

PATENT TERM LIMITS, ANTI-TRUST LAW, AND THE
HATCH-WAXMAN ACT: WHY DEFENSE OF A LEGALLY
GRANTED PATENT MONOPOLY DOES NOT VIOLATE ANTI-
TRUST LAWS.

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I. INTRODUCTION

In the interest of increasing public availability of prescription medication, Congress has enacted laws that make challenging the patents held by pharmaceutical companies not only easy, but also advantageous. In the wake of these legislative changes, patent validity challenges and accompanying patent infringement suits have been increasing in number.¹ In an effort to reduce the uncertainty inherent in patent litigation, reduce litigation costs, and ensure retention of the patent rights that protect their time-limited market share, many patent-holding pharmaceutical companies have attempted to settle litigations with generic pharmaceutical companies out of court. Unfortunately, the Federal Trade Commission (“FTC”) has been diligently pushing to declare all of these settlement agreements anti-competitive and inherently in violation of anti-trust laws, thereby categorizing them as illegal and invalid. This article will examine the issues in recent litigation settlements, the FTC’s misunderstanding of the most effective and correct application of anti-trust laws to situations involving government-granted patent monopolies, and how courts should treat current and future infringement suits and settlement agreements.

II. PATENT BASICS

Congress, pursuant to its Constitutionally granted power to promote scientific and intellectual progress,² enacted the patent code to promote

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1. U. of Houston Law Ctr., *U.S. Patent Litigation Statistics* (Jeffrey Johnson ed.), <http://www.patstats.org/Patstats3.html> (last visited Aug. 13, 2007).

2. U.S. CONST. art. 1, § 8, cl. 8.

invention and development and to ensure that inventors and researchers would have incentives to disclose their useful and novel developments to others in their fields and to the greater public.³ Under the US Patent Act, in exchange for divulging their inventions and passing a rigorous and detailed examination process through which novelty, originality, and other considerations are proven, inventors and developers are granted patents that provide monopoly rights by excluding all others from utilizing their patented developments for 20 years from the first relevant application filing date.⁴ This exclusionary right is granted “to allow the patentee to exploit whatever degree of market power it might gain thereby as an incentive, to include investment in innovation and the public disclosure of inventions.”⁵ Because of the challenging examination process that each applicant must undergo before a patent is granted, any court must presume that a patent is valid⁶ until it is conclusively proven otherwise by “clear and satisfactory proof. . .which overcomes every reasonable doubt.”⁷

III. ANTI-TRUST LAW BASICS

The United States economy is generally a competitive free market system that is driven by a basic intention to maximize both economic profit and consumer benefit. To ensure that a sufficient level of competition is maintained in the market, Congress passed the Sherman Act⁸ and the Clayton Act.⁹ The Sherman Act declares illegal “[e]very contract, combination . . . or conspiracy, in restraint of trade,” and expressly prohibits monopolies, whether attempted or actually acquired through conspiracy.¹⁰ Not finding this effective in and of itself, Congress passed the Clayton Act in 1914 to proscribe any sort of agreement if the “effect of such . . . may be to substantially lessen competition or tend to create a monopoly in any line of commerce.”¹¹

The situation changes, however, when a government-granted patent monopoly exists. The Supreme Court has ruled that a patent holder has the right to a legal monopoly and that all related anti-competitive activities are not subject to the Sherman Act unless they act “beyond the confines of the patent monopoly.”¹² In other words, a patent monopoly is perfectly acceptable so

3. 35 U.S.C. §§ 2, 101 (2000).

4. 35 U.S.C. §§ 101, 131, 154(d) (2000).

5. *In re Terazosin Hydrochloride Anti-trust Litig.*, 352 F. Supp. 2d 1279, 1296 (S.D. Fla. 2005) (citing *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003)).

6. 35 U.S.C. § 282 (2000).

7. Fed. Proc. § 60:1111 (L. Ed. 2006); *See Radio Corp. of Am. v. Radio Eng'g Labs.*, 54 Ct. 752, 753 (1934); *See also Washburn & Moen Mfg. Co. v. Beat 'Em All Barbed-Wire Co.*, 143 U.S. 275, 284 (1892).

8. Sherman Act, ch. 647, 26 Stat. 209 (1890) (codified as amended at 15 U.S.C. §§ 1-7 (2000 & Supp. 2004)).

9. Clayton Act, ch. 323, 38 Stat. 730 (1914) (codified as amended at 15 U.S.C. §§ 12-27 (2000 & Supp. 2004), 29 U.S.C. §§ 52, 53 (2000)).

10. 15 U.S.C. §§ 1-2 (Supp. 2004).

11. 15 U.S.C. § 14 (2000).

12. *In re Ciprofloxacin Hydrochloride Anti-trust Litig.*, 261 F. Supp. 2d 188, 248 (E.D.N.Y.

long as the monopoly only exists as to the patented invention and does not extend so far as to create a monopoly over a product or process that is not subject to the patent protection. The basic theory behind this principle maintains that a patent monopoly is legally justifiable, even in a competitive market economy, because the patent exclusivity does not deny the public access to some good that was previously available to it but “merely recognizes an invention that was not previously known.”¹³ The limited duration monopoly is justified by the inventor’s disclosure to the public. Additionally, the Supreme Court has also held that a settlement of claims involving patent infringement does not necessarily violate the Sherman Act, even though such agreements should always be scrutinized to “ascertain whether the restraints imposed are regulations reasonable under the circumstances, or whether their effect is to suppress or unduly restrict competition.”¹⁴

IV. HATCH-WAXMAN INCENTIVES

A. FDA licensing and New Drug Applications

Prior to 1984, every company seeking Food and Drug Administration (“FDA”) approval of a pharmaceutical drug was required to file a New Drug Application (“NDA”), regardless of whether the substance at issue was a new (“brand-name” or “pioneer”¹⁵) drug or a generic copy thereof.¹⁶ The term “generic” refers to a drug containing the exact same active ingredients in the same quantities as a pioneer pharmaceutical, but possibly including different excipient materials (binders or capsules).¹⁷ An NDA “must include exhaustive information about the drug, including reports of safety and efficacy studies.”¹⁸ Additionally, an NDA applicant is required to file the patent number and anticipated expiration date of any patent claiming the active ingredients or composition of the drug.¹⁹ The FDA eventually publishes this, along with other relevant drug information, under the title *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly called the *Orange Book*.²⁰ Until 1984, safety and efficacy tests had to be conducted even if approval was being sought for a generic drug with an active ingredient identical to that of an

2003) (citing *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948).

