Eleventh Circuit Holds "Reverse" Payments To Settle Infringement Litigation Under Hatch Waxman Not Per Se Illegal

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In a decision that puts it squarely at odds with the Sixth Circuit, the Eleventh Circuit has held that "reverse payments" to an alleged infringer to stay off the market are not *per se* illegal under the antitrust laws. *Valley Drug Co., et al. v. Geneva Pharmaceuticals*, Case No. 02-12091 (11th Cir. September 15, 2003). *Valley Drug* is the latest of a series of decisions involving patent settlements triggered by the unique framework of the Hatch Waxman Act. *Compare In re Cardizem* 332 F. 3d. 896 (6th Cir. 2003) (holding similar agreements *per se* illegal). This is an area which has also generated considerable enforcement activity by the FTC, including the agreement at issue in the *Valley Drug* case itself. *In re Abbott Laboratories*, FTC Docket No. C3945.

In reversing and remanding the District Court decision granting summary judgment in favor of plaintiffs on the grounds that such agreements were *per se* illegal, the Eleventh Circuit concluded that the *per se* finding was inappropriate because the settlement agreements did not exceed the exclusionary scope of the patents themselves. It further stated that payments from patentees to infringers to settle may be justified since under Hatch Waxman the alleged infringer has not yet caused the patentee any harm and the patentee does not have a damages claim to bargain with. The fact that one of the patents at issue was held invalid did not dissuade the Eleventh Circuit from this conclusion since "exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is later declared invalid would undermine the patent incentives." Slip Op. at p. 31.

The marketing and sale of pharmaceutical drugs requires the prior approval of the Food and Drug Administration ("FDA"). Under Hatch Waxman, 21 U.S.C. § 355(j), a generic manufacturer of a branded drug is exempted from infringement suits during the FDA testing process but Congress also allowed extension of patent terms to compensate patent holders for the loss of that right. Hatch Waxman requires the patentee to submit patent information for filing in the FDA Orange Book. The generic applicant must then "certify" to such patents prior to FDA approval. If the certification is under Paragraph IV – that the listed patent is either invalid or not infringed – the patentee has 45 days to file an infringement suit. If suit is filed, this delays FDA approval of the generic another 30 months, or until there is a court decision that the patent is either invalid or not infringed. The final wrinkle in this unusual statutory scheme is that the first generic to file a paragraph IV and successfully challenge the scope or validity of a patent is given a 180 day exclusivity period.

In a nutshell, Hatch Waxman permits infringement suits before the infringer has made any sales and, until that issue is resolved, other generics are effectively barred from market entry due to the 180 day exclusivity period granted the first one. This statutory framework thus creates a series of incentives for the patentee and the first generic to "settle" their lawsuit by payments from the patentee to the infringer to stay off the market, thereby

creating a "bottleneck" which blocks entry by other generics. Unlike the usual settlement where defendant pays plaintiff, the payments here flow from the plaintiff to defendant and hence the phrase "reverse payments."

In *Valley Drug*, the patentee was Abbott Laboratories ("Abbott"), the brand name drug was Hytrin, and it filed an infringement suit against the first generic, Geneva Pharmaceuticals, while another generic, Zenith, filed suit to delist Abbott's patents from the Orange Book, a suit in which Abbott counterclaimed for infringement. While the infringement litigation was pending, Abbott reached an agreement with Geneva whereby it would pay Geneva $4.5 million monthly until one of several events occurred, including one that Geneva obtained a court judgment that it did not infringe the patent. At about the same time, Abbott reached an agreement with Zenith to pay it $6 million every three months in return, *inter alia*, for dismissal of the delisting litigation and Zenith's acknowledgement of the validity of each of its patents. Geneva also agreed not to transfer or otherwise give up its 180 day exclusivity right, and both agreed not to sell or distribute any pharmaceutical product with the same active ingredient as Hytrin, and not to aid others in challenging Abbott's patents. After the agreements were signed, the *Geneva* court found one of Abbott's patents invalid, a ruling later affirmed by the appellate court.

The District Court characterized these agreements as market allocation agreements between competitors, essentially allocating the entire market to Abbott, who then shared its monopoly profits with the other two companies. 164 F. Supp. 2d 1340 (S.D. Fla. 2000). Since such agreements are *per se* illegal, the court granted plaintiff's summary judgment motion. *See also In re Cardizem*, 332 F. 3d 896 (6th Cir. 2003) (affirming summary judgment in reverse payments case involving similar agreements).

In its September 15, 2003 decision, the Eleventh Circuit reversed and remanded. While it recognized that normally monthly payments to competitors to exit or refrain from entering the market are *per se* illegal, this was the case where one of the parties owns a patent, and thus has a lawful right to exclude others. Since *Geneva* and *Zenith* agreed not to market infringing products only until the patent either expired or was held invalid, the agreements themselves were "no broader than the potential exclusionary effect of ['207] patent itself." Slip Op. at 25. Since the district court failed to consider the exclusionary power of the patent in its analysis, its *per se* condemnation was reversed.

The plaintiffs argued that, since one of the patents was declared invalid after the agreements were entered into, Abbott therefore never had any patent rights and thus the antitrust analysis need not consider the patent. The Eleventh Circuit rejected this argument, stating that the mere invalidity of the patent does not render the patent irrelevant to the antitrust analysis. It noted that the only circumstances in which the Supreme Court has held that patent immunity can be pierced is for enforcement of a patent with knowledge that it has been procured by fraud on the patent office under the *Walker Process* stating that "good faith procurement furnishes a complete defense to the antitrust claim." Slip Op. at p. 29. The Eleventh Circuit further noted that imposing antitrust liability for the exclusionary effects of a settlement within the patent monopoly because the patent was declared invalid would "undermine patent incentives." *Id.*

Finally, the Eleventh Circuit rejected plaintiff's argument that the reverse nature of the payments themselves justified *per se* treatment. Citing *In re Ciprofloxacin*, 261 F. Supp. 2d. 188 (E.D.N.Y. 2003), it noted the "asymmetries" of litigation risk created by Hatch Waxman, and that one could not conclude here that the size of the payments alone meant the infringement suits lacked merit, and such payments may well be reasonable compensation to the generics for lost profits during the course of the litigation. It noted the Sixth Circuit took a contrary view in *Cardizem*, 332 F. 3d. 896, 908 (6th Cir. 2003), but again emphasized that the antitrust analysis cannot ignore the scope of the patent exclusion.

Practice Areas

Antitrust and Competition