

Federal Circuit Affirms Ruling That Patent Settlement Between Brand-Name and Generic Drug Makers Did Not Violate Antitrust Law

In *In re Ciprofloxacin Hydrochloride Antitrust Litigation*,¹ the United States Court of Appeals for the Federal Circuit added its voice to the fiercely debated issue of the antitrust treatment of patent dispute settlements that involve a payment to the alleged infringer (a “reverse” payment) and a delay in the introduction of generic alternatives to branded drugs. The court considered whether the Sherman Act prohibited a settlement between Bayer and a generic manufacturer seeking to invalidate Bayer’s Cipro patent,² whereby Bayer paid the generic manufacturer \$398 million in return for an agreement admitting infringement and abandoning any efforts to enter the market. The Federal Circuit³ departed from the Federal Trade Commission’s strongly expressed views and rejected the rule set forth by the Sixth Circuit that such settlements are *per se* illegal. Instead the appellate court reached a result similar to the Eleventh and Second Circuits and ruled that a plaintiff bringing a “reverse-payment” case must demonstrate that the challenged agreements had an anti-competitive effect on the market beyond that permitted by the patent.

I. The Hatch-Waxman Act

Congress enacted the Hatch-Waxman Act in 1984 to preserve incentives for pioneers to develop new pharmaceuticals, while encouraging competition by providing incentives to generic manufacturers to challenge pioneers’ patents.⁴ The Act established a new method for resolving patent infringement claims. First, when the would-be generic manufacturer files an Abbreviated New Drug Application (“ANDA”), it may include in its application a “paragraph IV certification”⁵ stating that any patent on file with the Food and Drug Administration (“FDA”) covering the patented drug is either invalid or will not be infringed by the manufacture or sale of the generic drug, which typically gives rise to a patent infringement action by the patentee.⁶ When the infringement action is filed a 30-month stay goes into effect preventing the FDA from approving the generic drug, unless the court hearing the infringement action decides in the interim that the patent is invalid or not infringed.⁷ The first

¹ *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, No. 2008-1097, _ F.3d _, 2008 WL 4570669, at *1 (Fed. Cir. Oct. 15, 2008) (hereinafter *In re Cipro*), available at <http://www.cafc.uscourts.gov/opinions/08-1097.pdf>.

² Cipro is the brand name for ciprofloxacin hydrochloride, a successful anti-biotic drug. The defendants in the action were Bayer AG and Bayer Corp., which we refer to collectively as Bayer in this memorandum, as well as several generic drug manufacturers.

³ The Federal Circuit has exclusive appellate jurisdiction over complaints involving claims under the patent laws. 28 U.S.C. § 1295(a).

⁴ 15 U.S.C. §§ 68b-68c, 70b; 21 U.S.C. §§ 301, 355, 360cc; 28 U.S.C. § 2201 and 35 U.S.C. §§ 156, 271, 282. The Act established a new approval procedure, allowing an applicant to gain FDA approval for a generic drug by showing that the generic is chemically equivalent and “bioequivalent” to the patented drug. Significantly, the Act provided that an applicant may rely on the safety and efficacy data submitted by the patent holder in its New Drug Application. *In Re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 191 (2d Cir. 2006).

⁵ The Act provides four different certifications an ANDA applicant can make. *Id.* Only the paragraph IV certification is relevant to the discussion herein.

⁶ See *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 901 (6th Cir. 2003) (discussing the Hatch-Waxman Act, 21 U.S.C. §§ 301-399). After filing the paragraph IV certification the applicant must give notice to the patent-holder, who in turn has 45 days to file a patent infringement action against the applicant.

⁷ *Id.*

generic manufacturer to file a paragraph IV ANDA is entitled to a six-month exclusivity period to market the drug without any other generic competition.⁸

II. Hatch-Waxman Antitrust Cases in Other Circuits and the FTC

The Sixth Circuit in its 2003 decision *In re Cardizem CD Antitrust Litigation*,⁹ was the first circuit court to consider the legality of a reverse-payment Hatch-Waxman settlement. The ANDA applicant, in exchange for quarterly payments of \$10 million, agreed to not market its generic drug or non-infringing versions of the drug until a specified date, and to retain the six-month exclusivity period to which it was entitled under the Act.¹⁰ The court held that the settlement was a horizontal agreement to eliminate competition and thus a *per se* illegal restraint of trade.¹¹ Significantly, the court considered the strength of the patent in rejecting the patentee's argument that the generic manufacturer would have refrained from entering the market even in the absence of settlement payments.¹² The court held that a trier of fact could find that the patentee would not have paid \$89 million to keep the generic manufacturer out of the market were it confident in the strength of its patent, and therefore the payment was a necessary predicate to the generic drug being withheld from the market.¹³

