



A Look at The Drug Price Competition and Patent Term Restoration Act of 1984

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A Look at The Drug Price Competition and Patent Term Restoration Act of 1984 (2002 Third Year Paper)

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A “Lighthearted” Look
at
The Drug Price Competition

and
Patent Term Restoration Act
of 1984

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Combined Third-Year Paper/
Final Paper for Food and Drug Law (Winter 2001)
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I. INTRODUCTION

The Hatch-Waxman Act is significant to the U.S. healthcare system in many important respects. The robust generic drug industry owes its very existence to the Act, and patent term extensions or restorations are very important to the research-based pharmaceutical industry.¹ The Drug Price Competition and Patent Term Restoration Act of 1984 (DPC-PTR Act), also known as the Hatch-Waxman Act,² achieved many of its goals. Generic drugs became a major force in the pharmaceutical industry, quickly penetrating into the marketplace.³ Shortly after the enactment of the Act, a generic drug could capture thirty percent of the market in a single year after the expiration of a branded product's patent.⁴ One startling example of this was Naprosene. Three months after the patent on Naprosene, seventy-five percent of its market share was lost to the generic product.⁵ Research companies, in losing their exclusive markets for off-patent drugs, were pushed into increased research and development to search for new and more profitable drugs. "For research-intensive companies, the incentive of longer patent protection... has led to a large increase in the commitment to research in pharmaceuticals."⁶

The DPC-PTR Act was a piece of legislation that was fought over bitterly by the generic and research-based industries, and passed only when a tenuous balance was reached through last-minute negotiations.

¹Gerald J. Mossinghoff, *SYMPOSIUM ISSUE—STRIKING THE RIGHT BALANCE BETWEEN INNOVATION AND DRUG PRICE COMPETITION: UNDERSTANDING THE HATCH-WAXMAN ACT: Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 Food and Drug Law Journal 187, 194 (1999).

²Named after Representative Henry A. Waxman of California and Senator Orrin Hatch of ... Also known as the Waxman-Hatch Act.

³Peck, *supra* note 3, at 542. The generic industry went from under a billion dollars in sales before the passage of the DPC-PTR Act in 1984 to approximately \$5 billion in sales in 1986. For more on how the DCT-PTR Act has affected the drug industry, see the Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, CBO Study, (July 1998). For background on the economics of competition in pharmaceuticals before the enactment of the DPC-PTR Act, see MEIR STATMAN, *COMPETITION IN THE PHARMACEUTICAL INDUSTRY: THE DECLINING PROFITABILITY OF DRUG INNOVATION* (1983).

⁴Jonathan C. Peck, *The Long-Term Effects of Recent Legislation on the Drug Industry*, 43 Food Drug Cosmetic Law Journal 541, 5422 (1988).

⁵Mossinghoff, *supra* note 1, at 191.

⁶Peck, *supra* note 3, at 542

One indication of the controversial nature and sensitivity of the coalition was that there is almost none of the usual legislative history to this bill. There are no Senate reports, for example, and floor statements were extremely limited and dealt with only a small number of technical points. To really understand the intent of this legislation, one almost had to be there as it was negotiated.⁷

The passage of the legislation did not stop the two sides from feuding with each another. This naturally led to litigation. But due to the incomplete legislative history, ambiguous language of the Act, and the imaginative theories of the lawyers for the opposing drug companies, the courts have had to wrestle with the conflicting language and principles of the Act. With many millions of dollars often at stake, the outcomes of these cases were important to both innovators, copiers, and consumers. However, in spite of the seriousness of the matters that the DPC-PTR Act influenced, some of the opinions that resulted from litigation on the Act are perplexing. This paper will provide a general history of the passage and the first few years of the Drug Price Competition and Patent Term Restoration Act of 1984, and will examine the contrast between the serious nature of the Act and some of the “humorous” judicial opinions that resulted from it.

II. BACKGROUND

A. PATENTS

Patent law seeks to penetrate the very essence of human nature in that it appeals to a certain primal behavioral characteristic: it offers potential financial reward as an inducement to invent, to disclose, or to invest.”⁸ Patent law attempts to balance the creation of innovation with the dissemination of innovation. In exchange for publicly disclosing and teaching others how to practice a new innovation, the public grants the innovator exclusive rights to make, use, and sell the innovation for a limited period of time.

1. Justifications for Patents

The most widely accepted justification for patents in the United States is the consequentialist or utilitarian justification, which focuses on the consequences of patent law on the public welfare.⁹ Utilitarianism holds that by granting property rights to an inventor for a limited period of time, an incentive is created for individuals to invent. Although the public is temporarily burdened this monopoly, the net utility of the community is maximized, due to the increased innovation that will eventually become available for use.¹⁰

There are at least four types of incentives that patent law uses to spur innovation.¹¹ By allowing an investor to recoup the costs of invention through monopoly rights, an incentive to invest is created. Patent protection

⁸DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 1 (1998).

⁹Indeed, the predominant justification for American intellectual property law has been, without question, utilitarianism or consequentialism. The patent and copyright clause of the Constitution itself... can be read as predominantly utilitarian in nature. *Id.* at 46.

¹⁰The other major justification for patents is the deontological or natural rights justification, where the purpose of patent law is to protect the rights of the inventor, irrespective of the effects on public welfare. This justification is based in large part on Locke’s natural rights labor theory. *Id.* at 35-45.

¹¹*Id.* at 62.

give inventors an incentive to disclose their invention in a patent instead of relying on trade secret protections. Patents also give third parties an incentive to commercialize products and bring to market inventions that might otherwise be deemed too risky to invest in. Finally, by giving exclusive rights to one party to practice a particular invention, patent law creates an incentive to design-around the patent, thereby further spurring innovation to create new inventions.¹²

2. History of Patent Law

The modern patent system has its roots in Renaissance Italy, where the first patent statute was enacted in the Venetian Republic on March 19, 1474, and had many of the same requirements that modern patent statutes mandate.¹³ The system of patents spread quickly through Europe, due largely to the migration of Venetian artisans and craftsman.¹⁴ Patents became a way to attract foreign knowledge and to foster innovation in domestic industries.

The system of granting exclusive rights for inventions also made its way to England. However, the abuse of granting importation franchises and other monopolies as political favors led Parliament to enact the Statute

¹²These incentives were recognized by the Supreme Court. First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions, to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public. *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979).

¹³We have among us men of great genius, apt to invent and discover ingenious devices; and in view of the grandeur and virtue of our city, more such men come to us every day from diverse parts. Now, if provision were made for the works and devices discovered by such persons, so that others who may see them could not build them and take the inventor's honor away, more men would then apply their genius, would discover, and would build devices of great utility and benefit to our commonwealth. Therefore:

Be it enacted that, by the authority of this Council, every person who shall build any new and ingenious device in this City, not previously made in our Commonwealth, shall give notice of it to the office of our General Welfare Board when it has been reduced to perfection so that it can be used and operated. It being forbidden to every other person in any of our territories and towns to make any further device conforming with and similar to said one, without the consent and license of the author, for the term of 10 years. And if anybody builds it in violation hereof, the aforesaid author and inventor shall be entitled to have him summoned before any magistrate of the City, by which magistrate the said infringer shall be constrained to pay him hundred ducats; and the device shall be destroyed at once. It being, however, within the power and discretion of the Government, in its activities, to take and use any such device and instrument, with this condition however that no one by the author shall operate it. 6, Giulio Mandich, *Venetian Patents (1450-1550)*, 30 J. Pat. Off. Soc'y 166, 176-177 (1948).

¹⁴CHISUM, *supra* note 8, at 12.

of Monopolies in 1624. This statute declared all monopolies as void with the exception of patents granted to those who practiced a manner of new manufacture. which became the foundation of the British patent system. This system in turn shaped the development of patent law in the American colonies.

