

# COMMENTS

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## Antitrust Legality of "Reverse Payments" from Patentees to Accused Infringers Upheld: *In re Ciprofloxacin Hydrochloride Antitrust Litigation*

✓ Anti-competitive practices; Infringement; Patents; Pharmaceuticals; Settlement; United States

### Facts

The case is *In re Ciprofloxacin Hydrochloride Antitrust Litigation* 544 F.3d 1323 (Fed. Cir. 2008). Bayer owned US Patent No. 4,670,444 (the '444 patent), which covered the antibiotic ciprofloxacin hydrochloride, known as Cipro. In 1991, Barr filed an abbreviated new drug application ("ANDA") under the Hatch-Waxman Act, for a generic version of Cipro. Barr alleged invalidity and unenforceability of the '444 patent because, among other things, Cipro was an obvious compound and Bayer committed inequitable conduct before the United States Patent and Trademark Office (USPTO). The Hatch-Waxman Act provides that in such circumstances, the patent owner may file a patent infringement action (without acts of physical infringement) and the company that first challenged the patent, if successful in the ensuing litigation, is entitled to a 180-day period of market exclusivity for its version of the drug.

Just before trial, the parties entered into a settlement agreement providing:

- (1) Barr and associated companies would refrain from further challenge to the '444 patent's validity.
- (2) Barr would not try to market Cipro before the '444 patent expired in 2004.
- (3) Bayer would pay Barr approximately US \$50 million.

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In addition, Bayer paid Barr another US \$350 million on an installment basis until the patent expired, Barr agreed not to manufacture a generic version of Cipro, and the parties entered into a consent agreement in which validity and infringement were stipulated. (Agreements of this type, under which a patentee pays money to an alleged infringer, are called "reverse payment" agreements.) In this case the US \$400 million reverse payment has been said to exceed the amount that Barr could have made if it won the case, but to be less than Bayer would have lost if the patent went under.

In 1997 Bayer filed a petition in the USPTO for re-examination of the '444 patent, and eventually the USPTO confirmed the validity of Bayer's claim to Cipro. Four other generic drug companies later challenged the patent by filing their own ANDAs under the Hatch-Waxman Act, but Bayer overcame their validity challenges on motions for summary judgment, and the inequitable conduct charge was never adjudicated.

Various other groups (direct and indirect purchasers of Cipro and advocacy groups) then filed antitrust suits against Bayer, Barr, and the companies associated with Barr, alleging violations of ss.1 and 2 of the Sherman Act and of various state antitrust and consumer protection laws. The charges included fraud on the Patent and Trademark Office and sham, bad-faith litigation under the '444 patent.

The District Court granted summary judgment in favour of the defendants, and the Federal Circuit affirmed the judgment.

### Held

The agreements between Bayer and Barr were not in unreasonable restraint of trade, even though Bayer had and maintained market power in the relevant market (Cipro). The District Court properly found that agreements did not have an anticompetitive effect outside the "exclusionary zone" of the patent. The plaintiffs argued that the agreements insulated Bayer from the *risk* of having its patent held invalid. However, the Federal Circuit reasoned that "a patent by its very nature is anticompetitive", and because "the essence of the Agreements was [merely] to exclude the defendants from profiting from the patented invention", the effect was "well within Bayer's rights as the patentee". In addition, "there is a long-standing policy in the law in favour of settlements, and this policy extends to patent infringement litigation".

There is nothing wrong with the agreement not to challenge patent validity, the Federal Circuit insisted, notwithstanding the plaintiffs' contention that "there is a vital public interest in patent validity challenges to ensure that consumers are not burdened by unwarranted patent monopolies". Eliminating Barr as a validity challenger did not keep four other generic drug companies from mounting (unsuccessful) patent validity challenges. To be sure, the Federal Trade Commission (FTC) and US Antitrust Division (which filed *amicus curiae* briefs) question reverse payment agreements as potentially anticompetitive and the appeals court for the US Sixth Circuit has upheld a summary judgment that they are illegal per se. *In re Cardizem CD Antitrust*

*Litigation*.<sup>1</sup> However, to the extent that these others may disagree, the Federal Circuit said, “we respectfully disagree”. Unless a reverse payment agreement extends to unpatented products or otherwise is outside the “exclusionary zone” of the patent, any anticompetitive effects are merely the necessary effect of patent law.

