HATCH-WAXMAN ACT OF USA,
PARAGRAPH IV LITIGATION

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INTRODUCTION

The marketing approval process for a new drug has undergone significant changes at United States Food and Drug Administration (USFDA) in the year 1962. Prior to the year 1962, a new drug used to get marketing approval by USFDA on the basis of safety profile alone. However, in 1962, Kefauver-Harris Amendments made to the Federal Food, Drug, and Cosmetics Act added a new and compulsory requirement of "proof-of-efficacy" for obtaining marketing approval for a new drug. As a result, all drug products approved before 1962 by the USFDA were reviewed again for efficacy through the Drug Efficacy Study Implementation (DESI) program. DESI was a program initiated by the USFDA following Kefauver-Harris Amendments to establish safety and efficacy requirements for approval of new drugs as well as for reconsidering the safety and efficacy of prior approved drugs. To prove that new drugs were safe and effective enough so as to get the USFDA approval, new drugs manufacturers were required to conduct clinical trials on a limited number of human individuals so as to determine the efficacy and safety of the new drugs and submit the results of the same to the USFDA along with their New Drug Application (NDA).

Also, innovator drug manufacturers usually secure patent rights over the drug molecules produced in their R&D labs at an early development stage itself. They do so to exclude others from making, using, or selling their molecules at a later stage and also to gain profits in case a drug molecule succeeds to become a blockbuster drug. Usually, the discovery and development of new drug incurs a lot of monetary expense, efforts and time and hence the effective patent term for which the manufacturer can recoup the investments and reap benefits gets reduced as time is lost in developing the drug into a dosage form. To add to this lost time, USFDA approval required to market the drug takes another couple of years. Thereby the effective term of many drug patents gets shortened further due to the time required for obtaining the safety and efficacy data. Sadly, however, there was no provision for patent term extension prior to enactment of the Hatch Waxman Act, to make up for the time lost out of the total patent term during the marketing approval process.

On the other hand, those companies seeking to market a generic version of an innovator drug (also called branded drug) were also required to carry out their own safety and efficacy

studies i.e. clinical trials, much like the innovator drugs companies. Due to the high costs involved in conducting clinical trials, only a few generic companies showed interest in launching products in the US. As a result, by 1984, there were approximately 150 innovator drugs whose patents had expired, and for them there were no generic equivalents available in the market (according to the USFDA estimation). This indirectly maintained the monopoly of the patent holders of the innovator drugs as no other players were there in the market.

Another factor that complicated the approvals of generic drugs was the timing when the generic drug companies were allowed to perform their clinical trials. A generic drugs company was not allowed to begin the required USFDA approval process for a generic drug until the patents on the corresponding innovator drug had expired. Generally speaking, even if a generic drugs manufacturer gets access to the clinical data of the innovator drugs, making copies of a pharmaceutical product is not simple. Procuring active ingredients, performing bio-equivalence studies, assuring quality, putting together a dossier, establishing patient information leaflets and going through the regulatory process can take two to three years. Manufacturing needs another three to six months. Consequently, patent protection for the innovator drugs used to unduly get extended by two to three years before the generics manufacturers could come up with the approved generic versions for those innovator drugs. This discouraged the entry of generic drugs in the market.

In order to address the above mentioned problems, a provision in the law was needed which would allow the generic manufacturers to use the clinical trial data of the innovator drug and also allow the experimental use of the patented innovator drug so as to come up with the generic version of the innovator drug well before the patent for the innovator drug expires. This was needed in order to get the marketing approval of generic version before the expiry of the patent for the innovator drug so that the generic version could enter the market as soon as the patent for the innovator drug expires. This was also necessary to avoid the undue extra patent protection enjoyed by the innovator drug company and thereby avoid monopoly. Further, there was a need for a provision of extending the life term of patents related to pharmaceutical drugs to compensate for the time lost in seeking USFDA approvals.

To overcome the above mentioned problems as well as to address the inadequacies in the pharmaceutical regulatory system, the Drug Price Competition and Patent Term Restoration Act was passed by the Congress in 1984. This act is informally called the Hatch-Waxman Act.

This is an attempt to understand the history and evolution of the Hatch-Waxman Act (hereinafter, referred to as HWA) of 1984, to study the impact of the HWA on U.S.

Pharmaceutical Industry, to understand the need of Generic Drugs in U.S. and need to regulate it, to analyse the general provisions of HWA of 1984, to understand the process of Abbreviated New Drug Application(ANDA), to analyse provision relating to the Paragraph IV Litigation in detail and to analyse the latest case-law pertaining to the Paragraph IV litigation.

PART I
THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984

The Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 Act)[1] introduced several significant changes to the patent laws. These include patent term extension; a statutory exemption for patent infringement relating to regulatory marketing approval; procedures for challenging the validity of pharmaceutical patents; and a reward for challenging the validity, enforceability, or infringement of a patented and approved drug. Through these provisions, the 1984 Act attempts to balance two competing objectives within the pharmaceutical industry. First, the 1984 Act aimed to encourage the introduction of widely available generic drugs. Second, the 1984 Act hoped to ensure that adequate incentives remain for individuals to invest in the development of new drugs.[2]

The 1984 Act is today commonly known as the "Hatch-Waxman Act."[3] At the time of its enactment, however, the 1984 Act was generally referred to as the "Waxman-Hatch Act."[4] In light of this conflicting nomenclature, this report refers to the Drug Price Competition and Patent Term Restoration Act of 1984 as the 1984 Act.

1.1 Background of the 1984 Act

The Role of the FDA and the USPTO in the Pharmaceutical Industry.

Both the Patent and Trademark Office and the Food and Drug Administration (FDA) have a role to play in the pharmaceutical industry. The USPTO allows patents to issue on the compounds that comprise a pharmaceutical as well as methods of making and using them. Patents confer the right to exclude others from making, using, selling, offering to sell, or

[1] Pub. L. No. 98-417, 98 Stat. 1585 (1984).
[2] Rea, Teresa Stanek, *Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act-An Introduction of Speakers*, 54 FOOD DRUG LAW JOURNAL (1999), 223, 224.
[3] *See, e.g., Glaxo, Inc. v. Novopharm, Ltd.,* 110 F.3d 1562, 1568 (Fed. Cir. 1997).
[4] *See, e.g.,* McGough, Kevin J. , "Preserving the Compromise: The Plain Meaning of Waxman-Hatch Exclusivity," 45 *Food, Drug and Cosmetic Law Journal* (1990), 487.

importing into the United States the patented invention.[5]

The grant of a patent does not provide its proprietor with the affirmative right to market the patented invention, however.[6] For many products of the pharmaceutical industry, the FDA must approve the product for sale to consumers. Federal laws generally require that pharmaceutical manufacturers show their products are safe and effective in order to market these products.[7]

USPTO issuance of a patent and FDA marketing approval are distinct events that depend upon different criteria.[8] The FDA might consider a pharmaceutical safe and effective for consumer use, for example, but the USPTO could rule that the compound does not present a sufficient advance over public domain knowledge to be worthy of a patent. Alternatively, it is readily within the power of the FDA to judge that a pharmaceutical presents too great a risk for use as a medication within the United States, despite the fact that the USPTO has allowed a patent to issue claiming that pharmaceutical.

