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ANTITRUST

Does My Reverse-Payment Settlement Violate the Antitrust Laws?



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Agreements between competitors to stifle competition typically are illegal under the antitrust laws but, increasingly, brand-name pharmaceutical companies have settled patent infringement lawsuits against generic companies by paying them to defer market entry. It would seem these ''reverse-payment'' settlements should lead to antitrust liability for the settling competitors, yet most federal appellate courts that have reviewed such agreements have upheld them—provided certain requirements are satisfied. Against this trend in federal jurisprudence, the Federal Trade Commission and the Department of Justice continue to advocate strongly in favor of tighter standards that either could limit or eliminate these agreements altogether. Recent developments suggest that the legal landscape in this area remains uncertain and that the pendulum of the federal courts' treatment of reverse-payment settlements may be swinging back toward a more restrictive approach.

Courts generally analyze an alleged antitrust violation under either of two categories. A narrow band of agreements between competitors deemed consistently

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harmful to competition—including, among others, price fixing, bid rigging, and, notably, market allocation agreements—is condemned *per se*, meaning that liability can be established without proof of harm to competition in the specific instance. Most other agreements restraining competition are analyzed under the rule of reason, meaning that a court may find a violation only after weighing a particular agreement's specific anticompetitive effects against its pro-competitive benefits and concluding that, on balance, the former substantially outweigh the latter. This market analysis often is a complex, fact-intensive inquiry, requiring extensive expert testimony and making rule-of-reason cases substantially more expensive and difficult for plaintiffs than cases alleging a *per se* unlawful violation.

A reverse-payment settlement literally is an agreement under which a branded manufacturer pays its generic competitor to stay out of the market for a certain period of time. Generally, courts unhesitatingly condemn such market allocation agreements among competitors as *per se* unlawful. In the pharmaceutical industry, however, market dynamics and litigation incentives are altered by the Hatch-Waxman Act, which encourages generic drug manufacturers to file abbreviated new drug applications (ANDAs) even before the patents on a drug expire. The act allows manufacturers of generic drugs to mount noninfringement and validity challenges against patents for branded generic counterparts and gives the first generic filer a 180-day exclusivity period during which other ANDA applications on the same drug will not be granted. This process presents little risk for the generic company—some litigation costs, but typically no exposure to damages because no sales have taken place yet—but substantial litigation risk for the branded patent holder: loss of its patent monopoly. This makes it financially rational for the branded manufacturer to strike a monetary deal with the first-to-file generic, mitigating litigation risk and, via the Hatch-Waxman exclusivity period, staving off all generic entry for a time.

Federal Court Decisions

Consumers and government agencies challenging reverse-payment settlements had some early success in the Sixth Circuit. *In re Cardizem* held that a reverse-payment settlement delaying generic entry was a *per se* violation of the antitrust laws. *In re Cardizem*, 332 F.3d 896, 908-09 (6th Cir. 2003). The court explained that ''it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competition $40 million per year to stay out of the market.'' *Id.* at 908. Notably, the generic company agreed it would not market other (noninfringing) versions of the generic and promised not to relinquish its 180-day exclusivity period, thereby helping prevent any other generic from entering the market. *Id.* at 907. These two aspects of the agreement extended the patent holder's exclusionary power beyond the scope of the patent and, in light of later legal developments, placed the agreement in antitrust jeopardy.

Other circuits have subsequently rejected *per se* condemnation of these settlements. For example, in *Valley Drug Co. v. Geneva Pharm. Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003), the Eleventh Circuit noted there was no evidence the patent litigation was a sham or the patent itself was invalid. Absent those elements, the court stressed, ''there is a presumption that the patent is a valid one.'' The court did not apply a *per se* rule because the anticompetitive effect of the settlement would be no broader than the patent's own exclusionary power. *Id.* at 1309. The court reasoned that exposing reverse-payment settlements to antitrust liability would ''obviously chill such settlements.'' *Id.*

Two years later, the Eleventh Circuit again faced a reverse-payment settlement in *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056, 1058 (11th Cir. 2005) (3 PLIR 243, 3/11/05), which reviewed an FTC cease and desist order. The court followed its earlier decision in *Valley Drug* and further explained that a proper analysis requires an examination of (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed the scope; and (3) the resulting anticompetitive effect. *Id.* at 1066. In other words, only the anticompetitive effects that go beyond the patent's lawful exclusionary power are relevant to an antitrust claim. While stating that ''neither the rule of reason nor the *per se* analysis is appropriate'' for these type of agreements, the court ultimately used a rule-of-reason analysis in which the anticompetitive effects were limited to those restraints that exceeded the scope of the patent. *Id.* at 1065 & 1072-76.

