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NOTE

A GENERIC DRUG PRICE SCANDAL: TOO BITTER A PILL FOR THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT TO SWALLOW?

*Joseph P. Reid**

I. INTRODUCTION

In 1984, with health care costs rising astronomically, Congress drafted and enacted the Drug Price Competition & Patent Term Restoration Act (the Act).¹ The Act was written with two goals in mind: to reduce health care costs by making generic drugs available more rapidly, and to foster new innovations in drug treatment by granting back patent protection for time lost during the process of drug approval by the Food and Drug Administration (FDA). Once hailed as “the most important consumer bill of the decade,”² more recently the Act has been criticized repeatedly. First, corruption was discovered within the FDA.³ Then, the Act was chastised after some medical groups questioned the benefit of generic drugs for certain categories of patients,⁴ and again when the passage of the General Agreement on Tariff and

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1 Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 28, 35 U.S.C.). The Act is also known as the Hatch-Waxman Act after its two co-sponsors, Republican Sen. Orrin Hatch (Utah) and Democratic Rep. Henry Waxman (Cal.).

2 *Pharmaceutical Patent Issues: Interpreting GATT: Hearings on S. 1277 Before the Senate Judiciary Comm.*, 104th Cong. 93 (1998) (prepared statement of Sen. Orrin Hatch) (quoting an unnamed source).

3 See *infra* Part III.A.

4 See *infra* Part III.B.

Trade (GATT) led to confusion and controversy over changes in the patent system.⁵ However, in 1996, the Senate Judiciary Committee, led by the Act's co-sponsor, Senator Orrin Hatch, pronounced the Act healthy after hearings into its viability.⁶

That diagnosis, predicated primarily on the Act's successes in cost containment, may have been premature however. In December of 1998, following a year in which the prices of some generic drugs increased 3000%,⁷ the Federal Trade Commission (FTC), joined by ten states, brought a \$120 million suit against Mylan Laboratories, Inc. (Mylan) and three other drug companies for antitrust violations.⁸ In light of this latest development, this Note reexamines the Act to determine whether it is as healthy as pronounced by Congress, or whether it has failed to meet either or both of its goals. Part II of this Note begins with a brief discussion of the history and status of the American patent and health care systems leading up to 1984, followed by a detailed review of the Act's provisions. Part III will touch on each of the historic challenges to the Act, and how the Act survived or was amended, and Part IV will describe the current conditions which call the Act into question. Part V will conclude that, if the cost containment function continues to erode as it did in *Mylan*, we will no longer be able to afford, literally or figuratively, the loss of pharmaceutical innovation and the corresponding risks to societal health which the Act induces.

II. THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT'S EFFECTS ON THE AMERICAN PATENT AND HEALTH CARE SYSTEMS

A. *The Patent System Before 1984*

The power of Congress to establish the patent rights of inventors is drawn directly from the United States Constitution, which authorizes Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . inventors the exclusive Right to their respective . . . Discoveries."⁹ Using this power, Congress first

5 See *infra* Part III.C.

6 See *infra* Part III.D.

7 See *Definitely a Cause of Anxiety*, L.A. TIMES, Dec. 24, 1998, at B8.

8 See Complaint for Injunctive and Other Equitable Relief at 1, Federal Trade Comm'n v. Mylan Lab., Inc. [hereinafter FTC Complaint]. The complaint is available at the FTC webpage (visited Jan. 8, 1999) <http://www.ftc.gov/os/1998/9812/mylancomp.htm> (copy on file with Journal).

9 U.S. CONST. art. I, § 8, cl. 8.

recognized patents in 1790,¹⁰ and then created the Patent Office to review patent submissions in 1836.¹¹

In 1952, Congress significantly revamped the patent laws.¹² Under this scheme, which applies in large part today, inventors submit applications to the Patent and Trademark Office (PTO), which reviews them.¹³ Each application contains a description of the invention,¹⁴ with the inventor articulating the patent's scope.¹⁵ The application is then examined for how it meets three statutory requirements: novelty, usefulness, and nonobviousness.¹⁶ If granted, the patent bestows an authorized monopoly on the holder for twenty years, measured from the date of the application's filing.¹⁷

Patenting a pioneer drug¹⁸ may not bestow as much market protection as one might think, however. The human body is not a simple system in which only one drug will act in one particular way to produce one specified outcome; in such a system, patenting a drug would grant a complete monopoly to the manufacturer. Instead, the biochemical reactions which drugs affect are complex, multi-step processes. Consequently, essentially identical outcomes can be obtained either by targeting different intermediary steps in the reaction, or by targeting the same reaction step with slightly different biochemical agents. Drugs using the same basic mechanism as a pioneer are known as "me-too" drugs, and often appear on the market before a pioneer drug's patent protection has lapsed.¹⁹

10 See Patent Act of 1790, ch. 7, 1 Stat. 109.

11 See Act of July 4, 1836, ch. 357, 5 Stat. 117.

12 See Pub. L. No. 82-593, 66 Stat. 797 (1952) (codified as amended at 35 U.S.C. §§ 1-293 (1994)).

13 See 35 U.S.C. § 111 (1994).

14 Note that 35 U.S.C. § 101 (1994) includes new "composition[s] of matter" as an invention that is patentable; it is this definition that allows pharmaceuticals to be patented.

15 See *id.* § 112 (1994).

16 See *id.* §§ 101-03 (1994 & Supp. II 1996).

17 See Act of July 19, 1952, ch. 950, 66 Stat. 804 (codified as amended at 35 U.S.C. § 154(a)(2) (1994)).

18 Drugs and the companies that make them are grouped into different categories depending on their approach to the market. "Pioneer" companies, also known as "innovators," invest significant amounts in the research and development of new drugs, also known as "pioneer" drugs, "breakthrough" drugs, or "name brand" drugs. Once patent protection expires, "generic" drug companies combine the active ingredients of pioneer drugs with different inactive substances to produce "generic" drugs to compete with the name brand.

19 See CONG. BUDGET OFF., HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY ch. 1, at 3 (1998) [hereinafter INCREASED COMPETITION]. This report is available electronically,

B. *The Health Care System Before 1984*

1. Drug Regulation

Drug regulation as we now think of it began in 1938 with the passage of the Federal Food, Drug, and Cosmetic Act (FFDCA).²⁰ Because of the "Elixir Sulfanilamide" scandal which occurred during its drafting,²¹ one of the FFDCA's innovations was to distinguish between prescription drugs and those that could be sold over-the-counter.²² This development, coinciding with the discovery of revolutionary medicines such as penicillin, triggered a dramatic growth in the pharmaceuticals industry.²³

Although the original FFDCA increased the FDA's role in drug approval,²⁴ the premarket approval system in force today was actually created by amendments to the FFDCA, passed in 1962.²⁵ Under the

through the Congressional Budget Office's (CBO) webpage, (visited Jan. 15, 1999) <<http://www.cbo.gov/showdoc.cfm?index=655&sequence=0&from=1>>, and in hardbound form (pagination may differ between the versions; all citations herein refer to the electronic pages). The effect of competition from me-too drugs on prices can be complex. In examining the price trends of pioneer and me-too drugs over time, the CBO found that pioneer prices increased at a rate just over inflation even after me-too introduction in four out of five drug classes. The CBO suggests that competition from me-too drugs does not drive down prices as one might expect because of doctors' increased familiarity with the pioneer as compared with the me-too, or by me-too manufacturers increasing prices to levels comparable to those of pioneers after only a short time in the market. See *id.* ch. 3, at 9.

20 Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-95 (1994 & Supp. II 1996)).

21 The Elixir Sulfanilamide scandal occurred between the start of drafting in 1933 and the FFDCA's passage in 1938. One hundred people in Tennessee died after ingesting an untested drug which contained diethylene glycol, an organic solvent. See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1761 (1996). Under the laws at the time, manufacturers were not required to test new drugs for safety, but the FDA prosecuted the Massengill Company, maker of the drug, under a false advertising theory and won damages of \$26,100. See Susan Kopp Keyack, Note, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is It a Healthy Long Term Solution?*, 21 RUTGERS L.J. 147, 150 n.26 (1990).

22 See Keyack, *supra* note 21, at 151.

23 See *id.* at 151-52 & n.31 (citing statistics indicating a seven-fold increase in drug sales between 1938 and 1958).

24 See Merrill, *supra* note 21, at 1761-64.

25 Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended in scattered sections of 21 U.S.C.). The creation of these amendments was also spawned by a medical scandal, this time involving the sedative Thalidomide, which caused birth defects in the children of pregnant women who took the drug. The majority of the cases were in European countries, as the drug had only been approved for clinical trials in the United States. See Merrill, *supra* note 21, at 1764 & n.35; Keyack, *supra* note 21, at 152 & n.34.

1938 system, manufacturers merely notified the FDA before a new drug was marketed; the FDA had a given period in which to raise any objection, otherwise the drug could be placed on the market. In contrast, the 1962 amendments gave the FDA the power to examine the safety and efficacy of new drugs, to have a voice in how the clinical trials used to measure those variables were performed, and ultimately to approve or reject the sale of new drugs based on the results.²⁶ These broad powers remained intact through the Act's passage in 1984, with one minor exception. The Orphan Drug Amendments²⁷ targeted "orphan," or relatively uncommon, diseases by offering tax and market incentives to drug companies that might not otherwise develop treatments for them because of their rarity.²⁸

2. Increasing Prices

The health care cost situation which faced Congress in 1984 was a result of both the patent and drug regulatory laws as they existed until that year, as well as the pressures these laws placed on the parties in the medical marketplace. These parties included drug manufacturers, both pioneer and generic (although they faced different pressures), medical providers (doctors and hospitals), and patients (the ultimate consumers). The combination of pressures and the parties' corresponding reactions created a spiral of increasing costs and a simultaneous demand for lower costs, which ultimately led to formulation of the Act.

