THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984: A PANACEA OR A PLACEBO?

Introduction

On September 24, 1984, President Reagan signed into law the Drug Price Competition and Patent Term Restoration Act of 1984[1] (ANDA/PTR Act or Act), legislation which represents an attempt by Congress to remedy certain problems currently facing research intensive (pioneer) pharmaceutical manufacturers[2] and generic drug manufacturers.[3] The purpose of the Act is two-fold:[4] to make available to the public an increased number of low cost generic drugs, and to create new incentives for the research and development of products which are subject to the arduous governmental premarket review approval process.[5]

Ironically, many of the problems now facing the pharmaceutical industry are directly traceable to congressional action taken twenty-two years earlier, when the 1962 Drug Amendments[6] to the Food, Drug, and Cosmetic Act[7] were enacted. The Drug Amendments of 1962 have been criticized over the years for having been primarily responsible for the curtailment of pharmaceu-

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[1] Pub. L. No. 98-417, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1585 (to be codified in scattered sections of 21 U.S.C.; 35 U.S.C.; and 15 U.S.C.).

[2] Research intensive manufacturers are those firms which invest heavily in basic and applied research. U.S. OFFICE OF TECHNOLOGY ASSESSMENT, PATENT-TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY 3 (1982) [hereinafter cited as OTA REPORT].

[3] Generic manufacturers are those firms which are not generally involved in basic or applied research; such firms derive most, if not all, of their revenues from the manufacture and sale of copies of marketed drug products. *Id.* at 17.

[4] Title III of the Act, unrelated to generic drugs or patent term restoration, amends the Textile Fiber Products Identification Act and the Wool Products Labeling Act of 1939 and is not addressed in this comment. Pub. L. No. 98-417, §§ 301-307, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1585, 1603-05 (to be codified in scattered sections of 15 U.S.C.).

[5] H.R. REP. No. 857, 98th Cong., 2d Sess., Pt. 1, 14-15 (1984), *reprinted in* 1984 U.S. CODE CONG & AD. NEWS 2647-48.

[6] Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended at 21 U.S.C. §§ 321, 331, 332, 348, 351-353, 355, 357-360, 372, 374, 376, 381 (1982)).

[7] Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (current version at 21 U.S.C. §§ 301-392 (1982)).

tical innovation,[8] for substantial delay in the introduction of new drugs in the United States,[9] and for the denial to patients of access to valuable new drugs.[10]

These adverse effects have not gone unnoticed. Congressional recognition of the need for change in the regulatory review process was initially manifested in numerous hearings[11] and reports,[12] and later through a proposal addressing regulatory reform.[13] Nonetheless, the ANDA/PTR Act represents the first enactment by Congress of legislation aimed toward unraveling the tangled web of bureaucracy presently enmeshing the pharmaceu-

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8 *See* H. GRABOWSKI & J. VERNON, THE REGULATION OF PHARMACEUTICALS: BALANCING THE BENEFITS AND RISKS (1983); S. PELTZMAN, REGULATION OF PHARMACEUTICAL INNOVATION: THE 1962 AMENDMENTS (1974); Grabowski, *The Impact of Regulation on Innovation*, 34 FOOD DRUG COSM. L.J. 555 (1979); May, Wardell & Lasagna, *New Drug Development During and After a Period of Regulatory Change: Clinical Research Activity of Major United States Pharmaceutical Firms, 1958 to 1979*, 33(6) CLIN. PHARMACOL. THER. 691 (1983); Roberts & Bodenheimer, *The Drug Amendments of 1962: The Anatomy of a Regulatory Failure*, 1982 ARIZ. ST. L.J. 581 (1982); Wardell, *The Impact of Regulation on New Drug Development*, ISSUES IN PHARMACEUTICAL ECONOMICS 145 (R. Chien ed. 1979); Brownlee, *The Economic Consequences of Regulating Without Regard to Economic Consequences*, ISSUES IN PHARMACEUTICAL ECONOMICS 215 (R. Chien ed. 1979).

9 *See* GRABOWSKI & VERNON, *supra* note 8; Grabowski, *The Impact of Regulation on Innovation*, *supra* note 8; Roberts & Bodenheimer, *supra* note 8.

10 *See* Dorsey, *The Case for Deregulating Drug Efficacy*, 242(16) J.A.M.A. 1755 (1979). *See also* Roberts & Bodenheimer, *supra* note 8.

11 *See, e.g., Oversight—The Food and Drug Administration's Process for Approving New Drugs: Hearings Before the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 96th Cong., 1st Sess. (1979) [hereinafter cited as *Hearings on Drug Approval Process*]; *Drug Regulation Reform—Oversight: New Drug Approval Process: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 96th Cong., 2d Sess. (1980) [hereinafter cited as *Hearing on Drug Regulation Reform*].

12 *See, e.g.*, SUBCOMM. ON SCIENCE, RESEARCH AND TECHNOLOGY OF THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 96th Cong., 2d Sess., REPORT ON THE FOOD AND DRUG ADMINISTRATION'S PROCESS FOR APPROVING NEW DRUGS (Comm. Print 1980) [hereinafter cited as REPORT ON DRUG APPROVAL PROCESS]; HOUSE SUBCOMM. ON NATURAL RESOURCES, AGRICULTURE RESEARCH AND ENVIRONMENT AND THE HOUSE SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT, 97TH CONG., 2D SESS., FINAL REPORT OF THE COMMISSION ON THE FEDERAL DRUG APPROVAL PROCESS (Comm. Print 1982) [hereinafter cited as FINAL REPORT ON THE DRUG APPROVAL PROCESS]. *See also* Hutt, *Investigations and Reports Respecting FDA Regulation of New Drugs* (pts. I & II), 33(4) CLIN. PHARMACOL. THER. 537 (1983) and 33(5) CLIN. PHARMACOL. THER. 674 (1983).

13 Drug Regulation Reform Act of 1979, S.1075, 96th Cong., 1st Sess., 125 CONG. REC. 26,263-74 (1979). Although the Senate passed this drug regulation reform legislation, the House failed to report it out of Committee.

tical industry. Despite this laudable achievement, however, the Act serves only to address the symptoms of a complicated and burdensome drug approval process while failing to effect a much needed cure.

This Comment will examine the major provisions of the Act[14] together with the attendant ramifications on key affected groups, including the Food and Drug Administration (FDA), research intensive manufacturers, generic manufacturers and consumers. The Act presents a formidable challenge to both the "regulators" and the "regulated" in the pharmaceutical industry. The question remains whether this statute will be the panacea its supporters portend it to be or merely a placebo disguised as an answer to the problems presently existing in the regulatory arena.

Legislative History

It was not until 1906 that the first significant legislation in the area of food and drugs was enacted.[15] Although the nineteenth century was replete with examples of the sale of elixirs and nostrums for the purported treatment of every disease and symptom, Congress refused to take action to control such practices. Between 1879 and 1906, Congress defeated the passage of more than one hundred food and drug bills.[16]

Eventually, public concern and outrage over the issue of adulterated foods and drugs was roused by Upton Sinclair's novel, *The Jungle*,[17] and also by publicity over Dr. Harvey Wiley's "poison squad."[18] Soon others joined the crusade[19] to expose

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14 Due to the length and complex nature of the statute, a definitive analysis of each provision is beyond the scope of this comment. Many areas may be dealt with in a general manner. *See* Pub. L. No. 98-417, *supra* note 1.

15 Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906), *repealed in part by* Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (current version at 21 U.S.C. §§ 301-392 (1982)).

16 Roberts & Bodenheimer, *supra* note 8, at 582 (citing Janssen, *Pharmacy . . . and the Food and Drug Law*, 21 AM. PHARMACY, Apr. 1981, at 30-31).

17 THE JUNGLE revealed the practices of the meat-packing industry as being unsanitary. Hayes, *Food and Drug Regulation After 75 Years*, 246 J.A.M.A. 1223, 1223 (1981).

18 Roberts & Bodenheimer, *supra* note 8, at 582. *See also* P. TEMIN, TAKING YOUR MEDICINE 28 (1980). Dr. Harvey Wiley, Chief Chemist in the U.S. Department of Agriculture, organized his "poison squad" in 1902. The squad consisted of twelve volunteers who consumed specific diets containing various chemical additives. *Id.*

numerous instances of corruption and fraud, all of which ultimately prompted Congress to pass the Pure Food and Drugs Act of 1906.[20] Under this Act, "adulterated"[21] or "misbranded"[22] foods or drugs were prohibited from entering interstate commerce,[23] and the manufacture of such products was made unlawful.[24]

While the 1906 Act constituted a significant breakthrough, it proved inadequate in at least two respects. First, it was necessary for a "misbranded" or "adulterated" product to have been placed in interstate commerce before an enforcement action could be initiated.[25] Consequently, many unsafe products continued to gain admission into the marketplace.[26] Second, the scope of the misbranding provisions of the 1906 Act was ultimately found not to cover "all possible false statements, but only . . . such [statements] as determine the identity of the article, possibly including its strength, quality and purity. . . ."[27] Thus, whereas misstatements concerning the identity of the product were within the statute's intendment, false statements on a medicine bottle which, for example, alleged the elixir's effectiveness as a cure for cancer, were not covered, despite their misleading character.[28] This second failing, however, was subsequently

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Dr. Wiley's findings concluded that all such additives were harmful to the volunteers' health. *Id.*

19 Those who supported a federal law to protect the public from unsafe drugs included the American Medical Association, the Women's Christian Temperance Union, the National Temperance Society, state public health officials, and the press. Hayes, *supra* note 17, at 1223; Roberts & Bodenheimer, *supra* note 8, at 582.

20 Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906), *repealed in part by* Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (current version at 21 U.S.C. §§ 301-392 (1982)).

21 A drug was deemed to be adulterated if its strength, quality, or purity differed from recognized standards and its container failed to specify such deviation, or "[i]f its strength or purity [fell] below the professed standard or quality under which it [was] sold." *Id.* at § 7, 34 Stat. 768, 769-70 (1906).

22 A drug was deemed misbranded if its package or label contained "any statement . . . which shall be false or misleading in any particular. . . ." *Id.* at § 8, 34 Stat. 770 (1906).

23 *Id.* at ch. 3915, § 2.

24 *Id.* at § 1, 34 Stat. 768.

25 *Id.* at §§ 2, 5, 34 Stat. 768-69.

26 Roberts & Bodenheimer, *supra* note 8, at 583.

27 United States v. Johnson, 221 U.S. 488, 497 (1911).

28 *Id.* at 497.

remedied through passage of the Sherley Amendment in 1912.[29]

Despite the fact that legislation designed to remedy many of the defects of the 1906 Act and to broaden the powers of the FDA was introduced as early as 1933,[30] it was not until a tragedy struck that a new law was adopted. In 1937, the Massengill Company had marketed a liquid dosage form of sulfanilamide. Sulfanilamide, a safe and effective antibacterial agent, was marketed previously in a solid dosage form. The newly formulated liquid, known as Elixir Sulfanilamide, contained the solvent diethylene glycol (a common element of antifreeze). Although the solvent was tested by the manufacturer for appearance, fragrance and flavor, it was not tested for safety.[31] Once released into the marketplace, the solvent proved to be extremely toxic, and resulted in the deaths of over one hundred men, women and children.[32]

The public outcry following this catastrophe demanded a response. Congress, therefore, enacted the Food, Drug, and Cosmetic Act of 1938.[33] This statute, *inter alia*, prohibited the introduction or delivery of new drugs[34] into interstate commerce without the manufacturer first providing, in the form of a new drug application (NDA), scientific evidence demonstrating the safety of the drug to the Food and Drug Administration.[35]

By 1959, new concerns about the pharmaceutical industry

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29 Pub. L. No. 62-301, 37 Stat. 416 (1912), *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, § 902(a), 52 Stat. 1040, 1059 (current version at 21 U.S.C. § 352(a)). The Sherley Amendment broadened the definition of misbranding to prohibit the inclusion on packages or labels of "any statement . . . regarding the curative or therapeutic effect of such article . . . which is false and fraudulent." *Id.*

30 GRABOWSKI & VERNON, *supra* note 8, at 2; TEMIN, *supra* note 18, at 40.

31 Hayes, *supra* note 17, at 1224.

32 *Id.*; TEMIN, *supra* note 18, at 42. *See also* 108 CONG. REC. 16,413 (1962) (quoting Ottenberg, *It Takes a Jolt to Get New Drug Laws: A 1938 Parallel*, Wash. Star, Aug. 12, 1962).

