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Pharmaceutical Patent Settlements Under Fire on Both Sides of the Atlantic

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In recent weeks, the pharmaceutical industry has been in the crosshairs of antitrust enforcers in the U.S. and in Europe. Specifically, patent litigation settlements in which a brand pharmaceutical manufacturer makes a payment to a potential generic entrant in return for a delay of entry (so-called "reverse payment settlements") are under attack on both sides of the Atlantic.

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In the United States, reverse payment settlements now face attack on three fronts, at the Department of Justice ("DOJ"), the Federal Trade Commission ("FTC"), and in Congress.

- The DOJ, under the new administration's leadership, recently argued in an amicus brief to the Second Circuit that reverse payment settlements are presumptively unlawful under Section 1 of the Sherman Antitrust Act.[1] The DOJ's argument represents a change of course that aligns the DOJ's position on reverse payment settlements with that of the FTC.

- In an interim report, the FTC concluded that the increasingly common brand-generic patent litigation settlements that include a promise by the brand not to launch an authorized generic in return for a generic's agreement to delay entry can harm consumers.[2] Prior to this report, the FTC had not challenged such agreements. The FTC's finding may change that.

- In the meantime, both the U.S. House of Representatives[3] and the U.S. Senate[4] continue to consider legislation that would outlaw reverse payment settlements. The proposed legislation would ban all settlements providing consideration in exchange for delay of market entry, but both bills would allow the FTC to issue rules exempting agreements it finds benefit consumers.[5]

In addition, last week the European Commission weighed in on reverse payment settlements by issuing the final version of its Pharmaceutical Sector Inquiry Report and announcing an investigation involving brand-generic agreements. While the Report deals with a number of issues, the Commission specifically stated it would monitor "settlements that limit or delay the market entry of generic drugs."[6] Indeed, on the same day that the final Report was announced, the Commission announced an investigation of Les Laboratoires Servier and several generic companies, concerning unilateral behavior by Servier and "agreements [with the generic companies] which may have the object or effect of hindering entry on to the market of generic perindopril," a drug developed by Servier.[7]

The DOJ Reverses Course and Urges that Reverse Payment Settlements be Held Presumptively Illegal

On July 6, in a brief filed in response to an invitation from the court, the DOJ urged the Court of Appeals for the Second Circuit to hold that reverse payment patent settlements are presumptively unlawful under Section 1 of the Sherman Antitrust Act.[8] This

action is a significant change in direction for the DOJ, and it urges the Second Circuit to expressly overturn relatively recent Second Circuit precedent and do an about-face on the contentious issue of how antitrust law impacts settlements of patent litigation. The DOJ's change of course not only has important implications for the pharmaceutical industry, it also is one more signal that portents more aggressive antitrust enforcement under the new administration.

Prior to the DOJ's brief, the FTC was the leader in efforts to challenge reverse payment settlements, which the FTC pursued on numerous fronts. For example, in a related case in the Federal Circuit, *In re Ciprofloxacin Hydrochloride Antitrust Litigation*,[9] the FTC supported the plaintiffs' arguments for reversal of the trial court's holding that reverse payment settlements were lawful. The court disagreed, upholding the trial court's decision; the Supreme Court recently denied certiorari.[10] The FTC has also brought several cases on its own initative, such as the *Cephalon* case, in which the FTC alleges that Cephalon entered into unlawful reverse payment settlements with four generic manufacturers.[11]

Despite the FTC's efforts, the Second, Eleventh, and Federal Circuits have all held that, in the absence of additional anticompetitive restraints, reverse payment settlements of a bona fide patent litigation are within the exclusionary zone of the patent and therefore permissible under the antitrust laws.[12]