The Second Circuit adopted a similar approach in *In re Tamoxifen Citrate*, 466 F.3d 187, 206 (2d Cir. 2006), where it analyzed whether the ''exclusionary effects of the agreement'' exceed the ''scope of the patent's protection.'' *Id.* at 213. Since the agreement did not exceed the scope of the patent, the Second Circuit opined that the antitrust plaintiff only could prevail by proving either fraud or that the underlying infringement lawsuit was a sham. *Id.* The court also rejected a rule that would punish settlements if the payment to the generic company is ''excessive.'' *Id.* at 211. Acknowledging the ''troubling dynamic'' of conferring monopoly rights to weak patents, the court explained that ''the law allows the settlement even of suits involving weak patents with the presumption that the patent is valid and that settlement is merely an extension of the valid patent monopoly.'' *Id.*

The Second Circuit reiterated that approach in *In re Ciprofloxacin Hydrochloride*, No. 05-cv-2851 (2d Cir. April 29, 2010) (8 PLIR 579, 5/7/10). Interestingly, however, the *In re Ciprofloxacin* panel signaled a possible shift in the court's thinking on these issues by stating that its ruling was compelled by the *Tamoxifen* decision, inviting the plaintiffs to file a petition for *en banc* review, and describing several reasons why this case might be appropriate for reexamination by the full Second Circuit. *Id.* at 16-19. Most notably, the court cited DOJ's urging to repudiate *Tamoxifen*, and cited an FTC report that there is evidence that the practice of entering into reverse exclusionary payment settlements has increased since the court decided *Tamoxifen*. The Second Circuit's *en banc* review of the *Ciprofloxacin* decision, if it occurs, may be a good vehicle for the Supreme Court to weigh in on reverse-payment settlements (8 PLIR 675, 5/28/10).

The Federal Circuit also has rejected the *per se* approach, expressly endorsing a rule-of-reason test for reverse-payment settlements. *See In re Ciprofloxacin Hydrochloride*, 544 F.3d 1323, 1332 (Fed. Cir. 2008) (6 PLIR 1199, 10/24/08). The core issue for the Federal Circuit was whether there were any anticompetitive effects

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outside the patent's exclusionary zone. The court also reiterated that the ''long-standing policy in the law in favor of settlements'' also extends to ''patent infringement litigation'' (*id.* at 1333), and concurred with the Second and Eleventh Circuits that, unless there is evidence of fraud before the Patent and Trademark Office or sham litigation, the court need not consider patent validity as part of the antitrust analysis.

Thus, under current case law, the primary focus for litigants considering a reverse-payment settlement is whether the settlement exceeds the exclusionary scope of the patent. Exceeding the patent's scope does not necessarily create antitrust liability but, under current law, anticompetitive effects beyond the patent's exclusionary zone will be subject to antitrust scrutiny.

Practical Guidance

In light of the above case law, settling parties should examine contemplated agreements carefully to minimize the likelihood that the agreement exceeds the scope of the underlying patent's protection. For example, extending the generic manufacturer's agreement to stay off the market to generic products other than the accused ANDA product could lead to antitrust liability as a market allocation agreement that—at least insofar as the other generic products are not the subject of infringement litigation—could not be achieved through the exclusionary power of the patent. Courts likely would analyze such an agreement under the *per se* rule. The Sixth Circuit in *In re Cardizem* did not develop the distinction that subsequent circuit courts made between agreements within and beyond the scope of the patent protection, but this was the precise result of the case. The generic company agreed to keep noninfringing generics off the market and the court condemned the agreement as *per se* unlawful.

