

PENDING LEGISLATION REGULATING PATENT INFRINGEMENT SETTLEMENTS

*By Edward W. Correia**

A number of bills have been introduced in the United States Congress this year that are intended to eliminate perceived anticompetitive settlements of patent infringement litigation between generic and brand-name pharmaceutical manufacturers. As discussed below, the Federal Trade Commission (FTC) has argued in a number of cases that settlements involving “reverse payments”—payments made to a generic manufacturer in return for a commitment to delay market entry—can defer legitimate competition by generic manufacturers. These bills attempt to address such situations by amending the Hatch-Waxman Act to ban certain agreements between patent holders and generic manufacturers and to prevent the creation of “bottlenecks” preventing market entry by other generic manufacturers. This article discusses the current statutory framework, the perceived problems, the proposed legislative remedy and the policy issues raised by the proposed legislation.

BACKGROUND: THE HATCH-WAXMAN ACT

The patent infringement settlements at issue arise pursuant to procedures established by the Hatch-Waxman Act of 1984.¹ The Hatch-Waxman Act amended the procedures for gaining approval for new drugs under the Food, Drug, and Cosmetic Act.² The goals of the Hatch-Waxman Act were to promote innovation in the pharmaceutical sector and facilitate market entry of generic drugs.³ The Act extended patents under certain conditions and, at the same time, made it easier for generics to obtain approval from the Food and Drug Administration (FDA) for equivalent products. Prior to the Hatch-Waxman Act, generic manufacturers had to wait until the expiration of all of a drug’s patents before seeking FDA approval for their generic version of the drug. The Act es-

Copyright © 2007 Latham & Watkins LLP

* Edward Correia is of counsel in the Washington, D.C. office of Latham & Watkins, where his practice focuses on antitrust, consumer protection regulation of advertising and marketing practices, and export control issues, including regulations enforced by the Departments of Commerce, Treasury and State. Mr. Correia also advises clients in dealing with Congress and executive branch agencies on public policy issues and serves as antitrust counsel for a number of trade associations. He frequently represents clients before the Federal Trade Commission. He is former Special Counsel to President Clinton for Civil Rights. He can be reached at edward.correia@lw.com and 202/637-2220.

1. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355(j)).

2. Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

3. See, e.g., Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?: Hearing on S. 316 Before the S. Comm. on the Judiciary, 110th Cong. 122 (2007) (statement of Jon Leibowitz, Comm’r, Federal Trade Commission).

tablished an Abbreviated New Drug Application (ANDA) process under which generic drug manufacturers can apply for approval to market and sell a generic equivalent of an FDA-approved drug before the expiration of the drug's patents.⁴

To take advantage of the ANDA process, an applicant must show that the new drug is a "bioequivalent" of an already-approved drug.⁵ In addition, the applicant must make one of the following certifications: (1) the previously approved drug is not subject to any patents; (2) all patents covering the previously approved drug have expired; (3) the generic drug will not be on the market until all patents covering the previously approved drug expire; or (4) the patents covering the previously approved drug are invalid or are not infringed.⁶ These certifications are respectively known as Paragraph I, II, III and IV certifications.

If a drug manufacturer files an ANDA with a Paragraph IV certification, the applicant must notify the owner of the patents it certifies are invalid or not infringed.⁷ The patent holder then has 45 days to bring a patent infringement suit. If the patent holder brings an infringement suit within the 45-day period, the FDA automatically delays the acceptance of the ANDA for 30 months or until the patents expire or are deemed invalid by a court.⁸

To encourage the challenge of weak drug patents, the Hatch-Waxman Act grants the "First Filer" of an ANDA making a Paragraph IV certification a period of 180 days during which it has the exclusive right to market a generic version of the patented drug.⁹ The exclusive marketing period is triggered by the "first commercial marketing of the [generic] drug."¹⁰ The FDA cannot approve any subsequent ANDA for the same patented drug before the end of this exclusive marketing period.¹¹ However, there are certain triggering events which can force the First Filer to "use or lose," or outright forfeit, its exclusive marketing period (e.g., failure to market, withdrawal of application, etc.).¹²

Beginning in 2000, the FTC brought a number of antitrust enforcement actions based on patent litigation settlements between patent holders and generics involving "reverse payments" that the FTC concluded were anticompetitive.¹³ These enforcement actions attracted the attention of Congress, which included a provision in the Medicare Moderniza-

4. 21 U.S.C. § 355(j).

