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THE EXPERIMENTAL USE EXCEPTION IN JAPAN: A MODEL FOR U.S. PATENT LAW?

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Abstract: The patent laws of the United States and Japan contain provisions that permit the experimental use of patented inventions. In the United States, the common law experimental use exception has been utilized to permit the use of a patented invention to satisfy intellectual curiosity, as long as the use is not commercial. In 1984, the Hatch-Waxman Act provided a statutory experimental use exception in 35 U.S.C. § 271(e)(1). It amended the Patent Act to allow a generic drug company to experiment with a pioneer drug during the pioneer drug's patent term to generate data for obtaining regulatory approval. In contrast, § 69(1) of the Japanese Patent Law provides for a general statutory experimental use exception that allows use of any patented invention for experiment or research. The general experimental use exception in Japan is much broader than the two experimental use provisions in the United States and permits more beneficial uses.

The experimental use approaches taken in the United States have been problematic. To remedy these problems, the United States Congress has proposed several bills, each with differing breadth, which would protect additional types of experimental use or modify the Hatch-Waxman Act. No such reform has passed to date. This Comment argues that the United States may benefit from adopting a general statutory experimental use exception like Japan's. This Comment further argues that broadening the experimental use exception in the United States would not decrease the incentives created by the patent system. Furthermore, since the Japanese approach is more consistent with the patent systems of other countries, it facilitates patent harmonization better than the narrow exception provided in the United States.

I. INTRODUCTION

In a recent Rose Garden press conference, President Bush proposed regulations to “reduce the cost of prescription drugs in America by billions of dollars and ease the financial burden for many citizens, especially our seniors.”¹ The proposed regulations aim to bring cheaper generic drugs to the market more quickly by removing legal loopholes that pioneer drug companies have exploited to artificially extend their patent monopolies.² Thus, patent law has moved to the forefront of the U.S. healthcare debate.

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¹ *Bush Proposes Rules to Boost Generic Drugs*, at <http://www.cnn.com/2002/ALLPOLITICS/10/21/bush.generic.drugs/index.html> (last visited Jan 28, 2003) [hereinafter *Bush Proposes Rules*].

² *Id.* For the purpose of this Comment “pioneer drug companies” are pharmaceutical companies that perform extensive research and development to develop new drugs.

Patents encourage technical progress and protect the investments and commercial interests of inventors by vesting exclusive rights to the invention in the patent holder for a limited time.³ In exchange for this exclusive right, the inventor must publicly disclose the invention.⁴ However, these rights are not absolute.⁵ For example, in instances where strong public policies outweigh the policies behind granting patent exclusivity, the scope of a patent may be limited.⁶

The experimental use exception to infringement, also referred to as a defense to infringement,⁷ is employed in many different circumstances. Depending on the patent law of the country, an experimental use exception may cover experiments to verify the truth and sufficiency of a disclosure in a patent specification;⁸ experiments conducted to satisfy intellectual curiosity with no intent of profiting from the invention;⁹ experiments conducted in preparation for licensing;¹⁰ experiments aimed at acquiring data about a product to satisfy regulatory agencies;¹¹ and experiments aimed at finding a new use for a patented invention.¹²

Both the United States and Japan have provisions that permit experimental use in their patent laws. A comparison of the experimental use exceptions in these two countries, however, reveals that the United States and Japan have taken drastically different approaches. The U.S. experimental use provisions include a common law experimental use exception and a pharmaceutical industry-specific provision provided in the Hatch-Waxman Act.¹³ The Hatch-Waxman experimental use provision was enacted to ensure that generic drug manufacturers could conduct tests with a patented pioneer drug for regulatory approval of a generic formulation.¹⁴ Japan also allows generic drug manufacturers to experiment with patented drugs to obtain regulatory approval, but accomplishes this through a general

³ U.S. CONST. art. I, § 8, cl. 8 (The Constitution gives Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”); David Gilat, *Experimental Use and Patents*, in 16 STUDIES IN INDUSTRIAL PROPERTY AND COPYRIGHT LAW 2-3 (1995).

⁴ J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc., 534 U.S. 124, 142 (2001).

⁵ DONALD S. CHISUM, CHISUM ON PATENTS § 16.03 [1] (2002).

⁶ Gilat, *supra* note 3, at 17.

⁷ CHISUM, *supra* note 5, § 16.03 [1]; *Madey v. Duke Univ.*, 307 F.3d 1351, 1361 (Fed. Cir. 2002).

⁸ Gilat, *supra* note 3, at 20.

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ See discussion *infra* Parts II.A & C. This Comment does not discuss experimental use in relation to the public use and on sale bars in 35 U.S.C. § 102(b).

¹⁴ See discussion *infra* Part II.C.

statutory experimental use exception.¹⁵ Although both countries allow experimentation for obtaining regulatory approval, their divergent approaches to experimental use have resulted in experimental uses being allowed in Japan that are not allowed in the United States.¹⁶ A comparison of the U.S. and Japanese experimental use exceptions is especially important because Europe, Japan and the United States dominate the US \$343 billion pharmaceutical industry.¹⁷

This Comment argues that the U.S. experimental use approach is problematic and advocates that the United States adopt an experimental use provision similar to that of Japan. Part II of this Comment describes the development and current state of the experimental use exception in U.S. patent law, while Part III addresses the experimental use exception in Japan. Part IV discusses the criticisms of the U.S. experimental use exceptions, while Part V considers the experimental use exception in the Trade-Related Aspects of Intellectual Property Rights Agreement and patent harmonization efforts. Finally, Part VI evaluates prior attempts to bring the United States closer to the Japanese model and argues that the United States may benefit from a general statutory experimental use exception.

II. THE EXPERIMENTAL USE EXCEPTION IN THE UNITED STATES

In the United States there are two types of experimental use exceptions to patent infringement: the common law experimental use exception and a statutory experimental use exception. The common law experimental use exception, developed over one hundred years ago, permits the use of a patented invention to satisfy intellectual curiosity as long as there is no commercial purpose. After the Federal Circuit held that a generic drug manufacturer could not experiment with a pioneer drug to obtain regulatory approval under the common law experimental use exception, Congress enacted the Hatch-Waxman Act. The act added a narrow statutory experimental use exception that permits the use of a patented drug for purposes “reasonably related” to obtaining Food and Drug Administration (“FDA”) approval. This statutory exception has been interpreted broadly and many seemingly commercial activities have been found reasonably

¹⁵ See discussion *infra* Part III.

¹⁶ See discussion *infra* Parts III.D & IV.

¹⁷ *Global Pharma Market Facts*, (Helmet Weissner ed.), at http://www.pharma-outsourcing.com/open/library/global_pharma_market/facts.htm (last visited Jan. 28, 2003).

related to obtaining regulatory approval. Although the Hatch-Waxman Act superseded the common law experimental use exception with respect to inventions that require FDA approval, the common law exception survives in all other areas.

A. *The Common Law Experimental Use Exception (Pre-1984)*

First developed by Supreme Court Justice Story in 1813, the common law experimental use exception is based on the reasoning that “[i]t 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.”¹⁸ Throughout the nineteenth century, the experimental use exception was continually recognized, and it became well-established that experiments conducted with a patented invention did not infringe the patent if they were performed for the sole purpose of satisfying intellectual curiosity or for mere amusement.¹⁹ The common law developed with the assumption that these types of experiments did not disturb the rights of the patent holder, as long as there was no commercial purpose.²⁰

From the mid-nineteenth century until 1983, only a handful of accused infringers successfully relied on the experimental use defense to infringement.²¹ The exception was premised on the idea that a patentee will not uncover a *de minimis* experimental use with no commercial purpose or spend valuable resources to enforce his patent rights when damages will be limited.²² The common law experimental use exception’s limited utility prevented it from becoming a commonly used defense in patent infringement actions.²³ In 1984, however, the experimental use exception

¹⁸ *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (No. 17,600) (C.C.D. Mass. 1813), *quoted in Roche Prods., Inc. v. Bolar Pharmaceutical Co. Inc.*, 733 F.2d 858, 862 (Fed. Cir. 1984).

¹⁹ CHISUM, *supra* note 5, § 16.03 [1]; *See, e.g., Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (No. 11,279) (C.C.S.D.N.Y. 1861); *Byam v. Bullard*, 4 F. Cas. 934, 935 (No. 2,262) (C.C.D. Mass. 1852); *Sawin v. Guild*, 21 F. Cas. 554, 555 (No. 12,391) (C.C.D. Mass. 1813).

²⁰ CHISUM, *supra* note 5, § 16.03 [1].

²¹ *Id.*; *see, e.g., Dugan v. Lear Avia*, 55 F. Supp. 223 (S.D.N.Y. 1944), *aff’d*, 156 F.2d 29 (2d Cir. 1946) (finding no infringement when a defendant built the device only experimentally and did not manufacture or sell it); *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305 (N.D.W.Va. 1937) (holding that the defendant’s use of a patented machine was experimental and did not amount to infringement when there was no intent to profit from the use); and *Chesterfield v. United States*, 159 F. Supp. 371 (Ct. Cl. 1958) (holding that the use of a patented metal alloy by the United States was not infringement because the alloy was used only for testing and experimental purposes).

²² CHISUM, *supra* note 5, § 16.03 [1] (stating that the “experimental purpose doctrine ‘is nothing more than an expression of the maxim *de minimis non curat lex.*’”).