As a result of the independence of patent ownership and marketing approval, the pharmaceutical industry must account for both. In order to sell a drug without fear of civil or criminal liability, an enterprise must both obtain FDA approval and consider whether that drug has been patented. Often the entity which owns the patent on a pharmaceutical is the first to be awarded marketing approval. Sometimes the enterprise which has been awarded marketing approval and the patent owner are separate entities, however. In this latter case, the patentee may commence infringement litigation against the approved drug manufacturer. A court may issue an injunction and award monetary liability for patent infringement despite the fact of FDA marketing approval.

Although the 1984 Act maintained the independence between the award of a patent and the process of seeking FDA market approval, it did establish a procedural interface between these two events. Before describing these procedures in greater detail, this report first considers core features of the patent and food and drug laws as they stood prior to the 1984 Act.

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[5] 35 U.S.C. § 271(a).
[6] Chisum, Donald S., *Principles of Patent Law* (Foundation Press, New York, New York, 1998), 5.
[7] 21 U.S.C. §355(b). Prior to 1962, the drug approval process was solely directed towards safety. *See* Mossinghoff, Gerald J., *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD AND DRUG LAW JOURNAL 187 (1998).
[8] See *In re Brana,* 51 F.3d 1560 (Fed. Cir. 1995).

1.1.1 The Generic Drug Approval Process.

Since 1962, federal law has required pharmaceutical manufacturers to demonstrate that their products are safe and effective.[9] Prior to the 1984 Act, however, the federal food and drug law contained no separate provisions addressing generic versions of drugs that had previously been approved.[10] The result was that would-be generic drug manufacturers had to file their own "New Drug Application" (NDA) in order to market their drug. Some generic manufacturers could rely on published scientific literature demonstrating the safety and efficacy of the drug. These sorts of studies were not available for all drugs, however. Further, at times the Food and Drug Administration requested additional studies to deal with safety and efficacy questions that arose from experience with the drug following its initial approval. The result is that some generic manufacturers were forced to prove independently that the drug was safe and effective, even though their product was identical to that of a previously approved drug.

Some commentators believed that the approval of a generic drug was a needlessly costly, duplicative and time-consuming process prior to the 1984 Act.[11] FDA safety and efficacy requirements sometimes required clinical trials, for example, which could prove very expensive. Some observers noted that although patents on important drugs had expired, manufacturers were not moving to introduce generic equivalents for these products.[12] As the introduction of generic equivalents often causes prices to decrease, the interest of consumers was arguably not being served through these observed costs and delays.[13]

1.1.2 Generic Drug Development and Patent Infringement.

The patent law grants patent proprietors the right to exclude others from making, using selling, offering to sell, or importing into the United States the patented invention.[14] Accused infringers may offer several defenses to avoid liability for patent infringement, however. One

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[9] 21 U.S.C. § 355(b). Prior to 1962, the drug approval process was solely directed towards safety. *See* Mossinghoff, *supra* note 7, at 187.

[10] Engelberg, Alfred B., "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?," 39 *IDEA: Journal of Law and Technology* (1999), 389, 396. Generic drugs are versions of brand-name prescription drugs that are often sold without a trademark and that contain the same active ingredients, but not necessarily the same inactive ingredients, as the original. *United States v. Generix Drug Co.,* 460 U.S. 435, 455 (1983).

[11] Buchanan, J. Matthew, *Medical Device Patent Rights in the Age of FDA Modernization: the Potential Effect of Regulatory Streamlining on the Right to Exclude*, 30 UNIVERSITY OF TOLEDO LAW REVIEW 305, 316 (1999).

[12] Engelberg, supra note 10, at 396-97.

[13] Buchanan, *supra* note 11.

[14] 35 U.S.C. § 271(a).

potential defense lies under the so-called "experimental use" doctrine. Perhaps the first discussion of this infringement defense occurred in the 1813 decision in *Whittemore v. Cutter.*[15] There, Justice Joseph Story explained that "it could never have been the intention of the legislature to punish a man, who constructed such a [patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." By 1861, the court in *Poppenhausen v. Falke* was able to state that the law was "well-settled that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement of the rights of the patentee."[16]

Commentators have noted that the number of accused infringers who have successfully pled an experimental use defense are few, however.[17] As a practical matter, perhaps infringement charges were only rarely brought against philosophers or amusement seekers.[18] The possibility of an experimental use defense took on a new characteristic with the advent of drug marketing approval procedures, however. When a competitor becomes interested in marketing the generic equivalent of a drug patented by another, it may wish to commence the clinical trials and other procedures during the term of the patent. As a result, the competitor would be able to market the drug immediately upon expiration of the patent. Whether the regulatory compliance activities of a generic drug manufacturer amounted to a patent infringement, or were exempted by the experimental use defense, was for many years an open legal question.

The 1984 decision of the Court of Appeals for the Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co*[19] resolved this question conclusively in favor of a finding of patent infringement. In that case, Roche Products, Inc. (Roche) marketed a prescription sleeping pill under the trademark "Dalmane." Roche also was the proprietor of a patent claiming a chemical compound, flurazepam hcl, that was the active ingredient in Dalmane.[20] The Roche patent issued on January 17, 1967, and expired on January 17, 1984.

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[15] 29F.Cas. 1120, 1121 (C.C.Mass. 1813)(No. 17,600).
[16] 19F.Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).
[17] *See* Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE LAW JOURNAL 2169 (1991).
[18] Richard E. Bee, *Experimental Use as An Act of Patent Infringement*, 39 JOURNAL OF THE PATENT OFFICE SOCIETY 357 (1957).
[19] 733 F.2d 858 (Fed. Cir. 1984).
[20] *See* U.S. Patent No. 3, 299, 053 (Novel 1 and/or 4 - substituted alkyl 5 – aromatic - 3H - l, 4 benzodiazepines and benzodiazepine-2-ones).

Bolar Pharmaceutical Co. (Bolar), a manufacturer of generic drugs, grew interested in marketing a generic equivalent of Dalmane. Bolar recognized that FDA approval of a drug was a time-consuming process and wished to begin selling a generic equivalent immediately after the Roche patent expired. As a result, in mid-1983, Bolar obtained a supply of flurazepam hcl from a foreign manufacturer. It began to form the flurazepam hcl into dosage form capsules to obtain stability data, dissolution rates, bioequivalency studies and blood serum studies necessary to file an NDA with the FDA.

Roche brought suit against Bolar on July 28,1983, seeking to enjoin Bolar from using flurazepam hcl for any purpose during the life of the patent. The district court ultimately denied Roche's request on October 11,1983. The district court concluded that Bolar's use of the compound for federally mandated testing did not infringe the Roche patent because Bolar's use was minimal and experimental.[21]

Roche promptly appealed to the United States Court of Appeals for the Federal Circuit, which reversed the district court. Writing for a three-judge panel, Judge Nichols initially observed that the 1952 Patent Act states that whoever "uses ... any patented invention, within the United States during the term of the patent therefore, infringes the patent."[22] This language on its face prohibits all unauthorized uses of the patented invention, the Federal Circuit reasoned, and many judicial opinions had so held.[23]

The Federal Circuit next considered two contentions offered by Bolar. First, Bolar urged that the experimental use defense exempted its efforts to comply with federal food and drug law. After reviewing the precedents, Judge Nichols disagreed, concluding:

> Bolar's intended "experimental" use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the [Roche] patent. Bolar may intend to perform "experiments," but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention. It is obvious here that it is a misnomer to call the intended use de minimus. It is no trifle in its economic effect

[21] 572 F. Supp. 255 (E.D.N.Y. 1983).
[22] 35 U.S.C. § 271(a).
[23] 733 F.2d at 862-64.