5. *Id.* at § 355(j) (2) (A) (iv).

6. *Id.* at § 355(j) (2) (A) (vii).

7. *Id.* at § 355(j) (2) (B).

8. *Id.* at § 355(j) (5) (B) (iii).

9. *Id.* at § 355(j) (5) (B) (iv) (I).

10. *Id.*

11. *Id.*

12. 21 U.S.C. § 355(j) (5) (D) (i).

13. Hearing on S. 316, *supra* note 3, at 133 (2007) (statement of Jon Leibowitz, Comm'r, Federal Trade Commission).

tion Act of 2003 (MMA)¹⁴ to require brand-name and generic manufacturers to notify the FTC of all agreements between the two companies regarding the brand-name drug, equivalent generic drug, or the 180-day exclusive marketing period available to First Filers.¹⁵

The MMA also amended the ANDA procedures to allow generic manufacturers to force the First Filer to use or lose its exclusive marketing period if another generic manufacturer obtained a declaratory judgment of patent invalidity or non-infringement against the brand-name manufacturer.¹⁶ The US Court of Appeals for the Federal Circuit recently affirmed that federal courts have subject matter jurisdiction over declaratory judgment actions brought pursuant to ANDA procedures.¹⁷ Subsequent court decisions discussed further below, however, have prompted Congress to revisit the ANDA process.

THE FTC'S POSITION

The FTC has recently testified to Congress that certain settlements of patent infringement litigation between patent-holding, brand-name drug manufacturers and generic drug manufacturers are anticompetitive and harm consumers by delaying entry of generic versions of brand-name drugs.¹⁸ The settlements of concern involve "reverse payments" in which the brand-name manufacturer pays the generic manufacturer to settle the patent infringement suit brought by the brand-name manufacturer and delay the market entry of the generic drug. These reverse payments can take the form of a brand-name manufacturer licensing the generic manufacturer's products in a "side deal,"¹⁹ or simply making cash payments to the generic manufacturer.²⁰

The FTC contends that "[s]uch settlements restrict competition at the expense of consumers, whose access to lower-priced generic drugs is delayed, sometimes for many years."²¹ The potential impact of anti-consumer settlements that delay market entry of generic drugs is significant given that generic drugs can be priced up to seventy percent less than

14. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-18, 117 Stat. 2066 (2003).

15. *Id.* at § 1112.

16. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

17. See *Teva Pharm. USA, Inc., v. Novartis Pharm. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007); See also *Medimmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764, 774 n.11 (2007) (abrogating previous test of "reasonable apprehension of imminent suit" in deciding whether a case or controversy exists in a declaratory judgment action).

18. Hearing on S. 316, *supra* note 3, at 121 (2007) (statement of Jon Leibowitz, Comm'r, Federal Trade Commission).

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

20. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005), *petition for cert. filed*, 75 U.S.L.W. 3333 (U.S. Dec. 13, 2006) (No. 06-830); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

21. Hearing on S. 316, *supra* note 3, at 121 (statement of Jon Leibowitz, Comm'r, Federal Trade Commission).

brand-name drugs.²² Two recent appellate court decisions, however, have rejected the FTC's position by upholding the validity of reverse payments in the settlement of patent infringement suits brought by brand-name drug manufacturers against generic drug manufacturers.²³ The FTC believes that the decisions in these two cases were incorrect and cited the two cases in its support of the pending legislation.²⁴