Another way the agreement could extend beyond the scope of the patent protection is if the generic company agrees to stay off the market for any period after the patent expires. Such an agreement likely also would be condemned as a *per se* unlawful allocation of the market for the period following patent expiration.

While the most straightforward example of a reverse-payment settlement is a cash outlay to the generic company in exchange for the generic company's agreement to stay out of the market for a period of time, most of these agreements are substantially more complex—often involving licensing agreements or other means of compensating the generic manufacturer. Companies considering such an agreement should keep in mind that what matters is not the form of payment, but the fact of consideration in exchange for delayed entry. In other words, if the brand name pharmaceutical company provides the generic company with something of value other than cash—such as a joint licensing agreement—courts still may consider that reward to be a reverse payment.

For example, sometimes a brand-name company may agree that it will not allow its own authorized generic to compete with the generic company during the generic's 180-day exclusivity period, thereby refraining from cutting into the generic's profits during that exclusivity period. The FTC takes the position that the brand-name company's agreement to stay off the market in this fashion is a form of reverse payment, although the FTC has yet to bring a case challenging a settlement that included such a ''no-authorized-generic'' provision.

Another common example occurs when the brand-name and generic companies enter into a concurrent marketing or co-development agreement and the brand-name manufacturer agrees to pay the generic company disproportionately large amounts for these services. This is what the government alleged in the Plavix case, which, based upon efforts to conceal the arrangement from federal regulators, led to indictments and the resignation of Bristol-Myers's general counsel. *See* DOJ press release, http://www.justice.gov/atr/public/press_releases/2008/232525.htm (April 23, 2008) (6 PLIR 479, 4/25/08). The FTC and DOJ view such agreements as a ploy to hide the reverse payment.

Brand and generic companies also have structured complex settlement agreements wherein several Hatch-Waxman cases on different drugs that were in dispute are settled at once. Analysis of this package arrangement should consider the pro-competitive advantages of allowing multiple products to enter the market, even where one of the cases in the package is weak for the brand-name company. The FTC, however, is likely to focus on the weakest of the patent cases in the package and may initiate an investigation to determine whether the weakest case, by itself, can justify a reverse-payment settlement. This suggests that brand and generic companies for which the cost of an FTC investigation would be substantially burdensome may be well-advised to stay away from such complex arrangements.

The FTC likely would support small reverse payments that effectively compensate the generic company for the cost of litigation and development of its generic product. *See Schering-Plough*, 402 F.3d at 1062. As long as the payment exceeds this small exception, however, the agency is unlikely to deem the amount of the reverse payment particularly relevant. It nevertheless is possible, in this rapidly developing area of law, for courts to begin comparing the size of the payment to the strength of the patent, such that parties contemplating reverse payment settlements should be mindful of the relationship between the two. The Second Circuit in *Tamoxifen*, for example, recognized the troubling dynamic at play with large settlements and weak patents. 466 F.3d at 211.

If an agreement includes extra, nonpatent restraints on competition that do not reach the level of a *per se* antitrust violation, companies could increase the likelihood of surviving antitrust scrutiny by including pro-competitive provisions to offset anticompetitive effects in a rule-of-reason analysis. Common examples of nonpatent restraints that may be pro-competitive include permitting the generic company to enter the market before the patent expires, permitting the settling generic to enter the market as soon as any other generic enters the market, permitting other generic companies to enter the market as ''authorized generics'' at the same time as the settling generic company, and providing access to the brand-name company's know-how as part of the agreement.

Agency Posture

The state of the law is further complicated by the fact that both U.S. antitrust agencies have taken the position—albeit in somewhat different ways—that the courts' current approach to these issues is wrong. Because all pharmaceutical patent infringement settlements that involve a reverse payment must be filed with both agencies no later than 10 days after execution, the

agencies are likely to scrutinize each of them carefully. The rules also require the filing of all concurrent agreements between the parties, including concurrent agreements concerning distribution, licensing, marketing, research, and other collaborations. A prudent approach to these settlements therefore must include an assessment of the dynamics and effects of all such arrangements together, and the likelihood that they may provoke an agency investigation regardless of their merits under current law.