> on the parties even if the quantity used is small. It is not dilettante affair such as Justice Story envisioned. We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of "scientific inquiry," when that inquiry has definite, cognizable, and not insubstantial commercial purposes.[24]

Bolar finally urged the Federal Circuit to resolve a perceived conflict between the Food, Drug and Cosmetic Act[25] and the 1952 Patent Act.[26] Bolar observed that substantial regulatory delays were associated with the receipt of FDA marketing approval. According to Bolar, if a generic manufacturer could not commence seeking FDA approval until the appropriate patents had expired, then the patentee could preserve its market exclusivity beyond the statutory patent term. Bolar characterized this situation as a de facto patent term extension inconsistent with the Patent Act.[27]

The Federal Circuit also rejected this argument. According to Judge Nichols, the judiciary was not the proper forum to engage in policy argumentation inconsistent with the patent statute. The court observed that bills addressing these issues had been placed before Congress and suggested that any aggrieved parties seek redress there.[28] The Federal Circuit remanded the decision to the district court with instructions to fashion the appropriate remedy.[29]

1.2 Principal Provisions of the 1984 Act

The Federal Circuit's suggestion that a legislative forum may better suit the interests of the parties proved prophetic. On September 24, 1984, President Ronald Reagan signed into law the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Act"). The 1984 Act is codified in Titles 15, 21, 28 and 35 of the United States Code.[30] Although the 1984 Act is a complex statute, observers have frequently noted that it presents a fundamental trade-off: In exchange for permitting manufacturers of generic drugs to gain FDA marketing approval by relying on safety and efficacy data from the original manufacturer's NDA, the original manufacturers received a period of data exclusivity and

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[24] 733F.2d at 863.
[25] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 et seq.).
[26] Pub. L. No. 82-593, 66 Stat. 792 (1952) (codified as amended 35 U.S.C. § 1 et seq.).
[27] 733 F.2d at 863-64.
[28] 733 F.2d at 864-66.
[29] 733 F.2d at 865-67.
[30] The specific provisions are 15 U.S.C. §§ 68b-68c, 70b; 21 U.S.C. §§ 301, 355, 360cc; 28 U.S.C. §2201; and 35 U.S.C. §§ 156, 271, 282.

patent term extension.[31] A review of the legislation's more significant provisions follows.

1.2.1 Accelerated Generic Drug Approval Process.

The 1984 Act created a new type of application for market approval of a pharmaceutical. This application, termed an Abbreviated New Drug Application (ANDA), may be filed at the FDA.[32] An ANDA may be filed if the active ingredient of the generic drug is the bioequivalent of the approved drug. An ANDA allows a generic drug manufacturer to rely upon the safety and efficacy data of the original manufacturer. The availability of an ANDA often allows a generic manufacturer to avoid the costs and delays associated with filing a full-fledged NDA. Through the ANDA procedure, a generic manufacturer may often place its FDA-approved bioequivalent drug on the market as soon as the patent on the original drug expires.[33]

1.2.2 Patent Term Restoration.

The 1984 Act also provides for the extension of patent term. Ordinarily, patent term is set to twenty years from the date the patent application is filed.[34] The 1984 Act provides that for pharmaceutical patents, the patent term may be extended for a portion of the time lost during clinical testing. More specifically, this term extension is equal to the time between the effective date of the investigational new drug application and the submission of the NDA, plus the entire time lost during FDA approval of the NDA.[35]

The 1984 Act sets some caps on the length of the term restoration. The entire patent term restored may not exceed five years. Further, the remaining term of the restored patent following FDA approval of the NDA may not exceed 14 years.[36] The 1984 Act also provides that the patentee must exercise due diligence to seek patent term restoration from the USPTO, or the period of lack of diligence will be offset from the augmented patent term.[37]

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[31] Gregory J. Glover, *Regulatory Concerns & Market Exclusivity*, HEALTH CARE M&A 2000, 1175 Practising Law Institute (2000), 629, 633.
[32] 21 U.S.C. § 355(j).
[33] Ibid.
[34] 35 U.S.C. § 156. Prior to United States adherence to the World Trade Organization, patents were granted a term of 17 years from the date of issuance. On June 8, 1995, the effective patent term was changed to 20 years measured from the date the patent application was filed. Patents in existence as of June 8, 1995, or patents that issued from applications pending at the USPTO as of the date, have a term equal to the greater of 17 years from issuance or 20 years from grant.
[35] 35 U.S.C. § 156.
[36] 35 U.S.C. § 156(c).
[37] 35 U.S.C. § 156(d)(2)(B).

Patent term extension does not occur automatically. The patent owner or its agent must file an application with the USPTO requesting term extension within 60 days of obtaining FDA marketing approval. According to a senior legal advisor in the Special Program Law Office of the Patent and Trademark Office, between 50 and 60 such applications are filed each year.[38]

1.2.3 Market Exclusivity.

The 1984 Act includes provisions that create market exclusivity for certain FDA-approved drugs. The FDA administers these provisions by issuing approval to market a pharmaceutical to only a single entity. A grant of market exclusivity does not depend on the existence of patent protection and the two rights may actually conflict.

The length of market exclusivity is contingent on whether or not the drug is considered a new chemical entity (NCE). The 1984 Act defines an NCE drug as an approved drug which consists of active ingredients, including the ester or salt of an active ingredient, none of which has been approved in any other full NDA.[39] If the approved drug is not an NCE, then the FDA may not approve an ANDA for a generic version of the approved drug until three years after the approval date of the pioneer NDA.[40]

In contrast, if the approved drug is an NCE, then a would-be generic manufacturer cannot submit an ANDA until five years after the date of the approval of the pioneer NDA.[41] The effect of this provision is to restrict a potential generic manufacturer from bringing a product to market for five years plus the length of the FDA review of the ANDA. One noted expert has recently observed that the review time for an ANDA exceeds 18 months.[42]

1.2.4 Patent Infringement.

The 1984 Act includes elaborate provisions governing the mechanisms through which a potential generic manufacturer may obtain market approval on a drug that has been patented by another. Among these provisions are a statutory exemption from claims of patent infringement based on acts reasonably related to seeking FDA approval; special provisions

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[38] Karin L. Tyson, *The Role of the Patent and Trademark Office Under 35 U.S.C. Section 156*, 54 FOOD AND DRUG LAW JOURNAL 205 (1999).
[39] 21 U.S.C. § 355(j)(4)(D)(I).
[40] 21 U.S.C. § 355(j)(4)(D)(iii).
[41] 21 U.S.C. § 355(j)(D)(ii).
[42] Glover, *supra* note 31, at 634.

for challenging the enforceability, validity or infringement of approved drug patents; and a reward for challenging patent enforceability, validity or infringement consisting of 180 days of market exclusivity to the first generic applicant to file a patent challenge against any approved drug.

The 1984 Act modified the 1952 Patent Act by creating a statutory exemption from certain claims of patent infringement. As codified in § 271(e)(1), this provision mandates that "It shall not be an infringement to make, use, offer to sell, or sell within the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use or sale of drugs or veterinary biological products." This provision effectively overturns the opinion of the Court of Appeals for the Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*[43] As a result, generic manufacturers may commence work on a generic version of an approved drug any time during the life of the patent, so long as that work furthers compliance with FDA regulations.

