

COMMENT

Biovail v. Hoechst Aktiengesellschaft, Inc: An Analysis Under the Sherman Act and the Noerr-Pennington Doctrine

John F. Resek, Ph.D.*

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* J.D. Candidate, December 1999, Fordham University School of Law. The author thanks the editors of the Fordham Intellectual Property, Media & Entertainment Law Journal for their guidance and critique. This Comment is dedicated to my wife, Judy.

INTRODUCTION

The Hatch-Waxman Act¹ of 1984 regulates approval by the Food and Drug Administration (“FDA”) of generic counterparts to patented drugs. In a series of recent cases, large pharmaceutical companies have been accused of exploiting Hatch-Waxman in violation of the antitrust laws.² In essence, the allegations are concerned with the large pharmaceutical companies that have paid manufacturers not to market inexpensive generic versions of patented drugs, thereby restraining trade and maintaining a monopoly.³

In the case of *Biovail v. Hoechst Aktiengesellschaft, Inc.*, the generic drug manufacturer, Biovail, sued Hoechst Aktiengesellschaft (“Hoechst”), a pharmaceutical company, for antitrust violations resulting from Biovail’s effort to gain approval from the FDA to market a generic version of Cardizem, a heart drug patented by Hoechst.⁴ The claims are that Hoechst unfairly manipulated the Hatch-Waxman Act to prevent Biovail from obtaining FDA approval for a generic counterpart to Cardizem.⁵

Even though the defendant Hoechst, may have intended to exclude the plaintiff, Biovail, as competitors, Hoechst will be substantially immune from antitrust liability under the Noerr-Pennington doctrine (“Noerr Immunity”), because Hoechst was acting within its constitutionally protected rights.⁶ The Noerr Immunity enjoyed by Hoechst is necessary to insure that the free-competition goals of the antitrust laws do not destroy Hoechst’s right to petition the government, as guaranteed by the First Amendment.⁷

1. 21 U.S.C. § 355(j) (1994 & Supp. IV 1998).

2. See Anne Marie Squeo, *FTC Investigates Drug Makers’ Patents*, SUN-SENTINEL, March 10, 1999, at 3D.

3. *Id.*

4. 49 F. Supp. 2d 750 (1999) (denying motion of FTC dismissal).

5. *Id.*

6. *Eastern R.R. Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 145 (1961) (holding that the antitrust laws do not prohibit people from associating together to petition a branch of the government, even if the desired action is anticompetitive.)

7. U.S. CONST. amend. I. “Congress shall make no law respecting an establishment

Part I of this Comment discusses both the legal framework of the Hatch-Waxman Act as well as Biovail's claims. Part II analyzes Biovail's claims with respect to potential violations by Hoechst under section 1 and section 2 of the Sherman Antitrust Act (the "Sherman Act"). Part III analyzes Hoechst's immunity under the Noerr Immunity doctrine. This Comment concludes that the Noerr Immunity doctrine protects Hoechst, even if they intended to manipulate the Hatch-Waxman Act.

I. LEGAL FRAMEWORK

Biovail's claims against Hoechst invoke issues of patent infringement and the Hatch-Waxman Act. This section reviews both of these aspects, and presents Biovail's claims.

A. Patent Infringement

Hoechst, like any patent owner, has the right to exclude others from making, using or selling Cardizem in the United States during the lifetime of its patent.⁸ Under current law, the lifetime of a United States patent grant shall be "for a term beginning on the date on which the patent was issued and ending twenty years from the date on which the application for the patent was filed in the United States."⁹ Any competitor who sells a generic version of Cardizem commits an act of patent infringement: an individual or company that "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."¹⁰ An individual or corporation who infringes a U.S. patent may be found liable to the patent owner for treble damages.¹¹

Manufacturers of generic pharmaceuticals, such as Biovail,

of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances." *Id.*

8. See 35 U.S.C. § 271(a) (Supp. III 1997); 35 U.S.C. § 283 (1994).

9. 35 U.S.C. § 154(a)(2) (1994). Special rules apply for patents if the application on which it issues was filed prior to June 8, 1995. See 35 U.S.C. § 154(c)(1) (1994).

10. 35 U.S.C. § 271(a).

11. 35 U.S.C. § 284 (1994).

may seek FDA approval to sell patented drugs under the Hatch-Waxman Act, prior to the expiration of the U.S. patent.¹² Seeking approval from the FDA under the Hatch-Waxman Act for a patented drug, however, constitutes an act of patent infringement.¹³

B. *FDA Approval of Patented Drugs Under the Hatch-Waxman Act*

Under the Hatch-Waxman Act, the FDA approval process requires that the generic manufacturer file an Abbreviated New Drug Application (“ANDA”).¹⁴ The ANDA allows a generic equivalent of brand name drugs to forego expensive and lengthy clinical testing and rely on the test results of the brand name counterpart.¹⁵ In addition, the process requires the generic manufacturer to state that the patent for the drug is invalid or will not be infringed by the generic counterpart and to notify the holder of the patent that an ANDA has been filed.¹⁶ Once notified, the patent holder may sue the applicant for patent infringement on the basis of the ANDA.¹⁷

Since the cost and risk of patent litigation is high,¹⁸ Hatch-Waxman provides an incentive for generic manufacturers to challenge patents on drugs which may be invalid, unenforceable or not infringed by the ANDA.¹⁹ The incentive is the right to a 180-day exclusivity period for the first manufacturer to submit an ANDA for a specific generic drug.²⁰ The exclusivity period starts from the

12. 21 U.S.C. § 355(j) (1994 & Supp. IV 1998).

13. 35 U.S.C. § 271(e)(2) (1994).

14. 21 U.S.C. § 355(j)(2)(A)(vii) (1994).