Just after 1962, pioneer manufacturers found themselves in a complicated position. The previous decade and a half had been a boom time for the pharmaceutical industry, featuring short market approval times and long periods in which to recoup drug development costs. Together, these trends resulted in an average of fifty-three new drugs marketed each year from 1955 to 1962.²⁹ Following the FFDCA amendments of 1962, however, the pioneer industry took a step backwards. The new FDA controls, which mandated stricter clinical trials and an elongated review period, reduced pioneer productivity to an average of seventeen new drugs annually between 1963 and 1972,³⁰ and to twelve in 1980.³¹ The pioneer companies thus

26 See Merrill, *supra* note 21, at 1764-66.

27 Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended in scattered sections of 15, 21, 26 U.S.C.).

28 See Merrill, *supra* note 21, at 1790-92 & nn.116-19.

29 See Keyack, *supra* note 21, at 152 & n.39.

30 See *id.*

31 See Ronald L. Desrosiers, Note, *The Drug Patent Term: Longtime Battleground in the Control of Health Care Costs*, 24 NEW ENG. L. REV. 115, 124 (1989).

faced two obstacles: increasing development costs due to the more elaborate testing requirements, and decreasing returns as FDA approval consumed larger portions of the then seventeen year patent term. As a result, following the 1962 amendments to the FFDCA, pioneer firms began to raise prices, become more aggressive in their patent protection,³² and lobby legislatures for statutory protection in the form of "antissubstitution" laws.³³

Generic manufacturers faced a similar set of economic pressures—at least in the area of drug development. Like the pioneers, they too were burdened by FDA review times for their generic drugs. But, because of the pioneers' patents, there was an extra delay in their ability to get products into the marketplace; FDA review and approval for generic products could not realistically begin until the brand name drugs' patents lapsed. Additionally, although the active ingredients used in the generic drugs had already been tested and approved by the FDA for the brand name companies, the generic manufacturers were forced to run their own clinical trials before FDA review could begin on the generic versions. The brand name trial results, which could have saved the generic companies this time, effort, and expense, were protected by trade secret laws.³⁴ This situation, although more attractive than the one confronting the pioneers, still motivated generic manufacturers to begin clinical trials as early as possible and to lobby Congress for a reduction in the patent term.³⁵

Doctors and hospitals, the intermediaries in the medical marketplace, did nothing to ameliorate the situation. Unlike managed care programs which predominate today and often dictate which drugs can

32 See Keyack, *supra* note 21, at 152–53. After slumping in the late 1980s and early 1990s, the number of civil suits by pioneer companies have increased, indicating that they are once again becoming aggressive in protecting their intellectual property. This trend may be attributable to the effects of ever-increasing competition. See *infra* Part IV.A.2. See generally Richard Korman, *Lo! Here Come the Technology Patents. Lo! Here Come the Lawsuits*, N.Y. TIMES, Dec. 27, 1998, § 3, at 4.

33 State legislatures responded to pioneer manufacturer pressure by passing "antissubstitution" statutes that prohibited generic substitution by pharmacists. See Keyack, *supra* note 21, at 153 n.42. Meanwhile, the pioneer companies also lobbied Congress, arguing that the patent term was too short. See Ralph A. Lewis, Comment, *The Emerging Effects of the Drug Price Competition and Patent Term Restoration Act of 1984*, 8 J. CONTEMP. HEALTH L. & POL'Y 361, 362 (1992).

34 See INCREASED COMPETITION, *supra* note 19, Summary, at 4.

35 See Keyack, *supra* note 21, at 153–55. Adding to the motivation for the generic drug companies was the fact that the patents on several popular and extremely profitable drugs, including the analgesic Motrin and sedatives Valium and Haldol, would expire between 1984 and 1987. See *id.* at 154 n.57.

or should be prescribed,³⁶ care givers before 1984 were often unaware of drug costs or generic drug availability.³⁷ As a result of this “ignorance,” and a desire to avoid malpractice claims, doctors in this period often ordered tests and treatments which, while not completely uncalled for, were only moderately or slightly informative. This trend increased health care costs overall.

As a result of these trends, patients—the ultimate consumers in the medical marketplace—faced steadily increasing costs after the 1962 amendments took effect. In response to these higher prices the public called for legislative change, and state legislators responded by repealing the ant substitution laws.³⁸ This reaction, however, increased the pressure on pioneer companies even further, and probably exacerbated competition between the pioneer and generic companies.

In 1983, these tensions spilled into the courtroom. Roche Products, Inc. (Roche), a pioneer company and the holder of patent for the sedative Dalmane, filed suit against Bolar Pharmaceutical Co. (Bolar), a generic manufacturer, claiming that Bolar had begun its

36 As *Increased Competition* describes, managed care has significantly changed the pharmaceutical market. While many different kinds of managed care organizations exist, they operate on the general idea that by gathering large groups of customers and reducing the use of high cost services, the organizations can, in effect, negotiate “volume discounts” from doctors and hospitals. Many plans have now also affiliated with pharmaceutical benefit management companies (PBMs), which, again by offering a volume of customers, negotiate with pharmacies for lower prices. PBMs furnish the pharmacies with “formularies,” lists of drugs which are preferred for the plan. To keep costs down, these formularies often specify the substitution of generic drugs for brand names. This system is complicated by the fact that many brand name companies have now begun giving PBMs discounts or rebates in order to be included in their formularies. Another confounding factor is that while drugs are expensive, hospital and doctor treatment is even more so, and as a result, managed care patients may actually receive more prescription drugs than non-managed care patients in another effort to reduce costs. See generally INCREASED COMPETITION, *supra* note 19, ch. 2, at 1–9. Needless to say, as the number of people in such plans increases (26% of full-time workers in medium to large businesses were enrolled in managed care plans in 1988 as compared to 61% in 1995), the effect of such plans will also increase. See Dept. of Labor, Bureau of Labor Statistics, *BLS Reports on Employee Benefits in Medium and Large Private Establishments, 1995* (press release, July 25, 1997), cited in INCREASED COMPETITION, *supra* note 19, ch. 2, at 1.

37 See David A. Balto, *A Whole New World?: Pharmaceutical Responses to the Managed Care Revolution*, 52 FOOD & DRUG L.J. 83, 83 (1997).

38 See Keyack, *supra* note 21, at 153 n.42. In addition to public pressure, the repeal of ant substitution laws was also motivated by an FTC study about drug prices in the early 1980s. See Balto, *supra* note 37, at 83.

clinical trials before the Dalmane patent expired.³⁹ At trial, the district court denied injunctive relief, holding that Bolar, which had conceded its possession and testing of Dalmane's active ingredient, had not violated Roche's patent because its actions could not "be connected with any act of competition or profit during the term of the patent."⁴⁰ On appeal, however, the Court of Appeals for the District of Columbia reversed,⁴¹ flatly rejecting both Bolar's definition of "use," as well as its argument that public policy favoring generic drugs merited an exception to the wording of § 271(a). The court grounded this holding in its belief that "Bolar's intended 'experimental' use [wa]s solely for business reasons."⁴²

Instead of breaking new legal ground, *Roche* merely confirmed what most believed to be the law concerning drug patents—that is, generic manufacturers could not begin clinical testing until the pioneer companies' patents expired, because such an action constituted a prohibited use of the product. The case illustrated the frustrations of both sides of the industry, however, and this led both groups, along with consumer advocates, to pressure Congress for a solution.

C. *The Drug Price Competition and Patent Term Restoration Act of 1984*

In response to industry lobbying and public pressure, in 1983 Congress approached the dilemma facing the pharmaceutical industry. Acknowledging complaints from generic manufacturers and cost-cutting advocates, the House of Representatives considered a bill to shorten the application and approval procedures for generic drugs.⁴³ Simultaneously, both houses of Congress also introduced legislation to restore patent protection time lost during FDA approval to pioneer drugs.⁴⁴ Once legislators realized that neither measure had enough support to pass individually,⁴⁵ the two ideas were combined.⁴⁶

39 *Roche Prod., Inc. v. Bolar Pharm. Co.*, 572 F. Supp. 255 (E.D.N.Y. 1983), *rev'd* 733 F.2d 858 (D.C. Cir. 1984). Roche claimed Bolar's actions were a violation of § 271(a) of the patent code, which provides, "Whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a) (Supp. II 1996).

40 *Roche Prods.*, 572 F. Supp. at 257.

41 733 F.2d 858 (D.C. Cir. 1984).

42 *Id.* at 863.

43 See Lewis, *supra* note 33, at 361-62 & n.7.

44 See *id.* at 362-63.

45 See *id.* at 363.

46 The Act as passed contained three sections. Titles I and II had significance for the pharmaceutical industry, while Title III of the Act dealt with textile labeling.