Courts have interpreted § 271(e)(1) liberally, reasoning that the statute exempts from infringement a wide variety of acts. Exemplary is the decision of United States Magistrate Judge Brazil in *Intermedics, Inc. v. Ventritex, Inc.*[44] There, the court reasoned that it would not always be clear to prospective pharmaceutical suppliers exactly which kinds of information, and in what quantities, would be required to obtain FDA approval. The court therefore concluded that parties should be given some latitude in making judgments about the nature and extent of otherwise infringing activities needed to generate information that would satisfy the FDA.

The *Intermedics* court then applied this reasoning to the facts before it, concluding that a number of accused activities fell within the safe harbor of § 271(e)(1). The court held that device sales to foreign distributors were reasonably related to developing information to be submitted to the FDA because all of the devices were resold to FDA-approved clinical investigators.[45] Foreign testing activities were also found noninfringing because the data they generated was also sent to the FDA.[46]

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[43] See supra notes 19-29 and accompanying text.
[44] 775 F. Supp. 1269 (N.D. Cal), *affirmed,* 991 F.2d 808 (Fed. Cir. 1993).
[45] Ibid at 1283.
[46] Ibid at 1284.

The Supreme Court decision in *Eli Lilly & Co. v. Medtronic* is also notable for its expansive interpretation of § 271(e)(1).[47] There, the Court held that the infringement exemption is available not only to drug and veterinary products, but also to medical devices that cannot be marketed without Food and Drug Administration approval.

Although the 1984 Act provides a safe harbor from patent infringement, it also requires would-be manufacturers of generic drugs to engage in a specialized certification procedure. The core feature of this process is that a request for FDA marketing approval is treated as an "artificial" act of patent infringement. This feature was intended to allow judicial resolution of the validity, enforceability and infringement of patent rights before generic competition enters the market.[48]

Under the 1984 Act, each holder of an approved NDA must list pertinent patents it believes would be infringed if a generic drug were marketed before the expiration of these patents. The FDA publishes this list of patents in its list of approved products.[49] This list is commonly known as the "Orange Book."[50]

An ANDA applicant must certify its intent with regard to each patent associated with the generic drug it seeks to market. Four possibilities exist under the 1984 Act:

(1) that patent information on the drug has not been filed;
(2) that the patent has already expired;
(3) the date on which the patent will expire; or
(4) that the patent is invalid or will not be infringed by the manufacture, use or sale of the drug for which the ANDA is submitted.

These certifications are respectively termed paragraph I, II, III, and IV certifications.[51] An ANDA certified under paragraphs I or II is approved immediately after meeting all applicable regulatory and scientific requirements.[52] An ANDA certified under paragraph III must, even after meeting pertinent regulatory and scientific requirements, wait for approval until the

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[47] 496 U.S. 661 (1990).
[48] *See* Engelberg, *supra* note 10, at 402.
[49] 21 U.S.C. § 355(b)(1), 355(j)(2)(A)(vi).
[50] Food & Drug Administration, Center for Drug Evaluation & Research, *Approved Drug Products with Therapeutic Equivalence Evaluations*; Dickinson, Elizabeth A., *FDA's Role in Making Exclusivity Determinations*, 54 FOOD AND DRUG LAW JOURNAL 195, 196 (1999).
[51] Mossinghoff, *supra* note 100, at 189.
[52] 21 U.S.C. §§ 355(j)(5)(A), (B)(1).

drug's listed patent expires.

If the ANDA applicant files a paragraph IV certification, it must notify the proprietor of the patent. The patent owner may bring a patent infringement suit within 45 days of receiving such notification.[53] If the patent owner timely brings a patent infringement charge against the ANDA applicant, then the FDA must suspend approval of the ANDA until one of the following events occurs:

> (1) the date of the court's decision that the listed drug's patent is either invalid or not infringed;
> (2) the date the listed drug's patent expires, if the court finds the listed drug's patent infringed;[54] or
> (3) subject to modification by the court, the date that is thirty months from the date the owner of the listed drug's patent received notice of the filing of a Paragraph IV certification.[55]

The 1984 Act provides prospective manufacturers of generic pharmaceuticals with a reward for challenging the patent associated with an approved pharmaceutical. The reward consists of a 180-day generic drug exclusivity period awarded to the first generic applicant to file a paragraph IV certification. This provision is intended to encourage generic applicants to challenge a listed patent for an approved drug product.[56]

The decision of the United States Court of Appeals for the D.C. Circuit in *Mova Pharmaceutical Corp. v. Shalala* considered the 180-day exclusivity provision and its implementation by the FDA.[57] Before *Mova,* the FDA took the position that in order to win the 180-day exclusivity period, the generic applicant had to defend successfully a patent infringement suit brought by the patentee under paragraph IV. In *Mova,* the D.C. Circuit held that the FDA had improperly imposed this requirement of a successful defense. According to Judge Wald, this requirement was "gravely inconsistent with the text and structure of the statute."[58]

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[53] 21U.S.C. § 355(c)(3)(C).
[54] 35 U.S.C. §§ 271(e)(4)(A).
[55] 21 U.S.C. §§ 355(j)(5)(B)(iii)(I)(III).
[56] Dickinson, *supra* note 50, at 199.
[57] 140 F.3d 1060 (D.C. Cir. 1998).
[58] 140 F.3d at l069.

The holding in *Mova* may be considered in light of the reality that no provision of the 1984 Act requires the first entity to challenge a patent to pursue that challenge diligently in the courts. The first patent opponent may file a paragraph IV certification, be charged with infringement by the patentee, and then simply decide not to pursue the matter further. Nonetheless, if the patent has not yet expired, the 1984 Act prevents the FDA from approving a subsequently filed ANDA until 180 days after either (a) a court holds the challenged patent invalid, not infringed or unenforceable; or (b) the first patent challenger markets the pertinent pharmaceutical.[59]

Suppose, for example, that generic manufacturer "Alpha" is the first to file a paragraph IV certification. The patentee then commences patent infringement litigation against Alpha in the courts. Assume further that Alpha loses, or that Alpha has a change of heart and decides not to further contest the charge of infringement. Another generic manufacturer, "Beta," then files its own paragraph IV certification. Following a patent infringement lawsuit brought by the patentee against Beta, the courts hold that the patent was invalid.

Under these circumstances, the FDA may not approve a subsequently filed ANDA until Beta has obtained ajudicial judgment adverse to the patent. Further, the FDA must wait 180 days after the court's judgment before granting market approval to Beta. Because Beta was not the first to challenge the patent, Beta receives no market exclusivity under the 1984 Act.