15. *Id.*; See also Melissa K. Davis, *Monopolistic Tendencies of Brand-Name Drug Companies in Pharmaceutical Industry*, 15 J.L. & COM. 357, 363-65 (1995). The policy basis for Hatch-Waxman is to increase the number of generic drugs available to consumers by providing an accelerated mechanism whereby generic manufacturers can challenge patented drugs. Hatch-Waxman also benefits companies that develop new drugs by extending the patent lifetime when approval for new drug results in a shortened marketing period during which the drug enjoys patent protection. *Id.*

16. 21 U.S.C. § 355(j)(2)(A)(vii).

17. 35 U.S.C. § 271(e)(2). The filing of a patent suit based on an ANDA delays the marketing of the generic drug by 30 months or until resolution by the parties, whichever comes first. *Id.*

18. Damages paid by the infringing party may be up to three times the actual damages incurred by the plaintiff. 35 U.S.C. § 284 (1994).

19. 21 U.S.C. § 355(j)(5)(B)(iv) (Supp. IV 1998).

20. *Id.*

earlier of either: (i) the day that the initial applicant first markets the drug (the “commercial marketing trigger”) or (ii) the day a court decides the original patent is invalid or not infringed by the generic drug (the “court decision trigger”).²¹ During the exclusivity period, the FDA will not approve any subsequent ANDAs.²² Consequently, the first company to file an ANDA can market its drug without generic competition for 180-days, thus increasing the likelihood that the first company will become the dominant generic supplier when the exclusivity period expires.²³

In *Biovail*, the first company to apply for an ANDA to sell generic Cardizem was the drug manufacturer Andrx.²⁴ Andrx filed an ANDA in September of 1995 and thereafter served on Hoechst certification that the ANDA did not infringe any outstanding Hoechst patents.²⁵ Hoechst responded by filing a patent infringement action against Andrx.²⁶ On September 15, 1997, the FDA gave preliminary approval for Andrx to market the generic form of Cardizem.²⁷ On September 26, 1997, Hoechst and Andrx entered into a partial settlement agreement.²⁸ Under the partial settlement, Hoechst and Andrx agreed to continue litigating the infringement suit in the courts.²⁹ However, Hoechst promised to make quarterly payments to Andrx in the amount of ten million dollars.³⁰ In exchange, Andrx agreed to refrain from marketing its generic drug until the resolution of the suit and to assert its right of exclusivity, as the first in line, against other potential producers of generic Cardizem.³¹ Since reaching the agreement, neither Hoechst nor Andrx have actively advanced the litigation.³²

21. *Id.*

22. 35 U.S.C. § 271(e)(2) (1994).

23. *Id.*

24. *See* Aetna U.S. Healthcare, Inc., v. Hoechst Aktiengesellschaft, Inc., 54 F. Supp. 2d 1042, 1046 (1999) (remanding to Kansas state court for lack of subject matter jurisdiction).

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.*

On June 19, 1997, Biovail filed an ANDA with the FDA for approval of a generic form of Cardizem.³³ However, Biovail was prevented from obtaining preliminary FDA approval for its generic Cardizem because Andrx's 180-day exclusivity period had not yet been triggered and therefore had not expired.³⁴ Consequently, Biovail was locked out of the Cardizem market.

C. *Biovail's Claims*

Biovail brought suit against Hoechst alleging that the partial settlement agreement between Hoechst and Andrx violated the Sherman Antitrust Act³⁵ because it represented an illegal agreement between competitors to restrain trade and willfully maintain a monopoly by Hoechst.³⁶ Hoechst responded by seeking dismissal of the claims, asserting that Biovail could not show a sufficient set of facts to make a prima facie case that Hoechst violated the anti-trust laws in any way that might entitle Biovail to relief.³⁷ Thus, the issue in the case was whether Biovail's complaint should be dismissed or whether the claims merited a trial.³⁸

In a motion to dismiss, all of Biovail's well-pleaded complaints are accepted as true and all reasonable inferences are drawn in favor of Biovail.³⁹ Hoechst's motion to dismiss would be granted if the court found "beyond doubt that . . . [plaintiff could] . . . prove no set of facts in support of [its] claim which would entitle [it] to relief".⁴⁰

Hoechst acknowledged that the partial settlement agreement with Andrx included that (1) Hoechst would continue to prosecute its patent infringement claims against Andrx; (2) Andrx would withdraw its counterclaims against Hoechst; (3) Hoescht would make quarterly payments in the amount of ten million dollars to Andrx; (4) Andrx agreed to refrain from marketing generic Cardizem until the resolution of the suit; (5) Andrx would continue to

33. See *Biovail*, 49 F. Supp. 2d at 757.

34. See *id.* at 758.

35. 15 U.S.C. §§ 1, 2 (1994).

36. *Biovail*, 49 F. Supp. 2d at 758.

37. *Id.*

38. FED. R. CIV. P. 12(B)(6).

39. *Cruz v. Beto*, 405 U.S. 319, 323 (1972).

40. *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957).

prosecute its claim for FDA approval; and (6) Andrx would assert its right as first in line to bar others from gaining FDA approval and thereby entering the Cardizem market.⁴¹ Hoechst also did not dispute that at the time of their motion to dismiss that they sold 80% of the Cardizem in the United States.⁴²

II. ANALYSIS OF BIOVAIL'S CLAIMS UNDER THE SHERMAN ANTITRUST ACT

Whether Biovail's claims were sufficient to maintain an action against Hoechst was decided under the Sherman Act⁴³, which protects consumers from high prices and reduced output caused by cartels and monopolies.⁴⁴ Biovail's claims were properly brought under the Sherman Act because the claims alleged that the Hoechst-Andrx suit and partial settlement unfairly blocked Biovail from selling an inexpensive, generic version of Cardizem, and that Hoechst thereby illegally restrained interstate trade and maintained an illegal monopoly on Cardizem.

In this section the antitrust elements of Biovail's claims are analyzed and the decision of the district court is presented.