13. Ramon A. Klitzke, *Patents and Monopolization: The Role of Patents Under Section Two of the Sherman Act*, 68 MARQ. L. REV. 557, 560 (1985).

14. *Standard Oil Co. (Ind.) v. United States*, 283 U.S. 163 (1931).

15. *In re Terazosin Hydrochloride Anti-trust Litig.*, 352 F. Supp. 2d 1279, 1287 (S.D. Fla. 2005).

16. 21 U.S.C. § 355(a) (2000).

17. BLACK’S LAW DICTIONARY 535 (8th ed. 2004).

18. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003); see generally 21 U.S.C. § 355(b) (Supp. 2004).

19. 21 U.S.C. § 355(b)(1) (Supp. 2004).

20. See *Bristol-Myers Squibb Co., Analysis to Aid Public Comment*, 68 Fed. Reg. 12080-01 (2003); see also 21 U.S.C. § 355(j)(7)(A) (2000).

already-approved pioneer drug.²¹ This created a number of conflicts because, prior to 1984, any utilization of a patented drug, even experimental use directly related to an FDA application filing, was considered infringement of patent exclusivity.²² In 1984, however, legislation altered this restriction to allow the use of a patented invention “solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”²³

B. Introduction of Hatch-Waxman and Abbreviated New Drug Applications

In 1984, to increase prescription drug availability and reducing consumer cost, Congress amended the Federal Food, Drug, and Cosmetics Act (“FFDCA”) to include the Drug Price Competition and Patent Term Restoration Act, known commonly as the Hatch-Waxman Act (“Hatch-Waxman”).²⁴ Among other things, Hatch-Waxman added a new section (j) to the FFDCA, thereby creating an option for companies seeking generic drug approval from the FDA to expedite their application by filing an Abbreviated New Drug Application (“ANDA”).²⁵ By filing an ANDA, an applicant is able to bypass many of the testing and proof of safety requirements in exchange for making a few admissions.

An ANDA allows an applicant to incorporate safety and efficacy test results conducted by a prior NDA applicant into its application so long as the active ingredient in the generic drug is the same as, or the “bioequivalent” of, the active ingredient in the NDA.²⁶ Additionally, an ANDA applicant must certify one of the following about the NDA: (1) the relevant patent information has not been filed and published in the *Orange Book* by the original NDA-filing entity; (2) the relevant patent has expired; (3) the date on which the patent will expire; or (4) the patent is invalid for some reason or will not be infringed by the manufacture, use, or sale of the drug specified in the ANDA.²⁷ The first three options pose relatively no legal challenge and applications containing such certifications will be approved either immediately or on the expiration date of the patent. However, the fourth certification requires additional legal action because it inherently shows that the applicant intends to market the new product before the natural expiration date of the

21. *Valley Drug*, 344 F.3d at 1296.

22. 35 U.S.C. § 271(a) (2000); *see also* Merck KGAA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005) (holding that the safe harbor provision codified at 35 U.S.C. § 271(e)(1) (Supp. 2004) could also protect some experimental use not directly leading to FDA certification).

23. 35 USC § 271(e)(1).

24. *Mylan Pharm., Inc. v. FDA*, 454 F.3d 270, 271 (4th Cir. 2006).

25. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1538 (relevant section codified at 21 U.S.C. ' 355(j) (2000).

26. 21 U.S.C. § 355(j)(2) (2000).

27. 21 U.S.C. § 355(j)(2)(A)(vii).

relevant patent, and therefore requires additional regulation.²⁸ When Congress amended 25 USC § 271(e) in 1984 to allow infringing use of patented subject matter if such use is reasonably related to an FDA filing, it thereby also created an infringement action accruing upon such a filing if the intention of the filing party is to commercially manufacture or market the patented subject matter prior to the natural expiration of the patent.²⁹ Therefore, if an ANDA is filed with a paragraph four certification, it creates a cause of action for infringement. Along with filing an ANDA, an applicant must notify the owner of the patent as well as the holder of the approved NDA within 20 days of the postmark on the ANDA.³⁰ The ANDA will be approved automatically if the patent holder does not file an infringement action within 45 days of receiving notification.³¹ The filing of a paragraph four certification automatically creates a cause of action for a patent infringement suit because the certification itself specifies that the bioequivalent of the patented active ingredient from the pioneer drug is going to be sold in the United States immediately upon FDA approval, and therefore will be in direct violation of 35 U.S.C. § 271.³² This cause of action is relatively unique in patent law because it accrues prior to any actual infringing activity.³³ If such an action is filed, the FDA will delay approval for up to 30 months, unless the district court holds that the patent is invalid or not infringed upon or orders that the delay period be extended or shortened.³⁴ It should be noted, however, that the wording of the statute specifies that, barring a court order requiring further approval delay, the generic drug “approval *shall* be made effective” (emphasis added) no longer than 30 months after delivery of notification.³⁵ Thus, the ANDA applicant can receive FDA licensing before a court has determined whether marketing of the pharmaceutical will be in violation of the patent protection held by the original NDA filer.

Congress has given the ANDA applicant a few incentives to file a paragraph four certification application, virtually guaranteeing a high stakes infringement suit. The first such applicant will receive, after FDA approval, a 180-day exclusive right to market the generic drug in the United States.³⁶ This exclusivity right ensures that no other ANDA for the same product can receive FDA approval, and thereby be legally sold, until 180 days after the original ANDA applicant first commercially markets the drug.³⁷ Additionally, by

28. See *AAI Pharma, Inc. v. Thompson*, 296 F.3d 227, 232 (4th Cir. 2002).

29. See 35 USC § 271(e)(2)(A).

30. 21 U.S.C. § 355(j)(2)(B) (Supp. 2004).

31. 21 U.S.C. § 355(j)(5)(B)(iii).

32. 35 U.S.C. § 271(e)(2)(A).

33. The recent Court of Appeals for the Federal Circuit case, *Medimmune, Inc. v. Genentech, Inc.*, 219 Fed. Appx. 986, 2007 WL 930720 (2007), is distinguishable because the parties in that case had already entered into a licensing agreement before the issues of infringement and patent validity arose.

34. 21 U.S.C. § 355(j)(5)(B)(iii).

35. 21 U.S.C. § 355(j)(5)(B)(iii)(I).

36. 21 U.S.C. § 355(j)(5)(B)(iv).

37. *Id.*

allowing infringement suits to begin prior to any actual infringement, the generic applicant is not liable to the pioneer drug patent holder because no illegal sale has taken place. Although the patent holder must bring suit to protect his patent rights, he cannot receive damages even if he is successful. With very little to lose, and much to gain by winning an infringement suit, a potential generic competitor has great incentive to face a lawsuit in the hopes of winning the court's and the FDA's approval.