Based on its design as a compromise measure, certain aspects of the Act benefitted each side of the drug industry. In order to increase access to generic drugs, and thus lower costs, Title I of the Act significantly altered 21 U.S.C. § 355, part of the FDCA, creating an innovative process for obtaining “abbreviated new drug approval” (ANDA).⁴⁷ Under this new system, any party meeting the statutory conditions could file an ANDA and would receive an answer from the FDA within 180 days.⁴⁸ The conditions were specifically tailored to fit the generic drug industry: they essentially required an informational showing that the ANDA drug was similar or identical in all important respects to a pre-existing, FDA-approved drug, and a certification that the new drug would not infringe upon any pre-existing drug’s patent.⁴⁹ Title I

47 See Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585–92 (1984) (current version at 21 U.S.C. § 355(j) (1994 & Supp. III 1997)).

48 See § 101, 98 Stat. at 1588–89 (codified as amended at § 355(j) (5) (A) (1994 & Supp. III 1997)).

49 The original version of 21 U.S.C. § 355(j) (2) provided in relevant part:

(A) An abbreviated application for a new drug shall contain—

- (i) information to show that the conditions of use prescribed . . . have been previously approved for [another] drug . . . ;
- (ii) (I) if the . . . drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

- (iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug . . . ;
- (iv) information to show that the new drug is *bioequivalent* to the listed drug . . . and the new drug can be expected to have the same therapeutic effect as the listed drug . . . ;
- (v) information to show that the labeling proposed for the new drug is the same . . . except for changes required because . . . the new drug and the listed drug are produced or distributed by different manufacturers;
- (vi) [information about the components, manufacturing, processing, packaging, labeling of the new drug];
- (vii) a certification . . . with respect to each patent[ed drug] . . .
 - (I) that such patent information has not been filed,
 - (II) that such patent has expired,
 - (III) of the date on which such patent will expire, or
 - (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug . . . ; and
- (viii) if with respect to the listed drug . . . information was filed . . . for a method of use patent which does not claim a use for which the applicant is seeking approval, . . . a statement that the . . . patent does not claim such a use.

of the Act also established grounds for rejecting an ANDA or withdrawing ANDA approval in the interests of safety.⁵⁰ Furthermore, Title II of the Act amended the patent code to address the *Roche* controversy about generic clinical trials. Section 271 on patent infringement was rewritten, so that generic companies could manufacture and use patented products or methods solely for the purpose of meeting federal regulations regarding market approval.⁵¹

The provisions designed to benefit the pioneer industry, and thereby encourage innovation, were slightly different. Title I of the Act provided a limited amount of market exclusivity for nonpatented drugs.⁵² Additionally, Title II added section 156, which allows the holder of a patent on certain products to extend the term of patent protection in order to recoup some of the time lost in testing and

§ 101, 98 Stat. at 1585–86 (amended 1992, 1997) (emphasis added). The definitions of “bioequivalent” and a related term, “bioavailability” were provided elsewhere in the statute. Bioavailability is defined as “the rate and extent to which the active ingredient . . . is absorbed . . . and becomes available at the site of drug action,” while bioequivalence requires a “show[ing] that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug . . . and . . . can be expected to have the same therapeutic effect,” or a condition where “the rate and extent of absorption of the drug do not show a significant difference from . . . [those] of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions” § 101, 98 Stat. at 1592 (codified as amended at 21 U.S.C. § 355(j) (1994 & Supp. III 1997)). These definitions would later be scrutinized when questions arose about generic drug quality. See *infra* Part III.A–B.

Note that if the pre-existing drug’s patent had expired (or if the drug was not patented), the FDA approval was immediately effective; otherwise, the approval became effective at the expiration of the patent. See § 101, 98 Stat. at 1588–89 (codified as amended at 21 U.S.C. § 355(j)(5)(B)(i), (iii) (1994 & Supp. III 1997)).

50 See *id.* § 102(a)(3), (b)(3)–(4), 98 Stat. at 1593 (codified as amended at 21 U.S.C. § 355(d), (e) (1994 & Supp. III 1997)).

51 See *id.* § 202, 98 Stat. 1585, at 1603 (codified as amended at 35 U.S.C. § 271(e) (Supp. II 1996)). This provided that “mak[ing], us[ing], or sell[ing] a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs,” is “not . . . an act of infringement”; whereas, “it shall be an act of infringement . . . to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.” *Id.*

52 See § 101, 98 Stat. at 1590–91 (codified as amended at 21 U.S.C. § 355(j)(4)(D)(i)–(v) (1994 & Supp. III 1997)). For example, if the nonpatented drug were approved between January 1, 1982 and September 24, 1984 (the date of the Act’s enactment), it would receive ten years of market exclusivity before an ANDA on the product could become effective. There were additional time periods ranging from two to five years given to nonpatented drugs under varying circumstances. See *id.*

approval.⁵³ While this benefit sounds sweeping, it came with many restrictions. Only certain products, including drugs, medical devices, and certain additives, qualify for the extension due to their FDA review.⁵⁴ Also, the extension is only granted if certain conditions are met,⁵⁵ and even then, the extension only applies to the specific uses approved for the original product.⁵⁶ Furthermore, the duration of the extension is not necessarily equal to the time required for approval; instead, it is calculated via a statutory formula⁵⁷ which includes one half of the clinical testing time plus the time of FDA review. But, the extension itself cannot be more than five years, and the resulting patent protection cannot be greater than fourteen years after FDA approval.⁵⁸

Overall, the passage of the Act in 1984 was met with considerable optimism by its drafters, who viewed it as a clever compromise. Senator Hatch summarized this perspective when he said that the Act created "a finely tuned balance" between its two seemingly conflicting

53 See *id.* § 201, 98 Stat. at 1598–1603 (codified as amended at 35 U.S.C. § 156 (1994 & Supp. III 1997)).

54 See § 201, 98 Stat. at 1600 (codified as amended at 35 U.S.C. § 156(f)(1) (1994 & Supp. III 1997)).

55 The conditions for patent extension include,

- (1) the term of the patent has not expired before an application . . . for its extension;
- (2) the term . . . has never been extended;
- (3) an application for extension is submitted . . . in accordance with the requirements . . . ;
- (4) the product has been subject to a regulatory review . . . ;
- (5)(A) except as . . . in . . . (B), the permission for the commercial marketing or use . . . after such regulatory review . . . is the first permitted commercial marketing or use . . . under the . . . law . . . which [requires] such regulatory review; or

- (B) in the case of a patent which claims a method of manufacturing . . . which primarily uses recombinant DNA . . . the permission for the commercial marketing or use . . . after such regulatory review . . . is the first permitted . . . under the process claimed in the patent.

§ 201, 98 Stat. at 1598 (codified as amended at 35 U.S.C. § 156(a) (1994 & Supp. III 1997)).

56 See *id.* (codified as amended at 35 U.S.C. § 156(b) (1994 & Supp. III 1997)).

57 See § 201, 98 Stat. at 1598–99 (current version at 35 U.S.C. § 156(c) (1994 & Supp. III 1997)).

58 See *id.*; INCREASED COMPETITION, *supra* note 19, ch. 4, at 1–5. According to the CBO, clinical trials usually require six to eight years, while FDA approval generally takes two more. The CBO believes that it is the 14 year limitation that is the most restrictive on patents, as most products that would qualify for almost the full five years on average receive only three because of the cap. See *id.*

goals: cost containment through increased generic availability, and encouragement of innovation through patent restoration.⁵⁹ In reality, however, the generic manufacturers essentially received everything they could hope for—a streamlined approval process, decreased production costs (because of their new ability to rely on the results of pioneers' clinical testing), and a shortened time to the marketplace (since required testing could now be performed while the original drug remained under patent). Conversely, the pioneer companies achieved only one of their goals, an increase in the patent term, which was not even as substantial as they had hoped. Additionally, they now faced increased competition from the burgeoning generic industry. Neither side, however, could predict the challenges which would face the Act in the coming years.

III. CHALLENGES TO THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT

Just after the Act's passage, the new system appeared to work exactly as envisioned. In the first eight months after its implementation, the FDA received almost five hundred ANDAs.⁶⁰ Simultaneously, generic drug manufacturers, many of which had been smaller specialized companies, experienced tremendous economic growth almost overnight.⁶¹ Generic drugs became so profitable that many pioneer companies began producing their own generics or established subsidiaries to produce them.⁶² As generic drugs consumed an increasing portion of the market share, the extent of the financial savings created by the Act surprised both legislators and the public;⁶³ both would

59 See William Christiansen II, Comment, *Patent Term Extension of Pharmaceuticals in Japan: So You Say You Want to Rush That Generic Drug to Market in Japan . . . Good Luck!*, 6 PAC. RIM L. & POL'Y J. 613, 616 (1997).

60 See Sari Horwitz, *New Law Stimulating Generic-Drug Market; Certification Process Simplified*, WASH. POST, June 28, 1985, at B1.

61 See Lewis, *supra* note 33, at 367. Lewis details the growth of Mylan, today the second largest generic drug manufacturer in the world, which experienced a 166% growth in profits and an 800% growth in its stock price over an eighteen month period. See *id.*

62 See INCREASED COMPETITION, *supra* note 19, ch. 3, at 22–24.

63 The FTC reported that in 1984, the Act's first year, Americans substituted generic drugs for a name-brand equivalent on approximately 15% of prescriptions, yet that change saved approximately \$130 million. See *Generic Drugs Save \$130 Million*, L.A. TIMES, Jan. 15, 1986, at 1. Estimates of the Act's savings potential before passage had only predicted a savings of one billion dollars over 12 years. See, e.g., Lewis, *supra* note 33, at 366; Molly Sinclair, *FDA Lets Some Drugs Take Effect Slowly*, WASH. POST, June 8, 1984, at A21.

also be shocked at the challenges and revelations of the next few years.