A. Section 1 of the Sherman Antitrust Act

In order to establish a violation of section 1 of Sherman Act,⁴⁵ Biovail must establish that Hoechst engaged in (1) a conspiracy (2) to unreasonably restrain trade.⁴⁶ A conspiracy "must comprise an

41. *Biovail*, 49 F. Supp at 761; *Aetna U.S. Healthcare, Inc., v. Hoechst Aktiengesellschaft, Inc.*, 54 F. Supp. 2d 1042, 1046 (1999).

42. *Biovail*, 49 F. Supp at 761.

43. 15 U.S.C. §§ 1, 2 (1994).

44. HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY THE LAW OF COMPETITION AND ITS PRACTICE, 50 (1994).

45. 15 U.S.C. § 1. Section 1 states "every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal." *Id.*

46. *Id.*; *Summit Health, Ltd v. Pihos*, 500 U.S. 322, 330 (1991) (holding that an interstate nexus must be shown to establish Federal jurisdiction.) The plaintiff or the prosecution must allege and prove that the defendant's illegal activities had a substantial impact under the commerce clause. This requires a showing that the defendant's act is itself in interstate commerce or that it has an effect on interstate commerce. In *Summit Health* the Court held that a boycott designed to deny hospital staff privileges to a surgeon was reachable under the Sherman Act because the hospital itself was within the

agreement or meeting of the minds between at least two competitors, for the purpose or with the effect of unreasonably restraining trade”.⁴⁷ The making of the illegal agreement itself is the violation.⁴⁸ Completing the conspiracy, an act furthering the conspiracy, or the success of the conspiracy do not have to be shown because they are not elements of the offense.⁴⁹ Parties are liable so long as they made an illegal agreement.⁵⁰

An unreasonable “restraint of trade” . . . [refers to] . . . a particular economic consequence, which may be produced by quite different sorts of agreements”⁵¹ Economic consequences may include eliminating competition, creating a monopoly, price fixing or interfering with free market forces.⁵²

The courts have developed three methods of analyzing agreements to determine whether they constitute conspiracies to unreasonably restrain trade. The first analysis concerns agreements, which are illegal “per se.”⁵³ An agreement is illegal per se when the restraint of trade has no legitimate justification, lacks any redeeming competitive purpose and “would always or almost always tend to restrict competition and decrease output.”⁵⁴ Examples of per se violations include price fixing, allocations of markets and

reach of congress and both the hospital and the plaintiff regularly served out-of state patients. In *Biovail*, the parties did not dispute the effect on interstate commerce. See *Biovail*, 49 F. Supp. 761 n. 4.

47. Meredith E.B. Bell & Elena Laskin, *Antitrust Violations*, 36 AM. CRIM. L. REV. 357, 359 (1999) citing 15 U.S.C. § 1 (1994).

48. United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 223-24 n.59 (1940) (holding that an agreement to reduce output by independent members of a cartel violated Section I of the Sherman Antitrust Act, even though the agreement did not directly fix prices).

49. *Socony-Vacuum*, 310 U.S. at 223-24 n. 59.

50. *Id.*

51. *Business Elec. Corp. v. Sharp Elec. Corp.*, 485 U.S. 717, 731 (1988).

52. See Bell, *supra* note 47, at 360.

53. *Id.*

54. *Broadcast Music v. Columbia Broad. Sys.*, 441 U.S. 1; 19-20 (1979). (holding that a blanket license arrangement which literally involved price fixing was not a per se violation of the Sherman Act because the arrangement so significantly reduced transaction costs that it effectively made mass marketing of performance rights feasible); See also *United States v. Topco Ass'n.*, 405 U.S. 596 (1972) (holding that the allocations of markets was a per se violation of Section 1 of the Sherman Antitrust Act).

group boycotts.⁵⁵ When an alleged agreement is illegal per se, no facts need to be proven beyond the making of the agreement.⁵⁶

The second analysis is the “Rule of Reason”.⁵⁷

Rule of Reason analysis focuses on the state of competition with, as compared to without, the relevant agreement. The central question is whether the relevant agreement likely harms competition by increasing the ability or incentive profitably to raise price above or reduce output, quality, service, or innovation below what likely would prevail in the absence of the relevant agreement.⁵⁸

The Rule of Reason analysis allows courts to factor in the defendant’s assertion that an allegedly anti-competitive agreement may increase economic efficiency and competitiveness, and therefore not constitute a violation of the Sherman Act.⁵⁹ The nature of the agreement and the absence of market power to control output or fix prices may actually demonstrate the absence of anticompetitive harm.⁶⁰

The third analysis is the quick look doctrine.⁶¹ The quick look doctrine combines per se analysis with the more in depth inquiry of the Rule of Reason.⁶² The quick look doctrine is used to determine the legality of agreements that are not inherently competitive.⁶³ Under the quick look doctrine, the court is allowed to consider procompetitive justification for an agreement asserted by the defendant.⁶⁴ If the defendant successfully presents a procompetitive justification, then the court must do a complete examination under the Rule of Reason.⁶⁵

55. See Bell, *supra* note 47, at 360, n.45.

56. *Socony-Vacuum*, 310 U.S. at 223-224 n. 59.

57. *National Soc’y of Prof’l. Eng’rs. v. United States*, 435 U.S. 679, 692 (1978) (holding that under Rule of Reason, the defendant must show that a particular practice is not anticompetitive.)

58. Antitrust Guidelines for Collaborations Among Competitors, (visited Apr. 28, 2000) <<http://www.ftc.gov/os/1999/9910/jointventureguidelines.htm>> [hereinafter, Antitrust Guidelines]

59. *Professional Eng’rs*, 435 U.S. at 687-89.

60. See Antitrust Guidelines, *supra* note 58.

61. See Bell, *supra* note 47, at 360.

62. *Broadcast Music v. Columbia Broad. Sys.*, 441 U.S. 1; 17, n. 27 (1979).

63. See Bell, *supra* note 47, at 360.

64. *Id.*

65. *Broadcast Music*, 441 U.S. at 20-25.