V. PREVIOUS CASES

The FTC first took action in the conflict between generic and pioneer pharmaceutical companies in 1999, when it objected to settlement agreements related to Hatch-Waxman between Abbott Laboratories ("Abbott"), a pioneer drug patent holder, and Geneva Pharmaceuticals ("Geneva") and Zenith Goldline Pharmaceuticals ("Zenith"), generic drug producers and ANDA filers.³⁸ Since that first case, numerous situations have arisen in which the FTC has objected to settlement agreements as anti-competitive and in violation of the Sherman Act. In 2003, the then-Chairman of the FTC reported to the House of Representatives that the FTC would not tolerate settlements or conduct that effectively "game" the regulatory system of Hatch-Waxman with the intention of preventing generic drug companies from entering the market.³⁹ The following case situations and resulting consent decrees forced by the FTC show the current balance between patent exclusivity, settlement rights, and anti-trust law obligations.

A. *Hytrin & Tamoxifen Citrate Hydrochloride*

Abbott is a pharmaceutical company that held the patent on dihydrate terazosin hydrochloride, the active ingredient in the branded, pioneer drug Hytrin.⁴⁰ In 1998, Abbott entered into a settlement with Zenith. Under this agreement, Abbott would pay roughly \$6 million every three months until the patent expired, was declared invalid, or another generic manufacturer entered the market, if Zenith acknowledged the validity of Abbott's patent and agreed not to market an infringing product or assist another in doing so in the same period of time.⁴¹ In 1998, Abbott settled with Geneva on similar terms, but agreed to pay \$4.5 million per month in return for Geneva's guarantee to refrain from entering the market.⁴² However, because Geneva controlled the

38. See *In re* Abbott Labs. and Geneva Pharm., Inc., Docket No. C-3945, 2000 WL 681848 (F.T.C. 2000).

39. Timothy Muris, Chairman, Fed. Trade Comm'n., Prepared Statement of the Federal Trade Commission Before the Committee on Judiciary Anti-trust Task Force United States House of Representatives Concerning an Overview of Federal Trade Commission Anti-trust Activities (July 24, 2003) (available at <http://www.ftc.gov/os/2003/07/anti-trustoversighttest.htm> (last visited Feb. 11, 2007)).

40. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d at 1296, 1300 n.13 (11th Cir. 2003).

41. *Id.* at 1300.

42. *Id.*

180-day exclusivity granted by the Hatch-Waxman Act, Abbot agreed that it would continue the monthly payments until Geneva entered the market if Geneva was successful in court.⁴³ Both of these agreements were terminated in 1999 as a result of FTC pressure, and were recently declared unlawful as inappropriate restraints of trade in violation of the Sherman Act.⁴⁴

Part of the FTC's main objection to these two settlement agreements was the existence of "reverse payments", or a transfer of money from the patent holder to the generic pharmaceutical company.⁴⁵ "Typically, in patent infringement cases, the payment flows from the alleged infringer to the patent holder,"⁴⁶ but in reverse payment situations, the potentially infringing party receives payment from the patent holder. Although the FTC has expressed a desire to have any settlement containing a reverse payment declared *per se* invalid, the Eleventh and Second Circuits have held that such payments alone cannot justify *per se* invalidity because such a strict ruling would fail to take into account the exclusionary power inherent in patent protection.⁴⁷ However, the FTC was eventually successful in revoking the settlement on an anti-competitive basis because the details of the agreement between Abbott and Geneva provided for the continuation of reverse payments even after the patent was declared invalid, and prohibited Geneva from marketing any Terazosin hydrochloride product (and not solely the product that was the subject of the suit).⁴⁸ The settlement agreement provided for an extension of patent-like exclusivity even beyond the life span of the patent itself, and therefore was held unacceptably anti-competitive.

B. K-Dur 20, Klor Con M20, & Micro-K 20

Schering-Plough Corporation ("Schering") is the producer of K-Dur 20, a potassium chloride supplement unique for its extended-release coating and was once protected by patent number 4,863,743 ("743 patent").⁴⁹ Following a 1997 settlement agreement between Upsher-Smith Laboratories ("Upsher") and Schering, the FTC entered a consent decree with Upsher, which prohibited Upsher from entering any agreements through which it received anything of value in return for not marketing a generic product.⁵⁰ The settlement between Schering and Upsher specified that Upsher would not market a generic version of K-Dur 20 until September 1, 2001, approximately

43. *In re Terazosin Hydrochloride Anti-trust Litig.*, 352 F. Supp. 2d 1279, 1291 (S.D. Fla. 2005).

44. *Valley Drug*, 344 F.3d at 1301; *See In re Terazosin*, 352 F. Supp. 2d 1279.

45. *See In re Abbott Labs.*, Docket No. C-3945, 2000 WL 681848 (F.T.C. 2000).

46. *In re Tamoxifen Citrate Anti-trust Litig.*, 429 F.3d 370, 389 (2nd Cir. 2005) (citing David A. Balto, *Pharmaceutical Patent Settlements: The Anti-trust Risks*, 55 Food & Drug L.J. 321, 335 (2000)).

47. *Valley Drug*, 344 F.3d at 1306; *In re Tamoxifen*, 429 F.3d at 389.

48. *See In re Terazosin*, 352 F. Supp. 2d at 1315-1317.

49. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005).

50. *See In re Schering-Plough Corp.*, Docket No. C-9297, 2002 WL 1488085 (F.T.C. 2002).

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five years before the 743 patent's expiration date, and also included an agreement that Schering would pay a total of \$70 million and 10%-15% in royalty payments in return for a license to market five Upscher products.⁵¹

The Eleventh Circuit had a chance to review this situation, however, when it evaluated the legality of another agreement between Schering and a second generic pharmaceutical company, ESI Lederle, Inc. ("ESI"). This agreement was entered into upon the recommendation of a court-appointed magistrate supervising the mediation between these two companies.⁵² This second agreement allowed ESI to market its generic version of K-Dur 20, labeled Micro-K 20, at the beginning of 2004, three years ahead of the expiration of 743 patent. In return, ESI became responsible for a \$5 million payment, representing legal fees, and a \$10 million payment contingent upon Micro-K 20 receiving FDA approval.⁵³

