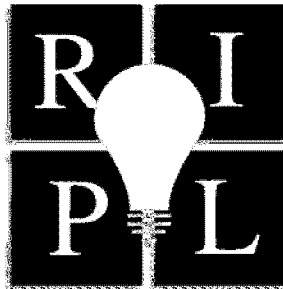


THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



HAS THE SUPREME COURT INCORRECTLY EXPANDED § 271(e)(1) TO RISK A
REGULATORY TAKING?

TARA STUART

ABSTRACT

The U.S.S.C. expanded the scope of the Hatch-Waxman Act's safe harbor provision in *Merck III* to include protection for infringing use of any type of invention as long as a researcher intended to perform research reasonably relevant to FDA approval. This broad interpretation is inconsistent with the legislative intent of the Hatch-Waxman Act, and the policies of the U.S. patent system. Many patent owners may unnecessarily experience such a reduction in their property rights as to constitute a regulatory taking. The proposed narrow interpretation would rectify the constitutional problems and inconsistencies in infringement exemptions. Section 271(e)(1) should apply only to the invention studied, and even then, "solely" for the limited purpose of obtaining FDA approval. This approach would allow courts to balance the need for safe and effective drug equivalents with the right of the patent owner to the exclusive use of his invention in addition to promoting the progress of science.

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TARA STUART*

INTRODUCTION

“As far as the text is concerned . . . we have before us a provision . . . that is not plainly comprehensible on anyone’s view.”¹

Twice, the United States Supreme Court (“U.S.S.C.”) has attempted to define the scope of 35 U.S.C. § 271(e)(1), the safe harbor provision intended to expedite the entry of generic pharmaceuticals into the market, by providing a limited exemption against patent infringement lawsuits.² In the course of defining the scope of the exemption, the U.S.S.C. created a broad safety zone against infringement lawsuits, protecting not only generic pharmaceutical companies, but also pharmaceutical companies that create innovative drugs.³

To bring an innovative pharmaceutical to market requires an average of fourteen years and financial expenditures ranging between \$500 million and \$2.2 billion.⁴ Before a company is permitted to market a drug, whether innovative or generic, the Federal Food, Drug, and Cosmetic Act (“FDCA”) requires testing to ensure the drug is effective and safe for human consumption.⁵ The large expenditures required to develop and market an innovative drug would likely deter many companies from engaging in the endeavor were it not for U.S. patent laws, which grant the right to exclude all others from the use and sale of the patented item for a period of time.⁶ In exchange for the right to exclude, the inventors obtaining the

* J.D. Candidate, May 2007, The John Marshall Law School. B.S. Chemistry, June 1996, De Paul University. M.S. Chemistry, August 2002, Indiana University. I would like to specifically thank my husband Doug for his patience and encouragement, and my son Colin for making life fun and interesting. Finally, thank you to the staff of The John Marshall Review of Intellectual Property Law, particularly Karen Mitch and Art Sokolov, for their invaluable editorial assistance. Any mistakes in this article are my own.

¹ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990).

² *Id.* at 663; *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2376 (2005).

³ *See Merck*, 125 S. Ct. at 2382.

⁴ *See* TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT, OUTLOOK REPORT 1 (2002), <http://csdd.tufts.edu/infoservices/outlookpdfs/outlook2002.pdf> (estimating the average cost of a new pharmaceutical at \$800 million, and the typical time at 10 to 15 years); *see also* FED. TRADE COMM’N & DEPT. OF JUSTICE-ANTITRUST DIV., COMPETITION IN THE PHARMACEUTICAL MARKETPLACE 4 (2002), <http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf> (statement of Gregory J. Glover on behalf of the Pharmaceutical Research and Manufacturers of America) (“average total pharmaceutical development time [was] 14.2 years in the 1980s and 1990s”); Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Pharmaceutical Development: Is It Really \$802m?*, SOC. SCI. RES. NETWORK (Dec. 2004), <http://ssrn.com/abstract=640563> (analysis of the typical cost to bring a new pharmaceutical to market).

⁵ *See generally* 21 U.S.C. § 355 (2000).

⁶ 35 U.S.C. § 154(a)(2).

patent must fully disclose their invention.⁷ In the case of drugs, this disclosure allows generic drug companies to copy the innovative drug immediately upon expiration of its patent term.

Although ensuring the safety and efficacy of drugs is an important public policy, the Food and Drug Administration (“FDA”) approval process had some undesirable effects on the patent term, which were detrimental to innovative pharmaceutical companies, generic pharmaceutical companies, and consumers.⁸ Prior to 1984, the year § 271(e)(1) was enacted, innovative pharmaceutical companies spent a substantial part of their patent term performing testing needed to gain approval by the FDA.⁹ This reduced the time of exclusivity in the market, which was when the innovative pharmaceutical companies were most likely to recoup their research and development expenditures and earn a profit. Before 1984, the FDA also required generic drug companies to perform extensive tests on their products before they were sold, even if they were seemingly identical to an innovative drug already on the market.¹⁰ However, the generic pharmaceutical companies could not begin testing of their generic drugs pursuant to FDA approval until the patent term of the equivalent innovative drug expired.¹¹ To do otherwise would risk an infringement suit along with attendant injunctions and monetary damages. Because the required generic drug testing could only begin at the end of the innovative drug’s patent term, patent holding pharmaceutical companies maintained their exclusivity in the market well beyond the expiration of the patent.¹² Thus, from the consumer’s perspective, the pre-1984 FDA regulations delayed access to inexpensive generic drugs.

In response to the unique delays the FDA approval process caused within the pharmaceutical industry, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”).¹³ The Hatch-Waxman Act primarily seeks to rectify the inequities in patent protection that resulted from the federal regulatory process,¹⁴ and speed the entry of generic drugs into the market.¹⁵

⁷ 35 U.S.C. § 112 (requiring an inventor to disclose in a patent application “the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same”).

⁸ See generally JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 261–62 (Aspen Publishers 2003) (explaining that generic pharmaceutical companies would have to wait until the patented drug’s patent expired before they could begin accumulating the required FDA data, so the patent holder would have extended market exclusivity).

⁹ See *Roche Prods. v. Bolar Pharm. Co.*, 733 F.2d 858, 864 (Fed. Cir. 1984).

¹⁰ See MUELLER, *supra* note 8, at 262.

¹¹ See MUELLER, *supra* note 8, at 262.

¹² See MUELLER, *supra* note 8, at 262.

¹³ Drug Price Competition and Patent Term Restoration Act of 1984, Pub L. No. 98-417, 98 Stat. 1585; see Amy Stark, *The Exemption from Patent Infringement and Declaratory Judgments: Misinterpretation of Legislative Intent?*, 31 SAN DIEGO L. REV. 1057, 1060–63 (1994) (summarizing the legislative intent of the Act).

¹⁴ George Fox, *Intellectual Property: Note, Integra v. Merck: Limiting the Scope of the 271(e)(1) Exception to Patent Infringement*, 19 BERKELEY TECH. L.J. 193, 196 (2004). There are two distortions in the patent term. *Id.* at 197. First, a new pharmaceutical company experiences a “front end distortion,” which is a period of time where no economic benefit is derived from a pharmaceutical patent because the pharmaceutical is in the process of gaining regulatory approval. *Id.* Second, the same patent owner will experience “back end distortion” of the patent term. *Id.* This occurs when the patent on the pharmaceutical expires, but the market exclusivity continues

It was codified in two parts: Part one restored to innovative pharmaceutical companies some of the market exclusivity that was lost to FDA approval by granting an extension of the patent term proportional to the time lost; part two, codified as § 271(e)(1), intended to expedite entry into the market by allowing generic drug companies to manufacture and test their generic drug before the innovative drug's patent term expired.¹⁶

Unfortunately, the text of the resulting legislation does not reflect this intent. Instead of exempting the use of a patented drug, it exempts the use of "a patented invention."¹⁷ Also, rather than explicitly limiting the exemption for showing a drug's safety and efficacy for FDA approval, the statute exempts infringing acts that are "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 . . ."¹⁸ The differences between the purported intent, which is specific, and the text of the statute, which is not, led to numerous discussions concerning the proper scope of § 271(e)(1).¹⁹

In *Integra Lifesciences I, Ltd. v. Merck KGaA* ("Merck IP"), the Court of Appeals for the Federal Circuit ("Federal Circuit") limited application of the safe harbor provision to clinical trials, which are human studies.²⁰ This decision sparked controversy, because while clinical trials are often required to gain FDA approval of a

because generic companies need to gain regulatory approval before marketing the equivalent pharmaceutical. *Id.*

¹⁵ See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 865 (Fed. Cir. 2003). The Federal Circuit identified two reasons for the Hatch-Waxman Act:

In the first place, the 1984 act sought to restore patent term to pharmaceutical inventions to compensate for the often-lengthy period of pre-market testing pending regulatory approval to sell a new pharmaceutical. These regulatory delays can deprive a patentee of many years of its patent's term. The second reason for the 1984 act responded to this court's decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*

Id. (citations omitted).