B. Section 2 of the Sherman Antitrust Act

Biovail also alleged that Hoechst violated section 2 of the Sherman Act⁶⁶ by monopolizing or attempting to monopolize the market for Cardizem.⁶⁷ Section 2 prohibits monopolization, attempts to monopolize and conspiracies to monopolize.⁶⁸ Monopolization is shown by “(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.”⁶⁹ Attempted monopolization differs from actual monopolization by requiring a showing of anticompetitive or predatory behavior, a dangerous probability of successful monopolization, and a specific intent to monopolize.⁷⁰

In order to determine whether a firm has committed illegal monopolization, it is first necessary to define a relevant market.⁷¹ The relevant market is defined according to the product at issue and

66. 15 U.S.C. § 2 (1994). Section 2 states, “Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons to monopolize . . . shall be deemed guilty of a felony . . .” *Id.*; Unlike section 1, section 2 may apply to the conduct of single entities. *See United States v. Griffith et al.*, 334 U.S. 100, 107 (1948). As stated by Mr. Justice Douglas for the Court majority:

A man with a monopoly of theatres in any one town commands the entrance for all films into that area. If he uses that strategic position to acquire exclusive privileges in a city where he has competitors, he is employing his monopoly power as a trade weapon against his competitors. It may be a feeble, ineffective weapon where he has only one closed or monopoly town. But as those towns increase in number throughout a region, his monopoly power in them may be used with crushing effect on competitors in other places.

Id.

Conspiracy to monopolize was not alleged in *Biovail* and will not be considered. *See Biovail*, 49 F. Supp. at 761.

67. *Biovail*, 49 F. Supp. at 761.

68. 15 U.S.C. § 2.

69. *United States v. Grinnell Corp.*, 384 U.S. 563, 570-571 (1966) (holding that section 2 of the Sherman Act was violated by a high percentage of the market which was obtained in large part by unlawful and exclusionary practices).

70. *Spectrum Sports, Inc., v. McQuillan*, 506 U.S. 447, 456 (1993) (holding that attempted monopolization may be proved where a defendant has engaged in predatory or anticompetitive conduct with specific intent to monopolize and that there is a dangerous probability that the defendant will achieve monopoly power); *See also HOVENKAMP, supra* note 44, at 248-49.

71. *See HOVENKAMP, supra* note 44, at 82-83.

geography.⁷² The product market is defined according to the ability of consumers to find substitutes for the product.⁷³ The geographic market can be defined locally, regionally or nationally by considering whether consumers are able to travel to other districts to obtain the goods at issue.⁷⁴

Having defined the relevant market, a court will ordinarily compute the defendant's percentage of output in the relevant market.⁷⁵ The existence of monopoly power "ordinarily may be inferred from the predominant share of the market."⁷⁶ However, monopoly power may also be defined as a large amount of market power in a relevant market⁷⁷ where market power is the "ability of a firm to increase its profits by reducing output and charging more than a competitive price for its product".⁷⁸

Thus, monopolization is likely to be found if there are no product substitutes in the relevant market and a firm may raise prices or reduce output without causing customers to seek substitute products in such numbers that a price increase would be unprofitable.⁷⁹

C. Patent Misuse

Significantly, Biovail did not argue that Hoechst violated section 2 of the Sherman Act by abusing patent rights. Courts do not presume that the patent holder's right to exclude establishes market power in an antitrust sense.⁸⁰ As described by the Federal Circuit, "[t]he virtually unlimited variety and scope of patented inventions and market situations militate against per se rules in these situations."⁸¹ Moreover, the patent holder's right to exclude competi-

72. *Id.*

73. *Grinnell*, 384 U.S. at 571.

74. *Id.* (holding that the market at issue was nationwide rather than local. In a patent case the geographic market is defined nationally.)

75. See HOVENKAMP, *supra* note 44, at 82.

76. *Grinnell*, 384 U.S. at 571.

77. See HOVENKAMP, *supra* note 44, at 243.

78. *Id.* at 79.

79. See *id.* at 242

80. *Abbot Labs. v. Brennan*, 952 F. 2d 1346, 1354 (Fed. Cir. 1991) (holding that existence of patent does not of itself establish presumption of market power in antitrust sense).

81. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1368 (Fed. Cir. 1998).

tors by itself does not constitute monopoly power forbidden by the section 2.⁸² Antitrust laws do not require a “patent holder to forfeit the exclusionary power inherent in his patent the instant his patent monopoly affords him monopoly power over a relevant market.”⁸³

However, a firm that engages in patent misuse will be liable under section 2.⁸⁴ Patent misuse occurs when a patent is being used anticompetitively and outside the scope of the patent grant.⁸⁵ The patent misuse doctrine is typically invoked as a defense when a patent owner sues a defendant for patent infringement.⁸⁶ For example, in *Walker Process* the Supreme Court found patent misuse occurred when a patent owner sued a defendant for infringement on a patent that the patent owner knew was obtained through fraud.⁸⁷

D. Analysis of Biovail’s Claims Under the Sherman Act

Biovail claimed essentially that Hoechst subverted the FDA regulatory scheme for anticompetitive purposes.⁸⁸ Biovail argued that under a Rule of Reason analysis, the Hoechst-Andrx partial settlement violated section 1 because it harmed competition and restrained trade.⁸⁹ The partial settlement was an agreement between the competitors, Hoechst and Andrx, which kept Biovail out of a market that Biovail would be allowed to enter in the absence of the agreement.⁹⁰ Biovail argued, the ongoing infringement ac-

82. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177-78 (1965) (holding that obtaining a patent by fraud was a violation of Section 2 of the Sherman Antitrust Act).

83. *SCM Corp. v. Xerox*, 645 F.2d 1195, 1204 (2d Cir. 1981) (holding that the accumulation of all patents in a market area, thus making it much more difficult for other firms to compete, does not violate antitrust laws).