33 Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 52-717, 52 Stat. 1040 (current version at 21 U.S.C. §§ 301-392 (1982)).

34 "New drugs" under the 1938 Act were considered to be those drugs not generally recognized as safe. Two exceptions, however, were made to this definition. A drug was not considered "new" if it had been subject to the provisions of the 1906 Act and its labeling had remained unchanged. The other exception provided that a drug would not be considered "new" if it had become recognized as safe as a result of clinical investigations. *Id.* § 201(p), 52 Stat. 1040, 1041-42 (current version at 21 U.S.C. § 321(p) (1982)).

35 *Id.* § 505(b)(1), 52 Stat. 1040, 1052 (current version at 21 U.S.C. § 355(b)(1) (1982)).

spurred congressional inquiry into possible changes to the 1938 measure.[36] Hearings were conducted by Senator Estes Kefauver, Chairman of the Senate Antitrust and Monopoly Subcommittee, to investigate the purportedly anti-competitive pricing and marketing practices of drug manufacturers.[37] Kefauver's committee also examined whether legislative action was necessary to halt the introduction of drugs of questionable efficacy.[38] Eventually, in 1961, these hearings resulted in legislation designed to remedy the identified problems.[39] The remedial proposal, however, met vigorous opposition,[40] and failed to receive approval prior to the end of the 87th Congress.

Shortly thereafter, however, another drug-related disaster occurred. This time the culprit was found to be thalidomide, a sedative-hypnotic which was extensively marketed in European countries. In 1962, it was discovered that thousands of infants had been born with severe birth defects as a result of the administration of this drug to women during early pregnancy.[41] Once again, it took a tragedy of this magnitude to overcome congressional inertia. The perceived need for more stringent regulation of drug products moved Congress to enact the Drug Amendments of 1962[42] (Amendments).

The most significant portions of the 1962 Amendments required, as a prerequisite for the approval and marketing of a new drug, that the manufacturer provide "substantial evidence"[43] that a particular drug is "effective," in addition to "safe," for its

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36 107 CONG. REC. 5638 (1961). *See also* TEMIN, *supra* note 18, at 122.

37 S. REP. No. 1744, 87th Cong., 2d Sess. *reprinted in* 1962 U.S. CODE CONG. & AD. NEWS 2884, 2887.

38 *Id.* at 2887, 2891-93. *See also* PELTZMAN, *supra* note 8, at 6.

39 S.1552, 87th Cong., 1st Sess., 107 CONG. REC. 5642 (1961).

40 *See* 108 CONG. REC., *supra* note 32.

41 S. REP. No. 1744, *supra* note 37, at 2905. Thalidomide had not been approved by the Food and Drug Administration for sale in the United States, although it had been dispensed for investigational studies by an American licensee, the Wm. S. Merrell Co. *Id.* at 2906.

42 Pub. L. No. 87-781, 76 Stat. 780 (codified as amended in scattered sections of 21 U.S.C.); *see supra* note 6.

43 The term "substantial evidence" is defined as:

> evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to

intended use.[44] Ironically, it was recognized that the addition of an efficacy standard could not prevent a future tragedy similar to thalidomide.[45] In addition, the Amendments increased FDA's regulatory control over new drugs, through the investigational new drug (IND) exemption procedure.[46]

Also originating as a result of the 1962 Amendments was the concept of abbreviated new drug applications (ANDAs).[47] As required by the 1962 Amendments, FDA was not only charged with reviewing new drugs, but also was confronted with the enormous task of reviewing each previously marketed drug covered by an NDA to determine its "effectiveness." This review was to encompass all drugs marketed between 1938 and 1962, which amounted to 2,824 drug products.[48] By 1965, FDA had not yet complied with the legislative mandate to conduct such reviews.[49] As a consequence, FDA contracted with an independent scientific authority, the National Academy of Sciences/National Research Council (NAS/NRC), to implement these reviews.[50] Thus, the Drug Efficacy Study Implementation (DESI)[51] Review was established, composed of thirty panels of experts in specific drug categories.[52] Products were reviewed and each therapeutic claim was evaluated and categorized into one of six classifications.[53] These

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have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

21 U.S.C. § 355(d) (1982).

44 21 U.S.C. § 355(a), (b), (d) (1982).

45 108 CONG. REC. 16,412 (1962) (remarks by Rep. Sullivan); 108 CONG. REC. 21,971 (1962) (quoting Hayley, *More Political Quackery, New Drug Controls Will Impede Progress, Not Foster Safety* (distributed by the National Agricultural Chemicals Association)).

46 21 U.S.C. § 355(i) (1982). Under this procedure, an exemption allowing the initiation of clinical studies in humans can be granted only after the manufacturer or sponsor has submitted adequate reports of pre-clinical testing. *Id.* at § 355(i)(1). In addition, the applicant is required to establish and maintain specified records and to submit reports concerning adverse reactions promptly to the FDA. *Id.* at § 355(i), (j).

47 H.R. REP. NO. 857, *supra* note 5, at 16.

48 SMITH KLINE & FRENCH LABORATORIES, A CHRONOLOGY AND REVIEW OF THE NATIONAL ACADEMY OF SCIENCES/NATIONAL RESEARCH COUNCIL DRUG EFFICACY STUDY 12 (1971).

49 *Id.* at 11.

50 *Id.* at 12.

51 *Id.* at 21.

52 *Id.* at 13.

53 The evaluations consisted of the following:

reviews were submitted to FDA for evaluation, and FDA's finding with regard to each drug's effectiveness was then published in the *Federal Register*.

Once a drug had been found to be effective by the DESI Review, a party who subsequently wished to market the drug was not required to repeat clinical studies to demonstrate safety and effectiveness. All that was required was the submission of an ANDA, which had to include evidence that the individual version of the reviewed drug was bioequivalent, properly labeled and manufactured.[54]

Effects of the 1962 Drug Amendments

The Drug Amendments of 1962 have had several far-reaching adverse effects on the drug development and approval process. Some commentators have imputed the increased time required for the approval of a new drug directly to the 1962 Amendments.[55] For example, it has been reported that prior to the enactment of the 1962 Drug Amendments, an average of only two and one-half years' time elapsed between the initial discovery of a new drug and its ultimate approval by FDA.[56] By 1980, that same process had increased dramatically, ranging anywhere from

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(1) *Effective.*
(2) *Probably effective.* Additional evidence required to be determined. Remedy could be additional research or modification of claims or both.
(3) *Possibly effective.* Little evidence of effectiveness, but possibility of additional evidence should not be ruled out.
(4) *Ineffective.* No acceptable evidence to support claim of effectiveness.
(5) *Effective, but . . .* Effective for claimed indication but not approved form of treatment because better, safer or more conveniently administered drugs available.
(6) *Ineffective as a fixed combination.* Combination drugs for which there is no substantial reason to believe that each ingredient adds to the effectiveness of the combination.

R. MERRILL & P. HUTT, FOOD AND DRUG LAW, CASES AND MATERIALS 373 (1980).

54 H.R. REP. No. 857, *supra* note 5, at 16.

55 *See, e.g.*, Brownlee, *supra* note 8, at 216-17; Dorsey, *supra* note 10; Roberts & Bodenheimer, *supra* note 8; Wardell, Hassar, Anavekar & Lasagna, *The Rate of Development of New Drugs in the United States, 1963 Through 1975*, 24(2) CLIN. PHARMACOL. THER. 133 (1978); PELTZMAN, *supra* note 8, at 17-18; GRABOWSKI & VERNON, *supra* note 8, at 3, 5; Grabowski, *supra* note 8, at 555. *See also* OTA REPORT, *supra* note 2, at 5.

56 Roberts & Bodenheimer, *supra* note 8, at 586.

seven to thirteen years.[57] One of the detrimental consequences of this extended regulatory review was that between 1966 and 1979, the average effective patent life for drug products exhibited a decline from 13.6 years to 9.5 years.[58]

The magnified cost of drug development is another significant problem which owes its genesis, at least in part, to the additional testing requirements imposed by the Amendments. It has been estimated that the cost of drug development has risen from $10 million in 1962 to $54 million in 1976 dollars.[59] More recent estimates place the cost of developing a new drug in the range of $70-85 million.[60]

The decrease in the annual rate of new drug introductions is yet another indication of the substantially adverse impact of the 1962 Amendments. This rate has seen a precipitous drop to less than one-third of the rate which existed prior to 1962.[61] Between 1955 and 1960, for example, the average number of new chemical entities (NCEs) introduced per year was approximately fifty. During the periods covering 1965-1970 and 1975-1980, however, the number of NCEs introduced per year averaged only seventeen for each six-year period.[62]

In response to these adverse effects, Congress initiated an investigation into the federal drug approval process. In 1979 and 1980, several hearings were conducted,[63] the reports of which concluded that changes in the drug review and approval process were necessary.[64] Nonetheless, the legislative attempt to reform this process proved futile.[65]

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57 REPORT ON DRUG APPROVAL PROCESS, *supra* note 12, at 13.

58 Lourie, *A Political History of Patent Term Restoration (Part I)*, 5(1) PHARMACEUTICAL EXECUTIVE 46 (1985); OTA REPORT, *supra* note 2, at 20, 30.

59 R.W. Hansen, *The Pharmaceutical Development Process: Estimates of Current Development Costs and Times and the Effects of Regulatory Changes*, ISSUES IN PHARMACEUTICAL ECONOMICS 151, 180 (R. Chien ed. 1979); Stetler, *Economic Impact of Drug Regulation*, 34 FOOD DRUG COSM. L.J. 550, 551 (1979). *See also* REPORT ON DRUG APPROVAL PROCESS, *supra* note 12, at 13.

60 S. REP. No. 138, 97th Cong., 1st Sess. 2 (1981).

61 Grabowski, *supra* note 8, at 556.

62 GRABOWSKI & VERNON, *supra* note 8, at 29.

63 *Hearings on Drug Approval Process*, *supra* note 11; *Hearing on Drug Regulation Reform*, *supra* note 11.

64 REPORT ON DRUG APPROVAL PROCESS, *supra* note 12, at 80; FINAL REPORT ON THE DRUG APPROVAL PROCESS, *supra* note 12, at 6.

65 Drug Regulation Reform Act of 1979, *supra* note 13.

ANDA/PTR Act of 1984

Impetus for Passage of the Act

The failure to achieve regulatory reform of the drug review and approval process[66] resulted in the formulation of an alternate approach. If the review process could not be streamlined, the proposed solution was to provide some compensation in the form of patent extensions to products whose effective market life had been eroded through regulatory delays.[67]

Consequently, in 1981, a congressional investigation into the decline of pharmaceutical innovation was initiated.[68] Hearings were conducted[69] and reports were issued[70] concerning the plausibility of granting such extensions to patents. It was concluded that developers of products which required premarket approval prior to commercial sale should be compensated for the time lost to regulatory review,[71] and that this should be achieved through extended patent terms.[72] Indeed, the view was expressed that, "[t]here is no valid reason for a better mousetrap to receive 17 years of patent protection and a lifesaving drug less than 10 years."[73]

In addition, the Subcommittee on Courts, Civil Liberties and the Administration of Justice commissioned the Office of Technology Assessment (OTA) to undertake a study in order to evaluate the issue.[74] The OTA also concluded that the granting of

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66 *See supra* notes 11-13, 63-65 and accompanying text.

67 For a comprehensive discussion of the legislative history culminating in final passage of the Act, see Lourie, *A Political History of Patent Term Restoration* (pts. I & II), 5(1) PHARMACEUTICAL EXECUTIVE 46 (1984) and 5(2) PHARMACEUTICAL EXECUTIVE 44 (1985).