In *Valley Drug v. Geneva Pharmaceuticals*, decided a few months after *Cardizem*, the Eleventh Circuit rejected the Sixth Circuit's *per se* rule and held that the settlements between a patentee and two generic challengers had to be parsed by the district court to first determine which provisions excluded competition consistent with the patent, and then whether provisions that went beyond the patent's scope violated antitrust law.¹⁴

In *Schering-Plough v. FTC*,¹⁵ a patentee for a time-released supplement reached separate settlements with two ANDA applicants that allowed each to enter the market several years prior to the patent's expiration. Schering-Plough, the patentee, agreed to pay one applicant a cash settlement and to license several of the other applicant's products.¹⁶ The Federal Trade Commission ("FTC") filed an administrative complaint alleging the settlements violated the Sherman Act, and the full Commission ultimately held that the agreements were illegal.¹⁷ The defendants appealed to the Eleventh Circuit and the appellate court reversed, applying the reasoning from its earlier decision in *Valley Drug* and holding that the anticompetitive effect of a settlement may not exceed the exclusionary scope of the patent. The court observed that patents naturally limit competition and stated that the proper analysis for antitrust liability in a patent context was to examine the scope of the patent's exclusionary

⁸ *Id.*

⁹ *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003).

¹⁰ *Id.* at 907-08.

¹¹ *Id.* at 908.

¹² *Id.* at 915.

¹³ *Id.*

¹⁴ *Valley Drug v. Geneva Pharmaceuticals*, 344 F.3d 1294, 1311-13 (11th Cir. 2003).

¹⁵ *Schering-Plough v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

¹⁶ *Id.* at 1059-61.

¹⁷ *Id.* at 1061-62.

potential, the extent to which the settlement exceeds that scope and the resulting anticompetitive effects.¹⁸ The court found that the settlements did not exceed the protections of Schering-Plough's patent and thus were legal.¹⁹

In *In re Tamoxifen Citrate Antitrust Litigation*,²⁰ the Second Circuit expanded upon the reasoning of the Eleventh Circuit in *Valley Drug* and *Schering-Plough* and ruled more broadly that settlements within the exclusionary zone of a patent are not illegal. The court also concluded that the validity of the patent need not be considered unless fraud is alleged or the infringement suit is objectively baseless.²¹

In its amicus brief to the Federal Circuit in *In re Cipro*, the FTC stated that it generally views settlements of Hatch-Waxman cases involving exclusion or "reverse" payments as collusive and anti-competitive.²² The FTC characterized such settlements as a "stratagem" to "frustrate Congress' resolve to eliminate unwarranted patent obstacles to generic entry."²³ The FTC takes the position that many patents involved in Hatch-Waxman cases are of questionable validity, and that many patentees have used settlements to collude with generic manufacturers to split the supracompetitive price of brand-name drugs at consumers' expense.²⁴ The FTC strongly urged that the strength of the patent was a critical factor to be considered to determine whether a settlement was merely a payment to prevent competition, or a legitimate resolution of a dispute of patent validity.²⁵

III. The Federal Circuit's Decision in *In re Cipro*

The plaintiffs in *In re Cipro* were direct and indirect purchasers of Cipro, a brand name antibiotic, who alleged that a settlement between Bayer and Barr Labs, a generic manufacturer seeking to invalidate Bayer's Cipro patent, violated the Sherman Act and resulted in higher prices to them.²⁶ The plaintiffs also alleged that Bayer unlawfully monopolized the ciprofloxacin market by enforcing a patent it had obtained through fraud on the Patent and Trademark Office ("PTO").²⁷

In the underlying patent infringement action Barr Labs had been sued by Bayer after filing an ANDA challenging Bayer's Cipro patent.²⁸ Bayer and Barr agreed that Bayer would pay a total of \$398 million in exchange for Barr's forbearance from challenging Bayer's patent and from marketing a generic version of Cipro

¹⁸ *Schering-Plough v. FTC*, 402 F.3d at 1066 (citing *Valley Drug Co.*, 344 F.3d at 1312).

¹⁹ *Id.* at 1076.

²⁰ *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006).

²¹ *Id.* at 213

²² See FTC *Amicus Br.* at 3-4.

²³ *Id.* at 3.

²⁴ *Id.* at 3-4, 26-27.

²⁵ *Id.* at 16-19.

²⁶ *In re Cipro*, 2008 WL 4570669, at *6.

²⁷ *Id.* at *7.

²⁸ *Id.* at *4.