84. See Barry Evans, *Boundaries have Changed for Patent Misuse Defense, Despite Limitations Reports of Its Death Exaggerated*, N.Y.L.J., February 17, 1998, at S6, col. 3.

85. See HOVENKAMP, *supra* note 44, at 218.

86. See *id.*

87. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

88. See *Woods Exploration & Producing Co. v. Aluminum Co. of Am.*, 438 F.2d 1286, 1303 (5th Cir. 1971), *cert denied*, 404 U.S. 1047 (1972) (holding that policies of the Sherman Act should not be sacrificed simply because defendants employ governmental processes to accomplish anticompetitive purposes).

89. *Biovail*, 49 F. Supp. 759-760.

90. *Id.*

tion and partial settlement was evidence of an agreement which violated section 1. Hoechst, by engaging in tactics to forestall marketing generic Cardizem, reduced competition in Cardizem and, consequently, was able to charge elevated prices and reap illegal profits.⁹¹

Biovail's claims under section 2 of the Sherman Act asserted that Hoechst had achieved monopoly power in the relevant market for Cardizem because Hoechst sold 80 % of the Cardizem in the United States and, therefore, monopolization could be inferred from its predominant share of the market.⁹² Biovail further alleged that Hoechst violated section 2 by willfully seeking to maintain its monopoly power. Biovail claimed that Hoechst, having the intent to monopolize, engaged in anticompetitive conduct because by using the ongoing infringement suit and partial settlement agreement to block all sales by later ANDA applicants. Thus, Hoechst's actions maintained a monopoly for Hoechst.

Hoechst responded that Biovail's injury was speculative.⁹³ First, Hoechst argued that Biovail's claims were not ripe because Biovail had not yet been granted tentative approval by the FDA for its generic Cardizem.⁹⁴ Therefore, Biovail could not show that it was being kept out of a market to which it was otherwise entitled. Second, Hoechst argued Biovail could not show that the Hoechst-Andrx agreement unreasonably restrained trade. Regardless of the partial settlement, Andrx may have decided not to start marketing Cardizem, until the conclusion of the Hoechst-Andrx patent infringement trial.⁹⁵ Hoechst noted that should Andrx go forward with marketing before the conclusion of the infringement suit, Andrx might be subject to triple damages for willful patent infringement in the event that Andrx lost the suit. Hoechst argued that even the FDA recognized that "a prudent ANDA applicant" may wish to delay marketing to avoid the risk of potentially devastating damages.⁹⁶ Third, Hoechst responded that Biovail's claim

91. *Id.*

92. *Id.* at 766, *relying on* United States v. Grinell Corp., 384 U.S. 563, 571 (1966).

93. *Id.*

94. *Id.*

95. *Id.*

96. *Id.*

consisted of nothing more than frustration with the Hatch-Waxman exclusivity period.⁹⁷

E. The Decision of the District Court

While the court admitted that Hoechst's arguments were significant, it did not dismiss the case. The court reasoned that

while it is possible that Andrx is not marketing its generic product because it does not want to risk potential patent infringement damages, it is certainly possible that Andrx is not marketing its generic product-and hence stalling the exclusivity period because the defendant is paying it forty million dollars.⁹⁸

Since Hoechst could not show the absence of a prima facie, the case was not dismissed.⁹⁹

III. HOECHST ENJOYS IMMUNITY FOR ALLEGED VIOLATIONS OF THE SHERMAN ANTITRUST ACT UNDER THE NOERR-PENNINGTON DOCTRINE

Even if Biovail succeeds in making a prima facie case under the Sherman Act, it is likely that Hoechst will enjoy substantial Noerr Immunity for the partial settlement and the Hoechst-Andrx lawsuit.¹⁰⁰ Noerr Immunity limits the antitrust laws by insuring that private activities aimed at influencing the government are immune from prosecution, even though such activities may restrain trade or result in a monopoly.¹⁰¹ The policy behind Noerr is that if the antitrust laws were not so limited then, the antitrust laws would violate the right to petition the government as guaranteed under the First Amendment of the Constitution.¹⁰² Thus, Noerr Immunity

97. *Id.*

98. *Id.*

99. *Id.* at 777.

100. *See* Parker v. Brown, 317 U.S. 341 (1943) (stating that the Noerr doctrine is based on the presumption that the government cannot violate the antitrust laws). *See also* Eastern R.R Conference v. Noerr Motor Freight, Inc, 365 U.S. 127, 145 (1961) (holding that a restraint upon trade or monopolization resulting from a valid governmental action can result in a violation of the Sherman Act).

101. *Eastern R.R.*, 365 U.S. at 145.

102. *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508 (1972)

necessarily balances the Sherman Act's interest in promoting competition against the constitutionally guaranteed right to petition the government for a redress of grievances.

A. *The Noerr-Pennington Doctrine*

The Noerr Immunity doctrine was originally articulated in *Eastern Railroad Conference v. Noerr Motor Freight, Inc.*¹⁰³ In *Eastern Railroad*, the issue was whether the defendant's railroads violated sections 1 and 2 of the Sherman Act by conducting a publicity campaign urging the passage of state laws that would harm the trucking industry.¹⁰⁴ The Court held that even though the railroads may have used unethical business practices to destroy the truckers as competitors, the Sherman Act was not applicable because the activities at issue were limited to soliciting the Legislature and the Executive to pass and enforce specific laws.¹⁰⁵ The Court held:

[i]n a representative democracy such as this, these branches of government act on behalf of the people and, to a very large extent, the whole concept of representation depends upon the ability of the people to make their wishes known to their representatives. To hold that the government retains the power to act in this representative capacity and yet hold, at the same time, that the people cannot freely inform the government of their wishes would impute to the Sherman Act a purpose to regulate, not business activity, but political activity, a purpose which would have no basis whatever in the legislative history of that Act. Secondly, and of at least equal significance, such a construction of the Sherman Act would raise important constitutional ques-

(holding that it would be destructive of rights of association and of petition to hold that groups with common interests may not, without violating antitrust laws, use channels and procedures of state and federal agencies and courts to advocate their causes and points of view respecting resolution of their business and economic interests vis-a-vis their competitors); James B. Perrine, *Defining the Sham Limitation to the Noerr-Pennington Antitrust Immunity Doctrine: An Analysis of the Professional Real Estate Investors v. Columbia Pictures Industries Decision* 46 ALA. L. REV. 815 (1995).

