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Antitrust Implications of Reverse Payments

By Jim Long

The Federal Circuit recently adopted a new antitrust liability standard for reverse payment patent settlement agreements *In Re Ciprofloxacin Hydrochloride Antitrust Litigation* that virtually insulates such settlements from antitrust scrutiny. In a reverse payment patent settlement, an alleged infringer agrees not to infringe the patent in exchange for a money payment from the patent holder. The Federal Circuit held that a reverse payment settlement does not give rise to an antitrust violation so long as the settlement: (1) does not extend the patent beyond the exclusionary zone of the patent; (2) is not a settlement of sham litigation; or (3) there was no fraud before the PTO. This may not be the final word on these settlements, but it is the present standard.

In Re Cipro arises out of settlement of patent litigation between Bayer, the owner of a patent covering the active ingredient in the drug Cipro, and Barr, a manufacturer of an allegedly infringing generic drug. Bayer sued Barr for patent infringement; Barr counterclaimed for a declaration that the patent at issue was invalid and unenforceable, and that its generic drug did not infringe the patent. Just before trial, the case was settled by plaintiff Bayer agreeing to make payments to defendant Barr which totaled $398.1 million, in exchange for Barr's agreement not to challenge the validity or enforceability of the patent, and to not market its generic drug until expiration of Bayer's patent.

A group of direct and indirect purchasers of Cipro filed lawsuits claiming that the settlement agreement violated Sections 1 and 2 of the Sherman Act. The antitrust claim was that the settlement allowed Bayer to exclude a horizontal competitor who agreed not to compete in the marketplace in exchange for payments of approximately $400 million. Plaintiffs argued this constituted a horizontal market allocation, which is a *per se* violation of Section 1 of the Sherman Act.

The Federal Circuit affirmed the district court's grant of summary judgment for defendants, holding that settlement of patent claims is "not precluded by the Sherman Act even through it may have some adverse effects on competition." The key element of the opinion is the Federal Circuit's conclusion that a court should not consider the validity of the patent, nor the payment amount, in the antitrust analysis of a settlement agreement involving a reverse payment.

The Federal Circuit's ruling presents two competing concerns. On the one hand, accomplishing a market allocation through payment from one competitor to another outside of the patent settlement context clearly would violate antitrust laws. On the other hand, any antitrust analysis that includes evaluating the merits of the underlying patent dispute raises the possibility that the court hearing the antitrust case will also have to litigate the patent case already settled. The uncertainty of whether a case the parties wished to settle might be tried in a different context could provide a disincentive to settlements.

The Federal Circuit's decision *In Re Cipro* may not be the final word on reverse payment patent settlements. The FTC filed an amicus brief with the Federal Circuit arguing that uncertainty of patent validity must be considered in the antitrust analysis, a position the Federal Circuit rejected. It is likely that a cert petition will be filed with the U.S. Supreme Court and the FTC will support the Court granting the petition for review. At present, according to the Federal Circuit, any reverse payment by a patent holder to an alleged infringer, regardless of the amount of the payment or whether the settlement is reasonable given the merits of the litigation at issue, is *per se* legal in the Federal Circuit so long as it meets the aforementioned requirements.