Patents in the colonies were initially granted by the individual states. After the Revolutionary War, the individual states still retained the power to grant patents under the Articles of Confederation. However, the framers of the Constitution saw the need for a unified federal patent system. Congress was therefore given the power [t]o promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.¹⁵

The first patent statute was the Patent Act of 1790.¹⁶ It designated a patent board, which examined patent applications to see if the invention or discovery was important enough to warrant a patent. In 1793 the examination system was replaced by a registration system, which did not examine the applications, opening the door for deception and fraud. The 1836 Patent Act reintroduced the requirement that a patent application be examined for novelty¹⁷ and utility.¹⁸ In 1850 the Supreme Court's decision in *Hotchkiss v. Greenwood*¹⁹ added the nonobviousness requirement to the list of requirements that an invention.²⁰

Congress, in more recent times, has made changes to the patent statute when the decisions made by courts do not offer enough protection. The 1952 Act responded to the weakening of patent protection that had been occurring as a result of the negative attitudes of the Supreme Court towards patents. This Act once again make patents an important incentive for American inventors and companies.²¹ In 1982 Congress, reacting to the inconsistencies in patent doctrine amongst the various circuit courts, established the Federal Circuit Court of Appeals, for the purpose of unifying patent law in the United States.²² Today, patents are critical

¹⁵Art. 1, Sec. 8, Clause 8.

¹⁶Act of Apr. 10, 1790, ch. 7, 1 Stat. 109.

¹⁷The innovation must not have been practiced before in the country. See 35 U.S.C. §102.

¹⁸The invention must be useful. See 35 U.S.C. §101.

¹⁹*Hotchkiss v. Greenwood*, 52 U.S. 248 (1850).

²⁰The invention must not be obvious to a person who is of ordinary skill in the field of the invention. See 35 U.S.C. §103.

²¹CHISUM, *supra* note 8, at 22-23.

²²*Id.* at 23-25.

assets to companies involved in new technologies, and have been a major driving behind the great advances in technological innovations over the past few decades.

3. Obtaining a U.S. Patent

To obtain a patent on a new invention, an inventor submits an application to the Patent and Trademark Office (PTO) that includes a disclosure, or description, of the invention and specific claims as to what is being patented. The application then undergoes an examination process where the PTO determines whether or not the invention meets the statutory requirements to be granted a patent. The invention must meet the requirements of novelty, utility, and non-obviousness. The description is scrutinized to make sure that it sufficiently describes the invention and allows others to practice the invention once the patent expires.²³ The application must also have at least one claim, which specifies what the invention is that the applicant is requesting a patent for.

Prior to the enactment of the DPC-PTR Act, the term of a patent for all inventions was 17 years from its date of issuance.²⁴ An inventor had to file an application for a patent within a certain time period after knowledge of the invention becomes public.²⁵ This requirement prevented the unnatural lengthening of the term of a patent.

²³The disclosure must 1) be sufficient in detail to teach others how to practice the invention without undue experimentation (enablement), 2) disclose the best method known to the inventor of practicing the invention (best mode), and 3) be sufficient in detail to show others that the patent holder possess the invention (written description). See 35 U.S.C. §112.

²⁴The 17-year term for patents was changed as a result of the Uruguay Round Agreements of 1994. The Trade-Related Aspects of Intellectual Property Agreement (TRIPS) led to a harmonization of the term for U.S. patents with that of the international community. For patent applications filed on or after June 8, 1995, the length of a patent term is now 20 years from the date of filing the patent application.

²⁵A person shall be entitled to a patent unless... (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States... 35 U.S.C. §102(b).

4. Rights That a Patent Provides

A patent confers upon its holder the right to exclude others from practicing the invention for the term of the patent; others are not allowed to make, use, sell, or offer to sell the invention within the United States without permission from the patentee.²⁶ Patentees can bring cases for damages as well as injunctive relief to stop infringers from practicing the claimed invention. Cases involving patent issues are litigated in federal district courts, with all appeals going to the Federal Circuit Court of Appeals.

Patents within the pharmaceutical industry are particularly valuable.²⁷ The nature of the industry is one where there are very large initial costs for research and development, but subsequent manufacture of the drug is relatively inexpensive, and therefore the ability to copy the drug by others is low. Research-based pharmaceutical companies have relied upon the protection provided to them by patents to charge higher prices on their drugs in order to recoup their initial investments in R & D. The revenue from a blockbuster drug must also cover the investment made in the hundreds of other compounds that went through various stages of testing but did not reach the commercial market.

Patents for pharmaceuticals are also very controversial. Many find the idea of corporations profiting on monopolistic prices for drugs to be unethical, especially for life-saving medications. Prescription drugs are also largely consumed by the elderly, who tend to have more trouble coping with the higher prices of patented drugs. In fact, many countries have resisted granting patents on drugs, or have compulsory licenses that

²⁶35 U.S.C. §271.

²⁷At no time in history has there been greater public expectation that the science and technology community will devise solutions to dietary, health, environmental, and other problems. It is to this community that the public and public officials look for the prevention or cure of heart disease, cancer, and AIDS, for better biodegradable materials, for more efficient energy use, etc.

This clamor for new technology comes at a time when there is public resistance to higher taxes, which are necessary to support high levels of government spending on research and development. Universities and private firms must rely increasingly on private financing for both basic and applied research, which may be unavailable without the prospect of financial return to which patents can contribute. DONALD S. CHISUM AND MICHAEL JACOBS, UNDERSTANDING INTELLECTUAL PROPERTY 1-2, n. 1 (1992).

allow generic drug companies to manufacture copies of life-saving drugs at a reduced cost.

B. FOOD AND DRUG LAW

The adulteration of the food supply is an ancient problem. For centuries consumers often had to look out for themselves. Today, the governmental regulation of the food supply protects the consumer against fraud; prevents the sale of unsafe foods; and informs the consumer about nutrition. It has also expanded to cover not only foods, but drugs, food additives, and medical devices.

1. History of FDA

Formerly the Chemical Division of the U.S. Department of Agriculture, the Food and Drug Administration (FDA) regulates the safety of foods, and the safety and efficacy of drugs, medical devices, and biologics.²⁸ Throughout its history FDA has had essentially the same assignment: to assure that the products it regulates are safe and truthfully labeled.

In response to the growing need for a uniform national regulation of the food supply, the 1906 Act was enacted, which forbade interstate commerce in adulterated and misbranded foods and drugs. The Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA), responding to the deaths caused by Elixer Sulfanilamide, required a premarket review of drugs before they were able to enter the market.²⁹ This Act, as well as its amendments, kept this basic format of the 1906 Act but enlarged the scope of the legislation with new definitions of adulteration and misbranding.³⁰

²⁸PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 5 (2^d ed. 1991).

²⁹*Id.* at 476.

³⁰*Id.* at 12.

2. Regulation of Drugs

The worldwide scare caused by thalidomide in the middle of the 20th century brought about the 1962 Drug Amendments. These amendments made the regulation of drugs the single most controversial, and perhaps the most important, of FDA's activities.³¹

a. Pre-1962 Approval Process

The 1938 Act looked primarily to see if a drug was labeled falsely or in a misleading manner. To implement the provisions of the statute, FDA used a system by which applications for the approval of new drugs were allowed to become "effective." In 1942, in order to reduce the volume of work, FDA began to distinguish new drugs from old drugs. Manufacturers of old drugs could obtain an opinion letter from FDA (or alternatively, make their own determination) that their product was considered generally recognized as safe (GRAS), if an NDA was in effect for a version manufactured by another company. A new drug that received an NDA became known the pioneer, and all the subsequent versions of the drug became known as generic or me-too drugs.³²

b. The 1962 Drug Amendments

The Drug Amendments of 1962³³ transformed the system of premarket notification into one that required individual premarket approval of the safety and effectiveness of every new drug submitted to FDA. FDA began the process of inserting the efficacy requirements into the approval process by extending the definition

³¹*Id.* at 13.

³²*Id.* at 477-478.

³³Pub. L. No. 87-781, 76 Stat. 780 (1962).

of a new drug to comprise drugs not generally recognized as safe and effective. The data reporting requirements of the new drug approval procedure were amended to require submission of data showing efficacy, and a positive act of approval was now required to approve an NDA.