1.3 Subsequent Legislative Developments

Two significant legislative developments occurred subsequent to the enactment of the 1984 Act. First, Congress incorporated animal drugs into the structure of the 1984 Act with the 1988 Generic Animal Drug and Patent Term Restoration Act.[60]

Second, the Uruguay Round Agreement Act (URAA),[61] also amended the 1984 Act. Among the provisions of the URAA were changes to the term for which patents endure. Prior to the URAA, patents expired 17 years after the date they issued. The URAA provided that patent term would be set to 20 years from the date the patent application was filed. The URAA also included a transitional provision: patents in effect on June 8, 1995, or patent applications pending at the USPTO on that date would get the term of 20 years from the filing date or 17

[59] 21 U.S.C. § 355(j)(5)(B)(iv)(I), (II).
[60] Pub. L. No. 100-670, 102 Stat. 3971 (1988).
[61] Pub. L. No. 103-465, 108 Stat. 4809 (1994).

years from the issue date, whichever was longer. Because the USPTO had issued many patents less than three years after an application had been filed, this so-called "Delta Period" amounted to a patent term extension.[62]

The drafters of the URAA recognized that some individuals may have made commercial plans based on the date they believed a competitor's patent would expire. Such plans would be upset if the term of the patent was unexpectedly increased. The URAA therefore included provisions that accounted for the interests of the patentee's competitors. In essence, the URAA denied the patentee the ability to prevent competitors from using the patented invention during the Delta Period. Instead, the patentee may claim an "equitable remuneration" from those who use the patented invention during the Delta Period. These provisions in effect call for a compulsory license.[63]

Although they are not formally associated with the 1984 Act, legislation relating to orphan and pediatric drugs is worthy of mention here. Both the Orphan Drug Act[64] and the Food and Drug Administration Modernization Act,[65] as amended by P.L. 107-109, the Best Pharmaceuticals for Children Act, encourage the research, development and marketing of certain drugs. The Orphan Drug Act provides drug researchers and manufacturers with several incentives concerning pharmaceuticals effective against rare diseases or conditions. These include federal funding of grants and contracts for clinical trials of orphan products; a tax credit of fifty percent of clinical testing costs; and the grant of an exclusive right to market the orphan drug for seven years from the date of FDA marketing approval.[66]

The Food and Drug Modernization Act aimed to increase the number of pharmaceuticals available for children.[67] The act provides a so-called "pediatric exclusivity" to encourage drug manufacturers to conduct research concerning the effectiveness of their drugs in children. Pediatric exclusivity attaches to any children's drug products with the same so-called "active moiety," which is that portion of the drug that causes its physiological or pharmacological reaction.[68] It typically extends the approved manufacturer's existing

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[62] *See Bristol-Myers Squibb v. Royce,* 69 F.3d 1130 (Fed. Cir. 1995).
[63] Mossinghoff, *supra* note 100, at 188.
[64] Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified at 21 U.S.C. § 360aa et seq.).
[65] Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified at 28 U.S.C. § 352(a)).
[66] Dickinson, *supra* note 143, at 201-03.
[67] Ibid.
[68] Kurt R. Karst, *Pediatric Testing of Prescription Drugs: The Food and Drug Administration's Carrot and Stickforthe Pharmaceutical Industry*, 49 AMERICAN UNIVERSITY LAW REVIEW 739, 750 (2000).

protection for an additional six months.[69] The product must be one for which studies on a pediatric population are submitted at the request of the Secretary of Health and Human Services. Note that the Food and Drug Administration Modernization Act does not require that a study be successful in demonstrating safety and effectiveness in a pediatric population in order to trigger the added six-month exclusivity period. Thus, the statute is merely intended to create incentives for enterprises to conduct research and submit their results.[70]

1.4 Implementation of the 1984 Act

There has been on-going congressional interest in the 1984 Act since it was passed 18 years ago. Current concerns over the price and availability of drugs in the United States has again focused attention on the legislation because of its effort to balance innovation in the pharmaceutical industry and costs to the public. In attempting to determine any results of the implementation of the 1984 Act, it is necessary to consider the state of the pharmaceutical industry in order to assess changes in both the generic drug and brand name (or innovator) drug markets. The relationship between these sectors was the basis for prior congressional action; whether and/or how this relationship has changed to meet the objectives of the law underlies any future discussion on the 1984 Act.

PART II

PARAGRAPH IV FILING AND LITIGATION

An ANDA certified under paragraphs I or II is approved immediately after meeting all applicable regulatory and scientific (efficacy, safety and bioequivalence) requirements. This means that the generic drugs manufacturer may get immediate approval for manufacturing the generic versions of the branded drugs upon filing an ANDA if, the patent information on the branded drug has not been filed by the branded drug manufacturer or if the patent for the branded drug has expired. A Para III filing is made when the ANDA applicant does not have any plans to sell the generic drug until the original drug is off patent. In case of Para III the application is processed for approval, however its approval status depends upon the product's patent expiry. ANDA approval under para III certification is made effective from the date of patent expiration.

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[69] Ibid at 203.
[70] Glover, *supra* note 124.

An ANDA applicant filing a paragraph IV certification must notify the proprietor of the patent. The patent holder may bring a patent infringement suit within 45 days of receiving such notification. If the patent owner timely brings a patent infringement charge against the ANDA applicant, then the USFDA suspends the approval of the ANDA until:

- the date of the court's decision that the listed drug patent is either invalid or not infringed;
- the date on which the listed drug patent expires, if the court finds the listed drug's patent is infringed; or
- the date that is 30 months from the date the owner of the listed drug's patent received notice of the filing of a Paragraph IV certification. (Subject to modification by the court). This means that for 30 months from the date of receipt of notice of Para VI filing, no ANDA can be approved.

In other words, once the branded drug company indicates its intent to begin a patent infringement suit against the generic company as a result of the paragraph IV filing, the USFDA is prohibited from approving the drug in question for thirty months or until such time that the patent is found to be invalid or not infringed. If, prior to the expiration of thirty months, the court holds that the patent is invalid or would not be infringed, then the USFDA approves the ANDA when that decision occurs. Conversely, if the court holds that the patent is valid and would be infringed by the product proposed in the ANDA prior to the expiration of thirty months, then the USFDA does not approve the ANDA until the patent expires.

The first generic applicant to file a paragraph IV certification is awarded a 180-day market exclusivity period by the USFDA. The 180-day market exclusivity period ordinarily begins on the earlier of two dates:

- The day the approved generic drug is first commercially marketed; or
- The day a court decision holds that the patent which is the subject of the certification is invalid or not infringed.

A successful defense of a patent infringement suit is not necessary to obtain this exclusivity period.

Paragraph IV filings are generally associated with litigations. The issues that arise in ANDA patent infringement litigation are generally the same as those which arise in other patent litigations. One exception is that a patent holder usually cannot recover monetary damages in an ANDA case because the infringement is prospective in nature. This means that within the

period an ANDA has been filed by a generic drug manufacturer and an infringement suit is filed by the innovator, no commercial use of the drug takes place. This is the reason why the patent holder does not get any monetary damages.

PART – III

CASE STUDY

3.1. Lambert Co. v. Apotex Corp.[71]

Warner-Lambert (hereinafter, Lambert) Company owned US patent 5084479 (herein after '479), entitled "Novel Methods for Treating Neurodegenerative Diseases." '479 patent claimed the use of certain cyclic amino acid compounds, one of them being Gabapentin, for the treatment of neurodegenerative diseases such as stroke, Alzheimer's disease, Huntington's disease, Amyotrophic Lateral Sclerosis (ALS), and Parkinson's disease. Lambert had other expired U.S. Patents 4024175 (herein after '175), 4087544 (herein after '544), and 4894476 (herein after '476). The `175 patent (the product patent), entitled "Cyclic Amino Acids," claimed the compounds (including Gabapentin) used in neurodegenerative method patent '479. The`544 patent (the "epilepsy method patent"), entitled "Treatment of Cranial Dysfunctions using Novel Cyclic Amino Acids," disclosed and claimed a method of treating certain forms of epilepsy using the compounds claimed in the '175 patent and used in the '479 patent, again including Gabapentin. The '476 patent the ("monohydrate patent"), entitled, "Gabapentin Monohydrate and a Process for Producing the Same" claimed a specific crystalline form of Gabapentin monohydrate.

