Cosmetic Act. It was codified as 35 U.S.C. § 271(e)(1) and states:

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 (other than a new animal drug or veterinary biological product . . .) 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.⁷⁰

¶28 This section was introduced to remedy the delayed market entry of generic drugs resulting from the inability of generic drug manufacturers to undertake the necessary FDA studies for regulatory approval prior to the expiration of the patent on the competitor drug product.⁷¹ The provision was intended to benefit generic medicine manufacturers and research-based pharmaceutical companies.⁷² Although the statutory exemption was passed with a limited and very specific purpose in mind (the correction of the pharmaceutical patent distortion),⁷³ the language of the provision is broader than this narrow purpose. This has led to some divergent results among the courts.

¶29 Judicial interpretations of 271(e)(1) fall into two broad categories: those decisions concerned with the subject matter of 271(e)(1); and those concerned with the range of permissible activities under 271(e)(1). The scope of subject matter falling within the phrase “patented invention” in the Bolar exemption was settled by the Supreme Court in *Eli Lilly*⁷⁴ which held that “patented invention” in 271(e)(1) includes all categories of FDA regulated products.⁷⁵

⁶⁷ See *Roche*, 733 F.2d at 862.

⁶⁸ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. ss 68b-68c, 70b (1994); 21 U.S.C. §§ 301 note, 355, 360cc (1994); 28 U.S.C. § 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

⁶⁹ 35 U.S.C. § 271(e)(1) (2000).

⁷⁰ *Id.*

⁷¹ See, e.g., *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990); *Intermedics, Inc. v. Ventitrex, Inc.*, 775 F. Supp. 1269, 1272-73 (N.D. Cal. 1991); *Integra Lifesciences, Inc. v. Merck KGaA*, 331 F.3d 860, 865 (Fed. Cir. 2003), *vacated by* 125 S. Ct. 2372 (2005). In exchange patent drug manufacturers obtained a patent restoration to correct for the loss of market time due to obtaining regulatory approval and various other non-patent exclusivity provisions.

⁷² *Glaxo, Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) (citing H.R. Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48).

⁷³ *Integra*, 331 F.3d at 866-67.

⁷⁴ *Eli Lilly*, 496 U.S. 661.

⁷⁵ *Eli Lilly*, 496 U.S. at 665; *Abtox Inc. v. Exitron Corp.*, 122 F.3d 1019, 1027-29 (Fed. Cir. 1997). Derzko has criticized the expansion in *Eli Lilly* beyond what she terms the clear language specifying the applicability of 271(e)(1) to “drugs or veterinary biological products” citing economic reasons for a distinction between drugs and other inventions. Derzko, *supra* note 2, at 10. It is important to note, though, that the language of 271(e)(1) does *not* refer to drugs but rather to a “Federal Law which

¶30 The second aspect of 271(e)(1), the range of activities that the exemption permits, has prompted several interpretations because of the ambiguous statutory language. The phrase “solely for uses reasonably related to” in 271(e)(1) can be interpreted in two possible ways: (1) the word “solely” can be used to limit the word “uses”; or (2) “solely” might limit the listed activities: “make, use, offer to sell or sell.”

¶31 The difference in interpretation is of significant practical effect and emerges from the fact that any one activity can have multiple simultaneous purposes. Suppose that inventor A has invented and patented the pharmacologically active compound P. Then suppose that innovator B, without authorization from A, makes drug D, a drug with different medical indications to A’s drug, but which contains P. The purpose of manufacturing D is to test the manufacturing process. B also runs tests comparing P to D in order to determine the effectiveness of the manufacturing process. B also sells the newly manufactured D for reasons unrelated to the regulatory approval process. B has engaged in three distinct activities: making, using and selling. Under interpretation (2) above, where “solely” qualifies the listed activities, any activity that has the generation of FDA-related data as a direct purpose will qualify under the exemption, even if there is some other non-FDA-related purpose also emerging from that activity. Under interpretation (1) where “solely” qualifies “purposes,” any activity with a non-FDA-related purpose will fail, even if the primary purpose of that activity is an FDA-related purpose.

¶32 In the example above, the purpose of using P is to test the efficiency of the manufacturing process. This is reasonably related to the FDA approval process. Using P has no other purpose, and so under both interpretations the activity “using” will qualify for exemption. The purpose of making is two-fold: the first purpose is to test the ability to manufacture D; the second is a long-term goal of making a commercial profit by eventually manufacturing and selling D. Because the “making” activity has two purposes, one of which is non-FDA-related, it will pass under interpretation (2) but will fail under interpretation (1). The third activity of selling is (for the purposes of this example) not related to FDA approval and would therefore fail under both approaches.

¶33 One of the first reported decisions considering 271(e)(1) is *Scripps v. Genentech*,⁷⁶ a district court decision on a motion for summary judgment.⁷⁷ In that case the court held that although the infringing use of the patent at issue might eventually lead to the submission of data to the FDA, the use was not solely for that purpose.⁷⁸ It also had other non-FDA related uses and therefore failed to qualify under the exemption.⁷⁹

¶34 The next decision under the statute was *Intermedics*,⁸⁰ also decided by the Court for the Northern District of California. Between the *Scripps* decision and *Intermedics*, the Supreme Court decided the *Eli Lilly* case, which expanded the scope of exempted subject

regulates . . . drugs.” 35 U.S.C. § 271(e)(1) (2000). The Food and Drug Administration Act is undoubtedly such a law, and that Act incorporates other subject matter beyond drugs, something of which Congress was clearly aware as Justice Scalia points out in the *Eli Lilly* judgment. *Eli Lilly*, 496 U.S. at 672-73.