A. *FDA Crisis*

By 1987, fewer name brand drugs faced patent expiration, and the generic boom tapered. This, in turn, promoted rivalry and competition between the generic drug manufacturers.⁶⁴ During that year, some generic companies, including Mylan, experienced problems obtaining ANDA approval. When Mylan's complaints to the FDA went unheeded, Mylan hired a private investigator to discover whether competitors had illegally influenced the FDA.⁶⁵ When the detective found incriminating evidence of payoffs in the garbage of Charles Chang, the chemist in charge of the FDA's generic drug division, he instigated what would become a six year federal investigation.⁶⁶ Mylan presented the evidence to the House Energy and Commerce Subcommittee on Oversight and Investigations (the Subcommittee). And, in 1988, the Subcommittee's own inquiry led to an initial round of charges and convictions of FDA officials, drug firms, and their executives.⁶⁷

64 See Sandra Skowron, *Generic Drug Probe Still Going Strong*, CHI. TRIB., Nov. 22, 1992, § 7, at 13A. While Skowron estimated that there were approximately 350 generic drug manufacturers, she noted that 30 to 50 companies were the most powerful. See *id.* This generally agrees with CBO estimates, which describe the generic drug market as "not particularly concentrated," with Mylan and Geneva, the two largest companies, combining to account for almost 30% of all generic drug sales in 1994, while other firms had 1% to 5% each. See INCREASED COMPETITION, *supra* note 19, ch. 3, at 24. Despite the overall similarity in numbers, the generic market may have changed players between 1992 and 1994, as Skowron estimated that 60% of the generic drugs were made by pioneer firms or their subsidiaries, while the CBO attributes only 46% of 1994 total sales to pioneers and pioneer subsidiaries and suggests that the proportion has decreased even further. See INCREASED COMPETITION, *supra* note 19, ch. 3, at 21-24; Skowron, *supra* note 64, at 13A. In addition to an unconcentrated market with a large number of opposing firms, competition between generics is inspired by the higher profits which can be reaped by the first generic manufacturer to reach the market with a given product. Several studies have shown that generic prices decline steadily as the number of manufacturers increase. The CBO suggests that this effect is caused by the economic theory of price dampening; due to the inherent lack of distinctiveness between generic drugs, demand is spread evenly among any products in the market, causing intense price competition. See INCREASED COMPETITION, *supra* note 19, ch. 3, at 31-34.

65 See Lewis, *supra* note 33, at 369.

66 See Skowron, *supra* note 64, at 13A.

67 The FDA officials included Chang, who pled guilty to racketeering, and three of his subordinates. Chang also pled guilty to perjury, and cooperated with investigators regarding his acceptance of almost \$20,000 from five different companies in ex-

The scandal continued, however. Investigators from the Departments of Justice and Health and Human Services discovered that not only had drug companies used cash and gifts to sway FDA officials, but some had also submitted fraudulent data with their ANDAs.⁶⁸ Most shockingly, some generic companies had taken name brand drugs, re-packaged them as samples of their own products, and submitted them for bioequivalency tests.⁶⁹ This "dismal picture" of "corruption, fraud, . . . and . . . malpractice"⁷⁰ led Representative John Dingell (D, Michigan), Chairman of the Subcommittee, to conclude that "no one at the FDA knows the composition, much less the bioavailability, of the medicine . . . sold to the unsuspecting public."⁷¹ He also pronounced the generic drug industry to be "the most pervasively corrupt [industry] this subcommittee has ever uncovered."⁷²

As a result of the scandal, thirty individuals and nine drug companies were found guilty or admitted their role in FDA corruption.⁷³ The largest corporate offender was the defendant from the *Roche* case, Bolar. The government fined Bolar ten million dollars and Bolar paid another forty million dollars to settle with SmithKline Beecham, whose blood pressure drug, Dyazide, Bolar had copied.⁷⁴ In addition, one of Bolar's founders was convicted on fraud and antitrust charges, fined \$1.25 million, and sentenced to five years in prison.⁷⁵

Despite the many negative acts involved in the FDA scandal, some positive changes resulted from them. As the scandal broke, the FDA reduced its approval rate for new generic drugs to a standstill, not resuming a normal pace until 1991.⁷⁶ Appalled by the "substantial evidence . . . [of] significant corruption" at the FDA⁷⁷ and spurred on

change for preferable treatment. See Lewis, *supra* note 33, at 369-70 & n.69; Skowron, *supra* note 64, at 13A.

68 See Skowron, *supra* note 64, at 13A; Paul W. Valentine, *More Indictments Expected in Generic Drug Probe*, WASH. POST, Dec. 20, 1990, at A4.

69 See Lewis, *supra* note 33, at 370 & n.70.

70 See Valentine, *supra* note 68, at A4.

71 Lewis, *supra* note 33, at 370.

72 Valentine, *supra* note 68, at A4.

73 See Milt Freudenheim, *Bolar Co-Founder Receives a 5-Year Sentence for Fraud*, N.Y. TIMES, Jan. 23, 1993, § 1, at 37. It should be noted that these figures include only those that had serious legal action taken against them. At one point during the scandal, sources on the Subcommittee revealed to reporters that, "of 39 generic drug companies [investigated], . . . only about a half dozen appear free of criminal or regulatory taint." Valentine, *supra* note 68, at A4.

74 See Freudenheim, *supra* note 73, at 37.

75 See *id.*

76 See *id.*

77 Pub. L. No. 102-282, § 1(c), 106 Stat. 149, 149 (1992).

by Representative Dingell, Congress approved the Generic Drug Enforcement Act of 1992 (GDEA).⁷⁸ The GDEA provided the FDA with punitive weapons against persons and corporations⁷⁹ abusing the drug regulatory system. The sanctions imposed under the GDEA include debarment,⁸⁰ denial or withdrawal of product approval,⁸¹ suspension of product distribution,⁸² and the possibility of civil penalties.⁸³ Furthermore, the criticism surrounding the scandal seemed to energize the FDA in its role as a regulatory agency, to the point where one drug company official remarked "everybody [in the drug industry] is scared to death about the FDA [because] they know the FDA means business."⁸⁴

B. Medical Questions About Generic Drugs

A related controversy about the quality of generic drugs also emerged during the FDA crisis in the late 1980s. Like other generic products, generic drugs combine the active ingredient of the original name brand drug with different minor components and packaging. But just as users may find a generic dish soap to be less effective than a name brand, doctors began to question the medical effectiveness of generic drugs.

78 Pub. L. No. 102-282, 106 Stat. 149 (1992) (codified at 21 U.S.C. § 335a (1994)).

79 Professor Fleder notes that the GDEA distinguishes between individuals and business entities for purposes of debarment and suggests that piercing the corporate veil is within the FDA's powers under the GDEA. See John Fleder, *The History, Provisions, and Implementation of the Generic Drug Enforcement Act of 1992*, 49 FOOD & DRUG L.J. 89, 92 & n.22 (1994).

80 See 21 U.S.C. § 335a (1994). The effect of debarment is defined by § 335a(c) to be a condition where the FDA will "not accept or review . . . [ANDAs] submitted by or with the assistance of a person debarred." § 335a(c)(A). Section 335a(a) provides for mandatory, permanent debarment of individuals and business entities that have been convicted of felonies relating to ANDA approval so long as debarment proceedings are initiated within five years of the conviction, while (b) gives the Secretary of Health and Human Services the discretion to debar individuals and business entities for no more than five years for conduct relating to ANDA approval that results in a misdemeanor conviction, an aiding or abetting or conspiracy conviction, or even no conviction at all. See § 335a(a), (b), (c)(2). The code also provides for permissive debarment of "any high managerial agent," i.e., officers, directors, partners, or other employees or agents, who either worked or consulted with an individual who was debarred, had knowledge or avoided knowledge of the other's illegalities, or did not report illegal activity. § 335a(b)(2)(B)(iv).

81 See *id.* §§ 335a(f), 335c.

82 See § 335a(g).

83 See *id.* § 335b.

84 Skowron, *supra* note 64, at 13A.

As detailed in Part II, for an ANDA to be approved by the FDA under the Act as originally passed, its manufacturer had to demonstrate, with respect to the composition of the drug: 1) that the active ingredient was the same as in the previously approved name brand;⁸⁵ 2) that the "route of administration, the dosage form, and the strength" of the new drug was the same;⁸⁶ and 3) that the new drug was bioequivalent to the preexisting drug.⁸⁷ Just after the Act's passage in 1984, some of the name brand manufacturers petitioned the FDA and launched an advertising campaign, claiming generic drugs were not as effective as the pioneer products.⁸⁸ For the most part, however, the public and the government dismissed these claims as merely the protestations of the frustrated pioneer companies, which had lost more than they had gained under the Act's "compromise."⁸⁹

In the late 1980s, however, doctors' groups also began to question whether the Act's bioequivalency standards for generic drugs sufficiently guaranteed effectiveness and patient safety.⁹⁰ In part, this was a response to the discovery of illegalities and sample substitutions during the FDA scandal. But physicians also questioned the quality of generic drugs approved without any irregularities. In 1989, a study by the American Academy of Family Physicians (AAFP) found that the inactive components of some generic drugs could increase or reduce the body's uptake by as much as forty percent.⁹¹ Doctors considered this difference especially significant for "critical-dose" drugs, with which small changes in amount can have large physiological consequences, such as anticoagulants (blood thinners), sex and thyroid hormones, and many kinds of heart medications.⁹² As a result of these findings, the AAFP urged doctors not to prescribe generic drugs for patients who were considered to have the highest risk of problems,

85 See 21 U.S.C. § 355(j)(2)(A)(ii) (1994).

86 § 355(j)(2)(A)(iii).