68 S. REP. No. 138, *supra* note 60; *Patent Term Restoration Act of 1981: Hearings on H.R. 1937, H.R. 6444, and S.255 Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 97th Cong., 1st Sess. (1981).

69 *Hearings on H.R. 1937, H.R. 6444, and S.255*, *supra* note 68; *Patent Term Restoration Act of 1981: Hearings on S.255 Before the Senate Comm. on the Judiciary*, 97th Cong., 1st Sess. (1981); *Patent Term Extension and Pharmaceutical Innovation: Hearing Before the House Subcomm. on Investigations and Oversight of the Comm. on Science and Technology*, 97th Cong., 2d Sess. (1982).

70 S. REP. No. 138, *supra* note 60; H.R. REP. No. 696, 97th Cong., 2d Sess. (1982); OTA REPORT, *supra* note 2.

71 S. REP. No. 138, *supra* note 60; H.R. REP. No. 696, *supra* note 70, at 1.

72 S. REP. No. 138, *supra* note 60; H.R. REP. No. 696, *supra* note 70.

73 S. REP. No. 138, *supra* note 60.

74 H.R. REP. No. 696, *supra* note 70, at 6.

patent-term extension would increase the incentive to invest in additional research and development.[75]

Throughout the 96th and 97th Congresses, all efforts to legislate in the area of patent term extension foundered.[76] It was not until the 98th Congress that legislative activity in this area was sufficiently intense to produce a bill that would satisfy all interested parties.[77] While this consensus was building, another bill was also attracting the interest and energies of the research intensive pharmaceutical firms. This proposal promoted a streamlined approval process for generic drugs. It did not, however, address the issue of patent-term extension.[78] In an effort to merge the two initiatives into one, Congressman Henry Waxman (D-California), entered into protracted negotiations with the two primary trade associations, the Pharmaceutical Manufacturer's Association (PMA) and the Generic Pharmaceutical Industry Association (GPIA).[79] These two groups lobbied extensively to protect their respective interests. The PMA pursued its long sought after patent extension provisions for brand-name products, in order to correct any inequity resulting from the federal drug approval process. The GPIA fought to gain a greater market share of off-patent products by extending FDA's established ANDA policy to post-1962 drug products.

Following heated debate, lengthy negotiations,[80] and twenty-five draft proposals,[81] a compromise was finally reached[82] which appeared to address the competing interests of both trade

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75 OTA REPORT, *supra* note 2, at 45.

76 H.R. REP. No. 857, 98th Cong., 2d Sess., Pt. 2, 3-4 (1984), *reprinted in* 1984 U.S. CODE CONG. & AD. NEWS 2686. The closest the patent extension bill came to passage was in September, 1982. At that time, H.R. 6444 was brought up on the Suspension calendar. However, it failed to achieve the required two-thirds vote by five votes, 250-132. 128 CONG. REC. 6986-87 (daily ed. September 15, 1982). The Senate had previously passed a similar bill. 127 CONG. REC. 7354-56 (daily ed. July 9, 1981).

77 *See infra* notes 80-82 and accompanying text.

78 H.R. 3605, 129 CONG. REC. 5273, E3581 (daily ed. July 19, 1983). The bill, in its original form, was one and one-half pages in length and was introduced by Representative Henry Waxman (D-Calif.). H.R. REP. No. 857, *supra* note 76, at 4.

79 H.R. REP. No. 857, *supra* note 76, at 4.

80 Shacknai & Fisher, *The ANDA/Patent Extension Law: What Lies Within*, 5(1) PHARMACEUTICAL EXECUTIVE 36 (1985).

81 Sun, *The Price for More Generic Drugs*, 224 SCIENCE 369 (1984).

82 H.R. 3605, *reprinted in* H.R. REP. No. 857, *supra* note 5, at 1-14. *See also* Sun, *supra* note 81.

associations.[83] Although the compromise was supported by the PMA, several of the largest PMA member firms broke rank with PMA's position.[84] These firms, designated the "Coalition,"[85] issued a statement in response to Congressman Waxman's announcement of his compromise bill in which they asserted that while they "fully support the goals of the legislation . . . it fails to achieve an appropriate balance between these goals."[86]

The Coalition was particularly concerned with several points contained in the proposed legislation. These concerns addressed the FDA's limited authority to assure the safety and efficacy of generic drugs; the probable increase in patent litigation; the encouragement of patent infringement; the limitations on the types of patents eligible for restoration; the disclosure of trade secret data; and, finally, the inadequacy of the bill's transition provisions.[87] Thus, the stage was set for an intensive and hard-fought battle over a number of the bill's controversial provisions.

Ultimately, the Coalition was successful in obtaining relief on some of the key provisions in the bill. Particularly important were the elimination of a number of restrictions on the types of patents that would be entitled to patent restoration and the addition of marketing exclusivity in certain circumstances.

Despite the complexity of this bill, hearings were limited to

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[83] Support for this compromise was encouraged by such groups as the American Federation of Labor and Congress International Union of Industrial Organizations, United Automobile, Aerospace and Agricultural Implement Workers of America, and the American Federation of State, County and Municipal Employees. H.R. REP. No. 857, *supra* note 76, at 6-7.

[84] Statement by a coalition of the nation's leading research-based pharmaceutical companies (June 12, 1984) [hereinafter cited as Coalition Statement]. *See also Accord May Lead to Cheaper Drugs*, N.Y. Times, June 2, 1984, at 1, col. 1; *How Much Haven for Drug Pioneers*, N.Y. Times, June 25, 1984, at 14, col. 1; *Drug Manufacturers Oppose Bill that Would Double Sales of Generics*, Star-Ledger, June 25, 1984, at 14, col. 1.

[85] The "Coalition" was the self-appointed name by which the opposing PMA member firms chose to refer to themselves. The Coalition was represented by American Home Products Corp., Bristol-Myers Company, Carter-Wallace, Inc., Hoffmann-La Roche Inc., Johnson & Johnson, Merck & Co., Inc., Norwich Eaton Pharmaceuticals, Inc. (A Procter and Gamble Company), Schering-Plough Corporation, Squibb Corporation, Stuart Pharmaceuticals (Div. of ICI Americas Inc.). Those less sympathetic to the Coalition's position referred to them less affectionately as the "Dissident Group."

[86] Coalition Statement, *supra* note 84.

[87] Coalition Position Paper (June 12, 1984).

one day each in both the House[88] and the Senate.[89] Six amendments were considered by the House Committee on the Judiciary, only two of which were adopted.[90] The bill received consideration, and was passed by the Senate on August 10, 1984.[91] Several amendments were incorporated into the House version,[92] and subsequent ratification of these changes by the Senate was achieved on September 12, 1984.[93] It is this ratified bill which exists today.

Major Provisions of the Act

Title I: Abbreviated New Drug Applications

Fundamental to an understanding of the Act is a familiarity with the basic terminology associated with the drug approval process. A "new drug" is one which is not generally recognized as safe and effective,[94] and requires the submission to and approval by FDA of a new drug application (NDA) before the drug may be marketed.[95] Such an application must contain full reports of human and animal investigations which demonstrate the drug's safety and effectiveness.[96] These new drugs are commonly referred to as "pioneer drugs," and their respective NDA's are termed "pioneer NDAs" or "full NDAs."[97]

Approval also may be sought for a new drug based upon its equivalence to a previously approved pioneer new drug. Such drugs are called "generic drugs," and, unlike those drugs governed by "full NDAs," these drugs do not require independently conducted animal and human clinical studies to establish safety and effectiveness. The applications for such drugs are termed

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88 *Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judicary* (June 27, 1984). A formal hearing report was not prepared. For a summary of the hearing, see H.R. REP. No. 857, *supra* note 76, at 7-10.

89 *Hearing Before the Senate Comm. on Labor and Human Resources* (June 28, 1984). No Senate report on this legislation is available.

90 H.R. REP. No. 857, *supra* note 76, at 7.

91 130 CONG. REC. S10,503-S10,513 (daily ed. Aug. 10, 1984).

92 130 CONG. REC. H9105-H9151 (daily ed. Sept. 6, 1984).

93 130 CONG. REC. S10,981-S10,990 (daily ed. Sept. 12, 1984).

94 21 U.S.C. § 321(p) (1982).

95 21 U.S.C. § 355(a) (1982).

96 21 U.S.C. § 355(b) (1982).

97 The present statute adds a new term to this panoply of trade definitions, a "listed drug," which is synonymous with an approved pioneer drug.

"abbreviated NDAs" (ANDAs), "paper NDAs"[98] or "generic applications."

Prior to enactment of the ANDA/PTR Act, abbreviated applications could be submitted only for those drugs introduced between 1938-1962 and already reviewed for safety and effectiveness.[99] Although additional safety and effectiveness data were not required for such applications, bioavailability[100] and bioequivalency[101] data were necessary for approval. The new statute retains these requirements. More importantly, the Act extends to post-1962 drugs a procedure for the approval of ANDAs. This procedure is virtually identical to that which was in place for drugs approved prior to 1962.

The Act amends section 505 of the Food, Drug, and Cosmetic Act[102] by adding a new subsection[103] which governs the procedures and requirements for ANDAs.[104] The required con-

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98 A paper NDA differs in one respect from an abbreviated NDA. Whereas an ANDA relies primarily upon the reports of studies sponsored by the pioneer applicant, a paper NDA is, in effect, a full NDA, but satisfies the requirement of demonstrating safety and efficacy via the submission of published scientific literature summarizing the results of clinical studies conducted by others. Pub. L. No. 98-417, § 103, 1984 U.S. CODE CONG. & AD. NEWS 1585, 1593-97 (to be codified at 21 U.S.C. § 355(b)).

99 *See supra* notes 47-54 and accompanying text.

100 The term "bioavailability" is defined as "the rate and extent to which the active drug ingredient or therapeutic moiety is absorbed from a drug product and becomes available at the site of drug action." Bioavailability and Bioequivalence Requirements, 21 C.F.R. § 320.1(a) (1984).

101 Bioequivalent drug products are defined as:

> pharmaceutical equivalents or pharmaceutical alternatives whose rate and extent of absorption do not show a significant difference when administered at the same molar dose of the therapeutic moiety under similar experimental conditions, either single dose or multiple dose. Some pharmaceutical equivalents or pharmaceutical alternatives may be equivalent in the extent of their absorption but not in their rate of absorption and yet may be considered bioequivalent because such differences in the rate of absorption are intentional and are reflected in the labeling, are not essential to the attainment of effective body drug concentrations on chronic use, or are considered medically insignificant for the particular drug product studied.

21 C.F.R. § 320.1(e) (1984).

102 21 U.S.C. § 355 (1982).

103 Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1585, 1585-92 (to be codified at 21 U.S.C. § 355(j)). "Section 505 of the Federal Food, Drug, and Cosmetic Act is amended by redesignating subsection (j) as subsection (k)" with the concomitant addition of a new subsection (j). *Id.*

104 *Id.* In addition, the Act amends § 505(b) of the Federal Food, Drug, and Cos-

tents of such an application are specifically delineated. In general, the application must contain information regarding: the drug's conditions for use; active ingredient(s); route of administration; dosage form; strength; bioequivalence; labeling; manufacturing and control data; and, certification of patent status of the pioneer drug.[105] The "certification" requirement mandates that the applicant attest to one or more of the following: the pioneer NDA failed to include the required patent information;[106] the patent on the pioneer drug has expired;[107] the date on which the pioneer drug's patent will expire;[108] or the challenged patent is not valid or will not be infringed.[109]

An ANDA may be submitted for a generic drug which is either considered the "same" as the pioneer drug, or "different" from the pioneer drug. In order to be considered the "same," the generic product must mirror the pioneer drug as to its conditions of recommended use,[110] active ingredient(s),[111] route of administration,[112] dosage form,[113] strength,[114] bioequivalence[115]

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metic Act to establish a formalized procedure for the filing of paper NDAs. *See id.* § 103, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1594-97 (to be codified at 21 U.S.C. § 355(b)).

