

**THE WAR ON DRUGS: HOW *KSR v. TELEFLEX* AND
MERCK v. INTEGRA CONTINUE THE EROSION OF
PHARMACEUTICAL PATENT PROTECTION**

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I. INTRODUCTION

Build a better mousetrap and the world will beat a path to your door, or so the old axiom goes. This statement summarizes one of the basic pillars of capitalism; that a person who fills an important need for society will (and perhaps more importantly should) be rewarded for his ingenuity, and for his contribution to society. There are important steps that must occur, however, before the world can beat that path to your door. In modern society commercialization of innovations requires a great deal of investment, from building factories and hiring employees to finding a way to advertise your improved mousetrap.

The founders of our republic understood that technological innovation was an important driver for a strong economy, and they understood the important link between securing the financial rights of inventors and the investment necessary to fund innovative research. This is evident by the language of the Constitution which states that Congress has the power to grant patents (and also copyrights) “[t]o promote the progress of Science

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Prior to law school I worked in the pharmaceutical industry as a medicinal chemist for several years. I point this out not because I have an ax to grind regarding the relatively short patent lives of prescription drugs, but rather because after having worked in the industry I have a perspective that is unique amongst law students, and patent attorneys (who tend to treat most types of patents as relatively interchangeable). While working as a scientist I was always confused and disheartened by the negative perception of the industry and the desire to curtail any profits that manufacturers of prescription drugs generate. It seemed counterintuitive. To phrase it another way; who deserves to make a profit more than a corporation that employs people in one of the most productive sectors of the U.S. economy, and produces a much needed products that help to both prolong and enrich the lives of millions?

and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹

The pharmaceutical-drug industry is especially dependant on patents for protection of their investment in research. In pharmaceuticals, unlike disciplines such as the computer hardware industry, the patent is, more often than not, for the ultimate product.² To illustrate the difference, imagine all of the parts of a printer attached to your home computer, every motor, every wheel, even the exterior design of the printer itself is probably patented, but it is unlikely that the whole finished product is patented. Contrast that with a pharmaceutical product. The patent is not for the pill shape, or the fillers that are inevitably part of the production process, no, the patent is for the active ingredient (and most likely to structurally similar analogs as well). The illustration points out why patents are so much more valuable to the pharmaceutical industry. Without a patent, a competitor can reverse engineer your drug and then sell the exact same product, thus, making the investment in discovering the therapy worthless.

Another reason why patent protection is so important to the pharmaceutical industry is the large amount of time and dollars spent discovering new therapies and acquiring the data necessary for obtaining U.S. Food and Drug Administration (FDA) approval. The pharmaceutical industry spent \$51.3 billion dollars in 2005 on research and development.³ Current estimates per new FDA-approved therapy include 10–15 years of research,⁴ \$800 million dollars,⁵ and between 5,000 and 10,000 compounds tested.⁶ The time required to obtain FDA approval has also risen, from 3.1 years on average in the 1960s to 8.6 years in the 1990s.⁷ And, while the costs and time required to bring a new therapy to market continue to grow, the effective lifetime of a pharmaceutical patent has shrunk to 11.5 years.⁸ Perhaps most surprising, only about three out of every ten marketed drugs

¹ U.S. CONST. art. 1, § 8, cl. 8.

² BRUCE LEHMAN, *THE PHARMACEUTICAL INDUSTRY AND THE PATENT SYSTEM* 7 (2003), <http://www.earth.columbia.edu/cgsd/documents/lehman.pdf>.

³ PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *PHARMACEUTICAL INDUSTRY PROFILE 2006* 2 (March 2006), *available at* <http://www.phrma.org/files/Profile2006.pdf>.

⁴ *Id.*

⁵ *Id.*

⁶ *Id.* at 4.

⁷ *Id.* at 5.

⁸ *Id.* at 8.

produce revenue that exceeds the average cost of research and development.⁹

An additional factor in patent value is the average time that a drug enjoys market exclusivity, that is, the time that a pioneer drug (one that is the first of its kind to treat a particular disease state) enjoys a monopoly in the market. For while a patent grants the patentee the exclusive right to make, use, or sell their product, it does not guarantee a monopoly or even a profit. On this point, “[a] recent study from Tufts University researchers showed that the amount of time between the entry of the first and second drug in a class has fallen by about 78 percent since 1970.”¹⁰ The researchers attribute this to competition in the pharmaceutical industry.¹¹ This highlights the pressure that pioneer firms have to maximize the lifetime of their patents. All of these statistics illustrate the point that without patent protection; why would anyone engage in the costly research necessary to discover new treatments (not to mention the expense and time required to gain FDA approval), when they could just wait for a competitor to do the heavy lifting and come in when the process of commercialization is beginning and steal the ultimate product?

The exclusive right that is given to inventors via the grant of a patent is the classic property right—the right to exclude.¹² This right is enforceable through the courts when another has infringed the patent. Generally, it is an act of patent infringement to “mak[e], us[e], offe[r] to sell, or sell any patented invention . . . during the term of the patent therefor.”¹³

⁹ Henry G. Grabowski, John Vernon & Joseph A. Dimasi, *Returns on Research and Development for 1990s New Drug Introductions*, 20 PHARMACOECONOMICS SUPP. III 11, 27 (Dec. 2002).

¹⁰ PHARMACEUTICAL INDUSTRY PROFILE, *supra* note 3, at 8–9 (citing J. A. DiMasi and C. Paquette, *The Economics of Follow-on Drug Research and Development: Trends in Entry Rates and the Timing of Development*, 22 PHARMACOECONOMICS, SUPP. II 1–14 (2004)).

¹¹ *Id.*

¹² *See, e.g., Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984) (“[U]nlicensed experiments conducted with a view to the adaption of the patented invention to the experimenter’s business is a violation of the rights of the patentee to exclude others from using his patented invention.”).

¹³ *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 195 (2005) (quoting 35 U.S.C. § 271(a)).

A patent thus confers the right¹⁴ to exclude others by providing a civil action against an alleged-infringer for making, using, or selling a patented invention without permission.¹⁵ That is in every industry but one—the pharmaceutical industry. In 1984, Congress signed into law the Hatch-Waxman Act.¹⁶ The Act provides a safe harbor from otherwise infringing activity to some types of pharmaceutical research.¹⁷

This portion of the Act was Congress' attempt to deal with back end distortions of the lifetime of pharmaceutical patents.¹⁸ The Act had two other significant provisions that are pertinent to this Comment; the Act provides for an accelerated approval process (Abbreviated New Drug Application) for generic manufacturers of pharmaceutical products,¹⁹ and it provides an incentive for generic manufacturers to challenge an innovator drug company's patent.²⁰ The latter provision will be discussed as it provides the backdrop for a discussion of the Supreme Court's 2007 decision in *KSR International Co. v. Teleflex Inc.*²¹ and how it may likely impact pharmaceutical patent life.

II. THE HISTORY OF FDA REGULATION OF DRUGS

The Hatch-Waxman Act is unique when placed in the category of legislative acts that increased the influence of the FDA. The Act undoubtedly expanded FDA influence as it has provisions that, among other things: allow for a safe harbor from patent infringement, it allows the FDA to use safety and efficacy data of pioneer drugs to expedite generic drug approval, it allows the FDA to grant a limited period of generic exclusivity for the first generic to challenge a pioneer's patent, and it provides for a patent term extension for pioneer firms whose FDA approval process takes longer than usual.²² All but the last of these have a

¹⁴ “This right commences on the date that the patent issues and ends twenty years from the date the application for the patent was filed in the United States” Anna McMinn, Comment, 16 ALB. L.J. SCI. & TECH. 195, 199–200 (2006).

¹⁵ 35 U.S.C. § 281 (2000).

¹⁶ Drug Price Competition and Patent Term Restoration Act of 1984, § 202, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355).

¹⁷ 35 U.S.C. § 271(e)(1) (2000).

¹⁸ See *infra* note 87 and accompanying text.

¹⁹ 21 U.S.C. § 355(j) (2000).

²⁰ Federal Food Drug and Cosmetics Act, § 505(j)(5)(B)(iv) (codified as amended at 21 U.S.C. § 505).

²¹ 127 S. Ct. 1727, 1735 (2007).

²² See 21 U.S.C. § 355(j).

negative impact on the value of pioneer patents. Yet these negative aspects do not make the Hatch-Waxman Act unique. Previous legislative expansions have also eroded pharmaceutical patents, if by nothing more than requiring additional information and testing results be submitted by the pioneer firms before approval. These additional showings obviously take valuable patent life from pioneer firms and increase the costs associated with research and development. Conversely, however, previous legislative amendments were prompted by a much different public policy.