87 See § 355(j)(2)(A)(iv); see also *supra* note 49 discussing the definition of bioequivalence.

88 See Horwitz, *supra* note 60, at B2. In particular, Hoffman-LaRoche, the maker of Valium, petitioned the FDA just before its patent expired, claiming test results that showed generic forms of the drug did not work as well as Valium itself. See *id.*

89 See *id.* Some legislators also criticized the pioneer companies' efforts, including Democratic Sen. Howard Metzenbaum (Ohio) and Rep. Waxman, who called the pioneers' claims "false and misleading." Lewis, *supra* note 33, at 368.

90 See Tim Friend, *Growth in Generic Drugs: Experts Want to Limit Use of Generic Drugs*, USA TODAY, Aug. 8, 1989, at 1A.

91 See *id.*

92 See Kathleen Doheny, *Generic Drugs—Just As Good As Brand Names?*, L.A. TIMES, July 18, 1995, at E3.

including the elderly, asthmatics, diabetics, and those with heart trouble.⁹³

Although the FDA and generic drug manufacturers denied the problems suggested by the AAFP's study,⁹⁴ the government eventually revamped the FDA's procedures for reviewing generic drug quality prior to approval. While the statutory definitions of bioequivalence and bioavailability remained intact,⁹⁵ the FDA did revise the federal regulations governing ANDA approval. In particular, the new regulations clarified acceptable testing procedures and considered a wider variety of drug types in designing its testing structure.⁹⁶

C. *Problems with GATT*

In 1994, the United States, in order to further its multinational trading partnerships, participated in the GATT Uruguay Round negotiations. One of the many objectives of these trade talks was to create uniform protection for intellectual property within all World Trade Organization countries.⁹⁷ As part of the accord reached at the talks, member nations signed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), which required patents to be protected for a period of twenty years, beginning at the filing date of the patent application.⁹⁸ To implement this agreement, Congress passed the 1994 Uruguay Round Agreements Act (URAA), amending the patent code.⁹⁹

As noted in Part II, the patent protection granted in the United States had always been seventeen years, measured from the time the patent was granted by the PTO. While the URAA represented a significant change for all technical industries, it was especially so for the pharmaceutical industry. Parts II and III discussed the controversy over the loss of patent protection to FDA approval time. The passage

93 See Friend, *supra* note 90, at 1A.

94 See *id.*

95 See 21 U.S.C.A. § 355(j)(8) (West Supp. 1998); see also *supra* note 49.

96 The current regulations regarding bioequivalence and drug regulation are contained in 21 C.F.R. §§ 314, 320 (1998) and were last revised in 1998. For a discussion of the previous regulations, and the proposals the FDA considered in making its changes, see 57 Fed. Reg. 17,950-18,001 (1992).

97 See Michelle Marks, *The Impact of the Patent Term Provisions of the 1994 Uruguay Round Agreements Act on the Drug Price Competition and Patent Term Restoration Act*, 51 FOOD & DRUG L.J. 445, 446 (1996).

98 See *id.*

99 Pub. L. No. 103-465, 108 Stat. 4809 (1994) (codified as amended at 35 U.S.C. § 154 (1994 & Supp. III 1997)).

of the URAA created yet another temporal obstacle for pioneer manufacturers to overcome.¹⁰⁰

While the effect of the new URAA term was clear as to drugs which had not yet entered the patent process,¹⁰¹ the question of how to implement the URAA in regard to currently existing patents remained. After launching several proposals on how to deal with this situation, the PTO issued its final position, which held that patents in force when the URAA took effect were entitled to either: 1) seventeen years of protection, measured from the time of issuance, with the possibility of restoration under the Act, or 2) twenty years from the earliest filing date, without the possibility of restoration, whichever was longer.¹⁰²

As one might expect, this ruling led to considerable amounts of litigation.¹⁰³ While the complicated details of these cases are unnecessary for this discussion, the events surrounding GATT and the URAA are important in two respects. First, they represented a substantial departure from the existing patent system, in that they changed both the patent term as well as the way it is calculated. Second, and more importantly, the passage of the URAA was another legislative action which signified insensitivity to the needs of the pioneer manufacturers.

D. 1996 Senate Judiciary Committee Hearings

The result of the Senate Judiciary Committee's (the Committee) 1996 hearings were foreshadowed by Senator Orrin Hatch's opening

100 As Marks describes, the changing of the starting point for patent protection would have no net effect if the term is measured from the time of the last-filed application and the PTO takes exactly three years to issue the patent. See Marks, *supra* note 97, at 447-48. Neither of these assumptions is justified, however, as 35 U.S.C. § 154 (1994 & Supp. III 1997) dictates that the patent term begins running at the date a patent is first filed, and when one disregards patent applications which are abandoned, the average time for patent issuance by the PTO is greater than three years. See *id.* Because these assumptions fail, the URAA effectively shortens the patent term available for pioneer manufacturers.

101 The URAA by its own terms became effective on June 8, 1995. See Pub. L. No. 103-465, 108 Stat. 4809 (1994) (codified as amended at 35 U.S.C. § 154 (1994 & Supp. III 1997)).

102 See Determination of New Expiration Dates of Certain Patents, 60 Fed. Reg. 30,069 (1995).

103 For an award-winning review of three such cases, see Marks, *supra* note 97, at 456-50, in which she analyzes in detail *Merck & Co. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996), *Bristol-Myers Squibb Co. v. Royce Laboratories, Inc.*, 69 F.3d 1130 (Fed. Cir. 1995), and *DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397 (Fed. Cir. 1995) (per curiam).

remarks: “[A]t the time of its passage, [the Act] was called the most important consumer bill of the decade and I think that that statement is still true today.”¹⁰⁴ Although Senator Hatch went on to pose the question, “If we placed our ‘legislator’s level’ on the Hatch-Waxman Act today, would it still be in balance?” the answer, so far as the Committee was concerned, was never in doubt.¹⁰⁵

The Act’s coauthor and the hearings’ first witness, Representative Henry Waxman, echoed Senator Hatch’s praise of the Act’s effectiveness, saying, “I consider . . . the very positive results that have occurred as a result of [the Act] . . . among my proudest achievements. . . . We had the right balance then and we have had the results we hoped for”¹⁰⁶ He went on to justify his feelings for the Act primarily with cost-savings statistics.¹⁰⁷ As for the state of innovation stimulation, Representative Waxman commented that “we have achieved [cost containment] without undermining our second goal of assuring a patent period that successfully encourages research and development,” a claim which he supported only with data that research and development expenditures had “increased dramatically since the Act was passed.”¹⁰⁸

The Committee went on to hear the testimony of several generic drug industry representatives, who, as expected, were less than impartial regarding the Act. They maintained that the Act, “ain’t broke,” and “doesn’t need fixing,” and characterized criticism of the Act as merely the “importuning of some brand name drug companies.”¹⁰⁹ In defense of their position, they, like Representative Waxman, alluded primarily to cost-savings provided by generic drugs.¹¹⁰ They also complimented Congress’s bipartisan support of the Act’s “grand compromise” which, in their opinion, had “balance[d] those very generous benefits to the brands . . . [by giving the generic companies] two basic rights: [a] speeded up and simplified processing of generic applications . . . [and the ability] to prepare for and achieve FDA ap-

104 *Pharmaceutical Patent Issues: Interpreting GATT: Hearings on S. 1277 Before the Senate Judiciary Comm.*, 104th Cong. 93 (1998) (prepared statement of Sen. Orrin Hatch).

105 *Id.* at 94.

106 *Pharmaceutical Patent Issues: Interpreting GATT: Hearings on S. 1277 Before the Senate Judiciary Comm.*, 104th Cong. 96 (1998) (statement of Rep. Henry Waxman).

107 *See id.* at 96–97.

108 *Id.* at 97.

109 *Pharmaceutical Patent Issues: Interpreting GATT: Hearings on S. 1277 Before the Senate Judiciary Comm.*, 104th Cong. 101 (1998) (prepared statement of John Klein, Chairman, Generic Pharmaceutical Industry Association, and Tom Russlo, Vice-Chairman, National Association of Pharmaceutical Manufacturers).

