

In re Ciprofloxacin Hydrochloride Antitrust Litig.

No. 08-1097, Fed. Cir. (Schall, Prost,* Ward)

[I]n the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.

On October 15, 2008, the Federal Circuit affirmed the district court's summary judgment that a reverse payment settlement agreement between Bayer and generic drug manufacturers Barr, Hoechst Marion Roussel, Rugby, and Watson did not violate Sherman Act § 1 because any anti-competitive effects were within the exclusionary zone of U.S. Patent No. 4,670,444, which related to ciprofloxacin hydrochloride (sold by Bayer as Cipro®). The Federal Circuit stated:

The Sherman Act provides that “[e]very 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.” Although by its terms, the Act prohibits any “restraint of trade,” the Supreme Court “has long recognized that Congress intended to outlaw only unreasonable restraints.” Courts will presumptively apply a “rule of reason” analysis to determine whether an agreement imposes an unreasonable restraint on competition. [The district court] 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. Thus, the 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 court concluded that the plaintiffs failed to meet their burden under the first step of the rule of reason analysis, it did not find it necessary to consider the second or third steps of the analysis.

The appellants assert, however, that the district court erred in concluding that the Agreements were within the “exclusionary zone” of the '444 patent, in essence treating them as per se legal. . . . The district court did not treat the Agreements as per se legal. Rather, the court simply recognized that any adverse anti-competitive effects within the scope of the '444 patent could not be redressed by antitrust law. This is because a patent by its very nature is anticompetitive; it is a grant to the inventor of “the right to exclude others from making, using, offering for sale, or selling the invention” Thus, “a patent is an exception to the general rule against monopolies and to the right of access to a free and open market.” The district court appreciated this underlying tension between the antitrust laws and the patent laws when it compared the anti-competitive effects of the Agreements with the “zone of exclusion” provided by the claims of the patent. Because the court found no anti-competitive effects outside the exclusionary zone of the patent, it concluded that the Agreements were not violative of section 1 of the Sherman Act. [We agree.]

Pursuant to the Agreements, the generic defendants agreed not to market a generic version of Cipro until the '444 patent expired and not to challenge the validity of the '444 patent, and Bayer agreed to make payments and optionally supply Cipro for resale. Thus, the essence of the Agreements was to exclude the defendants from profiting from the patented invention. This is well within Bayer's rights as the patentee. Furthermore, there is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation. Settlement of patent claims by agreement between the parties—including exchange of consideration—rather than by litigation is not precluded by the Sherman Act even though it may have some adverse effects on competition. [T]he mere fact that the Agreements insulated Bayer from patent validity challenges by the generic defendants was not in itself an antitrust violation. Indeed, there is no evidence that the Agreements prevented challenges by other generic drug manufacturers to the validity of the '444 patent. In fact, four other generic manufacturers—Ranbaxy, Mylan, Schein, and Carlsbad—filed Paragraph IV ANDAs and initiated challenges of the validity of the patent.

[Where] all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent. In addition, we agree with the Second and Eleventh Circuits and with the district court that, in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment. . . . We disagree that analysis of patent validity is appropriate in the absence of fraud or sham litigation. . . . 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. Thus, the district court correctly concluded that there is no legal basis for restricting the right of a patentee to choose its preferred means of enforcement and no support for the notion that the Hatch-Waxman Act was intended to thwart settlements.

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