After reviewing the settlement agreements between Schering and the two generic pharmaceutical companies, in 2001 the FTC brought a complaint claiming violation of the Sherman Act and unlawful monopolization of the potassium supplement market.⁵⁴ When this complaint was tried before an Administrative Law Judge ("ALJ"), it was determined that a finding of anti-competitive action required that the patent be invalid or not infringed upon by the generic products.⁵⁵ With respect to the 743 patent, because neither of these options had factual or legal basis, the agreements were held not to be anti-competitive.⁵⁶ In reviewing the situation, the Eleventh Circuit determined that *per se* invalidity is highly inappropriate and is only to be applied in situations where the agreements in question "have a pernicious effect on competition and lack . . . any redeeming virtue."⁵⁷ The Eleventh Circuit also rejected the more traditional rule of reason analysis in patent cases because it exclusively looks "to determine whether the challenged conduct had an anti-competitive effect on the market."⁵⁸ Patents, in their very essence, restrict competition because they grant an exclusivity right that allows the patent owner to prevent others from making, using, offering to sell, or selling the subject matter of a patented invention.⁵⁹ The court found that the necessary consideration must take into account "the extent to which anti-trust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent anti-trust liability for such exclusionary effects."⁶⁰ In light of these concerns, the Eleventh Circuit adopted a new standard of analysis that

51. See *Schering*, 402 F.3d at 1058-1060.

52. *Id.* at 1060.

53. *Id.* at 1060-1061 n. 6-8.

54. *Id.* at 1061.

55. *Id.*

56. *Id.*

57. *Id.* at 1064 n.11 (citing *Continental T.V. Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 59 (1977)).

58. *Id.* at 1064-1065.

59. See 35 U.S.C. § 271 (Supp. 2004).

60. *Schering*, 402 F.3d at 1066.

includes an investigation of: “(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anti-competitive effects.”⁶¹

The Eleventh Circuit first established that patents are presumed valid and inherently provide the patent owner with a permissive monopoly, and continued the analysis by stating that some balance between a patent’s exclusionary power and the societal benefits achieved through anti-trust law must be achieved.⁶² The court considered the public policy interest in litigation settlement, the inherent uncertainty in patent litigation itself, and the fact that the Hatch-Waxman essentially removes many of the financial barriers that previously prevented generic drug manufacturers from challenging patents.⁶³ The court criticized the FTC’s presumption that any reverse payments are unnecessary to settlement, finding instead that settlement could not occur without sacrifice by both sides.⁶⁴ The court stated that “the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer’s ability to research, develop, and market the patented product,”⁶⁵ and eliminating settlement possibilities could eventually have a chilling effect on research, development, and innovation itself. Ultimately, the court held that because of a patent’s exclusionary rights, some anti-competitive action is acceptable, but that such activities become illegal and unacceptably anti-competitive when they extend beyond the scope of the patent rights.⁶⁶ Protection, through agreements of legally acquired patent rights are perfectly acceptable so long as the scope of the protection acquired through the agreement does not function to extend the scope of the rights acquired through the grant of a patent.

While creating a different result, the U.S. District Court for the District of New Jersey followed a similar analysis structure in a sister case. The court held that the agreements overstepped the bounds of the patent power by restricting generic companies from marketing any generic competitor to K-Dur 20 for a period of time, regardless of whether such a product would have infringed upon the 743 patent itself.⁶⁷ Because these agreements created a greater monopoly than that granted by the original patent (in that they disallowed competing products that would not fall under the protection of the patent itself), they were willfully anti-competitive and therefore illegal.⁶⁸

61. *Id.* (citing *Valley Drug*, 344 F.3d at 1312).

62. *Id.* at 1066-1067.

63. *See id.* at 1056.

64. *Id.* at 1074-1075.

65. *Id.* at 1075.

66. *Id.*; *See also Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003).

67. *In re K-Dur Anti-trust Litig.*, 338 F. Supp. 2d 517, 532-33 (D.N.J. 2004).

68. *Id.*

C. *Cardizem CD*

Unlike the Eleventh Circuit, the Sixth Circuit has been less accepting of Hatch-Waxman driven patent infringement settlements. Hoescht Marion Russell, Inc. (“HMR”) held the patent on Cardizem CD, a drug used for treatment of hypertension and reduction of heart attack and stroke risk. HMR faced significant financial loss in 1995 when Andrx Pharmaceuticals (“Andrx”) filed a paragraph four certification in connection with an ANDA for a generic version of Cardizem CD.⁶⁹ During the ensuing litigation, the two companies entered a settlement agreement which was held anti-competitive because Andrx was able to ensure HMR’s market monopoly by refraining from triggering the running of its 180-day exclusivity period.⁷⁰ The 180-day market exclusivity does not actually begin to run until the generic product that is the subject of an ANDA is actually marketed and sold.⁷¹ By refraining from sales, Andrx was able to effectively keep other producers of generic and bioequivalent versions of Cardizem CD from gaining FDA approval and out of the market. The agreement between Andrx and HMA was an unreasonable restraint of trade because it was designed not only to settle a patent infringement litigation and protect an established, legal patent exclusivity right, but also to prevent other manufacturers (and potential competitors) from bringing any generic or bioequivalent product to the market.⁷² The court stated, “[i]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent’s effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market.”⁷³

D. *Paxil & Paroxetine Hydrochloride*

In line with the Eleventh Circuit’s approach, the U.S. District Court for the Northern District of Illinois analyzed a settlement through which GlaxoSmithKline, PLC, (Glaxo), the patent holder, and Pentech Pharmaceuticals, Inc., (Pentech), an ANDA filer, agreed to cease litigation and enter into a license agreement. Under the settlement agreement, Glaxo licensed Pentech to sell Paxil, a drug for the treatment of depression,⁷⁵ using a different name, in return for a hefty royalty.⁷⁶ In his analysis of the settlement, Judge Posner found that, in light of the general favor of litigation settlements, a patent infringement suit settlement is in violation of the Sherman

69. *In re Cardizem CD Anti-trust Litig.*, 332 F.3d 896, 901-902 (6th Cir. 2003).

70. *Id.* at 896.

71. 21 U.S.C. § 355 (j)(5)(B)(iv) (2003).

72. *In re Cardizem CD*, 332 F.3d at 904, 907.

73. *Id.* at 908.

75. Anti-Depressant Crystalline Paroxetine Hydrochloride Hemihydrate, U.S. Patent No. 4,721,723 (filed Oct. 23, 1986) (issued Jan. 26, 1988).

76. *Asahi*, at 989.