103. 365 U.S. 127, 145 (1961).

104. *Id.*

105. *Id.*

tions. The right of petition is one of the freedoms protected by the Bill of Rights, and we cannot, of course, lightly impute to Congress an intent to invade these freedoms.¹⁰⁶

In *California Motor Transportation Co. v. Trucking Unlimited*, the Court definitively extended Noerr Immunity to also protect the right to petition administrative agencies and the courts.¹⁰⁷ In *California Motor*, it was alleged that the antitrust defendants engaged in a concerted effort to bring actions against the plaintiffs before state and federal agencies in order to destroy the plaintiffs as competitors.¹⁰⁸ It was further alleged that the defendants brought these actions irrespective of the merits and with the sole purpose of destroying the competitive ability of the plaintiffs.¹⁰⁹ The Court held that Noerr Immunity allowed the defendants to have the right to access courts and agencies to defeat the applications of competitors because the Sherman Act could not be construed to limit access to agencies or the courts.¹¹⁰ The Court stated:

[t]he same philosophy governs the approach of citizens or groups of them to administrative agencies (which are both creatures of the legislature, and arms of the executive) and to courts, the third branch of Government. Certainly the right to extends to all departments of the Government. The right of access to the courts is indeed but one aspect of the right of petition. We conclude that it would be destructive of rights of association and of petition to hold that groups with common interests may not, without violating the anti-trust laws, use the channels and procedures of state and federal agencies and courts to advocate their causes and points of view respecting resolution of their business and economic interests vis-à-vis their competitors.¹¹¹

106. *Id.* at 137-38.

107. 404 U.S. 508 (1972).

108. *Id.*

109. *Id.*

110. *Id.* at 519.

111. *Id.* (citation omitted).

B. *The Sham Exception to Noerr-Pennington*

However, in *California Motor*, the Court recognized that immunity under the Noerr Immunity doctrine was limited.¹¹² The Court held that Noerr Immunity did not apply to litigation which “is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor [In that case] . . . the application of the Sherman Act would be justified.”¹¹³

The Court did not specify the types of activities that constitute a sham lawsuit. As they observed, “[o]pponents before agencies or courts often think poorly of the other’s tactics, motions or defenses and may readily call them baseless.”¹¹⁴ The majority opinion, written by Justice Douglas, suggested that sham litigation was apparent when there was “a pattern of baseless, repetitive claims . . . which leads the factfinder to conclude that the administrative and judicial process have been abused.”¹¹⁵

Justice Stewart’s concurring opinion in *California Motor* was that sham litigation analysis required a subjective inquiry that accounted for the intent of the accused.¹¹⁶ The plaintiffs “are entitled to prove that the real intent of the conspirators was not to invoke the processes of the administrative agencies and courts but to discourage and ultimately to prevent the respondents from invoking those processes.”¹¹⁷ Upon the showing of intent, “the application of the Sherman Act would be justified”.¹¹⁸

This disagreement between Justice Douglas and Justice Stewart, whether analysis of sham litigation should be determined using an objective or intent based test, represented a dispute which continued in the Court for several years. In the words of one commentator, “[t]he Court’s uncertainty concerning what constitutes a sham has been remarkable. In almost every Noerr case since *Pennington* in 1965 the court has rephrased its standard for determin-

112. *Id.* at 511.

113. *Id.* (quoting *Eastern R.R.*, 365 U.S. at 144.)

114. *Id.* at 513.

115. *Id.*

116. *Id.* at 516.

117. *Id.* at 518.

118. *Id.* (quoting *Eastern R.R.*, 365 U.S. at 144).

ing whether antitrust conduct would be viewed as a sham.”¹¹⁹

In *Professional Real Estate Investors v. Columbia Pictures* (“PRE”), the Supreme Court finally held that the sham inquiry contained an indispensable objective, as well as a subjective component.¹²⁰ Justice Thomas, writing for the majority, outlined a two-part test under which an antitrust plaintiff must first show that a lawsuit is objectively baseless and then show that the lawsuit was initiated with bad faith to destroy the plaintiff as a competitor:

First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail. Only if a challenged litigation is objectively meritless may a court examine the litigant’s subjective motivation. Under the second part of our definition of a sham, the court should focus on whether the baseless litigation conceals an attempt to interfere directly with the business relationships of a competitor.¹²¹

The court compared the objectively baseless standard for sham litigation to bringing a wrongful civil proceeding.¹²² The Court reasoned by analogy that for the defendant to not have Noerr Immunity, the antitrust plaintiff must demonstrate that there was absolutely no objective merit to the defendant’s position because the claims were so baseless that no reasonable litigant could realistically expect to secure favorable relief.¹²³ Since in a wrongful civil proceeding “the absence of probable cause is an essential element of the suit,” the defendant could defeat an allegation of sham litigation by showing probable cause.¹²⁴ Moreover, the court held, as in a wrongful civil proceeding action, “[p]robable cause to institute civil proceeding requires no more than a reasonable belief that

119. Perrine, *supra* note 102, at 825, n. 61.

120. *Professional Real Estate Investors v. Columbia Pictures*, 508 U.S. 49 (1993) (holding that an objectively reasonable effort to litigate cannot be “sham,” within meaning of exception to Noerr doctrine immunity from antitrust liability, regardless of plaintiff’s subjective intent).

121. *Id.* at 60-61.

122. *Id.* at 58.

123. *Id.* at 62.

