

Valley Drug Co. v. Geneva Pharmaceuticals, Inc.: Enlarging the Patent Exclusionary Right Through Hatch-Waxman Settlement Agreements Is Not Per Se Anticompetitive?

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I. INTRODUCTION

Abbott Laboratories originally patented terazosin hydrochloride in 1977 and has secured other patents on various formulations and methods of its use and preparation in the drug Hytrin.¹ Generic drug manufacturers Geneva Pharmaceuticals and Zenith Goldline Pharmaceuticals intended to produce terazosin.² These companies filed separate abbreviated new drug applications (ANDAs) with the FDA in accordance with the terms of the Hatch-Waxman Act³ by certifying that Abbott’s patents were not valid and would not be infringed by their manufacture, use, or sale of the drug.⁴

Abbott brought an infringement action against Geneva based on its tablet version of the drug, claiming it infringed Abbott’s Patent No. 5,504,207 (’207).⁵ Geneva admitted infringement, but disputed the patent’s validity.⁶ Abbott failed to file an infringement action against Geneva’s capsule ANDA, which was later approved.⁷ Zenith was required by the FDA to amend its certification after it filed its ANDA because Abbott secured two patents, including the ’207 patent.⁸ Zenith sought a declaratory judgment that the patents were invalid and Abbott counterclaimed for infringement.⁹

1. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1298 (11th Cir. 2003).
2. *Id.*
3. Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417 (1984) (codified as amended at 21 U.S.C. § 355 (2000)).
4. *Valley Drug*, 344 F.3d at 1298-99.
5. *Id.* at 1299.
6. *Id.*
7. *Id.*
8. *Id.* at 1299 & n.12.
9. *Id.* at 1299.

Abbott entered into settlement agreements with Geneva and Zenith to secure its rights to the market.¹⁰ The terms of the Geneva Agreement precluded Geneva from selling or distributing any drug containing terazosin until Abbott's 4,215,532 ('532) patent expired, another company introduced a generic terazosin drug, or Geneva had obtained a nonappealable, final judgment that the '207 patent was not infringed or was invalid.¹¹ Geneva agreed to the following: not to transfer or sell its rights under its approved ANDA including the 180-day exclusivity period; to oppose any subsequent attempt to seek a valid ANDA by another company; and to assist Abbott in securing an extension on a 30-month stay in approving Geneva's tablet ANDA.¹² In turn, Abbott agreed to pay Geneva \$4.5 million per month until a generic product was introduced or Abbott was successful on its infringement claim.¹³

The Zenith Agreement dismissed all claims between Zenith and Abbott.¹⁴ Zenith acknowledged the validity of Abbott's patents and admitted any terazosin product they might market would infringe the patents.¹⁵ Zenith agreed to the following: not to market any terazosin drug until another manufacturer produced a generic version of the drug or until the '532 patent expired; not to sell or transfer its rights under its ANDA; not to aid any person in seeking FDA approval of a terazosin drug; and not to aid any person opposing Abbott's patents on terazosin.¹⁶ In return, Abbott would initially pay Zenith \$3 million, an additional \$3 million after three months, and \$6 million every quarter thereafter until the Agreement terminated or in approximately two years.¹⁷

Subsequent to the Agreements, the '207 patent was held invalid.¹⁸ The plaintiffs filed suit alleging that the Agreements violated § 1 of the Sherman Act.¹⁹ The United States District Court for the Southern District of Florida held that the Agreements were per se violations of the Sherman Act because they constituted "horizontal market allocation agreements [that] would tend to inhibit domestic output and price

10. *Id.* at 1300.

11. *Id.*

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.* at 1301, 1305 n.16; see *Abbott Labs. v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1318 (Fed. Cir. 1999), *cert. denied*, 528 U.S. 1078 (2000).

19. *Valley Drug*, 344 F.3d at 1301.

competition without creating efficiencies for American consumers.”²⁰ The United States Court of Appeals for the Eleventh Circuit reversed and *held* that the district court had not considered whether the Agreements’ market exclusionary effects were broader than the patent holder’s right of exclusion, and therefore the Agreements were not per se illegal under § 1 of the Sherman Act. *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003).