A. Prior Expansions of FDA Influence Were Motivated by Public Health Crises

The modern FDA can trace its roots to the original Food and Drugs Act which was passed by Congress on June 30, 1906, and was subsequently signed into law by President Theodore Roosevelt.²³ The Act prohibited adulterated or misbranded foods, drinks, and drugs from being sold in interstate commerce.²⁴

Shortly after the enactment, the Supreme Court was faced with determining the regulatory scope of the Act.²⁵ Before it was a case where a manufacturer of elixirs was indicted under the Act for delivering into interstate commerce packages and bottles and drugs that were misbranded in violation of the Act.²⁶ While the Court made no mention of any harm to

²³ U.S. Food & Drug Admin., *Milestones in U.S. Food and Drug Law History*, (Aug. 2005), available at <http://www.fda.gov/opacom/backgrounders/miles.html> [hereinafter *Milestones*].

²⁴ *Id.*

²⁵ *Id.* (citing *United States v. Johnson*, 221 U.S. 488 (1911)).

²⁶ *Johnson*, 221 U.S. at 495. The product was titled “Dr. Johnson’s Mild Combination Treatment for Cancer” and the label purported that the products were “Guaranteed under the Pure Food and Drugs Act, June 30, 1906.” *Id.* at 499 (Hughes, J., dissenting). One of the elixirs stated:

Blood Purifier. This is an effective tonic and alternative. It enters the circulation at once, utterly destroying and removing impurities from the blood and entire system. Acts on the bowels, kidneys, and skin, eliminating poisons from the system, and when taken in connection with the Mild Combination Treatment, gives splendid results in the treatment of cancer and other malignant diseases. I always advise that the Blood Purifier be continued some little time after the cancer has been killed and removed and the sore healed.

Id.

consumers, it found that the product was wholly worthless as a therapy.²⁷ However, the Court held that the Act did not proscribe false claims about a product's efficacy, but rather only prohibited false or misleading statements about the ingredients or identity of a drug.²⁸ In response to this adverse ruling, Congress enacted the Sherley Amendment, which, for the first time, made it a crime to label medicines with false therapeutic claims.²⁹

In 1924, the Food and Drugs Act had its sphere of influence expanded again by the Supreme Court. The Court held that the Act "condemn[ed] every statement, design, and device which may mislead or deceive."³⁰ This holding allowed for prosecution of true statements under the Food and Drugs Act if they were potentially misleading.

In 1938, Congress decided to wade into the arena of regulating drug safety, with the enactment of the Federal Food Drug and Cosmetic Act of 1938 (FDCA).³¹ The legislation had been stalled for several years, that is, until a series of deaths related to the use of a poison as a solvent in the manufacturing of a drug product.³² The deaths highlighted the necessity for pre-market regulation of drug safety, and helped to force the legislation through.

When more than one hundred people died before the compound was pulled off the market, Congress did not content itself adopting an expanded definition of contamination; rather, the 1938 act vested the FDA with the broad power premarket review. Firms that wanted to market a new drug had to file an application that provided sufficient information about the compound in question and the uses for which it would be put for the FDA to determine whether the product should be licensed for sale.

²⁷ *Id.* at 495 (majority opinion).

²⁸ *Id.* at 497–98.

²⁹ See *Milestones*, *supra* note 23.

³⁰ *Id.* (citing *United States v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar*, 265 U.S. 438, 442–43 (1924)).

³¹ *Id.* (citing Federal Food Drug and Cosmetic Act, 75 Pub. L. No. 717, § 505(a), 52 Stat. 1040, 1052 (1938)).

³² Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POL'Y 295, 302 (1999) ("[1938] saw a major public health crisis in the distribution of elixir sulfanilamide, a solution which, notwithstanding its medicinal properties, also contained diethylene glycol, a poisonous solvent.").

The application was deemed approved unless the FDA, within 60 days after the application was filed, requested further information, at which point a final decision had to be made within 180 days of filing.³³

The Act had several new provisions, including: requiring that safe tolerances be set for unavoidable poisonous substances, authorizing standards of identity, quality, authorizing factory inspections, and adding the remedy of court injunctions to the previous penalties of seizures and prosecutions.³⁴

The Act was not significantly expanded again until 1962, after the Thalidomide disaster of the 1960s.³⁵ The drug, which was never marketed in the U.S., was prescribed to pregnant women as a sedative to alleviate morning sickness symptoms but caused birth defects in the developing fetuses that were exposed to the drug.³⁶ The fact that the drug was prevented from entering the U.S. market bolstered public support for increased pre-market regulation and prompted Congress to pass the Kefauver-Harris Drug Amendments to the FDCA and created what is essentially the modern FDA.³⁷ The new amendments required that pharmaceutical innovators prove the effectiveness of their product before they could obtain regulatory approval.³⁸

The logic behind the gradual enlargement of the FDA's regulatory scope is undeniable, but its effect on the market is an economic reality that the industry and the American consumer must come to grips with. It is rather obvious that consumers would be loathe to buy a pharmaceutical product that was entirely safe but also ineffective at treating its disease

³³ RICHARD A. EPSTEIN, *OVERDOSE: HOW GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION* 111 (2006). Federal Food Drug and Cosmetic Act, 75 Pub. L. No. 717, § 505(a), 52 Stat. 1040, 1052 (1938) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug."). Section (b) then requires the submission of, among other things, "(I) full reports of investigations which have been made to show whether or not such drug is safe for use." The reports are supplemented by information on the components, composition and methods of manufacturing the drug, along with samples of the drug and proposed labels. *See also id.* § 505(c).

³⁴ Federal Food Drug and Cosmetic Act, 75 Pub. L. No. 717, § 505(c).

³⁵ EPSTEIN, *supra* note 33, at 112.

³⁶ *See Milestones, supra* note 23 (citing Drug Amendments of 1962, Pub. L. No.87-781, § 102(a), 76 Stat. 780, 781).

³⁷ *Id.*

³⁸ *Id.*

state. Yet the opposite is also true; that consumers would be more than hesitant to purchase a product that was effective but may be very dangerous to their health.

It is clear that historically the influence of the FDA has been expanded to deal with public health risks.³⁹ That is what sets the Hatch-Waxman Act apart, for while it undoubtedly expands the powers granted to the FDA, and correspondingly erodes the value of pharmaceutical patents, it was prompted by mainly economic concerns.

III. CONGRESS ANTICIPATED THE EXEMPTION FROM INFRINGEMENT TO BE A NARROW ONE AND THE SUPREME COURT'S DECISION IN *MERCK* EXTENDED IT FAR BEYOND WHAT WAS INTENDED

A. *The Common Law Exemption from Infringement*

As stated above, it is generally an act of infringement to make, use, or sell a patented invention.⁴⁰ However, early on the common law recognized that some uses should fall outside of the scope of the infringement statute.⁴¹ Scholars trace the origin of the experimental use or research exemption to the case of *Whittemore v. Cutter*.⁴² The language from Judge Story which gave rise to the experimental use doctrine is:

that the making of a machine . . . with a design to use it for profit, was an infringement of the patent right, for which an action was given by the statute. This limitation of the making was certainly favorable to the defendant, and it was adopted by the court from the consideration, that it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.⁴³

And he followed up with a subsequent case decided the same year wherein he held that:

³⁹ *Id.*

⁴⁰ 35 U.S.C. § 271(a) (2000).

⁴¹ *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C. Mass. 1813).

⁴² *See, e.g.*, Phillip B.C. Jones, *Navigating the Hatch-Waxman Act's Safe Harbor*, 57 FOOD & DRUG L.J. 475, 475 (2002).

⁴³ *Id.* (quoting *Whittemore*, 29 F. Cas. at 1121).

[t]he making of a patented machine to be an offence . . . must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification. . . . In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.⁴⁴

In other words, Judge Story was saying that the alleged infringer must have some profit or business motive in mind to have truly infringed the patentee's rights. Contrast that with activity wherein the infringer is merely making the invention "for philosophical experiments or for the purpose of ascertaining the sufficiency of the machine"⁴⁵ Thus, experimental uses motivated by profit would fall outside of the doctrine.

*B. Roche Products, Inc. v. Bolar Pharmaceuticals Co.*⁴⁶ *An Argument for a Pharmaceutical Research Exemption*

Prior to the Hatch-Waxman amendments to the FDCA a would-be generic manufacturer who wanted to market an existing drug in the United States was required to perform all of the efficacy and safety testing that was required of the original manufacturer.⁴⁷ Moreover, the would-be manufacturer had to wait until the current patent expired to begin this testing or risk being liable for infringement.⁴⁸ In *Roche*, Bolar attempted to expand the common law experimental use exception in order to begin testing for FDA approval of a generic version of Roche's sleep-aid, Dalmane.⁴⁹ The district court was unwilling to fit Bolar's activities within the common law doctrine because its uses could "not be classified as merely for amusement or philosophical gratification."⁵⁰ However, it held that because Bolar's experimentation was "in line with the sort of commercial experiments without profit, manufacture, or sale during the patent term" the company would not be held liable for infringement.⁵¹ The

⁴⁴ *Id.* at 476 (quoting *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813)).

⁴⁵ *Whittemore*, 29 F. Cas. at 1121.