²³ *Id.*

acquired increasing prominence with the Court of Appeals for the Federal Circuit's landmark decision, *Roche v. Bolar*.²⁴

B. Roche v. Bolar: The Common Law Experimental Use Exception at the Forefront

In *Roche v. Bolar*, the Federal Circuit found that the common law experimental use exception did not apply to the "use of a patented drug for testing and investigation strictly related to [Food and Drug Administration] drug approval requirements during the last [six] months of the term of the patent."²⁵ Roche owned the rights to the active ingredient of a popular sleeping pill.²⁶ Bolar, interested in manufacturing a generic version, began testing to generate data for FDA approval prior to the expiration of Roche's patent.²⁷ Bolar argued that experimenting with the drug prior to patent expiration should be allowed because FDA approval often takes more than two years and the success of a generic drug is related to how quickly the drug enters the market after the pioneer drug patent expires.²⁸ The Federal Circuit reversed the district court's decision that Bolar's use fell under the experimental use exception and held that Bolar infringed the Roche patent.²⁹

The Federal Circuit reasoned that Bolar's use of the patented drug was not merely for amusement or philosophical inquiry; rather, the company intended to use the data to meet the requirements for commercialization of the generic drug.³⁰ Therefore, Bolar infringed Roche's patent because its use was for business purposes and did not fall within the common law experimental use exception.³¹ The court declined to increase the scope of the exception, describing the common law experimental use exception as "truly narrow."³²

Bolar also argued the case on policy grounds, stating that the Federal Circuit should reconcile the conflicting policies and purposes of the Patent Act and the Federal Food, Drug, and Cosmetic Act ("FDCA").³³ The FDCA sets forth the requirements for obtaining FDA approval, which include

²⁴ *Roche Prods., Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (Fed. Cir. 1984).

²⁵ *Id.* at 861.

²⁶ *Id.* at 860.

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.* at 861.

³⁰ *Id.* at 863.

³¹ *Id.* at 860, 865.

³² *Id.* at 863.

³³ *Id.*

proving the safety and efficacy of a new drug.³⁴ At the time of *Roche*, it routinely took seven to ten years to comply with these regulatory requirements.³⁵ Because drug patents are generally issued prior to FDA testing, the time that a pioneer drug was on the market before the patent term expired under the Patent Act of 1952 was often significantly less than the full patent term of seventeen years at that time.³⁶ Some of the patent term was “restored,” however, as generic drug companies were prohibited from generating data required to satisfy FDA requirements until after the original drug patent expired.³⁷ This effectively added the time needed to obtain data and regulatory approval of the generic drug to the pioneer drug’s patent term.³⁸ The Federal Circuit, by denying that such testing fell within the common law experimental use exception, refused to address this conflict and invited Congress to consider the issue.³⁹

C. *The Hatch-Waxman Act: Congress’ Response*

Congress resolved the conflict between the FDCA and the Patent Act by enacting the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.⁴⁰ The Hatch-Waxman Act negated the Federal Circuit’s decision in *Roche v. Bolar* by providing that the use of a patented drug for the generation of data required for regulatory approval is not an infringing use. The Hatch-Waxman Act added § 271(e)(1) of the Patent Act to provide that:

[i]t 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 drugs⁴¹

³⁴ 21 U.S.C. § 355(b)(1) (2000).

³⁵ *Roche Prods., Inc.*, 733 F.2d at 864.

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.* at 865.

⁴⁰ Drug Price Competition and Patent Term Restoration Act of 1984, P.L. 98-417, 98 Stat. 1585 (1984) (codified as amended at Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355 (2000); Patent Act, 35 U.S.C. §§ 156, 271, 282 (2000)) [hereinafter the Hatch-Waxman Act].

⁴¹ 35 U.S.C. § 271 (e)(1) (2000).

In addition, the Hatch-Waxman Act extended a pioneer drug's patent term for up to five years,⁴² to restore the patent term that was effectively lost while the pioneer drug was obtaining regulatory approval.⁴³

The Hatch-Waxman Act also amended the FDCA to establish new, abbreviated requirements for generic drug FDA approval.⁴⁴ Unlike approval for pioneer drugs, generic drug approval does not require that the generic drug is proven safe and effective.⁴⁵ Rather, the generic drug manufacturer has to prove only that the generic drug is a bioequivalent of the pioneer drug, that the generic drug has the same active ingredients as the pioneer drug, and that the route of administration, dosage, and strength of the generic drug is the same as the pioneer drug.⁴⁶ This abbreviated procedure, called an Abbreviated New Drug Application ("ANDA"), aims to decrease the time and experimentation required for a generic drug to gain approval.⁴⁷ The act also requires that when a generic drug manufacturer files with the FDA it must certify that either: (1) there is no patent on the pioneer drug; (2) there is a patent on the pioneer drug, but that the patent has expired; (3) there is a patent on the pioneer drug, but that the patent will expire on a specified date; or (4) the patent on the pioneer drug is invalid or not infringed by the generic drug manufacturer.⁴⁸

This certification process determines when the generic drug company may begin commercial production of the generic drug. FDA approval is effective immediately if the generic manufacturer states that there is no patent on the pioneer drug or that the patent has expired.⁴⁹ If the generic drug manufacturer certifies that the pioneer drug's patent will expire on a certain date, approval is effective as soon as the pioneer drug patent has expired.⁵⁰ If the generic drug manufacturer certifies that the pioneer drug patent is invalid or not infringed, the generic drug is approved only after the generic drug manufacturer notifies the pioneer drug manufacturer that the generic drug manufacturer has filed an application for FDA approval, and has certified that the pioneer drug patent is either invalid or not infringed.⁵¹ This type of certification is frequently referred to as a Paragraph IV ANDA

⁴² 35 U.S.C. § 156 (2000).

⁴³ H.R. REP. NO. 98-857, pt. I, at 18 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2651.

⁴⁴ *Id.* at 1.

⁴⁵ *Id.* at 16.

⁴⁶ 21 U.S.C. § 355(j)(2)(A)(ii-iv) (2000).

⁴⁷ H.R. REP. NO. 98-857 at 18.

⁴⁸ 21 U.S.C. § 355(j)(2)(A)(vii).

⁴⁹ *Id.* § 355(j)(5)(B)(i).

⁵⁰ *Id.* § 355(j)(5)(B)(ii).

⁵¹ *Id.* § 355(j)(5)(B)(iii).

filing.⁵² The generic drug application is approved only if the pioneer drug manufacturer has not commenced a lawsuit for infringement within forty-five days after receiving notice.⁵³ If the patent holder does file suit, approval is suspended until: (1) a court finds that the patent is invalid or not infringed; (2) the patent expires; or (3) thirty months, whichever occurs first.⁵⁴

D. *Interpreting the Scope of the § 271(e)(1) Experimental Use Exception*

Since the Hatch-Waxman Act became law, a significant amount of litigation has stemmed from the experimental use exception provided in § 271(e)(1).⁵⁵ For example, in *Eli Lilly and Co. v. Medtronic*, the Supreme Court defined the scope of the experimental use exception under § 271(e)(1).⁵⁶ Eli Lilly, the holder of a patent for a cardiac defibrillator, filed an infringement action against Medtronic for its use of a similar defibrillator.⁵⁷ Medtronic relied on § 271(e)(1) and denied infringing the Eli Lilly patent on the grounds that Medtronic's use of the defibrillator was reasonably related to obtaining data for FDA approval.⁵⁸ Eli Lilly argued that § 271(e)(1) applies only to drugs and not to medical devices.⁵⁹ The Court held that all of the products eligible for patent term extension under the Hatch-Waxman Act fall within the scope of the § 271(e)(1) experimental use exception.⁶⁰ Thus, medical devices, food additives, color additives, new drugs, antibiotic drugs, and human biological products may be used during the original patent term without infringing the original patent, as long as the use is reasonably related to obtaining data for FDA approval.⁶¹ Consequently, the Court held that Medtronic did not infringe Eli Lilly's defibrillator patent.⁶²

⁵² Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD DRUG L.J. 187, 189 (1999).

⁵³ 21 U.S.C. § 355(j)(5)(B)(iii).

⁵⁴ *Id.* § 355(j)(5)(B)(iii)(I-III).

⁵⁵ See, e.g., *Eli Lilly & Co. v. Medtronic, Inc.* 496 U.S. 661 (1990); *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992); *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997); and *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd*, 1993 U.S. App. LEXIS 3620, at *2 (Fed. Cir. Feb. 22, 1993) (affirmed in an unpublished opinion).

⁵⁶ 496 U.S. 661.

⁵⁷ *Id.* at 663.

⁵⁸ *Id.* at 664.

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.* at 674.

⁶² *Id.* at 679.

The District Court for the Northern District of California's decision in *Intermedics, Inc. v. Ventritex Co., Inc.* further interpreted the scope of § 271(e)(1) by clarifying which activities are "reasonably related" to obtaining FDA approval and thus within the § 271(e)(1) experimental use exception.⁶³ The district court interpreted activities "reasonably related" to obtaining FDA approval broadly, holding that Ventritex's use of an implantable defibrillator was experimental and did not infringe Intermedic's patent.⁶⁴ First, the court found that Ventritex's manufacture of several hundred defibrillators qualified as experimental use under § 271(e)(1), as most of the devices were used in tests that generated data for FDA approval.⁶⁵ Second, selling the device to U.S. hospitals was also permitted, as there was no evidence that the device was used outside of clinical testing.⁶⁶ The court also allowed Ventritex to sell the defibrillators to hospitals and to continue generating clinical data even after submission of their application to the FDA, since the FDA might later require more clinical data.⁶⁷ Third, Ventritex's sale of the defibrillators to international distributors was also deemed reasonably related to obtaining FDA approval, as the devices were subsequently resold to approved FDA clinical investigators.⁶⁸ Fourth, the court permitted Ventritex's testing of the device in Germany.⁶⁹ It emphasized that all of the defibrillators sold in Germany were used by investigators to generate data for FDA approval only.⁷⁰ There was no evidence that the data was ever submitted to German authorities for approval in Germany.⁷¹ Finally, demonstration of the defibrillator at various scientific trade shows was also an experimental use and reasonably related to getting FDA approval.⁷² The court reasoned that demonstration of the device, even at a commercial venue, was not an infringing use since the FDA might eventually require Ventritex to recruit additional investigators.⁷³ Therefore, the district court defined "reasonably related" very broadly, and many seemingly commercial uses fell under the § 271(e)(1) experimental

⁶³ 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd*, 1993 U.S. App. LEXIS 3620, at *2 (Fed. Cir. Feb. 22, 1993) (affirmed in an unpublished opinion).