105 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1585-86 (to be codified at 21 U.S.C. § 355(j)(2)(A)(i)-(viii)).

106 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(2)(A)(vii)(I)). The failure of a pioneer manufacturer or sponsor to include patent information in an NDA is a ground for disapproval of a pending NDA or withdrawal of an approved NDA. *Id.* § 102(a)(3)(A), (B), 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1593 (to be codified at 21 U.S.C. § 355(d)(6), (e)(4)). In the case of withdrawal of an approved NDA, the pioneer NDA holder must first be notified by FDA of the deficiency. The NDA holder then has thirty days in which to remedy the deficiency by submitting the required patent information. *Id.* § 102(a)(3)(B) (to be codified at 21 U.S.C. § 355(e)(4)).

107 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1586 (to be codified at 21 U.S.C. § 355(j)(2)(A)(vii)(II)).

108 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(2)(A)(vii)(III)).

109 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). More specifically, this subsection provides that the generic applicant must certify "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. . . ." *Id.*

110 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1585 (to be codified at 21 U.S.C. § 355(j)(2)(A)(i)).

111 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1585 (to be codified at 21 U.S.C. § 355(j)(2)(A)(ii)(I)-(II)).

112 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1585 (to be codified at 21 U.S.C. § 355(j)(2)(A)(iii)).

113 *Id.*

and labeling.[116] The Act specifically states that FDA "may not require that an abbreviated application contain information in addition" to the categories of information delineated by statute.[117] Consequently, these "same" generic drug products face the least stringent requirements for approval under the Act.

A generic drug, however, which is "different" in one or more of the above-noted respects faces a substantially greater burden to obtain approval. To submit an application for a "different" generic drug, a petition must first be submitted seeking permission to file such an application.[118] In contrast to generic drugs which are the "same" as a pioneer drug, an application for a generic drug which is "different" may be subject to additional unspecified requirements.[119]

In addition to the categories of required information stated above, if a claim of patent invalidity or non-infringement has been stipulated, the Act imposes a duty upon the generic applicant to include a statement that notice of such claim will be provided to the patent owner and to the holder of the approved

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114 *Id.*

115 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1586 (to be codified at 21 U.S.C. § 355(j)(2)(A)(iv)). However, if the generic application is for a drug which is "different" from the pioneer drug, other criteria are imposed. *Id.*

116 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1586 (to be codified at 21 U.S.C. § 355(j)(2)(A)(v)). A generic drug which is approved for less than all of the indications claimed by the pioneer applicant is not deemed to be "different" if its labeling is not identical to that of the pioneer drug. *Id.*

117 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1585-86 (to be codified at 21 U.S.C. § 355(j)(2)(A)). Nonetheless, H.R. REP. No. 857 explicitly sets forth Congress' intent that additional information can be required:

> Finally, the Committee intends that an ANDA contain any information available to the applicant regarding reports of adverse effects not reflected in the labeling, an environmental impact analysis pursuant to FDA regulations, statements regarding the protection of human subjects in clinical investigations as required by FDA regulations, and a statement regarding compliance with good laboratory practices in nonclinical investigations as required by FDA regulations.

H.R. REP. No. 857, *supra* note 5, at 22-23.

118 Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1585, 1587 (to be codified at 21 U.S.C. § 355(j)(2)(C)). Within ninety days, FDA is required to either approve or disapprove a petition. *Id.*

119 H.R. REP. No. 857, *supra* note 5, at 23. If a petition for a change from the pioneer drug is granted, FDA may require the generic sponsor to provide such additional information regarding the change as the Agency deems necessary. *Id.*

pioneer application.[120] Although the statute is silent as to when this notice must be given, it was clearly Congress' intent that the notice be transmitted simultaneously with the ANDA submission.[121]

Eleven grounds for disapproval of a generic application are expressly set forth in the statute.[122] Due to the very nature of an ANDA, these grounds are significantly more objective than the grounds for disapproval of a full NDA.[123] The Act requires the Agency to approve or disapprove an ANDA no later than 180 days following receipt by FDA.[124] If the ANDA is disapproved, the applicant must be given a notice of opportunity for a hearing on the issue.[125] Procedures and time periods for the conduct of such a hearing are expressly set forth in the Act.[126]

Also included within the ANDA section of the Act are several innovative rules which prohibit FDA from approving certain ANDAs for specified time periods.[127] In essence, these "transition rules" establish varying periods of market exclusivity for pioneer drug products irrespective of the product's official patent status.[128] These provisions may be viewed as "non-patent" patents and, as such, have far-reaching economic importance to pioneer manufacturers.

There are two key determinants utilized to establish the appropriate period of exclusivity. The first is whether the pioneer

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120 Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1585, 1586-87 (to be codified at 21 U.S.C. § 355(j)(2)(B)).

121 H.R. REP. No. 857, *supra* note 5, at 24.

122 Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1587-88 (to be codified at 21 U.S.C. § 355(j)(3)(A)-(K)).

123 21 U.S.C. § 355(d) (1982).

124 Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1588 (to be codified at 21 U.S.C. § 355(j)(4)(A)). This time frame is absolute unless the generic applicant agrees to an extension. *Id.*

125 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1589-90 (to be codified at 21 U.S.C. § 355(j)(4)(C)).

126 *Id. See also infra* notes 219-221 and accompanying text. There are also several circumstances under which an approved ANDA must be withdrawn or suspended. Such situations include the withdrawal or suspension of approval of the referenced pioneer NDA on "safety" or "efficacy" grounds. Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS 1585, 1591 (to be codified at 21 U.S.C. § 355(j)(5)).

127 Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1585, 1590-91 (to be codified at 21 U.S.C. § 355(j)(4)(D)(i)-(v)).

128 *Id.*

drug is considered to be a new chemical entity (NCE).[129] The second is whether the subject pioneer NDA was approved by FDA prior or subsequent to the statute's enactment.

Under the criteria set forth in the Act, ten years of market exclusivity is granted to any pioneer NDA for an NCE which received FDA approval between January 1, 1982 and September 24, 1984, the date of the statute's enactment.[130] Under this scheme, no ANDA or paper NDA may be *approved* by FDA until ten years following FDA approval of the pioneer NDA.[131]

A second type of exclusivity provision also applies to NCEs, but only those which received FDA approval after September 24, 1984. In this case, no ANDA or paper NDA may be *submitted* to FDA until five years following approval of the pioneer NDA.[132] There is one exception to this provision. If the generic application contains a certification of patent invalidity or non-infringement, an ANDA may be submitted four years following FDA approval of the pioneer NDA.[133]

Three years of market exclusivity may be available for certain non-NCE NDAs[134] or NDA supplements[135] approved after enactment. The granting of this period of exclusivity, however, is subject to two conditions. The NDA or supplement must contain reports of clinical investigations which were "essential" to the applicant's obtaining FDA approval.[136] These studies cannot be merely bioavailability studies,[137] and they also must be "new;"[138]

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129 The term "new chemical entity" as used in the Act refers to those pioneer drugs which had never before been approved by FDA in another application. *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS 1590 (to be codified at 21 U.S.C. § 355(j)(4)(D)(i)). A non-NCE is a drug which includes an active ingredient which had been previously approved in another application. *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(4)(D)(iii)).

130 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(4)(D)(i)).

131 *Id.* "[T]he Secretary may not make the approval . . . effective before the expiration of ten years." *Id.* Although ANDAs and paper NDAs may not be approved during this time period, the same stricture does not apply to full NDAs.

132 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(4)(D)(ii)).

133 *Id.*

134 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(4)(D)(iii)).

135 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1590-91 (to be codified at 21 U.S.C. § 355(j)(4)(D)(iv)). NDA supplements are submitted in many instances, for example, to broaden the drug's indications for use, or to add new dosage forms.

136 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(4)(D)(iii), (iv)).

137 *Id.*

that is, not previously submitted to FDA. The latter condition mandates that the clinical investigations be conducted or sponsored by the applicant.[139] The three-year exclusivity period applicable to these NDAs or supplements is measured from the FDA approval date of the non-NCE NDA or supplement.[140]

The last exclusivity period applies to pioneer NDAs for non-NCE drugs which were approved by FDA between January 1, 1982 and September 24, 1984. Under this provision of the Act, such products benefit from a grant of two years exclusivity following *enactment*.[141] Thus, if an ANDA is submitted which references a non-NCE drug approved between January 1, 1982 and September 24, 1984, the FDA may not approve that ANDA until September 24, 1986.[142] In practical effect this provision may result in a period of exclusivity of greater than two years. For example, if the pioneer received approval in January, 1982, its period of exclusivity would extend to September 24, 1986.

As illustrated by the foregoing, many circumstances affect the date upon which a generic drug may be approved for marketing. In this regard, there is yet another situation which may affect the date a generic application may be approved. As stated above,[143] one of the categories of information to be submitted with a generic application consists of a "certification" by the generic applicant of the patent status of the pioneer drug.[144] The date upon which FDA may approve a generic drug depends upon which type of certification is made. For example, if the generic applicant certifies either that the required patent information was not filed with the pioneer NDA,[145] or that the subject patent has expired,[146] approval of the application may be made effective im-

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138 *Id.*

139 *Id.*

140 *Id.*

141 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1591 (to be codified at 21 U.S.C. § 355(j)(4)(D)(v)).

142 *Id.*

143 *See supra* text accompanying notes 106-109.

144 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1586 (to be codified at 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV)).

145 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(2)(A)(vii)(I)); *see supra* note 106 and accompanying text.

146 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1586 (to be codified at 21 U.S.C. § 355(j)(2)(A)(vii)(II)); *see supra* note 107 and accompanying text.

mediately.[147] If a certification stipulates a particular date on which the pioneer's patent will expire, the application may be made effective on the date certified.[148]

A certification which claims patent invalidity or non-infringement, however, raises collateral issues. Absent a challenge by the pioneer applicant to such a certification, approval may be made effective immediately. The patent owner and NDA holder, however, must be notified of a certification of patent invalidity or non-infringement,[149] and they have forty-five days within which to bring an infringement action.[150] With certain exceptions, in those instances where an infringement action is brought, the approval of the generic application is statutorily tolled for thirty months following the date when the required notice was received.[151]

The Act also provides a mechanism which provides an incentive to generic applicants who successfully challenge the patent status of a pioneer drug and who would subsequently confront competition from other generic applicants. Thus, if a generic application is submitted which certifies patent invalidity or non-infringement, a second applicant's ANDA may not be made effective until one of two situations arise. One hundred and eighty days must elapse following either the commercial marketing of the first generic application's product, or following a judicial determination that the challenged patent is invalid or not infringed.[152]

Title II: Patent Extension

A very significant aspect of the ANDA/PTR Act is its effect

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147 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1588-89 (to be codified at 21 U.S.C. § 355(j)(4)(B)(i)).

148 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1589 (to be codified at 21 U.S.C. § 355(j)(4)(B)(ii)).

149 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(2)(B)(i),(ii)).

150 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(4)(B)(iii)).

151 *Id.* Should the court find a failure by either party to the action to reasonably cooperate, the thirty-month period may be shortened or lengthened. In addition, a court's decision regarding patent status may affect the ultimate effective date of the generic application. For example, a finding of patent invalidity or non-infringement prior to the thirty-month holding period requires approval to be made effective on the date of the court's decision. *Id.*

152 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(4)(B)(iv)).

on the United States' patent law. Prior to enactment of this legislation, the term of a U.S. patent had remained unchanged for over 120 years.[153] Ordinarily, the grant of a patent gives to its holder the exclusive right to make, use or sell the invention[154] for a period of seventeen years.[155] The Act adds a new section to Title 35 of the United States Code, entitled, "Extension of patent term,"[156] which allows the term of a patent to be extended if the patented product[157] has been subject to federal pre-market testing and approval requirements.[158] The types of products now eligible for patent extension include human drug products (or processes, in the case of recombinant DNA technology), medical devices, food additives and color additives.[159]

Before a patent can be considered for extension, however, certain criteria must be met to establish eligibility. That is, the patent term must not have expired before the application for extension is submitted; the patent term must not have been previously extended; the patent owner must submit a patent extension application; the product must have been subject to a regulatory review period prior to its commercial marketing or use, and, finally, the product whose regulatory review period will be used to extend the patent must be the first permitted commercial marketing or use of that product.[160]

After eligibility is established, the length of the extension to be granted must be resolved. This is determined, in part, by the

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153 *See* Lourie, *supra* note 58, at 46.