⁴⁶ *Roche Prods., Inc. v. Bolar Pharm. Co.*, 572 F. Supp. 255, 256 (E.D.N.Y. 1983), *rev'd*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

⁴⁷ See *infra* note 73 and accompanying text.

⁴⁸ *Roche*, 572 F. Supp. at 256.

⁴⁹ *Id.*

⁵⁰ *Id.* at 257.

⁵¹ *Id.* at 258.

court went on to say that “[t]o find infringing use there must be a benefit at the expense of the patent.”⁵² Therefore, the court held that because Bolar’s alleged infringing activities were *de minimis*, it would not grant an injunction.⁵³

Roche appealed and was successful yet again by convincing the Court of Appeals for the Federal Circuit that Bolar’s use was not the type intended by the common law experimental use exception.⁵⁴ More importantly, the Federal Circuit did not agree with the district court’s rationale regarding the policy behind awarding patent infringement damages—that “there must be a benefit at the expense of the patent”—and overturned that holding.⁵⁵ Bolar, after losing on the equity argument that worked so well in the district court and having conceded that their use did not fall within the “‘traditional limits’ of the experimental use exception,”⁵⁶ argued that “its tests [were] ‘true scientific inquiries’” to which a literal interpretation of the experimental use exception logically should extend⁵⁷ However, the court was unwilling to break from the traditional boundaries of the exception and held that Bolar’s proposed expansion of the exception was unjustified.⁵⁸

Specifically, the court distinguished Bolar’s activities from those that Bolar attempted to cite as precedent for expansion of the exception by noting that

Bolar’s intended “experimental” use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. . . . Bolar may intend to perform “experiments,” but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimenter’s business is a violation of the rights of the patentee to exclude others from using his patented invention. . . . We cannot construe the

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 862–64 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

⁵⁵ *Id.* at 864.

⁵⁶ “Bolar concedes, as it must, that its intended use of flurazepam hcl does not fall within the ‘traditional limits’ of the experimental use exception as established in these cases or those of other circuits. Its concession here is fatal.” *Id.* at 863.

⁵⁷ *Id.*

⁵⁸ *Id.*

experimental use rule so broadly as to allow a violation of the patent laws in the guise of “scientific inquiry,” when that inquiry has definite, cognizable, and not insubstantial commercial purposes.⁵⁹

When Bolar’s argument that there was judicial precedent for expansion of the doctrine failed, they fell back on the public policy argument—that public policy required the court to “create a new exception”⁶⁰ Then Bolar attempted to persuade the court to resolve a perceived conflict between the policies and purposes behind the Patent Act and Federal Food Drug and Cosmetic Act.⁶¹

The court, however, refused to “engage in legislative activity”⁶² and further stated that

[i]t is the role of Congress to maximize public welfare through legislation. Congress is well aware of the economic and societal problems which the parties debate here No matter how persuasive the policy arguments are for or against these proposed bills, this court is not the proper forum in which to debate them. Where Congress has the clear power to enact legislation, our role is only to interpret and apply that legislation.⁶³

In sum, the Federal Circuit defined the lines of the experimental use exception narrowly—keeping in line with the precedent that established the doctrine.⁶⁴ The court found that this type of use by generic manufacturers was indeed “experimental”⁶⁵ but not entitled to the exception because it was undertaken “solely for business reasons”⁶⁶ and directed at “adapt[ing] the patented invention to the experimenter’s business”⁶⁷ The court then clarified its formulation of the exception as not applying to uses unless they were motivated by “idle curiosity or for

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.* at 863–64.

⁶² *Id.* at 864.

⁶³ *Id.* at 865.

⁶⁴ *Id.* at 863.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

strictly philosophical inquiry.”⁶⁸ Furthermore, the court was not persuaded by Bolar’s argument that without the expansion of the exception; (1) there would be an unintended extension of pharmaceutical drug patents, and because of this unintended extension; (2) generic manufacturers would continue to accrue unnecessary costs when applying for FDA approval—costs which inevitably must be carried on to the consumer.⁶⁹ Rather than decide the issue, the court left this type of law-making to the legislature.⁷⁰

C. *The Hatch-Waxman Act’s Safe Harbor*

Shortly after the decision in *Roche*, Congress, at the behest of both the pioneer and generic drug manufacturers, did act.⁷¹ In fact, the purpose of the Drug Price Competition and Patent Term Restoration Act was, at least in part, to reverse the holding of the court in *Roche*,⁷² and to deal with the underlying problem that was at issue—the undue extension of marketing exclusivity for FDA approved medicines.⁷³

Prior to the Hatch-Waxman Act, a would-be drug manufacturer (pioneer or generic) was required to file safety and efficacy data with the FDA.⁷⁴ This process of gaining FDA approval had risen to about eight years by the time *Roche* was decided.⁷⁵ The back-end extension of the patent term that was at issue in *Roche* was due to the fact that the would-be generic manufacturers had to undertake the same safety and efficacy testing as pioneer companies, and could not begin the time-consuming testing cycle until the relevant patent expired or be found liable for infringement as Bolar Pharmaceuticals eventually was.⁷⁶

⁶⁸ *Id.*

⁶⁹ *Id.* at 863–65.

⁷⁰ *Id.* at 865.

⁷¹ *Roche* was decided on April 23, 1984. *Id.* at 858. The Drug Price Competition and Patent Term Restoration Act passed both the House and Senate in September of 1984. Pub. L. No. 98-417, 98 Stat. 1585.

⁷² 1984 U.S.C.C.A.N. 2647, 2711.

⁷³ “In *Eli Lilly and Co. v. Medtronic, Inc.* . . . the Supreme Court explained that the Hatch-Waxman Act was passed to respond to certain distortions of the . . . patent period.” *Teva Pharmaceuticals USA, Inc. v. Abbott Lab.*, 301 F. Supp. 2d 819, 826 (N.D. Ill. 2004) (citing *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 669–70 (1990)).

⁷⁴ 21 U.S.C. 355 (a)–(b) (2000).

⁷⁵ See *supra* note 7 and accompanying text.

⁷⁶ *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 864, 867 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

Because public policy demanded that consumers have access to low cost drugs, Congress came up with a solution.⁷⁷ It would deal with the generic filers problem on two fronts: (1) Congress allowed the generic filers to rely on the pioneer's accumulated safety and efficacy data through an Abbreviated New Drug Application,⁷⁸ and (2) Congress provided a safe harbor⁷⁹ for the experimentation that generics must perform so as to minimize the time between pioneer patent expiration and generic entry into the market.⁸⁰

1. The Congressional Record of the Hatch-Waxman Act Demonstrates an Intent to Fashion a Narrow Safe Harbor

The policy behind providing this safe harbor was the broad notion of providing lower cost pharmaceutical drugs to consumers.⁸¹ However, when read in concert with the other provisions of the Act, and the congressional record, it becomes clear that Congress had a rather narrow view of the safe harbor in mind. Congress wanted the safe harbor to apply to the situations exemplified in *Bolar*—that of a generic filer attempting to gain FDA approval as quickly as possible after the relevant patent expired.

a. The Congressional Record

The Hatch-Waxman Act, as a whole, did not come about from the decision in *Bolar*. In fact, several of the sections had been under congressional scrutiny for several years.⁸² The safe harbor, however, was prompted by the decision in *Bolar*.⁸³ In fact, section 271(e)(1) was introduced as having “the net effect of reversing the holding of the court in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*”⁸⁴

The relevant section of the Act states:

⁷⁷ 1984 U.S.C.A.N. 2647, 2647.

⁷⁸ See 21 U.S.C. § 355(j) (2000).

⁷⁹ See 35 U.S.C. § 271(e)(1) (2000) (“It shall not be an act of infringement to make, use, offer to sell or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information [to the FDA] . . .”).

⁸⁰ See *infra* note 86 and accompanying text.

⁸¹ See *infra* note 87 and accompanying text.

⁸² George Fox, Note, *Integra v. Merck: Limiting the Scope of the 271(e)(1) Exception to Patent Infringement*, 19 BERKELEY TECH. L.J. 193, 197 (2004).

⁸³ *Id.*

⁸⁴ *Id.* at 198 (quoting H.R. Rep. 98-857, pt. 2, at 27, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2711).

[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 (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug and Cosmetic Act of March 4, 1913) . . .) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs⁸⁵

The congressional record details exactly what is meant by that statement:

The purpose of sections § 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after the patent expires, is not a patent infringement In [*Roche v. Bolar*], the Court of Appeals for the Federal Circuit held that the experimental use of drug product prior to the expiration of a patent claiming that drug product constitutes patent infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires. It is the Committee's view that experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but prevention of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date.⁸⁶

The legislative history then spells out just what type of activity the safe harbor is intended to encompass:

[t]he only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. The patent holder retains the right to exclude others from the major commercial marketplace during the life of the patent. Thus, the nature of the interference with the rights

⁸⁵ 35 U.S.C. § 271(e)(1) (2000).