⁷⁶ *Scripps Clinic & Research Found. v. Genentech Inc.*, 666 F. Supp. 1379 (N.D. Cal. 1986), *rev’d on other grounds*, 927 F.2d 1565 (Fed. Cir. 1991).

⁷⁷ *Id.*

⁷⁸ *Id.* at 1396.

⁷⁹ *Id.*

⁸⁰ *Intermedics, Inc. v. Ventitrex, Inc.*, 775 F. Supp. 1269 (N.D. Cal. 1991).

matter beyond drugs to all categories of FDA regulated goods.⁸¹ The *Intermedics* court interpreted the *Eli Lilly* judgment to mean that Congress was not concerned with the de facto length of the patent holder's monopoly when it enacted 271(e)(1), but rather with ensuring that new medically beneficial cost-competitive drugs would reach the market upon expiration of existing patents.⁸² Because of this reading of the statute, the court reversed the approach it had taken in *Scripps*. The court found that "the inquiry is not generally whether the allegedly infringing party has engaged in conduct that shows that it has purposes beyond generating and presenting data to the FDA."⁸³ Because the hope of profit or a business purpose underlies almost every use of a patented invention, the court was of the opinion that no use would ever be exempted under 271(e)(1) with the application of this test.⁸⁴ The *Intermedics* court ultimately assessed the legality of the contested activities by asking whether it was objectively reasonable for the person invoking the exemption to believe that there was a decent prospect that the use in question would contribute relatively directly to the purposes permitted by 271(1)(e).⁸⁵

¶35 The difference between *Scripps* and *Intermedics* emerges from the two possible interpretations of 271(e)(1) offered above. The *Scripps* court recognised that a single use of a patented invention may serve multiple purposes. Instead of requiring all of those multiple purposes to relate to the generation of information for the FDA, it requires that for a use to be covered by the exemption the primary purpose of the use must be the generation of information for the FDA.⁸⁶ In other words, the court adopted interpretation (2).

¶36 In contrast, the *Intermedics* court assumed interpretation (1) applied. As we have seen, the consequence of this reading is that any activity which has any purpose other than generating information for the FDA process will fail to qualify under the exemption even where one of the purposes is FDA-related. To mitigate the consequences of this interpretation the *Intermedics* court held that uses that have commercial interests as their primary objective will qualify for the exemption where those activities also have at least a decent prospect of generating information for submission to the FDA.⁸⁷ Instead of

⁸¹ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 665 (1990).

⁸² *Intermedics*, 775 F. Supp. at 1273, 1277. *But cf.* *Glaxo, Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) (interpreting *Eli Lilly* as implying that Congress was concerned with providing a limited extension of patent holder's monopoly rights in order to recover time lost during lengthy FDA review of drugs).

⁸³ *Intermedics*, 775 F. Supp. at 1278.

⁸⁴ *Id.* at 1279-80.

⁸⁵ *Id.* at 1280.

⁸⁶ *Scripps* employs the following set of steps to reach its result: (1) Assess each use that is made of the patented invention to determine whether that use is reasonably related to the generation of information for the FDA regulatory procedure; (2) Any uses which are so reasonably related will fall within the exemption; (3) Any use that is not so related will not fall within the exemption and will be infringing. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 865-66 (Fed. Cir. 2003), *vacated by* 125 S. Ct. 2372 (2005).

⁸⁷ The *Intermedics* approach is then followed in subsequent cases, including *Teletronics Pacing Sys. Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1525 n.5 (Fed. Cir. 1992), *Abtox Inc. v. Exitron Corp.*, 122 F.3d 1019, 1027-29 (Fed. Cir. 1997), and *Amgen, Inc. v. Hoechst Marion Roussel, Inc.* 3 F. Supp. 2d 104, 108 (D. Mass. 1998). Derzko has criticized the *Intermedics* decision on other grounds. Derzko, *supra* note 2, at 12-21.

adopting interpretation (2), the court effectively read the word “solely” out of the statute.⁸⁸

¶37 In the next case, *Telectronics*,⁸⁹ the Federal Circuit Court of Appeals found that displaying an infringing invention at several medical conferences fell within the Bolar exemption because this activity was directed toward finding investigators who would be willing to conduct the necessary approval trials.⁹⁰ Finding suitable investigators for the FDA process⁹¹ occurs after preliminary research takes place, but before the activities covered by the statutory exemption. If the activities preparatory to the statutory exception are not covered, this would undermine the protection that Congress sought to confer on the generic drug manufacturer.⁹² The court found that while the primary purpose of the activity must be the generation of data for FDA purposes, the activity will not become infringing merely because that data is also put to other uses beyond the primary purpose.⁹³

¶38 Derzko criticises the *Telectronics* decision on the grounds that, like *Intermedics*, it effectively strikes the word “solely” out of the statute.⁹⁴ *Intermedics* writes the word “solely” out of the statute by the creation of a commercial test in place of the statutory test. *Telectronics*, however, does not. In *Telectronics*, the court simply followed the *Scripps* interpretation, and read the provision as solely permitting activities that are reasonably FDA-related.