154 35 U.S.C. § 271 (1982).

155 35 U.S.C. § 154 (1982).

156 Pub. L. No. 98-417, § 201, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1585, 1598-1603 (to be codified at 35 U.S.C. § 156).

157 Three types of patents are covered under the Act: a product patent; a process patent (covering a method of manufacturing a product); and a use patent (covering a method of using a product). *Id.* § 201, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1598 (to be codified at 35 U.S.C. § 156(a)).

158 *Id.* § 201, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1598 (to be codified at 35 U.S.C. § 156(a)(4)).

159 *Id.* § 201, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1600-01 (to be codified at 35 U.S.C. § 156(f)).

160 *Id.* § 201, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1598 (to be codified at 35 U.S.C. §§ 156(a)(1)-(5)). Recombinant DNA processes are excepted from the "first permitted commercial marketing or use" requirement. The patents for these processes may be extended without regard to the marketing status of the product itself. The only limitation stipulates that the new process cannot have been approved previously. *Id.* § 201 (to be codified at 35 U.S.C. § 156(a)(5)(B)).

time lost to the regulatory review process. For human drugs, the review period begins on the date an investigational new drug (IND) exemption becomes effective, and ends on the date FDA approves the NDA for marketing.[161]

In general, the term of patent extension is equivalent to the total regulatory review period, subject to four major limitations. First, the calculated regulatory review period may be reduced by any time during which the applicant failed to act with "due diligence."[162] Due diligence is defined in the Act as "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period."[163] The second limitation provides that only one-half of the period devoted to IND testing may be included in computing the applicable review period.[164] Third, the product's total effective patent life after extension may not exceed fourteen years.[165] Fourth, only one patent per product may be extended for the same regulatory review period.[166]

Another limitation of the Act sets the maximum extension of a patent at five years. The full five years of extension may be granted to patents which issue after the date of enactment. With regard to patents issued prior to enactment, however, the period of allowable extension may be limited to two years. The key consideration in determining the allowable period of extension for

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161 *Id.* § 201, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1601 (to be codified at 35 U.S.C. § 156(g)(1)(B)). The criteria for calculating the regulatory review period for food and color additives differ due to the fact that virtually all testing for safety is conducted in animals. *Id.* § 201 (to be codified at 35 U.S.C. § 156(g)(2)(B)).

162 *Id.* § 201, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1598 (to be codified at 35 U.S.C. § 156(c)(1)). FDA is not required to institute a due diligence determination on its own intiative. Such a proceeding may be implemented only if FDA receives a petition requesting such an inquiry. *See also infra* notes 228-236, 271-275 and accompanying text.

163 Pub. L. No. 98-417, § 201, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1600 (to be codified at 35 U.S.C. § 156(d)(3)).

164 *Id.* § 201, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1599 (to be codified at 35 U.S.C. § 156(c)(2)).

165 *Id.* § 201 (to be codified at 35 U.S.C. § 156(c)(3)). The computed extension would be as follows: After the appropriate time reductions, the calculated regulatory review period for Drug X totalled seven years. The remaining patent term for Drug X equals ten years. In this situation, the patent for Drug X would not be extended for the full seven years' time lost to the review process. Due to the fourteen-year maximum, Drug X could benefit from only four years of patent extension.

166 *Id.* § 201 (to be codified at 35 U.S.C. § 156(c)(4)).

such patents is whether clinical investigations on the subject compound had been initiated as of the date of the statute's enactment. To illustrate the foregoing, the entire five years of patent term restoration is available if the subject patent had been issued prior to enactment and an IND had not yet been submitted. However, only two years of patent extension will be granted if the subject patent had issued prior to enactment and an IND had been filed before September 24, 1984.[167] In no event, however, may the product's total effective patent life, after extension, exceed fourteen years.[168]

The Act also amends that portion of the patent law relating to patent infringement.[169] In this regard, the Act departs substantially from preexisting law and raises serious constitutional issues.[170] Prior to enactment, the well-established law of patents unambiguously set forth the rights of a patent owner to exclusively make, use and sell a patented invention for seventeen years.[171] Any unauthorized testing of a patented product during that term was considered to be infringement. Under the terms of the Act, however, it is no longer considered infringement for anyone to make, use or sell a patented human drug if it is solely for purposes of testing, development and ultimate submission to FDA of an ANDA or paper NDA.[172] It is an act of infringement, however, to submit an ANDA or a paper NDA for a drug if the purpose of the submission is to obtain approval of the applica-

167 *Id.* § 201, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1602 (to be codified at 35 U.S.C. § 156(g)(4)(A)-(C)).

168 To summarize this complicated process, assume an IND is submitted for Drug A. The IND period lasts six years and the NDA period spans four years. Three years (one-half of the IND) period plus the entire four-year NDA period would theoretically make Drug A eligible for an extension of seven years. Nonetheless, the five-year cap on extensions would limit Drug A's patent extension to five of the potential seven years. The next consideration must be the number of years actually remaining on the patent after FDA approval. If eight years remain, then Drug A would be granted the full five year extension, since the five year extension plus the eight years remaining patent life would not exceed the fourteen year limit.

169 *Id.* § 202, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1603 (to be codified at 35 U.S.C. § 271(e)(1), (2)).

170 *See infra* notes 174-207 and accompanying text.

171 35 U.S.C. §§ 154 and 271(a) (1982).

172 Pub. L. No. 98-417, § 202, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1603 (to be codified at 35 U.S.C. § 271(e)(1)).

tion prior to the expiration of a valid patent.[173]

Implications of the Act

Constitutional Issue

To certain critics, a disturbing provision in the ANDA/PTR Act, at least from a constitutional standpoint, is the section relating to non-infringing uses of a patented drug product.[174] By virtue of the new legislation, Section 202 of the Act now allows third parties to make, use or sell a patented drug product to develop data for purposes of obtaining FDA approval of an application.[175] This provision can be viewed as undercutting the basic premise upon which our patent laws are based; that is, to reward those who have invested their time, effort and expense in creating an innovative product with a grant of seventeen years' *exclusivity*. Permitting others to impinge upon this exclusivity substantially dilutes the rights which heretofore were vested solely in the patent holder, and represents a radical departure from our deep-rooted constitutional policy of promoting scientific progress and the useful arts.[176]

Patents are considered property rights. "That a patent is property, protected against appropriation both by individuals and government, has long been settled."[177] As a property right, patents are protected by the Fifth Amendment's prohibition against the taking of property for public use without just compensation.[178] Heretofore there has been historical adherence to these property rights. This was acknowledged in 1843 by the United States Supreme Court in *McClurg v. Kingsland.*[179] The Court noted that new patent legislation "can have no effect to impair the right of property then existing in a patentee. . . ."[180] In this regard, a constitutional problem arises from the retroac-

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173 *Id.* § 202, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1603 (to be codified at 35 U.S.C. § 271(e)(2)).

174 *Id.* § 202 (to be codified at 35 U.S.C. § 271(e)(1)). This provision is limited to human drug products. It does not cover veterinary drugs, medical devices, food or color additives. *Id.*

175 *Id.* § 202 (amending 35 U.S.C. § 271).

176 U.S. CONST. art. I, § 8.

177 Hartford-Empire Company v. United States, 323 U.S. 386, 415 (1945).

178 U.S. CONST. amend. V.

179 42 U.S. 202 (1843).

180 *Id.* at 206.

tive application of Section 202. That is, the provision applies not only to prospective patents which will be issued after enactment, but also retrospectively to patents in existence as of enactment, thus impairing the exclusive rights of their holders.

Additionally, the exclusive rights granted to patent holders have long been recognized and protected by the United States Supreme Court. In *Continental Paper Bag Co. v. Eastern Paper Bag Co.*,[181] the Court stated, "an inventor receives from a patent the right to exclude others from its use for the time prescribed in the statute."[182] Furthermore, in a more recent decision the Court noted, "the essence of a patent grant is the right to exclude others from profiting from a patented invention."[183]

The Court, in *Kaiser Aetna v. United States*,[184] also made it clear that the right to exclude others, whether it be under the aegis of patent law or elsewhere, is an essential element of property rights.[185] The facts in *Kaiser* are directly analogous to the effect of Section 202 on pharmaceutical patents. In *Kaiser*, the federal government sought to require a privately owned and developed marina to open itself to use by the general public without payment of just compensation.[186] The Court described the right to exclude others as "one of the most essential sticks in the bundle of rights that are commonly characterized as property. . . ."[187] Thus, the Court held, "the 'right to exclude,' so universally held to be a fundamental element of the property right, falls within this category of interests that the Government cannot take without compensation."[188] Furthermore, the substantiality of the amount taken is not relevant to the issue of whether just compensation is required, and nominal payment for a compulsory taking will not remedy the deprivation.[189]

In 1984, in *Roche Products v. Bolar Pharmaceutical Co.*,[190] the

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181 210 U.S. 405 (1908).
182 *Id.* at 425.
183 Dawson Chemical Company v. Rohm and Haas Company, 448 U.S. 176, 215 (1980).
184 444 U.S. 164 (1979).
185 *Id.* at 176.
186 *Id.* at 168.
187 *Id.* at 176.
188 *Id.* at 179-80.
189 Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419 (1982).
190 733 F.2d 858 (1984), *cert. denied*, — U.S. —, 105 S.Ct. 183 (1984).

Court of Appeals for the Federal Circuit (CAFC), the highest patent court in the country, confronted the question of whether pre-approval testing constituted patent infringement. In that case, Bolar, a generic drug manufacturer, used a substance patented by Roche[191] in order to develop data for submission to FDA.[192] The primary purpose of Bolar's use of the patented drug was to gain a market advantage immediately following the expiration of the patent held by Roche.[193] The CAFC held that a patent grant includes the exclusive right to use the patented invention for the development of further data involving a patented product.[194] Moreover, the testing performed by Bolar was found to have infringed the patent held by Roche.[195] The effect of the ANDA/PTR Act is the total legislative reversal of the *Bolar* decision, which may be construed as a taking of property without just compensation and in clear contravention of the Fifth Amendment.

A taking can occur not only through a direct physical invasion by the government, but also where governmental interference has resulted in the defeat of reasonable investment-based expectations.[196] The latter situation invokes a comparative assessment of the value of the property retained versus that which is destroyed, but applies only in cases where the government has restricted the owner's use of his property.[197] In those situations where the government has invaded or authorized the public to share the private property of another, such a comparative analysis is inappropriate.[198] Even if the unaffected portion of the property taken retains significant value to the owner, a compensable taking will be found.[199]

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191 733 F.2d at 860. The substance was flurazepam hydrochloride (flurazepam HCl), the active ingredient in "Dalmane," a prescription hypnotic, manufactured by Roche. *Id.*

192 *Id.* at 860.

193 *Id.*

194 *Id* at 861.

195 *Id.* at 867.

196 Penn Central Transportation Co. v. New York City, 438 U.S. 104, 124 (1978).

197 *Id.* at 104. *See also* Memorandum of Laurence H. Tribe Regarding the Constitutional Issues Posed by Section 202 of the Patent Extension Provisions of H.R. 3605 and S.2748 (Aug. 6, 1984).

198 Memorandum of Laurence H. Tribe, *supra* note 197.

199 *See, e.g.*, Kaiser Aetna v. United States, 444 U.S. 164 (1979); *supra* notes 184-188 and accompanying text.