FDA was required to refuse approval of any NDA if, after notice and opportunity for hearing, it was determined that on the basis of information submitted that there was a lack of substantial evidence that the drug would have the effect that it claimed to have. FDA could withdraw approval of any drug after notice and opportunity for hearing if it was found that substantial evidence of efficacy was lacking after reviewing the new information presented. The FDA could also withdraw approval of a NDA if there was an imminent hazard to health.³⁴

c. Post-1962 NDAs

The post-1962 process for obtaining FDA approval of a new drug is long, time-consuming, and expensive. The sponsor of a new drug first spends several years determining the few compounds out of thousands that merit additional research. Preclinical data on the chemistry, pharmacology, and toxicology of the compound is then gathered and submitted to FDA in a Claimed Exemption for an Investigational New Drug, or IND. If the IND is not rejected, clinical studies in humans is initiated.

There are three phases of clinical testing. Phase I involves only a few healthy subjects to test for adverse effects. Phase II then examines if there are actual therapeutic effects when the drug is administered to patients with the disease to be treated. Phase III calls for administering the drug to hundreds of patients to detect adverse effects, potential interactions with other drugs, etc. If the drug passes all three phases

³⁴HUTT, *supra* note 28, at 476-477.

successfully, the data is gathered into a New Drug Application (NDA) and submitted to FDA for approval. FDA then makes a determination as to the safety and effectiveness of the drug and whether the benefits of the drug outweigh the risks. Only after FDA approves the NDA can a manufacturer begin to market the drug.

The period of time it took for a new drug to move from the filing of an IND to final NDA approval had been steadily increasing. Meanwhile, the term of the patent, which is usually issued well before the NDA is submitted, is effectively shortened by the approval process.

d. The Problem with Generics

As stated above, the 1938 Act did not require FDA to affirmatively approve NDAs, but rather allowed them to become effective. When the Drug Amendments of 1962 were enacted, they required FDA to review all NDAs that had become effective in the past twenty-four years to determine if they met the new effectiveness standards. In 1966, manufacturers submitted information on their drugs to the National Academy of Science (NAS) to review their effectiveness.³⁵ In 1968 FDA announced that it would apply the findings from the studies to the me-too versions of the pioneer drug, and the pre-1962 opinion letters on old drugs were withdrawn. An abbreviated NDA was created, which required information only on biological availability and manufacturing controls.

Due to the backlog of abbreviated NDAs, FDA informally began to allow the marketing of me-too drugs upon submission of an abbreviated NDA, without having to wait for formal approval. It then proposed regulations that would not require an NDA or abbreviated NDA for me-too drugs that were generics of a pioneer drug that had passed the DESI program. This issue was brought to the Supreme Court, where it was

³⁵ *Id.* at 477-483.

determined that the Act's definition of drug includes inactive as well as active ingredients, and so therefore every generic is required to submit an NDA or abbreviated NDA if there is any significant difference with the pioneer.³⁶

Essentially, a generic manufacturer was able to file an abbreviated NDA for a generic version of a pre-1962 pioneer drug that had passed the new approval requirements. However, the FDA insisted that a full NDA be submitted for any generic version of a post-1962 new drug. Because data from the pioneer NDAs was considered confidential and were not disclosed to the public³⁷ (and therefore to generic manufacturers), the only way to submit a full NDA was to conduct clinical testing. In 1978, FDA announced that it would accept a paper NDA that used published information on the pioneer's safety and effectiveness, but only a small fraction of drugs would have sufficient data published on them for generics to use in a paper NDA. Thus, in many cases, generic drugs were effectively excluded from entering the market and competing with pioneer drugs.³⁸

³⁶United States v. Generic Drug Corp., 460 U.S. 455 (1983).

³⁷Exemption 4 of the Freedom of Information Act. 5 U.S.C. §552 (1982).

³⁸HUTT, *supra* note 28, at 484-485.

III. HISTORY OF THE ACT³⁹

A. The Basic Dilemma

This Act [the DPC-PTR Act] resulted in part from two unintentional effects of FDA's implementation of the 1962 drug amendments. On the one hand, the stringent efficacy requirements of the '62 amendments resulted in a substantial loss of patent life during the lengthy period necessary for FDA to review a new drug application (NDA). On the other hand, because it became so difficult to obtain an NDA, the NDA itself provided a form of exclusivity, a type of patent in fact, a result that stymied the development of generic pharmaceuticals.⁴⁰

These undesired changes in the effective patent term became known as the front-end and back-end distortions, respectively. There were over 150 drugs that were "off-patent" and had no generic competition. FDA had been working on implementing regulations that would have allowed generics to finally enter the market of drugs that had gone off-patent, but was running into constant delays. If this happened without an increase in the effective patent term, it would have seriously cut into the revenue of the owners of these drugs, hampering innovation from the pioneer drug companies.

B. Attempts at Patent Restoration

In 1978 President Carter initiated a domestic policy review of industrial innovation, the goal of which was to stimulate jobs, improve the balance of trade, and improve other economic conditions.⁴¹ Several of the advisory subcommittees recommended lengthening the patent term to make up for time consumed in governmental regulatory requirements. The effective life of a patent for a pharmaceutical product had been steadily decreasing, to the point where it became clear that less than half the patent life remained by the

³⁹For a more complete description of the events that led to the enactment of the Drug Price Competition and Patent Term Restoration Act, See Alan D. Lourie, *Patent Term Restoration*, 66 *Journal of the Patent Office Society* 526 (1985); Fox, *supra* note 7. The Annotated Bibliography provides a compilation of the legislative predecessors of the Act.

⁴¹Lourie, *supra* note 39, at 526-7.

time the average drug product was approved for marketing.⁴²

In response, Congressman Symes of Ohio introduced H.R. 3589 in 1979. This simple bill proposed to set the expiration date of a patent for a human or animal drug to be 17 years after approval to market the drug or 27 years from the issuance of the patent, whichever came first. The Chemical Manufacturers Association (CMA) and Pharmaceutical Manufacturers Association (PMA) also started working on the problem. This produced S. 2892, introduced in 1980 by Senators Bayh, Thurmond, Mathias, Morgan, and Percy, and H.R. 7952, by Congressmen Kastenmeier and Sawyer.

The bill defined a regulatory review period for human and animal drugs⁴³, beginning from the filing of documents with the regulatory review agency and ending with the grant of approval to market the product. In attempting to reduce opposition to the bill, the promoters did not try to overreach. The bill provided for a maximum extension of 7 years, and the total effective life of the patent could not exceed 17 years; patents covering chemical products and processes were covered, but not processes of manufacture. Furthermore, the extension did not cover all compounds of the involved patent or claim, nor all uses.⁴⁴ The system was administratively simple, merely requiring review by the PTO of data on the regulatory delay before extension of the patent. However, no action was taken on the bill due to the schedule, so the issue was pushed to the next Congress.

On Jan 27, 1981, S. 255, sponsored by Senator Mathias et al., was introduced. It was very similar to previous bill. However, one change was made to extend patent term extension to any type of product subject to premarket regulatory review. This was done to bring in as much support as possible for the bill from other interest groups. The bill also limited the amount of extension available to products already in the process of regulatory review. S. 255 was passed by full Senate in a voice vote on July 9, 1981.

⁴²*Id.* at 527.

⁴³The bill also defined a regulatory review period for medical devices, food and color additives, pesticides, and chemicals regulated under the Toxic Substances Control Act.

⁴⁴Known as the Kodak Amendment, under the reasoning that a compound should not receive lengthened patent protection for use as a drug and for other uses. Lourie, *supra* note 39, at 528.

In the House, H.R. 1937 was introduced by Congressmen Kastenmeier and Sawyer. But opposition had arisen from generic drug manufacturers, retired persons groups, and public interest groups, who testified against the bill at the hearings on the bill.⁴⁵ This led to the request for the Office of Technology Assessment to study the matter. Its report, in 1982, confirmed that patent extension could encourage the development of new drugs through incentives provided to the patent owner.⁴⁶

A clean bill, H.R. 6444, was reported out to the subcommittee on Courts, Civil Liberties, and the Administration of Justice. Among the amendments were further restrictions on the amount of patent extension that could be granted, including the Kastenmeier prospectivity amendment No. 5, which precluded extension of patents granted prior to the enactment of the bill. Process patents were also made eligible for extension, provided there wasn't a patent on the product as well that had been extended. The bill was reported out to the full Judiciary committee, and then to the House floor on July 28, 1982. A combination of intense lobbying and unusual circumstances on the day of voting left the bill short by 5 votes on Sept. 15, 1982.⁴⁷

C. ANDA Legislation

The patent term restoration bill had been defeated through the efforts of Representative Waxman, chairman of the health subcommittee of the House Committee on Energy and Commerce. Waxman wanted to pass legislation that would allow generics to obtain FDA approval quickly, *i.e.* via abbreviated NDAs.⁴⁸ He introduced H.R. 3605 on July 19, 1983. The bill removed the requirement that evidence of safety and efficacy need to be submitted to FDA for a generic version of a drug, as long as met the same standards of

⁴⁵Lourie, *supra* note 39, at 530.