The FTC has made banning reverse-payment settlements a top priority. It considers reverse-payment settlements *per se* unlawful and has called for a complete end to them. In January 2010, the FTC published a study that accused the Eleventh, Second, and Federal Circuits of misapplying antitrust law to uphold these settlements, which the FTC describes as ''pay-for-delay'' agreements (8 PLIR 95, 1/22/10). The FTC's urgency to outlaw reverse-payment settlements stems from its estimate that they will cost American consumers $3.5 billion per year over the next 10 years, and recent court defeats have not diminished the agency's desire to investigate and litigate these cases. As of January 2010, the FTC was litigating two cases in the trial courts and had multiple investigations under way.

Even if the FTC cannot persuade the courts that the federal antitrust laws should prohibit reverse-payment settlements, it can reach beyond traditional federal antitrust law and rely instead on the unfair competition prong of Section 5 of the FTC Act to challenge these arrangements. Although most commentators agree that Section 5 is broader than the Sherman Act, the FTC rarely has invoked it as the stand-alone basis for a cause of action to reach conduct that would be legal under the antitrust laws. The FTC did test Section 5's boundaries in the early 1980s, but mostly was rebuffed and, until very recently, has shied away from basing its actions exclusively on Section 5. Recent statements and speeches by some FTC commissioners, however, have emphasized that the agency, as a matter of policy, is determined to seek opportunities to bring pure Section 5 cases in the future. Indeed, in late 2009, the FTC exercised this policy goal when it filed a massive antitrust action against Intel that was expressly based upon a substantive Section 5 claim. The law governing Section 5 claims is sparse and, not surprisingly, no court has yet ruled on the legality of reverse-payment settlements under Section 5 alone. Even absent such a ruling, companies considering a reverse-payment settlement should proceed with caution, as an FTC investigation can be significantly burdensome and expensive regardless of its ultimate merit.

The FTC also has lobbied Congress to pass legislation prohibiting these settlements. Such a prohibition, in fact, made it into the initial version of the health care bill recently passed by the House, but did not survive the horse-trading to make it into law. It could, however, reappear in future legislation.

DOJ takes the position that reverse-payment settlements should be analyzed under the rule-of-reason, but that the customary burdens of proof should be altered by relieving the plaintiff from the initial burden of showing an anticompetitive effect. According to DOJ, a reverse-payment settlement should be presumed illegal, placing the burden on the settling parties to show that the agreement does not harm competition substantially. In this context, the settling parties must focus on a comparison between competition under the settlement and competition as it would have occurred if the patent suit had been litigated to judgment. According to DOJ, the settling parties clearly would rebut the presumption of illegality by showing that the reverse payment was commensurate with the patent holder's avoided litigation costs. If the payment greatly exceeds a reasonable measure of those costs, however, the inquiry would shift to the competitive implications of other terms of the settlement, and particularly to the nature and extent of the exclusion of generic competition and its relation to the parties' reasonable expectations if the patent litigation had proceeded to judgment.

Although DOJ contends that a trial-within-a-trial would not be necessary to evaluate what would have occurred had the patent infringement suit been litigated to judgment, it is difficult to see how courts could practically avoid such a result. Courts adopting DOJ's approach likely would need to examine the strength of the underlying patent in order to assess how competition under the settlement compares to competition in a litigated-judgment world. In carrying out such an assessment, it is difficult to see how a court could exclude evidence of patent validity and infringement, or draw a line at a quantum of evidence short of the amount that would have been introduced in the underlying patent litigation.

Conclusions

Although plaintiffs and government agencies have had only limited success in challenging reverse-payment settlements under the antitrust laws, the strong push by the Obama administration and the FTC to minimize or eliminate these agreements eventually could succeed, either through legislation or litigation. Indeed, DOJ's efforts already have had an effect, as the most recent Second Circuit panel to address these issues cited the administration's position as one important reason why the circuit should review the case *en banc*. DOJ's record of significant influence in affecting certiorari decisions also could lead the Supreme Court to review a reverse-payment settlement in the relatively near future.

Against this background, the legal landscape concerning reverse-payment settlements remains uncertain and subject to change. Parties considering reverse-payment settlements should remain alert to late-breaking developments and tread carefully.

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