⁸⁶ Fox, *supra* note 82, at 197–98 (quoting H.R. Rep. 98-857, pt. 1, at 45–46, *reprinted in* 1984 U.S.C.C.A.N. at 2678–79).

of the patent holder is not substantial [T]he Committee . . . reasoned that section 202 of the bill was essential to implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent.⁸⁷

Beyond these statements, there were additional efforts to made to limit the scope of the safe harbor even further. One representative even went so far as to say that the safe harbor “constituted an unconstitutional taking of property without just compensation,”⁸⁸ and “argued that patent holders should not have to give up certain property rights during the life of their patents.”⁸⁹ However these arguments were rejected because they would have partially frustrated the purpose of providing generic substitutes as quickly as possible.⁹⁰

From all of this it is indisputable that Congress’ intention was to create a very narrow exception aimed at enabling generic manufacturers to obtain FDA approval as quickly as possible.

2. *Judicial Interpretation of § 271(e)(1): Merck KGaA v. Integra Lifesciences I, Ltd.*⁹¹

In the twenty-four years since the signing of the Hatch-Waxman Act; the courts have had many opportunities to interpret that scope of the safe harbor. Some opinions have kept the scope in line with the obvious congressional intent,⁹² but recently the Supreme Court decided *Merck* and expanded the scope of activities covered by section 271(e)(1) considerably beyond what Congress intended.

a. *Facts of the Dispute*

Integra Lifesciences I, Ltd. and the Burnham Institute, were the owners of five patents related to the tripeptide sequence known as the “RGD peptide,” a sequence known to promote cell adhesion to substrates both *in*

⁸⁷ *Id.* at 198–99 (quoting H.R. Rep. 98-857, pt. 2, at 8, *reprinted* in 1984 U.S.C.C.A.N. at 2692–93).

⁸⁸ McMinn, *supra* note 14, at 206–07.

⁸⁹ *Id.*

⁹⁰ H.R. Rep. 98-857, pt. 2, at 8, *reprinted* in 1984 U.S.C.C.A.N. at 2692–93.

⁹¹ 545 U.S. 193 (2005).

⁹² *See, e.g.,* Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 673–74, 679 (1990) (expanding the safe harbor to include medical devices, which are subject to FDA approval).

vitro and *in vivo*.⁹³ The cell adhesion achieved with the RGD peptide was due to its interaction with certain receptors on cell surface proteins called integrins.⁹⁴ Dr. David Cheresh, a scientist at Scripps, discovered that inhibiting these very receptors would reduce angiogenesis, the process of producing new blood vessels.⁹⁵ Inhibiting angiogenesis was thought to be a promising way to treat a wide array of diseases.⁹⁶

Recognizing the potential for a therapy based on Dr. Cheresh's discovery, Merck hired Dr. Cheresh and Scripps in the hopes that they would identify drug candidates for inhibition of angiogenesis.⁹⁷ Subsequently, Dr. Cheresh identified a cyclic peptide identified as EMD 66203 that displayed the desired inhibition of the receptor.⁹⁸ "Merck then entered into an agreement with Scripps to fund the 'necessary experiments to satisfy the biological bases and regulatory (FDA) requirements for the implementation of clinical trials' with EMD 66203 or a derivative thereof."⁹⁹

The research that followed at Scripps identified several promising candidates, and these candidates were examined under a battery of experiments.¹⁰⁰ The experiments included assessing the specificity, efficacy, toxicity, histopathology among others aimed at ascertaining the "mechanism by which these drug candidates work, and to determine which candidates were effective and safe enough to warrant testing in humans."¹⁰¹ In other words, Scripps and Merck were examining these candidates with an eye on marketing a new pharmaceutical drug based on the RGD peptide.

When Integra learned of the plans of Merck and Scripps, it believed that the research involved infringed its patents.¹⁰² Integra offered Merck licenses to the patents above, but after lengthy negotiations no agreement

⁹³ *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 862 (Fed. Cir. 2003). The patents involved in the dispute were U.S. Patent Nos. 4,789,734; 4,879,237; 4,792,525; 4,988,621; and 5,695,997. *Id.* "RGD" refers to a three amino acid peptide having the sequence arginine, glycine, aspartic acid.

⁹⁴ *Id.*

⁹⁵ *Id.* at 863.

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

could be reached.¹⁰³ Subsequently, Integra filed suit against Merck, Scripps and Dr. Cheresch for infringement of the RGD patents.¹⁰⁴ Integra sought only a declaratory judgment against Scripps and Dr. Cheresch; these were dismissed on motion.¹⁰⁵ However, Integra sought damages for Merck's alleged infringing activities.¹⁰⁶ Merck responded by alleging that the patents were invalid, or in the alternative that the relevant research fell under the safe harbor.¹⁰⁷

At trial, the jury returned a verdict for Integra on the infringement of four of the five patents at issue, and found that the activity did not fit within the exemption of section 271(e)(1).¹⁰⁸ Correspondingly, the jury awarded a royalty of \$15,000,000 to Integra for the infringement.¹⁰⁹

b. The Court of Appeals

Merck appealed all three portions of the district court's holding.¹¹⁰ A divided panel of the Federal Circuit remanded the case to the district court for additional findings regarding the royalty award, but affirmed the district court's construction of the claims at issue, and its determination that Merck's activity did not fall within the safe harbor.¹¹¹

When analyzing the scope of the safe harbor the Federal Circuit first looked at the legislative history to identify the objective of the Act.¹¹² The court noted that the activity intended to be covered by the safe harbor should be merely "a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute[.]" and that the interference with the patent holder's right to exclude should not be "substantial, but de minimus [sic]."¹¹³

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*; see also 35 U.S.C. § 271(e)(1).

¹⁰⁸ *Integra*, 331 F.3d at 863.

¹⁰⁹ *Id.* at 862.

¹¹⁰ *Id.* at 864.

¹¹¹ *Id.* at 872. On remand the district court reduced the damages award to \$6.375 million. *Integra Lifesciences I, Ltd. v. Merck KgaA*, No. CV-96-CV-1307-B(AJB), 2004. WL 2284001, at *1 (S.D. Cal. Sept. 7, 2004).

¹¹² *Integra*, 331 F.3d at 865.

¹¹³ *Id.* (citing H.R. Rep. 98-857, pt. 1, at 8, reprinted in 1984 U.S.C.C.A.N. 2647, 2692).

The court noted that while it had in the past had opportunities to examine the intended scope of section 271(e)(1), it had yet to consider whether the safe harbor should cover experiments that did not “supply information for submission to the [FDA]” but rather were further “down the chain of experimentation” and “instead identified the best drug candidate to subject to future clinical testing”¹¹⁴ The court then examined the plain language of the statute focusing on the phrase “solely for purposes reasonably related to the development and submission of information” to the FDA.¹¹⁵

The appeals court noted that the phrase contained two distinct elements, a “reasonable relationship test” and a limitation on the test—the word “solely.”¹¹⁶ As the Federal Circuit saw it, in order to qualify for the exemption the experimentation must “reasonably relate to the development and submission of information for FDA’s . . . approval process.”¹¹⁷ And, that whatever testing was covered should further the Act’s objective of “facilitate[ing] the immediate entry of safe, effective generic drugs into the marketplace upon expiration of a pioneer drug patent.”¹¹⁸ The court determined that Congress, simply by using the phrase “reasonably related,” could not have intended for the safe harbor to cover “all stages of the development of new drugs merely because those new products will also need FDA approval.”¹¹⁹ The holding, in effect, drew a line between testing, on the one hand, FDA approved, patented products, and, on the other, conducting research that “may rationally form only a predicate for future FDA clinical tests.”¹²⁰

In dissent, Judge Newman argued for overturning the district court’s holding of infringement on two fronts.¹²¹ First, she argued that the Scripps/Merck activities fell under the common law research exemption.¹²² Second, she stated that whatever aspects of the alleged infringing activity did not fall under the common law rule would naturally be covered by section 271(e)(1).¹²³

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 866.

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 866–67.

¹¹⁹ *Id.* at 867.

¹²⁰ *Id.*

¹²¹ *Id.* at 874–78 (Newman, J., dissenting).

¹²² *Id.* at 876.

