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Antitrust and Intellectual Property:

Recent Developments in the Pharmaceuticals Sector

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I. INTRODUCTION

During his campaign for the Presidency, then-Senator Barack Obama promised that he would direct his administration to "reinvigorate antitrust enforcement," placing special emphasis on competition in health care and pharmaceuticals.[2] Among other things, he promised to "ensure that the law effectively prevents anticompetitive agreements that artificially retard the entry of generic pharmaceuticals onto the market . . . ."[3] That promise has been echoed by President Obama's choice to head the Federal Trade Commission ("FTC"), Jon Leibowitz, long an outspoken critic of so-called "reverse settlement" or "pay-for-delay" agreements between manufacturers of branded and generic pharmaceuticals. More recently, the Antitrust Division of the Department of Justice ("DOJ"), under new Assistant Attorney General Christine Varney, has taken a significantly more aggressive stance toward such agreements than the DOJ has taken before.

As yet, however, the policy position advanced by the FTC, and now adopted by the DOJ, has not gained acceptance in any federal court of appeals. And recent Supreme Court and Courts of Appeals decisions have had the effect of limiting, rather than expanding, the range of antitrust claims that may be brought against holders of pharmaceutical patents for their conduct in the marketplace—especially when such conduct is unilateral. The practical effect of the agencies' stated commitment to heightened enforcement in the pharmaceutical sector, therefore, may be limited by their ability to articulate theories of anticompetitive harm that the federal courts deem viable.

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[2] Statement of Senator Barack Obama for the American Antitrust Institute (Sept. 27, 2007) ("AAI Statement"), available at http://www.antitrustinstitute.org/archives/files/aai-%20Presidential%20campaign%20-%20Obama%209-07_092720071759.pdf.

[3] *Id.*

II. THE DOJ'S REVERSAL OF ITS POSITION ON REVERSE SETTLEMENTS

Reverse settlement agreements arise in pharmaceutical patent disputes in which the manufacturer of a branded drug sues a would-be competitor for patent infringement when it seeks federal regulatory approval to market a generic version of the drug. If litigated to a judgment, such disputes typically require a court to address the validity of the patent at issue. Given the risks associated with invalidation of a patent on a successful pharmaceutical product, branded manufacturers arguably have an incentive to settle such claims by paying the generic competitor to delay its entry into the market.

While the FTC has long taken the view that such agreements are anticompetitive and harmful to consumers, the Antitrust Division's response to reverse settlements has been considerably more tolerant. In 2006, the FTC and DOJ took conflicting positions on a petition for certiorari in *FTC* v. *Schering-Plough*,[4] a case in which the Eleventh Circuit Court of Appeals had rejected the FTC's allegations that a reverse settlement agreement concerning the drug K-Dur 20 unreasonably restrained competition by delaying entry of a generic competitor. The FTC sought *certiorari* from the Supreme Court to correct what it characterized as "fundamental legal errors by the court of appeals that not only depart from settled antitrust and administrative law principles, but also dramatically alter Congress's intended balance between the patent and antitrust laws as applied to generic drugs."[5] In a separate *amicus* brief, filed at the invitation of the Supreme Court, DOJ argued that *certiorari* should be denied because the case did not present "an appropriate opportunity for this Court to determine the proper standards for distinguishing legitimate patent settlements, which further the important goals of encouraging innovation and minimizing unnecessary litigation, from illegitimate settlements that impermissibly restrain trade in violation of the antitrust laws."[6] Throughout the previous administration, the FTC and DOJ remained split on how reverse settlements were to be treated under the antitrust laws.

That split has narrowed, if not disappeared. Departing from its previous positions in cases like *Schering-Plough*, DOJ recently argued—in an *amicus* brief filed at the invitation of the United States Court of Appeals for the Second Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*—that reverse settlement agreements in the pharmaceutical industry should be treated as "presumptively unlawful" under the antitrust laws.[7] To the extent adopted by the Court, DOJ's newly articulated position would mark a departure from existing precedent in the Second Circuit and other federal courts involving challenges to such agreements.

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[4] 402 F.3d 1056 (11th Cir. 2005).

[5] FTC v. Schering-Plough, No. 05-273, Petition for a Writ of Certiorari (Aug. 2005), available at http://www.ftc.gov/os/2005/08/050829scheringploughpet.pdf.

[6] *Id.*, Brief of the United States as Amicus Curiae (May 17, 2006), available at http://www.usdoj.gov/atr/cases/f216300/216358.pdf.

[7] Brief for the United States in Response to the Court's Invitation, In re Ciprofloxacin Hydrochloride Antitrust Litig., No. 05-2851-cv (2d Cir. July 6, 2009) ("Cipro Brief"), available at http://www.usdoj.gov/atr/cases/f247700/247708.pdf.