¹⁶ H.R. REP. NO. 98-857(I), at 14–18 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48. The Bill had two titles, each with a different purpose:

The purpose of Title I of the Bill is to make available more low cost generic pharmaceuticals by establishing a generic pharmaceutical approval procedure for pioneer pharmaceuticals first approved after 1962. . . .

The purpose of Title II of the Bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval. The incentive is the restoration of some of the time lost on patent life while the product is awaiting pre-market approval.

Id.

¹⁷ *Id.*

¹⁸ 35 U.S.C. § 271(e)(1) (2000).

¹⁹ See, e.g., Brian D. Coggio & Dominic Cerrito, *The Safe Harbor Provision of the Hatch-Waxman Act: Present Scope, New Possibilities, and International Considerations*, 57 FOOD & DRUG L.J. 161 (2002); Natalie M. Derzko, Article, *In Search of a Compromised Solution to the Problem Arising from Patenting Biomedical Research Tools*, 20 SANTA CLARA COMPUTER & HIGH TECH L.J. 347, 366–87 (2004) (discussing the scope of the Hatch-Waxman Act in relation to the biotechnology industry).

²⁰ See *Integra*, 331 F.3d at 866.

generic drug, other types of research are often needed or desirable. Thus, this narrow construction was contrary to the purpose of the exemption.²¹

The U.S.S.C. granted certiorari to define the limits of the statute in *Merck KGaA v. Integra Lifesciences I, Ltd.* (“*Merck III*”).²² However, instead of clarifying the scope of the provision, the U.S.S.C. introduced more uncertainty when it expanded the provision beyond mere testing of generic drugs to exempt infringing activities during innovative drug research.²³ With many of the formerly defined research boundaries of the exemption gone, it remains unclear under what circumstances a § 271(e)(1) exemption will be granted.²⁴ Furthermore, such an expansion could render all “research tool”²⁵ patents useless,²⁶ potentially violating these patent owners’ constitutional rights.²⁷

This comment focuses on the problems associated with the application of section § 271(e)(1) as interpreted by the U.S.S.C. in *Merck III*. Part I describes the general process of bringing a drug to market, the Hatch-Waxman Act, and interpretations of the Hatch-Waxman Act in the context of the *Merck* decisions. Part II analyzes the legislative intent and policy issues surrounding the safe harbor provision, as well as the new standard and limits of § 271(e)(1) in light of the Federal Circuit and the U.S.S.C. interpretations. Part III proposes a narrower interpretation of § 271(e)(1) which would avoid a regulatory taking of research tool patents and provide adequate notice to scientific researchers concerning potentially infringing activities.

I. BACKGROUND

A. Drug Development and Approval Processes

The drug development approval process is costly and time consuming.²⁸ Drug development has no set course prior to the FDA regulatory approval process, because

²¹ See Derzko, *supra* note 19, at 377–78; see also Gina C. Freschi, Comment, *Navigating the Research Exemption’s Safe Harbor: Supreme Court to Clarify Scope Implications for Stem Cell Research in California*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 855, 893 (2005).

²² See *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2376 (2005).

²³ See *id.* at 2383.

²⁴ See, e.g., *Third Wave Tech., Inc. v. Stratagene Corp.*, 381 F. Supp. 2d 891, 913 (W.D. Wis. 2005) (holding the court was “not convinced that a remote desire to obtain FDA approval for products . . . is sufficient to satisfy the ‘reasonably related’ standard.”).

²⁵ The National Institutes of Health (“NIH”) defines research tools as “the full range of resources that scientists use in the laboratory.” NAT’L. INST. OF HEALTH, REPORT OF THE NIH WORKING GROUP ON RESEARCH TOOLS (1998), <http://www.nih.gov/news/researchtools/#backgrnd>.

²⁶ See, e.g., 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, 955 (2004); Kevin Sandstrom, Note and Comment, *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, 1105 (2004).

²⁷ U.S. CONST. amend. V. The “Takings Clause” provides “private property [shall not] be taken for public use, without just compensation.” *Id.*

²⁸ See FED. TRADE COMM’N & DEPT. OF JUSTICE ANTITRUST DIV., *supra* note 4, at 4; Adams, *supra* note 4, at 3.

a candidate for a drug can be identified in several ways. A drug can be discovered in a formal drug research process at a pharmaceutical company,²⁹ an informal manner such as in the course of basic science research at a university or research institution,³⁰ or even by accident.³¹ Because of this variability, the type, quality, and amount of data on a particular drug candidate gathered prior to its identification as a potentially marketable drug varies greatly.

However, once an innovative drug candidate is identified as such, pursuant to FDA regulations it is tested by research scientists, often at a pharmaceutical company, to provide evidence of its safety and efficacy.³² The FDA approval process requires a pharmaceutical company to file two different types of applications before marketing a drug: Investigational New Drug Applications (“INDs”) and New Drug Applications (“NDAs”).³³ The INDs are filed before each of three phases of closely monitored clinical trials required by the FDA for approval of a drug.³⁴ Each application includes extensive data from previous *in vitro* or *in vivo* studies, which may simply consist of the information gathered prior to the formal identification as a potential drug candidate.³⁵

After the INDs are approved and clinical trials are completed, the pharmaceutical company must file an NDA.³⁶ The NDA contains the data from the clinical trials, as well as data from pre-clinical trials.³⁷ The FDA examines this data, and approves the drug for the market if the pharmaceutical company has sufficiently demonstrated the drug is “safe and effective.”³⁸ Gaining approval for a new drug

²⁹ See, e.g., Matthew J. Plunkett & Jonathan A. Ellman, *Combinatorial Chemistry and New Drugs*, SCI. AM. Apr. 1997, at 68 (describing combinatorial chemistry as a method for drug discovery).

³⁰ Basic science research is defined by the American Cancer Society as “laboratory studies that are not aimed at specific problems, but that provide the necessary knowledge and background for later applied research.” American Cancer Society Glossary—Basic Science Research, http://www.cancer.org/docroot/GRY/GRY_0.asp?dictionary=&pagKey=B (last visited Mar. 17, 2006).

³¹ E.g., Sir Alexander Fleming, Nobel Lecture (Dec. 11, 1945), *in* FROM NOBEL LECTURES, PHYSIOLOGY OR MEDICINE 1942–1962 (Elsevier Publishing Co., Amsterdam, 1964). One famous example is the discovery of penicillin, which was serendipitously discovered by Alexander Fleming in 1928. *Id.* Fleming noticed that mold that had grown on a dirty agar plate appeared to inhibit staphylococcal growth. *Id.* This mold, penicillin, is an antibiotic still used today.

³² 24 C.F.R. § 314.2 (2005). Pharmaceuticals will be approved when shown to be “safe and effective.” *Id.*

³³ 21 C.F.R. § 312.20(a) (2005). “A sponsor shall submit an IND to FDA if the sponsor intends to conduct a clinical investigation with an investigational new pharmaceutical that is subject to § 312.2(a).” *Id.*

³⁴ *Id.* § 314.21(a)–(c). “An IND may be submitted for one or more phases of an investigation.” *Id.* Phase I studies are closely monitored small scale human studies “to determine the metabolism and pharmacologic actions of the pharmaceutical in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.” *Id.* § 314.21(a). Phase II studies the “effectiveness of the pharmaceutical . . . the common short-term side effects and risks associated with the pharmaceutical.” *Id.* § 314.21(b). Phase III studies are large scale studies “to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the pharmaceutical and to provide an adequate basis for physician labeling.” *Id.* § 314.21(c).