¶39 Unlike the narrowing that has occurred with respect to the common law experimental use exemption, judicial interpretations of 271(e)(1) allow coverage of a broad range of activities under the exemption.⁹⁵ The cause of this broadening does not lie in the “reasonably related” part of the statutory language to which Derzko has directed criticism, but rather in the courts’ findings about what is and what is not FDA-related. The range of supposedly FDA-related activities has been drawn too widely because of the substitution of a commercial purpose test in the *Intermedics* decision for interpretation (2) of the statute.

¶40 The other cause of this over-breadth in determining the range of ostensibly FDA-related activities emerges from the judicial preference for an objective evaluation of the purpose of an activity over a subjective assessment.⁹⁶ Not only does determining the purpose of an otherwise infringing activity in a vacuum unnecessarily broaden the statute, but it allows activities which objectively bear a relationship to the generation of FDA-related data to pass under the statute even where the parties concerned had no intention of using the data generated for FDA purposes. For example, in *Abtox* the court of appeals

⁸⁸ Derzko, *supra* note 2, at 19.

⁸⁹ *Telectronics*, 982 F.2d 1520.

⁹⁰ *Id.* at 1523.

⁹¹ Accepting the Court’s factual determination as to the purpose of those activities.

⁹² This was a concern raised by Judge Newman in a dissenting judgment in *Integra*. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 872-73 (Fed. Cir. 2003) (Newman, J., dissenting), *vacated by* 125 S. Ct. 2372 (2005).

⁹³ *Telectronics*, 982 F.2d at 1524. Here again, this argument is made accepting the Court’s factual findings at face value although issue can probably be taken with what the primary purposes of the activities in issue were.

⁹⁴ Derzko, *supra* note 2, at 16.

⁹⁵ *Id.* at 25.

⁹⁶ *See id.* at 18; *Intermedics, Inc. v. Ventitrex, Inc.*, 775 F. Supp. 1269, 1274-1275 (N.D. Cal. 1991).

held that certain otherwise infringing uses of a patented drug were covered by the exemption even though on the evidence the use was plainly for the purpose of obtaining patent approval abroad rather than for FDA approval.⁹⁷ The court held that the use fell within the exemption because, viewed objectively, there was a reasonable prospect that these uses could give rise to information that might be useful to FDA-approval.⁹⁸

¶41 The latest decision by the court of appeals appears to endorse *Scripps, Telectronics* and interpretation (2) of 271(e)(1). In *Integra Lifesciences v. Merck*,⁹⁹ the Court of Appeals for the Federal Circuit held that any infringing use of an invention must be for a purpose that is reasonably related to the purpose specified in 271(e)(1). No other uses are permissible.¹⁰⁰ The court held that:

Activities that do not directly produce information for the FDA are already straining the relationship to the central purpose of the safe harbor. The term ‘reasonably’ permits some activities that are not themselves the experiments that produce FDA information to qualify as ‘solely for uses reasonably related’ to clinical tests for the FDA. Again, however, the statutory language limits the reach of that relationship test.¹⁰¹

¶42 In this case, Merck had infringed Integra’s patent by using Integra’s patented peptide sequence in tests aimed at identifying a suitable drug candidate for a pharmaceutical compound.¹⁰² According to the court, this was a purpose in which the FDA had no interest.¹⁰³ The court’s view of 271(e)(1) was that it was designed to cover only those activities that contribute relatively directly to information that the FDA considers in granting approval to a drug already on the market.¹⁰⁴ The court was very concerned that the patent infringement should be kept at de minimus levels and that not all drug development activities should be brought within the exemption.¹⁰⁵ Although the court makes no mention of the *Intermedics* decision, *Integra* appears to over-rule it by implication.

¶43 In a dissent, Judge Newman agreed with the majority that 271(e)(1) cannot reach back to cover the identification and development of new drugs.¹⁰⁶ However, Judge Newman found that Merck’s activities fell within the permissible bounds of the common law experimental use exemption.¹⁰⁷ Judge Newman reasoned that the common law exemption exists in order to advance R&D by allowing inventors to experiment with

⁹⁷ *Abtox Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029-30 (Fed. Cir. 1997).

⁹⁸ *Id.* See also *NeoRX Corp. v. Immunomedics, Inc.* 877 F. Supp. 202, 207 (D.N.J. 1994).

⁹⁹ *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *vacated by* 125 S. Ct. 2372 (2005). See also Mueller, *supra* note 17, at 947-61 (for an in-depth analysis of the experimental use defense in the *Integra* decision).

¹⁰⁰ *Integra*, 331 F.3d at 867.

¹⁰¹ *Id.* at 866.

¹⁰² *Id.*

¹⁰³ *Id.* at 866-67.

¹⁰⁴ *Id.* at 867. Presumably the use of the word ‘drug’ in the court’s holding is not restrictive given its concessions to the broader subject matter of *Eli Lilly*.

¹⁰⁵ *Integra*, 331 F.3d at 867.

¹⁰⁶ *Id.* at 877.