Lambert sold Gabapentin under the trade name Neurontin. In 1993, Lambert obtained approval for NDA from USFDA for marketing Gabapentin adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy, one of the several indications claimed in the expired epilepsy method patent '544. Significantly, the FDA did not approve Gabapentin for any additional uses, let alone for the uses claimed in the '479 neurodegenerative method patent.

Apotex filed an ANDA under the HWA at the USFDA on April 17, 1998, seeking approval to market a generic formulation of Gabapentin upon the expiration of Lambert's

[71] Warner-Lambert Co. v. Apotex Corp., No. 98 C 4293, 2001 U.S. Dist. LEXIS 14592, 2001 WL 1104618 (N.D. Ill. Sept. 14, 2001).

epilepsy method patent ‘544 on January 16, 2000 for the same indication for which Lambert’s Neurontin was approved, i.e., for “adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. Along with the bioavailability/bioequivalence test data required to be included in its ANDA, Apotex filed a paragraph IV certification, declaring that its proposed manufacture, use, and sale of Gabapentin would not infringe either the monohydrate patent ‘476 or the neurodegenerative method patent ‘479. According to Apotex, its formulation would be anhydrous (i.e., would not contain water), and would accordingly be outside the scope of the monohydrate patent ‘476.

Moreover, Apotex declared that its pharmaceutical product’s labeling does not include any indication for use in the treatment of either neurodegenerative or neurogenerative diseases. Because all of the claims of the neurodegenerative method patent ‘479 were directed to a use of Gabapentin in the treatment of neurodegenerative diseases, Apotex argued that the manufacture, use, or sale of its Gabapentin products would not infringe the neurodegenerative method patent ‘479.

As required by the HWA, Apotex notified Lambert that it had filed the ANDA and paragraph IV certification. Also, Apotex provided in its notice letter a detailed statement of the factual and legal basis for its opinion of non-infringement of the neurodegenerative method patent ‘479. It explained that its indicated use for its pharmaceutical product is partial seizure and that the ‘479 patent does not claim a method of using gabapentin and its derivatives for partial seizure.

Lambert started the ‘479 patent infringement action alleging that Apotex’s ANDA was an act of infringing the neurodegenerative method patent ‘479. Lambert argued that, although the USFDA had not approved the use of Gabapentin for any of the indications claimed in the neurodegenerative method patent ‘479, and that 21 C.F.R. § 202.1 (e) (4) forbids the promotion of unapproved uses by NDA or ANDA holders, patients will use the Apotex’s Gabapentin for all purposes for which Lambert’s Neurontin product has been and customarily is used, and doctors will prescribe the Apotex’s’ Gabapentin product for such uses, including the treatment of neurodegenerative diseases. Apotex then moved for summary judgment.

Lambert opposed Apotex’s motion, arguing that:

a. USFDA does not regulate the uses for which doctors prescribe drugs once they are approved;

b. More than three-quarters of the prescriptions written by doctors for Lambert's Neurontin are for indications other than epilepsy, including the treatment of neurodegenerative diseases, and

c. Doctors, health care organizations, and other institutions commonly and routinely substitute generic drugs for all indications for which the branded drug is used.

Lambert further argued that Apotex knows and expects that its generic Gabapentin will be prescribed by doctors for all the same reasons they prescribe Neurontin including the treatment of neurodegenerative diseases. The District Court denied Apotex's motion. However, Apotex again moved for summary judgment, and the district court granted that second motion.

Subsequently, when the matter moved to the Federal Circuit, it was concluded that it is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA.

3.2. Glaxo v. Quigg72 and Abbott Laboratories v. Young73

Glaxo was the assignee of a patent ('320 patent) for cefuroximine axetil, an antibiotic drug, issued on May 12, 1981. It sought received approval from FDA to market the drug in 1985 and received approval on December 28, 1987. Cefuroximine axetil is an ester of cerfuoximine. Cerfuoximine and two of its salts are claimed in a patent owned by Glaxo. These salts, in various forms and dosages, had been approved by FDA for marketing in 1983, 1986, and 1987. When Glaxo sought a patent extension term for its '320 patent, the Commissioner of the PTO denied the extension, asserting that the 1987 approval was not the first permitted commercial marketing or use of the "product" and therefore was ineligible for extension. The Commissioner's interpretation rests on the fact that both products, after ingestion, produce the same therapeutically active substance within the body.

The Federal Circuit upheld the district court's decision, concluding that "section 156(f)(2)'s terms, 'active ingredient of a new drug… including any salt or ester of the active ingredient,' all have a plain meaning." The court looked to the legislative history to see if it could find a clear intent contrary to the plain meaning of the statutory language. Although the Commissioner's interpretation was consistent with the general purposes of the DPC-PTR Act, the court determined that it is the statutory text that must be controlling, for "the plain

[72] Glaxo Operations UK Limited v. Quigg, 894 F.2d 392 (Fed. Cir. 1990).
[73] Abbott Laboratories v. Young, 920 F.2d 984 (D.C. Cir. 1990).

meaning can be said to provide exactly how the general objectives of the Act are to be sought. This is all the more so when, as here, the two objectives are divergent if not in outright opposition to one another."[74]

In Abbott v. Young, an agency's interpretation of "active ingredient" to mean "active moiety" was again at issue. Abbott Laboratories (Abbott) received approval from FDA to market Depakene, an antidepressant drug. The chemical ingredient that performs the therapeutic function is valproic acid, which is both the active ingredient and the active moiety. In 1982 FDA granted approval to Abbott to market Depakote for the treatment of seizures. The active moiety in Depakote was the same as in Depakene, but the active ingredient was a "salt" of valproic acid. Since approval was granted during the two-year window for "pipeline drugs", Depakote was eligible for a period of exclusivity. However, FDA determined that Depakote could only be granted a 2-year period of exclusivity because it was a salt of the active ingredient of the prior-approved Depakene. FDA subsequently rejected Abbott's petition for a ten-year period of exclusivity. The district court affirmed FDA's decision, and Abbott appealed to the D.C. Circuit.

The D.C. Circuit concluded that "the language is ambiguous as it relates to the issue before us." Applying the two-part *Chevron* test, the court found that 1) Congress did not manifest an "unambiguously expressed intent" on the statute's meaning, but that 2) the government's construction does not fall within the bounds of reasonableness.

However, the court also declined to adopt Abbott's interpretation. "Abbott's interpretation, unlike the FDA's, is possible linguistically but fails to serve any conceivable statutory purpose." The court was therefore left with "an unusual case in which both the appellant and the government present us with unreasonable interpretations of a statute we think ambiguous."[75]

Being unable to place its own construction on the statute, the court remanded the case back to FDA. "Congress did not directly address the 'precise question at issue,' ... and therefore the FDA (not the judiciary) is entitled to place its reasonable construction on the ambiguous statute."[76] The dissent criticizes the majority decision, agreeing with the Federal Circuit in *Glaxo* that the "plain language" of the statute should be controlling.