In 1984, the Supreme Court in *Ruckelshaus v. Monsanto Co.*[200] again set forth unequivocally the bases for finding a compensable taking.[201] At issue in that case was the constitutionality of the government's use of Monsanto's trade secret data to evaluate a subsequent application and the public disclosure of a portion of that data.[202] The *Ruckelshaus* Court placed great weight on the government's interference with Monsanto's reasonable investment-based expectations.[203] The Court was clear that the usefulness of such data to the owner even after disclosure is irrelevant in considering the economic impact of the government's action on the owner's property right.[204] In this regard the Court stated, "[t]he economic value of that property right lies in the competitive advantage over others that [the owner] enjoys by virtue of its exclusive access to the data, and disclosure or use by others of the data would destroy that competitive edge."[205]

Thus, the decisions of the Supreme Court make it clear that governmental interference with the vested rights conferred by the patent grant constitutes a compensable taking under the Fifth Amendment.[206] Section 202 of the Act runs counter to these holdings. In effect, the Act transfers the patentee's exclusive right to use the patented product to the patentee's competition in order that the competitor may conduct pre-marketing tests.[207] Such use substantially undercuts the patentee's rights, defeats his reasonable expectations, and consequently deprives him of his exclusive property right.

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200 — U.S. —, 104 S.Ct. 2862 (1984).

201 104 S.Ct. at 2875.

202 104 S.Ct. at 2866-67.

203 104 S.Ct. at 2875 (citing Kaiser Aetna, 444 U.S. at 175; Penn Central, 438 U.S. at 124).

204 104 S.Ct. at 2878.

205 *Id.*

206 Analyses and accord on this issue were obtained from such notable constitutional scholars as Laurence H. Tribe, Henry Paul Monaghan, and Norman Dorsen. *See* Memorandum of Laurence H. Tribe Regarding the Constitutional Issues Posed by Section 202 of the Patent Extension Provisions of H.R. 3605 and S. 2748 (Aug. 6, 1984); Statement by Henry Paul Monaghan on S.2748, the Proposed Amendments to the Food, Drug, and Cosmetic Act and the Patent Act (Aug. 6, 1984); Statement of Norman Dorsen before the House Subcomm. on Courts, Civil Liberties and the Administration of Justice of the Comm. on the Judiciary (June 27, 1984).

207 *See supra* notes 169, 176 and accompanying text.

Effect on the FDA

Of all those sectors, both public and private, which will feel the impact of this legislation, the FDA undoubtedly will be significantly affected. Numerous provisions of the Act place additional and substantial responsibilities on an agency already overburdened and understaffed.[208] Such responsibilities include the review and prompt action on ANDA submissions, publication of patent information, promulgation of implementing regulations, determinations of "due diligence," and monitoring civil patent litigation proceedings.[209]

The review of newly filed ANDA submissions alone may prove to easily overwhelm this regulatory agency.[210] By the end of 1985, an estimated 150-160 additional drug products will be eligible for submission as ANDAs under the terms of the Act.[211] These are products which were approved for commercial marketing after 1962, and whose patents have or will expire by the end of 1985. Simple mathematical calculations are sufficient to illustrate the potential deluge of ANDA filings which may innundate FDA. There are an estimated six hundred generic drug manufacturers which rely on the sale of nonpatented products as their primary source of revenues.[212] Due to the relative ease with which an ANDA can be filed, it can be anticipated that these manufacturers will take immediate advantage of the ANDA mechanism to increase their share of these now available post-1962 drug products. The FDA, nonetheless, has estimated conservatively the effect of this legislation. It anticipated the receipt of only nine hundred applications during the first six months after enactment, and approximately four hundred ANDAs within the

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208 Halperin, *Predictions on Pharmaceutical Regulations in the 1980's*, DRUG INFORMATION J. 71, 72 (April/June 1981); *New Drug Application Backlog Keeps Mounting at FDA*, 17(5) WASH. DRUG LETTER 1 (Feb. 4, 1985); Crout, *The Drug Regulatory System: Reflections and Predictions*, 36 FOOD DRUG COSM. L.J. 106, 109 (1981).

209 *See infra* text accompanying notes 210-243.

210 Shacknai & Fisher, *The ANDA/Patent Extension Law: What lies within*, 5(1) PHARMACEUTICAL EXECUTIVE 36, 43-44 (1985).

211 H.R. REP. No. 857, *supra* note 5, at 19. *See also* Statement by Mark Novitch, M.D., Acting Commissioner of Food and Drugs, Department of Health and Human Services, before the Senate Committee on Labor and Human Resources (June 28, 1984).

212 *See* OTA REPORT, *supra* note 2, at 17.

second six months.[213]

Commentators on the legislation view its effect differently. One commentator estimated the number of applications to be more realistically in the range of 3,000 to 5,000.[214] This estimate is based upon the number of post-1962 drugs whose patents will expire by the end of 1985 (160), multiplied by an expected twenty to thirty applications for each product.[215] This estimate, however, fails to consider the vast number of generic firms which may take advantage of the ANDA procedure. If each of the six hundred generic manufacturers elects to submit an ANDA on only ten to twenty of the 150 products which will be available, the number of applications requiring FDA review could range between 6,000 and 12,000.

The volume of applications to be reviewed by FDA is further complicated by the limited time frame within which FDA is required to act upon these submissions. The Act stipulates that FDA must approve or disapprove each ANDA within 180 days of initial receipt.[216] This requirement is tempered only by the caveat that the Secretary of Health and Human Services and the applicant may agree to an extension of that time period.[217]

Prior to enactment of the bill, FDA urged Congress to reconsider this time frame provision because of the burdensome backlog of applications it would create. Specifically, Mark Novitch, M.D., then Acting Commissioner of Food and Drugs, told Congress that they "should be aware that [FDA] would be unable to act on each application within the 180 day time-frame specified in the bill if . . . confronted by the staggering volume of applications that we anticipate receiving."[218] Despite this warning, the 180 day limit was retained; however, in practical effect, it is highly unlikely that compliance with this time frame provision can be achieved.

To encumber the process even more, the FDA cannot avoid

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213 Statement by Mark Novitch, M.D., *supra* note 211.

214 S. Gilston, *Patent/ANDA Bill: Its Impact on FDA*, 3 MED. ADVER. NEWS 20, 21 (1984).

215 *Id.*

216 Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1588 (to be codified at 21 U.S.C. § 355(j)(4)(A)).

217 *Id.*

218 Statement by Mark Novitch, M.D., *supra* note 211.

this stricture by disapproving an application. Should FDA decide to disapprove an application, its responsibility under the Act is compounded further. The applicant must be given a notice of opportunity for a hearing.[219] If this opportunity is accepted, it must be held no later than 120 days after the notice, unless otherwise agreed to by the Secretary and the applicant.[220] Such hearings, in any case, must be conducted on an expedited basis, with a final ruling issued within ninety days after final briefs are filed.[221]

In addition to the vast duties imposed by the ANDA portion of the Act, the FDA also has responsibilities involving implementation of the patent extension provisions. Any application for patent term extension[222] must include "a brief description of the activities undertaken by the applicant during the applicable regulatory review period . . . and the significant dates applicable to such activities."[223] Within thirty days of FDA's receipt of a copy of the application from the Patent Office, FDA must accomplish four tasks. A review of the dates pertinent to the regulatory review period must be undertaken. Based upon such a review, a determination must be made concerning the appropriate regulatory review period. Notice of the determination must then be sent to the Commissioner of Patents and such notice must be published in the *Federal Register*.[224] Accordingly, in its review, FDA will be required to undertake an examination of all of its records pertaining to the particular subject drug, medical device, color or food additive. Such a review will be necessary in order to verify that the dates provided by the applicant are correct, and to determine the regulatory review period which will form the basis of any patent extension to be granted.

In spite of a plea by the Agency to eliminate this additional burden of review,[225] the requirement was retained in the bill's

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219 Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1589-90 (to be codified at 21 U.S.C. § 355(j)(4)(C)).

220 *Id.*

221 *Id.*

222 *See supra* notes 157-166 and accompanying text.

223 Pub. L. No. 98-417, § 201(a), 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1599 (to be codified at 35 U.S.C. § 156(d)(1)(D)).

224 *Id.* § 201(a) (to be codified at 35 U.S.C. § 156(d)(2)(A)).

225 Statement by Mark Novitch, M.D., *supra* note 211. The same concern was transmitted to the Chairman of the House Committee on the Judiciary. Letter from

final version, and is now law. According to FDA, "the Agency would have to store and retrieve information in a form which otherwise would be of little or no utility to it."[226] Rather than require FDA to independently determine the applicable regulatory review period within a restrictive thirty-day time frame, the Agency proposed an alternative; that is, that the applicant determine the regulatory review period, with discretionary review conducted by FDA.[227]

An additional obligation may be imposed upon FDA even after a regulatory review period determination has been completed. Once the Agency's final determination of such a period has been published, any interested person may, within 180 days of such publication, submit a petition challenging the presumption that an NDA holder acted with "due diligence" during the review period.[228] Any petition which reasonably evinces an applicant's failure to act with such diligence triggers FDA's responsibility to conduct a due diligence determination.[229] As with many other of the Act's provisions, FDA must take action within stipulated time frames. Not later than ninety days following receipt of such a petition, the Agency must complete its due diligence inquiry and publish its decision in the *Federal Register*.[230] Within sixty days after such publication, any interested person may request an informal hearing on the determination.[231] This hearing must be held within thirty days after the date of the request, unless the challenger requests the hearing be postponed to not later than sixty days.[232] Following the hearing, FDA has thirty days within which to affirm or revise its decision, and to

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Cynthia C. Root, Deputy Assistant Secretary for Legislation (Health) to Hon. Peter W. Rodino, Jr. (July 24, 1984).

226 Statement by Mark Novitch, M.D, *supra* note 211, at 9.

227 *See id*, at 9-10.

228 Pub. L. No. 98-417, § 201(a), 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1599-1600 (to be codified at 35 U.S.C. § 156(d)(2)(B)). *See also supra* text accompanying notes 162-163.

229 Pub. L. No. 98-417, § 201(a), 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1599-1600 (to be codified at 35 U.S.C. § 156(d)(2)(B)). *See also* H.R. REP. No. 857, *supra* note 5, at 41-42.

230 Pub. L. No. 98-417, § 201(a), 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1599-1600 (to be codified at 35 U.S.C. § 156(d)(2)(B)(i),(ii)).

231 *Id.* § 201(a) (to be codified at 35 U.S.C. § 156(d)(2)(B)(ii)).

232 *Id.*

publish any revision in the *Federal Register*.[233]

Again, the FDA voiced opposition to inclusion of the "due diligence" provision.[234] It conceded that the congressional intent was "to make patent restoration as fair as possible by disallowing time during which the development of a product was not vigorously pursued."[235] The Agency, however, pointed out that:

> we believe that the overwhelming majority of applicants would be entitled to the . . . maximum allowable patent restoration. . . . Nonetheless, under the bill, FDA would be required to promulgate regulations, review petitions, prepare due diligence determinations and conduct hearings. As a practical matter, therefore, it appears that a complex system would be established that would require FDA resources to implement and maintain for no net public benefit. We therefore strongly urge that this feature of the bill be deleted.[236]

Nonetheless, these admonitions were not heeded in the passage of the bill.

A further drain on FDA resources will result from the need for the Agency to monitor civil patent litigation proceedings. FDA is required, under the Act, to delay the effective date of approval of an ANDA pending resolution of civil litigation for patent invalidity or non-infringement.[237] In addition, in those instances where a generic manufacturer submits an ANDA which ultimately results in successful patent litigation, the effective date of any subsequently filed ANDAs must be delayed.[238] Under this scheme, FDA must await the outcome of the litigation and then postpone the effective date of such subsequent ANDAs until a court determines that the challenged patent is invalid or not infringed, or until the first generic drug involved in the patent challenge has been marketed for 180 days.[239]

Other factors affecting FDA's ability to implement the Act include several administrative directives. FDA is required to promulgate regulations necessary to administer the new law within one year

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233 *Id.*

234 Statement by Mark Novitch, M.D., *supra* note 211, at 10.

235 *Id.*

236 *Id.* at 10-11.

