Keywords: **reverse payments, antitrust, Hatch-Waxman**

General: **In the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of a patent in the antitrust analysis of a settlement agreement involving a reverse payment.**

In re Ciprofloxacin Hydrochloride Antitrust Litigation
88 U.S.P.Q.2d 1801 (Fed. Cir. 2008)
Decided October 15, 2008

I. Facts

Bayer holds U.S. Patent No. 4,670,444 (the '444 patent), which includes claims to ciprofloxacin hydrochloride, sold under the trade name Cipro®. In October 1991, Barr filed an Abbreviated New Drug Application (ANDA) containing a Paragraph IV certification that the '444 patent was invalid and unenforceable. Under the Hatch-Waxman Act, the first filer of a Paragraph IV certification is automatically entitled to an 180-day period of exclusivity. In the version of the Act in effect at the time, the period would begin to run on the first day the generic was brought to market or on the date of a final court decision finding the patent to be invalid or not infringed, whichever is earlier.

On January 16, 1992, Bayer sued Barr for patent infringement in the Southern District of New York. Before trial, Bayer and Barr (along with several other involved parties) settled the litigation. The settlement agreements ("the Agreements") provided that none of the defendants would challenge the validity or enforceability of the '444 patent, and that Barr would convert its Paragraph IV certification to a Paragraph III certification and not market its generic Cipro® until the '444 patent expired.

In addition, these Agreements provided that Bayer would sell Cipro® to Barr for resale or make quarterly payments ("reverse payments") until December 31, 2003. In return, Barr agreed not to sell a generic version of Cipro® until at least six months before the '444 patent expired. The court noted that Bayer had paid Barr a total of $398 million under this agreement.

On July 25, 1997, Bayer filed for re-examination of the '444 patent. The PTO reaffirmed the validity of the claims in question in the suit between Bayer and Barr. Thereafter, four other generic drug companies (Schein, Mylan, Carlsbad, and Ranbaxy) filed ANDAs on the re-examined '444 patent. The issue of inequitable conduct was not raised in any of these actions. Bayer defeated Schein and Mylan on summary judgment, and won a bench trial against Carlsbad. The Ranbaxy's suit was dismissed when it withdrew its Paragraph IV certification.

In 2000 and 2001, several different groups, including patient advocacy groups and purchasers of Cipro®, filed antitrust actions challenging Bayer's settlement agreement with Barr. The cases were consolidated in the Eastern District of New York. In this suit, the plaintiffs raised four counts under Federal antitrust law. A fifth count in the suit was under a state antitrust law, a Walker Process type antitrust claim, alleging that the '444 patent was obtained through fraud on the Patent Office and the actions were sham litigations. The district court granted summary judgment for Bayer on the antitrust counts, and dismissed the state law claims as being barred by preemption. This decision was based on the district court's determination that all of the misconduct alleged involved misconduct before the PTO (as opposed to misconduct in the marketplace, for example).

The plaintiffs then appealed to the Federal Circuit.

II. Issues

A. Were the Agreements between Bayer and Barr per se unlawful, or were they unlawful under a properly-applied rule of reason analysis?

B. Did the Agreements fall within the "exclusionary zone" of the '444 patent?

C. Did the district court properly consider the law of regional circuits and governing agencies in considering the legality of the Agreements?

D. Did the district court properly consider the anti-competitive effects on other generic manufacturers?

E. Did the district court properly consider evidence showing that the Agreements preserved Barr's claim to the 180-day exclusivity period?

F. Did the district court properly dismiss the Walker Process claim under preemption?

III. Discussion

A. The Agreements were lawful under a properly applied rule of reason analysis.

The appellants argued that the Agreements allowed Bayer to exclude competitors, not by enforcing rights as a patent holder, but by ceasing to enforce its rights and paying the competitor instead. Accordingly, the appellants argued that the Agreements were *per se* unlawful. The Federal Circuit rejected applying a *per se* analysis, reasoning that no basis existed for the district court to "confidently predict" that the agreements were unlawful without undertaking a rule-of-reason analysis.