110 *See id.* at 105.

proval during the patent period.”¹¹¹ In referring to this second right, the generic representatives also jibed the D.C. Circuit and its *Roche* decision, describing Congress’s action as “a ratification of what *most . . . had thought was the rule.*”¹¹²

This testimony was followed by that of Gerald Mossinghoff, President of the Pharmaceutical Research and Manufacturers of America (PhRMA), representing the pioneer companies. After conceding the successes of the generic industry in cost containment,¹¹³ Mossinghoff went on to detail the decreases in incentives for pharmaceutical innovation under the Act, saying that “[t]he dilemma is that although pharmaceuticals are extremely expensive and difficult to develop, they can be copied cheaply and easily.”¹¹⁴ While concurring with Representative Waxman’s statistics regarding the increases in research expenditures, Mossinghoff had a much different analysis of the trend; instead of representing an increase in development fostered by the Act, he contended that it merely represented how “expensive and risky” research had become.¹¹⁵ After discussing how strong patent protection is directly related to an encouragement of innovation,¹¹⁶ Mossinghoff summarized by noting the history of health improvement caused by drug development and the promising potential created by recent scientific advances, but concluded that these goals would only be reached if innovation continued.¹¹⁷

After listening to the views from each side of the industry, the Committee heard from several witnesses representing different coalitions concerned about the Act and pharmaceutical prices. An official from the biotechnology giant Genentech spoke, as did consumer experts from the Alliance for Aging Research and the Gray Panthers. Henry Grabowski, a noted economist, also testified regarding the market effects of the Act; like those before him, he maintained that “[i]n terms of facilitating generic competition, the Act ha[d] clearly been a

111 *Id.* at 104.

112 *Id.* (emphasis added).

113 *See Pharmaceutical Patent Issues: Interpreting GATT: Hearings on S. 1277 Before the Senate Judiciary Comm.*, 104th Cong. 120–23 (1998) (prepared statement of Gerald Mossinghoff, President PhRMA). “[I]t is evident that, while the second objective [cost control] has been accomplished, the first is in some jeopardy.” *Id.* at 121.

114 *Id.* at 119.

115 *Id.*

116 Mossinghoff cited examples from the United States and abroad. The most prominent American example was the Orphan Drug Act, which he credited with raising the number of drugs to treat rare diseases from ten in the decade before the law to 99 in the decade following its passage. *See id.* at 119–20.

117 *See id.* at 127.

tremendous success.”¹¹⁸ However, Grabowski concurred with Mos-singhoff that “[a]mong all high tech industries, [the] pharmaceuticals [industry] is the one with the lowest ratio of imitation costs to innova-tion costs”¹¹⁹ As to the Act’s effectiveness in stimulating innova-tion, Grabowski concluded, “[T]he current rules on patent term restoration have the undesirable feature that breakthrough prod-ucts . . . will end up with below-average effective patent lifetimes. . . . This is a provision that warrants particular attention by Congress”¹²⁰

Near the end of the hearings, Senator Hatch admitted some am-bivalence about the Act’s balance. First he confessed that he “always questioned the [patent term], whether that is enough”¹²¹ He then quickly suggested, however, that any weaknesses were justified because “we knew the consumers would be big winners if we could get drugs off patents immediately into generic form.”¹²² Although he went on to concede that, “if we’re going to wreck the innovative com-panies and not put enough money into finding a cure for [serious diseases,] . . . then we’re not . . . doing a very good job,” Senator Hatch closed by “emphasiz[ing] that . . . this hearing [is] a celebration of Hatch-Waxman not a wake.”¹²³ Thus, the Committee made no sig-nificant changes to the Act, and this was the last time that Congress questioned whether there was a need for change.

IV. CURRENT CONDITIONS

As Part III of this Note details, the Act withstood several chal-lenges between its passage in 1984 and the 1996 hearings which pro-nounced its continuing viability. Of the Act’s dual purposes, stimulation of innovation and cost containment, the pre-1996 criti-cisms focused solely on satisfaction of the first goal, stimulation of in-novation. No one has disputed that generic drugs were more cost effective than name brands, and the data supported that belief.¹²⁴ To-day, however, while the criticism of the Act’s innovation stimulation continues, it has been joined by another, more disturbing trend:

118 *Pharmaceutical Patent Issues: Interpreting GATT: Hearings on S. 1277 Before the Senate Judiciary Comm.*, 104th Cong. 156 (1998) (prepared statement of Henry Grabowski, Professor of Economics, Duke University).

119 *Id.* at 157.

120 *Id.*

121 *Pharmaceutical Patent Issues: Interpreting GATT: Hearings on S. 1277 Before the Senate Judiciary Comm.*, 104th Cong. 166 (1998) (statement of Sen. Orrin Hatch).

122 *Id.*

123 *Id.* at 167.

124 *See supra* Part III.D.

problems with cost containment. This Section discusses both of these criticisms in turn.

A. *Dissatisfaction with Innovation Stimulation*

To be sure, the pioneer drug companies have enjoyed tremendous success in the United States. Domestic pharmaceutical companies developed almost half of the new medicinal products released worldwide between 1970 and 1992, accumulating a half a billion dollar trade surplus on sixty-nine billion dollars in revenues in 1993.¹²⁵ However, the industry does face problems which are not remarkably different than those articulated during the 1996 Senate hearings and before the Act's passage in 1984. Three essential problems exist, each begetting the next. Pioneer companies face (1) ever-increasing research and development costs, which are exacerbated by (2) the limits on their ability to protect intellectual property from competition, which in turn decreases revenue, and (3) the litigation risks of companies producing potentially dangerous products, which increase expenditures.

1. Research and Development Costs

The research and development required to create new drugs is an inherent part of the industry; by definition, the pioneer companies create, and it is only through numerous failed experiments and projects that new, successful drugs are produced. The problem with this reality, however, is that the cost of creating these new products is steadily rising,¹²⁶ for a variety of reasons.

The most obvious source of the increase in research costs is inflation. Even if the same experiments were performed today as in 1960, they would be more expensive. But the design of clinical trials has also contributed to the increase in costs. Although the overall approach to clinical trials of drugs has not changed significantly over the decades,¹²⁷ many recent changes in clinical testing involve the

125 See COUNCIL ON COMPETITIVENESS, *ENDLESS FRONTIER, LIMITED RESOURCES* app. on pharmaceuticals, at 1 (last modified Aug. 13, 1996) <http://nii.nist.gov/pubs/coc_rd/coc_rd_apdx.txt> [hereinafter *ENDLESS FRONTIER*] (copy on file with Journal).

126 The U.S. Office of Technology Assessment estimated that in 1993 it took an average of \$359 million to introduce a single new drug into the marketplace. See *id.* at 2 & n.6. Niblack suggests an even higher figure of \$400–\$500 million. See John Niblack, *Why are Drug Development Programs Growing in Size and Cost? A View From Industry*, 52 *FOOD & DRUG L.J.* 151, 151 (1997).

127 As *Endless Frontier* describes, “[m]ost of the industry’s R&D efforts still proceed in a fairly linear manner, with clearly defined stages, many of them determined by law.” *ENDLESS FRONTIER*, *supra* note 125, at 2. Initially, companies create new mole-

number of subjects utilized in each phase of the trials. Sample sizes have increased, sometimes dramatically, thus elevating the cost of the testing, as each experiment must be replicated many more times.¹²⁸

Another root of spiraling costs for the pioneer industry is that the goals of research have become more difficult to achieve. Genetic conditions, ranging from baldness to cancer, virulent viruses such as HIV, and antibiotic-resistant bacteria require more complex solutions than the diseases treated previously.¹²⁹ As the amount of scientific knowledge expands, answers to the next iteration of questions become that much harder to decipher. To combat these new obstacles, companies are utilizing the latest in biotechnology and are hiring masses of scientists and technicians.¹³⁰ These approaches require additional capital, yet pioneer companies must constantly fight to keep prices low in order to stay competitive.

One solution implemented by pioneer companies has been an increased association with nonprofit research entities, such as universities. Academic researchers, commonly believed to pursue intellectual rather than fiscally profitable projects, have faced their own economic crisis as the availability of grant monies has decreased.¹³¹

cules in the hopes that some will have medicinal properties. A small number of the new substances are selected for pre-clinical trials; these trials are performed either on cell cultures or a series of animal models or both in order to test for potential toxicity to humans. Following pre-clinical testing, chemicals are typically examined through three phases of clinical testing: an initial phase, which tests dosage tolerance and measures dosage effects on healthy humans, a second phase, utilizing a small number of diseased patients to measure benefits and risks of the treatment, and a final phase, where many more subjects are given the treatment in response to a wider range of symptoms. *See id.*

128 For example, in tests of antimicrobials between 1978 and 1983, clinical trials involved an average of 2000 subjects, whereas similar tests utilized an average of 3500 subjects between 1986 and 1990. Other studies have suggested that the number of subjects required by the FDA increased 10 times over the years between 1979 and 1993. *See id.* at 5; *see also* Niblack, *supra* note 126, at 152.

129 *See* ENDLESS FRONTIER, *supra* note 125, at 5.

130 For example, research employment in 1991 had increased 27% since 1985. Furthermore, almost two thirds of domestic personnel at pioneer companies are scientists or professionals. The average expenditure per employee at these companies rose over 10% between 1990 and 1991 to an amount over \$135,000. *See id.* at 3.