⁶⁴ *Id.* at 1280, 1289.

⁶⁵ *Id.* at 1282.

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.* at 1283.

⁶⁹ *Id.* at 1284.

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.* at 1287.

⁷³ *Id.* at 1288.

use exception. The Federal Circuit affirmed the district court decision in an unpublished opinion.⁷⁴

Although the Federal Circuit's *Intermedics v. Ventritex* opinion lacks precedential weight, the Federal Circuit explicitly endorsed the district court's broad interpretation of § 271(e)(1) in *Telectronic Pacing Systems v. Ventritex*.⁷⁵ In another dispute regarding the use of an implantable defibrillator, the Federal Circuit found that Ventritex's display of its defibrillator at seven medical conferences and use of clinical data for fundraising purposes were "reasonably related" to obtaining FDA approval and fell within the scope of the § 271(e)(1) experimental use exception.⁷⁶ The court reasoned that Congress was aware of the need for companies to raise funds to develop their products and to prepare for entry into the marketplace once the original patent has expired.⁷⁷ Since Congress did not include a provision prohibiting the use of clinical testing data for fundraising and other business purposes, uses other than those absolutely required for FDA approval might also be permitted.⁷⁸ "As long as the activity is reasonably related to obtaining FDA approval, [the accused infringer's] intent or alternative uses are irrelevant to its qualification to invoke the section 271(e)(1) shield."⁷⁹

E. The Common Law Experimental Use Exception After the Hatch-Waxman Act

Although the experimental use exception in § 271(e)(1) has been interpreted broadly, this exception only relates to experimental uses for obtaining FDA approval.⁸⁰ Other experimental uses are not specifically included in the Hatch-Waxman Act.⁸¹ Therefore, it is unclear whether experimental uses other than those for FDA approval are still protected under the narrow common law experimental use exception.⁸²

While the Hatch-Waxman legislative history demonstrates that the act was a response to the interpretation of the common law experimental use

⁷⁴ *Intermedics, Inc. v. Ventritex, Inc.*, 1993 U.S. App. LEXIS 3620, at *2 (Fed. Cir. Feb. 22, 1993).

⁷⁵ *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1525 n.5 (Fed. Cir. 1992).
⁷⁶ *Id.* at 1525.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997).

⁸⁰ See discussion *supra* Parts II.C & D.

⁸¹ See discussion *supra* Parts II.C & D.

⁸² CHISUM, *supra* note 5, § 16.03 [1]. For a discussion of the common law experimental use exception, see discussion *supra* Part II.A.

exception, it is silent as to whether the common law experimental use exception survived the Hatch-Waxman Act.⁸³ The common law experimental use exception in *Roche* permitted the experimental use defense to infringement only when the use was for amusement, to satisfy idle curiosity, or for strict philosophical inquiry.⁸⁴ In *Roche*, the Federal Circuit continued its narrow interpretation of this exception and found that Bolar's use of the patented drug for obtaining regulatory approval was not permitted under the common law exception since its use was commercial.⁸⁵ Less than six months later, Congress enacted the Hatch-Waxman Act.⁸⁶ Although the act prevents the application of the common law experimental use exception to drugs, medical devices and other products covered by § 271(e)(1),⁸⁷ there has been confusion regarding whether the common law experimental use exception still applies to other inventions.⁸⁸

The U.S. Court of Claims, predecessor of the Federal Circuit, stated that "although [the act] changed that narrow application of the doctrine affecting reporting requirements for federal drug laws, Congress did not disturb the Federal Circuit's enunciation of the parameters of the experimental use exception."⁸⁹ Ten years later, the Federal Circuit acknowledged the precedential value of the Court of Claims' decision and recognized the common law experimental use exception.⁹⁰ Even as recently as October 2002, the Federal Circuit again recognized the judicially created common law experimental use exception, albeit in its very limited form.⁹¹

In contrast, the District Court for the Northern District of California implied that the common law experimental use exception no longer exists, stating "Congress enacted § 271(e)(1) in 1984 in order to reverse the opinion of the [Federal Circuit] in [*Roche v. Bolar*]."⁹² Because the legislative history of the Hatch-Waxman Act does not show congressional intent to preempt the common law experimental use exception,⁹³ and since the U.S.

⁸³ Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 26 (2001).

⁸⁴ *Roche Prods., Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 862-63 (Fed. Cir. 1984); see *supra* Part II.

⁸⁵ 733 F.2d at 861.

⁸⁶ Gilat, *supra* note 3, at 5.

⁸⁷ Mueller, *supra* note 83, at 27.

⁸⁸ CHISUM, *supra* note 5, § 16.03 [1].

⁸⁹ *Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 632 n.14 (Cl. Ct. 1990).

⁹⁰ *Embrex, Inc. v. Service Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000).

⁹¹ *Madey v. Duke Univ.*, 307 F.3d 1351, 1360-61 (Fed. Cir. 2002) (reaffirming the validity of the experimental use exception in a very limited form).

⁹² *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1276 (N.D. Cal. 1991).

⁹³ Mueller, *supra* note 83, at 26.

Court of Claims and the Federal Circuit have endorsed a narrow common law experimental use exception, the common law exception likely survives the Hatch-Waxman Act, although its application remains strictly limited to activities with no commercial purpose.⁹⁴

In summary, there are two types of experimental use provisions in the United States. First, the narrow common law experimental use exception permits experimental uses of any patented invention, as long as it is merely to satisfy intellectual curiosity and has no commercial purpose.⁹⁵ Second, § 271(e)(1) allows manufacturers to experiment with patented pharmaceutical and medical inventions, as long as the use is “reasonably related” to obtaining FDA approval.⁹⁶ Many activities relating to commercialization of a drug have been permitted, as § 271(e)(1) has been interpreted broadly. Finally, these two experimental use exceptions coexist in the United States.

III. THE EXPERIMENTAL USE EXCEPTION IN JAPAN

The experimental use exception in Japan is contained in § 69(1) of the Japanese Patent Law, which provides that “the effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research.”⁹⁷ Enacted in 1909, while Japan was still a developing country and net importer of intellectual property, this exception was introduced to spur industrial growth through reverse engineering.⁹⁸ Furthermore, the policy underlying the Japanese experimental use exception is to promote the development of new technologies.⁹⁹ The Japanese Supreme Court recently held that the experimental use of a patented drug to generate data for regulatory approval of a generic drug is permitted under

⁹⁴ *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

⁹⁵ See discussion *supra* Part II.A.

⁹⁶ See discussion *supra* Part II.B.

⁹⁷ Tokkyoho [Patent L.], Law No. 121 of Apr. 13, 1959 (Japan), amended by Law No. 24 of Apr. 17, 2002 (Japan), art. 67(2), translated in JAPANESE LAWS RELATING TO INDUSTRIAL PROPERTY (Japanese Patent Office trans., 1996) [hereinafter Patent L.].

⁹⁸ Katsuya Tamai, Remarks at Center for Advanced Research on Intellectual Property High Technology Summit (July 20, 2001) (transcript on file with author) [hereinafter Tamai Remarks]; Reverse engineering refers to the process of analyzing the components of an invention and how they interact in order to recreate or modify it.

⁹⁹ Keiji Kondo, *Clinical Testing Falls into Permissible R & D Exception of Patent Infringement*, 26 AIPPI JOURNAL 290, 291 (Sept. 2001).

§ 69(1).¹⁰⁰ In contrast to the statutory experimental use exception in the United States, the Japanese statutory exception applies to all inventions and is not limited to drugs, medical devices, and similar products.¹⁰¹

A. *Japanese Pioneer and Generic Drug Approval Process*

Under the Pharmaceutical Affairs Law (“PAL”), the Ministry of Health, Welfare and Labor must approve both new and generic drugs before their commercial production and sale.¹⁰² The PAL is similar to the FDCA, in that the requirements for obtaining approval for new and generic drugs differ.¹⁰³ For a new drug to be approved, the applicant must demonstrate its safety and efficacy, usually through clinical trial data.¹⁰⁴ However, approval of generic drugs does not require that the drug is proven safe and effective.¹⁰⁵ Generic drug approval requires only that the generic drug is a biological equivalent to the pioneer drug, that the drug is stable and that the generic drug’s chemical and physical properties are certified.¹⁰⁶ Unlike the FDCA, the Japanese PAL does not contain a specific set of remedies for the pioneer drug manufacturer.¹⁰⁷

Japanese Patent Law § 67(2) includes a patent term extension provision similar to that in the Hatch-Waxman Act.¹⁰⁸ This section permits patent term extension for a period of up to five years because of the necessity of obtaining regulatory approval.¹⁰⁹

B. *Conflicting Case Law Relating to the Experimental Use Exception in Japan*

Japan’s status as a civil law country implies that judges are limited to interpreting codes and that judicial decisions have little precedential value.¹¹⁰

¹⁰⁰ See discussion *infra* Part III.C.

¹⁰¹ Patent L., *supra* note 97, art. 69(1).

¹⁰² Kondo, *supra* note 99, at 290-91.

¹⁰³ *Id.*

¹⁰⁴ *Id.* at 291.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ Yakuji-Ho [Pharmaceutical Affairs Law], No. 145 of 1960 (Japan), amended by Law No. 96 of Jul. 31, 2002 (Japan), translated in 8 EHS LAW BULLETIN Series XA (Einbun-Horei-Sha, Inc., ed. 2001).

¹⁰⁸ Patent L., *supra* note 97.

¹⁰⁹ *Id.* art. 67(2).

¹¹⁰ William T. Christiansen II, Note, *Patent Term Extension of Pharmaceuticals in Japan: So You Say You Want to Rush that Generic Drug to Market in Japan . . . Good Luck!*, 6 PAC. RIM L. & POL’Y J. 613, 637 (1997).