¹⁰⁷ *Id.* at 876.

inventions with the aim of improving them, finding new uses for them, or designing around them.¹⁰⁸ Drawing a distinction between research and development, Judge Newman reasoned that research with a patented invention will fall within the exemption while research on an invention (development and commercialisation) will not.¹⁰⁹ The fact that profit might be the ultimate goal or hope should not disqualify the activity.¹¹⁰ The Judge concluded that it would be illogical if the initial exploratory phases of Merck's research were covered by the common law exemption and the final regulatory stages by the statutory exemption, and yet activity in the intervening stages was infringing.¹¹¹ If this were the case, the "infringement gap" in the middle of the research process would defeat the purposes of both the statutory and common law exemptions.¹¹²

¶44 The problem with Judge Newman's reasoning is that it is made without reference to *Madey*.¹¹³ Identification of drug candidates is part of the routine business of a company such as Merck and it is therefore doubtful whether the common law research exemption would cover this use. If that is the case, then no gap exists and licenses are required for all the preparatory stages leading up to the statutory exemption.

III. THE EXPERIMENTAL USE EXEMPTION IN JAPANESE LAW¹¹⁴

¶45 Japan has a statutory experimental use exemption in Article 69(1) of its patent law. This provision provides as follows: "The effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research."¹¹⁵

¶46 The rationale underlying the exemption was understood to be the advancement of technology, and in one of the earliest decisions interpreting this section, research or experiments for commercial use were therefore excluded from the exemption.¹¹⁶ Similarly, experiments conducted for the purposes of gaining regulatory approval were not considered to advance technology.¹¹⁷ Five judicial decisions in 1996 reinforced this interpretation of section 69(1) by holding that section 69 did not apply to generic manufacturing and production for the purpose of obtaining regulatory approval during the subsistence of an existing patent.¹¹⁸

¶47 Two subsequent decisions rejected this line of reasoning. In *Wellcome Foundation Ltd v. Sawai Pharmaceutical*,¹¹⁹ the Tokyo District Court had to determine whether Sawai, a Japanese pharmaceutical company, had infringed Wellcome's patent by

¹⁰⁸ *Id.* at 876-77.

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 876-77.

¹¹¹ *Integra*, 331 F.3d at 867-77.

¹¹² *Id.* at 877.

¹¹³ *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002).

¹¹⁴ Unlike the United States, Japan has a civil law system in which judicial decisions do not form binding law, as they do in the United States system. However, judicial decisions in Japan are indicative of the way in which a statutory provision should be interpreted. Johnson, *supra* note 3, at 511.

¹¹⁵ Tokkyo ho [Patent Law], Law No. 121 of 1951, art. 69, no. 1.

¹¹⁶ Tessensohn, *supra* note 1, at 25 (citing *Monsanto Co. v. Stauffer Japan K.K.*, 1246 Hanrei Jiho 128 (Tokyo Dist. Ct. 1987)). See also Johnson, *supra* note 3, at 512-13.

¹¹⁷ Tessensohn, *supra* note 1, at 25-26.

¹¹⁸ Tessensohn, *supra* note 1, at 26-27; Johnson, *supra* note 3, at 513-16.

¹¹⁹ Tessensohn, *supra* note 1, at 6.

applying for manufacturing approval and conducting tests and research on drugs similar to Wellcome's patented drug during the subsistence of the Wellcome patent.¹²⁰ The court found that Sawai's research was aimed at achieving technical progress in terms of Article 69(1).¹²¹ Sawai did not earn any direct profit from these activities, nor did it compete in the same economic market as Wellcome.¹²² However, activities directed towards manufacturing or selling the product before the expiration of the patent would fall outside of section 69(1).¹²³

¶48 In *Daiichi Pharmaceutical Co., Ltd v. Shiono Chemical K.K.*,¹²⁴ the Tokyo District Court emphasized the incentive to innovate justification of patent law and the policy purposes underlying section 69(1), namely to strike a balance between the interests of the patentee and the general public and to allow for the improvement of technology and the development of industry.¹²⁵ The court held that section 69(1) is not limited to experiments or research directed at working improvements to existing technology.¹²⁶ The court held that if generic drug manufacturers were required to wait until the expiration of the patent on the brand name drug before they were permitted to undertake the tests and manufacturing necessary to secure regulatory approval, this would grant the patent holder a de facto period of market exclusivity beyond the end of the patent term.¹²⁷ This, the court held, is contrary to the very purposes of the patent regime.¹²⁸ As in the *Wellcome* case, the court noted that *Shiono* did not obtain any profits from these activities nor did it compete with Daiichi during the subsistence of the patent.¹²⁹

¶49 The change in direction by the courts seems to have stemmed primarily from two factors. First, in addition to benefiting from a statutory patent term extension scheme,¹³⁰ pharmaceutical manufacturers were obtaining a de facto term extension of three years due to the regulatory delay faced by the generic drug manufacturers. Second, the generic drug manufacturers relied on the research exemptions of the US and the EU to demonstrate that Japanese patent law was out of line with the other major pharmaceutical manufacturing jurisdictions.¹³¹

¶50 In *Ono Pharmaceutical v. Malco Pharmaceutical K.K.*, however, the Nagoya District Court decided differently than the Tokyo District Court in *Wellcome* and *Daiichi*. The *Nagoya* court found that clinical tests conducted solely for the purposes of obtaining regulatory approval amounted to patent infringement.¹³² However, the court refused to

¹²⁰ Tessensohn, *supra* note 1, at 7; Johnson, *supra* note 3, at 513-16.