II. BACKGROUND

Justice Murphy once commented that patents are “exception[s] to the general rule against monopolies and to the right to access to a free and open market.”²¹ The Federal Circuit regards the intersection between patent and antitrust laws as complementary.²² A patentee has a statutory right to exclude others from making, selling, or using the invention.²³ This provides long-term incentives for innovation, investment, and public disclosure.²⁴ Antitrust laws promote competition and lower prices by preventing certain types of conduct that threaten the free market.²⁵ In cases where the patented invention creates its own economic market or consumes a large section of an existing market, the policies behind patent and antitrust laws seem to conflict.²⁶ Yet, antitrust liability will only arise if the patentee abuses his patent power by eviscerating the competition unfairly.²⁷

Section 1 of the Sherman Act provides: “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 declared to be illegal.”²⁸ The Supreme Court has narrowly interpreted the language to reach bilateral conduct that constitutes an unreasonable restraint on trade.²⁹ In these situations, the Court applies either the per se

20. *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1354 (S.D. Fla. 2000).

21. *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945).

22. *See Carl Schenck, A.G. v. Nortron Corp.*, 713 F.2d 782, 786 n.3 (Fed. Cir. 1983) (“That the property right represented by a patent . . . may be *used* in a scheme violative of antitrust laws creates no ‘conflict’ between . . . those property rights and the antitrust laws.”).

23. *See* 35 U.S.C. § 261 (2000).

24. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989).

25. *See generally* PHILLIP E. AREEDA & HERBERT HOVENKAMP, *FUNDAMENTALS OF ANTITRUST LAW* § 5.01 (2003).

26. *See Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990).

27. *See id.*

28. 15 U.S.C. § 1 (2000).

29. *See State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997).

rule or the rule of reason.³⁰ Restraints that are so clearly and predictably anticompetitive, and lacking procompetitive benefits, can be deemed illegal per se.³¹ For example, price-fixing or tying arrangements have been held per se illegal.³²

In the context of patent rights, two situations may impute antitrust liability to patentees under the Sherman Act. The first is attempted enforcement of a patent procured through fraud or misrepresentation.³³ The other occurs when a patentee bolsters a patent's effectiveness beyond what is statutorily granted through agreements with other entities.³⁴ For example, patent licenses may not provide for the purchase of unpatented products from the licensor because this allows the licensor to exploit his patent right and diminish competition in a different market.³⁵ These agreements often arise as settlements between litigants involved in patent litigation.³⁶

One reason Congress enacted the Hatch-Waxman Act was to allow firms to efficiently market generic drugs.³⁷ A generic can use safety and effectiveness studies of the pioneer drug manufacturer if the drugs are "bioequivalent."³⁸ After establishing bioequivalence, the generic can file an ANDA with the FDA and certify that the generic drug will not interfere with a patent of the original drug.³⁹ The generic may certify that the patent is invalid or its manufacture, use, or sale of the new drug will not infringe the patent.⁴⁰ The generic must notify the pioneer of its ANDA.⁴¹ The pioneer then has 45 days to file an infringement action or the ANDA will be approved.⁴² The FDA will stay ANDA approval thirty months if the suit is filed.⁴³ The first approved ANDA enjoys a 180-day exclusivity period in which the generic has the exclusive right to market

30. *See id.*

31. *See id.*

32. *See* Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 9 (1984).

33. *See, e.g.,* Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 176-77 (1965) (allowing treble damages against a plaintiff-patentee who fraudulently procured and attempted to enforce a patent it knew was invalid).

34. *See id.*

35. *See* Int'l Salt Co. v. United States, 332 U.S. 392, 395-96 (1947).

36. *See, e.g.,* United States v. Singer Mfg. Co., 374 U.S. 174, 189 (1963).

37. *See* Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 32 (D.D.C. 2000).

38. *See id.*

39. *See id.*

40. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000). This is commonly referred to as "paragraph IV certification." *See Mylan Pharms.*, 81 F. Supp. 2d at 32.

41. *See* 21 U.S.C. § 355(j)(2)(B) (2000).

42. *See id.* § 355(j)(5)(B)(iii).