Analysis of Japanese case law, however, is an integral part of understanding Japanese law since the courts play a crucial role in law making, through their interpretation of Japanese statutes.¹¹¹ Commentators suggest that case law analysis is a critical step in understanding Japanese law because case law precedent is *de facto* law in Japan and because of prominent judicial activism in the country.¹¹² As one scholar comments, “one cannot tell how a case in contract or tort will be decided by the court if one merely looks at the text of the Civil Code without reference to precedent.”¹¹³ Therefore, a discussion of Japanese case law relating to the experimental use exception provides insight into the policy considerations motivating Japanese courts and illustrates how courts may resolve cases based on different facts.

Japanese case law relating to the experimental use exception in § 69(1) began with the Tokyo District Court’s 1987 decision in *Monsanto v. Stoffer Japan K.K.*¹¹⁴ Monsanto, the owner of a patented herbicide, filed an infringement action against Stoffer Japan.¹¹⁵ Stoffer Japan admitted to using Monsanto’s patented herbicide in experiments required for obtaining government approval for their generic version of the herbicide, but argued that their use was permitted under the Japanese experimental use exception in § 69(1). The Tokyo District Court held that Stoffer Japan’s use did not fall under the Japanese experimental use exception,¹¹⁶ and therefore, Stoffer Japan infringed Monsanto’s patent.¹¹⁷ The court stated that “[a]grochemical experiments carried out for the purpose of securing government registration of the herbicide are not intended to advance technology and therefore do not fall within the scope of the ‘experiment or research’ exception to an otherwise infringing use.”¹¹⁸ The court focused its interpretation on the legislative intent behind § 69(1), reasoning that the Japanese experimental use exception protects only research or experiments that advance

¹¹¹ THE JAPANESE LEGAL SYSTEM, 143 (Hideo Tanaka ed., 1976) [hereinafter JAPANESE LEGAL SYSTEM].

¹¹² Christiansen, *supra* note 110, at 638.

¹¹³ JAPANESE LEGAL SYSTEM, *supra* note 111.

¹¹⁴ Kondo, *supra* note 99, at 291; John A. Tessensohn, *Reversal of Fortune—Pharmaceutical Experimental Use and Patent Infringement in Japan*, 4 J. INT’L LEGAL STUD. 1, 25-26 (citing Monsanto Co. v. Stoffer Japan K.K.). The abbreviation “K.K.” stands for “Kabushiki Kaisha” and means “Incorporated.” E-mail correspondence from Rob Britt, University of Washington, to Jennifer Johnson, Comment Author, *Pacific Rim Law and Policy Journal* (Jan. 29, 2003) (on file with author).

¹¹⁵ Kondo, *supra* note 99, at 291-92.

¹¹⁶ Tessensohn, *supra* note 114, at 25-26 (citing Monsanto Co. v. Stoffer Japan K.K.).

¹¹⁷ *See id.*

¹¹⁸ Christopher Heath, *The Patent Exemption for “Experimental Use” in Clinical Trials: Germany, Japan, and the U.S. Compared*, 22 AIPPI JOURNAL 267, 270 (Nov. 1997).

technology.¹¹⁹ The court reasoned that experiments for obtaining regulatory approval are solely commercial in character, do not advance science, and thus do not fall within the § 69(1) experimental use exception.¹²⁰ Despite the *Monsanto* decision, many Japanese generic drug manufacturers assumed they were allowed to begin clinical testing of the generic drug two to three years before the expiration of the pioneer drug patent term,¹²¹ as long as they did not market the drug while the patent was still in force.¹²²

In 1996, five cases decided in the Nagoya High Court and Nagoya District Court, referred to as the *Synthelabo* cases, confirmed the *Monsanto* opinion prohibiting use of a patented substance to obtain data for regulatory approval.¹²³ *Synthelabo*, a French pharmaceutical company, owned two patents on drugs used to treat brain arteriosclerosis and Parkinson's disease.¹²⁴ Operating under the assumption that § 69(1) exempted their activities from infringement actions, several major Japanese generic drug manufacturers began clinical testing.¹²⁵ *Synthelabo* brought patent infringement actions against the generic drug manufacturers.¹²⁶ Following the rationale in *Monsanto*, the courts claimed that § 69(1) did not apply to experiments to gain regulatory approval because the uses were commercial and did not advance technology.¹²⁷ Hence, the generic drug manufacturer's activities constituted infringement.¹²⁸ The courts issued provisional injunctive orders to prevent the generic drug manufacturers from using the patented drug during its patent term.¹²⁹ *Synthelabo's* success encouraged other pioneer drug companies to initiate actions against generic drug manufacturers and caused a flood of litigation in the late 1990s focusing on the § 69(1) experimental use exception.¹³⁰

¹¹⁹ David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 Hous. J. Int'l L. 615, 652-53 (1994).

¹²⁰ Tessensohn, *supra* note 114, at 26.

¹²¹ *Id.* at 27.

¹²² Heath, *supra* note 118, at 274.

¹²³ Tessensohn, *supra* note 114, at 26 (reporting on the five *Synthelabo* cases: *Synthelabo S.A. v. Toyo Pharma K.K. & Yoshindo K.K.*, *Synthelabo S.A. v. Daito K.K. & Nihon Pharmaceutical K.K.*, *Synthelabo S.A. v. Horita Pharmaceutical Synthesis K.K.*, *Synthelabo S.A. v. Malco Pharmaceutical K.K.*, and *Synthelabo S.A. v. Taiyo Pharmaceutical K.K.*).

¹²⁴ Heath, *supra* note 118, at 274 (reporting on the *Synthelabo* decisions).

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *Id.* at 275.

¹²⁸ *Id.* at 274-75.

¹²⁹ Kondo, *supra* note 99, at 292 (reporting on the *Synthelabo* decisions).

¹³⁰ Christopher Heath, *Japan: Patent Act, Secs. 69(1), 100(1)*-“*Synthelabo*”, 28 IIC 398, 398-399 (1997) (reporting on *Synthelabo v. Taiyo Yakuhin*).

Just one year later, generic drug manufacturers finally prevailed, benefiting from a change in policy regarding experimental use as articulated in *Ono Pharmaceutical K.K. v. Kaigai Pharmaceutical K.K.*¹³¹ Ono Pharmaceuticals sued seven generic drug manufacturers for producing and importing generic versions of their patented drug.¹³² Once again, a generic drug manufacturer claimed that its use of the patented drug to obtain regulatory approval was permitted under § 69(1).¹³³ In a dramatic shift from its position in *Monsanto*, the Tokyo District Court dismissed the case based on § 67(1) of Japanese Patent Law that limits a patent term to twenty years after the filing date of the application.¹³⁴ The court allowed the generic drug company's use of the patented drug because prohibiting experimental use to gather data for regulatory approval would artificially extend the patent term articulated in § 67(1).¹³⁵ Although the rationale of the *Ono Pharmaceutical* decision was not based on the statutory experimental use exception in § 69(1), the Tokyo District Court began a trend of permitting experimental uses to gain regulatory approval.¹³⁶

Throughout 1997 and 1998, at least seven Japanese high court and district court decisions permitted generic drug testing of a patented drug to obtain data for regulatory approval under the experimental use exception in § 69(1).¹³⁷ In one case, *Otsuka Pharmaceutical K.K. v. Towa Yakuin K.K.*, the Tokyo District Court held that a generic company's use of a patented bronchodilator for clinical trials was not infringement.¹³⁸ The court again retreated from its earlier position in *Monsanto* that a generic formulation is not a scientific advancement and even questioned whether a scientific advancement or improvement was required for a use to fall within the scope of the § 69(1) experimental use exception.¹³⁹ The court suggested that even if the advancement requirement applied, generic drugs enhance medical

¹³¹ Tessensohn, *supra* note 114, at 5 (reporting on *Ono Pharmaceutical K.K. v. Kaigai Pharmaceutical K.K.*).

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.* at 5-6.

¹³⁵ *Id.* at 6.

¹³⁶ See discussion *infra* Parts III.B & C.

¹³⁷ Christopher Heath, *Japan: Patent Act, Sec. 69—"Procterole"*, 30 IIC 454, 455 (1999) (translating a portion of the Tokyo High Court's decision in *Otsuka Pharmaceutical Co., Ltd. v. Towa Yakuin K.K.*).

¹³⁸ Jinzo Fujino, *Latest Developments in Japanese IP Cases: Otsuka Pharmaceutical Co., Ltd. v. Towa Yakuin K.K.*, 22 AIPPI JOURNAL 296 (Nov. 1997) (reporting on *Otsuka Pharmaceutical Co., Ltd. v. Towa Yakuin K.K.*).

¹³⁹ Heath, *supra* note 118, at 276 (reporting on Tokyo District Court's decision in *Otsuka Pharmaceutical Co., Ltd. v. Towa Yakuin K.K.*).

technology.¹⁴⁰ In addition, clinical trials during the pioneer drug's patent term did not interfere with Patent Law's goal of granting exclusive commercial use for the entire duration of the patent.¹⁴¹ Prohibiting experimentation for obtaining regulatory approval under § 69(1) would have the undesirable effect of artificially lengthening the pioneer drug's patent term and thereby conflicted with the purpose of the Patent Law.¹⁴² The Tokyo High Court affirmed and held that testing to determine whether a generic drug is a bioequivalent of a patented drug is a technological advancement, allowing it to fall under the § 69(1) experimental use exception.¹⁴³

The Japanese courts, however, inconsistently interpreted the § 69(1) experimental use exception with respect to the technical advancement requirement. Some courts interpreted § 69(1) to lack the technological advancement requirement, while others held that the advancement requirement was maintained and a generic formulation represented such an advancement. In *Wellcome Foundation Ltd. v. Sawai Pharmaceutical K.K.*, the Tokyo District Court allowed Sawai's testing of a generic drug for regulatory approval since, similar to the position taken by the Tokyo High Court in *Otsuka*, a generic drug was technical progress and thus within the scope of § 69(1).¹⁴⁴ Two months later, in *Daiichi Pharmaceutical Co., Ltd. v. Shiono Chemical K.K. & Choseido Pharmaceutical K.K.*, the Tokyo District Court articulated that "experiment or research" under § 69(1) is not subject to the requirement that the experiment advance technology.¹⁴⁵ Although the distinction does not change the ultimate result of including experiments for generic drug approval under the § 69(1) umbrella, this distinction may prove important when interpreting § 69(1) outside the pharmaceutical context.