Act only if it “is a device for circumventing anti-trust law.”⁷⁷ The inherent uncertainties of patent infringement suits provide ample motivation for settlement and such agreements are generally acceptable ways of enforcing validly held patent exclusivity rights.⁷⁸

Banning settlements that provide for reverse payments could have a chilling effect on the type of infringement suits that Hatch-Waxman sought to promote. If companies cannot settle in a manner that is beneficial to both sides, there is significantly less motivation to enter into suit in the first place.⁷⁹ Some settlements, such as those in the patent supplement cases mentioned above,⁸⁰ actually promote competition in the market by allowing a company’s entry into the market before the patent would normally expire. The U.S. Department of Justice currently argues that settlements can actually stimulate competition because forcing companies to litigate in lieu of settling is not in the public interest.⁸¹

E. Cipro & Ciprofloxacin Hydrochloride

Bayer Corporation (“Bayer”), which held U.S. Patent 4,670,444 (“444 Patent”) on Cipro, the most prescribed antibiotic in the world, received over \$1 billion in U.S. net sales from this drug alone.⁸² Barr Laboratories, Inc. (“Barr”), filed an ANDA on a bioequivalent that eventually led to a large settlement agreement between Barr, Bayer, and various other generic pharmaceutical companies that also had interests in the patent infringement and FDA licensing situation.⁸³ The large settlement agreement stipulated that all potential infringers acknowledge the validity of the 444 Patent: that Barr amend its ANDA to contain a paragraph III certification instead of a paragraph IV certification (such a certification amendment necessarily involves forfeiture of any 180-day exclusivity period and prevents FDA approval from occurring before the natural end of the patent term);⁸⁴ and that Bayer pay \$49 million into an escrow account retained for the benefit of other settling parties to the lawsuit (other potential generic infringers).⁸⁵ Additionally, Bayer was to either: (1) supply the generic competitors with Cipro for price-controlled generic distribution; or (2) pay \$15-\$17 million quarterly into an escrow account until the termination of the 444 Patent in December 2003.⁸⁶ The parties to the agreement submitted a consent judgment that was summarily signed by

77. *Id.* at 991.

78. *Id.* at 992-993.

79. *Id.* at 994.

80. *See* Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).

81. *Colluding Drugmakers: How Big Pharma is Carving Up Profits With Should-Be Rivals*, FIN. TIMES, Sept. 4, 2006, available at 2006 WLNR 15320921.

82. *In re* Ciprofloxacin Hydrochloride Anti-trust Litig., 261 F. Supp. 2d 188, 194 (E.D.N.Y. 2003); US Patent No. 4,670,444 (issued June 2, 1987).

83. *In re* Ciprofloxacin, 261 F. Supp. 2d at 194-96.

84. 21 U.S.C. §§ 355 (j)(5)(D) (Supp. IV 2000).

85. *In re* Ciprofloxacin, 261 F. Supp. 2d. at 196.

86. *Id.*

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the judge and voluntarily submitted for re-examination to the United States Patent and Trademark Office, who confirmed that the 444 Patent was legal and valid.⁸⁷

After reviewing this case and the settlement agreement, in 2003 the U.S. District Court of Massachusetts found that according to the Hatch-Waxman Act, the FDA is not required to wait for a valid court ruling of patent invalidity or non-infringement prior to approving an ANDA and legalizing market release of the drug.⁸⁸ The only time-limit mentioned in the Hatch-Waxman Act merely requires a court order or case ruling to extend a delay of FDA approval over the 30-month limit.⁸⁹ In essence, the federal regulatory agency can approve marketing of a new and infringing drug before it is conclusive that such a release will not be in violation of the patent protection held by a pioneer drug company. Therefore, in addition to increasing the number of new patent infringement suits a pharmaceutical company must face, the Hatch-Waxman Act also requires that if infringement suits are not settled or concluded by the end of a 30-month period, a patent holder must acquire a preliminary injunction to protect his or her patent rights. Courts are reluctant to give such injunctions, often holding that such action would violate an infringing company's right to compete while the status of the patent is still tentative.⁹⁰

The District Court also held that the right to settlement in patent litigation is more favored than in ordinary litigation because "patent litigation is inherently uncertain"⁹¹ and:

[N]o matter how valid a patent is – no matter how often it has been upheld in other litigation . . . or successfully reexamined. . . it is still a gamble to place a technology case in the hands of a lay judge or jury. . . Even the confident patent owner knows that the chances of prevailing in [patent] litigation rarely exceed seventy percent.⁹²

Like other courts who have considered the issue, the Massachusetts District Court dismissed *per se* analysis in favor of a rule of reason analysis, thus allowing consideration of such mitigating factors as the existence of a valid patent and the willingness of Barr to vacate the right to a 180-day exclusivity term by altering the ANDA certification from a paragraph IV-type to a paragraph III-type.⁹³ This is relevant because protection of a reexamined patent certainly seems more valid than protection of a patent that is still in question and is voluntarily foregoing generic market exclusivity. Barr eliminated the possibility that Bayer's patent exclusivity rights could be unreasonably extended through any underhanded use of the Hatch-Waxman

87. *Id.* at 196-197.

88. *Id.* at 202.

89. 21 U.S.C. § 355(j)(5)(B)(iii) (Supp. IV 2000).

90. *In re* Ciprofloxacin, 261 F. Supp. 2d at 202-203 (citing *Zeneca Ltd. v. Pharmachemie B.V.*, 16 F. Supp. 2d 112 (D. Mass 1998)).

91. *Id.* at 208.

92. *Id.*

93. *Id.* at 233.

incentives.⁹⁴ The court held that payments made by Bayer were perfectly reasonable under the circumstances because litigation settlements must be achieved through both sides being able to sacrifice and benefit.⁹⁵ Bayer avoided uncertain patent litigation but paid almost \$400 million for peace of mind; Barr received a great deal of money for dropping a suit it would not have necessarily won.⁹⁶

Finally, the court analyzed the principles inherent in the Hatch-Waxman amendments to the FFDCA. The original intent of the Hatch-Waxman amendments was to lower public drug costs by stimulating challenges of weak or invalid pharmaceutical patents.⁹⁷ Unfortunately, by preventing generic pharmaceutical companies from deciding for themselves when to pursue highly expensive patent infringement litigation, the end result could be a serious chilling effect on the type of lawsuits Hatch-Waxman desired to stimulate.⁹⁸ If pioneer drug patent-holding pharmaceutical companies are unable to reduce their exposure by settling uncertain patent litigations in the manner most practical to them, there is a likelihood that such companies will either suffer economic losses unfairly or simply avoid entry into the pharmaceutical market in the first place.⁹⁹ The research and innovation that drives the U.S. pharmaceutical market as well as its intended societal benefits, could be greatly reduced by the results of the Hatch-Waxman incentives.