131 Again, the data regarding grant funding are complicated. Many federal grant institutions publish their funding rates and other data. *See, e.g.*, NAT'L INSTS. OF HEALTH, NIH EXTRAMURAL DATA AND TRENDS, FISCAL YEARS 1986-95 (last modified Nov. 26, 1996) <http://www.nih.gov/grants/award/trends95/ANNOTATE.HTM>; NATIONAL SCIENCE FOUNDATION, AWARD SIZE AND FUNDING RATE—NSF (visited Jan. 23, 1999) http://www.nsf.gov/home/grants/grants_awards.htm (copy on file with Journal). Although these agencies show only slight decreases in their funding rates during the 1990s, the factor which has truly reduced the money available for academic

Therefore, partnership between these two philosophical opposites has escalated, with some very positive results. However, some worry that the expansion of this trend will ultimately be limited by either conflicts of interest, as competing pioneer companies attempt to align with the same institutions, or conflicts of philosophy between business-oriented researchers concerned about the bottom line and academics searching for knowledge regardless of the cost.¹³²

Other solutions have developed within the industry itself. Companies frequently utilize "benchmarking," a technique which specifies the maximum number of days a product can spend at any one stage of development.¹³³ Furthermore, companies have become increasingly cost-conscious regarding manufacturing and disposal costs, as litigation and regulations concerning environmental hazards have multiplied.¹³⁴

2. Competition

While early reviews of the Act summarized the effectiveness of its patent extension provisions as "unclear,"¹³⁵ we now have more hindsight with which to gauge its success. The average marketing period of pioneer drugs still under patent protection has increased since the passage of the Act from about nine years to eleven or twelve years.¹³⁶ But despite this success, at least two negative trends predominate. First, despite the two to three year average increase in patent term, the extensions have not proven to be as accessible or effective as originally thought. Of the 101 drugs approved by the FDA between 1992 and 1995 eligible for an extension, only two-thirds of them have either received extensions or have applications pending.¹³⁷ The other third were prevented from extending for a variety of reasons, but perhaps

research is the "indirect cost rate," the amount of each grant dollar which goes to non-research related costs (examples include electricity, photocopies, support staff, etc). As colleges and universities have increased these costs, the amounts actually available to the scientists have dropped. At some universities, indirect costs have risen to over 50%, meaning that for every dollar of grant money acquired by a researcher, less than \$0.50 will be used to cover actual research costs. At the University of California (UC) system, for example, the average 1998-99 indirect cost rate for the nine UC campuses is 48.6%. See UNIV. OF CAL., OFF. OF THE PRESIDENT, INDIRECT COST RATES FOR THE PERIOD JULY 1, 1998 THROUGH JUNE 30, 1999 (visited Jan. 23, 1999) <<http://ovcr.ucdavis.edu/ind98.htm>> (copy on file with Journal).

132 See ENDLESS FRONTIER, *supra* note 125, at 6-7.

133 See *id.* at 6.

134 See *id.* at 5.

135 Lewis, *supra* note 33, at 376.

136 See INCREASED COMPETITION, *supra* note 19, ch. 4, at 2.

137 See *id.* ch. 4, at 5.

the most significant was the fourteen year cap. This was the primary obstacle for almost half of the thirty-eight drugs not extending.¹³⁸ Furthermore, while Congress designed the extension provisions to protect the pioneer industry's returns on its original investments, which even before the Act's passage often did not cover research and development costs,¹³⁹ the CBO admits that protection from the extensions has been less than complete, meaning that pioneer companies operate on an even thinner margin than before.¹⁴⁰

The second negative trend for the pioneer industry is a positive one for the generic industry: name brand drugs now face more competition in a shorter span of time. Generic drugs are now available on a dramatically higher percentage of once-patented drugs.¹⁴¹ Furthermore, because of the pre-expiration testing once decried by *Roche*, generic drugs reach the market in only a fraction of the time it took under the pre-Act regime.¹⁴² Ultimately, because of these trends and the preference for generic drugs by managed care companies, physicians,¹⁴³ and the public,¹⁴⁴ the average generic market share for multiple source drugs almost quintupled during the Act's first fourteen years.¹⁴⁵ Pioneer companies have attempted to slow this competition through lawsuits,¹⁴⁶ but as demonstrated by the market share statistics, this tactic has had little, if any, effect.

138 *See id.*

139 Industry estimates suggest that of drugs introduced between 1980 and 1984, only one third earned back their production costs. *See* ENDLESS FRONTIER, *supra* note 125, at 2.

140 *See* INCREASED COMPETITION, *supra* note 19, ch. 4, at 1.

141 *See id.* The CBO estimates that before the Act's passage, 35% of drugs faced generic competition, whereas today that number is almost 100%. *See id.*

142 *See id.* ch. 4, at 1-2. Whereas before the Act generic entry took between three to four years, it now takes only a couple of months. *See id.*

143 Despite the concern regarding generic quality in the late 1980s, the number of prescriptions filled with generics has continued to increase. In 1995, the chance of getting a generic on a prescription was 40%, and estimates suggested by the year 2000, the odds would increase to 50%. *See* Doheny, *supra* note 92, at E3; *see also supra* note 36 and accompanying text (discussing the effects of managed care and PBMs).

144 Following the Act's passage, as well as the FDA crisis and the concerns over generic quality, many people, especially the elderly, were "confused" about generics. *See* Horwitz, *supra* note 60, at B2. It is unclear whether public perception of generics has changed, but it is likely that, with the increase in their usage, the public has become more comfortable with the idea of generic drugs.

145 *See* INCREASED COMPETITION, *supra* note 19, ch. 4, at 1-2.

146 *See* Korman, *supra* note 32, § 3, at 4.

3. Products Liability Complications

In addition to the economic pressures outlined previously, pharmaceutical companies have also felt the effects of increased litigation and rising damages awarded to products liability plaintiffs. The general counsel for Johnson & Johnson put it simply: "In this litigation climate, it's almost impossible to know how to plan your costs."¹⁴⁷

Under the current products liability regime in most states,¹⁴⁸ plaintiffs can sue product manufacturers under any or all of three possible theories: plaintiffs can allege defects in manufacturing, warning, or design of the product.¹⁴⁹ Manufacturing defect claims can be launched against drug manufacturers in the same way as against the producers of other products; if the drug was improperly produced in violation of its design, the manufacturer is liable for harm the defect causes.¹⁵⁰ The main drawback to manufacturing defect claims is a proof problem, as it is often difficult to establish that the product was faulty at the time it was made.

In contrast to the relatively straightforward manufacturing claims, warning and design claims are complicated for drugs by the "learned intermediary" doctrine and the Restatement Second's comment k to section 402A, respectively. In proceeding with a warning claim, the plaintiff alleges that the seller or manufacturer was negligent and should be held liable for failing to warn of the dangers associated with the product or its use. Prescription drugs, however, which most pioneer drugs happen to be, are not dispensed directly from the manufacturer to the consumer. Instead, it is the plaintiff's doctor who writes the prescription, and as a result, most jurisdictions regard the prescribing physician, an expert in the medical field, as a "learned intermediary." That is, the burden of warning the plaintiff is shifted

147 Tamar Lewin, *Pharmaceutical Companies Are the Hardest Hit*, N.Y. TIMES, Mar. 10, 1985, § 3, at 1.

148 The laws of the various states were inspired primarily by the Restatement (Second) of Torts (Restatement Second) § 402A. See, e.g., David Owen, *Products Liability Restated*, 49 S.C. L. REV. 273 (1998) ("From the mid-1960s to the mid-1980s, section 402A's doctrine . . . spread like wildfire from state to state . . .") It remains to be seen how widely accepted the new Restatement (Third) of Torts: Products Liability (Restatement Third) will be.

149 While Restatement Second § 402A defines products liability generally, these three categories of defects have developed through the case law. See, e.g., W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 99, at 695 (5th ed. 1984). To embrace the changes in products liability, Restatement Third now also utilizes these distinctions. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(a)-(c) (1998).

150 See Justin Toth, *Prescription Drugs and Medical Devices: The Impending Impact of the Restatement (Third) of Torts in Texas*, 35 HOUS. LAWYER, May-Apr. 1998, at 41.

from the drug maker to the doctor, so long as the manufacturer has completely informed the doctor of the risks of the drug.¹⁵¹

The success of design defect claims against drug manufacturers has varied from jurisdiction to jurisdiction, depending on the courts' views about comment k to section 402A.¹⁵² Comment k describes drugs as "unavoidably unsafe products" which, "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use."¹⁵³ Instead of embracing comment k as a shield to design defect claims, however, many courts have viewed it as an affirmative defense, to be examined on a case-by-case basis, often utilizing the same risk-utility test applied to other products.¹⁵⁴ As a result of this view, combined with the escalation in punitive damage awards in all kinds of cases and the "snowball" effect of litigation, many pioneer manufacturers have experienced severe losses in design defect suits.¹⁵⁵ As the general counsel of Johnson & Johnson described, "Even if we win almost every case against us, the few verdicts we lose engender more suits, and make all the other suits more expensive and more difficult to settle."¹⁵⁶ Insurance rates for pioneer companies have reflected the increased number of suits and the high costs of losing them.¹⁵⁷ Consequently, manufacturers have made cost-benefit choices regarding what kinds of drugs to produce and to avoid.¹⁵⁸

151 See, e.g., *Felix v. Hoffmann-LaRoche, Inc.*, 540 So.2d 102, 105 (Fla. 1989); *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1324 (Kan. 1986); *Niemiera v. Schneider*, 555 A.2d 1112, 1119 (N.J. 1989).

152 For an example of a court which considered the substantive issues and each of the different views regarding comment k, see *Grundberg v. Upjohn Co.*, 813 P.2d 89, 92-95 (Utah 1991).

153 RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

154 See Toth, *supra* note 150, at 41.

155 See Lewin, *supra* note 147, § 3, at 1.

156 *Id.*

157 During a two year period in the mid 1980s, Johnson & Johnson's company insurance premiums rose 50%. The president of Lederle Laboratories summarized the insurance trends by saying, "deductibles are going up, and the upper limit of insurance that's available is coming down." *Id.* § 3, at 9.