237 Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1589 (to be codified at 21 U.S.C. § 355(j)(4)(B)(iii)).

238 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(4)(B)(iv)).

239 *Id.*

of the statute's enactment.[240] In addition, every thirty days the Agency must update its list of all drugs approved by FDA,[241] including new approvals, pertinent patent information,[242] and the decision as to whether *in vitro* or *in vivo* bioequivalence studies, or both, are required for ANDAs.[243]

The cost to FDA of implementing the ANDA/PTR Act also must be recognized. In its June 19, 1984 report to the House Committee on Energy and Commerce, the Congressional Budget Office (CBO) estimated the potential costs to FDA to be approximately $1.1 million.[244] This estimate was based upon the need for fifteen new FDA employees at an average salary, including fringe benefits, of $70,000.[245] Less than two months later, however, the CBO revised its personnel cost estimate, reporting a potential increase of $2.2 million.[246] Unlike the first estimate reported by the CBO, the second report failed to reveal the breakdown which formed the basis for the new estimate.[247] An even more recent estimate projected the need for seventy-three additional personnel to implement the Act, at a cost of $3.2 million.[248] If the additional personnel required for implementation should number seventy-three, the actual cost to the FDA will be even greater. Taking the average cost of $70,000 per employee previously utilized by the CBO, the additional cost to the government could amount to $5.1 million.

Effect on Pioneer Manufacturers

Obvious benefits will accrue to research intensive pharmaceutical manufacturers as a direct result of the Act. The Act's marketing exclusivity sections[249] are an example of one such ben-

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240 *Id.* § 105(a), 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1597.

241 *Id.* § 101, 1984 U.S. CODE CONG. & AD. NEWS. (98 Stat.) 1591 (to be codified at 21 U.S.C. § 355(j)(6)(A)(ii)).

242 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(6)(A)(iii)).

243 *Id.* § 101 (to be codified at 21 U.S.C. § 355(j)(6)(A)(i)(III)).

244 Letter from Eric Hanushek, U.S. Congress, Congressional Budget Office, to Hon. John D. Dingell, Chairman of the House Committee on Energy and Commerce (June 19, 1984), *reprinted in* H.R. REP. No. 857, *supra* note 5, at 19-20.

245 *Id.*

246 Statement of the Congressional Budget Office, report from Rudolph G. Penner, Director, to Hon. Peter W. Rodino, Jr., Chairman, House Committee on the Judiciary, *reprinted in* H.R. REP. No. 857, *supra* note 76, at 31-33.

247 *Id.*

248 *See Patent/ANDA Bill: Its Impact on FDA*, *supra* note 214, at 21.

249 *See supra* text accompanying notes 127-142.

efit. Under these provisions, a limited number of products, irrespective of their patent status, will be protected from generic competition for periods ranging from two to ten years.[250] Consequently, pioneer manufacturers will gain from the additional exclusive market share of these drugs, which otherwise would face stiff competition from generic manufacturers.

Aside from the market exclusivity provisions, the Act also permits the term of a patent on certain products to be extended.[251] Thus, many drugs developed by pioneer manufacturers will be protected from generic competition for an additional term of two to five years.[252] As a result of both the marketing exclusivity and patent term extension provisions, pioneer manufacturers will derive increased revenues from the sale of their products. This, in turn, may encourage further expenditures for research into the development of more innovative compounds.[253] Pioneer firms may also reconsider the development of compounds they had previously decided not to pursue due to inadequate patent life.[254]

Despite the advantages to pioneer firms, the compromise nature of the Act results in many disadvantages as well. Prior to this enactment, it was extremely difficult for a generic manufacturer to obtain the data necessary to support FDA approval of a drug marketed after 1962. As a consequence, pioneer firms, for the most part, retained an administrative monopoly on such products even after patent expiration. With the advent of the new ANDA procedure, such data are no longer necessary. Hence, following patent expiration, generic firms will almost immediately be able to compete with pioneer manufacturers in the sale of these post-1962 drug products.[255] In this area, pioneer manufacturers will experience a substantial reduction in revenues.

A further disadvantage to pioneer firms stems from the Act's definition of "non-infringing uses" of a patented drug by a ge-

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250 *Id.*

251 *See supra* text accompanying notes 154-167.

252 *See supra* text accompanying notes 161-167.

253 Shacknai, *supra* note 210, at 36.

254 *A Drug Compromise that Benefits Everyone*, BUS. WK. 120H, 120K (June 11, 1984).

255 Shacknai, *supra* note 210, at 36.

neric competitor.[256] A generic firm is now free to use a *patented* drug to conduct the necessary testing required to gain FDA approval.[257] Prior to this statute, any unauthorized use of a patented product was considered infringement.[258] Now, however, the generic competitor will be assured of having the data it needs to file an ANDA immediately following the patent's expiration, and, consequently, is guaranteed rapid entry into the marketplace.

The question of the possible constitutional infirmity of the non-infringing use provisions also has been raised.[259] That is, the act of retroactively allowing a third party to use a patented product without authorization constitutes a "taking" of property in violation of the Fifth Amendment.[260] Should pioneer firms elect to defend the property rights inherent in their patents and pursue this constitutional challenge, they will be faced with the expense of protracted litigation.

An additional source of potential litigation for pioneer firms may be the relative ease with which the Act allows a generic firm to challenge the validity of a pioneer drug's patent. In this regard, the generic applicant can certify that, in its opinion, and to the best of its knowledge, a particular patent is not valid or will not be infringed.[261] In the event such a certification is made, and absent a suit for infringement within forty-five days by the pioneer manufacturer,[262] the generic application can be made effective immediately upon approval.[263] Even if such an application is made and is subsequently found to constitute infringement, the remedies available to pioneer firms may be limited. For example, monetary damages can be awarded only if the third party has ac-

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256 *See supra* notes 169 and 176 and accompanying text.

257 Pub. L. No. 98-417, § 202, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1603 (to be codified at 35 U.S.C. § 271(e)(1)).

258 *See supra* notes 169-172 and accompanying text.

259 *See supra* text accompanying notes 174-207.

260 *See supra* text accompanying notes 178-207.

261 Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1586 (to be codified at 21 U.S.C. § 355 (j)(2)(A)(vii)(IV)).

262 In an infringement action, the statute sets forth defenses which must be affirmatively pleaded. *Id.* § 203, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1603 (to be codified at 35 U.S.C. § 282).

263 Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1589 (to be codified at 21 U.S.C. § 355(j)(4)(B)(iii)).

tually marketed the drug.[264] If commercial sales have not yet occurred, the court is again limited. The court must issue an order requiring FDA to withhold the effective date of approval of the generic application until a date not earlier than the expiration date of the infringed patent.[265] Consonant with such an order, an infringer may be enjoined from engaging in the commercial manufacture, use, or sale of the generic drug.[266] The only other available relief may be an award of attorney's fees.[267]

As evidenced by the foregoing, a generic manufacturer has little to lose, and much to gain, by challenging the validity of a pioneer drug's patent. Furthermore, if the challenge is successful, the generic firm may gain yet another advantage. If this firm is the first challenger, six months of market exclusivity will be awarded to the victor over subsequent generic competitors.[268] Due to the limited remedies available to pioneer firms, as well as the market exclusivity advantage awarded to the first successful generic challenger, the statute, in essence, encourages patent challenges. As a consequence, research based firms may be forced into a defense of their patents, with a multitude of groundless patent challenges the likely result.

An additional drawback of the statute is its restrictive eligibility provisions for patent extension. Patent extension is available only as the result of a regulatory review period leading to the first permitted commercial marketing or use of a product.[269] Since the term "product," as defined in the Act, is limited to the drug's active ingredient(s),[270] this definition will not encompass certain subsequent improvements to the product. For example, even if a company develops a new and useful dosage form for an existing product, patent extension would not be available. This

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264 *Id.* § 202, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1603 (to be codified at 35 U.S.C. § 271(e)(4)(C)).

265 *Id.* § 202 (to be codified at 35 U.S.C. § 271(e)(4)(A)).

266 *Id.* § 202 (to be codified at 35 U.S.C. § 271(e)(4)(B)).

267 *Id.* § 202 (to be codified at 35 U.S.C. § 271(e)(4)).

268 *See supra* note 152 and accompanying text.

269 Pub. L. No. 98-417, § 201, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1598 (to be codified at 35 U.S.C. § 156(a)(5)(A)).

270 *Id.* § 201, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1600-01 (to be codified at 35 U.S.C. § 156(f)(2)). "The term 'human drug product' means the active ingredient of a new drug, antibiotic drug, or human biological product . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient." *Id.*

would be true even though the new dosage form application had been subjected to FDA review. Consequently, the Act fails in this regard to provide an incentive to pioneer firms to seek significant improvements to their existing products.

Another cause of concern to pioneer firms rests in the Act's due diligence provisions. The statute allows *any interested person* to challenge FDA's due diligence determinations.[271] Therefore, firms could be subject to attack from almost anyone, including their competitors. The expansive nature of this section portends ramifications for the pioneer firms' internal documentation procedures, as well as their relationships with FDA.[272] In anticipation of the possibility of such future due diligence proceedings, the pharmaceutical industry will feel compelled to document each and every FDA request or response, and reasons in support of their contrary views.[273] One pharmaceutical attorney expressed the concern felt by research intensive companies as follows:

> What are the choices—to follow blindly the agency's research design recommendations, which is tantamount to government control of research; to document massively the record in order to support the sponsor's decisions, which obviously will antagonize the agency's scientists and fuel the adversarial character of the proceeding; or to choose not to conduct . . . conferences, which effectively would deny all the benefits of the conferences and the innovative spur they are thought to contain?[274]

Thus, the due diligence provision represents yet another potential problem for which the pharmaceutical industry must be prepared. The unfortunate consequence of this dilemma may be that informal agreements and the candid exchange of scientific ideas may prove to be stifled.[275]

Finally, and equally as important, is the pioneer manufacturers' legitimate concern about the Act's effect upon the FDA, especially in

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271 *Id.* § 201 1984 U.S. CODE CONG & AD. NEWS (98 Stat.) 1599-1600 (to be codified at 35 U.S.C. § 156(d)(2)(B)(i),(ii)); *see also* text accompanying notes 162-163, 228-236.

272 Kaplan & Becker, *ANDA/Patent Extension Balancing Act* (written by Miller), 5(2) PHARMACEUTICAL EXECUTIVE 58, 58-60 (1985).

273 *Id.* at 60.

274 *Id.*

275 *Id.*

regard to the review and approval of potentially thousands of ANDAs within a limited time frame.[276] The research based industry is fearful that, of necessity, FDA's focus will be shifted away from the review of NDAs, as well as supplemental NDAs, in order to comply with the 180-day mandate within which to review ANDAs. The same concern was voiced by FDA Commissioner, Frank Young, M.D.[277] While Dr. Young conceded that resources would have to be redeployed, he promised to do so in a way which would minimize the effect on ongoing activities.[278]

Only the test of time will provide the answer as to what impact the Act will have upon the NDA review process and pioneer manufacturers as a whole. As one commentator so aptly stated, "the drug industry should be prepared at least for a period of confusion. If this hurts the NDA review process, the gains made from the patent extension law may prove to be a Pyrrhic victory."[279]

Effect on Generic Manufacturers

Overall, generic manufacturers have much to gain from the new law. The Act affords these manufacturers the opportunity to file ANDAs on drug products which are no longer protected by patent.[280] By year end 1985, there will be approximately 150 of such products from which to choose. In 1983, these brand name drugs represented almost $4 billion in sales. The positive economic effect on the generic drug industry, therefore, is projected to be tremendous. It is estimated that what is now a $700 million a year business for generic firms, could increase more than threefold by 1988.[281] Such an increase in volume could revolutionize the generic drug industry.