¹²³ *Id.* at 877.

c. The Supreme Court

The Supreme Court granted certiorari to review the Federal Circuit's construction of section 271(e)(1).¹²⁴ The result was a unanimous decision¹²⁵ overruling the circuit court and holding that the safe harbor "extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA."¹²⁶ The Court noted that "[t]here is simply no room in the statute for excluding certain information from the exemption" based solely on the phase of research for which it is conducted.¹²⁷

The Court agreed with the Federal Circuit's holding that the safe harbor would not include all experimental activity that at some point *may* lead to a submission to the FDA.¹²⁸ The Court went on to state that section 271(e)(1) would *not* apply to "[b]asic scientific research . . . performed without the intent to develop a . . . drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce"¹²⁹

The Court noted that the Federal Circuit's construction would effectively "limit assurance of exemption to the activities necessary to seek approval of a generic drug"¹³⁰ The Supreme Court was not willing to make the exemption so narrow, emphasizing that Congress intended not only to provide an exemption for generic filers, but also to provide a safe harbor for alleged infringers for "*all* uses of patented compounds reasonably related" to the process of obtaining FDA approval.¹³¹

The Court clarified its view of the proper scope of section 271(e)(1) by stating that the safe harbor did not exclude "(1) experimentation on drugs 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."¹³² In addition, the Court defined the "reasonable relation" test, stating that "where a drugmaker has a reasonable basis for believing that a compound may work, through a particular biological process, to produce a

¹²⁴ Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 202 (2005).

¹²⁵ *Id.* at 194.

¹²⁶ *Id.* at 202.

¹²⁷ *Id.*

¹²⁸ *Id.* at 205.

¹²⁹ *Id.* at 205–06.

¹³⁰ *Id.* at 206.

¹³¹ *Id.* (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 674 (1990)).

¹³² *Id.*

particular physiological effect, and uses the compound in research that, if successful would be appropriate to include in a submission to the FDA” then that use is covered by section 271(e)(1).¹³³

D. Analysis

The Supreme Court took a very different route in examining the issue than did the Court of Appeals. The Court made no mention of the *Bolar* case or its obvious influence on the legislation. *Bolar* is mentioned by name several times in the legislative history, and is in the congressional statement of the purpose of the safe harbor.¹³⁴ However, the Court held that all uses of patented compounds, as long as they are reasonably related to the submission of data to the FDA, should be covered. This is a long way from the holding in *Bolar*, the underpinning of Congress’ action, and as such could not be farther from what Congress initially intended.

1. The Supreme Court Expanded the Scope Beyond What Congress Intended

Both the Supreme Court and the Federal Circuit failed to adequately explore the differences between the *Bolar* case, the foundation for the safe harbor, and the case at bar. The Federal Circuit made several references to the *Bolar* case in its opinion, and reached a decision that was in line with the intent of Congress.¹³⁵ However, the Court of Appeals failed to adequately distinguish the glaring difference between the activities of *Bolar* and *Merck*, namely that *Bolar* was engaged in research to gain FDA approval of a *generic* formulation of an *existing product*,¹³⁶ and *Merck* was attempting to develop a *new product*.¹³⁷ Now, however, this discussion is moot as the Supreme Court’s holding reshapes the safe harbor and treats both generic and pioneer firms identically.¹³⁸

As noted, Congress intended for the scope of the safe harbor to be narrow.¹³⁹ Emphasizing that the effect on the patent holder’s right to exclude should *not be substantial*, but *de minimis*.¹⁴⁰ However, the Supreme Court’s holding expands the scope nearly as far as the statutory

¹³³ *Id.* at 207.

¹³⁴ See *supra* notes 82–86 and accompanying text.

¹³⁵ See *supra* notes 83–86 and accompanying text.

¹³⁶ See *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 860 (Fed. Cir. 1984).

¹³⁷ See *Merck*, 545 U.S. at 195–99.

¹³⁸ See *supra* note 133 and accompanying text.

¹³⁹ See *supra* note 87 and accompanying text.

¹⁴⁰ See *supra* note 87 and accompanying text.

language can be stretched. With the new formulation of the “reasonable relationship” test, the Court is essentially including any activities that pharmaceutical firms might wish to perform and only excluding those activities which are too far removed from commercialization to be considered relevant to an FDA approval process.¹⁴¹ Nearly all research conducted by pharmaceutical firms is performed with the goal of an FDA submission down the line—it is the nature of their business, and, as such it is difficult to imagine a scenario that would not fit within the Supreme Court’s new formulation of section 271(e)(1).

In addition, the Supreme Court essentially wrote the word “solely” out of section 271(e)(1). In the latter half of the opinion by Justice Scalia, the Court used the term “reasonable” more than a dozen times and the term “solely” only once. The Supreme Court through its holding, in essence, rewrote the statute and eroded pharmaceutical patent protection.

2. *The Supreme Court’s Holding Was in Line with the Principle of the Act*

The principle that motivated Congress to begin formulating the Hatch-Waxman Act was to lower health care costs by providing low cost drugs to the American consumer.¹⁴² The focus of the Act and the safe harbor in particular, however, was on speeding up the approval process, and lowering approval costs for generic filers.¹⁴³ The Supreme Court’s expansion of the safe harbor runs counter to the intent of Congress, but is in line with the goal that Congress began with.

While the Hatch-Waxman Act was initially designed to increase competition in the marketplace through expediting generic entry into the market,¹⁴⁴ the Supreme Court’s expansive reading will further the underlying policy in an unforeseen way, namely by increasing competition between pioneer firms. It is counterintuitive that any company might support a decision that would weaken its patent protection. However, while the pioneer firms give up some of their rights to exclude, they gain the right to use their competitor’s products, and this is a trade-off that most of the large firms welcome for the potential value derived.¹⁴⁵

¹⁴¹ See *supra* note 133 and accompanying text.

¹⁴² See *supra* note 86 and accompanying text.

¹⁴³ See *supra* note 86 and accompanying text.

¹⁴⁴ See *supra* note 86 and accompanying text.

¹⁴⁵ Stanton J. Lovenworth & Melissa P. Cohen, *The Research Tool Conundrum: ‘Merck’ Decision leaves Open Questions on Boundaries of Safe Harbor*, N.Y.L.J., Oct. 17, 2005, at 4, col. 1.

By allowing pioneer firms the leeway to conduct experiments utilizing their competitors patented compounds, it will speed up the process of discovering new therapies.¹⁴⁶ Pharmaceutical firms will be able to study many important aspects of marketed products.¹⁴⁷ This will allow for a better understanding of the underlying disease states and how more effective therapies may be designed. This, in turn, will speed up the development of new and improved therapies. Also this expansion of the safe harbor will increase competition in the pioneer market by allowing competitors to develop follow-on therapies with different safety or efficacy profiles. This will have the effect of decreasing the time that pioneer firms can enjoy a monopoly.

While there are positives to this formulation of section 271(e)(1), it is important to note that the expansion is clearly beyond what Congress intended to exempt from infringement. If Congress intended for the exemption to be more broad, it was certainly within its powers to amend section 271(e)(1). However, in the twenty-two years between its enactment and the holding in *Merck*, Congress did not expand the scope of the safe harbor. Perhaps this is because there was no need, or perhaps because the large pharmaceutical firms support this broad exemption, there is no resistance to the expansion.

However, it is of paramount importance to note that this is a large erosion of the patent holder's right to exclude. Because this is essentially a taking of property rights, it is solely within the realm of Congress to authorize. While Congress intended to exempt only would-be generic manufacturer's activities, after the holding in *Merck*, a patentee is prevented from suing for virtually all pharmaceutical research that its competitors wish to use its products for.¹⁴⁸ The right to exclude in the pharmaceutical industry has become, essentially, only the right to prevent a competitor from selling a patent holder's product—a serious reduction of the right to exclude.

¹⁴⁶ Ian Jaquette, Note, *Merck KGaA v. Integra Lifesciences I, Ltd: Implications of the Supreme Court's Decision for the People Who Matter Most . . . The Consumer*, 33 AM. J.L. & MED. 97, 111–12 (2007).

¹⁴⁷ *Id.* at 112.

¹⁴⁸ See *supra* note 131 and accompanying text.

IV. THE LAW OF OBVIOUSNESS:
KSR INTERNATIONAL CO. V. TELEFLEX, INC.

The requirement that an invention be non-obvious is codified in title 35, section 103 of the United States Code,¹⁴⁹ and is generally the most demanding requirement that an applicant must meet,¹⁵⁰ earning it the nickname of the “ultimate condition of patentability.”¹⁵¹ The concept of non-obviousness has also been one which has been difficult to conceptualize and apply judicially.

In *Graham v. John Deere Co. of Kansas City*,¹⁵² the Supreme Court set out a framework for applying the statutory language of section 103,¹⁵³ language itself based on the logic of the earlier decision in *Hotchkiss v. Greenwood*¹⁵⁴ and its progeny.

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.¹⁵⁵

Thus, if during an initial examination or an infringement suit, it is determined that, after completing the factual inquiries above, the claims are obvious, they are deemed invalid under section 103.

Besides being a high bar to cross initially during examination, obviousness is also important in patent litigation. It is often raised as a

¹⁴⁹ The relevant statutory inquiry states: “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.” 35 U.S.C. § 103(a) (2000).

¹⁵⁰ Lee Petherbridge & R. Polk Wagner, *The Federal Circuit and Patentability: An Empirical Assessment of the Law of Obviousness*, 85 TEX. L. REV. 2051, 2059 (2007).