Previously, the FTC's efforts were best unaided, and perhaps even hampered, by the DOJ, which opposed the FTC's attempt to present this issue to the Supreme Court and refrained from endorsing the position that a reverse payment settlement should be deemed presumptively unlawful.[13] When the Second Circuit recently took the unusual step of inviting the DOJ to file a brief on the issue – an issue on which the court had already ruled in the *Tamoxifen* case – all eyes were on the DOJ to see what position the new administration would take. Assistant Attorney General Christine Varney apparently seized the opportunity to make good on her promise to align the DOJ with the FTC's efforts on the reverse payment issue[14] as well as to illustrate President Obama's commitment to reinvigorating antitrust enforcement.[15]

The DOJ's Brief: Reverse Payment Patent Settlements Presumptively Unlawful

In its brief, the DOJ urged the Second Circuit to abandon the standard the court had articulated in the *Tamoxifen* case (that non-sham patent settlements do not violate the antitrust laws so long as the excluded product falls within the facial bounds of the patent claims). Instead, while not going so far as to advocate a *per se* unlawful approach, the DOJ went *almost* that far and urged a standard of presumptive unlawfulness under the rule of reason that could be rebutted only by a showing that the payment to the generic entrant did not exceed avoided litigation costs – in other words, that the payment was not for exclusion.

Summarizing the regulatory context of the Hatch-Waxman Act, the DOJ emphasized that it can often be to the economic advantage of both the patent holder and the generic manufacturer to settle if the patent holder provides a reverse payment.[16] Given this context, the DOJ emphasized that the Act struck a carefully crafted balance that allows a patentee to enforce its legitimate patent rights but at the same time face the threat of invalidity.[17] Private settlement avoids the risk[18] of invalidity. Thus, while non-sham patent litigation is immune from antitrust liability, the DOJ argues that settlement of patent litigation is a private measure to avoid the risk of having a patent declared invalid and is not immune from antitrust scrutiny.[19] Thus, the DOJ argues that the standard set out in the Second Circuit's *Tamoxifen* decision, immunizing non-sham patent settlements, is incorrect and upsets the balance struck by Congress.[20]

The DOJ attacks two arguments upon which the Second Circuit relied in *Tamoxifen*. First, the DOJ rejects the contention that while one generic firm may have settled with the patentee, other generics may seek entry into the market, thereby forcing infringement litigation.[21] The DOJ states that entry by other generics may be delayed because of aspects of the Hatch-Waxman context, including the 180-day exclusivity period for the first filer and the substantial amount of time litigation and application for generic approval can take.[22] Second, the DOJ argued that the presumption of patent validity is simply a rebuttable presumption assigning the burden of proof when litigating validity issues.[23] Applying it to private settlements would result in a virtually conclusive presumption of validity in a context where many patents are held invalid and would "treat all but the most obviously invalid patents as potent bulwarks against competition from generic drugs." [24]

The DOJ thus argued that substantial reverse payments from the patentee to the generic manufacturer presumptively violate Section 1 of the Sherman Act.[25] This is because, absent another explanation, DOJ believes that such a payment is naturally viewed as consideration for the generic firm's "delay of entry beyond the point that would otherwise reflect the parties' shared view of the likelihood that the patentee would ultimately prevail in litigation," that is, beyond the parties' shared view of the merits of the case.[26]

Furthermore, the DOJ emphasized that it would be inappropriate to analyze whether the patent holder would have prevailed in the patent infringement litigation.[27] Rather, "[l]iability properly turns on whether . . . the parties have by contract obtained more exclusion than warranted" by the possibility that the patent would have been ruled invalid.[28] Thus, the DOJ seems to be arguing that the risk of and uncertainty about invalidity is the very thing the antitrust law is meant to protect and buying out of that risk is unlawful – even if the actual "but for" scenario in the absence of a settlement would be a litigated outcome that upholds the validity of the patent and precludes generic entry for the full life of the patents at issue.[29]