Ciprofloxacin, still pending before the Court of Appeals, was brought by purchasers of the antibiotic Cipro. They sued Bayer, the manufacturer of Cipro, and Barr Laboratories, the manufacturer of a generic alternative, for allegedly violating the antitrust laws by entering into a reverse settlement of a prior patent infringement suit brought by Bayer against Barr. Under the settlement agreement, Bayer allegedly made a series of payments to Barr in return for an agreement to delay the generic version of Cipro until six months before the Cipro patent would expire. In 2005, the District Court for the Eastern District of New York granted defendants' motion for summary judgment, holding that plaintiffs had failed to prove that the challenged settlement agreement had an actual adverse effect on competition.[8] The District Court concluded that it would be "inappropriate to engage in an after-the-fact analysis of the patent's validity;" rather, an existing patent should be treated as presumptively valid.[9] The proper test for determining the validity of a reverse settlement agreement, the court held, is whether the agreement would constrain competition *beyond* the scope of the underlying patent.[10] Applying this test to Bayer's settlement agreement with Barr, the court determined that plaintiffs had not shown any restraint of competition beyond that achieved by the Cipro patent itself.

In response to the Second Circuit's invitation to submit a brief on the reverse settlement issue, DOJ maintained, as in prior cases, that such agreements do not constitute *per se* antitrust violations. For the first time, however, DOJ argued that reverse settlement agreements in the pharmaceutical context "should be treated as presumptively unlawful under Section 1 of the Sherman Act."[11] Defendants may rebut that presumption, it contended, by offering evidence that the challenged payments did not purchase a reduction in competition.[12] For example, where defendant can show that the payment to an alleged infringer was "no more than an amount commensurate with the patent holder's avoided litigation costs," the agreement is likely to be upheld.[13] By contrast, where the challenged payment "is greatly in excess of avoided litigation costs," and the agreement precludes generic competition throughout the term of the underlying patent, the agreement is likely to violate the Sherman Act.[14]

In addition to advocating the adoption of a "presumptively unlawful" standard, the Division urged the Second Circuit to revisit its own 2006 decision in *In re Tamoxifen Citrate Antitrust Litigation*.[15] In *Tamoxifen*, on which the District Court relied in *Ciprofloxacin*, the Court of Appeals had held "absent an extension of the monopoly beyond the patent's scope, . . . and absent fraud, . . . the question is whether the underlying infringement lawsuit was objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits."[16] This holding, DOJ asserted, was "incorrect."[17] In particular, the Division maintained

[8] In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514 (E.D.N.Y. 2005).
[9] *Id.* at 539.
[10] *Id.* at 540.
[11] Cipro Brief at 10.
[12] *Id.* at 27-32.
[13] *Id.* at 28.
[14] *Id.* at 29.
[15] 466 F.3d 187 (2d Cir. 2006).
[16] *Id.* at 213 (internal quotation marks omitted).

that *Tamoxifen*'s "objectively baseless" standard effectively barred antitrust scrutiny of reverse settlement agreements and offered "no protection to the public interest in eliminating undeserved patents."[18]

Finally, DOJ directly reversed a position it had advanced in *Schering-Plough*—that courts weighing the anticompetitive effects of a reverse settlement payment, "at a minimum should take into account the relative likelihood of success of the parties' claims" in the underlying infringement lawsuit.[19] In its *Ciprofloxacin* brief, DOJ maintained that "[i]f the settlement involves a payment in exchange for the generic manufacturer's agreement to withdraw its challenge to the patent and to delay entry, there is no need to determine whether the patent would in fact have been held invalid in order to conclude that the settlement likely disadvantaged consumers."[20] Aligning itself with the FTC's opinion in another case where the two agencies had previously been at odds,[21] DOJ argued that a reverse settlement payment is itself enough to raise a "red flag," mandating further inquiry by the court, without examination of whether the underlying infringement suit had merit.

Whether ultimately endorsed by the Second Circuit in *Ciprofloxacin*, DOJ's brief reflects an important shift in its views of reverse settlement agreements in the pharmaceutical context. This issue is likely to continue to garner attention from both the FTC and the DOJ in the form of *amicus* briefs and also legislative efforts under the new administration. FTC Chairman Jon Leibowitz has repeatedly called on Congress to pass legislation restricting the ability of pharmaceutical companies to make such agreements.[22] And, last March, Representative Bobby Rush of Illinois re-introduced a bill, the Protecting Consumer Access to Generic Drugs Act of 1999, that would ban reverse settlement payments in pharmaceutical patent disputes. The extent to which the FTC and DOJ increase their own enforcement activities with respect to reverse settlements and other practices surrounding pharmaceutical patents—as well as the involvement of private plaintiffs in this type of litigation—may depend on how quickly such legislation moves through the Congress, as well as on the outcome of cases such as *Ciprofloxacin*.

