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The Latest Advance in the Debate Over Reverse Payment Settlements: Will the Supreme Court Punt, Again?

On April 24, 2009, a group of professors of law, economics and business, together with the American Antitrust Institute, the Public Patent Foundation, and AARP (collectively "amici") filed an amicus brief urging the Supreme Court to grant certiorari and reverse the decision of the Federal Circuit Court of Appeals in *In re Cirpoflaxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008) ("*Cipro*"). This is the latest advance in the heated debate over the legality of reverse payment settlements in the pharmaceutical industry, *i.e.*, settlements of patent disputes in which the brand-name pharmaceutical company makes a "reverse" or "exclusion" payment to the would-be generic competitor to delay its entry into the relevant drug market. Such settlements have garnered significant attention and debate over the years because they implicate important policy considerations underlying antitrust and patent laws, as well the vital public interest in curbing soaring healthcare costs.

Cipro began with an underlying patent infringement suit between Bayer (the brand-name patent holder) and Barr Labs (the would-be generic competitor). In 1987, Bayer was issued a patent for the active ingredient in its brand-name drug, Cipro, and received FDA approval to begin marketing. A few years later, Barr filed an Abbreviated Drug Application ("ANDA") with the FDA (pursuant to the regulatory framework of the Hatch-Waxman Act, 21 U.S.C. § 301 *et seq*.), seeking to market a generic version of Cipro before expiration of Bayer's patent in 2003. Barr made a "Paragraph IV" certification that Bayer's patent was invalid and unenforceable. As the first-to-file a Paragraph IV ANDA, Barr was entitled to a 180-day market exclusivity period, during which time no other generic firms could enter the Cipro market. In response, Bayer sued for patent infringement. Just before trial, the parties entered into a settlement agreement which required Bayer to pay quarterly payments to Barr until 2003, totaling over $398 million. In return, Barr entered into a consent judgment affirming the validity of Bayer's patent and admitting infringement. Barr also agreed to convert its ANDA to a "Paragraph III" certification, seeking to market its generic only after Bayer's patent expired.

In 2000 and 2001, direct and indirect purchasers of Cipro, along with several advocacy groups, brought federal and state antitrust claims against Bayer and Barr, alleging that the defendants' settlement constituted an anticompetitive agreement to allocate the Cipro market. On summary judgment, the lower court rejected plaintiffs' argument that the agreement was per se unlawful and instead employed a rule of reason analysis. The court concluded that any anticompetitive effects caused by the settlement agreement were within the "exclusionary zone" of the patent,

and hence could not be redressed by antitrust law. 363 F. Supp. 2d 514 (E.D.N.Y. 2005).

The Federal Circuit affirmed, noting the underlying tension between patent and antitrust laws, and agreeing with the lower court that a patent, by its very nature, is anticompetitive. "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." 544 F.3d at 1337. So long as the settlement is within the "exclusionary zone" of the patent, the court noted, the existence of a reverse or exclusion payment will not change the analysis. Because the settlement in this case did not delay Barr's entry into the market beyond the 2003 expiration date of the patent; did not prevent Barr from marketing other drugs not covered by the Cipro patent; and did not create a bottleneck preventing other generic firms from seeking earlier entry into the Cipro market, the court held that the settlement was within the exclusionary zone of the patent. The Federal Circuit also held that, in the absence of evidence of fraud before the Patent and Trademark Office or sham litigation, the court need not consider the validity of the underlying patent.

In support of plaintiffs' petition for certiorari, the amici urge the Supreme Court to grant the petition and reverse the Federal Circuit's opinion, which would otherwise shield many anticompetitive agreements from antitrust scrutiny, "causing great harm to competition, to U.S. consumers, and (by unjustifiably raising the costs of needed medicines) to public health." 2009 WL 1144190 (U.S. Apr. 24, 2009). According to the amici, the Federal Circuit's holding was based on the mistaken premise that, absent fraudulent procurement, a patent grants full immunity for any and all anticompetitive effects from horizontal agreements, so long as they are within the so-called "exclusionary zone" of the patent. The Federal Circuit's approach assumes the validity of the patent, and that every patent holder has an absolute right to bar potential competitors.

According to the amici, however, a patent confers only a *presumption* of validity. The Federal Circuit failed to acknowledge that nearly half of all litigated patents are ultimately found invalid, and that in pharmaceutical cases, patent holders lose nearly 73% of all infringement cases. Thus, a patent holder who makes a reverse payment is essentially buying an assurance that its patent will not be invalidated -- an assurance that the patent alone cannot confer. And that assurance is bought with profits that come directly "from the pockets of consumers: users of medicines who would [have been] able to purchase lower cost medications if the generic manufacturer's legal arguments [had been] successful" but end up continuing to pay higher prices because the generic manufacturer agreed not to enter the market in exchange for payment. Under the Federal Circuit's approach, the interests of the consumers who are adversely affected by the reverse payment settlement are not given any weight. Neither is the general public interest in testing and invalidating weak patents, which is integral to the operation of the patent system overall.

The facts of this case, the amici argue, present a prime example of how a reverse payment settlement can work to maximize the profits of both the brand-name and generic manufacturers, to the detriment of consumers and competition. The settlement allowed Bayer to continue to reap monopoly profits on sales of Cipro and guaranteed that it would not face any competition from Barr until the patent expired. At the same time, the exclusion payment of $398 million was more than twice the profits that Barr hoped to earn from early entry into the Cipro market. Accordingly, even if both parties were absolutely certain that the patent was invalid and that Barr

was legally entitled to early market entry, both would nevertheless be better off agreeing to delayed entry in exchange for payment. Indeed, in cases such as this one, the amici contend, the large sum of money paid to the generic to stay out of the market may be a strong indication that the parties -- those with the most knowledge of the facts -- viewed the patent as likely to be held invalid or not infringed.

The amici also urge the Supreme Court that the *Cipro* case is the appropriate vehicle to resolve the important questions presented. The settlement involved a straightforward payment to Barr to stay out of the market, unlike previous cases in which the reverse payments were commingled with other business relationships. Also, the Court's review is necessary to resolve the growing split among the lower courts and government entities. According to the amici, the Second Circuit has adopted a rule of near per se legality, *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); the Sixth Circuit has adopted a rule of per se illegality, *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); and the Eleventh Circuit has adopted a modified version of the rule of reason analysis that inquires into the underlying validity of the patent before characterizing the legality of the settlement, *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003). Finally, the Federal Trade Commission has taken an aggressive stance over the years against the legality of such agreements, *see e.g.*, *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005), but the Department of Justice has not always agreed. See Brief for United States as Amicus Curiae Supporting Respondents, *Fed. Trade Comm'n v. Schering-Plough Corp.*, No. 05-273, 2006 WL 1358441 (U.S. May 17, 2006).

The Supreme Court has rejected petitions on this very issue before, *Joblove v. Barr Labs, Inc.*, 127 S.Ct. 3001 (2007); *Fed. Trade Comm'n v. Schering-Plough Corp.*, 548 U.S. 919 (2006), and it remains to be seen whether it will once again decline review. What is clear, however, is that until the Supreme Court finally decides this important issue, the debate over the legality of reverse payment settlements in the pharmaceutical industry will remain at the forefront of the intersection of antitrust and patent laws.

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