Finally, the DOJ would allow defendants to rebut the presumption that the reverse payment purchased reduced competition.[30] Defendant's "burden is to show that, despite the reverse payment, the agreed upon entry date and other terms of entry reasonably reflected [the parties] contemporaneous evaluations of the likelihood that a judgment in the patent litigation would have resulted in

generic competition before patent expiration."[31] On the one hand, a reverse payment equal or not greatly in excess of the patent holder's avoided litigation costs would rebut the presumption.[32] The DOJ would also allow a modest reverse payment to "bridge the gap" between the parties' different assessments of the merits of the infringement case.[33] On the other hand, a payment greatly in excess of litigation costs is much harder to justify, and if it also allows no generic competition until patent expiration, the settlement cannot be justified because it "eliminates the *possibility* of competition from the generic prior to the expiration of the patent."[34] Thus, the ultimate inquiry is whether the settlement "preserved a degree of competition reasonably consistent with what had been expected if the infringement litigation went to judgment."[35] The DOJ would also allow a defendant to rebut the presumption by showing that the reverse payment bought something other than a limitation on competition.[36]

The European Commission's Pharmaceutical Sector Inquiry Report: Commission Undertakes Further Focused Monitoring of Reverse Payment Settlements

The European Commission's final Pharmaceutical Sector Inquiry Report comes 6 months after it issued a preliminary report. The aim of the inquiry was to "examine the reasons for observed delays in the entry of generic medicines to the market and the apparent decline of innovation" as illustrated by the number of new medicines coming to market.[37] Competition Commissioner Neelie Kroes has expressed her commitment to ensuring early generic entry: "When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices."[38]

Among the practices identified in the Report that possibly lead to delay of generic entry were patent settlements between brand pharmaceutical manufacturers and generic entrants.[39] The Report identifies over 200 such settlements between 2000 and June 2008.[40] Approximately half of these settlements restricted the ability of the generic company to market its products.[41] And a significant proportion of these restrictive settlements involved a value transfer from the patent-holder pharmaceutical company to the generic company.[42] The Commission considered both direct payments, which occurred in more than 20 settlements, and side-deals.[43] The Commission noted that this type of settlement has attracted antitrust scrutiny in the United States.[44]

The Report strongly implies that reverse payment settlements run afoul of EC competition law, especially if "the motive of the agreement is the sharing of profits via payments from [patent-holding pharmaceutical companies] to generic companies to the detriment of patients and public health budgets."[45] Thus, the Report suggests and the Commission has committed itself to undertake "further focused monitoring of settlements that limit generic entry and include a value transfer from [a patent-holding pharmaceutical] company to a generic company."[46] The Les Laboratoires Servier investigation illustrates this commitment. On the regulatory front, the Commission stressed the urgent need for a unified patent litigation system in Europe to lend certainty and uniformity to patent litigation.[47] Furthermore, the Commission invited EU members to institute policies facilitating generic uptake and generic competition.[48]

Conclusion

Patent litigation between brand and generic pharmaceutical manufacturers is almost inevitable. Companies need to be able to settle such litigation, and the current regulatory environment often creates situations in which a "reverse payment" is a rational means to do so. There are, however, substantial questions regarding such fundamental issues as what constitutes a "payment" and in what situations would a "payment" be subject to antitrust scrutiny. As the antitrust agencies on both side of the Atlantic expand their efforts in this area, it will be important for pharmaceutical companies to carefully structure litigation settlements to avoid competition issues. While the courts in the U.S. have been solicitous of so-called reverse payment settlements, given the DOJ's new stance, that may change. And in Europe, the European Commission's recent actions portend greater enforcement in this area.

Footnotes

[1] Brief for the United States in Response to the Court's Invitation, *Ark. Carpenters Health & Welfare Fund v. Bayer, AG*, No. 05-2851 (2d. Cir. July 6, 2009) [hereinafter *DOJ's Brief*].

[2] Federal Trade Commission, Authorized Generics: An Interim Report (June 2009), *available at* http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf.