⁴⁶*Id.* at 530.

⁴⁷*Id.* Bad weather that day prevented some congressmen who were in favor of the bill from getting to Washington to cast their votes, and the rules committee did not allow for a second vote.

⁴⁸*Id.* at 533.

identity, strength, quality, purity, stability, bioavailability, and bioequivalence as the pioneer drug.⁴⁹

Duplicates of the patent term bill that had passed the Senate in 1981, S. 1306 and H.R. 3502, were also introduced during this time. The two sides began talks in an attempt to bring about a compromise that would combine the two bills. The Pharmaceutical Manufacturers Association (PMA)⁵⁰ and the Generic Pharmaceutical Industry Association (GPIA) became the two main advocates, respectively, for the research-based industry and the generic companies.⁵¹

D. The Waxman Drafts

In January 1984, a compromise in principle was agreed upon by both parties. It called for a maximum restoration period of 5 years, and the total effective life for a patent could not be extended beyond 14 years. There would only be a 2 year restoration available for drugs already in the process of regulatory approval. Furthermore, only one patent per product could be extended, and diligence must have been used to pursue regulatory approval.

Generic products were to be approved as long as they were shown to be bioequivalent to the pioneer drug. As a concession to the research based industry, several exclusivity periods were provided. There was to be a 10-year delay before any ANDA could be approved for a generic version of a drug that was first approved between January 1, 1982 and the enactment of the bill (a pipeline drug). There was also to be a 4-year period when ANDAs could not be approved for unpatentable products.

Most importantly, the court decision in the recently decided *Pfizer v. International Rectifier*⁵² was to be

⁴⁹*Id.*

⁵⁰For more on the PMA, see WILLIAM C. CRAY, THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION: THE FIRST 30 YEARS (1989).

⁵¹*Id.*

⁵²*Pfizer v. International Rectifier*, 217 U.S. P.Q. 157 (C.D.Cal. 1982).

reversed. This case held for the first time that it was patent infringement to conduct research and testing when the patent was still effective, even if the data was not submitted to FDA until after the patent term expired. Waxman strongly felt that a patent holder should not be entitled to the additional exclusivity that would result from delaying the studies required to obtain approval from the FDA.⁵³

1. The First Waxman Draft

The first Waxman draft was produced on April 4, 1984. The research-based industry was not pleased with it for a number of reasons. The major source of discontent was the issue of evergreening. Generic companies contended that pioneer drug companies would procure multiple product, process, and use patents on the same drug, over a period of years. This, in effect, lengthened the time in which a product would enjoy exclusivity under a patent. The pioneer companies argued that multiple patents on a drug resulted from continued invention and innovation, and that subsequent patents with new claims did not preclude others from using inventions claimed in the earlier, expired patents.⁵⁴

The anti-evergreening provisions in the first Waxman draft prevented extension of a patent where the product was disclosed or claimed in an earlier issued patent, no matter who owned the patent or what country the patent was issued from. Additionally, new use patents were not eligible for extension, and process patents could only be extended if there was no prior patent on the compound, the method of use, or the preparation process. Furthermore, there would be no patent extension if the patent covered any earlier approved product. A mandatory diligence review was also required for patent extension requests.

While the first Waxman draft had much that the research-based companies were unhappy about, it made

⁵³Insistence on this point would lead to much controversy and difficulty in the coming months. Lourie, *supra* note 39, at 535.

⁵⁴“Already, it has been noted that companies have a disincentive for research into small but real improvements in drug formulation or delivery for existing products.” Peck, *supra* note 3, at 543.

it relatively easy for generic companies submitting ANDAs to get approval. The FDA was not allowed to require proof of safety and efficacy, and a second ingredient in a combination was allowed to be varied upon petition. An ANDA applicant would certify when the relevant patent would expire, and would not receive approval until after that date. However, the generic companies wanted to be able to challenge patents that it felt were invalid. If the generic applicant certified that a relevant patent was invalid or infringed by sale of the generic product, approval would be deferred for only 30 days to give the patent owner time to go to court and enforce their patent through a preliminary injunction.

This remedy was not acceptable for the research-based companies. Preliminary injunctions normally require a showing that the patent is valid beyond question, a very difficult standard to meet without prior adjudications of validity or evidence of acquiescence by others to the patent's validity. The Waxman bill would have allowed ANDAs to be submitted and approved soon after a pioneer drug's NDA had been approved, giving little time for these types of evidence to exist. Retroactively pulling the generic from the market after years of litigation would not remedy the considerable harm to the pioneer drug's market share in the interim.

2. The Second Waxman Draft

A second draft came into being on April 25. Disclosure in foreign patents were no longer a bar to patent extension. Furthermore, extension was no longer barred by the mere disclosure of a compound in a prior patent, but a generic claim was. This was a problem due to the procedural nature of obtaining patents and restriction requirements in the PTO. The diligence review was no longer mandatory, only occurring on petition.

To address the concerns of the research-based industry regarding the approval of ANDAs, a patent owner

would have 60 days instead of 30 to defer approval of an ANDA by either 1) seeking a preliminary injunction through the court system, or 2) using the PTO's reexamination process to determine whether the allegations raised a substantial new question on patentability. The ANDA would be delayed until 1) a preliminary injunction was denied by the court, or 2) when the PTO determined that there was no new question of patentability and a declaratory judgment by the patent owner was ruled in favor of the challenger. However, this offer by the drafters was also undesirable to the research-based industry. The addition of a 180-day period of exclusivity for the first successful challenger to an invalid patent also made the research-based industry feel as if they were being specifically targeted.

A few days before the second draft came out, the recently-created Federal Circuit decided *Roche v. Bolar* (*Roche-Bolar*),⁵⁵ which made the decision in *Rectifier* the national rule of law. Pre-patent expiration activities conducted for the purpose of obtaining data for submission to a federal regulatory agency now constituted infringement. The research-based companies were now even more unwilling to accept the compromise bill.

3. The Third Waxman Draft

The drafters working on the bill now had to deal with the new Federal Circuit decision. The solution devised by the Waxman staff was to reverse the holding in *Roche-Bolar* only to the extent that a generic company had no intent to commercialize the drug before the patent expiration date, but only conducted formerly infringing activities for the purpose of gathering information for FDA approval. This intent would be shown by the notice that a generic manufacturer gave to a patentee indicating the nature of the patent certification submitted to the FDA. If the generic company stated that the patents were valid, then the ANDA would be approved after the date the patent expired.

⁵⁵*Roche Prods. Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984).

However, if a generic company wanted to challenge patents that it felt were invalid or not infringed upon, the ANDA applicant's notice would state their intent to obtain marketing approval prior to the patent's expiration date. The drafters then defined this act to be an infringement of the patent, which would then allow the patent owner to bring suit. Approval of an ANDA would be delayed until the litigation between the two parties was finished.

This type of action was highly structured; the process described in the statute was the only one available, and venue for the declaratory judgment action was limited to the principal place of business for the defendant or a regular and established place of business.⁵⁶ The trigger date for litigation was to begin with the submission of an ANDA, with an 18-month period of delay in ANDA approval. The anti-evergreening statutes were also changed so that a prior generic patent claim of another party would not preclude extension of a patent on a later compound, but a later-use patent could not get an extension.

H.R. 3605 was then reported out by the Energy and Commerce Committee as the Drug Price Competition and Patent Term Restoration Act of 1984. Senators Hatch, Mathias, Kennedy, and DeConcini sponsored the comparable Senate bill, S. 2748.