124. *Id.* at 63.

there is a chance that [a] claim may be held valid upon adjudication.”¹²⁵

Although Justice Stevens concurred with the results of the decision in *PRE*, he sharply disagreed with the objectively baseless standard advanced by the Court.¹²⁶ He argued that the objectively baseless standard for determining whether a lawsuit was a sham was too broad because the standard would encompass lawsuits that reasonable litigants could expect to win, but which were nevertheless a sham designed to keep competitors out of a market.¹²⁷ Stevens believed sham litigation was “appropriately applied to a case, or series of cases, in which the plaintiff is indifferent to the outcome of the litigation itself, but has nevertheless sought to impose a collateral harm on the defendant”.¹²⁸

The different standards articulated by the majority and concurring opinions in *PRE* reflected the different policy concerns. Thomas was concerned that a subjective test would undermine Noerr Immunity.¹²⁹ Thus, he believed that an objectively baseless standard would give “real intelligible guidance” as when to apply the sham exception.¹³⁰ Stevens, on the other hand, was concerned that the objectively baseless standard would allow monopolists to bring actions, which had “a colorable basis in law” but, were nonetheless designed to harass potential competitors.¹³¹ Thus, Stevens thought that the objective standard would allow potential antitrust defendants to escape liability. He advanced a standard, which allowed for the analysis of sham litigation on a case by case basis.¹³²

125. *Id.* (quoting *Hubbard v. Beatty & Hyde, Inc.*, 343 Mass. 258, 262 (1961)).

126. *Professional Real Estate*, 508 U.S. at 67.

127. *Id.*

128. *Id.* at 68 (Stevens, J., concurring).

129. *Id.* at 60.

130. *Id.* (quoting *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 503 (1988)).

131. *Id.* at 73 (Stevens concurrence quoting *Grip-Pak, Inc. v. Illinois Tool Works, Inc.*, 694 F.2d 466, 472 (1982)).

132. Stevens stated:

[i]n sum, in this case I agree with the Court’s explanation of why respondents’ copyright infringement action was not “objectively baseless,” and why allegations of improper subjective motivation do not make such a lawsuit a “sham.” I would not, however, use this easy case as a vehicle for announcing a rule that may govern the decision of difficult cases, some of which may involve abuse of

C. Noerr-Immunity Protects Hoechst from Liability

Noerr Immunity protects Hoechst from liability for Biovail's antitrust injuries arising out of the Hoechst-Andrx suit and the partial settlement. Since Noerr immunizes Hoechst's right to petition the government for grievances, Hoechst is protected from liability for the Hoechst-Andrx lawsuit. Hoechst cannot incur antitrust liability for bringing suit against Andrx because to do so would deny Hoechst access to the courts.

Noerr also immunizes the Hoechst-Andrx partial settlement because the partial settlement agreement is a private action which is incidental to a valid effort to influence government action. As explained in *Allied Tube*, "where, independent of any government action, the anticompetitive restraint results directly from private action, the restraint cannot form the basis for antitrust liability if it is "incidental" to a valid effort to influence governmental action."¹³³ Thus, Andrx's agreement with Hoechst not to sell Cardizem, thereby preventing the exclusivity period from being triggered is protected under Noerr.

Moreover, Hoechst is operating within the scope of their patent rights by limiting Andrx's production of a patented drug. Since the Cardizem patents are presumed valid for the duration of the Hoechst-Andrx lawsuit, Hoechst has the right to prevent Andrx from making and selling Cardizem for the duration of the trial.¹³⁴ If necessary, Hoechst could obtain a preliminary injunction to prevent Andrx from selling Cardizem for the duration of the lawsuit.¹³⁵ Any law that prevented Hoechst from limiting Andrx's production and sale of Cardizem during the trial would effectively limit Hoechst's access to the courts to enforce their patent, violating

the judicial process. Accordingly, I concur in the Court's judgment but not in its opinion.

Id. at 75.

133. *Allied Tube*, 486 U.S. at 499.

134. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1369 (Fed. Cir. 1998) (holding that clear and convincing affirmative evidence is required to show that the presumption of validity is not justified and that the patent is being misused to create an antitrust violation).

135. The purpose of a preliminary injunction is to preserve the status quo pending either a permanent injunction or a trial on the merits. FED. R. CIV. P. 65 (A) (1); *See O'CONNOR'S FEDERAL RULES*, Chapter 2, § 3, 63 (1998).

Hoechst's First amendment right to petition the government for grievances.¹³⁶

Noerr also immunizes Andrx's agreement to assert its rights as the first ANDA applicant because Andrx is merely exercising its rights before the FDA. If Andrx could not petition the FDA to block later ANDA applicants, then Andrx's right to petition the government for grievances would be blocked.

Hoechst cannot be liable for Biovail's inability to enter the Cardizem market because the antitrust harm to Biovail is the result of the exclusion period of the Hatch-Waxman Act in combination with the patent laws, rather than a direct action of Hoechst or Andrx. Hoechst is merely pursuing its own interest under Hatch-Waxman. As the Supreme Court stated in *City of Columbia v. Omni Outdoor Advertising*:¹³⁷

Any lobbyist or applicant, in addition to getting himself heard, seeks by procedural and other means to get his opponent ignored. Policing the legitimate boundaries of such defensive strategies, when they are conducted in the context of a genuine attempt to influence governmental action, is not the role of the Sherman Act.¹³⁸

Preventing Hoechst from pursuing their interests under Hatch-Waxman cannot be accomplished without limiting Hoechst's First Amendment right to petition the government. Thus, even though Hoechst's activities may have been part of a strategy to dominate the Cardizem market, they are immune under Noerr for antitrust injuries to Biovail.

D. *The Hoechst Suit Against Andrx is not a Sham*

Biovail would probably respond to Hoechst's claim for immunity under the Noerr Immunity doctrine by arguing that the Hoechst-Andrx dispute was an example of sham litigation, intended to keep Biovail from entering the Cardizem market. However, under the objectively baseless standard articulated in *PRE*,

136. U.S. CONST. amend. I.

137. 499 U.S. 365, 367 (1990).