In *Schering-Plough v. FTC*,²⁵ the Schering-Plough Corporation (Schering) settled with two generic drug manufacturers that sought FDA approval for generic versions of Schering's K-Dur 20 drug used to treat high-blood pressure and congestive heart disease. As part of the settlement with the first generic manufacturer, Schering agreed to license some of the generic manufacturer's drugs in return for the generic manufacturer delaying the market entry of its generic version of K-Dur 20.²⁶ In settling with the second generic manufacturer, subject to certain conditions, Schering agreed to make cash payments to the generic drug manufacturer to delay the introduction of its version of K-Dur 20.²⁷

The FTC filed an administrative claim against Schering and the generic manufacturers alleging that settlements between Schering and the generic manufacturers were anticompetitive.²⁸ Although the Administrative Law Judge sided with the settling companies, the FTC concluded that the settlements were unlawful.²⁹ On appeal, the US Court of Appeals for the Eleventh Circuit held that "the proper analysis of antitrust liability requires an examination 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 anticompetitive effects."³⁰ The court found that the settlement agreements were within the scope of Schering's patent³¹ and that the settlements were not anticompetitive.³²

In *Tamoxifen Citrate Antitrust Litig.*,³³ the terms of the patent infringement settlement required the generic manufacturer to delay its entry into the market in return for cash payments. The Second Circuit, relying on the Eleventh Circuit's analysis in Schering, found that the settlement was

22. Hearing on S. 316, *supra* note 3, at 166 (statement of Michael Wroblewski, Project Director, Consumer Education and Outreach, Consumers Union).

23. *In re Tamoxifen*, 466 F.3d 187; *Schering-Plough*, 402 F.3d 1056.

24. Hearing on S. 316, *supra* note 3, at 134 (statement of Jon Leibowitz, Comm'r, Federal Trade Commission).

25. *Schering-Plough*, 402 F.3d 1056.

26. *Id.* at 1059-60.

27. *Id.* at 1060-61.

28. *Id.* at 1061. The FTC alleged violation of both Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and Section 1 of the Sherman Act, 15 U.S.C. § 1.

29. *Schering-Plough*, 402 F.3d at 1061.

30. *Id.* at 1066 (citing *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003)).

31. *Id.* at 1066-68, 1072.

32. *Id.* at 1069-71, 1072-75.

33. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005), *petition for cert. filed*, 75 U.S.L.W. 3333 (U.S. Dec. 13, 2006) (No. 06-830).

not anticompetitive because it did not exceed the scope of exclusion granted by the patent.³⁴

In the FTC's view, *Schering* and *Tamoxifen* were both incorrectly decided and have resulted in a surge of anticompetitive and anti-consumer settlements.³⁵ The correct analysis, the FTC believes, can be found in the Sixth Circuit's decision in *Cardizem CD Antitrust Litig.*³⁶ In *Cardizem*, the patent infringement settlement agreement between the brand-name and generic manufacturer involved cash payments from the brand-name manufacturer to the generic manufacturer in return for the generic manufacturer agreeing not to market its own drug in the United States until one of a number of conditions occurred.³⁷ The agreement also prohibited the marketing of the generic drug even after the FDA had approved the ANDA for the generic drug.³⁸ The Sixth Circuit found that the settlement violated antitrust laws because it was "a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade."³⁹

In addition to its concern about reverse payments, the FTC also argues that generic drug manufacturers and brand-name drug manufacturers can collude to create a bottleneck in the drug approval procedures by misusing the statutorily granted 180-day exclusive marketing period available to the First Filer. The FTC's concern is based on a scenario in which, as part of a settlement, the First Filer agrees to refrain from any commercial marketing which would trigger the start of the 180-day exclusivity period.⁴⁰ Such an agreement could delay the approval of an ANDA by another generic manufacturer since, under the statute, the FDA cannot approve any new ANDAs before the end of the First Filer's exclusive marketing period. If the brand-name manufacturer also declines to sue other generic drug manufacturers that file an ANDA with a Paragraph IV certification, these other generic drug manufacturers are deprived of the opportunity—by prevailing in infringement litigation with the patent holder—to force the First Filer to use or lose its exclusive marketing period.⁴¹ Prior to 2003, this left generic manufacturers unable to force the First Filer to use or lose its 180-day exclusive marketing period by getting a judgment of patent invalidity or non-infringement against the brand-name manufacturer.