The court then turned to the issue of whether the rule of reason analysis was properly applied. The Federal Circuit used Second Circuit law to determine the proper scope of the rule of reason analysis, noting that such an analysis was a three-prong process in which the plaintiff bears the burden of showing that the challenged action has had an actual adverse effect on competition as a whole in the relevant market. Then, if the plaintiff succeeds, the burden shifts to the defendant to establish the pro-competitive redeeming virtues of the action. Should the defendant carry this burden, the plaintiff must then show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition.

The Federal Circuit found that the district court properly applied the rule of reason analysis. It first determined that the relevant market is ciprofloxacin and that Bayer had market power within that market. It then determined that there was no evidence that the Agreements created a bottleneck on challenges to the '444 patent or otherwise restrained competition outside the "exclusionary zone" of the patent. The district court concluded that the plaintiffs had failed to demonstrate that the Agreements had an anti-competitive effect on the market for ciprofloxacin beyond that permitted by the patent. Because the district court concluded that the plaintiffs failed to meet their burden under the first step of the rule of reason analysis, it was proper not to consider the second or third steps of the analysis.

B. The Agreements were within the exclusionary zone of the '444 patent.

The appellants argued that the district court erred in concluding that the Agreements were within the "exclusionary zone" of the '444 patent because the patentee's right to exclude competition is

not defined by the facial scope of the patent, but rather is limited to the right to exclude others from profiting from the patented invention. The appellants argued that the Federal Circuit noted that Bayer was seeking not simply to enforce its patent rights, but to insulate itself from competition and avoid the risk that the patent is held invalid.

The Federal Circuit found that the essence of the Agreements was to exclude the defendants from profiting from the patented invention, which was within Bayer's rights as the patentee. The court also noted that there is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation.

C. The district court properly considered the law of regional circuits and governing agencies in considering the legality of the Agreements.

The appellants raised the issues brought up in *In re Cardiezem CD Antitrust Litigation*, a Sixth Circuit case upholding a summary judgment ruling by the district court that a reverse payment agreement is *per se* illegal.

The Federal Circuit distinguished the Agreements and the conduct of the parties in this case with those in the *In re Cardiezem CD Antitrust Litigation*. These distinctions included that the Agreement in the *Cardiezem* case involved restrictions on sales of non-infringing versions of the generic drug, and an agreement whereby the generic manufacturer did not relinquish its 180-day exclusivity period, thus creating a real impediment and delay in the ability of other generic manufacturers from entering the marketplace. These provisions created anticompetitive effects outside the exclusion zone of the patent in that case, which were not features of the Agreements at issue here.

D. The district court properly considered the anti-competitive effects of the Agreements.

The appellants argued that the brand name manufacturer, by paying off the first Paragraph IV ANDA filer, can protect its monopoly from competition for years—particularly near the end of the patent term—even if its patent is "fatally weak."

The Federal Circuit noted that there seemed to be no evidence of other generic manufacturers from being discouraged from challenging Bayer, and referred to the four subsequent challenges to the '444 patent, which was upheld as valid.

E. The Agreements did not restrain competition outside of the scope of the '444 patent by allowing Barr to maintain the 180-day exclusivity period.

The Federal rejected the contention that the Agreements were unlawful because Barr retained its claim to the 180-day exclusivity period. The Federal Circuit noted that Barr had no right to such a period because Barr converted its Paragraph IV ANDA to a Paragraph III ANDA. Thus, the court concluded that Barr had failed to satisfy the successful defense requirement necessary to be eligible for the 180-day exclusivity period.

F. The dismissal of the Walker Process claim was proper, under the doctrine of federal preemption.

The Federal Circuit agreed with the district court that the misconduct alleged by plaintiffs was misconduct that occurred before the Patent Office, and that the issue was one of patent law, which fell exclusively under federal law.