Several specific provisions of the Act are certain to be advantageous to generic firms. One such advantage lies in the non-infringing use provision. Anyone is now free to use any patented drug for the purpose of developing and submitting data "under a

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276 *See supra* notes 209-218 and accompanying text.

277 *FDA Ability to Meet Review Deadlines Is Part of Comm. Young's Action Plan of Policy Objectives; Resource Allocation Is Key to Drug Bill Implementation*, 46 (39) F-D-C REPORTS 3 (Sept. 24, 1984).

278 *Id.*

279 Gilston, *supra* note 214, at 27.

280 *See supra* notes 99-119 and accompanying text.

281 *Generic Drama*, FINANCIAL WORLD 17 (Oct. 17-30, 1984).

Federal law which regulates the manufacture, use or sale of drugs."[282] Thus, generic firms will be able to complete the testing required for approval long before the drug it wishes to market "comes off" patent. Prior to the Act, such use would have been considered infringement.[283] Now, however, the generic firm will be able to immediately file an ANDA on the date a patent lapses, and thus be assured that commercial marketing can begin as soon as approval is received. Nonetheless, it is again necessary to raise the caveat to the use provision that the constitutionality of allowing such unauthorized use may be challenged.[284] If this section is ultimately held to be unconstitutional, the possibility exists that any data generated through unauthorized use may prove valueless for submission to FDA.

Generic firms also will benefit if FDA can adhere to the expedited review process required by the Act. The statute mandates that any ANDA be reviewed within 180 days of initial receipt,[285] a time frame which is considerably shorter than the 18-24 months previously reported for review of ANDAs.[286]

Additionally, the relative ease with which a generic manufacturer can challenge the validity of a patented drug is a plus. A generic firm will gain a substantial advantage if its attack on a patented drug proves to be successful. In that case, the generic

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282 Pub. L. No. 98-417, § 202, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1603 (to be codified at 35 U.S.C. § 271(e)(1)). It has been postulated that the ambiguous wording of this section may implicate laws other than the Food, Drug, and Cosmetic Act. As the argument is presented, several other laws regulate the manufacture, use, or sale of drugs. Such laws include the Controlled Substances Act, the Lanham Act and possibly the Federal Trade Commission Act. Since the present Act does not specify a particular law, it raises the question as to whether a competitor can test a patented drug, for example, to determine the validity of the patent holder's claims and submit such data to another agency with a complaint that the claims violate a particular Act. Address by Andrew S. Krulwich, Statutory Reversal of Roche v. Bolar: What You See Is Only the Beginning of What You Get, Food and Drug Law Institute Meeting, Washington, D.C. (Nov. 13, 1984). Despite the Act's ambiguity, the House Report may clarify this wording. Specifically, the Report states that "[t]he information which can be developed under this provision is the type which is required to obtain approval of the drug." H.R. REP. No. 857, *supra* note 5, at 45.

283 *See supra* text accompanying notes 169, 191-195.

284 *See supra* text accompanying notes 174-207.

285 Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1588 (to be codified at 21 U.S.C. § 355(j)(4)(A)).

286 BUS. WK., *supra* note 254, at 120H.

firm will be rewarded with six months of market exclusivity over subsequent generic competitors.[287]

Notwithstanding these benefits, generic firms also will suffer several disadvantages. Some of the drawbacks stem directly from certain provisions of the Act, while others emanate from external forces. One direct effect which will adversely affect generic firms originates from the market exclusivity provisions of the Act.[288] These provisions prevent generic firms from competing with certain pioneer drug products for periods ranging from two to ten years.[289] There are approximately fifty-six drug products which, despite their patent status, generic firms will be prohibited from marketing for ten years.[290] Many other products will be protected from generic competition for either two, three or five years. Thus, the protection of these drugs from competition forecloses generic firms from sharing in the sizeable profits which these drugs will generate during the periods of exclusive marketing.

Generic firms also will be placed at a disadvantage as a result of the Act's new definition of infringement.[291] The Act has amended the patent law, making it an act of infringement to *submit* to FDA an application for a drug whose patent has not yet expired, "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . before the expiration of such patent."[292] Prior to the Act there was no such limitation on the submission of material to the FDA. Therefore, a generic firm previously could have received FDA approval to market a patented drug. Even with such approval, however, the generic firm was not entirely free to market the drug, for if it did so, it would be subject to an infringement action. Before enactment of the statute, therefore, a generic firm was able to submit its application, receive FDA ap-

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287 Pub. L. No. 98-417, § 101, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1589 (to be codified at 21 U.S.C. § 355(j)(4)(B)(iv)).

288 *See supra* notes 127-142 and accompanying text.

289 *Id.*

290 *Pfizer, Roche & Upjohn Have Four New Drug Chemical Entities That Get 10 Years of ANDA Protection Under Transition Sections of ANDA/Patent Legislation*, 46 F-D-C REPORTS S4 (Sept. 10, 1984).

291 Pub. L. No. 98-417, § 202, 1984 U.S. CODE CONG. & AD. NEWS (98 Stat.) 1603 (to be codified at 35 U.S.C. § 271(e)(2)).

292 *Id.*

proval, and then market the drug, albeit at the risk of an infringement action.

The overall impact of this legislation on the generic pharmaceutical industry is also worthy of consideration. The Act has unleashed hundreds of previously unavailable drug products for marketing as generic drugs. Due to the relatively low investment required by generic firms to market such drugs, the potential profits to be realized therefrom will amount to millions of dollars. It would not be unlikely, therefore, to see an increase in the number of generic manufacturers, both domestically and internationally, who will be interested in taking advantage of this newly created market. As the number of firms increase, generic firms will have to contend with the attendant increase in competition for a share of the market on those drug products. In order to maintain a competitive edge against these newly emerging firms, generic manufacturers may be forced to expend greater revenues than ever before on advertising. Accordingly, the expected profits to be gained from the availability of these additional generic drugs may prove, in the long-term, to be somewhat illusory.

Another obstacle which may prevent generic firms from fully realizing the benefit of the new law is the longstanding aversion to the use of generic drugs.[293] Although the trend has been changing over recent years,[294] physicians still have a greater tendency to write prescriptions for brand name drugs. Pharmacists are hesitant to substitute a generic equivalent for a brand name product because of potential liability should that generic product cause injury. Finally, consumer preference for brand name products adds even further to the generic dilemma.[295] Government cost containment programs which mandate the purchase of low-cost pharmaceutical products may help to counteract some of these practices. Nonetheless, generic firms will still face a challenge in attempting to eliminate these barriers to acceptance.

Effect on Consumers

The ANDA/PTR Act has been acclaimed as the most impor-

293 OTA REPORT, *supra* note 2, at 6.

294 Foley, *Pharmacy Substitution Promises to Come on Stronger in 1985*, 129(7) DRUG TOPICS 67 (April 1, 1985).

295 *Id.*; *Generic Drama*, *supra* note 281.

tant consumer bill adopted by Congress during 1984.[296] As a result of this legislation, the number of generic drugs available to the consuming public will substantially increase. Since the cost of generic drug products is considerably less than their brand name counterparts, consumers are expected to realize savings of approximately $1 billion over the next twelve years.[297] Those who will benefit most will be the elderly and chronically ill.

By providing added incentives to pioneer manufacturers to invest in research and development, consumers will also be the indirect beneficiaries of the Act's overall goals. The therapeutic use of pharmaceutical products in the treatment of many types of disease represents a much less costly alternative to other forms of health care, such as hospitalization and surgery. Consumers, therefore, will continue to benefit as new pharmaceutical products are developed by pioneer manufacturers. Furthermore, these innovative products should become more readily available if the additional revenues expected to be derived from the patent term restoration aspects of this legislation are reinvested into research and development of new compounds and uses.

Whereas the benefits, in terms of savings to consumers, appear to be substantial, the expense of implementing, enforcing and upholding this legislation also should be considered. Two areas in particular are almost certain to result in indirect costs to the taxpaying public. The first is the cost associated with FDA's implementation of the Act.[298] Estimated *annual* costs to FDA have been reported to be in the range of $3.2 million.[299] The second cost will be incurred in the likely event a challenge is made concerning the constitutionality of the Act.[300] Should such a challenge materialize, the costs of litigating such an issue could prove to be quite substantial. In the end analysis, all such costs must be factored in the determination of how much the consumer will eventually gain through enactment of this law.

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296 *Drug Bill Approved by House*, Wash. Post, Sept. 7, 1984, at A1, col. 6.

297 BUS. WK., *supra* note 254, at 120H; *Accord May Lead to Cheaper Drugs*, N.Y. Times, June 2, 1984, at 1, col. 1; *Drug Manufacturers Oppose Bill That Would Double Sale of Generics*, Star-Ledger, June 28, 1984, at 14, col. 1; *Drug Bill Approved by House*, Wash. Post, Sept. 7, 1984, at A1, col. 6.

298 *See supra* notes 244-248 and accompanying text.

299 *See Patent/ANDA Bill: Its Impact on FDA*, *supra* note 214, at 21.

300 *See supra* notes 174-207 and accompanying text.

Conclusion

Few will dispute the need for an unbiased regulatory body to conduct indepth reviews of new drug applications. Such scrutiny is necessary in order to ensure that the public will benefit from safe and effective drugs. The problematic nature of the controversy rests in the length of time required to conduct such reviews.

The ANDA/PTR Act undoubtedly represents a giant step forward in attempting to alleviate the recognized inequities resulting from the protracted regulatory review process. Nonetheless, the Act addresses only the symptoms of the problem while failing to effect a remedy. The review of applications for new drugs continues to take an inordinate amount of time. The Act will not change that situation. Rather, the statute complicates matters further by placing additional burdens on FDA. Without adequate staffing, the time required to process the tremendous volume of work will continue to increase and may eventually neutralize the benefits gained from patent term restoration.

While numerous studies have identified deficiencies in the FDA approval process,[301] recent efforts to address this long-standing problem have been initiated by PMA. The PMA has created task forces to work with FDA to evaluate key areas impacting on the drug approval process.[302] These task forces are examining: the possibility of imposing "user fees" for each drug reviewed;[303] computerization at FDA; decentralization of FDA's activities; advisory committees; and incentives.[304] The FDA already has taken steps aimed toward improving the drug review process. Revised regulations have been issued governing NDA

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301 Hutt, *supra* note 12.

302 Address by Kenneth P. Berkowitz, Assistant Vice President and Director, Public Policy and Communications, Hoffmann-La Roche Inc., to the New Jersey Health Sciences Group, March 5, 1985.

303 *PMA "User Fee" Proposal*, 983 SCRIP 15 (Mar. 20, 1985) (quoting Gerald Mossinghoff, President of the Pharmaceutical Manufacturer's Association); THE FOOD & DRUG LETTER (Feb. 22, 1985); *User Fees: A Recurring Theme in President's Proposed Budget*, 27(6) PMA NEWSLETTER 1 (Feb. 11, 1985). Authorization for the establishment of user fees by government agencies is provided for by statute. 31 U.S.C. § 9701.

304 Address by Kenneth P. Berkowitz, *supra* note 302.

submissions.[305] In addition, FDA has developed an action plan to be issued in the near future, a key portion of which will address the review process.[306] But, neither FDA nor private industry can accomplish this task alone. Support and involvement of consumer groups, the media and, especially Congress, are urgently needed. Only through the combined efforts of all will a resolution to the problem be possible.

*Linda J. Honeycheck**

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[305] New Drug and Antibiotic Regulations, 50(36) Fed. Reg. 7452-7519 (1985) (to be codified in scattered sections of 21 C.F.R.).

> The regulations are expected to shorten the total elapsed time required to approve the average application . . . from about 27 months to 21 months —an average savings of six months. The average approval time for applications involving important new chemical entities is projected to improve from about 19 months to 17 months—an average savings of 2 months.

50(36) Fed. Reg. 7454.

[306] *FDA Ability to Meet Review Deadlines Is Part of Comm. Young's Action Plan of Policy Objectives; Resource Allocation Is Key to Drug Bill Implementation*, 46(39) F-D-C REPORTS 3 (Sept. 24, 1984).

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