¹²¹ *Id.*

¹²² Tessensohn, *supra* note 1, at 8; Johnson, *supra* note 3, at 513-16.

¹²³ *Id.*

¹²⁴ Tessensohn, *supra* note 1, at 9; Johnson, *supra* note 3, at 513-16.

¹²⁵ Tessensohn, *supra* note 1, at 13-14.

¹²⁶ *Id.* at 14.

¹²⁷ *Id.* at 16.

¹²⁸ *Id.* at 31. *See, e.g.*, Tokkyo ho [Patent Law], Law No. 121 of 1951, art. 1. (stating that: "The purpose of this Law shall be to encourage inventions by promoting their protection and utilization so as to contribute to the development of industry.").

¹²⁹ Tessensohn, *supra* note 1, at 17. *See also* the *Kyorin* and *Ono* cases described by Tessensohn which were decided in favour of generic drug manufacturers on grounds other than section 69.

¹³⁰ *Id.* at 29-30.

¹³¹ *Id.* at 29.

¹³² *Id.* at 20-21.

grant a preliminary injunction against the generic manufacturer and instead granted compensation for damages.¹³³

¶51 The Japanese Supreme Court has aligned itself with the Tokyo District Court decisions and has held that the use of a patented invention for the purpose of obtaining a licence to market the generic equivalent of a patented medicine will fall within the scope of the statutory exemption.¹³⁴

¶52 Tessensohn has argued that, given the Japanese courts' concern with the promotion of the public interest, any non-regulatory research activity would probably not fall within section 69 as non-regulatory research activities would not promote any general public interest. This view is probably too narrow. Hanabusa states that experiments and research activities not typically aimed at commercial profit, performed with the purpose of contributing to progress and development, and not infringing on the interests of the patentee will fall within section 69.¹³⁵ It is also important to realize that unlike the United States exemption, the Japanese exemption is not limited to drugs and medical devices but applies to all patented products.¹³⁶

IV. THE EXPERIMENTAL USE EXEMPTION IN U.K. LAW

¶53 Section 60 of the U.K. Patents Act defines direct and indirect infringement of patent rights and provides for certain exemptions from infringement.¹³⁷ Section 60(5) states that “[a]n act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if – (a) it is done privately and for purposes which are not commercial; (b) it is done for experimental purposes relating to the subject matter of the invention.”¹³⁸ Section 130(7) specifies that section 60 should have the same effects in the UK, so far as is practicable, as the European Patent Convention, the Community Patent Convention and the Patent Cooperation Treaty each have in their respective areas of operation.¹³⁹

¶54 There are very few cases interpreting these provisions.¹⁴⁰ In *Monsanto Co. v Stauffer Chemical Co.*,¹⁴¹ the defendant sought to rely on section 60(5) of the Patent Act to carry out field trials with an allegedly infringing pesticide product that was already the subject of an injunction restraining the defendant from further use or sale of the pesticide.¹⁴² The court denied the application and held that the exemption was limited to:

experiments directed to the patented invention as such, experiments such as testing whether a patented product can be made, or a patented article

¹³³ *Id.*

¹³⁴ Derzko, *supra* note 2, at 63 (citing *Otsuka Pharm. Co., Ltd. v. Towa Yakuhin K.K.*, Japanese Supreme Court). *See also* Johnson, *supra* note 3, at 510-11.

¹³⁵ MASAMI HANABUSA, AN ANALYSIS OF JAPANESE PATENT LAW 196-97 (Tsuneo Hanabusa trans., Brunswick Publishing 1992).

¹³⁶ Johnson, *supra* note 3, at 511.

¹³⁷ Derzko, *supra* note 2, at 50-51 (citing PATENTS ACT § 60 (1977)).

¹³⁸ *Id.*

¹³⁹ Derzko, *supra* note 2, at 50-51 (citing PATENTS ACT § 130 (1977)).

¹⁴⁰ ACIP, *supra* note 4, at 41.

¹⁴¹ [1985] R.P.C. 515.

¹⁴² *Id.*

made to work, as described in the patent specification, or experiments to see whether the patented invention can be improved or testing the effect of a modification in some particular [way] to see whether it is an improvement or not.¹⁴³

¶55 The court held that the exemption did not extend to using a patented product or process for testing or evaluating some other product or process, nor did the exemption apply to achieving or extending the acceptance of some commercial embodiment of the patented invention.¹⁴⁴ Such experiments are disqualified because they do not relate to the subject matter of the patented invention.¹⁴⁵

¶56 This interpretation of section 60(5) was upheld on appeal.¹⁴⁶ The appeals court recognized, as did Judge Newman in *Integra*, that all activities of companies would have commercial ends in view and that this alone did not defeat the experimental use exemption.¹⁴⁷ In the court's example, an experiment limited to determining capacity to manufacture a quality product commercially in accordance with the patent specifications would be covered by the exemption.¹⁴⁸ The court limited the scope of the experimental use exemption by defining the word "experiment" to mean "trials carried out in order to discover something unknown or to test a hypothesis."¹⁴⁹ This includes tests to determine whether something known to work under particular conditions also works under other conditions.¹⁵⁰ Tests conducted in order to amass information or to demonstrate that a product or process works as claimed do not qualify as experiments under section 60(5).¹⁵¹ The court recognized that the purpose of a trial may be difficult to determine or may have a mixed purpose, and held that it was for the courts to determine the purpose of the activity on the basis of the evidence led by the defendant.¹⁵² Generally, where the use of a trial is mixed (part pure research part commercial use), English law favors a narrow approach that considers the use to be infringing.¹⁵³