³⁵ See generally *id.* § 314.50

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.* § 314.105(c).

after submission of an NDA takes between one and two years,³⁹ and the approval time of INDs varies greatly.⁴⁰ Because pharmaceutical patent applications are typically filed prior to filing an IND, the innovative pharmaceutical company, prior to the enactment of the Hatch-Waxman Act, lost a substantial period of market exclusivity granted by the patent.⁴¹

Generic drugs, although seemingly equivalent to their innovative drug counterparts, can only gain FDA approval if they are shown safe and effective by the generic pharmaceutical company.⁴² Because innovative drug companies typically hold patents on their drugs, prior to 1984 the manufacture and testing of generic equivalents of these drugs pursuant to FDA approval before the expiration of the patent was an act of infringement.⁴³ This effectively extended the patent holder's market exclusivity to include the time needed for the generic drug company to gain FDA approval.⁴⁴ Thus, innovative drug companies experienced a delay of entry into the market at the beginning of the patent term, but an addition to market exclusivity at the end of the patent term.⁴⁵

In 1984, Congress enacted the Hatch-Waxman Act to rectify the distortion of the patent term of innovative drugs and help speed the entry of generic drugs into the market.⁴⁶ The Hatch-Waxman Act provides generic pharmaceutical companies with an abbreviated approval process whereby some tests already performed by the innovative drug companies are not required⁴⁷ as well as a statutory exemption from patent infringement in pursuit of FDA approval.⁴⁸ Because of this exemption, upon the expiration of the innovative drug's patent term, the equivalent generic drug

³⁹ U.S. FDA CENTER FOR DRUG EVALUATION AND RESEARCH, FDA'S DRUG REVIEW AND APPROVAL TIMES (2001), <http://www.fda.gov/cder/reports/reviewtimes/default.htm> (stating FDA approval time was reported as sixteen months in 2000, including "FDA review time for the first submission of an NDA to the Agency, plus any subsequent time during which a pharmaceutical sponsor addresses deficiencies in the NDA and resubmits the application, plus subsequent FDA review time").

⁴⁰ See 21 C.F.R. §§ 314.21(a), 312.23(a)(5)(iii) (indicating the experimental conditions required for approval will vary with each drug, and the amount of information required will also vary).

⁴¹ MUELLER, *supra* note 8, at 262. While it is not mandatory to file the patent application in any particular phase of the regulatory approval process, an inventor typically files a patent application as soon as he is able to do so. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990). A rival company could copy or independently invent the same drug. Failure to file a patent application early not only exposes the company to an increased risk of competition in the market, but also a potential bar from the use of his own invention if a year lapses since the invention date, or a rival company files a patent application first. 35 U.S.C. § 102 (2000) (describing the "statutory bars" to patentability of an invention).

⁴² 21 C.F.R. § 314.94(a).

⁴³ MUELLER, *supra* note 8, at 262.

⁴⁴ MUELLER, *supra* note 8, at 262.

⁴⁵ *Eli Lilly & Co.*, 496 U.S. at 669–70.

⁴⁶ *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 865 (Fed. Cir. 2003).

⁴⁷ 21 U.S.C. § 355(j) (2000). The Abbreviated New Drug Application ("ANDA") requires that the generic company demonstrate the pharmaceutical is "bio-equivalent" to the patented pharmaceutical. *Id.* This allows the researcher to bypass many clinical and pre-clinical studies performed pursuant to the patented pharmaceutical's IND and NDA. See H.R. REP. NO. 98-857(I), at 14–18 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48.

⁴⁸ 35 U.S.C. § 271(e)(1) (2000). The Act allows innovative pharmaceutical companies to extend their patent term to compensate for time lost in the approval process. *Id.* § 156(c).

would already be tested and approved by the FDA, and could immediately enter the market.

B. The Hatch-Waxman Act and Section 271(e)(1)

The Hatch-Waxman Act appears in different sections of the United States Code,⁴⁹ but the portion of the Hatch-Waxman Act that protects generic drug companies from infringement during testing was codified as 35 U.S.C. § 271(e)(1). This section states that it is not infringement to use a “patented invention . . . solely for uses reasonably related to the development and submission of information” under a regulatory federal law.⁵⁰ According to House Reports, the intent in passing this provision was to allow the research and testing needed for FDA approval to commence before the expiration of the innovative drug’s patent term, so that upon expiration of the patent, the public would immediately have access to generic drugs, which are typically less costly than innovative drugs.⁵¹ However, the plain text of the statute does not specifically mention drugs or the FDA approval process.⁵²

In *Eli Lilly v. Medtronic*, the U.S.S.C. expanded the scope of the statutory safe harbor provision beyond the realm of generic drugs.⁵³ This case applied § 271(e)(1) to the testing of a cardiac defibrillator, a medical device,⁵⁴ because such devices, like drugs, are subject to extensive federal regulation.⁵⁵ When trying to follow *Eli Lilly*, courts generally continued to interpret the statute broadly; however, some inconsistencies developed in defining the specific “patented inventions” exempted from infringement by § 271(e)(1),⁵⁶ as well as the permissible uses of these

⁴⁹ *Id.* §§ 156(c), 271(e)(1).

⁵⁰ *Id.* § 271(e)(1).

⁵¹ H.R. REP. NO. 98-857(I), at 14–18, *reprinted in* 1984 U.S.C.C.A.N. at 2647–48.

⁵² 35 U.S.C. § 271(e)(1).

⁵³ *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (expanding the scope of § 271(e)(1) to include the testing of medical devices).

⁵⁴ *Id.* at 664. A medical device subject to regulation under the Food Drug and Cosmetics Act, and the basis of the U.S.S.C.’s finding is that the Patent Act classifies a medical device as a “human drug product,” thus falling within the statutory text of § 271(e)(1). *Id.* at 671 (referring to 35 U.S.C. § 156(f)).

⁵⁵ *Id.* at 674.

⁵⁶ *Compare* *Infigen Inc. v. Advanced Cell Tech., Inc.*, 65 F. Supp. 2d 967, 980 (W.D. Wis. 1999) (declining to extend § 271(e)(1) to protect use of method and patented cell medium, stating “[m]y own research shows no cases granting the § 271(e)(1) exemption from the otherwise infringing use of any product other than those pharmaceuticals, medical devices, food and color additives defined specified in [35 U.S.C. § 156 (2000)].”), *and* *Baxter Diagnostics, Inc. v. AVL Scientific Corp.*, 798 F. Supp. 612, 620 (C.D. Cal. 1992) (testing of class I and class II medical devices is not protected by § 271(e)(1) because they have a shorter regulatory review period than class III devices), *with* *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Mass. 1997) (holding the safe harbor provision of § 271(e)(1) does apply to class II medical devices).

inventions.⁵⁷ The debate came to a head in *Telios Pharmaceuticals v. Merck KGaA* (“*Merck I*”).⁵⁸

C. *The Merck Cases*

In the *Merck* line of cases, the scope of § 271(e)(1) was again called into question.⁵⁹ A California District Court, the Federal Circuit, and the U.S.S.C. faced several new issues in interpreting the statute, as the statutory text did not indicate whether the scope of § 271(e)(1) should extend to activities related to new drug development.⁶⁰

In *Merck I*, the defendants, Merck KGaA (“Merck”), Dr. Cheresch, and the Scripps Research Institute, raised § 271(e)(1) as a defense to their infringing use of a particular tri-peptide that they believed to be a good candidate for a new drug.⁶¹ The tri-peptide, patented by the plaintiff Telios Pharmaceuticals (“Telios”) and later purchased by Integra Lifesciences Corporation (“Integra”), was known to bind to specific cellular receptors and promote cellular adhesion.⁶² However, Telios, a small biotechnology company, did not file an IND because it was unable to find a potentially marketable use for their compound.⁶³

Dr. Cheresch, an angiogenesis scientist at Scripps, discovered it was possible to inhibit tumor growth by binding a compound to the same cellular receptors bound by the patented Telios tri-peptide.⁶⁴ Merck and Dr. Cheresch collaborated to develop an anti-tumor drug using tri-peptides that purportedly infringed Telios’ patent.⁶⁵ Dr. Cheresch screened several similar tri-peptides for anti-tumor activity, and found a promising drug candidate.⁶⁶ Merck planned to proceed with the regulatory approval process.⁶⁷

⁵⁷ See *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, No. 02-1280, 2001 U.S. Dist. LEXIS 19361, at *27–28 (S.D.N.Y. Nov. 27, 2001) (holding § 271(e)(1) can be applied to use of patented drug intermediates in generic development process); see also *Nexell Therapeutics, Inc. v. AmCell Corp.*, 199 F. Supp. 2d 197, 205 (D. Del. 2002) (holding the use of patented antibodies to develop a cell-separating device pursuant to FDA approval fell within scope of § 271(e)(1)).

⁵⁸ *Telios Pharms., Inc. v. Merck KGaA*, No. 96-CV-1307 1997 U.S. Dist. LEXIS 24187, at *1 (S.D. Cal. Sept. 11, 1997) *aff’d*, *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 863 (Fed. Cir. 2003) *rev’d*, *Merck KGaA v. Integra Lifesciences, Inc.*, 125 S. Ct. 2372, 2376 (2005).

⁵⁹ *Merck KGaA v. Integra Lifesciences, Inc.*, 125 S. Ct. 2372, 2376 (2005).

⁶⁰ *Id.*

⁶¹ *Telios*, 1997 U.S. Dist. LEXIS 24187, at *6.