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until Bayer's patent had expired.²⁹ The settlement required Barr to enter into a consent judgment with Bayer affirming the validity of Bayer's patent and admitting that its generic drug infringed the patent.³⁰

The district court denied plaintiffs' motion for partial summary judgment that the settlement was *per se* illegal under the Sherman Act.³¹ The district court granted Bayer and Barr summary judgment, holding that the anticompetitive effects of the settlement were within the "exclusionary zone" of Bayer's patent, and thus not susceptible of redress by antitrust law.³²

The Federal Circuit,³³ agreeing that *per se* condemnation was not appropriate, discussed whether the district court should have considered the strength or validity of the underlying patent in determining whether the settlement violated antitrust law,³⁴ but concluded that such analysis was unnecessary in the absence of fraud before the PTO or sham infringement litigation.³⁵ Instead, following the Eleventh and Second Circuits, the Federal Circuit held that the proper test was whether the settlement restricted competition beyond the exclusionary zone of the patent.³⁶ The Court stated that "[a] settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled – a monopoly over the manufacture and distribution of the patented invention."³⁷

The court noted that the settlement did not prohibit Barr from marketing a ciprofloxacin drug after the patent's expiration,³⁸ nor did it prevent other generic manufacturers challenging Bayer's patent.³⁹ Indeed, four other generic manufacturers attempted unsuccessfully to invalidate the patent after the settlement.⁴⁰ Also, Barr did not retain the six-month exclusivity period, as it had withdrawn the paragraph IV certification of its ANDA.⁴¹ Thus, the settlement went no further than to exclude Barr from profiting from the patented invention, which was well within Bayer's right as patent holder.⁴²

²⁹ *Id.* at *5. However, by the terms of the settlement Barr would be permitted to market a ciprofloxacin product beginning six months before Bayer's patent expired. *Id.*

³⁰ *Id.*

³¹ *Id.* at *7.

³² *Id.*

³³ The appeal was transferred to the Federal Circuit by the Second Circuit upon the defendants-appellees' motion on the ground that one of the claims arose under the patent laws. *In re Cipro*, No. 05-2863-CV (2nd Cir. Nov. 7, 2007). See generally *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800 (1988).

³⁴ Such an analysis was strongly advocated for by the FTC in an *amicus* brief it submitted to the Federal Circuit. See *In re Cipro*, 2008 WL 4570669, at *21.

³⁵ *Id.* at *20.

³⁶ *Id.* at *19.

³⁷ *Id.* at *21-*22.

³⁸ *Id.* at *5.

³⁹ *Id.* at *24.

⁴⁰ *Id.*

⁴¹ *Id.* at *25.

⁴² *Id.* at *14.

IV. Observations

1. If a trend is to be observed, it appears that since the 2003 *Cardizem* decision, the appellate courts have moved away from an examination of the strength and validity of the underlying patent and towards an analysis of the “zone of exclusion” based on the assumption that the patent is valid.

2. Whereas the Eleventh Circuit in *Valley Drug* explicitly mentioned that its decision was at odds with the Sixth Circuit’s *In re Cardizem* decision and its per se treatment of reverse payment settlements,⁴³ the Federal Circuit and the Second Circuit both distinguished the facts of their cases from *In re Cardizem*, pointing to the generic manufacturer’s retention of the six-month exclusivity and its agreement not to market non-infringing equivalents in *In re Cardizem*. The *In re Cipro* plaintiffs-appellants may seek *certiorari* in the United States Supreme Court on the basis of a circuit split between the Sixth Circuit on the one hand, and the Federal, Eleventh and Second Circuits on the other. Although the Department of Justice did not join the FTC’s request that the Supreme Court review the *Schering-Plough* decision, by the time the Solicitor General may be asked to express the United States’ views on the matter, a new administration will be in charge of the Department of Justice.

3. The FTC retains its role in reviewing Hatch-Waxman settlements, especially in light of the 2003 amendments to the Act which require notification of Hatch-Waxman patent dispute settlements and, unless the Supreme Court rules on the issue, may continue its vigorous enforcement program in this area even though its ability to sustain challenges to such settlements as violating antitrust law now seems diminished outside the Sixth Circuit.

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If you have any questions about the issues addressed in this memorandum or if you would like a copy of any of the materials mentioned, please do not hesitate to call or email Elai Katz at 212.701.3039 or ekatz@cahill.com or Dean Ringel at 212.701.3521 or dringel@cahill.com or Laurence T. Sorkin at 212.701.3209 or lsorkin@cahill.com.

⁴³ See *Valley Drug Co.*, 344 F.3d at 1311 n.26.