43. *See id.* If the court determines that the patent is invalid or not infringed prior to the thirty-month stay, ANDA approval becomes immediately effective.

the generic drug.⁴⁴ This period begins when either the generic drug is first marketed or by judicial determination that the patent is invalid or noninfringed.⁴⁵

This 180-day exclusivity period serves as an incentive to generics to be the first to submit an ANDA.⁴⁶ Patent litigation is an inevitable result. Instead of litigating the merits of the patent, pioneers elect to enter into settlement agreements to exclude potential competitors and to avoid costly litigation.⁴⁷ Antitrust problems arise when the patent's validity is questionable and the agreements bolster the patentee's exclusionary power.⁴⁸

The United States Court of Appeals for the Sixth Circuit recently held an exclusion agreement, similar to the Geneva Agreement in the noted case, was illegal per se under § 1 of the Sherman Act.⁴⁹ The agreement required the generic to: (1) be excluded from the market until the infringement action was determined by a court or until the pioneer entered into a license agreement with either the generic or a third party, (2) to dismiss all antitrust claims, (3) to prosecute diligently its ANDA, and (4) not to relinquish any rights under its ANDA including the 180-day exclusivity period.⁵⁰ In exchange, the generic received \$40 million per year after FDA approval.⁵¹ The court held that this horizontal market agreement was a classic example of a per se violation because the 180-day exclusivity right of the generic delayed the entry of all competitors indefinitely from introducing a generic drug into the market.⁵² The court clarified that the patentee broadened the scope of the exclusionary right by entering into such an agreement.⁵³

However, the United States District Court for the Eastern District of New York has recently held that pharmaceutical patent settlement agreements were not per se § 1 violations. In *In re Tamoxifen Citrate Antitrust Litigation*, a settlement agreement dismissed all claims and allowed other generic manufacturers to challenge the validity of its patent

44. See *id.* § 355(j)(5)(B)(iv).

45. See *id.*

46. See *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 33 (D.D.C. 2000).

47. See *id.*

48. See Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley*, 87 MINN. L. REV. 1789, 1807 (2003).

49. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

50. *Id.* at 902.

51. See *id.* A \$100 million per year payment was to be made if certain conditions were met. See *id.* at 903.

52. *Id.* at 907-08.

53. See *id.* at 908 n.13.

as a means of entering the market.⁵⁴ Furthermore, the pioneer manufacturer's patent was litigated and upheld in subsequent proceedings against other ANDA filers.⁵⁵ Thus, the lack of competition was attributed to the existence of a valid exclusionary right derived from the patent and therefore did not warrant a finding of a per se violation under the Sherman Act.⁵⁶

In *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, a patent settlement agreement was upheld for two reasons.⁵⁷ First, the patent covered a single active ingredient of a drug and not a formulation patent.⁵⁸ Thus, the agreement prohibiting all uses of a generic drug was not beyond the scope of the patent itself. Second, the agreement settled the patent litigation and the generic forfeited its right to a 180-day exclusivity period.⁵⁹ Therefore, the plaintiff could not establish that the agreements restricted competition beyond the patentee's right of exclusion.⁶⁰ Applying a per se standard, the plaintiff did not establish any anticompetitive conduct under § 1 of the Sherman Act.⁶¹

III. THE COURT'S DECISION

In the noted case, the United States Court of Appeals for the Eleventh Circuit agreed with the *Ciprofloxacin* court that the threshold analysis is to determine the scope of the patentee's exclusionary right.⁶² It reversed the district court's determination that the agreements between Abbott and the generic manufacturers were per se illegal as market allocation agreements under § 1 of the Sherman Act, because the district court had not properly considered Abbott's exclusionary rights arising from its '207 patent.⁶³ It also decided that a subsequent invalidation of the '207 patent did not effect the legality of the agreements.⁶⁴ Furthermore, the lawful right of exclusion necessarily included a right to pay competitors not to produce infringing products so long as the settlement agreements did not bolster the patent's effectiveness.⁶⁵ Finally,

54. 277 F. Supp. 2d 121, 129 (E.D.N.Y. 2003).

55. *See id.* at 133.

56. *See id.* at 136.

57. 261 F. Supp. 2d 188 (E.D.N.Y. 2003).