¹⁵¹ *Id.* (citing NONOBVIOUSNESS: THE ULTIMATE CONDITION OF PATENTABILITY (John F. Witherspoon ed., 1980)).

¹⁵² 383 U.S. 1 (1966).

¹⁵³ *Id.* at 15–17.

¹⁵⁴ 11 How. 248, 13 L. Ed. 683 (1851).

¹⁵⁵ *Graham*, 383 U.S. at 17–18.

defense to a claim of infringement—that the patent claim is invalid as obvious “at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains”¹⁵⁶—as was the case in the Supreme Court’s 2007 foray into patent law.¹⁵⁷

A. *Background of the Dispute*

Teleflex acquired the rights to a patent for a particular brake-pedal design.¹⁵⁸ Subsequently, KSR designed a brake-pedal, and was manufacturing the pedal for General Motors.¹⁵⁹ Teleflex inspected the design and believed that the KSR pedal incorporated the components of Teleflex’s patent and that KSR was thus infringing the patent.¹⁶⁰ The companies could not come to an accord on a “royalty arrangement,”¹⁶¹ and because KSR intended to continue manufacturing the pedals, Teleflex brought suit for patent infringement in the United States District Court for the Eastern District of Michigan.¹⁶²

B. *The Lower Court Rulings*

At trial KSR answered Teleflex’s allegation of patent infringement on the grounds that the patent was invalid for obviousness, and moved for summary judgment pursuant to the invalidity of the underlying patent.¹⁶³ After applying the *Graham* factual inquiries,¹⁶⁴ the district court granted summary judgment to KSR and ruled the patent invalid.¹⁶⁵ On appeal, the Federal Circuit vacated the decision of the District Court and remanded the case for further inquiry into the determination of obviousness.¹⁶⁶

¹⁵⁶ 35 U.S.C. § 103(a) (2000); *see, e.g.*, *Teleflex, Inc. v. KSR Int’l Co.*, 298 F. Supp. 2d 581, 585 (E.D. Mich. 2003) (summarizing KSR’s claim that the “patent is invalid because it would have been obvious to someone with ordinary skill in the art of designing pedal systems to combine an adjustable pedal system with an electronic pedal position sensor to work with electronically controlled engines increasingly being used in motor vehicles”).

¹⁵⁷ *See KSR Int’l Co. v. Teleflex, Co.*, 127 S. Ct. 1727 (2007).

¹⁵⁸ *See id.* at 1737.

¹⁵⁹ *Teleflex*, 298 F. Supp. 2d at 584.

¹⁶⁰ *Id.* at 585.

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *Id.*; *see also supra* note 156 and accompanying text.

¹⁶⁴ *Teleflex*, 298 F. Supp. 2d at 587–96.

¹⁶⁵ *Id.* at 596.

¹⁶⁶ *Teleflex, Inc. v. KSR Int’l Co.*, 119 Fed. App’x 282, 290 (Fed. Cir. 2005).

The Federal Circuit's rationale for remand was that the district court had misapplied the "teaching, suggestion, or motivation" (TSM)¹⁶⁷ standard for obviousness.¹⁶⁸ It held that a more "rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references"¹⁶⁹ was necessary. More specifically, the Court of Appeals wanted "finding[s] as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of [the] invention to make the combination in the manner claimed."¹⁷⁰ The court noted prior case law in order to emphasize that particular findings must be made to demonstrate the reasons that a skilled artisan would have combined the prior art references "*in the manner claimed*" by the inventor.¹⁷¹ The Federal Circuit held that by not making specific factual findings, demonstrating a teaching suggestion, or motivation to combine the prior art teachings in the manner claimed by the invention, it was inappropriate to find, as a matter of law, that the claimed invention was obvious to a skilled artisan.¹⁷²

C. *The Supreme Court*

The Supreme Court granted certiorari to resolve the issue of how the lower courts should address the issue of obviousness, in particular the application of the TSM test.¹⁷³ The Court rejected the "rigid approach"¹⁷⁴ of the Federal Circuit and unanimously overruled the lower court.¹⁷⁵

The Court began its analysis of the issue with a history of the Supreme Court decisions that "set forth an expansive and flexible approach" to the problem of obviousness.¹⁷⁶ While noting that *Graham* recognized the need for "uniformity and definiteness" in the patent law, the Court also stated

¹⁶⁷ *KSR Int'l Co. v. Teleflex Co.*, 127 S. Ct. 1727, 1734 (2007) (The Supreme Court explained that "under [the TSM test] a patent claim is only proved obvious if 'some motivation or suggestion to combine the prior art teachings' can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art." (internal citations omitted)). See also *infra* notes 191 & 192 and accompanying text.

¹⁶⁸ *Teleflex*, 119 Fed. App'x at 290.

¹⁶⁹ *Id.* at 285 (citing *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999)).

¹⁷⁰ *Id.* at 288 (quoting *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000)).

¹⁷¹ *Id.* at 286 (quoting *Kotzab*, 217 F.3d at 1371).

¹⁷² *Id.*

¹⁷³ *KSR Int'l Co. v. Teleflex Co.*, 127 S. Ct. 1727, 1735 (2007).

¹⁷⁴ *Id.* at 1739.

¹⁷⁵ *Id.* at 1733, 1746.

¹⁷⁶ *Id.* at 1739.

that the holding in *Graham* reaffirmed the “functional approach” first laid down in *Hotchkiss*.¹⁷⁷

The Court then went on to state that caution should be employed when “granting a patent based on the combination of elements found in the prior art.”¹⁷⁸ To emphasize the particular point of law that the Court illuminated, the opinion next discussed three past cases—*United States v. Adams*,¹⁷⁹ *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*,¹⁸⁰ and *Sakraida v. Ag Pro Inc.*¹⁸¹—that all dealt with the appropriate circumstances in which to grant patents for the combination of elements that were previously disclosed.¹⁸²

The Court used *United States v. Adams*, a case that was decided the same year as *Graham*, to demonstrate that it is more likely that an invention which combines elements known in the prior art is non-obvious if the prior art teaches away from combining the elements.¹⁸³ At the time that Adams designed his invention, the relevant prior art warned risks were inherent in his intended design.¹⁸⁴ However, the fact that his elements worked together to produce unexpected and fruitful results rendered the combination non-obvious.¹⁸⁵

Conversely, the Court used *Anderson’s* to demonstrate a negative element of the obviousness doctrine.¹⁸⁶ Namely, that while a combination of known elements may produce something useful, if it “add[s] nothing to the nature and quality of the [invention] already patented”—it is not due a patent.¹⁸⁷

Finally, the Court discussed *Sakraida*, another combination-case, noting that past Courts synthesized the doctrine that when an invention “simply arranges old elements with each performing the same function it

¹⁷⁷ *Id.* (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 18 (1966), and *Hotchkiss v. Greenwood*, 11 How. 248, 13 L. Ed. 683 (1851)).

¹⁷⁸ *Id.*

¹⁷⁹ 383 U.S. 39 (1966).

¹⁸⁰ 396 U.S. 57 (1969).

¹⁸¹ 425 U.S. 273 (1976).

¹⁸² *KSR*, 127 S. Ct. 1739–41 (citing *Adams*, 383 U.S. at 40; *Anderson’s-Black Rock, Inc.*, 396 U.S. at 90; and *Sakraida*, 425 U.S. at 282).

¹⁸³ *Id.* at 1739–40.

¹⁸⁴ *Id.* at 1740.

¹⁸⁵ *Id.* (citing *Adams*, 383 U.S. at 51–52).

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* (quoting *Anderson’s-Black Rock*, 396 U.S. at 62).

had been known to perform” and yields no more than one would expect such an arrangement, the combination is obvious.¹⁸⁸

In summing up the teachings of these cases, the Court stated that it is a reviewing court’s duty to ask if the “improvement is more than the predictable use of prior art elements according to their established functions.”¹⁸⁹ In other words, with reference to the *Graham* inquiries, would a person of ordinary skill in the art recognize that a technique used to improve one device might also improve other devices? If so, then the innovation, while it may be useful, it is not worthy of a patent. Finally, the Court noted that, although the inquiry may be difficult in some situations, it is *not* necessary to find teachings directed at the specific subject matter of the challenged claim, in order to hold a claim obvious over the prior art.¹⁹⁰

The opinion then moved to a discussion of the teaching, suggestion, or motivation test. The Court began by noting that when the Court of Customs and Patent Appeals first formulated the test, “it captured a helpful insight.”¹⁹¹ The helpful insight is that most inventions rely upon long since uncovered building blocks, and in order to avoid a hindsight analysis of the innovation, “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.”¹⁹²

The Court then stated that a rigid and mandatory application of the TSM test was incompatible with the precedents that laid the foundation for the obviousness inquiry.¹⁹³ Then the Court emphasized that the analysis should not be confined by the “words teaching, suggestion, and motivation, or by overemphasis on published articles”¹⁹⁴ Because in many fields, there may be little if any published material on obvious techniques, moreover, in some fields market demand will drive the direction of research and it is unlikely to find express teachings in these situations.¹⁹⁵

The opinion next discussed the specific flaws in the Federal Circuit’s analysis of the case at bar.¹⁹⁶ The Court mentioned that most of the errors

¹⁸⁸ *Id.* (quoting *Sakraida*, 425 U.S. at 282).