138. *Id.* at 382.

Biovail probably will not prevail.

The objectively baseless standard allows an antitrust defendant to irrefutably defeat a claim of sham litigation by showing that they had probable cause to sue. Probable cause “requires no more than a reasonable belief that there is a chance that [a] claim may be held valid upon adjudication.” Hoechst will be able to show as a matter of law that they had probable cause to sue Andrx for patent infringement.

To appreciate the reason that Hoechst can show probable cause as a matter of law, it is useful to compare Hoechst’s claims to those of the plaintiff in *PRE*. In *PRE*, a motion picture studio, brought a copyright infringement suit against the operators of a hotel. The studio alleged that the defendant had infringed the plaintiff’s copyrights in various films by renting videocassettes to guests for viewing in hotel rooms.¹³⁹ The Court reasoned probable cause could be decided as a matter of law because there was no dispute as to the facts underlying the legal claims.¹⁴⁰

The Court noted that the studio’s copyright gave them the exclusive rights to perform the motion pictures publicly.¹⁴¹ The studio’s had this right regardless of whether “it intended any monopolistic or predatory use . . .”.¹⁴² “Indeed, to condition a copyright upon a demonstrated lack of anticompetitive intent would upset the notion of copyright as a ‘limited grant’ of ‘monopoly privileges’ intended simultaneously ‘to motivate the creative activity of authors’ and ‘to give the public appropriate access to their work product.’”¹⁴³ The Court concluded that since a reasonable copyright owner in the studio’s position would believe that it had some chance of winning an infringement suit against the defendant, the studio could show probable cause to sue the hotel owners. Having shown probable cause, the studio had defeated any claim by the hotel operators that the studio’s lawsuit was a sham.

139. *Professional Real Estate Investors v. Columbia Pictures*, 508 U.S. 49 (1993).

140. *Id.* at 62.

141. *Id.* at 64; 17 U.S.C. § 106 (4) (Supp. IV 1998).

142. *Professional Real Estate Investors*, 508 U.S. at 64.

143. *Id.*

As in *PRE*, the underlying facts of the Hoechst-Andrx patent infringement suit are not in dispute. Hoechst owns a valid patent in Cardizem. Andrx's ANDA filing gave Hoechst a cause of action to sue for patent infringement. Moreover, in the case of a patent infringement suit, a court will presume that the infringement suit was brought in good faith and was reasonable.¹⁴⁴ Therefore, Hoechst can show probable cause as a matter of law because any reasonable patent owner in their position would believe that it had some chance of winning an infringement suit against Andrx. Thus, Biovail will not be able to show that the Hoechst-Andrx lawsuit was objectively baseless.

Since under *PRE*, a plaintiff's intent with regard to allegations of sham litigation are only considered after a suit has been shown to be objectively baseless, a court will not be able to consider evidence on whether Hoechst intentionally created an anticompetitive situation by partially settling their suit with Andrx. However, even if Biovail could show an objectively baseless lawsuit they probably would not be able to show that Hoechst had the intent required for sham litigation. Under *PRE*, the intent required is that the plaintiff initiates the litigation to directly interfere with the defendant's business. Hoechst's intent was to stop Andrx from infringing their patent. Hoechst's intent was not directed at Biovail. Since Biovail could not show Hoechst initiated the litigation to interfere directly with Biovail's business, they can not show Hoechst had the required intent under *PRE* for sham litigation. As the Supreme Court has stated, "the purpose of delaying a competitor's entry into the market does not render lobbying activity a 'sham' unless . . . the delay is sought to be achieved only by the lobbying process itself, and not by the governmental action that the lobbying seeks".¹⁴⁵

It is interesting to speculate if the analysis presented by Justice Stevens in *PRE* might result in a different outcome for Biovail's claims. Stevens argued that the objectively baseless standard was too high because defendants who could establish probable cause, might nevertheless be engaged in sham litigation. He proposed to analyze whether litigation was a sham by determining if the liti-

144. C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1369 (Fed. Cir. 1998).

145. City of Columbia v. Omni Outdoor Advertising, 499 U.S. 365, 367 (1990).

gants were indifferent to the outcome of the suit. Under the Stevens's analysis, Biovail could argue the Hoechst-Andrx litigation was a sham because Hoechst was indifferent to the outcome of the patent infringement suit. Hoechst indifference was evident because after reaching a partial settlement neither Hoechst nor Andrx had advanced the litigation. Biovail could further assert that Hoechst was simply prolonging the litigation as a strategy to delay competitors from entering the Cardizem market. Thus, it is likely that under Stevens analysis, Hoechst would be liable for antitrust violations because their litigation qualified as a sham.

However, since the standard for determining whether a litigation is a sham is the objectively baseless standard articulated by the Supreme Court in *PRE*, Biovail would not prevail by arguing that the Hoechst-Andrx lawsuit is a sham.

CONCLUSION

Biovail v. Hoechst Aktiengesellschaft illustrates how the antitrust laws and Noerr Immunity are balanced between promoting competition and protecting the right to petition the government guaranteed by the Constitution. The Sherman Act prevents companies from illegally restraining trade or monopolizing markets. Noerr Immunity limits the Sherman Act from infringing on the right to petition when a party seeks to gain economic advantage through the political or judicial system. The Supreme Court has decided that the constitutional rights are sufficiently precious that the standard to defeat Noerr Immunity using the sham exception is very high.

In the present case, Noerr Immunity protects Hoechst from liability under the Sherman Act, even though Hoechst may have had the intent to manipulate the Hatch-Waxman Act to keep competitors out of the Cardizem market. The Noerr Immunity doctrine is justified because the alternative would be that the antitrust laws would regulate Hoechst's access to the courts, thereby jeopardizing rights protected under the First Amendment of the constitution.