As discussed above, the MMA amended the ANDA procedures to allow generic manufacturers to obtain a declaratory judgment of patent

34. *Id.* at 216.

35. Hearing on S. 316, *supra* note 3, at 134 (statement of Jon Leibowitz, Comm'r, Federal Trade Commission).

36. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

37. *Id.* at 902-03.

38. *Id.*

39. *Id.* at 908.

40. *See, e.g., In re Cardizem*, 332 F.3d 896.

41. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

invalidity or non-infringement even if the patent holder declined to initiate infringement litigation. However, the ability of generic manufacturers to obtain declaratory judgments has been limited by patent holders granting generic manufacturers covenants not to sue for patent infringement.⁴² A court has recently held that a covenant not to sue removes any “case or controversy,” as required by Article III of the Constitution, thereby depriving a court of subject matter jurisdiction in a patent infringement case.⁴³ Thus, the ability to create an ANDA approval bottleneck using the First Filer’s 180-day exclusive marketing period remains a concern as patentholders may now simply grant a covenant not to sue to any generic manufacturer in order to prevent a declaratory judgment against the patent holder.

A LEGISLATIVE RESPONSE

Three bills have recently been introduced (H.R. 1902, H.R. 1432 and S. 316) that would reverse the results in *Schering* and *Tamoxifen*.⁴⁴ The three bills are substantively very similar although there are minor differences. H.R. 1432 and S. 316 include a section of “Congressional Findings and Declaration of Purpose” that is absent from H.R. 1902. These two bills primarily amend the Clayton Act, while H.R. 1902 primarily amends the Food, Drug, and Cosmetic Act. In addition, S. 316 requires a study and report by the FTC regarding the impact of anticompetitive settlements in patent infringement suits on the pharmaceutical market. Hearings have been held on S. 316 and H.R. 1902, and S. 316 has been reported to the Senate. The discussion below focuses on H.R. 1902, the most recently introduced bill.

Known as the “Protecting Consumer Access to Generic Drugs Act of 2007” (2007 Act),⁴⁵ H.R. 1902 adopts a bright-line rule regarding patent infringement settlements. The bill makes it unlawful for any person to be party to a patent infringement settlement in which the ANDA filer receives anything of value and agrees to not research, develop, manufacture, market or sell the drug that is the subject of the infringement claim for any period of time.⁴⁶ Violations of the prohibition are deemed to be

42. H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1902 Before the Subcomm. on Commerce, Trade, and Consumer Protection, H. Comm. on Energy and Commerce, 110th Cong. *3 (2007) (statement of Bernard Sherman, Chief Executive Officer, Apotex Inc.), available at http://energycommerce.house.gov/cmtc_mtgs/110-ctcp-hrg.050207.Sherman-testimony.pdf.

43. See *Merck & Co., Inc. v. Apotex, Inc.*, No. C.A. 06-230, 2007 WL 1470453 (D. Del. May 21, 2007).

44. Protecting Consumer Access to Generic Drugs Act of 2007, H.R. 1902, 110th Cong. (2007); Preserve Access to Affordable Generics Act, H.R. 1432, 110th Cong. (2007); Preserve Access to Affordable Generics Act, S. 316, 110th Cong. (2007).