¹⁸⁹ *Id.*

¹⁹⁰ *Id.* at 1740–41.

¹⁹¹ *Id.* at 1741.

¹⁹² *Id.*

¹⁹³ *Id.*

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

¹⁹⁶ *Id.* at 1741–43.

arose from the Court of Appeal's narrow conception of the *Graham* inquiry as indicated by its application of the TSM test.¹⁹⁷ Specifically, the Court noted that "neither the particular motivation nor the avowed purpose of the patentee controls[]" the inquiry. Courts should not look only to the problem the patentee was attempting to resolve, but rather to any need or problem in the field of endeavor—which the Court of Appeals failed to do.¹⁹⁸

The second error that the Court highlighted, was the Federal Circuit's assumption that a person of ordinary skill would look only to the elements of the prior art directed to solving the same problem.¹⁹⁹ The Court implied that the Federal Circuit's rigid approach in this regard eliminated the use of common sense in this analysis and reduced the person having ordinary skill in the art to "an automaton."²⁰⁰ Specifically, the Court noted that the Federal Circuit, in this case, ignored the fact that a claim may be deemed obvious merely by showing that the combination of elements was obvious to try.²⁰¹

Lastly, the Court pointed out that the Federal Circuit's use of the TSM test placed too much emphasis on the risk of "hindsight bias."²⁰² Stating that while factfinders should be aware of the risk of falling prey to using hindsight analysis, "[r]igid preventative rules that deny . . . recourse to common sense . . . are neither necessary under our case law nor consistent with it."²⁰³

The Court wrapped up the opinion by applying a more flexible standard—one in line with Supreme Court precedent. It, therefore, held that the claim regarding the patent in dispute was obvious, and, as such was invalid.²⁰⁴

D. Analysis

The dispute between the Supreme Court and the Federal Circuit revolved around how broadly the TSM test should apply. Originally, the

¹⁹⁷ *Id.* at 1741.

¹⁹⁸ *Id.* at 1741–42.

¹⁹⁹ *Id.* at 1742 ("The first error of the Court of Appeals in this case was to foreclose this reasoning by holding that courts and patent examiners should look only to the problem the patentee was trying to solve.").

²⁰⁰ *Id.*

²⁰¹ *Id.*

²⁰² *Id.*

²⁰³ *Id.* at 1742–43.

²⁰⁴ *Id.* at 1743–45.

district court proposed a less rigid application wherein a claim could be found obvious without an express teaching, suggestion, or motivation.²⁰⁵ On the other hand, the Federal Circuit's decision indicated a stringent application of the TSM.²⁰⁶

To express it another way, the TSM standard can be seen to compose both a positive and a negative analysis. The positive; if an express teaching, suggestion, or motivation can be found to combine prior art references, then a claim is obvious and unpatentable. This characterization has never truly been in dispute and was upheld by the Supreme Court.²⁰⁷ The negative expression then would be that if no teaching, suggestion, or motivation can be found then the claim is not an obvious extension of the prior art and thus should be allowed. It is this interpretation that prompted the Supreme Court to hear this case.²⁰⁸

1. The Supreme Court's Rejection of the TSM Test

Overall, the Supreme Court was not pleased with the Court of Appeals description of what the TSM test captured. At oral argument several of the Justices expressed serious doubts about the test and its place in obviousness jurisprudence.

Justice Breyer stated that he understood what is meant by teaching and suggestion, but after many attempts could not ascertain what the test meant by the term motivation.²⁰⁹ Justice Alito questioned what exactly it is that the test adds to the traditional obviousness inquiry laid down in *Graham*.²¹⁰ The Chief Justice then followed up this query by adding that the test merely "add[ed] a layer of . . . jargon" to the inquiry, and rendered the test "worse than meaningless because it complicates the inquiry rather than focusing on the statute."²¹¹

Likewise, Justice Scalia stated that he did not understand what constituted the motivation element.²¹² When told that the TSM test was an inclusive test, Justice Scalia responded that the test "is meaningless," and

²⁰⁵ See *supra* note 169 and accompanying text.

²⁰⁶ See *supra* notes 166–70 and accompanying text.

²⁰⁷ See *supra* notes 193–95 and accompanying text.

²⁰⁸ *KSR*, 127 S. Ct. at 1735.

²⁰⁹ Transcript of Oral Argument at 9–10, *KSR*, 127 S. Ct. 1727 (No. 04-1350), http://www.supremecourtus.gov/oral_arguments/argument_transcripts/04-1350.pdf.

²¹⁰ *Id.* at 39–40.

²¹¹ *Id.* at 40.

²¹² *Id.* at 14.

added nothing to the relevant inquiry.²¹³ In case that he was not getting his point across, Justice Scalia later referred to the TSM test as both “gobbledygook” and “irrational.”²¹⁴

Justice Kennedy, on the other hand, was more diplomatic in his evaluation of the test. He stated that the test did have an important place—it demonstrated at least one way in which a claim can be proved obvious.²¹⁵ This is the positive implication of the test described above.²¹⁶ Justice Kennedy did, however, point out that it should not be the exclusive test for obviousness.²¹⁷ He added that perhaps the motivation test could be salvaged and supplemented with other means for demonstrating obviousness.²¹⁸

2. *Where Does the Supreme Court’s Holding Direct the Courts?*

One distinctly positive attribute that the Court of Appeals’ TSM test included was clarity. Previously, for the United States Patent and Trademark Office (USPTO) or a reviewing court to find a claim invalid as obvious, an express showing of the teaching, suggestion or motivation was required.²¹⁹ Now, however, it is not clear what standard the Supreme Court wants to employ for obviousness in the future. The Court stresses that common sense and flexibility should be employed, but provides only minimal guidance for how to exercise the common sense that one having ordinary skill in the art would have.²²⁰ In the end it will be up to the lower courts and, more specifically, the Federal Circuit to determine what standard will be used going forward.

The Supreme Court rejected the Federal Circuit’s application of the TSM test, but not the entire test. Although Justice Scalia called the test “gobbledygook,” and “irrational,”²²¹ the opinion fell short of totally annihilating the test. The Court held that the test “captured a helpful insight.”²²² In the end, however, the negative implication of the test is obviously not in line with the Supreme Court’s mandate. It is unclear,

²¹³ *Id.* at 36–37.

²¹⁴ *Id.* at 41.

²¹⁵ *Id.* at 11–12.

²¹⁶ *See supra* Section III.D.

²¹⁷ Transcript of Oral Argument, *supra* note 209, at 11–12.

²¹⁸ *Id.* at 19.

²¹⁹ *See supra* note 172 and accompanying text.

²²⁰ *See supra* note 178 and accompanying text.

²²¹ *See supra* note 214 and accompanying text.

²²² *KSR Int’l Co. v. Teleflex Co.*, 127 S. Ct. 1727, 1741 (2007).

however, what test will fill the void. All that is clear is that the Supreme Court wants the lower courts and the USPTO to exercise more common sense in obviousness inquiries.²²³

3. *A Move to Strengthen the U.S. Patent System*

The Court clearly felt that the Federal Circuit had sacrificed common sense for clarity in an effort to reduce hindsight bias.²²⁴ The TSM test was not just a test for the courts, however, it was also employed by the USPTO in examining patent applications. Indeed, one commentator has opined that the holding in *KSR* will have little effect on the jurisprudence of the Federal Circuit.²²⁵ Rather that the true effect will be felt at the USPTO.²²⁶ With the *KSR* holding, the USPTO will have more flexibility in rejecting applicants. The hope then is that by raising the standard for patentability, the U.S. patent system will be bolstered as a whole.²²⁷

4. *Implication of the KSR Decision on the Pharmaceutical Industry*

While the law of obviousness applies to all patent holders and applicants alike, the *KSR* decision will be felt quickly and in unique ways by the pharmaceutical industry. Patents are particularly important to the pharmaceutical industry, and, as such any uncertainty in the requirements for achieving a patent have specific implications for the drug industry. Along with providing a swifter route for obtaining FDA approval for generic filers, the Hatch-Waxman Act provides incentives to challenge pioneer firms patents in court.

With the holding in *KSR*, the standard for obtaining or defending a patent is not as clear as it once was. The Court stressed that the lower courts (and correspondingly the USPTO) should be free to use common sense in rejecting claims.²²⁸ This raises the bar, but to what degree is as yet unknown.

The doctrine of obviousness is related to the amount of predictability in the relevant art. If a particular art is very predictable, that is specific

²²³ See *supra* note 200 and accompanying text.

²²⁴ See *supra* note 200 and accompanying text.