4. Dissention in the PMA

⁵⁶For more on the venue provisions of the Act, see John C. O'Quinn, *NOTE: THERE'S NO PLACE LIKE HOME: FINDING PERSONAL JURISDICTION IN ANDA PATENT CASES AFTER ZENECA V. MYLAN PHARMACEUTICALS*, 13 Harv. J. Law & Tec 129 (1999).

By June many felt that a workable compromise had finally been reached.⁵⁷ There were hearings in the House on June 27, 1984. PTO Commissioner Gerald J. Mossinghoff objected to the remaining anti-evergreening provisions of the bill, and urged that Congress not overturn *Roche-Bolar*. He argued that these provisions weakened the United States' arguments to other countries that they should improve their patent protections. Mossinghoff also felt that the act would impose a significant burden upon the PTO. The next day, hearings were held in the Senate, with the Acting Commissioner of FDA, Dr. Mark Norvitch, objecting to certain parts of the ANDA provisions as burdensome to FDA. At the hearings, representatives of the PMA and GPIA stated that the bill was the best compromise that could be accomplished under the circumstances.

However, the PMA was divided, with many of the dissenting companies being among the industry leaders.⁵⁸ These companies felt that the bill was deficient in its anti-evergreening provisions, and were unhappy with the partial reversal of Roche-Bolar. Six of the leading dissenting companies attempted to stall the legislation to little avail.⁵⁹ These companies then began intensive lobbying efforts in Congress to defeat the bill.⁶⁰

A mark-up session on June 25 had the PTO, through Representative Moorhead, offer up several amendments addressing its concerns. All these amendments were struck down, as Kastenmeier, although he felt that the amendments did have some merit, did not want to upset the balance achieved by the parties involved. Amendments offered by the dissenting companies were also defeated. This did not stop them from continuing their lobbying and negotiation efforts. At this point there were eleven dissenting companies, who combined

⁵⁷Philip M. Boffey, *Accord May Lead to Cheaper Drugs*, N.Y. Times, June 2, 1984, at 1.

⁵⁸An industry source said the opponents included such giants as Hoffmann-La Roche Inc., Merck Sharpe & Dohme, the Bristol-Myers Company, Johnson & Johnson, E.R. Squibb & Sons Inc., the Ciba-Geigy Corporation, the Schering-Plough Corporation, the A.H. Robins Company, the American Cyanamid Company and the American Home Products Corporation. Id.

⁵⁹Irvin Molosky, *Big Drug Makers Fail to Stall Bill Aiding Generics*, N.Y. Times, June 8, 1984, at D2.

⁶⁰Martha M. Hamilton, *Bill Widening Availability to Generic Drugs Advances*, The Washington Post, June 13, 1984, at F1.

conducted about 50 percent of the research and development done in the pharmaceutical industry, therefore standing to lose the most from laws allowing generic drugs faster access to the market.

Intense negotiations with the dissenting companies led to the following last-minute changes in the bill.⁶¹ The default delay in the approval of an ANDA while a patent infringement suit was ongoing was extended from 18 months to 30. Most of the anti-evergreening provisions were deleted. A patent holder was now allowed to choose which patent they wanted to extend, and were not limited to just the first. There was a new provision that limited extension to one patent per regulatory review period.

A significant victory for the research companies was the inclusion of several new exclusivity periods. These new exclusivity periods for pioneer drugs were awarded independently from any patent term restoration, and even drugs that were unpatentable were able to get some exclusivity protection on the market.

There is no legislative history of these negotiations, and many criticized the way in which the deal was struck. Kastenmeier charged that the big brand-name drug companies had gained concessions as a "result of negotiations taking place in the back rooms of the Senate."⁶² He also stated that "[t]he agreement is not the result of thoughtful consideration but the result of a backroom deal of two branches of the drug industry."⁶³ However, this bill, S. 2926, with its new amendments was introduced to the Senate on August 10, 1984, and passed with only one dissenting vote.

In the House, Waxman insisted that one of the exclusivity provisions, the 5-year exclusivity provision, be changed to 4 years when the applicant is challenging the original NDA holder's patent. His intention was to allow a generic to enter the market more quickly should the patent be invalid or non-infringing. For the

⁶¹Martha M. Hamilton, *Drug Companies Lobby to Revise Compromise Bill*, The Washington Post, July 29, 1984, at G1.

⁶²Irvin Molotsky, House Endorses Measure Aiding Low-Cost Drugs, N.Y. Times, Sept. 7, 1984, at A1.

⁶³*Id.*

most part, though, little change was made, to avoid upsetting the tenuous balance that had been achieved. Some unrelated provisions were added,⁶⁴ and then the bill was passed by a 362-0 vote on September 6th. The Senate passed the House version by voice vote on Sept. 12, and President Reagan signed the bill on Sept. 24, 1984.

D. An Uneasy Compromise

The overwhelming vote in favor of passage should not be construed as near unanimous and unconditional support for the Act. It seems that many were afraid that any changes to the final compromise would be the death of the bill. In the debate on Sept. 6, 1984, over the change from the delay in approval of an ANDA from 18 months to 30 months, Waxman made the following comments in opposition to an amendment attempting to change the period back to 18 months: [T]he change from 18 months to 30 months was a change agreed upon as part of a package to bring along all of the groups that were interested in this legislation.⁶⁵

There were many, including members of the PMA⁶⁶ and Congress, who were unhappy with the partial

⁶⁴A textile labeling amendment was added to the bill.

⁶⁵Cong. Rec. of September 6, 1984, at H9115. Responding to an attempt to amend the bill, Waxman continued with the following explanation:

I must tell you that while we may want the legislative process to be only Congressmen and Senators discussing the issues on a certain academic, intellectual level, there is a practical level by which people deal in day-to-day life. And the pharmaceutical manufacturers had an enormous amount of distrust with the generic manufacturers, the feeling that they may challenge a lot of patents that were quite valid. And the distrust ran the other way as well....

The 18-month figure was a compromise. It was a compromise that brought onboard the Pharmaceutical Manufacturers Association along with the generic drug groups.

The change from 18 months to 30 months was a change that brought on the dissident groups within the PMA and has brought us to a package new that we can say with confidence is opposed by no one and backed by all of the groups concerned because their definition of reality has been redefined by virtue of this process having taken place... I appreciate the significance of the legislative process, but let us not elevate procedure over substance.

What we have here is substantively a very good bill in the public interest. The public will benefit twice; by the further incentive for research and development for new, innovative drugs and by the immediate reduction in drug prices when a generic is on the market as a competitor.

That is a very worthwhile objective for this Congress to accomplish. Cong. Rec. of September 6, 1984, at H9118.

⁶⁶Not all the research-intensive companies approved the compromise, particularly for having to cede the victory in Roche v.

reversal of *Roche v. Bolar*. Representative DeWine stated that [t]he Bolar decision is sound law and in my opinion should be retained... whether or not [the reversal of the Bolar decision] is constitutional, it seems to me it is bad public policy and should be rejected by this Congress.⁶⁷ Representative Moorhead remarked:

[T]he proposed reversal of Roche against Bolar, especially if done retroactively, is clearly in conflict with the position which the United States has advocated internationally... I would like the record to show: that there are some of us including the administration who strongly believe that that [sic] reversal of the Bolar case is not good policy. But I will nonetheless vote in favor of the compromise.⁶⁸

Perhaps the feelings of many of the parties involved was best summed up by Senator Metzenbaum: I still have reservations. I still have concerns. I will not oppose this legislation. I am not at all certain that the Senate, when it passes it his evening, will be doing the right thing, but I will not stand in the way of the passage.⁶⁹ Apparently, [t]he political appeal of a bill purporting to reduce senior citizens' expenses proved irresistible in an election year.⁷⁰

Bolar... Donald G. Daus, *Patent Term Restoration: New U.S. Legislation*, 83 Patent and Trademark Review 81, at 86 (1985).

⁶⁷Cong. Rec. of August 8, 1984, at H8710.

⁶⁹Cong. Rec. S10506 (daily ed. August 10, 1984)..

⁷⁰Daus, *supra* note 66, at 86.

IV. THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT

The DPC-PTR is not a simple piece of legislation. The following provides a brief overview of the result of the compromises agreed upon in the 98th Congress.⁷¹

The Act has three titles. Title I amends the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §355. Title II amends the Patent Statute. Title III is an unrelated amendment pertaining to the labeling of certain textiles and will not be discussed.