Just as generic drug companies began to feel comfortable testing their products during the pioneer drug's patent term, the Nagoya District Court resurrected the old hard-line position that clinical testing for market approval

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Id.* at 276-277.

¹⁴³ Tessensohn, *supra* note 114, at 66 n.234 (reporting on Tokyo High Court's decision in *Otsuka Pharmaceutical Co., Ltd. v. Towa Yakuhin K.K.*); Heath, *supra* note 137, at 456.

¹⁴⁴ Tessensohn, *supra* note 114, at 6-7 (citing *Wellcome Foundation Ltd. v. Sawai Pharmaceutical K.K.*).

¹⁴⁵ *Id.* at 10, 14 (citing *Daiichi Pharmaceutical Co., Ltd. v. Shiono Chemical K.K. & Choseido Pharmaceutical K.K.*).

infringed the pioneer drug's patent.¹⁴⁶ Although the court found that the pioneer drug patent was infringed, the court granted only monetary damages and refused to grant the important remedy of injunctive relief.¹⁴⁷ This weak damage award diminished the victory for big pharmaceutical companies and therefore did not completely return the playing field to its status immediately after *Monsanto*.¹⁴⁸

C. *The Japanese Supreme Court Allows Testing for Regulatory Approval Under the Experimental Use Exception in § 69(1)*

The Japanese Supreme Court's unanimous 1999 decision in *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd.* confirmed that tests during a patent term to obtain data required for regulatory approval are not infringing activities under § 69(1).¹⁴⁹ Ono Pharmaceuticals brought an infringement action against Kyoto Pharmaceuticals after learning that Kyoto Pharmaceuticals carried out experiments during the pioneer drug's patent term to obtain regulatory approval for its generic version.¹⁵⁰ Even though the original patent expired prior to this decision, Ono Pharmaceuticals sought to prevent Kyoto Pharmaceuticals from selling the generic drug for two and a half years to compensate Ono for part of its patent term lost by Kyoto Pharmaceutical's activities.¹⁵¹ In 1997, the Kyoto District Court, not considering whether § 69(1) applied in this situation, decided the case on the grounds that an injunction cannot be enforced after a patent expires.¹⁵²

On appeal to the Osaka High Court, Ono requested monetary damages as compensation for two and a half years of infringement.¹⁵³ The Osaka High Court found for Kyoto Pharmaceuticals based on the § 69(1)

¹⁴⁶ Soichi Okuyama, *Latest Developments in Japanese IP Cases: Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd.*, 24 AIPPI JOURNAL, 106, 108 (May 1999).

¹⁴⁷ Tessensohn, *supra* note 114, at 41.

¹⁴⁸ *Id.*

¹⁴⁹ Okuyama, *supra* note 146, at 108 (citing *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd.*); Christopher Heath, *Japan: Patent Act, Sec. 69—"Clinical Trials III"*, 30 IIC 448, 449 (citing *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd.*).

¹⁵⁰ Okuyama, *supra* note 146, at 108 (citing *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd.*).

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.* at 108-09.

experimental use exception and did not consider the remaining issues.¹⁵⁴ Ono Pharmaceuticals appealed to the Japanese Supreme Court.¹⁵⁵

In finding for Kyoto Pharmaceuticals on the grounds that § 69(1) allowed experimental use of a patented drug for obtaining regulatory approval, the Japanese Supreme Court focused on the policies behind the Patent Law.¹⁵⁶ The Court aimed to prevent the artificial extension of a pioneer drug's patent term during the two to three years required for the generic drug to gain approval from the Ministry of Health, Welfare and Labor.¹⁵⁷ The Court stated "it is one of the basic principles of the patent system to allow anyone to exploit freely a new technology after the expiry of the patent term, thereby generating a benefit to society."¹⁵⁸

Since the Japanese Supreme Court did not mention technological advancement,¹⁵⁹ it remains unclear whether the Court maintained the advancement requirement for the experimental use exception, finding that the creation of a generic drug was a technological advancement, or whether the Court eliminated the advancement requirement altogether.¹⁶⁰ Japanese patent law scholars have taken different positions on this issue. A law clerk for the Japanese Supreme Court commented that the absence of discussion on the advancement requirement implies that the Court abandoned the technological advancement requirement for § 69(1).¹⁶¹ An opposing position advanced by another scholar, however, is that the technical advancement requirement remains and a generic drug manufacturer's experiments are an advance because "the manufacturing process of [the] active ingredient and the composition of inactive ingredients are not disclosed."¹⁶² The Japanese Supreme Court had the opportunity to clarify its

¹⁵⁴ *Id.* at 109.

¹⁵⁵ *Id.*

¹⁵⁶ Heath, *supra* note 149, at 448 (citing *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd.*).

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ Kondo, *supra* note 99, at 293.

¹⁶⁰ Interview with Mr. Noriyuki Inoue, Japanese Patent Examiner, University of Washington, in Seattle, Wash. (Jan. 30, 2003).

¹⁶¹ Maiko Takabe, 1162 *JURISTO* 133, 133-35 (Nov. 1, 1999), synopsis of Japanese source based upon E-mail correspondence from Noriyuki Inoue, to Jennifer Johnson, Comment Author, *Pacific Rim Law and Policy Journal* (Jan. 29, 2003) (on file with the author).

¹⁶² Shoji Matsui, 45 *AIPPI JOURNAL* 87 (2000) partial translation of Japanese source based upon E-mail correspondence from Toshiko Takenaka, University of Washington, to Jennifer Johnson, Comment Author, *Pacific Rim Law and Policy Journal* (Jan. 31, 2003) (on file with the author).

position when *Otsuka Pharmaceutical* was appealed to the Court, but the Court did not grant the appeal.¹⁶³

The logical approach seems to support retaining the advancement requirement. First, keeping the advancement requirement for experimental use furthers the goal of the Patent Law to promote technological development. Second, if the advancement requirement is not maintained, the incentives for inventing may be decreased as competitors can get away with more uses of a patented invention, such as testing the commercial value of a patented invention.

The Japanese Supreme Court did set limits on the § 69(1) experimental use exception's application to pharmaceuticals, noting:

it is an act of infringement and impermissible, for a third party to manufacture generic drugs during the patent term to be assigned after the expiration of the patent or to make or use [the drug] beyond the extent that is necessary for experiments to be carried out in order to file under § 14 of the Pharmaceutical Affairs Law.¹⁶⁴

As a result of the Japanese Supreme Court's *Ono* decision, the general statutory experimental use exception in § 69(1) allows generic drug manufacturers to experiment with a patented drug to get regulatory approval.¹⁶⁵ The decision ended years of confusion over whether § 69(1) allowed such experimentation.¹⁶⁶ However, it is still unclear whether an experimental use must be an advancement in science to fall under § 69(1).¹⁶⁷

D. The Japanese Experimental Use Exception is Broader than the U.S. Experimental Use Exception.

The Japanese experimental use provision in § 69(1) is much broader than both the U.S. common law and § 271(e)(1) experimental use exceptions combined. The § 271(e)(1) experimental use exception is a pharmaceutical-

¹⁶³ John Tessensohn, *Patents: Infringement-experimental use exempted for clinical trials*, 21 EUROPEAN INTELLECTUAL PROPERTY REVIEW N-140 (1999) (reporting on *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd.*).

¹⁶⁴ Okuyama, *supra* note 146, at 112.

¹⁶⁵ *Id.* at 106.

¹⁶⁶ See discussion *supra* Part III.B.

¹⁶⁷ Interview with Mr. Noriyuki Inoue, Japanese Patent Examiner, University of Washington, in Seattle, Wash. (Jan. 30, 2003).

specific exception that allows generic drug manufacturers to use a patented pioneer drug to obtain data required for regulatory approval.¹⁶⁸ Although the common law experimental use exception applies to all inventions, the scope of experimental use in the United States is effectively limited to the pharmaceutical industry because the common law exception is limited to the rare instances where a patented invention is used with no commercial purpose.¹⁶⁹

In contrast, the Japanese statutory experimental use exception in § 69(1) applies to all inventions and is not expressly limited to experimentation in the context of generic drug testing.¹⁷⁰ The Japanese experimental use exception, however, is also not limited to inventions that require government approval.¹⁷¹ As a result of the Japanese Supreme Court decision in *Ono Pharmaceuticals*, § 69(1) covers either: (1) experiments that result in an advancement in technology or (2) all experiments and research, including those that do not advance technology.¹⁷² This requirement may not be difficult to satisfy, as making a generic drug formulation of a patented drug is not a monumental scientific accomplishment. Arguably, as long as an experiment is within the broad definition of an advancement in technology, it will fall within the scope of § 69(1). This breadth of the Japanese experimental use exception should permit many beneficial experimental uses such as investigating the patentability of an invention, analyzing the function of an invention, and developing and improving on an invention.¹⁷³

IV. CRITICISMS OF THE EXPERIMENTAL USE EXCEPTIONS IN THE UNITED STATES

Three major criticisms of the U.S. experimental use exceptions have emerged. First, the common law experimental use exception prevents inventors from advancing technology by prohibiting inventors from using a patented invention to improve on it, also known as “designing around” it. Second, the Hatch-Waxman Act paired the experimental use exception in

¹⁶⁸ See discussion *supra* Parts II & III.

¹⁶⁹ Mueller, *supra* note 83, at 24.