So apparently, the drafters of the DPC-PTR were able to make the term "active

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[74] *Glaxo,* 894 F.2d at 396.
[75] *Id.* at 985.
[76] *Abbott,* 920 F.2d at 989

ingredient" ambiguous and straightforward at the same time![77]

3.3. Eli Lilly v. Medtronic[78]

This litigation was initiated over the scope of 35 U.S.C. §271(e)(l). Eli Lilly claimed infringement by Medtronic of two of its patents related to a medical device. Medtronic countered with the assertion that its research and development of its product were covered by § 271(e)(1), since the Eli Lilly's product had undergone a regulatory review under the FFDCA, which also regulated drugs. The statute reads:

It shall not be an act of infringement to make, use, or sell 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 and the 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 drugs. 35 U.S.C. §271(e)(l).

Medtronic contended that if any Federal law had sections pertaining to the regulation of drugs, then the products regulated under any part of that law could take advantage of the § 271(e) exemption. Eli Lilly argued that the exemption was only available for products regulated by sections of the DPC-PTR Act that dealt directly with the regulation of drugs only.

Justice Scalia noted that what was important was not to examine the differences in the approval processes for drugs and for medical devices, but rather to determine if there was a distinction between patents for drugs and for medical devices. Scalia stated: "If only the former patents [patents for drugs] were meant to be included, there were available such infinitely more clear and simply ways of expressing that intent that it is hard to believe the convoluted manner petitioner suggests was employed would have been selected."[79] If Congress meant to limit the provision only to drugs, then it would have chosen clearer language. However, Scalia also noted that Medtronic did not have a clear-cut case either. "On the other side of the ledger, however, one must admit that while the provision more naturally means what respondent suggests, it is somewhat difficult to understand why anyone would want it to mean that. Why should the touchstone of non infringement be whether the use is

[77] As the ten-year exclusivity provision was only available to drugs within a narrow two-year window, there will most likely not be an attempt to reconcile the two different interpretations. For more on these two cases, see Kevin J. McGough, *Preserving the Compromise: The Plain Meaning of Waxman-Hatch Market Exclusivity,* 45 Food Drug Cosmetic Journal 487 (1990).
[78] Eli Lilly and Company v. Medtronic, Inc., 496 U.S. 661 (1989).
[79] *Id.* at 667.

related to the development and submission of information under a provision that happens to be included within an Act that, in any of its provisions, not necessarily the one at issue, regulates drugs?[80]

The Court looked to the legislative history, but found little guidance. As far as the text is concerned, therefore, we conclude that we have before us a provision that somewhat more naturally reads as the Court of Appeals determined, but that is not plainly comprehensible on anyone's view."[81] Although the Court found little guidance in the legislative history,[82] the Court affirmed the Federal Circuit's decision based upon "the structure of the 1984 act taken as a whole."[83]

In upholding the Federal Circuit's decision, the Court determined that adopting Eli Lilly's interpretation would result in an imbalance between sections 201 and 202 of the DPC-PTR Act. It seemed "implausible" to Scalia that Congress would extend the patent terms for medical devices, color additives, etc., but not allow testing under § 271(e)(1), thereby aggravating the back-end distortion of the patent term. Scalia also found that the Federal Circuit's decision was not contradicted by the other provisions of § 271(e), § 271(e)(2) and e(4), that are clearly to be used only in the context of the FDA drug approval process.[84] "No interpretation we have been able to imagine can transform §271 (e) into an elegant piece of statutory draftsmanship." So, in order to save the statute from its own inconsistencies, and to keep Congress from looking like they didn't know what was going on, Justice Scalia had to make a "drug" be more than drug.[85]

3.4. Hoechst Aktiengesellschaft v. Quigg[86]

Hoechst owned a patent on the drug pentoxifylline,[87] which was issued on June 5, 1973. It then submitted an NDA with the FDA, but did not receive approval for the drug until August 30, 1984, more than ten years after the patent had issued. On October 29, 1984,

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[80] *Id.* at 668.
[81] *Id.* at 669.
[82] Both parties seek to enlist legislative history in support of their interpretation, but that sheds no clear light. *Id.*
[83] *Id.*
[84] *Id.* at 678.
[85] For more on the interpretation of section 271(e), *see* James M. Flaherty Jr., *Article: PMA Primacy: Synthesizing the 35 U.S.C. § 156 Patent Term Extension, 35 U.S.C. § 271(e)(1) Patent Infringement Exemption as Currently Applied to Medical Devices, and Medical Device Preemption Jurisprudence to Yield a Cohesive Solution Regarding Scope of Coverage,* 56 Food Drug L.J. 339 (2001); David J. Bloch, *ARTICLE: If It's Regulated Like a Duck... Uncertainties in Implementing the Patent Exceptions of the Drug Price Competition and Patent Term Restoration Act,* 54 Food Drug L.J. Ill (1999); Brian D. Coggio and Francis D. Cerrito, *ARTICLE: THE APPLICATION OF THE PATENT LAWS TO THE DRUG APPROVAL PROCESS,* 52 Food Drug L.J. 345 (1997).
[86] Hoechst Aktiengesellschaft v. Donald J. Quigg$_i$ 917 F.2d 522 (Fed. Cir. 1990).
[87] The tradename for pentoxifylline was Trental.

Hoechst applied for a patent term extension under 35 U.S.C. §156. The PTO rejected the application, stating that the drug had not been subject to a regulatory review period within the meaning of the statute, §156(a)(4). Hoechst then appealed the Commissioner's decision in federal district court, which determined that the language of the statute was ambiguous, and that the legislative history did not show evidence of Congress' intent to provide patent extension to Hoechst's patent.[88]

The Federal Circuit reversed the decision of the district court, and granted Hoechst a 6.8-year extension on its patent covering pentoxifylline! In examining the issue of whether or not pentoxifylline underwent a regulatory review period under the definition of the statute, the court looked to the definition in sec. 156(g)(1).

The language at issue is sec. 156(g)(1)(A): to which the limitation described in paragraph (6) applies. Paragraph (6) defines three limitations. For patents issued after the date of the statute's enactment, an extension could be no longer than five years. If the patent issued before the date of enactment and no request for extension under (1)(B) was submitted *before* the date of the statute's enactment, the extension granted could be for no longer than 5 years. For patents that had issued before the act's enactment, but had not received approval as of the day of enactment, the extension was limited to two years. However, these three limitations did not cover the situation presented by Hoechst's patent, where the patent issued, the drug received approval before the date of enactment, and the request for approval came *after* the Act's enactment. The PTO argued that since this wasn't covered in paragraph (g)(6), Congress did not allow for a patent term extension. Hoechst argued that Congress's failure to place a cap on the length of term extensions for the Trental patent and the small number of other drug patents which received FDA approval shortly before the Act's passage, was simply an oversight.[89]

The Federal Circuit determined that it was unclear that Congress intended not to limit the extensions to drugs that had received approval shortly before the enactment of the Act. The legislative history is silent on this issue.[90] But it determined that Congress' intentions were clear in defining a regulatory review period and consequently awarding a patent term extension. Under the Federal Circuit's reading of the statute, the granting of a patent term extension and the limiting of a patent term extension were two totally separate

[88] Hoechst Aktiengesellshaft v. Quigg, 724 F.Supp. 398 (E.D. Va. 1989).
[89] *Hoechst,* 917 F.2d at 525.
[90] *Hoechst* 917 F.2d at 529.

Legislative history explicitly indicating that no patent term extension be greater than five years has no bearing on how Congress intended to define a regulatory review period under the Act. Whether a drug has undergone a regulatory review period and the related patent is eligible for a term extension and how that extension should be limited are two completely different issues.[91]

As a result, Hoechst not only received a patent extension, but a bonus as well!