F. Macrobid & Nitrofurantoin

In an interesting deviation from the norm, a recent case involved a patent holder who elected to compete in the new generic market rather than attempt a settlement that would inevitably result in FTC-driven anti-trust litigations such as those discussed above. Procter & Gamble (“P & G”) held the patent on Macrobid, an antibiotic commonly used to treat urinary tract infections,¹⁰⁰ faced market loss in 2004 when Mylan Pharmaceuticals, Inc., (“Mylan”) received ANDA approval on their paragraph IV certification application.¹⁰¹ Mylan, however, was not able to fully enjoy the 180-day exclusivity period it desired because P & G launched a competing generic version of Macrobid just as Mylan entered the market.¹⁰² The Fourth Circuit held that such an action by P & G was completely legal because P & G already possessed an FDA license through its previously approved NDA on Macrobid and was therefore entitled to enter the generic market as a competitor, and thereby significantly reducing

94. *See id.* at 240.

95. *Id.* at 251.

96. *Id.*

97. *Id.* at 256.

98. *Id.*

99. *Id.*

100. *Ferguson v. Procter & Gamble Pharm., Inc.*, 353 F. Supp. 2d 674, 675 (E.D. La. 2004).

101. *Mylan Pharm., Inc. v. FDA*, 454 F.3d 270, 271-274 (4th Cir. 2006).

102. *Id.* at 273.

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the profit anticipated by Mylan.¹⁰³

VI. PLAVIX CASE BACKGROUND

The aforementioned case history and situational conflicts are still relevant, and allow for an interesting analysis of the just-finalized litigation between Canadian generic pharmaceutical companies Apotex Inc. (“Apotex”) and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership (“BMS”) over the pioneer drug Plavix.¹⁰⁴ Plavix is an anti-platelet compound prescribed to reduce the dangers of stroke, heart attack, or vascular disease in those who have recently suffered such a thrombosis event.¹⁰⁵ Apotex filed an ANDA with a paragraph IV certification in late 2001 and BMS responded with a countersuit for infringement.¹⁰⁶ Under Hatch-Waxman, the timely filing of this infringement suit triggered an automatic 30-month delay in FDA approval of Apotex’s ANDA.¹⁰⁷ However, from here the case differs from those discussed above.

In October of 2005, Apotex informed BMS that it expected FDA approval imminently and, by letter, asserted that “it cannot be appropriate for Plaintiffs [BMS] to do nothing until launch is imminent and only then bring a motion for an injunction.”¹⁰⁸ Just days before January 20, 2006, when the FDA released official approval of Apotex’s ANDA, BMS and Apotex opened discussions to resolve the litigation.¹⁰⁹ Shortly into negotiations, both parties agreed that neither would launch a generic version of Plavix while they were still engaged in settlement discussions. A settlement agreement was finalized on March 17, 2006, subject to FTC approval.¹¹⁰ However, a state attorney general, in reviewing the settlement agreement, informed both sides that the settlement could not be approved.¹¹¹ A second agreement, containing provisions that would allow resumption of litigation if the second agreement was also denied regulatory approval, was also struck down.¹¹² The second agreement provided that BMS could not seek more than 50% of Apotex’s net sales of infringing products if BMS was eventually declared victorious in the litigation and that neither company would launch a generic product or seek a preliminary injunction until at least five days after regulatory denial of the second agreement.¹¹³ Finally, after the five-day period expired, BMS agreed not to launch a generic version of Plavix until Apotex did so, promised not to seek a

103. *Id.* at 276.

104. *Sanofi-Synthelabo v. Apotex Inc.*, 2007 WL 1746134 (S.D.N.Y. June 19, 2007).

105. *Information About Plavix*, www.plavix.com (last visited Feb. 11, 2007).

106. *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 322 (S.D.N.Y. 2006).

107. 21 U.S.C. § 355(j)(5)(B)(iii) (Supp. IV 2000).

108. *Apotex*, 488 F. Supp. 2d at 323.

109. *Id.*

110. *Id.* at 324.

111. *Id.*

112. *Id.* at 324-325.

113. *Id.*

temporary restraining order at any time, and guaranteed that it would not seek a preliminary injunction until Apotex launched a generic product and BMS had given Apotex five business days notice of its intention to do so.¹¹⁴ Interestingly enough, BMS filed for a preliminary injunction immediately upon the declaration of regulatory denial, but the motion was struck down because of the terms of the agreement.

Four days after BMS filed its preliminary injunction motion, Apotex flooded the market with generic Plavix and continued to maintain market competition until August 31, 2006, when BMS was granted a preliminary injunction.¹¹⁵ The preliminary injunction, which was affirmed in October 2006¹¹⁶ and again in June 2007,¹¹⁷ prevented Apotex from marketing any further generic Plavix, but did not require that Apotex recall the large amounts of generic clopidogrel bisulphate already on the market.¹¹⁸

VII. ANALYSIS

The conflict between Apotex and BMS is a functional example of how overly enthusiastic regulatory interference from the FTC can inhibit the progress of the court system and actually create a more anti-competitive situation than would exist if the litigants were allowed to settle in their own natural manner. This is not to say that the FTC should not have any regulatory power in the creation and enforcement of settlement agreements. As shown in many of the cases above, there is potential for even a patent holding company to exceed its legal rights of granted exclusivity and wander into the area of anti-competitive activity that is justifiably regulated by the FTC and the Sherman and Clayton Acts. However, with the pharmaceutical market already financially unstable, with the Hatch-Waxman incentives increasing patent validity litigation, and with the uncertainty of court rulings, perhaps the pressure on pioneer drug companies has extended far enough. Some of the settlement agreements should be allowed or there is a real risk of a chilling effect on the pharmaceutical market. The following analysis of some of the relevant numbers at hand will help clarify the situation.

The pharmaceutical industry is driven by research and development and the patent protection provided to the products of the breakthrough inventions such research produces.¹¹⁹ In the year 2000, the pharmaceutical industry spent \$26 billion on research and development alone, resulting in an average cost of \$802 million just to develop a single new drug.¹²⁰ In addition to these high

114. *Id.* at 325.

115. *Id.* at 325, 350.

116. *Apotex Loses Clopidogrel Preliminary Injunction*, WORLD GENERICS MARKETS, Oct. 18, 2006, available at 2006 WLNR 18078511.

117. *Sanofi-Synthelabo v. Apotex Inc.*, 2007 WL 1746134, at *42 (S.D.N.Y. June 19, 2007).

118. *Apotex*, 488 F. Supp. 2d at 348.

119. *In re Ciprofloxacin*, 261 F. Supp. 2d at 256.