⁶² *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 863 (Fed. Cir. 2003). Integra purchased U.S. Patent Nos. 4,988,621, 4,792,525, 5,695,997, 4,879,237, and 4,789,734 related to the “RGD peptide” from Telios. *Id.* at 862.

⁶³ *Id.* at 873 (Newman, J., dissenting).

⁶⁴ *Id.* at 863.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.* (stating “Merck then entered into an agreement with Scripps to fund the ‘necessary experiments’ to satisfy biological bases and regulatory (FDA) requirements for the implementation of clinical trials”).

As Merck began discussions with the FDA prior to filing an IND, Integra sued Merck, Dr. Cheresch, and Scripps for infringement.⁶⁸ The defendants raised § 271(e)(1) as a defense to infringement.⁶⁹ The § 271(e)(1) defense, if applied to this case, would broaden the scope of the statute, because the patented invention used by Dr. Cheresch was not tested for use as a generic drug, but as an innovative drug.⁷⁰ On a motion for partial summary judgment, the California District Court in *Merck I*, citing *Eli Lilly*, held that the type of invention used was irrelevant; instead the court focused on whether the information gathered was “solely for uses reasonably related to” FDA approval, holding the exemption may apply because some of the infringing use was aimed at drug research, albeit for an innovative drug rather than a generic drug.⁷¹ The District Court, however, limited the scope of permissible activities to those “solely” required for FDA approval, and held that a factual determination of the stage of research was needed to determine whether the provision would apply.⁷² On appeal to the Federal Circuit, following a jury verdict in the plaintiff’s favor, Merck argued that the District Court’s interpretation of § 271(e)(1) was incorrect.⁷³

The Federal Circuit examined the statute in the context of its legislative history to define its proper scope.⁷⁴ In *Merck II*, the Federal Circuit expressed concern that expanding the scope of the statute to cover activities in new drug development would adversely affect biotechnology patent owners’ rights.⁷⁵ The Federal Circuit read the statutory text, in particular the word “solely,” as a limitation on the scope of the allowable infringing activities.⁷⁶ Relying on the legislative history, the Federal Circuit held that the exemption would not apply to activities in *Merck II*, because the research was not specifically geared toward FDA approval.⁷⁷ The Federal Circuit also suggested that the exemption should only be applied in cases where the subject of study was an already approved drug or medical device.⁷⁸ The Federal Circuit upheld the verdict in favor of Integra,⁷⁹ and Merck appealed to the U.S.S.C.⁸⁰

⁶⁸ *Id.* Integra also filed suit against Dr. Cheresch and Scripps. *Id.* The defendants claimed the experimental use exemption in addition to § 271(e)(1). *Id.* Eventually, the suits against Dr. Cheresch and Scripps were dismissed. *Id.*

⁶⁹ *Id.* The defendants also raised the experimental use defense, however the jury was not instructed on that defense, nor did the Federal Circuit consider the issue on appeal. *Id.* at 864.

⁷⁰ See *Telios Pharms., Inc. v. Merck KGaA*, No. 96-CV-1307, 1997 U.S. Dist. LEXIS 24187, at *6 (S.D. Cal. Sept. 11, 1997). However, this question was not entirely novel, as the court noted in *Telios*, as one other district granted the exemption for the filing of an IND. *Id.* at *10 (citing, *NeoRX Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 204 (D.N.J. 1994) (holding infringing activities performed in pursuit of a new drug application were exempt under § 271(e)(1))). *Id.* at *7.

⁷¹ *Id.* at *14.

⁷² *Id.* at *18.

⁷³ *Integra*, 331 F.3d at 864.

⁷⁴ *Id.* at 865 (citing the House Committee’s characterization of the scope of the provision in H.R. REP NO. 98-857(II), at 8 (1984) reprinted in 1984 U.S.C.C.A.N. 2692, 2714 (“all that the generic can do is test the pharmaceutical for purposes of submitting data to the FDA for approval”).

⁷⁵ *Id.* at 867 (stating “expansion of § 271(e)(1) to include the Scripps-Merck activities would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents”).

⁷⁶ *Id.* at 866.

⁷⁷ *Id.* at 867.

⁷⁸ *Id.* at 866.

⁷⁹ *Id.* at 868. Judge Newman dissented, claiming either the common law experimental use exception or the § 271(e)(1) should apply, but did not discuss where the boundary might lie. *Id.* at 877. The dissent noted that § 271(e)(1) should not extend to innovative drug research. *Id.*

⁸⁰ *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005).

In *Merck III*, the U.S.S.C. attempted, for the second time, to establish parameters for the scope of the statutory safe harbor provision.⁸¹ The U.S.S.C. examined the issue in a different and broader light, focusing on text of the statute.⁸² The U.S.S.C. decision answered two questions: First, what “patented invention” may be used by experimenters to qualify for the § 271(e)(1) exemption; second, what uses of this invention would be “solely for uses reasonably related” to FDA approval.⁸³ The U.S.S.C. in *Merck III* referenced the plain text of the statute, which was silent on both matters.⁸⁴

The U.S.S.C. had previously examined this portion of the statute in *Eli Lilly*.⁸⁵ In that case, the patented invention was a medical device.⁸⁶ The Court relied on the definition of the term “invention” provided in 35 U.S.C. § 100(a) in holding “the phrase ‘patented invention’ in § 271(e)(1) is defined to include all inventions, not drug related inventions alone.”⁸⁷ The U.S.S.C. had not yet contemplated the possibility of inventions that could be considered “research tools” because the invention in that case did not qualify as a research tool.⁸⁸

In *Merck III*, the U.S.S.C. held that all information relevant to filing an IND would fall within the statute’s scope, including information discovered in the course of new drug development.⁸⁹ The U.S.S.C. also held that a “patented invention” could include a compound that is not actually submitted to the FDA for approval.⁹⁰ Thus, the Court overturned *Merck II* and held that Scripps’ and Merck’s activities were exempt under § 271(e)(1).⁹¹ However, the U.S.S.C. did not address whether these inventions, which may be used without liability for infringement, included research tools.⁹²

⁸¹ *Id.* at 2376.

⁸² *See id.* at 2380–84. The U.S.S.C. began the analysis of the scope of the statute by referring to the text, stating “we think it is apparent from the statutory text that § 271(e)(1)’s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA.” *Id.* at 2380.

⁸³ *Id.* at 2376.

⁸⁴ *Id.* at 2380.

⁸⁵ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 665 (1990).

⁸⁶ *Id.*

⁸⁷ *Id.* The court cited 35 U.S.C. § 100(a), which states “[w]hen used in this title unless the context otherwise indicates . . . the term ‘invention’ means invention or discovery”. 35 U.S.C. § 100(a) (2000).

⁸⁸ *See Eli Lilly & Co.*, 496 U.S. at 665. Medtronic sought an injunction to prevent Eli Lilly from testing and marketing a cardiac defibrillator. *Id.* at 664. The U.S.S.C. found that Eli Lilly’s activities were analogous to the testing of a generic drug, because the device was subject to a similarly rigorous regulatory approval process, and the goal of the infringing use was to gain such approval. *Id.* at 674.

⁸⁹ *Merck*, 125 S. Ct. at 2380. (holding “[t]here is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.”)

⁹⁰ *Id.* at 2382. The court stated “§ 271(e)(1)’s exemption from infringement [does not] categorically exclude either (1) experimentation on pharmaceuticals that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA.” *Id.* at 2380 n.7.

⁹¹ *Id.* at 2383.

⁹² *See id.* The U.S.S.C. did note the Federal Circuit’s concern with the matter of research tools patents, but stated that the matter was not before the Court. *Id.* The U.S.S.C. declined to rule on whether the use of research tools would fall within the scope of the exemption because neither party

D. Patent Rights and Property Rights

Patent rights are based in the United States Constitution, which gives Congress power to grant limited monopolies to promote the “[p]rogress of . . . useful [a]rts.”⁹³ The earliest patent statute was enacted in 1790.⁹⁴ Since their enactment, patent laws have been revised several times,⁹⁵ and are presently undergoing reform.⁹⁶

The constitutional goal of promoting progress is met by the two primary purposes of the patent system: providing incentive to invent, and granting the information to the public as soon as possible.⁹⁷ A patent accomplishes these goals by conferring to the holder the right to exclude others from making, using, or selling the invention for a limited period of time.⁹⁸

It is not novel to balance patent or property rights against strong competing public policies.⁹⁹ In 1813, Justice Story created an exemption to patent infringement, whereby he permitted strictly “philosophical experiments” with patented inventions.¹⁰⁰ This experimental use exemption as a defense to infringement still exists today, but in an extremely limited form.¹⁰¹

Although intellectual property, including patents, is not typically subject to the same rules as real or personal property, the modern view is that the right to exclude others conferred by a patent is a property right.¹⁰² As a property right, the right to exclude others from making, using, and selling a patented invention is protected by the Fifth Amendment to the United States Constitution, which states that “private

claimed the patented compound in question was a research tool. *Id.* The court further stated that based on the record, the compounds were not research tools. *Id.*

⁹³ U.S. CONST. art. I, § 8, cl. 8. “The Congress shall have Power . . . To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.” *Id.* This clause has been termed “both a grant of power and a limitation.” *Graham v. John Deere Co.*, 383 U.S. 1, 5 n.1 (1966).