V. THE EXPERIMENTAL USE EXEMPTION IN GERMAN LAW

¶57 The German experimental use provision, like the English statutory exemption, is modelled on the European Community Patent Convention. In *Klinische Versuche I*,¹⁵⁴ the Federal Supreme Court of Germany rejected the prior jurisprudence on experimental use,¹⁵⁵ holding that the meaning and scope of the experimental use privilege should be

¹⁴³ *Id.* at 522.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Monsanto Co. v. Stauffer Chemical Co. & Another*, [1985] R.P.C. 515.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.* at 538.

¹⁴⁹ *Id.* at 542.

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Monsanto Co. v. Stauffer Chemical Co.*, [1985] R.P.C. 515, 542.

¹⁵³ ACIP, *supra* note 4, at 41 (citing *SK& F v. Evans* [1989] F.S.R. 513, and *McDonald v. Graham* [1994] R.P.C. 515).

¹⁵⁴ *Klinische Versuche (Clinical Trials) I*, [1997] R.P.C. 623 (Fed. Sup. Ct. Germany).

¹⁵⁵ Tessensohn, *supra* note 1, at 54 (discussing *Ethofumesat* case).

interpreted in the light of the new EC Patent Convention.¹⁵⁶ Specifically, the court found that using a patented polypeptide in tests to ascertain further medical uses for the patented product fell within the statutory experimental use exemption.¹⁵⁷

¶158 Like the English courts, the Federal Supreme Court held that Section 11 No. 2 of the Patents Act is concerned with the purpose of the act not the type of act that is taking place.¹⁵⁸ The court gave a broad interpretation to the word “experiment,” holding that it includes any procedure for obtaining information irrespective of the intended use of the information, provided that the experiment relates to the subject matter of the invention.¹⁵⁹ Following this interpretation, any experiment directed at gaining information for scientific research into the subject matter of the invention is permitted as an experimental use.¹⁶⁰ This includes use of the invention.¹⁶¹

¶159 Importantly, the court held that because the statutory language contains neither quantitative nor qualitative limits on the experiments that may be performed, it does not matter whether the experiments are performed solely to verify statements made in the patent claim or to extract further unknown information.¹⁶² It also does not matter whether these experiments are employed for wider purposes such as commercial interests.¹⁶³ Once the initial requirement of an experimental purpose is satisfied the exemption will be granted regardless of the way in which the results of the experiment are used.¹⁶⁴ The Court’s interpretation was particularly informed by the view that further technical development is in the public interest and is the aim of patent law.¹⁶⁵

¶160 *Klinische Versuche II* also involved a patented genetically engineered polypeptide sequence.¹⁶⁶ The defendant had generated the same patented sequences as the patent holder but had used a different procedure than the one employed by the patent holder. The defendant then used this sequence in clinical trials with three purposes: (1) verification of certain animal test results; (2) generation of data for obtaining official pharmaceutical permission to market the product; and (3) comparison of certain properties of the patented version against the defendant’s version.¹⁶⁷ As in *Klinische Versuche I*, the Federal Supreme Court of Germany found that the defendant’s activities were covered by the statutory exemption.¹⁶⁸

¶161 The court accepted that these clinical experiments were carried out predominantly to obtain data for the regulatory pharmaceutical approval process.¹⁶⁹ Relying on its interpretation in *Klinische Versuche I* the court held that:

¹⁵⁶ *Klinische Versuche*, [1997] R.P.C. 623, 625.

¹⁵⁷ *Id.* at 646.

¹⁵⁸ *Id.* at 638.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.* at 639.

¹⁶¹ *Id.*

¹⁶² *Klinische Versuche*, [1997] R.P.C. 639.

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *Id.* at 643.

¹⁶⁶ *Klinische Versuche (Clinical Trials) II*, [1998] R.P.C. 423 (Fed. Sup. Ct. Germany).

¹⁶⁷ *Id.* at 423.

¹⁶⁸ *Id.* at 424.

¹⁶⁹ *Id.* at 432.

According to the wording of the law it does not make any difference whether the experiments supply scientifically or commercially usable results, or whether the test . . . achieves the aim of obtaining data for legal pharmaceutical permission, thus preparing the access to the market for after the expiration of the term of protection of the patent.¹⁷⁰

¶62 Because the Convention for the European Patent for the Common Market makes no mention of limits for experiments with commercial goals,¹⁷¹ the court held that commercial orientation will not “from the outset turn the commercial activity into an impermissible patent infringement.”¹⁷² Instead, as the British court did in *Stauffer*, the German court limited the range of permissible activities by defining what will and will not constitute an experiment.¹⁷³ Experiments must relate to “technological theory” and should not be undertaken in such proportions as to no longer allow for justification on research grounds.¹⁷⁴ Experiments carried out with the purpose of “persistently disturbing or hindering the inventor’s distribution of his product” will be impermissible.¹⁷⁵ In essence, in accordance with the German view of patent law as being for the purpose of technological advancement, the purpose of the experiment must be technological progress rather than the accomplishment of competitive purposes.¹⁷⁶ The court was aware of the economic reality that clinical research involving pharmaceuticals would almost invariably be based on commercial considerations because of the high costs of such R&D.¹⁷⁷