¹⁷⁰ Patent L., *supra* note 97, art. 69(1).

¹⁷¹ *Id.* art. 69(1).

¹⁷² See discussion *supra* Part III.C.

¹⁷³ NOBUHIRO NAKAYAMA, CHUKAI TOKKYOHU (ANNOTATED PATENT LAW) 675, 679 (3d. ed. 2000), partial translation based on E-mail correspondence from Toshiko Takenaka, University of Washington, to Jennifer Johnson, Comment Author, *Pacific Rim Law and Policy Journal* (Jan. 30, 2003) (on file with author). The effects on promoting research by allowing these uses are discussed at *infra* Part V.A.

§ 271(e)(1) with powerful remedies for pioneer drug manufacturers that have been abused to prevent the timely entry of generic drugs into the market. These two problems may be ameliorated if the United States adopts a general statutory experimental use exception. Finally, there is concern that the absence of a general statutory experimental research exception will have a stifling effect on university research. This concern has not been realized, however, as evidenced by the increase in inventive activities at universities.

A. Preventing the Advancement of the State of the Art by Designing Around a Patent

One criticism of the common law experimental use exception in the United States is that it does not permit advancing the state of the art by trying to design around a patent.¹⁷⁴ The Federal Circuit discussed this issue in *Embrex v. Service Engineering*.¹⁷⁵ Embrex exclusively licensed a patent for a method of inoculating chicks against diseases by injecting a vaccine into a specific region of the egg before hatching.¹⁷⁶ Embrex brought an infringement action against Service Engineering for attempting to achieve immunity by injecting a different part of the egg with vaccine that was not covered by the Embrex patent.¹⁷⁷ The tests were not successful in inducing immunity.¹⁷⁸ Furthermore, most injections accidentally penetrated the area covered by the Embrex patent.¹⁷⁹ After recognizing a narrow common law experimental use exception, the Federal Circuit stated that the Service Engineering consultant's acts infringed the Embrex patent because the test could not be deemed an experimental use.¹⁸⁰ The court commented that "while SEC tries to cloak these tests in the guise of scientific inquiry, that alone cannot immunize its acts."¹⁸¹ This case illustrates the current situation in the United States, that experiments to design around an existing patent are not protected by the common law experimental use exception.¹⁸²

In contrast, the general statutory experimental use exception in Japan permits the use of a patented invention to design around a patent.¹⁸³ The

¹⁷⁴ Mueller, *supra* note 83, at 29.

¹⁷⁵ *Embrex, Inc. v. Service Eng'g Corp.*, 216 F.3d 1343 (Fed. Cir. 2000).

¹⁷⁶ *Id.* at 1346.

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 1347.

¹⁷⁹ *Id.*

¹⁸⁰ *Id.* at 1349.

¹⁸¹ *Id.*

¹⁸² Mueller, *supra* note 83, at 29.

¹⁸³ NAKAYAMA, *supra* note 173, at 679.

Japanese experimental use provision is more clearly directed towards the policy goals of encouraging development of industry and encouraging scientific progress.¹⁸⁴ Permitting this type of experimental use allows Japanese researchers to use patented inventions to improve upon them, while in the United States this type of research amounts to infringement¹⁸⁵ and stifles scientific advancement. Therefore, unlike the common law experimental use exception in the United States, the Japanese experimental use exception permits use of a patented invention to design around it for scientific advancement.

B. *U.S. Law Creates Incentives to Delay Generic Drug Market Approval*

Perhaps the most significant criticism of the statutory experimental use exception in the United States is that it was enacted as part of a package that combines the experimental use exception in § 271(e)(1) with powerful remedies that pioneer drug manufacturers have used to delay the entry of generic drugs.¹⁸⁶ The Hatch-Waxman Act allows a pioneer drug manufacturer to delay approval of a generic drug ANDA for forty-five days while the pioneer drug company decides whether or not to bring an infringement action against the generic drug manufacturer.¹⁸⁷ Furthermore, if the pioneer drug manufacturer does file suit, the generic drug's approval is delayed for either thirty months or until the conclusion of the suit.¹⁸⁸

Considering that a blockbuster drug such as Prozac® generates U.S. sales of approximately \$4.75 million U.S. dollars per day, pioneer drug manufacturers have a huge incentive to delay generic drug approval by days, weeks or months, even if it means initiating litigation.¹⁸⁹ This practice was the focus of a recent Federal Trade Commission ("FTC") investigation and prompted President Bush to propose regulations that would limit the ability of pioneer drug companies to delay the market entry of generic drugs.¹⁹⁰ A FTC study found that pioneer drug companies routinely file frivolous lawsuits to intentionally delay cheaper generic drugs from obtaining FDA approval.¹⁹¹ The report also states that pioneer drug manufacturers can

¹⁸⁴ Tamai Remarks, *supra* note 98.

¹⁸⁵ *Embrex, Inc.*, 216 F.3d at 1343.

¹⁸⁶ 21 U.S.C. § 355(j)(5)(B)(iii); *see* discussion *supra* Part I.

¹⁸⁷ 21 U.S.C. § 355(j)(5)(B)(iii); *see* discussion *supra* Part II.C.

¹⁸⁸ 21 U.S.C. § 355(j)(5)(B)(iii).

¹⁸⁹ William Christiansen, Remarks at Center for Advanced Study and Research on Intellectual Property High Technology Summit (July 20, 2001) (transcript on file with author).

¹⁹⁰ *Bush Proposes Rules*, *supra* note 1.

¹⁹¹ *Id.*

effectively delay generic drug approval for many years by repeatedly invoking the thirty-month stay provision in the Hatch-Waxman Act.¹⁹² The Bush proposal allows a pioneer drug manufacturer only one thirty-month stay of a generic drug's ANDA and limits the other strategies that pioneer drug manufacturers have been known to rely on to extend their patent monopolies.¹⁹³ Bush did recognize, however, that pioneer drug manufacturers need strong patent protection during their legitimate patent term, because the development of a pioneer drug can cost upwards of US \$800 million.¹⁹⁴

By contrast, in Japan, pioneer drug manufacturers are unable to artificially extend their patent terms under provisions related to the experimental use exception in § 69(1). After the Japanese Supreme Court decision in *Ono Pharmaceuticals*, it is clear that generic drug manufacturers can use a patented drug to obtain the data required for regulatory approval.¹⁹⁵ If a pioneer drug manufacturer believes that the generic drug manufacturer is otherwise infringing its patent, the sole remedy for the pioneer drug manufacturer is to bring an infringement suit under § 68 of the Japanese Patent Law. Section 68 provides that "a patentee shall have an exclusive right to commercially work the patented invention."¹⁹⁶ The PAL does not provide any additional remedies for pioneer drug manufacturers who believe that their patents are being infringed by the generic drug manufacturer.¹⁹⁷ This same remedy is provided for all patent infringement suits and does not provide any special treatment for the pharmaceutical industry.

C. *Does the Limited U.S. Experimental Use Exception Have a Chilling Effect on University Research?*

One prominent criticism of the experimental use exception in the United States is that the absence of a general statutory experimental use exception, like that of Japan, has a chilling effect on basic research at universities.¹⁹⁸ Since the statutory experimental use exception § 271(e)(1)

¹⁹² *Id.*

¹⁹³ *Id.*

¹⁹⁴ *Id.*

¹⁹⁵ See Okuyama, *supra* note 146, at 106.

¹⁹⁶ Patent L., *supra* note 97, art. 68.

¹⁹⁷ Pharmaceutical Affairs Law, *supra* note 107.

¹⁹⁸ Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1022 (1989).

only addresses the pharmaceutical industry, university researchers must rely on the common law experimental use exception to exempt university research activities from infringing existing patents. The common law exception has been interpreted narrowly and excludes uses with a commercial purpose.¹⁹⁹ Therefore, university researchers cannot rely on the common law experimental use exception to exempt their research activities from infringing a patent, especially when industry collaborations are common and legislation has encouraged the commercialization of university research.²⁰⁰ In fact, the Federal Circuit recently declined to apply the common law experimental use exception to a university since its research activities “unmistakably further the institution’s legitimate business objectives, including educating and enlightening students and faculty participating in these projects.”²⁰¹ Without a broad experimental use exception, one commentator has argued that royalties and heightened transaction costs threaten to slow the progress of basic research at universities.²⁰²

An analysis of patent and research statistics, two measures of academic research activity, does not support the hypothesis that the narrow common law experimental use exception has stifled university research. A recent National Science Foundation study illustrated that from 1979 to 2000 the percentage of university patents as a percentage of total utility patents has steadily increased.²⁰³ Academic patents constitute almost five percent of all new U.S. patents, up from less than half a percent just twenty years ago.²⁰⁴ Additionally, the number of academic institutions receiving patents increased from about 300 in the 1970s to 3151 in 1998.²⁰⁵ The same study also found that since 1953, the average annual growth of academic research and development has been stronger than for any other research and development sector.²⁰⁶ Finally, academia performs forty-three percent of

¹⁹⁹ See discussion *supra* Parts II.A & E.

²⁰⁰ Patricia C. Kuszler, *Curing Conflicts of Interest in Clinical Research: Impossible Dreams and Harsh Realities*, 8 WIDENER. L. SYMP. J. 115, 123-27 (2001) (discussing the effects of the Stevenson-Wydler Technology Act and the Bayh-Doyle Act).

²⁰¹ *Madey v. Duke Univ.*, 307 F. 3d 1351, 1362 (Fed. Cir. 2002).

²⁰² Mueller, *supra* note 83, at 1.

²⁰³ U.S. Patent and Trademark Office, *U.S. Colleges and Universities—Utility Patent Grants, Calendar Years 1969-2000*, http://www.uspto.gov/web/offices/ac/ido/oeip/taf/univ/asgn/table_1.htm (last visited Jan. 28, 2003).