45. H.R. 1902, § 1.

46. *Id.* at § 2(a).

an unfair and deceptive act or practice and an unfair method of competition prohibited by section 5 of the Federal Trade Commission Act.⁴⁷

The bill provides for two exceptions to the bright-line rule. A generic manufacturer is not prohibited from receiving as part of a settlement: (1) the right to market the drug before the expiration of the patented drug's patent term; or (2) the waiver of damage claims for infringement based on prior marketing of the generic drug.⁴⁸ Additionally, the bill grants the FTC rulemaking powers to exempt other agreements from the bright-line rule if they are found to promote market competition and be pro-consumer.⁴⁹ The FTC is also given power to issue interpretative rules and statements of policy as to what practices are prohibited under the 2007 Act.⁵⁰

The bill also amends the ANDA procedures by providing that a First Filer must use or lose its exclusive marketing period if: (1) a court dismisses a declaratory judgment action brought by another generic manufacturer for non-infringement or patent invalidity, due to a lack of subject matter jurisdiction; or (2) an ANDA applicant files a covenant not to sue for patent infringement granted by the patent holder to the ANDA applicant.⁵¹ The bill also provides that a First Filer forfeits its exclusive marketing period if the FTC finds that an agreement submitted by the First Filer to the FTC violates the 2007 Act.⁵²

The bill also strengthens the MMA's notification requirements by requiring brand-name and generic manufacturers to disclose any agreement they enter into within 30 days of an agreement that is required to be reported to the FTC under the MMA.⁵³

Finally, the bill requires a certification to be filed with the Assistant Attorney General and the FTC. The Chief Executive Officer—or the company official negotiating the agreement—has to certify that the notice of agreement filed with the FTC represents the complete and final agreement between the parties and includes written descriptions of any oral agreements that have not been reduced to writing.⁵⁴

LEGAL POLICY ISSUES

The proposed legislation raises several key legal policy issues, which are discussed below.

47. *Id.* at § 2(c).

48. *Id.* at § 2(b).

49. *Id.* at § 3.

50. *Id.*

51. *Id.* at § 4.

52. *Id.*

53. *Id.* at § 5.

54. *Id.*

Consumer Access to Generic Drugs

The FTC supports the proposed legislation because it believes the legislation will restore the proper balance between patent and antitrust policy goals. The FTC contends that the decisions in *Schering* and *Tamoxifen* give “holders of drug patents the ability to buy more protection from competition than congressionally-granted patent rights afford.”⁵⁵ Settlements involving reverse payments, the FTC argues, reduce competition in the pharmaceuticals market by delaying entry of generic drugs and result in large costs for consumers.⁵⁶ Furthermore, the FTC believes the evidence shows that if pharmaceutical companies are forced to litigate infringement claims to the end, generic manufacturers prevail in a large percentage (seventy-three percent) of cases and consumers have access to cheaper generic drugs years ahead of original patent expiration dates.⁵⁷

Increased Litigation Costs

Opponents of the proposed legislation, including both brand-name and generic pharmaceutical companies, argue that the legislation may undermine their ability to settle patent infringement litigation. Pharmaceutical patent holders attempt to protect the validity of their patents, and thus their ability to recover the initial investment in their drugs, by settling infringement cases rather than risking going to trial and having the patent declared invalid.⁵⁸

Adopting a bright-line rule disallowing settlements in patent infringement cases filed pursuant to ANDA procedures will arguably force pharmaceutical patent holders to litigate infringement cases to the end, increasing the risk of a patent being declared invalid. Because of the increased risk, pharmaceutical innovators may be less willing to make the large initial investment into the research and development of new drugs. In addition, opponents argue that the increased cost of litigation resulting from the bright-line ban on settlements will result in higher costs to consumers.⁵⁹