VI. A COMPARATIVE ANALYSIS OF THE EXPERIMENTAL USE EXEMPTIONS

¶63 Of the four countries surveyed, the U.S. is alone in failing to craft a general statutory research exemption beyond the industry specific Bolar exemption. Amongst leading patent nations, a statutory exemption of this kind is the norm.¹⁷⁸

¶64 It is a common complaint in U.S. publications that the U.S. has a very narrow experimental use exemption. It is important to realize that this is only true in one sense. With respect to the range of patented goods covered by the exemption, the U.S. exemption is narrow and covers only medical products. Japan, Germany and the U.K. do not discriminate with respect to the subject matter of the patent. With respect to the range of permissible activities on exempted goods, however, the U.S. has the broadest exemption. Germany is next on the scale, permitting a certain amount of commercial use. Although German law permits commercial uses of inventions under their experimental use exemption, the German exemption is narrower than the American

¹⁷⁰ *Id.* at 433.

¹⁷¹ The Court implies that if the drafters wished to have created such limits they would have included them.

¹⁷² *Klinische Versuche (Clinical Trials) II*, [1998] R.P.C. 423, 434 (Fed. Sup. Ct. Germany).

¹⁷³ *Id.*

¹⁷⁴ *Id.* at 436.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Klinische Verusch II*, [1998] R.P.C. 437.

¹⁷⁸ Mueller, *supra* note 17, at 969.

exemption in that German law will not permit the use of a patented invention for clarifying commercial facts such as price acceptance, distribution possibilities and market needs, as these issues are not related to the subject matter of the invention.¹⁷⁹ Next on the scale are Japan and England which lie together near the narrow end of the spectrum and prohibit commercial activity.¹⁸⁰

¶65 As Strandburg's analysis demonstrates, countries should be less concerned with providing experimental use exemptions for product patents and more concerned with process patents. For product patents, the first-sale doctrine typically alleviates the need for an experimental use exemption,¹⁸¹ at least in respect of use. None of the nations reviewed here have drawn any distinction between product patents and process patents.

¶66 Several commentators have recognised Judge Newman's distinction in *Integra*¹⁸² between experimenting on and experimenting with as important, even perhaps determinative.¹⁸³ The U.S. has not, however, adopted this distinction. The German and English tests which require an experiment to relate to the subject matter of the invention are alternative formulations of the "experimenting on" and "experimenting with" distinction. Commentators concede that there will be difficulties at the margins in distinguishing differences between experimenting on and experimenting with, but argue that this does not diminish the importance of the distinction.¹⁸⁴

VII. THE IMPACT OF EXPERIMENTAL USE EXEMPTION ON R&D

¶67 Japanese pharmaceutical R&D lags behind that of both Europe and the U.S.¹⁸⁵ Between 1995 and 1998 Japan showed a decline in the number of new pharmaceutical products brought to market, with the number of new pharmaceutical products approved reaching the lowest number in ten years.¹⁸⁶ In 1996, more than half of the new pharmaceuticals approved for sale on the Japanese market had foreign patent holders.¹⁸⁷ The number of pharmaceutical patents granted also showed a decline during this period.¹⁸⁸

¶68 In the overall patent statistics for the year 2000, U.S. residents held just slightly less than 35% of the patents in the triadic patent families, followed by Japan at just over 25%, Germany at 13% and the U.K. at 4%.¹⁸⁹ They rank in the same order for gross domestic

¹⁷⁹ Derzko, 44 IDEA 1, *supra* note 2, at 59.

¹⁸⁰ *See id.* at 70-17. Derzko offers the same spectrum taking into account price control and patent term extension schemes. *Johnson*, 12 Pac. Rim L. & Pol'y 499. *Johnson* would classify Japan as broader than the U.S. because the Japanese exemption permits designing around a patent, which is blocked in the U.S. by the *Embrex* decision. *Embrex*, however, relates to the exceedingly narrow common law exception and to the broad statutory exemption.

¹⁸¹ Mueller, *supra* note 17, at 974.

¹⁸² *Integra*, *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *vacated by* 125 S. Ct. 2372 (2005).

¹⁸³ Mueller, *supra* note 17, at 956-57.

¹⁸⁴ *Id.*

¹⁸⁵ Tessensohn, *supra* note 1, at 44.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Compendium of Patent Statistics: 2004*. Organisation for Economic Co-Operation and Development (OECD) 15. The triadic patent family represents those patents filed at the United States Patent Office, the

expenditure on R&D financed by industry¹⁹⁰ and number of PCT applications filed.¹⁹¹ However, if one measures the number of triadic patent families held over gross domestic product, Japan scores the highest at a ratio of 3.8, followed by Germany at 3.0, the U.S. at 1.6 and the U.K. at 1.3¹⁹²

¶69 Since 1997, Japan has displayed an increasing number of triadic patent families per unit of industry-financed R&D, while the U.S. and Germany have both shown a marked decline. The U.K. was stable from 1997 to 1999, after which it also showed a decline.¹⁹³

¶70 This seems to indicate that of the four nations, Japan is getting more innovative output per unit of R&D input than the other nations, and generates a greater proportion of national income from its innovative outputs than the other nations. These findings are confirmed by results reported by Johnson indicating a growth of inventive activity in Japan, with Japan being predicted to outstrip the U.S. and all other nations in number of innovations per million residents.¹⁹⁴