²⁰⁴ National Science Foundation, *Academic Research and Development: Outputs of Scientific and Engineering Research: Articles and Patents*, <http://www.nsf.gov/sbe/srs/seind02/c5/c5s3> (last visited Jan. 28, 2003) [hereinafter National Science Foundation Study].

²⁰⁵ *Id.*

²⁰⁶ *Id.*

basic research and is the largest performer of basic research in U.S.²⁰⁷ These statistics make it difficult to believe that university research has suffered from a narrow common law experimental use exception.

In summary, two criticisms of the U.S. experimental use exceptions are persuasive. First, prohibiting experimental use of a patented invention may slow some beneficial advances, such as finding a new use for an already patented drug in the absence of a license. Second, the Hatch-Waxman Act has been a powerful tool to delay the market entry of generic drugs. However, the criticism that university research is stifled by a narrow common law experimental use exception may not be valid as universities are increasingly active contributors to basic research.

V. COMPLIANCE WITH INTERNATIONAL AGREEMENTS AND PATENT HARMONIZATION

The Trade-Related Aspects of Intellectual Property Agreement ("TRIPS"), signed by both the United States and Japan, sets forth minimum patent rights and protections. Article 30 of the TRIPS Agreement provides general standards relating to exceptions of exclusive rights. The experimental use exceptions in both the United States and Japan appear to comply literally with the vague standards in Article 30. Upon closer examination, however, the general statutory experimental use provision in Japan is consistent with the experimental use provisions of the rest of the world, while the U.S. experimental use provisions are not. Therefore, the United States provisions do not further patent harmonization.

A. *The TRIPS Agreement's Approach to Experimental Use*

In 1947, twenty-three countries signed the General Agreement on Tariff and Trade ("GATT") to stimulate the world economy by promoting access to protectionist markets and increasing international trade.²⁰⁸ GATT developed over eight rounds, resulting in the 1994 "Uruguay Round" version that addressed many significant barriers to trade.²⁰⁹ The United States became a signatory in December 1994, after the U.S. Congress passed, and

²⁰⁷ *Id.*

²⁰⁸ Ned Milenkovich, *Deleting the Bolar Amendment to the Hatch-Waxman Act: Harmonizing Pharmaceutical Patent Protection in a Global Village*, 32 J. MARSHALL L. REV. 751, 756-57 (1999).

²⁰⁹ *Id.*

President Clinton signed, the GATT agreement.²¹⁰ Japan is also a signatory to the GATT agreement.²¹¹

The GATT agreement includes a section that addresses global intellectual property rights and protections, designated TRIPS.²¹² Section five of TRIPS, which includes Articles 27 to 34, specifically addresses the patent aspects of GATT and provides minimum patent law standards for member countries.²¹³

Article 30 of the TRIPS agreement lists liberal conditions for exceptions to exclusive patent rights.²¹⁴ These conditions include: (1) the exceptions must be limited; (2) exceptions should not unreasonably conflict with the normal exploitation of the patent; and (3) exceptions should not unreasonably prejudice the legitimate interests of third parties.²¹⁵ This provision does not provide much guidance and allows national governments significant freedom to define the scope of exceptions to exclusive patent rights.²¹⁶ In fact, one commentator has suggested that the vague language of Article 30 illustrates the difficulties that the negotiating parties experienced in agreeing on the nature and extent of exceptions to exclusive patent rights.²¹⁷ Although the scope of Article 30 is unclear, the same commentator suggested that based on comparative law and other proposals the following uses are likely permitted under Article 30: acts done privately with a non-commercial purpose; uses for research; experimentation with the invention to verify its function or to improve on it; and experiments made for the purpose of acquiring regulatory approval for marketing a product after the expiration of the invention.²¹⁸

²¹⁰ *Id.*

²¹¹ See Mitsuo Matsushita, *A Japanese Perspective on Intellectual Property Rights*, 1992 COLUM. BUS. L. REV. 81 (1992).

²¹² Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Legal Instruments-Results of the Uruguay Round, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

²¹³ *Id.* arts. 27-43.

²¹⁴ *Id.* art. 30.

²¹⁵ *Id.*

²¹⁶ CARLOS M. CORREA, *INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT* 208 (Carlos M. Correa & Abdulqawi A. Yusef eds., 1998).

²¹⁷ Carlos Correa, *The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: New Standards for Patent Protection*, 16 EURO. INTELL. PROP. REV. 327, 330-333 (1994), reprinted in PAUL GOLDSTEIN, *INTERNATIONAL INTELLECTUAL PROPERTY LAW* 379 (2001).

²¹⁸ CORREA, *supra* note 216.

B. *Both the United States and Japan Literally Comply with Article 30*

Under the vague language of Article 30, the statutory experimental use exception in the United States appears to comply with TRIPS. First, permitting experimental use of a patented drug while obtaining data for regulatory approval under § 271(e)(1) in the United States is indeed a very limited exception, as it addresses a specific industry during a finite regulatory approval process.²¹⁹ Second, the statute requires that these experimental uses by generic drug manufacturers do not unreasonably conflict with the patent holder's exclusive right because generic drug manufacturers can only enter the market once the patent holders rights have expired or are invalidated.²²⁰ Finally, § 271(e)(1) also ensures that the legitimate interests of third parties are not unreasonably prejudiced by allowing generic drug manufacturers to experiment with a pioneer drug for uses reasonably related to obtaining FDA approval.²²¹ The public is not prejudiced because cheaper generic drugs can enter the marketplace immediately after the pioneer drug patent expires or is invalidated.²²² The common law experimental use exception also appears to comply with TRIPS using a similar analysis.

Assuming that the Japanese experimental use exception is limited to experimental uses that are advancements in technology, the Japanese exception set forth in § 69(1) also complies with TRIPS Article 30. This limitation ensures that the original patent holder's rights are not diminished as the benefits from the original patent still flow to the patent owner. Only advancements beyond the scope of the original patented invention are protected under § 69(1). In addition, this broader exception protects the legitimate interests of third parties allowing inventors and the public to benefit from experimental advances—a new use of a patented drug, for example. If the Japanese Supreme Court eliminated the advancement requirement for experimental use, the analysis under Article 30 is more problematic since the use is less limited and more likely to interfere with the normal exploitation of the patent. Arguably, this interpretation of § 69(1) may still comply with the vague language of Article 30.

²¹⁹ See discussion *supra* Parts II.C & IV.

²²⁰ 21 U.S.C. § 355(j)(5)(B).

²²¹ 35 U.S.C. § 271(e)(1); see discussion *supra* Parts II.C & D.

²²² 21 U.S.C. § 355(j)(5)(B).

C. *Although the United States Approach Literally Complies With TRIPS, It Does Not Further Patent Harmonization*

Even though both the experimental use exception in the United States and Japan comply literally with TRIPS, the exception in the United States runs counter to the underlying policy of patent harmonization behind the TRIPS agreement. The main goal of patent harmonization is to create efficiency and certainty regarding the patent laws of the world.²²³ TRIPS was just one of many attempts at harmonizing global intellectual property laws.²²⁴ While the U.S. experimental use exceptions are very narrow, a broad experimental use exception is generally recognized outside the United States.²²⁵ The narrow U.S. experimental use provisions are not the paradigm in other nations. The patent laws of Japan, the United Kingdom, Germany, Korea, the European Patent Convention and other countries contain broad statutory experimental use exceptions.²²⁶ Furthermore, other countries do not have provisions like the Hatch-Waxman Act that provide additional remedies for pioneer drug manufacturers.²²⁷ In this respect, when viewed in the context of international patent law, the Hatch-Waxman Act “really stands out like a sore thumb.”²²⁸ Although the United States may literally comply with TRIPS, it may wish to harmonize its experimental use provisions by adopting a general experimental use exception.

The Japanese experimental use exception is more consistent with the broad experimental use provisions in other countries.²²⁹ Therefore, Japan’s approach furthers the goal of harmonizing the patent laws of the world. In an effort to harmonize global patent law, the United States should adopt the Japanese approach. This would entail replacing the common law experimental use exception and the pharmaceutical specific experimental use exception in § 271(e)(1) with a general statutory experimental use exception.

²²³ Faryan Andrew Afifi, Note, *Unifying International Patent Protection: The World Intellectual Property Organization Must Coordinate Regional Patent Systems*, 15 LOY. L.A. INT’L & COMP. L.J. 453, 460-62 (1993).

²²⁴ Daphne Yong-d’Hervé, *Pre-TRIPS International Legal Framework; TRIPS Structure*, in INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE 8, 8-10 (ICC Publishing S.A. 1996).

²²⁵ Mueller, *supra* note 83, at 37.

²²⁶ John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L. J. 685, 718 (2002).

²²⁷ Thomas Borecki, Remarks at Center for Advanced Research on Intellectual Property High Technology Summit (July 20, 2001) (transcript on file with author).

²²⁸ *Id.*

²²⁹ Duffy, *supra* note 226, at 718.

VI. PROPOSED SOLUTIONS

Both legislative and judicial efforts have been made in the United States to solve the problems associated with the U.S. experimental use approach. During the past fifteen years, the legislature has considered two types of experimental use provisions: (1) a broad statutory experimental use provision; and (2) several industry-specific experimental use provisions that would permit experimental use in certain fields of research. None of the proposed legislative solutions have been successful. One court, however, has advanced a judicial solution to allowing a beneficial experimental use by interpreting the § 271(e)(1) experimental use provision extremely broadly. Since the United States has generally been unsuccessful in solving the problems associated with experimental use, the United States should again consider solutions that would bring it closer to the Japanese model. Limiting patent rights by allowing more experimental uses should not discourage inventive activity.

