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Client Alert

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And the Score is……Patent Law 3 Antitrust Law 1

When a branded drug manufacturer pays a generic manufacturer not to compete, it sounds like a blatant antitrust violation, right? Wrong! Recently, the Federal Circuit joined the Second and Eleventh Circuits in giving a pass to drug manufacturers that have made reverse payment settlements under the Hatch Waxman Act, indicating that such settlements generally pass muster under the antitrust laws. In the recent decision of In re Ciprofloxin Hydrochloride Antitrust Litigation, 2008 WL 4570669 (Fed. Cir. Oct. 15, 2008), the court had no problem with Bayer's several million dollar payment to Barr Labs in settlement of Barr's suit against Bayer regarding the popular antibiotic Cipro.

In October of 1991, Barr filed an abbreviated new drug application ("ANDA") for a generic version of Cipro. Barr's ANDA was filed just four years after FDA approved Cipro, and twelve years before Bayer's Cipro patent was to set to expire. Barr challenged Bayer's Cipro patent as invalid based on obviousness and contended as well that it was unenforceable due to inequitable conduct. Because Barr was the first to file an ANDA challenging Bayer's patent, it was entitled to receive the 180 day period of market exclusivity granted to the first challenger under the Hatch-Waxman Act.

On January 16, 1992, Bayer sued Barr for patent infringement. Barr counterclaimed for patent invalidity and also claimed that its generic product did not infringe the Bayer patent. Ultimately, Barr and Bayer settled the lawsuit, with Barr agreeing not to challenge the Bayer patent's validity and agreeing to convert its Paragraph IV ANDA into a Paragraph III, which meant that it would not market its generic Cipro until Bayer's patent expired. **After the parties settled, four other generic manufacturers filed ANDAs challenging the validity of the Cipro patent and were sued by Bayer. Bayer prevailed in each of those lawsuits, and the validity of the Cipro patent was affirmed.**

In 2000 and 2001, following the Bayer-Barr settlement, certain Cipro purchasers filed antitrust claims against Bayer, claiming, among other things, that the Bayer-Barr settlement agreement violated the Sherman Act's prohibition against contracts in restraint of trade. The district court employed a rule of reason analysis and determined that while Bayer had market power in the relevant market (which it defined as the market for Cipro), any adverse effects on competition were not improper because they fell within the patent's exclusionary zone. Because the patent was a "compound patent" for ciprofloxacin, the active ingredient in Cipro, Bayer had the patent right to exclude Barr from selling Cipro anyhow.

On appeal, the Federal Circuit Court of Appeals affirmed. In upholding the district court's finding of nonliability, the court of appeals began by approv-

ing the district court's decision not to consider the agreement per se unlawful because that type of invalidity is reserved for only the most pernicious and obvious violations of the antitrust laws. Instead, the court concluded that the district court properly had applied the three-step, Rule of Reason analysis which first requires that the plaintiff show that the challenged action had an actual adverse effect on competition in the relevant market. If it succeeds, then the burden shifts to the defendant to establish the pro-competitive nature of the agreement. If the defendant succeeds, then the plaintiff still has the opportunity to show that the desired competitive effect could be achieved by means less burdensome to competition.

The focus of the appeal was on the first step of the analysis: the plaintiff's burden to show an actual adverse effect on competition. The appellants contended that the district court erred in concluding that the settlement agreement gave Bayer no greater right than it had had under the patent in the first place. The court disagreed, noting that, as a patent holder, Bayer already had the right to exclude Barr from marketing its generic version of Cipro. That Barr gave up its right to challenge the Cipro patent in the settlement agreement was of no moment because other generic manufacturers still could challenge the patent and, in fact, four others had tried.

Nor was the court swayed by a contrary decision of the Sixth Circuit in In re Cardizem CD Antitrust Litigation, 332, F.3d 896 (6th Cir. 2003) which held that a reverse payment agreement was per se illegal. There, the settlement agreement included not only a reverse payment, but the generic manufacturer's agreement not to relinquish its 180 day exclusivity period, which resulted in an additional delay for other generics even after any patent issues would be resolved. Hence, that agreement had an anticompetitive component greater than that which the patent laws already provided.

Other facts also supported the Federal Circuit's decision, including previous decisions by the Second and Eleventh Circuits which validated reverse payment agreements on the same basis applied here: that they did not restrict competition beyond the exclusivity that the patent laws already provided. Moreover, at the time of the settlement in question here, Paragraph IV of the Act conditioned receipt of the 180 day exclusivity period on the "successful defense" of a Paragraph IV certification against the patent holder's challenge. As part of the settlement, Barr converted its Paragraph IV certification into a Paragraph III and also acknowledged the validity of the patent. Thus, because it converted to a Paragraph III, Barr did not meet the "successful defense" requirement and thus failed to obtain the 180 day exclusivity.

Interestingly, these two facts potentially set this case apart from others because in November of 1998, the FDA removed the "successful defense" requirement so it will not apply in future litigation. Moreover, unless the generic manufacturer in any subsequent settlement converts its certification from a Paragraph IV to a Paragraph III, the issue of the 180 day exclusivity will remain. As a result of these two peculiarities, the Bayer litigation may not provide quite the evidence that the courts exalt patent law over antitrust law that some critics of the decision contend. Nevertheless, it is an indication of the continuing trend toward limiting use of per se liability in the antitrust arena.