A. Title I

Title I of the Drug Price Competition and Patent Term Restoration Act amended the Federal Food, Drug, and Cosmetic Act (FFDCA).⁷²

1. ANDAs

Section 102 amends 21 U.S.C. §505 to allow for the creation of an abbreviated new drug application (ANDA) for the approval of a new drug.⁷³ For generic drugs that are the “same” as a pioneer drug that has been previously approved by the FDA, information is to be provided that eight requirements are met:

⁷¹For a more comprehensive look at the Act, see Ellen J. Flannery and Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosmetic Journal 269 (1985).

⁷²21 U.S.C. 355.

⁷³21 U.S.C. 355 §505(j).

- 1) All the indications that the generic drug is seeking approval for must have been approved for the pioneer drug.
- 2) All the active ingredients of the generic drug are the same as those in the pioneer drug
- 3) The route of administration, the dosage form, and the strength of the generic drug are the same as the pioneer.
- 4) The generic drug must be bioequivalent to the pioneer, defined in Section 505(j)(7)(B).
- 5) The labeling must be the same, except for the manufacturer.
- 6) Must have full list of components, full statement of the composition of the drug, full description of the manufacturing processes, samples, and specimens of the labeling.
- 7) Applicants must certify, with respect to any patents which cover the pioneer drug, 1) there is no patent, 2) the patent has expired, 3) the date a relevant patent will expire, or 4) that the applicant feels the patent is invalid or will not be infringed by the generic drug.
- 8) If there are use patents that cover the pioneer, applicant must state that approval is not being sought for the uses covered by the patent.

The FDA cannot require that information other than that specified in the statute to be submitted.⁷⁴

For drugs that are “different” from the pioneer drug, the applicant must first submit a petition to file an ANDA under section 505(j)(2)(C), demonstrating that the generic drug does not need to be submitted to the full NDA standards for human and animal safety and effectiveness studies. An ANDA that is submitted after approval of the petition must then meet the above eight requirements, as modified to accommodate the differences between the active ingredients.

If the applicant choose to request an approval date for its ANDA which precedes the expiration date of the pioneer drug, the patent owner and pioneer NDA holder must each be notified at the same time the

⁷⁴The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii). Sec. 505(j)(2)(A).

ANDA is submitted. As long as one patent is challenged, the notice provisions are triggered. As long as an infringement suit is brought on one patent, the thirty-month period where an ANDA cannot be made effective is invoked.

There are eleven reasons why the ANDA should disapproved:

- 1) If the methods and controls used to manufacture the drug are inadequate;
- 2) If there is inadequate information that each of the conditions that the drug will be used for have been previously approved for the listed drug;
- 3) If the active ingredient or ingredients is not the same as the listed drug, unless a petition for the difference has been granted;
- 4) If there is inadequate information that the route of administration, dosage form, or strength is different than the listed drug;
- 5) If the generic differs from the listed drug and the FDA does not receive additional information requested in addition to the petition,
- 6) If there is a failure to show bioequivalence with the listed drug;
- 7) If the proposed labeling for the generic is not shown to be the same as the listed drug;
- 8) If any of the inactive ingredients is shown to be unsafe;
- 9) If the listed drug has been withdrawn or suspended for reasons of safety or effectiveness;
- 10) If it does not meet all of the eight requirements listed in section 505 for an ANDA; and
- 11) If it contains untrue statements of material fact.

The FDA should approve or disapprove of the ANDA within 180 days of the receipt of the application. If the applicant certified according to paragraph (i) or (ii), then the approval can be effective immediately. A paragraph (iii) approval is made effective on the date that the patent expires.

An approved application with a paragraph (iv) certification is made effective immediately, unless an action is brought by the patent owner for infringement within 45 days of the receipt of the notice. If the action is brought, then approval shall be made effective in 30 months, or another period that the court decides upon. If the patent is declared invalid, the approval is effective immediately. If the court decides the patent is infringed, the approval is made effective subject to 35 U.S.C. 271(e)(4)(A). If the court issues a preliminary injunction before the expiration of the 30 month period, the approval shall be made after the court decides the patent is invalid or not infringed. No action can be made for a declaratory judgment with respect to the patent during the 45 day period.

2. Exclusivity Periods

Section 505(j)(4)(D) denotes five types of exclusivity for pioneer drugs after the approval of a pioneer NDA or supplemental NDA.⁷⁵

⁷⁵This provision applies to non-prescription over the counter drugs as well as prescription drugs. An attempted amendment to remove OTC drugs from the scope of the exclusivity provisions was defeated. *See* Cong. Rec. of Sept. 6, 1984 at H9120-H9125.

- 1) ANDAs for New Chemical Entities (NCEs) that have pioneer NDAs approved between Jan. 1, 1982 and Sept. 24, 1984 cannot be made effective until ten years after the date of approval of the pioneer NDA;
- 2) ANDAs for NCEs that obtain approval after Sept. 24, 1984 have exclusivity until five years after approval, unless a paragraph (iv) challenge is made to the patent on the drug, at which point the exclusivity is for four years;
- 3) ANDAs for generic versions of post-enactment non-NCEs cannot be approved until three years after the date of approval for a pioneer NDA;
- 4) Supplemental NDAs get three years of exclusivity, regardless of whether the drug was an NCE or not;
- 5) Non-NCE drugs approved between Jan. 1, 1982 and Sept. 24, 1984 get two years of exclusivity.

3. Pioneer NDAs, paper NDAs, and Trade Secret Information

Section 102 added new requirements for NDAs. Section 505(b) now requires NDA applicants to identify all relevant patents associated with the NDA. The FDA publishes approved NDAs with their associated patents.⁷⁶

Under the amended section 505(c), any pioneer NDAs approved or filed before the enactment of the bill must also have any relevant patent information submitted for publication.

A failure to submit patent information was made grounds for disapproval of a NDA under Section 505(d), but remedy can be made by submitting the information. An NDA can also be withdrawn if patent information is not submitted (Section 505(e)).

⁷⁶This published listing of drugs and their patents became known as the Orange Book.

Section 103 deals with paper ANDAs. Section 505(b)(2) now defines paper NDAs, which allow the submission of information on the safety and effectiveness of the drug from studies not conducted by the applicant. Paper NDAs are submitted under the same provisions as full NDAs, and must be submitted with certifications as to any relevant patents. FDA should treat paper NDAs in a similar manner as it treats ANDAs.

Section 104 of the act adds Sections 505(l) and (m) to the FDCA. Section 505(m) defined the patents referred to in the Act as being U.S. patents only. Section 505(l) codified FDA's existing regulations regarding the disclosure of safety and effectiveness data.⁷⁷ There are five circumstances under which information relating to safety and effectiveness submitted in an NDA are disclosed to the public:

- 1) the NDA has been abandoned;
- 2) the FDA determines that the NDA is not approvable and appeals have been exhausted;
- 3) if approval has been withdrawn and all appeals are exhausted;
- 4) the drug that is subject to the NDA is not a new drug; and
- 5) upon the effective date of an ANDA, or the date when an ANDA could be made effective if one had been submitted.

The loss of trade secret protection was a big concern amongst the major research companies. Representative Bliley was also concerned with reducing America's competitiveness with foreign companies:

⁷⁷130 Cong. Rec. S10,988-89 (daily ed. Sept. 12, 1984).