⁹⁴ 1 DONALD S. CHISUM, CHISUM ON PATENTS § 2 (2004). The earliest statute granted patents for inventions including “any useful art, manufacture, engine, machine, or device or any improvement therein” that were previously unknown, and “sufficiently useful and important.” *Id.*

⁹⁵ *Id.* §§ 2–3 (2004) (providing a historical synopsis of patent laws).

⁹⁶ Patent Reform Act of 2005, H.R. 2795, 109th Cong. *See generally* Steven R. Ludwig, *The Most Comprehensive Change to U.S. Patent Law*, INTELL. PROP. TODAY, July, 2005, at 8 (summarizing proposed Patent Reform Act of 2005).

⁹⁷ *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974). These two aspects of the patent system have been studied in detail. *See, e.g.*, Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024–30 (1989) (discussing the incentive to invent and incentive to disclose theories).

⁹⁸ 35 U.S.C. § 154(a)(1)–(2) (2000). An invention must meet certain requirements before a patent can be obtained. *Id.* §§ 101–103.

⁹⁹ *See, e.g.*, *Penn Cent. Transp. Co. v. New York City*, 438 U.S. 104 (1978); *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984).

¹⁰⁰ *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (1813). Justice Story created the experimental use exception by stating “it could never have been the intention of the legislature to punish a man who constructed such a machine for philosophical experiments.” *Id.*

¹⁰¹ *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (refusing to grant the exception to a University that used a patented invention for basic research, reasoning that the use was not purely philosophical because research furthered the institution’s business). The Federal Circuit reframed the limits of the exemption to exclude any activities that further the infringer’s “legitimate business.” *Id.*

¹⁰² *See, e.g.*, *Festo Corp. v. Shoketsu Kinzo Kabushiki Co.*, 535 U.S. 722, 730 (2002).

property [shall not] be taken for public use, without just compensation.”¹⁰³ A regulatory taking occurs when governmental regulation either “takes” the entire property right, or so substantially deprives an owner of his property rights that the property can be considered “taken.”¹⁰⁴ Whether a taking has occurred is typically determined by applying the *Penn Central* balancing test, which considers three factors: one, the economic impact of the regulation on the property owner; two, the character of the governmental regulatory action; and three, the extent the regulation interferes with reasonable “investment-backed expectations.”¹⁰⁵

The so called “takings clause” was first applied to intellectual property, as opposed to real or private property, in *Ruckelshaus v. Monsanto Co.* In that case, the U.S.S.C. held that trade secrets were a property right that should be protected by the Fifth Amendment.¹⁰⁶ While the idea of applying the takings clause to intellectual property is still relatively new, Congress acknowledged that the takings doctrine would apply to patents in the debates over the Hatch-Waxman Act, but concluded that the very limited use intended by lawmakers would not constitute a taking.¹⁰⁷ However, in reaching this conclusion, Congress had merely contemplated the very limited case of allowing a generic drug already being tested to show equivalence to an innovative drug as required by the FDA, and did not contemplate the provision being applied to the search for new drugs.

II. ANALYSIS

Part A of this section analyzes the underlying policy considerations and legislative history of the Hatch-Waxman Act. Part A also discusses the interplay between patent policy and policies of the Hatch-Waxman Act, and analyzes the changing role of legislative history in courts’ interpretation of the statute. Next, Part B considers the scope of § 271(e)(1) following *Merck III*. Last, Part C examines the potential constitutional problems associated with the new scope of § 271(e)(1).

A. Policy Considerations and Legislative History

1. The Relationship Between Patent Policies and Drug Policies

Before the enactment of the Hatch-Waxman Act, the FDA’s goal of providing safe and effective drugs¹⁰⁸ conflicted with the policies promoted by the patent

¹⁰³ U.S. CONST. amend. V. The “Takings Clause” provides “private property [shall not] be taken for public use, without just compensation.” *Id.* The takings clause is applicable to intellectual property. *See Ruckelshaus*, 467 U.S. at 1003–04.

¹⁰⁴ *See Penn. Coal v. Mahon*, 260 U.S. 393, 415 (1922).

¹⁰⁵ *Penn Cent. Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978).

¹⁰⁶ *Ruckelshaus*, 467 U.S. at 1003–04.

¹⁰⁷ H.R. Rep. No. 98-857(II), at 29–30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2713–14.

¹⁰⁸ H.R. REP. NO. 98-857(II), at 9, *reprinted in* 1984 U.S.C.C.A.N. at 2693. The stated policy objective of the Act was to expedite the entry of generic substitutes in the market. *Id.*

system.¹⁰⁹ The FDA approval process substantially shortened the useful term of the patent, and required significant financial expenditures.¹¹⁰ This shortening negatively affected the financial benefits provided by U.S. patent laws to innovative pharmaceutical companies, and threatened to discourage innovation.¹¹¹ Additionally, the pre-1984 FDA regulations adversely affected the second stated purpose of patent law,¹¹² providing the public with immediate knowledge but delayed use of the invention.¹¹³ While the public continued to have access to the innovative drugs, the public did not have the full power to use the information disclosed in the patent to produce low cost equivalents as soon as the patent term expired. The innovative drug companies' period of market exclusivity continued pending FDA approval of equivalent generic drugs. These considerations drove Congress to pass the Hatch-Waxman Act.¹¹⁴ Congress recognized the need to grant the public the immediate benefit of low cost drugs.

Many courts that have attempted to define the scope of § 271(e)(1) have also recognized the need to balance these competing interests.¹¹⁵ In *Merck II*, the court emphasized the need to preserve patent holders' rights, which resulted in a very narrow interpretation of the statute.¹¹⁶ In contrast, the U.S.S.C. in *Merck III* focused little on patent holders' rights, and emphasized the need to provide a broad exemption to further the goals of encouraging pharmaceutical development.¹¹⁷

2. The Courts' View of Legislative History

The Congressional reports related to the enactment of § 271(e)(1) clearly state that a primary purpose of the Hatch-Waxman Act is to provide the public with increased access to generic drugs.¹¹⁸ This goal is accomplished by abolishing the effective term extension enjoyed by pharmaceutical patent owners due to the generic drug regulatory approval period.¹¹⁹ Further policy rationale can be inferred from the original title of the Act, the "Drug Price Competition and Patent Term Restoration Act," which identifies the intent to provide competitive pricing for drugs.¹²⁰

In *Merck II*, the Federal Circuit revisited the Act's legislative history in greater depth.¹²¹ The Federal Circuit focused on phrases in the legislative history that

¹⁰⁹ *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974).

¹¹⁰ *Roche Prods. v. Bolar Pharm. Co.*, 733 F.2d 858, 864 (Fed. Cir. 1984). The court acknowledged "the remaining effective life of patent protection assertedly may be as low as 7 years." *Id.*

¹¹¹ *Kewanee Oil*, 416 U.S. at 480–81.

¹¹² H.R. REP. NO. 98-857(I), at 9, *reprinted in* 1984 U.S.C.C.A.N. at 2693.

¹¹³ *Kewanee Oil*, 416 U.S. at 480–81.

¹¹⁴ H.R. REP. NO. 98-857(I) at 14–15, *reprinted in* 1984 U.S.C.C.A.N. at 2647–48.

¹¹⁵ *See generally* *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

¹¹⁶ *See* *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 867–68 (Fed. Cir. 2003).

¹¹⁷ *See Merck*, 125 S. Ct. at 2382–83.

¹¹⁸ H.R. REP. NO. 98-857(I), at 14–15, *reprinted in* 1984 U.S.C.C.A.N. at 2647–48.

¹¹⁹ *Id.*

¹²⁰ *Id.* at 1, *reprinted in* 1984 U.S.C.C.A.N. at 2647.