58. *See id.* at 241.

59. *See id.* at 242.

60. *See id.* at 255.

61. *See id.* at 255-57.

62. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1294 (11th Cir. 2003).

63. *Id.* at 1306.

64. *Id.* at 1308.

65. *Id.* at 1309.

the court developed a framework for analysis of the agreement provisions for the district court to apply upon remand.⁶⁶

The court distinguished between agreements that would violate § 1 of the Sherman Act as market allocation agreements and those that simply reinforce the effects of a patent's exclusionary right.⁶⁷ It admitted that the nature of the patent right includes the right to exclude others from making, using, or selling the product, resulting in "anticompetitive tendencies," but not per se violations of the Sherman Act.⁶⁸ Insofar as Zenith and Geneva agreed not to market admittedly infringing products of the '207 patent before it expired or was declared invalid, the exclusionary effect of the agreement was no greater than the patent exclusion right itself.⁶⁹ Because this was the basis of the district court's determination that the agreements were per se violations, the court of appeals reversed and remanded for proper consideration of the exclusionary right granted by the '207 patent.⁷⁰ The court then elaborated on several other issues that would arise on remand.

Although the '207 patent was declared invalid subsequent to the agreements, the court held that this cannot be considered when determining whether the agreements were per se violations of § 1 of the Sherman Act.⁷¹ The reasonableness of the agreements must be determined at the time they were formed, thus making the valid '207 patent at the time of agreement relevant to determining antitrust liability.⁷² However, the court also noted that circumstances may permit antitrust liability when a unreasonable settlement agreement would not violate the patent policies of "encouragement of genuine invention and disclosure."⁷³

Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent. This uncertainty, coupled with a treble damages penalty, would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer is certain to lose. By restricting settlement options, which

66. *Id.* at 1312.

67. *Id.* at 1304-05.

68. *Id.* at 1305.

69. *Id.*

70. *Id.* at 1306.

71. *Id.* at 1306-07.

72. *Id.* at 1306.

73. *Id.* at 1308. These circumstances include when the patent procured through fraud is attempted to be enforced or there is sham patent litigation. *See id.* at 1309.

would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation.⁷⁴

Because the plaintiffs did not prove anything more than subsequent invalidity, the court concluded that the evidence was insufficient to impute antitrust liability.⁷⁵

The court then ruled that the exclusionary right derived from a valid patent may include the right to pay potential infringers to exit the marketplace to avoid costly litigation.⁷⁶ It reasoned that the “failure to produce the competing . . . drug, rather than the payment of money, is the exclusionary effect” on the generic manufacturers and this effect was not broader than the patent exclusion right.⁷⁷ To hold otherwise, the court believed “would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally.”⁷⁸ The court admitted that the size of the payment could suggest a patentee acted in bad faith, particularly when the payments are nonrefundable.⁷⁹ This is true even if the patentee prevails on infringement, but the court offered several factors to assess the reasonableness of the payments including lost profits from generic competition, risks of insolvent infringers, and high litigation costs.⁸⁰ Furthermore, although the structure of the payments correlating with the length of litigation was suspicious, the court rationalized this as mere compensation for Geneva’s lost profits during the litigation.⁸¹

The Court expressly disagreed with the Sixth Circuit’s conclusion in *In re Cardizem CD Antitrust Litigation*.⁸² The court suggested that the Sixth Circuit’s decision may have rested on several other provisions in the agreement which readily exceeded the patent’s exclusionary effect, such as the 180-day exclusivity period and the restriction of noninfringing products.⁸³ The court recognized that the Sixth Circuit had not compared the agreements to the exclusionary power of the patent nor distinguished which provisions of the agreement were within the exclusion scope.⁸⁴ Essentially, the court characterized the Sixth Circuit decision as an

74. *Id.* at 1308.

75. *Id.*

76. *Id.* at 1309.

77. *Id.*

78. *Id.*

79. *Id.*

80. *Id.* at 1309-10.

81. *Id.* at 1310.

82. 332 F.3d 896, 908 (6th Cir. 2003).

83. *Valley Drug*, 344 F.3d at 1311 n.26.