The bill reported by the Committee provides for the public disclosure of all of the extensive and costly research data generated by research-oriented pharmaceutical companies, even though those safety and effectiveness data may be of significant value to foreign competitors... By providing for the release of these data, the bill hands to foreign competitors of U.S. drug firms, for the mere price of photocopying charges, data which cost many millions of dollars to obtain and which can be sued to obtain approval to market drugs in competition with the owner and generator of the data. This provision of H.R. 3605 is hardly the way to protect and improve the competitiveness of America's pharmaceutical industry.⁷⁸

However, Representative Waxman replied that this scenario is highly unlikely, and that the FDA would have the discretion to withhold information that it felt was justified in being kept confidential:

In commenting on the FDA's proposed regulation, several commenters addressed this same point and argued that such data were trade secrets and should be withheld. The FDA reviewed those arguments and in the preamble of the regulations said 'none of the comments submitted demonstrated an likelihood that the full reports of such information, as contrasted with summaries, are required under foreign law in order to justify marketing abroad.'... However, the FDA said that extraordinary circumstances might justify denying disclosure if a 'specific instance arise[s] in which a competitive advantage can be demonstrated in concrete terms.' Section 104 of the bill adopts this same approach.⁷⁹

Under Section 105 of the Act, FDA must promulgate regulations implementing the act within one year of enactment. Section 105(b) provides interim procedures until the new regulations are enacted. Post 1962 ANDAs and paper NDAs can be submitted using the same process as pre-1962 applications. Furthermore, no ANDAs can be submitted until 60 days after the enactment of the Act (Nov. 23, 1984).

Finally, Section 106 of the Act amended 28 U.S.C. §2201, limiting actions brought with respect to drug patents to the ones described in section 505 of the FFDCA.

B. Title II

Title II of the 1984 Act made two major amendments to the patent statute. The first amendment was to add a new section, section 156, that allowed for the extension of the patent term for patents that covered

products subject to regulatory review.

The second amendment added a new subsection to section 271, the section on infringement, which 1) reversed the Federal Circuit decision in Roche-Bolar, and 2) defined the submission of an ANDA under paragraph IV to be an act of infringement.

1. Patent Term Restoration

Section 201 adds section 156 to the patent statute. It provides for the restoration of part of the patent term lost to FDA premarket drug testing and approval for human drugs, food additives, color additives, and medical devices.

Section 156(a) allows for extension product, use, and process patents are eligible to be extended, provided they meet the following requirements: 1) the patent has not expired; 2) the patent had not previously been extended; 3) a patent extension application is properly submitted; 4) the product was subject to regulatory review prior to commercial marketing or use; and 5) the particular commercial marketing or use must be the first marketing or use permitted by the regulatory statute, or the first use of the product manufactured by the process that is patented. However, processes that use recombinant DNA are not subject to this first permitted commercial marketing or use limitation.

Section 156(b) limits the rights that are extendable to either 1) the approved uses of the product for a product patent, 2) the approved uses and the claims of the patent for method patents, or 3) the methods of manufacture for process patents.

Section 156(c) limits the length of the patent extension granted to be equal to the length of the regulatory review period and also provides the formula for determining the length of an extension.

Section 156(d) outlines the procedure for submitting an application for extension, and requires that due diligence must be used. Under Section 156(e) the PTO is to make its determination solely upon application.⁸⁰

Section 156(f) gives the definitions for the terms used in the statute, and Section 156(g) provides the formula to be used for determining the length of the regulatory review period.

⁸⁰This provision is intended to reduce the administrative burden on the PTO.

2. “Artificial” Infringement

Sec. 202 of the Act amended section 271 of the patent statute so that the act of making, using, or selling a patented invention solely for uses reasonably related to the development of information to be submitted under a Federal law which regulates the manufacture, use, or sale of drugs.⁸¹ The enactment of this provision overturned the Federal Circuit’s decision in Roche-Bolar. Sec. 271(e)(3) prohibits the patent holder from seeking relief from actions that fall under 271(e)(1). Sec. 271(e)(2) makes it an act of infringement to submit an ANDA or paper NDA to FDA that challenges the validity of a patent (a paragraph (iv) ANDA submission). The exclusive remedy for a 271(e)(2) infringement is found in Sec. 271(e)(4).

As Justice Scalia describes it, The function of [Sections 271(e)(2) and (4)] is to define a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications.⁸² Scalia explained how the new provisions work in further detail:

This scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement. And that was precisely the disability that the new §271(e)(1) imposed, with regard to use of his patented invention only for the purpose of obtaining premarketing approval. Thus, an act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by §271(e)(2)- the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent. Not only is the defined act of infringement artificial, so are the specified consequences, as set forth in paragraph (e)(4). Monetary damages are permitted only if there has been ‘commercial manufacture, use, or sale,’ 35 U.S.C. § 271(e)(4)(C). Quite obviously, the purpose of (e)(2) and (e)(4) is to enable the judicial adjudication upon which ANDA and paper NDA schemes depend.⁸³

⁸¹35 U.S.C. 271(e)(1).

⁸²Eli Lilly and Company v. Medtronic, Inc., 496 U.S. 661, at (1989).

Sec. 203 of the Act amends Section 282 of the patent statute, so that patent term extensions that were granted due to a failure by the applicant or the Commissioner to comply with the requirements for extension are an affirmative defense to actions of infringement if the action is brought during the extended period.

V. POST-ENACTMENT

“This act is the most important statute affecting the drug industry since 1962. While the new law strikes a balance between increased patent protection and increased competition from generic drug products, it remains to be seen whether this balance is as even as Congress and the industry intended. This will become clear only after its implementation, and thus the law’s full impact may not be felt for several years.”⁸⁴

As illustrated above, the parties on both sides were not completely satisfied with the DPC-PTR Act, and also had a great deal of distrust for each another. The passage of the Drug Price Competition and Patent Term Restoration Act did not end the battling between the patent owners of pioneer drugs and the generic drug industry and their supporters.

A. “Serious” Actions After Enactment

In the time immediately following the passage of the DPC-PTR Act, the coalition that was formed to pass the Act fell apart. Generic drug manufacturers moved quickly to enter the market, and the pioneer drug companies did what they could to stop them.

The pioneer drug manufacturers were accused of attempting to slow down the approval process by swamping the FDA with paperwork. Critics point to the number of petitions that have been filed by brand-name companies as the reason for the slowdown in FDA approval of generics.⁸⁵ One example of this alleged behavior that critics pointed to was Hoffman-LaRoche’s submission of a petition to the FDA two days before its patent on Valium expired, objecting to the FDA’s guidelines for determining whether the generic drugs are the therapeutic equivalent of Valium. Hoffman-LaRoche asserted that a study by another company

⁸⁴Flannery, *supra* note 71, at 309.

⁸⁵Sari Horowitz, *New Law Stimulating Generic-Drug Market; Certification Process Simplified*, Washington Post, June 28th, 1985, at B2.

that compared generic versions with Valium found that the other drugs didn't work as effectively as Valium. The critics said that the Hoffman-LaRoche petition and other similar actions were merely attempts to delay generic-drug approval by requiring the same FDA personnel who would be approving generic-drug applications to examine and answer the petitions.⁸⁶

The lack of public knowledge also caused problems for generics attempting to enter the market. Many consumers did not know enough about generic drugs in order to make informed decisions.

“Consumers, in general, are confused about generics, according to AARP. In a national survey of about 1,000 consumers over age 45, 60 percent said they knew what a generic drug was. Of that group, 19 percent said they thought that brand-name drugs were required by the FDA to meet higher standards than generics, while 7 percent said they didn't know. Twenty-five percent thought that only a few generics had been found by the FDA to be equivalent to brand-name drugs, while 12 percent said they didn't know.”⁸⁷

Furthermore, the major pharmaceutical manufacturers were aggressively marketing their drugs to doctors, hinting that the quality of generic copies was not as safe or effective, or at the least, that it would be ill-advised to switch patients from a pioneer drug to a generic.⁸⁸

Representative Waxman, responding to these tactics, felt betrayed by the major pharmaceutical companies. Once the law was signed, the companies broke their commitments and launched an aggressive anti-generic campaign... They are spending millions of dollars on false and misleading advertising to raise doubts in the minds of physicians, pharmacists and consumers about the safety and effectiveness of generic drugs.⁸⁹

At this time there were also industry-wide increases in the prices of many pioneer drugs. “A . . . less benign effect of the 1984 legislation may be that the price of new drugs will be dramatically higher. . .”⁹⁰ This should have been seen as a natural outcome of the changes made to the law. “In part, the increased prices

⁸⁶ *Id.*

⁸⁸ Tamar Lewin, *Drug Makers Fighting Back Against Advance of Generics*, N.Y. Times, July 28, 1987, at A1.

⁸⁹ Sandy Rovner, *Cheaper Pills an Ocean Away; Rising Costs in U.S. Blamed on Research Expenses, Patent Protections*, Washington Post, July 10, 1985, at Health 7.