Although we are convinced that the plain language of the statute and the relevant legislative history mandate that a term extension be given to the '433 patent, we acknowledge that a 6.8 year term extension is a windfall for Hoechst that was probably not contemplated by Congress. Indeed, the undisputed fact that Congress wished to limit the maximum term extension to five years is what motivated the Commissioner to deny Hoechst a term extension in the first place. Nevertheless, 'it is not for us to distort the statute to 'fix' what Congress either intentionally or inadvertently failed to anticipate.'[92]

A pretty bizarre result, given that the court seems to have found clear legislative intent that Congress did not want to grant extensions to patents for more than five years.

3.5. SmithKline v. Watson Pharmaceuticals[93]

SmithKline obtained FDA approval to market its patented nicotine gum, Nicorette, on January 13, 1984, for prescription-only use at a 2 mg dosage. On June 8, 1992, SmithKline received approval from the FDA to market Nicorette at 4 mg for prescription use only, and on February 9, 1996, for over-the-counter use at the 2 mg and 4 mg dosages. SmithKline was able to receive a three-year period of exclusivity pursuant to 21 U.S.C. § 355(c)(3)(D)(iv), due to the additional clinical testing done on Nicorette.

In conjunction with the marketing of Nicorette, SmithKline developed a user's guide and audiotape, which was submitted to FDA for approval. The tape and guide became part of Nicorette's FDA-approved OTC labeling. SmithKline registered a federal copyright for the guide and audiotape script on April 21, 1998, and on February 9 (the last day of its three-year exclusivity period), SmithKline registered a copyright for the words and music for the tape.

After the three-year exclusivity period had passed, Watson submitted an ANDA to the FDA to obtain marketing approval for a generic version of Nicorette. In order to comply with

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[91] *Id.*
[92] *Id.*
[93] Smithkline Beecham Consumer Healthcare, L.P. v. Watson Pharmaceuticals, Inc., 211 F.3d 21 (2nd Cir. 2000)

the provision of the DPC-PTR Act, Watson had to submit a user's guide and audiotape that were virtually identical to the ones that are packaged with Nicorette. SmithKline then initiated a copyright infringement action, alleging willful infringement of its guide and tapes. SmithKline was able to obtain a preliminary injunction from a federal district court, enjoining Watson from infringing on its copyrighted label for Nicorette.[94] The FDA was asked by Watson and the district court for its opinion on the issue. The FDA initially held that there was enough leeway that could be used in the labeling to avoid copyright issues, but then reversed itself and said that under the statutes that govern it, the labeling had to be almost identical, while also stating that it was not empowered by Congress to deal with copyright concerns in drug labeling. Because of this, the court subsequently found that the balance of the hardships of an injunction would fall upon Watson, so the court dissolved the injunction.[95] SmithKline then received a stay and an appeal from the 2nd Circuit Court of Appeals.

We do not doubt that SmithKline has demonstrated the existence of substantial issues under the copyright laws, at least when they are considered in isolation... Absent more, the propriety of a preliminary injunction would seem clear.[96] The court therefore rejected Watson's implied license and fair use arguments. However, the court found that the FFDCA mandated that since generic drug producers are required to use the same label as the pioneer drug, it must be allowed to do so, even if the label has been copyrighted. Because those Amendments were designed to facilitate rather than impede the approval and OTC sale of generic drugs, the FDA's requirement that Watson use much of SmithKline's label precludes a copyright infringement action by SmithKline.[97] In doing so, the court looks explicitly to the principle purposes of each in making its interpretation. Congress would have provided explicitly that the Hatch-Waxman Amendments trump the copyright laws had it foreseen the statutory conflict exposed by the present action… we firmly believe that to be obvious.[98]

Therefore, Appellees cannot be liable for copyright infringement because the Hatch-Waxman Amendments require generic drug producers to use the same labeling as was

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[94] SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc., 63 F. Supp. 2d 467, 473 (S.D.N.Y. 1999).
[95] SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc., 1999 U.S. Dist. LEXIS 19677, No. 99 Civ. 9214, 1999 WL 1243894, at 5-7 (S.D.N.Y. Dec. 22, 1999).
[96] *SmithKline,* 211 F.3d at 25.
[97] *Id.* at 25.
[98] *Id.* at 29.

approved by the FDA for, and is used by, the producer of the pioneer drug.[99]

If nothing else, this case illustrates the extreme measures that research-based and generic drug companies have taken in attempts to protect or increase their market share.

CONCLUSION

India's pharmaceutical industry has evolved from almost non-existent to a world's leader in the production of high-quality, low-cost non-branded or generic drugs, accounting for nearly 20 percent of the world's production. India currently produces almost all its own drug needs and domestic companies control over 80 percent of the Indian market. It has made tremendous strides over the last two decades as the Indian domestic market almost doubled in value during 2000 - 2006. Because of low barriers to entry and low capital requirements, there are tens of thousands of companies producing pharmaceuticals in India. The vast majority of them are small by Western standards with revenues of less than $5 million.

With the re-introduction of product patents in 2005 and the fiercely price competitive nature of the Indian pharmaceutical industry, many smaller, less competitive producers were forced to abandon the industry as it begins slowly shifting away from vanilla generic drugs to becoming a regional hub for R&D, drug discovery, contract manufacturing, and technology licensing. In this transition, many mid-level Indian producers will turn to contract manufacturing, outsourcing, contract research, contract clinical trials, or other tie-ins with MNCs. Some Indian sources predict that MNCs will make up 60 percent of the Indian market by 2015.[76]

Since 2005, many MNCs began re-entering the Indian pharmaceutical market by setting up their own manufacturing and R&D facilities. This will gradually neutralize the cost advantages enjoyed by Indian pharmaceutical majors. These alliances and millions of dollars spent on establishing domestic and foreign-based manufacturing facilities, acquiring foreign drug manufacturing firms, as well as marketing and sales networks, will enable India's leading pharmaceutical producers to re-direct large sums of their cash flow to R&D and move up the value-added chain. These foreign acquisitions will enable Indian companies to gain a foothold in Western regulated markets, diversify their portfolios, acquire recognized brands, and gain R&D capabilities.

The United States has some of the highest drug prices in the world and has attracted

[99] *Id.* at 23.

imports of generic drugs from India and a number of low-cost countries. However, severe price compression and growing competition from other low-cost countries is forcing Indian majors to offset their losses by shifting their attention to Western Europe. Nonetheless, Indian companies have made tremendous strides in the U.S. market and companies like Ranbaxy are major sources of generic drugs. Indian companies also enjoy comparative advantages in cost, strength in reverse engineering skills, and number of U.S. FDA approved plants located in India. Indian companies have spent millions of dollars filing AND As with the U.S. FDA to gain exclusive production rights for many drugs losing their patent protection in the United States. Continued price competition in the U.S. market will mean cheaper prices for generic drugs and greater choice for U.S. consumers.

The Drug Price Competition and Patent Term Restoration Act was an uneasy union between two groups with an open distrust for one another. The changes made by the DPC-PTR weakened patent law and created complications in the interpretation of the statute. It also made an economic concern the driving force behind an amendment of the FFDCA rather than safety and effectiveness concerns. In hindsight, it may have been better for Congress to have passed patent term restoration, and allow FDA to issue regulations pertaining to ANDAs on its own. But despite the seriousness of the DPC-PTR, perhaps it is possible to look back on it now and laugh a little at some of the results.