120. *Id.*

research and development prices, as little as 30% of drugs that reach the market make profits equal-to or greater-than their development costs.¹²¹ Today, it is estimated that roughly 53% of all prescriptions filled in the United States are for generic versions of pioneer pharmaceuticals.¹²² On average, only two months after their initial release, generic drugs account for over 75% of the market for their active ingredient.¹²³ In June of 2005, there were 11,167 drugs listed in the *Orange Book* and roughly 8,400 had generic counterparts that cost up to 80% less than the branded pioneer drugs.¹²⁴ The 29 most-commonly used molecules with no patent protection currently sell in the United States for 50% of their selling prices in the vast majority of the rest of world.¹²⁵ Furthermore, the FTC found that 73% of cases involving pharmaceutical industry patent litigation in the last ten years were ruled in favor of the generic drug company.¹²⁶ Courts are finding patents invalid that have already had their claims subjected to incredibly rigorous scrutiny at the hands of the USPTO prior to the patent's original grant. This comes despite the existence of 35 U.S.C. § 282, which requires that these patents be considered legally granted and functionally intact at the outset of the court cases. Profits are highly subject to risk and it is no wonder that so many pioneer patent-holding pharmaceutical companies attempt to settle when they have the opportunity.

VIII. SUGGESTED SETTLEMENT STANDARD

Companies on both sides of an ANDA-induced patent infringement litigation currently have little certainty as to the outcome of their legal conflict. The existence of cases in which there is no evidence that the pioneer pharmaceutical company ever attempted to enter litigation or settlement negotiations with the generic company¹²⁷ shows that the rigorous study and draconian policy of the FTC has a chilling effect on settlement. Rather than face an uncertain court ruling and a settlement that would likely be declared invalid by the FTC, Proctor and Gamble elected to forgo any attempt at legal defense of its patent right in favor of a comparatively more beneficial market challenge.¹²⁸ To allow certainty for any of the players in these lawsuits, there

121. *Id.*

122. Linda A. Johnson, *Merck Woes are Symbol of Industry*, BERGEN COUNTY, N.J. RECORD, at B 01, available at 2005 WLNR 19554565 (Dec. 4, 2005).

123. Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA: THE INTELL. PROP. L. REV. 1, 24 (2005).

124. Andrew Humphreys & Nick D'Amore, *Generic Deluge: As U.S. Regulators Receive a Record Number of Generic Drug Applications, Pharmaceutical Companies Continue to Align With or Combat Generic Competition*, 24 MED AD NEWS 11, available at 2005 WLNR 19795634 (Nov. 1, 2005).

125. *Id.*

126. Abbott & Michel, *supra* note 123, at 12.

127. *See* Ferguson v. Proctor & Gamble Pharm., Inc., 353 F. Supp. 2d 674 (E.D. La. 2004).

128. *Id.*

has to be some established standard beyond the inconclusive legal precedent outlined above.

Such a standard should be made in compliance not only with the Sherman Act, but also with an understanding that patent protection and exclusionary rights exist to stimulate invention, experimentation, and productive research. The standard should be one of rational review utilizing an analysis that contemplates the totality of the circumstances under the rule of reason. Instead of following the FTC-favored approach pushing for *per se* invalidity, potential settlement agreements should be considered acceptable unless it is conclusive that such agreements unreasonably restrain competitiveness and market freedom by unacceptably extending of the protections offered by the existing valid patents. Virtually any absolute and conclusive evaluation standard would be better for the market, because the current uncertainty favors neither the generic companies nor the original patent-holding companies.

Settlements under which the generic company receives a reverse payment should be examined to determine whether there is additional opportunity for the generic competitor to enter the market prior to the scheduled natural expiration of the patent.¹²⁹ If the settlement allows for a generic company to gain such an early entrance into the market, one of the goals of the Hatch-Waxman Amendment is met,¹³⁰ giving the American public access to generic pharmaceuticals before they would have if an ANDA filing was not allowed. Such settlements should be given favor over those that simply restrain market freedom and generic drug availability for just this reason.

Additional consideration should be given to a generic pharmaceutical company's willingness to forego the 180-day exclusivity period. Once the initial lawsuit has been propagated, another original desire of Hatch-Waxman has been fulfilled: A patent has been challenged through a process that could promote availability of generic drugs.¹³¹ If the patent were truly so weak as to be vulnerable to a legitimate validity suit, the generic company would not be willing to forgo both the suit and the incredibly profitable 180-day exclusivity period. Rather than settling, the generic company instead would continue litigation and gain FDA approval and make use of the 180-day exclusivity period.

Finally, a different interpretation of the forfeiture of 180-day exclusivity period provision of Hatch-Waxman would lead to a less naturally monopolistic situation. It has been held that by refraining to market a generic version of a patented drug, a generic company could push back the start of the 180-day exclusivity period and thereby functionally extend the monopoly held by the patent owner.¹³² However, 21 U.S.C. § 355(j)(5)(D) stipulates that an ANDA

129. See *Schering v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005).

130. See *Mylan Pharm., Inc. v. FDA*, 454 F.3d 270, 271-272 (4th Cir. 2006).

131. *Id.*

132. *In re Terazosin Hydrochloride Anti-trust Litig.*, 352 F. Supp. 2d 1279, 1315 (S.D. Fla. 2005).

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filer forfeits its 180-day exclusivity if it does not market the drug in question within a period 75 days after a final court decision. If this section were merely interpreted to include court approval of a finalized settlement agreement, the worry over extending the patent monopoly could be foregone. If the initial paragraph IV certification filer lost its 180-day exclusivity period, by necessity, 75 days after entering into a settlement agreement, the market would still be open and competitive for any other generic company that desired to file for ANDA approval. So long as the settlement agreement did not extend beyond the projected life of the patent and did not prevent the parties to the agreement from marketing non-infringing products, it would be acceptable under current anti-trust laws because the 180-day exclusivity period would no longer be manipulated by an attempt to prevent non-settling generic companies from entering the market.

IX. IMPLEMENTATION OF THE NEW SETTLEMENT STANDARDS

There are a number of available methods whereby these recommended policy alterations can be effectively implemented. The Patent Act itself could be amended to more strongly emphasize the power of the presumption of patent validity, or a specific deference not conventionally awarded to litigants without legally granted patent monopoly protection could be given to patent litigation settlements. Alternatively, the Federal Food, Drug, and Cosmetics Act, as altered by the Hatch-Waxman Act, could be amended to allow for more free settlement between Hatch-Waxman litigants. The statute could include language to outline the amended review process and establish presumptions that must be considered by the FTC during its evaluation of the settlement validity. Statutorily establishing some absolute regulation for pharmaceutical litigation settlements between generic and branded drug companies could strengthen the entire industry by returning to it some of the security that it lost due to the Hatch-Waxman Act.