55. Hearing on S. 316, *supra* note 3, at 124 (statement of Jon Leibowitz, Comm’r, Federal Trade Commission).

56. Hearing on S. 316, *supra* note 3, at 124 (statement of Jon Leibowitz, Comm’r, Federal Trade Commission).

57. Hearing on S. 316, *supra* note 3, at 129 (statement of Jon Leibowitz, Comm’r, Federal Trade Commission).

58. See Hearing on S. 316, *supra* note 3, at 154 (statement of Billy Tauzin, Chief Executive Officer, PhRMA).

59. Hearing on S. 316, *supra* note 3, at 148-49 (statement of Billy Tauzin, Chief Executive Officer, PhRMA).

Decreased Incentives for Generic Manufacturers to Challenge Patents

One of the goals of the Hatch-Waxman Act is to promote challenges to weak patents.⁶⁰ The FTC supports increased challenges to pharmaceutical patents based on data that suggests that generic manufacturers are able to win many patent infringement suits that are not settled.⁶¹ However, the data cited by the FTC are disputed by opponents⁶² who argue that the broad ban on settlements may have the unexpected result of discouraging patent challenges by generic manufacturers. They argue that generic manufacturers may be more hesitant to file an ANDA with a Paragraph IV certification since it is likely that they will have to litigate the matter to the end, ending up with large litigation costs and no guarantee of securing anything through litigation.⁶³

Broad Scope of Legislation

Opponents of the legislation argue that the bright-line rule is overly broad and unnecessary. They argue that if a legislative solution is necessary at all, then it should be limited to the removal of the bottleneck caused by the First Filer when it refuses to undertake any marketing activity that triggers the start of its exclusive marketing period.⁶⁴ The proposed legislation removes this bottleneck by forcing the First Filer to either use or lose its exclusive marketing period if (1) a court dismisses a declaratory judgment action brought by a generic manufacturer for non-infringement or patent invalidity, due to a lack of subject matter jurisdiction, or (2) a generic manufacturer files a covenant not to sue for infringement granted to it by the patent holder.

Opponents further argue that forcing the First Filer to use or lose its exclusive marketing period based on a court's dismissal of a declaratory judgment action due to lack of subject matter jurisdiction is also overly broad and unwise.⁶⁵ Generic manufacturers seeking to force the hand of the First Filer will bring frivolous declaratory judgment actions precisely because these actions will be dismissed by courts due to lack of subject

60. See, e.g., *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 192 (2d Cir. 2005), *petition for cert. filed*, 75 U.S.L.W. 3333 (U.S. Dec. 13, 2006) (No. 06-830).

61. Hearing on S. 316, *supra* note 3, at 129 (statement of Jon Leibowitz, Comm'r, Federal Trade Commission).

62. See H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1902 Before the Subcomm. on Commerce, Trade, and Consumer Protection, H. Comm. on Energy and Commerce, 110th Cong. *11-*13 (2007) (statement of Phillip Proger, Partner, Jones Day), *available at* http://energycommerce.house.gov/cmte_mtgs/110-ctcp-hrg.050207.Proger-Testimony.pdf.

63. Hearing on S. 316, *supra* note 3, at 149 (statement of Billy Tauzin, Chief Executive Officer, PhRMA).

64. Hearing on H.R. 1902, *supra* note 62, at *25 (statement of Phillip Proger, Partner, Jones Day).

65. Hearing on H.R. 1902, *supra* note 62, at *25 (statement of Phillip Proger, Partner, Jones Day).

matter jurisdiction, forcing the First Filer to use or lose its exclusive marketing period.

Finally, opponents argue that the heightened notice requirements in the proposed legislation will chill all agreements between brand-name and generic drug manufacturers since the enhanced reporting requirements do not distinguish between agreements related to an infringement settlement and agreements that are routinely made in the course of business.⁶⁶

CONCLUSION

H.R. 1902 and similar proposals have the potential to dramatically alter the legal landscape in settlement of patent disputes involving pharmaceuticals. Some settlements of infringement litigation currently have the potential to delay market entry of generic drugs at the expense of consumers. The proposed legislation, however, has the potential to discourage legitimate settlements and even to reduce the incentives to challenge drug patents.

66. Hearing on S. 316, *supra* note 3, at 156-57 (statement of Billy Tauzin, Chief Executive Officer, PhRMA).