The Federal Circuit refused to factor into the analysis the probability that the patent would be held invalid, which the FTC as *amicus curiae* urged, because by statute (United States Code 35 USC § 282) patents enjoy a presumption of validity. The Federal Circuit pointed to the decision of the Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation*,<sup>2</sup> in which the Court did not find any antitrust violation even though the reverse payment agreement was made after the District Court had held the patent invalid and the case was on appeal to the Federal Circuit. Accordingly, the Federal Circuit held that unless the patent lawsuit is a sham, it does not matter whether the patent is valid, and courts should refuse to enquire into validity or the merits of the underlying suit.

## Comment

In *Lear Inc v Adkins*,<sup>3</sup> the US Supreme Court held that a promise implied by state common law not to challenge patent validity was against public policy and therefore unenforceable and ineffective. The Supreme Court’s decision was based in part on an earlier precedent, *Pope Mfg Co v Gormully*,<sup>4</sup> in which the Court had refused to enforce an express promise not to contest patent validity. In *Pope*, the Court had said:

“It is as important to the public that competition should not be repressed by worthless patents as that the patentee of a really valuable invention should be protected in his monopoly. . . .”<sup>5</sup>

Moreover, in *United States v Singer Mfg Co*,<sup>6</sup> the Court found an illegal conspiracy in restraint of trade where one element of the conspiracy was a collusive settlement of a patent interference “to secure as broad a patent monopoly as possible, invalidity considerations notwithstanding”, i.e. there was “collusion among [patent] applicants to prevent prior art from coming to or being drawn to the Office’s attention”.<sup>7</sup> The Federal Circuit’s ruling therefore conflicts, at least in principle, with Supreme Court precedent.

In this case, the patentee Bayer apparently paid Barr, the generic drug company, more money to leave the market than Barr would have made even if it had won the suit, although less than Bayer would have lost. Thus, Bayer must have thought that the risk of loss (as a probability percentage) times the potential loss exceeded the payment to Barr. Should the public interest in clearing the market of spurious patents

trump the patentee’s rational self interest in maximising its financial return by prudent settlement? Or should individual volition prevail?

Given the involvement of the FTC and Antitrust Division, as well as the apparently conflicting decision in the Sixth Circuit, it appears likely that this case will be appealed to the Supreme Court.

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## Syfait II: Restrictions on Parallel Trade within the European Union

(U) Abuse of dominant position; EC law; Parallel imports; Pharmaceuticals; Refusal to supply

### Introduction

On September 16, 2008, the European Court of Justice (ECJ) finally gave judgment in the long running dispute between wholesalers and pharmaceutical companies as to whether art.82 of the EC Treaty is breached when a pharmaceutical company refuses to supply orders for products in excess of the need of the wholesaler. The EC Treaty has at its heart a desire to create a free trading community of Member States and its articles provide the framework to achieve that aim, art.82 being aimed at the prevention of abuse of a dominant position. It is understandable that if the sole manufacturer of a product refused to supply that product, they might fall foul of art.82. Yet, states often fix the price at which pharmaceutical products may be sold, therefore, where the action of the manufacturer in restricting supply is aimed at countering state interference which is distorting the marketplace, it can equally be understood why art.82 might be considered unfair. The pharmaceutical companies argued that their restriction on supply still allowed market needs to be met, and it only restricted parallel imports across national boundaries that otherwise harmed their business. The wholesalers, on the other hand, claimed this practice was an abuse of a dominant position and led to national shortages of products. The ECJ’s decision on this dispute is therefore of great relevance to the entire pharmaceutical community.

The internal market of the European Union is one of the greatest achievements of the European project, yet there remain significant differences in the price of identical goods across the European Union from state to state. The reasons for the variation are numerous; demand for the products, the strength of a brand image between states, competition, taxation, exchange rate fluctuation, regulation and distribution costs. However, there is one industry which has greater obstacles than most and that is in the trade of medicinal products. Governmental interference in the pricing of medicinal products greatly distorts the market, creating variation in prices from state to state which in turn leads to parallel traders. Parallel traders who, outside the manufacturer’s official supply chain, buy

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

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

3 *Lear Inc v Adkins* 395 U.S. 653 (1969).

4 *Pope Mfg Co v Gormully* 144 U.S. 224 (1892).

5 *Pope* 144 U.S. 224 (1892) at 234.

6 *United States v Singer Mfg Co* 374 U.S. 174 (1963).

7 *Singer* 374 U.S. 174 (1963) at 197, 200.