¹²¹ *See* *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 865–68 (Fed. Cir. 2003).

promoted a narrower view, thus restricting the scope of the statute.¹²² The Federal Circuit held that an extension of § 271(e)(1) to activities associated with new drug development would ignore the text and purpose of the Act.¹²³

In *Merck III*, Justice Scalia did not consider the legislative history in his interpretation of the statute.¹²⁴ This is not surprising, given his analysis of § 271(e)(1) in the earlier *Eli Lilly* decision, where he stated that the statute was poorly written, and that the legislative history did not clarify the proper scope.¹²⁵ As a result, the Court held that § 271(e)(1) could apply to activities associated with development of a new drug.¹²⁶

B. The New Scope of the Safe Harbor Provision

The U.S.S.C.'s definition of the scope of § 271(e)(1) is extremely broad because the U.S.S.C. did not specifically exclude the use of any particular type of drug from the safe harbor of § 271(e)(1).¹²⁷ Indeed, rather than defining the scope of the provision in terms of the type of invention that may be used, the sole limitation imposed by the U.S.S.C. is based on the use of the patented invention.¹²⁸ Moreover, the U.S.S.C. broadened the scope of such permissible uses.¹²⁹ The statute now exempts the use of any patented compounds in preclinical studies and clinical studies, provided the experiments may produce the "types of information that are relevant to an 'IND or NDA.'"¹³⁰

According to *Merck III*, innovative drug companies can now use any patented inventions in the search for new drug candidates without fear of an infringement suit.¹³¹ The U.S.S.C.'s broad interpretation of the term "invention" ignored the warnings of the Federal Circuit about the potentially devastating effect of a broad interpretation of the statute on holders of biotechnology patents.¹³² Included among such patented biotechnology inventions are "research tools," which are inventions that aid in research.¹³³

¹²² *See id.* at 865. Specifically, the court focused on the Committee's description of appropriate pre-market activity as "a limited amount of testing so that generic companies can establish the bioequivalency of a generic substitute." *Id.* The Court also considered the Committee's statement that the "nature of the interference with the rights of the patent holder" would not be "substantial," but "de minimus." *Id.*

¹²³ *See id.* at 866.

¹²⁴ *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005).

¹²⁵ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990) (stating the statute was "not plainly comprehensible on anyone's view").

¹²⁶ *Merck*, 125 S. Ct. at 2383.

¹²⁷ *Id.* (substituting "patented compound" for the term "patented invention" found in the text of the statute).

¹²⁸ *See id.* at 2383.

¹²⁹ *See id.* at 2383.

¹³⁰ *Id.* at 2383–84 (quoting the Brief for United States as Amicus Curiae Supporting Petitioner at 15, *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005) (No. 03-1237)).

¹³¹ *See id.* at 2382.

¹³² *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 867 (Fed. Cir. 2003).

¹³³ *Id.* at 872 n.4. The Federal Circuit deferred to the National Institute of Health ("NIH") definition of research tools: "tools that scientists use in the laboratory, including cell lines,

The U.S.S.C. additionally expanded the scope of § 271(e)(1) by altering the Federal Circuit's interpretation of the phrase "solely for uses reasonably related."¹³⁴ The word "solely" has received inconsistent treatment in the courts, but when included in the interpretation, it is most often read to exclude activities that may have collateral purposes.¹³⁵ The U.S.S.C. did not include the term "solely" at all in the analysis in *Merck III*, nor did it expressly address the reason for its exclusion.¹³⁶ This omission implies that uses of patented inventions other than those "solely" for FDA approval are allowable under the exemption, and that the boundaries of the provision are simply imposed by the term "reasonably related."¹³⁷ Indeed, the U.S.S.C.'s focus was the definition of the "reasonably related" standard.¹³⁸

The U.S.S.C.'s holding that "*any* information" is relevant to the FDA, including all information related to an IND, imposes no boundaries on the scope of the statute.¹³⁹ Because the FDA does not exclude any information from submission, and requires a broad scope of information before clinical trials can begin, no data would ever be excluded under this reasoning.¹⁴⁰ Therefore, any information pertaining to a compound under investigation would be relevant. Given the U.S.S.C.'s broad treatment of the word "information" and neglect of the word "solely," any boundaries of § 271(e)(1) are necessarily imposed by the phrase "for uses reasonably related to the development and submission" of information under the FDA, a much broader standard than contemplated in *Merck II* or by Congress.¹⁴¹

The U.S.S.C. expressly stated that there is no basis for excluding information based on the phase of research, but in the end imposed its sole limitation on that very basis.¹⁴² The only guidance given by the U.S.S.C. in the interpretation of the scope of § 271(e)(1) is that basic science research is too remote, and that a reasonable relation

monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines." *Id.*

¹³⁴ *Merck*, 125 S. Ct. at 2383.

¹³⁵ *Compare* *Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379, 1396 (D. Cal. 1987) (declining to extend protection to tests by infringer that had "some reasonable relationship" to FDA approval because text should be interpreted to mean "solely" related to FDA approval), *and* *Biogen, Inc. v. Schering AG*, 954 F. Supp. 391, 396–97 (Mass. 1996) (declaring no safe harbor because "Biogen had done far more than merely do clinical trials for submission to the FDA"), *with* *Abtox, Inc. v. Exitron Corp.*, 122 F.3d. 1019, 1030 (holding text of 271(e)(1) should be interpreted as "reasonably related to FDA approval"), *and* *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1280 (N.D. Cal. 1991) (stating the appropriate analysis is to question whether it was reasonable for the defendant to believe "there was a decent prospect that the 'use' in question would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant in the processes by which the FDA would decide whether to approve the product"), *and* *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 108 (D. Mass. 1998) (holding the exemption should apply when there are "reasonable prospects of yielding information that might be relevant in the FDA approval process").

¹³⁶ *Merck*, 125 S. Ct. at 2383. The court states "[the statute] exempted from infringement all uses of patented compounds 'reasonably related' to the process of developing information." *Id.* The word "solely" is left out of the analysis entirely. *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.* at 2380 (emphasis in original).

¹⁴⁰ 21 U.S.C. § 355(b)(1)(a)(A) (2000). The statute requires reports of all studies aimed at showing safety or efficacy of a pharmaceutical. *Id.*

¹⁴¹ *See Merck*, 125 S. Ct. at 2380.

¹⁴² *Id.* at 2380.

should be determined by the intent of the research.¹⁴³ Unfortunately, scientific research is not divided into drug producing activities and non-drug producing activities, and the definition of “basic science” is very broad.¹⁴⁴ There is no set route to drug research, and some of the most useful drugs were serendipitous discoveries.¹⁴⁵ Despite frequent attempts to formalize the drug research process, innovative pharmaceutical companies often collaborate and fund basic science research to increase the odds of finding a viable drug.¹⁴⁶ Many basic scientists begin their research with the goal of understanding a physiological process, but often the process under investigation is the onset of a disease.¹⁴⁷ It is difficult to imagine finding a researcher who studies cancer, for example, that would admit to having no intent to discover a cure.¹⁴⁸ Even if such a researcher were to exist, what if he were told that the intent to develop a drug would allow him exemptions on patent infringement? An exemption to patent infringement that includes the “hunt for new drugs” gives anyone a free use of a patented invention under the guise of experimentation.

C. Constitutional Ramifications of the Merck Cases

Because Congress considered the possibility of a regulatory taking when it enacted § 271(e)(1), it is desirable to revisit this analysis in light of the *Merck* holdings.¹⁴⁹ The possible degree of invasion of a patent holder’s property rights under § 271(e)(1) can be viewed as a spectrum, with the generic drug patent holders on one end, research tool patent holders on the other end, and *Telios* (the plaintiff in the *Merck* cases) somewhere in the middle.

When Congress declared that § 271(e)(1) was constitutional under the takings clause, it applied the *Penn Central* analysis to the limited scenario intended by the statute.¹⁵⁰ The benefit that Congress deemed substantial, the reduced cost of drugs because of increased availability of generic drugs, was balanced against a “de minimus” interference of the patent holders’ rights, stating “all the generic can do is test the drug for purposes of submitting data to the FDA for approval.”¹⁵¹ Such a benefit outweighed the interference and hence, was declared constitutional.

¹⁴³ *Id.* at 2382 (excluding “basic science research . . . performed without intent to develop a particular pharmaceutical or a reasonable belief that the compound will cause an intended physiological effect”).

¹⁴⁴ See American Cancer Society Glossary, *supra* note 30.

¹⁴⁵ See, e.g., Fleming, *supra* note 31.