⁹⁰ Peck, *supra* note 3, at 544.

will reflect higher research costs. . . However, the Waxman-Hatch Amendments have put additional pressure on companies to price breakthrough products aggressively.”⁹¹

Members of the PMA cited the increasing costs of research and the need for readjustment that had been delayed. Critics came back with attacks that the increased cost was due to increased advertising and profiting, at the expense of the ill and elderly. Waxman stated that “one can only conclude that what is going on in this industry is greed on a massive scale.”⁹² In 1985 he called hearings on the issue of the sharply increasing costs in pharmaceuticals.⁹³

The research-based pharmaceutical companies were not the only ones criticized for abusing the changes in the law. In 1989, it was revealed that several generic drug companies had paid off FDA officials to expedite the approval of ANDAs they had submitted to the agency.⁹⁴ While there was no actual harm done to the health of the public, the scandal rocked the industry and FDA, setting off a flurry of internal reform and the re-emergence of active congressional oversight.

Many felt that Congress had placed too much emphasis on the speed of the generic approval process, sacrificing safety considerations.⁹⁵ The 1984 amendments, and Congress’ many signals to the FDA on their implementation, established a system that made the scandal perhaps not inevitable, but, in retrospect, at least probable.⁹⁶ The DPC-PTR had changed the basic nature and role of the FDCA and FDA. The

⁹¹Peck, *supra* note 3, at 544.

⁹²Associated Press, *Prescription Drug Costs Up 56% Since ‘81*, Los Angeles Times, July 16, 1985, at 1-1.

⁹³Associated Press, *House seeks Rx for Drug Prices Firms Reject Charges of ‘Greed’*, Chicago Tribune, July 16, 1985, at C4.

⁹⁴Larry Thompson, *How Safe ar the Drugs You Take, Scandal at FDA Raises New Questions About Generic Medicines*, Washington Post, August 22, 1985, at Z12.

⁹⁵Bruce N. Kuhlik, *The Origins of the Generic Drug Scandal and Proposed Amendments to the Federal Food, Drug, and Cosmetic Act*, 45 Food Drug Cosmetic Law Journal 385, 386 (1990).

⁹⁶*Id.* at 387.

DPC-PTR was mainly concerned with economical issues, instead of safety and effectiveness considerations. “Unlike other major amendments to the Act, the Hatch-Waxman Amendments have had more to do with economics than with safety and effectiveness... the Food and Drug Administration... was having to arbitrate purely competitive interests for essentially the first time.”⁹⁷

B. “Humorous” Interpretations by the Courts

On August 10, 1984, Senator Metzenbaum made the following remarks:

[T]here are many people asking what this bill is all about: what it means; how do you interpret it. Let me say, for one, that I interpret it in only one manner. Nobody can change the language of the legislation. It speaks for itself. So notwithstanding anybody who may feel that they can interpret the language of this legislation in one way or another, I want the courts to understand that the legislation speaks for itself and the interpretation which anyone may make on the floor does not really add anything to that interpretation.⁹⁸

Unfortunately, Senator Metzenbaum may be the only one who felt this way. Courts and others attempting to resolve controversies over interpretation of the Act will confront complex and often ambiguous statutory language. Their task of statutory construction will not often be facilitated by the legislative history, which is relatively sparse and fails to elucidate some of the Act’s key provisions.⁹⁹ The task is further complicated since the two principle purposes of the Act, to increase patent protection while also opening up the market to competitors, are in conflict with one another.

The following is a summary of some of the unusual and quirky decisions that resulted from litigation involving the DPC-PTR Act.

⁹⁷*Id.*

⁹⁹Flannery, *supra* note 71, at 271.

1. *Glaxo v. Quigg*¹⁰⁰ and *Abbott Laboratories v. Young*¹⁰¹

Glaxo was the assignee of a patent ('320 patent) for cefuroxime 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. Cefuroxime 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 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."¹⁰²

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

¹⁰⁰*Glaxo Operations UK Limited v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990).

¹⁰¹*Abbott Laboratories v. Young*, 920 F.2d 984 (D.C. Cir. 1990).

¹⁰²*Glaxo*, 894 F.2d at 396

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.”¹⁰³

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.”¹⁰⁴ The dissent criticizes the majority decision, agreeing with the Federal Circuit in *Glaxo* that the “plain language” of the statute should be controlling.

¹⁰³ *Id.* at 985.

¹⁰⁴ *Abbott*, 920 F.2d at 989

So apparently, the drafters of the DPC-PTR were able to make the term “active ingredient” ambiguous and straightforward at the same time!¹⁰⁵

2. *Eli Lilly v. Medtronic*¹⁰⁶

This litigation was initiated over the scope of 35 U.S.C. §271(e)(1). 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 FFDCFA, 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)(1).

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

¹⁰⁵As 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).

¹⁰⁶*Eli Lilly and Company v. Medtronic, Inc.*, 496 U.S. 661 (1989).

is hard to believe the convoluted manner petitioner suggests was employed would have been selected.”¹⁰⁷ 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 noninfringement be whether the use is 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?”¹⁰⁸

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.”¹⁰⁹ Although the Court found little guidance in the legislative history,¹¹⁰ the Court affirmed the Federal Circuit’s decision based upon “the structure of the 1984 act taken as a whole.”¹¹¹

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.¹¹²

“No interpretation we have been able to imagine can transform §271(e) into an elegant piece of statutory

¹⁰⁷ *Id.* at 667.

¹⁰⁸ *Id.* at 668.

¹⁰⁹ *Id.* at 669.

¹¹⁰ “Both parties seek to enlist legislative history in support of their interpretation, but that sheds no clear light. *Id.*

¹¹¹ *Id.*

¹¹² *Id.* at 678.

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.¹¹³

3. Hoechst Aktiengesellschaft v. Quigg¹¹⁴

Hoechst owned a patent on the drug pentoxifylline,¹¹⁵ 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, 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.¹¹⁶

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).

¹¹³For 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); Samuel M. Kais, *NOTE: A SURVEY OF 35 U.S.C. 271(e)(1) AS INTERPRETED BY THE COURTS: THE INFRINGEMENT EXEMPTION CREATED BY THE 1984 PATENT TERM RESTORATION ACT*, 13 Computer & High Tech. L.J. 575 (1997); 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. 111 (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).

¹¹⁴Hoechst Aktiengesellschaft v. Donald J. Quigg, 917 F.2d 522 (Fed. Cir. 1990).

¹¹⁵The tradename for pentoxifylline was Trental.

¹¹⁶Hoechst Aktiengesellschaft v. Quigg, 724 F.Supp. 398 (E.D. Va. 1989).

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.¹¹⁷

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.¹¹⁸ 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 issues.

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.¹¹⁹

¹¹⁷ *Hoechst*, 917 F.2d at 525.

¹¹⁸ *Hoechst*, 917 F.2d at 529.

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.'¹²⁰

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.

4. *SmithKline v. Watson Pharmaceuticals*¹²¹

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 audiotope, 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 audiotope 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

¹²¹Smithkline Beecham Consumer Healthcare, L.P. v. Watson Pharmaceuticals, Inc., 211 F.3d 21 (2nd Cir. 2000)

marketing approval for a generic version of Nicorette. In order to comply with 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.¹²²

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.¹²³ 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.¹²⁴ The court therefore rejected Watson's implied license and fair use arguments.

However, the court found that the FDCA 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.¹²⁵ 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

¹²²SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc., 63 F. Supp. 2d 467, 473 (S.D.N.Y. 1999).

¹²³SmithKline 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).

¹²⁴*SmithKline*, 211 F.3d at 25.

¹²⁵*Id.* at 25.

trump the copyright laws had it foreseen the statutory conflict exposed by the present action,... we firmly believe that to be obvious.¹²⁶

Therefore, Appellees cannot be liable for copyright infringement because the Hatch-Waxman Amendments require generic drug producers to use the same labeling as was approved by the FDA for, and is used by, the producer of the pioneer drug.¹²⁷

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.

¹²⁶ *Id.* at 29.

¹²⁷ *Id.* at 23.

VI. CONCLUSION

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 FDCA 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.