158 In the words of the Johnson & Johnson general counsel, "There has to come a point with a particular product, even if it's a good product, where you say, that's enough, and you get out of the market." *Id.* § 3, at 1. An example of this cost-benefit rationalizing is whooping cough vaccine, which, like most vaccines, exposes children to a weakened form of the disease. The inoculation causes brain damage in just over three children for every one million vaccinated, yet, plagued by lawsuits from those who incurred damages, two manufacturers of the vaccine left the market in 1985, leaving only one remaining, after even tenfold price increases could not make the vaccine profitable. The one remaining manufacturer, Lederle Laboratories, faced litigation worth 200 times the value of the vaccine's sales. As of 1985, Lederle was also the only manufacturer of the polio vaccine, whose risks are even less than whooping

Some have suggested that the pioneers' products liability problems may ease with the publication of the Restatement Third in the spring of 1998.¹⁵⁹ Section 6 of the Restatement Third specifically describes the liability for drug manufacturers under design, manufacturing, and warning defect claims. While section 6 alters manufacturing and warning claims in subtle ways, it considerably revamps the standards of the old section 402A. Under Restatement Third section 6(c), drugs and medical devices are defectively designed only if "the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients."¹⁶⁰ Thus, as commentators have noted, a plaintiff can only succeed if the drug, as designed, "provides no net benefit to any ascertainable patient class."¹⁶¹

This new standard is significantly elevated in comparison to the Restatement Second, where, as interpreted by most courts, a manufacturer could be liable if the risks of the drug even slightly outweighed its benefits. Thus, it would provide formidable protection for pioneer companies from design defect claims, currently the most successful of the three products liability actions, and thus insulate the pioneers from one large source of revenue loss. Unfortunately, the effects of the Restatement Third will not be known until it is either accepted or rejected by a majority of jurisdictions.

B. *Problems in Cost Containment*

As Part III details, competition among generic manufacturers spawned the corruption that led to the FDA crisis. While this power struggle has sometimes led to lower prices, the intensity of the rivalry among companies may have again escalated to the point where the public should be concerned. Since 1996, generic manufacturers have engaged in bitter market battles, slashing prices to drive out competitors and then raising prices once they have achieved market control.¹⁶² As with pricing wars in other industries, however, these recent

cough—one in every three million are paralyzed—yet it incurred \$20 million in damages from just one lawsuit that year. *See id.* § 3, at 9.

159 *See* Toth, *supra* note 150, at 40; Jeffrey Winchester, *Section 8(c) of the Proposed Restatement (Third) of Torts: Is It Really What the Doctor Ordered?*, 82 CORNELL L. REV. 644 (1997).

160 RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1998).

161 Toth, *supra* note 150, at 42.

162 *See* David J. Morfow, *Old Drugs, New Labels: Brand Name Generics and Other Anomalies*, N.Y. TIMES, June 13, 1998, at D1.

clashes have raised questions about the legality of generic companies' tactics.¹⁶³ In December 1998, Mylan, the innocent whistleblower in the FDA crisis, became the first generic company to face charges for its current behavior.¹⁶⁴

Until 1997, Profarmco,¹⁶⁵ the producer of active pharmaceutical ingredients (APIs) for drugs such as lorazepam and clorazepate,¹⁶⁶ sold its products to several American generic companies, including Mylan. At the time, Profarmco was the only supplier for several of these ingredients.¹⁶⁷ According to the complaint filed by the FTC,¹⁶⁸ in 1997 Mylan negotiated an agreement with Profarmco by which Mylan would receive an exclusive license to the APIs for a ten year period in return for a percentage of Mylan's sales of the drugs.¹⁶⁹ Because of Profarmco's status as sole supplier, this agreement effectively gave Mylan complete control over the lorazepam and clorazepate markets in the United States.

At about the same time, Mylan also approached FIS, one of Profarmco's competitors which had previously made and sold the lorazepam API but had withdrawn from the market.¹⁷⁰ Under Mylan's proposal to FIS, Mylan would not actually purchase any API from FIS. Instead, Mylan would pay FIS a portion of its lorazepam profits to keep FIS from producing and selling the lorazepam API, thus eliminating another potential source of the drug.¹⁷¹ FIS refused this arrangement, "at least in part out of concern that such an agreement could violate antitrust laws."¹⁷² Despite this minor setback, however,

163 See generally *Definitely a Cause of Anxiety*, *supra* note 7, at B8; Stephen Labaton, *A Drug Maker Is Said to Face a Suit on Prices*, N.Y. TIMES, Dec. 5, 1998, at A1 (discussing the events leading up to the FTC complaint against Mylan Laboratories, Inc.).

164 See Labaton, *supra* note 163, at A1.

165 Profarmco S.R.L. is an Italian subsidiary of Cambrex Corp., a Delaware pharmaceutical company. Profarmco sold its products in America through a distribution company named Gyma. See FTC Complaint, *supra* note 8, at 2, ¶ 9.

166 Lorazepam is a widely-prescribed sedative used to treat anxiety, insomnia, and as an anesthetic for surgery. Clorazepate is also an anti-anxiety drug but has additional uses in treating hypertension and several forms of addiction. See *id.* at 3, ¶ 15.

167 See *id.* at 2-4. For example, in 1997, Profarmco was the supplier for 90% of the lorazepam and all of the clorazepate sold in the United States. See *id.* at 5, ¶ 25.

168 The FTC suit was joined by 10 states, including Connecticut, Florida, Illinois, Pennsylvania, and New York. See Robert Pear, *U.S. Will Sue Drug Maker Over Pricing*, N.Y. TIMES, Dec. 22, 1998, at C1. California, which had filed its own class action suit, was expected to join soon after the complaint was filed. See *Definitely a Cause of Anxiety*, *supra* note 7, at B8.

169 See FTC Complaint, *supra* note 8, at 4-5.

170 See *id.* at 5.

171 See *id.*

172 *Id.*

Mylan allegedly continued with its plan, by denying lorazepam to any competitors that sought to purchase it from them, and then in 1998, by raising prices up to 3200 percent.¹⁷³ In response to this price increase, FIS, through its distributor SST, reentered the lorazepam market, selling the API to Geneva, a Mylan competitor. In doing so, however, FIS and SST raised their prices 19,000 percent.¹⁷⁴ Geneva, in turn, raised its prices for pharmacists and doctors to a level comparable with Mylan's.¹⁷⁵ This chain reaction touched off a wave of complaints from the public and their legislators, with the FTC estimating that the price increases cost the public over \$120 million.¹⁷⁶

In response, the FTC filed an eight count complaint, charging Mylan, Cambrex, Profarmco, and Gyma with antitrust violations, including restraint of trade,¹⁷⁷ monopolization,¹⁷⁸ and conspiracy.¹⁷⁹ In addition to the more typical injunctive relief, the FTC also prayed for financial damages, asking the court to disgorge Mylan and the other defendants of the \$120 million generated by the increased prices.¹⁸⁰ Some have called this second approach "unusual" and "aggressive"¹⁸¹ and see this as the FTC "testing a relatively new enforcement strategy."¹⁸² It remains to be seen whether the court embraces this approach. If not, and if actions like those of Mylan become more prevalent, the public may face a rapid reversal of the generic savings seen in the 1980s.

V. CONCLUSION

The biggest problem arising from the state of the pharmaceutical industry today may best be illustrated by examining the purpose of the Orphan Drug Amendments described in Part II. The Orphan Drug Amendments acknowledge that private industry will *only* manufacture

173 See *id.* For example, the wholesale price for a bottle of 500 tablets of clorazepate increased from \$11.36 to \$377. See Pear, *supra* note 168, at C1. As the FTC complaint points out repeatedly, these price increases were not associated with any concomitant increase in costs. See FTC Complaint, *supra* note 8, at 4-6.

174 See FTC Complaint, *supra* note 8, at 5-6.

175 See *id.* at 6.

176 See Pear, *supra* note 168, at C1.

177 Counts one and two allege restraint of trade violations of 15 U.S.C. § 45(a) (1994). See FTC Complaint, *supra* note 8, at 7.

178 Counts five and seven allege monopolization, while counts six and eight allege attempted monopolization. See *id.* at 9-11.

179 Counts three and four allege conspiracy to monopolize. See *id.* at 7-9.

180 See *id.* at 11.

181 Pear, *supra* note 168, at C18 (quoting Herbert Hovenkamp, Professor of Law, University of Iowa).

182 *Id.*

products when it is *profitable* to do so. Furthermore, the Amendments articulate the well-accepted public policy that medicines, even for the rarest of diseases, are valuable enough to society that it is willing to make economic sacrifices in order to promote their development. Given the implications of this policy, it may be that the Act's time has come and gone.

The Act's passage and the trends that have followed it have placed an increasing strain on the abilities of the pioneer drug industry. Simultaneously, society's expectations of the industry, as shown by the decrease of funding to non-profit research centers and the increased treatment of patients through pharmaceuticals by managed care, have only increased. It is true that the use of generic drugs since the Act's passage has saved countless consumer dollars, and those savings have repeatedly been used to justify the hardship imposed on the pioneer industry. However, health care costs have not decreased overall, and in light of the most recent developments with *Mylan*, which calls even the cost containment function of generic drugs into question, society must accept that, despite the cost, it will only be medically prepared for the new millennium by encouraging the pioneer industry to expand research and development.