¹⁴⁶ See, e.g., *Merck*, 125 S. Ct. at 2377–78. Dr. Cheresh was a researcher at Scripps that studied a physiological process, angiogenesis, who entered into a collaboration with Merck to attempt to find a viable drug candidate. *Id.*

¹⁴⁷ See Joseph Coates, *Where Science Is Headed—Sixteen Trends*, J. OF THE WASH. ACAD. OF SCL., Fall-Winter 2003, at 1. Trends in basic science research are closely tied to funding sources, which often require statements of potential benefits of the proposed research. *Id.*

¹⁴⁸ See Peter D. Goldsworthy & Alexander C. McFarlane, *Howard Florey, Alexander Fleming and the Fairy Tale of Penicillin*, 176 MED. J. OF AUSTL. 176, 180 (2002) (quoting the philosopher R. Rorty, who said “inquiry is never pure . . . it is always a matter of getting us something we want”).

¹⁴⁹ H.R. REP. NO. 98-857(II) at 27 (1984), *reprinted in* 1984 U.S.C.A.N. 2686, 2714.

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

Considering the broad scope of the statute after the *Merck III* decision, the same constitutional analysis leads to a different result when considering research tools. Judge Newman stated in *Merck II*, “[t]he use of an existing tool in one’s research is quite different from the study of the tool itself.”¹⁵² However, for some inventions, specifically research tools, the use of the invention as a tool is the invention’s only purpose.¹⁵³ For example, an invention that uses a test tube and a set of reagents to measure the decomposition rate of a drug in the body would significantly reduce the need for animal and human testing.¹⁵⁴ This invention would be of great value to innovative pharmaceutical researchers. If the inventor seeks a patent for his biodegradability test, the method of performing such tests would be disclosed and could be duplicated by anyone with access to the reagents.¹⁵⁵ Under the current scope of § 271(e)(1), a pharmaceutical company could manufacture and use the patented test under the guise of looking for new drugs, based on the description in the patent, without fear of an infringement lawsuit.

Applying the *Penn Central* analysis to the above hypothetical, it is clear that a regulatory taking has occurred. First, it can be assumed that such an inventor would have a distinct investment-backed expectation, as the inventor would likely market the invention toward pharmaceutical companies. Second, considering the nature of the government interference, allowing such a tool to fall within the scope of § 271(e)(1) deprives the patent owner of his only property right.¹⁵⁶ Finally, these factors must be balanced against the benefits to the public of potentially inexpensive drugs, not to mention the lives of many laboratory animals. These benefits may tip the scales in favor of allowing the exemption, however the nearly complete deprivation of intellectual property is a substantial detriment to the “need to stimulate innovation.”¹⁵⁷ In the above hypothetical, the inventor would either sue the government and recover a reasonable royalty for his invention or be left empty

¹⁵² *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 878 (Fed. Cir. 2003).

¹⁵³ See Janice M. Mueller, *Article: No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 10 (2001) (defining research tools as “the many varied resources used by scientists to conduct research and development of new pharmaceuticals, therapies, diagnostic methods, and other therapeutic products”). In some instances, the sole purpose of a research tool is to assist researchers in the study of a compound. *Id.*

¹⁵⁴ INDs and NDAs require data that establish biological decomposition rates. 21 C.F.R. § 312.23 (2005). Thus, the use of such an invention would lead to information “reasonably” related to FDA approval of a drug.

¹⁵⁵ 35 U.S.C. § 112 (2000). Section 112 requires an inventor to disclose in a patent application “the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same.” *Id.*

¹⁵⁶ See *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003–04 (1984) (applying the takings clause to intellectual property rights). For intellectual property the right to exclude is the property right. *Festo Corp. v. Shoketsu Kinzo Kabushiki Co.*, 535 U.S. 722, 730 (2002). If this right is effectively removed by a governmental regulation, a taking has occurred. See *Ruckelshaus*, 467 U.S. at 1003–04. See generally Courtenay C. Brinckerhoff, *Article: Medical Method Patents and the Fifth Amendment: Do the New Limits on Enforceability Effect a Taking?*, 4 U. BALT. INTELL. PROP. L.J. 147, 165–77 (1996) (discussing the application of the takings clause to regulations of medical method patents).

¹⁵⁷ H.R. REP. NO. 98-857(II), at 30, *reprinted in* 1984 U.S.C.C.A.N. 2686, 2714.

handed.¹⁵⁸ However, this scenario places a significant burden on the inventor of a research tool, as he would be required to file suit and prove the damages he incurred.

In the *Merck* line of cases, the *Penn Central* analysis leads to an uncertain result. It is not as clear what Telios' investment-backed expectation would be, because Telios was unable to find a productive use for the tri-peptide other than selling the patent that covered the peptide to Integra. However, for a small biotechnology company, this may well be a significant investment-backed expectation. It is reasonable, in any case, to assume that such companies set out with some expectation of a profit. Second, it is also difficult to determine the extent of the invasion of Telios' property right. The patent holder in the *Merck* line of cases did not lose the right to exclusively sell its invention, but rather lost the right to its exclusive use.¹⁵⁹ If Merck had managed to gain FDA approval for the tri-peptide, nothing in § 271(e)(1) gives Merck the right to sell it. At most, § 271(e)(1) diminished the value of the patents, because of lost licensing opportunities.¹⁶⁰ The third *Penn Central* factor as applied to the *Merck* line of cases would substantially outweigh any detriment to the patent holder, because the new use of the tri-peptide as an anti-tumor drug would be a significant benefit to society. Under these circumstances, it is difficult to predict whether a court would hold that a taking has occurred. If there is a taking, the "just compensation" that should be paid would also be great, given the compounds potential role as an anti-tumor agent. It is apparent that for uses falling between the two ends of § 271(e)(1)'s spectrum, whether a taking has occurred will require a case by case basis analysis of *Penn Central's* factors.

III. PROPOSAL

The current scope of the Hatch-Waxman Act, as defined by the U.S.S.C., is broad and uncertain.¹⁶¹ To maintain the current goals of our patent system, it is important to protect the patent owners' right to exclude when possible and avoid creating inconsistent exemptions to infringement.¹⁶² This comment proposes a narrow interpretation of the safe harbor provision, limiting the scope of § 271(e)(1) to the use of a patented drug or device solely to show equivalence for FDA approval.

¹⁵⁸ See Ruckelshaus, 467 U.S. at 1003–04.

¹⁵⁹ *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2383 (2005) (holding the infringing activities fell within the statutory safe harbor, therefore the patent holder lost the right to the exclusive use of his invention).

¹⁶⁰ See *Telios Pharms., Inc. v. Merck KGaA*, No. 96-CV-1307, 1997 U.S. Dist. LEXIS 24187, at *11 (S.D. Cal. Sept. 11, 1997).

¹⁶¹ See *Merck*, 125 S. Ct. at 2383 (holding § 271(e)(1) applies to any invention, not merely the subject of study, as long as the research will reasonably lead to information of interest to the FDA for approval of a drug). The U.S.S.C. acknowledged that almost all information in the course of research on a particular compound would be reasonably included. *Id.* at 2382. The only limitation imposed by the U.S.S.C. was the exclusion of basic science research on the grounds that the intent to develop a drug was absent. *Id.*

¹⁶² *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974).

A. *Limit "Invention" to Subject of Study*

In *Merck III*, the U.S.S.C. improperly declined to limit the "invention" that would be infringed to the subject of study.¹⁶³ This interpretation is not only contrary to the intent of the Hatch-Waxman Act,¹⁶⁴ it also may render research tool patents worthless,¹⁶⁵ leading to a regulatory taking.¹⁶⁶ Allowing § 271(e)(1) to apply to inventions that are not the subject of study does not further the goals of the Hatch-Waxman Act.¹⁶⁷ Certainly, there is a great advantage to innovative pharmaceutical companies if § 271(e)(1) is broadly interpreted, because they could use any patented invention without fear of infringement litigation.¹⁶⁸ However, although this would lower expenditures of pharmaceutical companies in their endeavors to discover new drugs, this would not necessarily translate to cheaper drugs for consumers. Furthermore, any cost saved by an innovative pharmaceutical company would be transferred either to the government, as the Fifth Amendment requires compensation to be paid in the case of a taking, or to inventors as they lose the opportunity to license their patented inventions.¹⁶⁹ Moreover, there is no patent term distortion when the patented invention is not the subject of study because there is no FDA-approval-based delay of the patent term.¹⁷⁰ It is also unlikely that this expansion would result in earlier entry of generic drugs into the market.¹⁷¹

Furthermore, expanding the scope of the exemption to include inventions that are not the subject of study is contrary to the goals of the patent system. Taking away licensing opportunities for any product that may be used in the course of drug research deters, rather than encourages innovation. It is difficult to imagine why any biotechnology company would invest in the development of new research tools with the probability of gaining no return on their investment. There is no benefit to disclosing the invention without the guarantee of exclusivity, and this may begin to

¹⁶³ *Merck*, 125 S. Ct. at 2383.