¶71 The U.K. was the leader for patent applications to the EPO for domestic inventions owned by foreign residents, with slightly less than 40% of all the U.K.'s domestic patents being foreign-owned. Germany scored 13%, the U.S. 12% and Japan 3%.¹⁹⁵ For domestic ownership of inventions made abroad and filed at the EPO the U.K. again ranked first of the four countries with 19%, followed by the U.S. with 18%, Germany with 12% and Japan with 3%.¹⁹⁶ These figures indicate that of the four nations, the U.K. is substantially more popular with foreign inventors. On the other hand, the U.K. inventors do not go offshore to patent their inventions to any significantly greater degree than either Germans or Americans. The Japanese are the least internationalized on both counts.

¶72 On these figures it seems that fears about research exemptions driving R&D offshore may well be misplaced. Although Japan showed a decline in its pharmaceutical industry as the courts began to favour generic manufacturers, the overall patent statistics do not show a move offshore by Japanese inventors and, in fact, indicate an increased innovative output.

VIII. CONCLUSION

¶73 This review of the patent statistics reveals that, contrary to predictions in the literature,¹⁹⁷ a narrow experimental use exemption might not correlate with reduced

European Patent Office, and the Japanese Patent Office.

¹⁹⁰ *Id.* at 24.

¹⁹¹ *Id.* at 20. 38% of the applications in 2001 were filed by United States residents, 13% by Japanese residents, 13% by German residents, and 5% by United Kingdom residents.

¹⁹² *Id.* at 22.

¹⁹³ *Id.* at 25.

¹⁹⁴ Johnson, *supra* note 3, at 531-32.

¹⁹⁵ ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, *supra* note 189, at 30.

¹⁹⁶ *Id.* at 31.

¹⁹⁷ Proposals by the European Union Parliament clearly equate experimental use provisions with increased competitiveness. See Derzko, *supra* note 2, at 62; Tessensohn, *supra* note 1, at 38. See also Sandstrom, *supra* note 3, who argues that countries with high innovative capacities all have broad experimental use exemptions in their law (citing Germany, Japan, Italy, Switzerland, France, Spain, Sweden, Canada and the United Kingdom). Sandstrom's analysis is based, however, on the presumption that the experimental use exemptions in these countries are broader than the exemption in the United States.

R&D. Based on the figures presented here, there is also no evidence of a movement of R&D offshore. Nor does a narrow experimental use exemption show evidence of reduced university research.¹⁹⁸

¶74 What also emerges from this analysis is that U.S. law is alone in founding its test exclusively on a distinction between commercial and non-commercial research. This is a test that is bound to fail, as it does not take into account the economic and practical realities of research that have resulted in a blurring of the distinction between pure research and applied research.¹⁹⁹ While the Japanese apply their commercial test based on the jurisprudential rationales underlying patent law,²⁰⁰ the American cases demonstrate the difficulty US courts have faced in trying to decide cases on the basis of a commercial analysis alone. The Japanese cases illustrate a marked change in direction when the commercial analysis is supplemented with a grounding in the jurisprudential bases of patent law. As Strandburg has demonstrated, the research exemption is intimately connected to the incentives to innovate theory, and to be successful any test implementing the research exemption must take that jurisprudence into account.

¶75 It is also clear, as Eisenberg,²⁰¹ Strandburg²⁰² and Judge Newman in *Integra* noted,²⁰³ that a distinction must be drawn between experimenting with a patented invention and experimenting on a patented invention so as to protect the interests of the research tool patentee.²⁰⁴ The experimental use exemptions of German and English law incorporate this distinction by requiring an experiment to relate to the subject-matter of the invention. In terms of the “incentive to innovate” theory, it makes sense to exclude research tools from any research exemption, as the German and English approaches attempt to do.²⁰⁵ Still, the distinction between experimenting on and experimenting with is not without its problems at the margins. This is especially true in the software and biotechnology fields.²⁰⁶ However, even in these hard cases, the distinction has the clarity to operate as a meaningful test that is both factual and objective.²⁰⁷

As this study has shown the experimental use exemptions in the United Kingdom, Germany and Japan are narrower than the US exemption. In addition, the study that Sandstrom relies upon does not measure the actual R&D output of the nations concerned, but rather innovative capacity, or the potential for innovation, based on the way in which R&D is funded, organized and integrated with other industry sectors.

¹⁹⁸ Johnson, *supra* note 3, at 523.

¹⁹⁹ ACIP, *supra* note 4, at 20, 56. *See also* *Integra Lifesciences I, Ltd. v. Merck KGaA.*, 331 F.3d 860, 872-78 (Newman, J. dissenting).

²⁰⁰ Strandburg, *supra* note 4, at 83.

²⁰¹ Eisenberg, *supra* note 21, at 1017.

²⁰² Strandburg, *supra* note 4, at 83.

²⁰³ *Integra*, 331 F.3d 860.

²⁰⁴ However, certain special cases may fall outside this rule. *See* ACIP, *supra* note 4, at 24, 53.

²⁰⁵ Strandburg, *supra* note 4, at 90-91.

²⁰⁶ *Id.*

²⁰⁷ *Id.*