Although the Hatch-Waxman Act intended to create an environment through which prescription drugs would be inexpensive and readily available to the public, the interest in immediate public welfare must be considered in light of the nature of pharmaceutical company profit, driving research and development. If it is not economically feasible to spend money creating new drugs with a great likelihood of recouping these expenditures in future profits, no logical company will continue to contribute to the market. The public would therefore invariably suffer because breakthrough medical treatments would no longer be available, and the general progress of the medical industry would halt.

If a standard like the one outlined above were accepted and made publicly available, generic pharmaceutical companies could readily file ANDA applications knowing that they would not be forced to litigate beyond a desired point. Pioneer drug companies could more confidently allocate their money to research and the production of future breakthrough medication with the

knowledge that their present investments would result in future profits to permit them to recover their investment. These pioneer drug companies would no longer have to gamble on such uncertain litigation outcomes and strict FTC reviews. Weak and unacceptable patents could still be challenged, and patents could still be declared invalid, because no generic company would settle a case if it were confident that it could win in court. In this manner, the intended purpose of the Hatch-Waxman amendments could be fulfilled and valid patent challenges leading to increased generic availability would still be encouraged. Additionally, litigation settlement could retain its favored status because each participant would be confident in the established rules as to what constitutes unacceptable anti-competitive activities. With this confidence, the stability and profitability benefits of the current pharmaceutical patent system could remain without losing the desired public access and price-control advantages that come with generic pharmaceutical competition.

X. PROPOSED FURTHER STATUTORY AMENDMENTS

In September 2006, Henry Waxman of the House of Representatives introduced further proposed amendments to the drug licensing and FDA approval process.¹³³ The proposed legislation would dramatically lower the requirements for gaining FDA approval for a biological product.¹³⁴ A biological product, or “biologic,” is a “virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, [or] allergenic product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.”¹³⁵ The proposed legislative amendment would alter the present regulatory framework by granting ANDA-like preferential treatment (including a similar 180-day exclusivity period) to companies that file applications for FDA approval of generic biologics prior to the expiration of the original biologics patent protection.¹³⁶ Under current regulations, any party seeking approval of a biologic must undergo a full examination requiring proof of safety, purity, and potency of the biologic,¹³⁷ but Representative Waxman’s proposed legislation would allow expedited approval upon a showing that the new biologic has “the same, or similar, active ingredient as a

133. Access to Life-Saving Medicine Act, H.R. 6257, 109th Cong. (2006). (This particular version of the law was stricken from the Congressional books at the end of the 109th session of congress, as is standard procedure for all propositions not passed at the end of a session. However, H.R. 1038, 110th Cong. (2007) is almost identical, and was introduced in February of 2007. See <http://www.govtrack.us/congress/bill.xpd?bill=s110-623>, last visited October 15, 2007).

134. Compare H.R. 6257, with 42 U.S.C. § 262 (2000). (The proposed law suggested an expedited FDA approval process, similar to that allowed for pharmaceuticals by the original Hatch-Waxman Act, for biologic substances, where the 2000 statute requires that full safety and efficacy testing are required for any biologic, generic or name brand, before full FDA approval can be granted).

135. 42 U.S.C. § 262(i).

136. H.R. 6257 §§ 3(a)(9), (16).

137. 42 U.S.C. § 262(d).

biological product for which a license has been approved.”¹³⁸

Industry concerns about this proposed legislation are warranted because “[b]iologics are made using living materials rather than chemicals,” and differences in cell lines almost guarantee that different companies will produce different protein products.¹³⁹ Interestingly enough, the FDA basically agrees with the industry. On May 30, 2006, the FDA first granted approval to Omnitrope, a “follow-on” biologic based upon an original Human Growth Hormone biologic,¹⁴⁰ but the FDA adamantly maintains that this does not establish precedent for widespread approval of generic biologics.¹⁴¹

In light of the pharmaceutical industry’s slim profit margins, the proposed legislation could further force the decline of functional development and research in the health-related biotechnology and pharmaceutical fields. Current market competition is so fierce that even prominent generic pharmaceutical producers are struggling to maintain financial profitability in the face of increasing generic competition.¹⁴² According to a recent Senatorial office press release, proponents of the biologics approval amendment seem to be far more focused on the short-term goal of reducing health care costs, without giving much thought to the financial situation of the progressive pharmaceutical and biologics industries themselves.¹⁴³ It does not seem at all unreasonable to expect that the loss of profitability in the industry will result in a reduction in advancement. There is little logical business motivation to spend enormous sums of money on developing new and breakthrough therapeutic treatments, biological products, and pharmaceuticals if there is little hope of recovering the research investments, let alone making a profit.

XI. CONCLUSION

While the introduction of ANDA applications may have resulted in easier access to prescription medication for a few people, the potential negative feedback to name-brand pharmaceutical company research and development still remains a threat if the current stringent settlement rules of the FTC are not altered. The patent system exists to promote scientific and intellectual progress.¹⁴⁴ Encouraging open contest of granted patents for the sake of cheaper pharmaceuticals, without some form of protection for the patent holder, acts contrary to the intended purpose of a patent monopoly grant. To

138. H.R. 6257 ' 2(2).

139. Katie Weeks, *Biological Confusion*, 27 SAN DIEGO BUS. J., May 8, 2006, at 17, 17-18.

140. F.D.A., *Omnitrope (somatropin [rDNA origin]) Questions and Answers*, May 30, 2006, available at <http://www.fda.gov/cder/drug/infopage/somatropin/qa.htm>.

141. *Id.*

142. See Eric Ladley, *Generics Junction: The Next Year May Reveal Which Generics Companies Succeed and Which Ones Will be Forced Out of the Industry*, MED AD NEWS 80, 2006 WL 17304172 (Sept. 1, 2006).

143. Waxman, *Schumer, Clinton Introduce "Access to Life-Saving Medicines Act,"* Sept. 26, 2006, available at <http://clinton.senate.gov/news/statements/details.cfm?id=264152&&>.

144. U.S. CONST. art. 1, § 8, cl. 8.

best balance both the patent system's power to foster development with the continued availability of affordable, safe, and effective pharmaceutical medication, the FTC should follow a system such as that suggested above that encourages review of patent validity suit settlements, but that also allows the parties to negotiate terms that take into consideration the legality and Constitutionality of granted patent monopolies.