[3] Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009) (referred to the H. Energy & Commerce and H. Judiciary Comms., March 25, 2009) *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1706ih.txt.pdf.

[4] Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009) (referred to the S. Comm. on the Judiciary, February 3, 2009) *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:s369is.txt.pdf.

[5] *See* H.R. 1706, 111th Cong. § 3 (2009); S. 369, 111th Cong. § 3(b) (2009).

[6] Press Release, European Commission, Antitrust: Shortcomings in Pharmaceutical Sector Require Further Action (July 8, 2009) [hereinafter *Commission Press Release*] *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1098&format=HTML&aged=0&language=EN&guiLanguage=en.

[7] Press Release, European Commission, Antitrust: Commission Opens Formal Proceedings Against Les Laboratoires Servier and a Number of Generic Pharmaceutical Companies (July 8, 2009) *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/322&format=HTML&aged=0&language=EN&guiLanguage=en.

[8] *DOJ's Brief*, *supra* note 5.

[9] 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 77 U.S.L.W. 3690 (U.S. June 22, 2009) (No. 08-1194).

[10] *Id.*; *see also* The Federal Circuit Cipro Decision: Another Blow to the FTC's Fight Against Reverse Payment Settlements, *available at* http://www.mofo.com/news/updates/files/14623.html.

[11] *See* FTC Takes 4-in-1 Shot at Reverse Payment Settlements, *available at* http://www.mofo.com/news/updates/files/13499.html.

[12] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006);*Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *In re Ciprofloxacin Hydrocholoride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).

[13] *See* Brief of the United States as Amicus Curiae, FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273).

[14] *Hearing of the S. Judiciary Comm.: The Nomination of Christine Anne Varney to be Assistant Attorney General in the Antitrust Division*, Fed. News Service, Mar. 10, 2009.

[15] *See e.g.*,Statement of Senator Barack Obama for the American Antitrust Institute, *available at* http://www.antitrustinstitute.org/archives/files/aai- Presidential campaign - Obama 9-07_092720071759.pdf.

[16] *DOJ Brief*, *supra* note 5, at 5-6.

[17] *Id.* at 13, 14, 30.

[18] A risk which the DOJ notes is especially high in the context of branded drug manufactures and generic entrants. *Id.* at 15-16.

[19] *Id.* at 14.

[20] *Id.* at 14-15.

[21] *Id.* at 17.

[22] *Id.* at 17-18; *see also id.* at 17 (citing the *Cephalon* case where the patentee settled with four generic manufacturers).

[23] *Id.* at 18.

[24] *Id.* at 19.

[25] *Id.* at 22. The DOJ concedes that settlements that merely divide the remaining life of the patent between a period of exclusion and a period of competition would generally be lawful. *Id.* at 21-22.

[26] *Id.* at 22. The DOJ suggests that any side deal between the patent holder and the generic firm should be presumed to be a disguised payment to the generic firm. *Id.* at 23 n.7.

[27] *Id.* at 24.

[28] *Id.* at 25.

[29] *See, e.g.*, *id.* at 26-27.

[30] *Id.* at 27.

[31] *Id.* at 30-31.

[32] *Id.* at 28-29.

[33] *Id.* at 29.

[34] *Id.* at 29-30.

[35] *Id.* at 30.

[36] *Id.* at 32.

[37] European Commission, Communication from the Commission: Executive Summary of the Pharmaceutical Sector Inquiry Report (July 8, 2009) [hereinafter *Executive Summary*] *available at* http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf. The full report is available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.

[38] *Commission Press Release*, *supra* note 6.

[39] *Executive Summary*, *supra* note 37, at 12.

[40] *Id.*

[41] *Id.* at 13

[42] *Id.*

[43] *Id.*

[44] *Id.*

[45] *Id.* at 20.

[46] *Id.* at 27; *see also Commission Press Release*, *supra* note 6.

[47] *Id.*

[48] *Id.*