A. Proposed Legislation to Bring the United States Closer to the Japanese Model

Several attempts have been made to enact different versions of an experimental use exception in the United States. In 1988, Congress considered adding a limited experimental use exception in a bill that would permit the patenting of transgenic animals.²³⁰ The Judiciary Committee stated that a research exemption already existed in case law and was not necessary in the bill, and subsequently removed the experimental use exception for transgenic animals from the bill.²³¹ However, the House Report suggested that "Congress should, at some future point, amend Title 35 to provide that use of a patented invention or process is not an act of infringement if done for the purpose of experimentation or research."²³² This requirement should not apply only to biotechnology, but should extend to all patented inventions."²³³

During hearings regarding the limited experimental use exception proposed for transgenic animals, many esteemed expert witnesses supported

²³⁰ H.R. REP. NO. 100-888, at 50 (1988). The term "transgenic animal" refers to animal whose genome contains genetic material from another source.

²³¹ *Id.* at 49-51.

²³² *Id.* at 51.

²³³ *Id.*

a general statutory research exemption. Professor Donald Chisum of the University of Washington School of Law,²³⁴ Howard Bremer of the Association of University Technology Managers²³⁵ and Dr. Stuart Newman of the Council for Responsible Genetics²³⁶ all expressly supported a broad statutory experimental use exception. Bremer, in a written statement, favored a broad research exemption encompassing all technologies rather than a piecemeal approach for various technologies and special interest groups.²³⁷

Shortly thereafter, the House Committee proposed the Patent Competitiveness and Technological Act of 1990.²³⁸ Title IV of the act provided that "the making or using of a patented invention solely for research or experimentation shall not be an act of patent infringement unless the patented invention has the primary purpose of research or experimentation."²³⁹ The House Report listed the following activities as falling under the proposed exemption: testing to determine how an invention works; testing to determine its sufficiency or compare it to the prior art; experimenting for the purpose of designing around a patented invention; experimentation on a patented invention to improve on it; and testing to determine whether the invention is acceptable for licensing and academic experimentation.²⁴⁰ Importantly, the report recognized that since Japan and Western Europe already have similar legislation in this area, "it cannot be strenuously argued that legislation will cause any serious trade distorting effects."²⁴¹ Manufacturing and intellectual property associations opposed the bill because they were concerned that a broad experimental use exception would diminish the incentives of the U.S. patent system and provide unnecessary protections for universities.²⁴² Despite the full Committee's recommendation to the House, the bill was not enacted.²⁴³

A more recent attempt at codifying an experimental use exception was specifically directed at the biotechnology industry. In March 2002, the Genetic Research and Diagnostic Accessibility Act of 2002 was introduced

²³⁴ *Id.* at 104. Professor Chisum is currently at the Santa Clara University School of Law.

²³⁵ H.R. REP. NO. 100-888, at 220 (1988). Howard Bremer is currently at the Wisconsin Alumni Research Foundation.

²³⁶ *Id.*

²³⁷ *Id.* at 208.

²³⁸ H.R. REP. NO. 101-960, pt. I (1990).

²³⁹ *Id.* at 2.

²⁴⁰ *Id.* at 45.

²⁴¹ *Id.*

²⁴² H.R. 101-960, at 67-69.

²⁴³ H.R. 101-960.

to address the concern that gene patenting may have a negative effect on biotechnology research and patient care by prohibiting the use of patented gene sequences in research and diagnostic testing.²⁴⁴ The sponsor, Representative Lynn Rivers, stated that the purpose of the bill is to “broaden the availability and usefulness of gene-based diagnostics in the overall health care system, while allowing essential medical progress to continue unabated.”²⁴⁵ The bill was referred to the House Subcommittee on Courts, the Internet, and Intellectual Property on May 6, 2002.²⁴⁶ There has been no action since.²⁴⁷

The Senate recently took a different approach to remedy the problems with the Hatch-Waxman Act when it passed the Greater Access to Affordable Pharmaceuticals Act of 2002 (“GAAP”) by a margin of 78-21.²⁴⁸ The GAAP proposes major modifications to the Hatch-Waxman Act, including prohibiting an extension of the thirty-month stay of the provision under Paragraph IV certification and making a failure to file a civil action for infringement within forty-five days of notice of a Paragraph IV filing a bar to later action.²⁴⁹ Merck, a pioneer drug company, opposed the GAAP because it would “upset the delicate balance of Hatch-Waxman” and would create uncertainty for patent protection.²⁵⁰ The House has not yet debated the bill, but a discharge petition has been introduced to force a vote on the bill.²⁵¹

B. *Judicial Solutions to Allow Designing Around a Patent Under § 271(e)(1)*

In *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer*, the District Court for the Southern District of New York recently took an innovative approach to allow the desirable use of designing around a patent, absent a

²⁴⁴ CONG. REC. E353 (Mar. 14, 2002),

available at http://www.house.gov/science_democrats/member/lr031402.htm (last visited Jan. 27, 2003).

²⁴⁵ *Id.*

²⁴⁶ *Bill Summary and Status for the 107th Congress*,

<http://thomas.loc.gov/cgi-bin/bdquery/z?d107:HR03967:@@X> (last visited Jan. 27, 2003).

²⁴⁷ *Id.*

²⁴⁸ *Id.*

²⁴⁹ *Id.*

²⁵⁰ Merck Action Network, *U.S. House of Representatives Considering Measure That Would Create Uncertainty for Patent Protection*, at http://www.capitolconnect.com/merck/pp/registration_form.asp?subject=357 (last visited Jan. 27, 2003).

²⁵¹ *Bill Summary and Status for the 107th Congress*, <http://thomas.loc.gov/cgi-bin/bdquery/z?d107:HR01862:@@L&summ2=m&> (last visited Jan. 27, 2003).

general experimental use exception.²⁵² Rhone-Poulenc Rorer (“RPR”) owned a patent for the process of making a popular anti-cancer drug named Taxol® and four intermediates used in manufacturing the drug.²⁵³ Bristol-Myers Squibb (“BMS”) admitted to using the intermediates in its research and development program regarding Taxol® analogs, but defended its use based on the § 271(e)(1) experimental use exception to infringement.²⁵⁴ BMS argued that its use was permitted under § 271(e)(1) because its uses were reasonably related to the development and submission of information for submission to the FDA.²⁵⁵ In holding that BMS did not infringe the patent, the court interpreted § 271(e)(1) activities “reasonably related” to obtaining FDA approval very broadly, stating “[w]e should ask: would it have been reasonable, objectively, for a party in defendant’s situation to believe that there was a decent prospect that the ‘use’ in question would contribute (relatively directly) to the generation of the kinds of information that was likely to be relevant in the process by which the FDA would decide whether to approve the product?”²⁵⁶ BMS did not infringe the RPR patent, since BMS’s research efforts to generate new Taxol® analogs were aimed at trying to get a drug that could someday be submitted to the FDA.²⁵⁷ The court, in dicta, stated that BMS would be protected even if its results were later abandoned for reasons unrelated to FDA approval.²⁵⁸ This approach is one solution to allowing the beneficial use of encouraging research and development by designing around a patent, at least in the context of the pharmaceutical industry.

C. *Following the Japanese Model Should Not Limit Inventive Activity*

Expanding the experimental use exceptions in the United States to a general statutory exception, like § 69(1) in the Japanese Patent Law, may solve many of the problems discussed above. Although it has been suggested that expanding the U.S. experimental use exceptions would

²⁵² Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., No. 95 Civ. 8833 (RPP), 2001 WL 1512597 (S.D.N.Y. Nov. 28, 2001).

²⁵³ *Id.* at *1.

²⁵⁴ *Id.* at *1-2.

²⁵⁵ *Id.* at *2.

²⁵⁶ *Id.* at *3.

²⁵⁷ *Id.* at *5.

²⁵⁸ *Id.* at *6.

discourage invention by reducing patent protection,²⁵⁹ it is unlikely that these fears will be realized.

In Japan, where a general statutory experimental use exception has been in place for over one hundred years,²⁶⁰ inventive activity is growing at an exceptional rate.²⁶¹ A Washington, D.C. think tank study created a National Innovation Index that measured real and projected innovations per million residents.²⁶² Although the United States ranked number one in this index in 1995, the study predicted that the United States will rank number six on the index by 2005.²⁶³ In addition, the study predicted that Japan will lead the world in innovative activity by 2005.²⁶⁴ Furthermore, the U.S. Patent and Trademark Office consistently finds that Japanese companies are as active as U.S. companies in seeking U.S. patents.²⁶⁵ Furthermore, inventive activity measured by publications in scientific journals has also increased dramatically.²⁶⁶ Between 1986 and 1999, Japan's output of scientific publications grew by nearly fifty percent.²⁶⁷ Therefore, the broad experimental use exception in Japan has not stifled inventive activity by decreasing incentives to obtain patent protection.

VII. CONCLUSION

Japan and the United States approach the experimental use exception in their respective patent laws very differently. The problems associated with the U.S. experimental use exceptions, such as preventing beneficial experimental uses with patented inventions, artificially extending pharmaceutical patent terms and inhibiting patent harmonization, warrants consideration of a different approach. One solution to the problems associated with experimental use in the United States is to adopt an experimental use exception that permits experiments or research with patented inventions that advance technology, similar to that of Japan. This

²⁵⁹ Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L. J. 2169, 2180 (1991).

²⁶⁰ Tamai Remarks, *supra* note 98.

²⁶¹ MICHAEL E. PORTER & SCOTT STERN, THE NEW CHALLENGE TO AMERICAN'S PROSPERITY: FINDINGS FROM THE INNOVATION INDEX 7 (1999), <http://www.compete.org/pdf/index.pdf> (last visited Feb. 17, 2003).

²⁶² *Id.* at 6.

²⁶³ *Id.* at 34-35.

²⁶⁴ *Id.* at 35.

²⁶⁵ JULIE L. DAVIS & SUZANNE S. HARRISON, EDISON IN THE BOARDROOM: HOW LEADING COMPANIES REALIZE VALUE FROM THEIR INTELLECTUAL ASSETS 4 (2001).

²⁶⁶ National Science Foundation Study, *supra* note 204.

²⁶⁷ *Id.*

solution may ameliorate the problems related to experimental use in the United States without compromising the goals of the patent system.