²²⁵ Rebecca S. Eisenberg, Commentary, *The Supreme Court and the Federal Circuit: Visitation and Custody of Patent Law*, 106 MICH. L. REV. FIRST IMPRESSIONS 28, 32–33 (2007), <http://www.michiganlawreview.org/firstimpressions/vol106/eisenberg.pdf>.

²²⁶ *Id.*

²²⁷ See generally Petherbridge & Wagner, *supra* note 150 (announcing a study regarding the Federal Circuit's patent jurisprudence).

²²⁸ See *supra* note 200 and accompanying text.

changes are likely to result in predictable results, then it is harder to prove that a change is not obvious. The counter is also true, if a particular art is unpredictable, that incremental changes are likely to produce unforeseen consequences, then the case for non-obviousness is easier. In this regard, the pharmaceutical industry may be at an advantage over some other industries. The chemical arts are regarded as rather less predictable than industries that deal with more mechanical innovations.²²⁹ With this in mind, the holding in *KSR* may not have as great an impact on the pharmaceutical industry at the USPTO as it will on others.

However, the holding has already had negative implications for pharmaceutical patents in more than one area—the first, the doctrine of “obvious to try.” The doctrine states essentially that if when presented with a particular problem, and there are a number of known possible solutions to the problem, it would be obvious to try those possible solutions, and, as such, a patent may not be granted for an application based on this advance.²³⁰

This has particular significance to pharmaceutical firms because there are only fifty-three FDA approved pharmaceutical salts.²³¹ Therefore, if a drug has, for example, formulation problems and salt formation is the only route to solve the problem—a drug maker has only a finite number of possible choices, and, as such is vulnerable to a challenge of obvious to try. This may occur when applying for a patent or in a patent infringement lawsuit after a more significant investment has been made.

This was exactly the case in *Pfizer, Inc. v. Apotex, Inc.*,²³² which the USPTO cites in its guidelines post-*KSR*.²³³ In *Pfizer*, the patent for an improved salt form of the active ingredient was held invalid under the obvious to try standard.²³⁴ This highlights one specific implication for the pharmaceutical industry.

In another post-*KSR* case, *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*,²³⁵ Aventis held a patent on a formulation of its ACE inhibitor ramipril.²³⁶ Lupin’s improved formulation was for ramipril “substantially

²²⁹ Jason Romrell, Note, *Biting Off More Than You Can Chew: The New Law of Enablement*, 23 BERKELEY TECH. L.J. 139, 152–56 (2008).

²³⁰ *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1365 (Fed. Cir. 2007).

²³¹ *Id.* at 1355.

²³² *Id.* at 1348.

²³³ Fed. Reg. 57,532 (Oct. 17, 2007).

²³⁴ *Pfizer*, 480 F.3d at 1371–72.

²³⁵ 499 F.3d 1293 (Fed. Cir. 2007).

²³⁶ *Id.* at 1296–98.

free of other isomers.”²³⁷ The district court held the patent was valid.²³⁸ On appeal, the Federal Circuit held the patent invalid as obvious.²³⁹ The court found that a purified form of a known mixture is prima facie obvious if a person having ordinary skill in the art would have some reason to believe that the mixture derives properties from a particular component.²⁴⁰ A prima facie case of obviousness would be nearly impossible to rebut in a pharmaceutical setting such as this where the potency of the impure form varies directly with the concentration of the active ingredient.

As stated above, the Hatch-Waxman Act contains a provision that encourages generic filers to be the first to successfully challenge a pioneer patent.²⁴¹ The relevant section grants a period of 180 days of marketing exclusivity to the challenging firm²⁴²—a powerful incentive. A Congressional Budget Office study points out that generic prices fall much like pioneer prices, when there is additional generic competition, thus exclusivity is also important for generic filers.²⁴³ The holding in *KSR* makes the likelihood of success in these challenges that much greater. As such, pharmaceutical patents holders will have to defend their patents more often, for if the *KSR* holding does indeed increase the likelihood of success for challengers, nearly every successful pharmaceutical product can expect a challenge.

V. CONCLUSION

*“The prospect of earning substantial revenues for successful drugs is a necessary incentive to encourage these investments.”*²⁴⁴

The pharmaceutical industry is under tremendous pressure to deliver high value drugs at a low cost. The viability of the industry is jeopardized by weakening patent protection. Without adequate patent protection, pharmaceutical firms will not make the investment necessary to develop

²³⁷ *Id.* at 1298.

²³⁸ *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, No. 2:05CV421, 2006 WL 2008962, at *49 (E.D. Va. July 17, 2006).

²³⁹ *Aventis*, 499 F.3d at 1295.

²⁴⁰ *Id.* at 1301–02.

²⁴¹ 21 U.S.C. § 355(j) (2000).

²⁴² 21 C.F.R. § 314.107(c)(1) (2007).

²⁴³ Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 32–34 (1998), available at <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf>.

²⁴⁴ Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93, 94 (2004) (emphasis added).

breakthrough therapies. One result may be that firms will focus more and more of their resources on over-the-counter products and less on actual innovation which is inherently more risky.

I do not believe that we will see the extinction of the pharmaceutical industry anywhere in the near future; however, we must be cognizant of the business realities of the industry. With the uncertainties created by the Supreme Court's holding in *Merck*, and the Supreme Court's lowering the bar for patent invalidation, pharmaceutical companies will find it harder and harder to protect the investments that they have already made, or to recoup their investments.

The realities of current patent protection for drugs must also be examined in light of the specter of compelled licensing. This is a relatively new concept but one which will continue to loom over the industry for years to come. We have seen this exemplified recently with Brazil's threats to force a low cost license agreement on H.I.V. drug makers.²⁴⁵ This is particularly threatening because therapies that treat the most life-threatening diseases are most likely to be subjected to compelled licensing or the like—thus rendering them less profitable. Correspondingly, therapies that successfully treat the worst diseases are provided less profit, thus destroying the incentive that pharmaceutical firms have to invest in the research in the first place. We need strong patent protection for the pharmaceutical industry in order to encourage future research into the diseases of tomorrow.

This was exemplified recently in the U.S. as well. After the attacks of September 11, 2001, there was a significant anthrax scare.²⁴⁶ Bayer's Ciprofloxacin was seen as the best front-line defense to anthrax exposure.²⁴⁷ In the uncertainty that reigned during that time, Congress examined a proposal to compel Bayer to license the drug so that the

²⁴⁵ Paulo Prada, *Brazil Near Deal With Abbott For Price Cut on AIDS Drug*, N.Y. TIMES, Oct. 5, 2005, at C7.

²⁴⁶ See, e.g., Clyde Haberman, *A Nation Challenged: An Overview: Oct. 23, 2001; New Urgency on Anthrax, Bombs and Blunders, the Ripple Effect*, N.Y. TIMES, Oct. 24, 2001, at B1; Eric Lipton, *A Nation Challenged: The New Cases; Anthrax Is Found in 2 More People*, N.Y. TIMES, Oct. 19, 2001, at A1; David Johnston & Alison Mitchell, *A Nation Challenged: The Widening Inquiry; Anthrax Mailed to Senate Is Found to Be Potent Form; Case Tied to Illness at NBC*, N.Y. TIMES, Oct. 17, 2001, at A1.

²⁴⁷ Andrew Pollack, *A Nation Challenged: Stockpiling; U.S. Moving to Buttress Defense Against the Bioterrorism Threat*, N.Y. TIMES, Oct. 15, 2001, at B8.

government could produce it.²⁴⁸ The scare died down before the license was executed. It is important to note that it need not be an acute national emergency, like the anthrax scare, to prompt exercise of this compulsory licensing. In light of the Supreme Court's decision in *Kelo v. City of New London*,²⁴⁹ it is possible that we could see pharmaceutical patents taken by eminent domain for a public health crisis such as diabetes. Such a possibility adds to the uncertainty of whether pioneer pharmaceutical companies can expect their products to be profitable.

This demonstrates the new found uncertainty in the pharmaceutical industry. The prospect that pharmaceutical firms must now deal with, their products may be usurped by governments exercising a "compulsory license." The implications for U.S. consumers are considerable as well for pioneer firms which must choose what diseases to treat, and if they suspect that a particular area is more risky than another, then common sense dictates that they will be more likely follow the less risky investment.

In all, the recent Supreme Court decisions have both positive and negative implications for pharmaceutical patents. But the erosion of drug patent protection is a serious matter and these decisions come at time when the pharmaceutical industry is under more pressure than the industry has seen before. Profitability is not the sole factor that pioneer firms weigh, but as patent protection continues to erode it can only become more significant. In order for the industry to continue to provide valuable life-saving therapies, pioneer firms need a stable patent system and firm patent protection.

²⁴⁸ Edmund L. Andrews, *A Nation Challenged: The Drug Maker; Demand for Cipro May Be a Break for Bayer, and a Headache*, N.Y. TIMES, Oct. 18, 2001, at B8.

²⁴⁹ 545 U.S. 469 (2005).