84. *Id.*

automatic imposition of liability when exit payments are made to a potential infringer.⁸⁵ In contrast, the Eleventh Circuit concluded that the presence of an exit payment does not necessarily establish a per se violation of § 1 of the Sherman Act.⁸⁶

The court determined that all of the provisions of the agreements, including the agreement not to produce “any” generic terazosin product, Geneva’s agreement not to market until a final, unappealable judgment of invalidity, and Geneva’s agreement not to waive its 180-day exclusivity period should be subjected to the same regulatory framework.⁸⁷ Upon remand, the district court will consider the following factors: (1) the scope of the patent’s exclusionary power under the terms of the patent and the statutory rights of the patentee, (2) the comparison of the provisions to the scope to ensure they are reasonable implementations that do not bolster the patent’s effectiveness, and (3) whether the provisions of the agreement are beyond the patent’s exclusionary power in violation of § 1 of the Sherman Act.⁸⁸ The court suggested that the final analysis will be highly dependent on the nature of the provision and while some provisions could be ostensibly anticompetitive, most will require analysis of the circumstances surrounding the restraint.⁸⁹ In cases in which only part of the provisions violate the Sherman Act, the court advised that these should be identified, but not considered in isolation when determining the overall anticompetitive effect.⁹⁰

IV. ANALYSIS

Patent settlement agreements save considerable expenses for litigants and are generally encouraged by courts, but they may be fraught with anticompetitive conduct in an already monopolized market. In effect, the Hatch-Waxman Act allows pharmaceutical companies to broaden the scope of patent protection by entering into an agreement with the first generic ANDA filer and securing its 180-day exclusivity period. This abates social benefits through reduced drug discovery and increased consumer costs. It also gives greater protection to potentially invalid patents. In the noted case, the Eleventh Circuit attempted to balance the policies of antitrust and patent laws, but instead broadened a patentee’s exclusionary right.

85. *Id.* at 1310-11.

86. *Id.* at 1309.

87. *Id.* at 1311-12.

88. *Id.*

89. *Id.* at 1313.

90. *Id.* at 1313 n.31.

Although patentees have the right of exclusion, they may not abuse it. Geneva's agreement not to transfer its 180-day exclusivity period in effect excluded all generic market competition because no other ANDAs could be approved until the period expired. The delay resulted in fewer products, higher consumer prices, and a longer term of Abbott's market control. This directly conflicts with patent policies.⁹¹ The pioneer will allocate its resources to exploit various formulations of a drug, suggesting necessary changes in patent scrutiny at the United States Patent and Trademark Office. Furthermore, this investment reduction in new drug technology will prolong high drug prices. Therefore, this is a naked restraint on trade and should be considered per se unlawful under § 1 of the Sherman Act.

Given that many patents are found invalid or not infringed upon, patentees will enter into settlements to preserve its rights to a potentially invalid patent.⁹² The probability of invalidity will reflect the agreement's terms, including the amount paid for the exclusion of the generic. The potential profit loss of the patentee will be significantly higher than potential profits received by a generic manufacturer. This makes it likely that a generic will delay entry into the market because it can receive greater profits in a settlement than the potential profit earned by making the drug.⁹³ Commentators have suggested that this type of payment should be presumptively unlawful and only rebuttable if the pioneer shows that (1) there was significant likelihood that it would prevail in the infringement suit and (2) the size of the payment would be equivalent to the cost of the lawsuit.⁹⁴ Proving that the pioneer would prevail in an infringement action neither comports with a patent's statutory presumption of validity, nor with the judicial clear and convincing evidence standard required to invalidate an issued patent.

As the court suggests, careful balancing is required when comparing the scope of the patent right to an exclusionary agreement to determine per se antitrust liability. But a 180-day exclusivity period that can be delayed indefinitely by the first generic filer readily deserves per se treatment under § 1 of the Sherman Act. Likewise, an agreement not to make "any" generic terazosin drug, when at least one patent has

91. *See id.*

92. This does not suggest the patent was procured through fraud.

93. Depending on the capacity of the manufacturer, it may allocate these research funds to new technology.

94. Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1759 (2003).

expired, is also per se unlawful. Upon remand, the district court will likely clarify that its decision was based on these provisions.

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