¹⁶⁴ H.R. REP. NO. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48. The committee stated that an unconstitutional taking was not present because "the only activity which will be permitted by the bill is a limited amount of testing so that generic companies can establish the bioequivalency of a generic substitute." H.R. REP. NO. 98-857(II), at 30, *reprinted in* 1984 U.S.C.C.A.N. 2686, 2714.

¹⁶⁵ *See Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 867 (Fed. Cir. 2003).

¹⁶⁶ U.S. CONST. amend. V. The "takings clause" provides "private property [shall not] be taken for public use, without just compensation." *Id.* The takings clause is applicable to intellectual property. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003-04 (1984) (holding trade secrets to be a property right that should be protected by the Fifth Amendment). A regulatory taking occurs when a governmental regulation extensively reduces a property right. *Penn. Coal v. Mahon*, 260 U.S. 393, 414-15 (1922). Congress acknowledged that the takings doctrine would apply to the Hatch-Waxman Act, but concluded that the very limited use contemplated would not constitute a taking. H.R. REP. NO. 98-857(II), at 30, *reprinted in* 1984 U.S.C.C.A.N. at 2714.

¹⁶⁷ H.R. REP. NO. 98-857(I), at 14-18, *reprinted in* 1984 U.S.C.C.A.N. at 2647-48.

¹⁶⁸ 35 U.S.C. § 112 (2005).

¹⁶⁹ U.S. CONST. amend. V.

¹⁷⁰ *See Fox*, *supra* note 14, at 197. The invention would not experience a delay in profitability because of the FDA approval process, so there is no front end distortion. The invention would not experience back end distortion because the patent term of the patent owner would not be affected by the potentially infringing activities.

¹⁷¹ In this case, the delay of entry into the market is due to incomplete pharmaceutical development, rather than a regulatory mechanism.

resemble a compulsory licensing scheme.¹⁷² Inventors will choose to keep their inventions as trade secrets, which, by avoiding disclosure, would not advance a primary goal of the patent system.

Limiting the “invention” to the subject of study would rectify these problems. There would no longer be a risk of a regulatory taking because there would be minimal deprivation of economic value,¹⁷³ and the promise of the right to exclude would remain as incentive to disclose useful information to the public.

B. Exclude the Hunt for New Pharmaceuticals from Permissible Activities

It is tempting to provide an exemption to patent infringement for activities that may provide the public with more, or better, drugs. Indeed, in the series of *Merck* cases, the infringing acts converted a seemingly useless compound into a potentially cancer curing agent.¹⁷⁴ This better, more efficient, use of resources should be rewarded. It may seem that an easy solution to lowering the cost of drugs is to lower the expense of pharmaceutical manufacture by providing incentives such as exemptions from patent infringement to avoid licensing fees. However, such exemptions would be far from certain.

The problem with the current analysis of § 271(e)(1) is that there are no definable boundaries to the exemption, and patent owners, as well as researchers, will have no notice about potentially infringing acts. Because all research related to a compound would be of interest to the FDA, and the compound never needs to be submitted for approval to trigger the exemption, it is difficult to imagine what information would not be included. The U.S.S.C. suggests that the way to delineate the boundary is to examine the intent of the research¹⁷⁵ and to exclude research conducted without intent to produce a drug.¹⁷⁶

This is certainly not the exemption envisioned by the legislature when it enacted § 271(e)(1).¹⁷⁷ The U.S.S.C.’s interpretation of § 271(e)(1) is inconsistent with

¹⁷² See generally Grace K. Avedissian, Note, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of “Super-Terrorism”*, 18 AM. U. INT’L L. REV. 237, 248–62 (2002) (providing an overview and analysis of U.S. and foreign positions on compulsory licensing of pharmaceuticals).

¹⁷³ *Penn. Coal v. Mahon*, 260 U.S. 393, 414–15 (1922). Limiting the invention would lead to the result reached by Congress in the debate of the Hatch-Waxman Act, because the infringing use would be insubstantial. H.R. REP. NO. 98-857(II), at 29–30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2713.

¹⁷⁴ *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2378 (2005).

¹⁷⁵ *Id.* at 2382. Examining intent in the context of patent infringement is controversial, and has been deemed inappropriate in the context of the doctrine of equivalents. *Warner-Jenkinson Co. v. Hilton-Davis Chem. Co.*, 520 U.S. 17, 36 (1997). This was also noted in *Madey*, where the court noted the difficulty in analyzing intent in the context of the experimental use exception in light of *Warner-Jenkinson*, but concluded “we do not view such an inconsistency as inescapable, and conclude the experimental use defense persists albeit in the very narrow form articulated by this court in *Embrex*.” *Madey v. Duke Univ.*, 307 F.3d 1351, 1361 (Fed. Cir. 2002).

¹⁷⁶ *Merck*, 125 S. Ct. at 2382. The U.S.S.C. held that research performed without the intent to develop a pharmaceutical should not be exempted. *Id.*

¹⁷⁷ H.R. REP. NO. 98-857(II), at 29–30, *reprinted in* 1984 U.S.C.C.A.N. at 2713–14. Congress considered the issue of a taking, but ultimately decided that the infringement would be insignificant and the benefits to the elderly and the poor by having faster generic pharmaceuticals would

holdings of the courts that properly narrowed the experimental use exemption for infringement, as there are substantial commercial objectives in the hunt for new drugs.¹⁷⁸ It is not logical to provide an exemption for research that satisfies “idle curiosity,” and for research that potentially finds new drugs, but not for academic research which often falls in the middle.¹⁷⁹

The expansion of the § 271(e)(1) exemption to include the hunt for new drugs goes beyond Congress’s intent, and intrudes on patent owners’ constitutional rights to their property.¹⁸⁰ Furthermore, allowing such a large class of researchers to use a patented invention without compensation exceeds the boundaries of “de minimus” use.¹⁸¹ The magnitude of the intrusion into the property rights is large, even though it has been stated that “infringement is not a question of degree.”¹⁸² To preserve the patent owner’s rights, the use of the invention should be strictly limited for purposes “solely” related to FDA approval, as it is stated in the text of § 271(e)(1).¹⁸³

IV. CONCLUSION

The U.S.S.C. expanded the scope of the Hatch-Waxman Act’s safe harbor provision in *Merck III* to include protection for infringing use of any type of invention as long as a researcher intended to perform research reasonably relevant to FDA approval.¹⁸⁴ This broad interpretation is inconsistent with the legislative intent of the Hatch-Waxman Act, and the policies of the U.S. patent system. Many patent owners may unnecessarily experience such a reduction in their property rights as to constitute a regulatory taking.

The proposed narrow interpretation would rectify the constitutional problems and inconsistencies in infringement exemptions. Section 271(e)(1) should apply only to the invention studied, and even then, “solely” for the limited purpose of obtaining

outweigh the detriment to the “investment backed expectations.” H.R. REP. NO. 98-857(II), at 29–30, *reprinted in* 1984 U.S.C.C.A.N. at 2713–14.

¹⁷⁸ *Madey v. Duke Univ.*, 307 F.3d 1351, 1361 (Fed. Cir. 2002) (holding the experimental use exemption to be “very narrow and strictly limited”); *Embrex, Inc. v. Service Eng’g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (stating that a broad experimental use exception would violate the patent laws if there were “definite, cognizable, and not insubstantial commercial purposes”).

¹⁷⁹ U.S. CENSUS BUREAU, *2002 Economic Census, Report: Scientific Resources and Development Services*, No. EC02-54I-07, tbl.2. There is a large disparity in profitability between academic pursuits and pharmaceutical pursuits. *Id.* The revenue for tax exempt establishments conducting scientific research was \$18 billion, compared with \$45 billion for establishments subject to federal income tax. *Id.*

¹⁸⁰ H.R. REP. NO. 98-857(I), at 14–18, *reprinted in* 1984 U.S.C.C.A.N. at 2647–48; *see also* *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003–04 (1984) (holding trade-secrets to be a property right that should be protected by the Fifth Amendment). The goals of the patent system are to promote the progress of science by providing the right to exclude others from using, making or selling an invention. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974).

¹⁸¹ H.R. REP. NO. 98-857(II), at 30, *reprinted in* 1984 U.S.C.C.A.N. at 2714. Congress relied on the substantial nature of the use of the patented invention to determine a regulatory taking. *Id.*

¹⁸² *Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 631 (1990). The court criticized the experimental use exception, stating that the damages may be small for certain infringing uses, but the act of infringement is “not a question of degree.” *Id.*

¹⁸³ 35 U.S.C. § 271(e)(1) (2000).

¹⁸⁴ *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2383 (2005).

FDA approval. This approach would allow courts to balance the need for safe and effective drug equivalents with the right of the patent owner to the exclusive use of his invention in addition to promoting the progress of science.