III. DOE V. *ABBOTT LABORATORIES:* A HIGHER STANDARD FOR PLAINTIFFS IN THE NINTH CIRCUIT AND BEYOND

The Ninth Circuit's recent decision in *Doe* v. *Abbott Laboratories* represents a significant development in case law concerning unilateral conduct by holders of pharmaceutical (and

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[17] Cipro Brief at 6, 15.

[18] *Id.* at 15.

[19] Brief for the United States as Amicus Curiae, Joblove v. Barr Labs., Inc., No. 06-830 (May 2007), available at http://www.usdoj.gov/atr/cases/f223500/223525.htm.

[20] Cipro Brief at 26.

[21] Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).

[22] *See* Jon Leibowitz, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution) (June 23, 2009), available at http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf; Jon Leibowitz, The Pill Not To Be Taken With Competition: How Collusion Is Keeping Generic Drugs Off the Shelves, Washington Post (Feb. 28, 2008), available at http://www.ftc.gov/speeches/leibowitz/080225CephalonOpEd.pdf.

other) patents.[23] *Doe* involved sales by Abbott of the branded drug Norvir, which is used to "boost" the effectiveness of protease inhibitors in treating HIV. According to plaintiffs' complaint, Abbott allegedly has a monopoly in the protease inhibitor booster market by virtue of its patent on Norvir. Abbott sells Norvir to other drug manufacturers, who sell it in combination with their own, standalone protease inhibitors. In addition, Abbott markets its own protease inhibitor compound, which incorporates Norvir, in a single pill called Kaletra.

The *Doe* plaintiffs alleged that Abbott "leveraged" its booster monopoly to attempt to monopolize the market in boosted protease inhibitors. Abbott allegedly did so by raising the price of Norvir from $1.71 to $8.57 per 100 mg, while keeping the price of Kaletra the same. Abbott moved to dismiss the Complaint, arguing that plaintiffs had failed to state a claim under Section 2 of the Sherman Act.

On appeal, the Ninth Circuit reversed the District Court's holding that plaintiffs had articulated a valid theory of monopoly leveraging based on the prior decision of the Court of Appeals in *Image Technical Services, Inc* v. *Eastman Kodak Co.*[24] "Time, and the United States Supreme Court," the Court of Appeals observed, had "overtaken this case." In particular, the Court held that plaintiffs' claim of monopoly leveraging was barred by the Supreme Court's recent decision in *Pacific Bell Telephone Co.* v. *linkLine Communications, Inc.*[25]—a case decided after the District Court's decision in *Doe* v. *Abbott*.

linkLine involved allegations of a "price squeeze" by an alleged monopolist, AT&T, in the market for high-speed Internet ("DSL") services. Plaintiffs in *linkLine* alleged that AT&T was selling wholesale DSL transport service to competing providers at a price so high, and retail DSL service to consumers at a price so low, that AT&T's retail competitors (and wholesale customers) were unable to turn a profit. Such conduct, the Court held, is lawful where defendant has no "antitrust duty to deal"—*i.e.*, no independent obligation to sell to rivals—and has not engaged in predatory pricing—*i.e.*, selling its products at a price that is below an appropriate measure of cost. After *Trinko*, the Court emphasized, it is "clear that if a firm has no antitrust duty to deal with its competitors at wholesale, it certainly has no duty to deal under terms and conditions that the rivals find commercially advantageous."[26]

Although plaintiffs' claim in *linkLine* had been styled as a "price squeeze," rather than as an attempt at monopoly leveraging, the Ninth Circuit concluded that the conduct at issue in *Doe* v. *Abbott* was the "functional equivalent." Furthermore, the Court of Appeals interpreted *linkLine* to require separate analysis of each relevant market at issue in plaintiffs' claim that Abbott had leveraged its monopoly power in standalone boosters in order to gain monopoly power in boosted protease inhibitors. Applying this analysis, the Court determined that plaintiffs failed to allege that Abbott had engaged in an anticompetitive refusal to deal in the standalone booster market (with Norvir) and also failed to allege that Abbott had engaged in

[23] Doe v. Abbott Labs., 571 F.3d 930 (9th Cir. 2009).
[24] 125 F.3d 1195 (9th Cir. 1997).
[25] 129 S. Ct. 1109 (2009).
[26] *Id.* at 1119 (citing Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 (2004)).

below-cost pricing in the boosted inhibitor market (with Kaletra). Absent such allegations, the mere fact that Abbott charged a "high" price for Norvir—where it already had a monopoly by virtue of its patent—and a "low" price for Kaletra—where it competed with other protease inhibitors—failed to state a claim under Section 2. As the Supreme Court observed in *linkLine*, "[c]utting price in order to increase business is often the very essence of competition."[27]

In holding that plaintiffs' claim was foreclosed by *linkLine*, the Court of Appeals rejected the argument that its own prior decision in *Image Technical* had made standalone monopoly leveraging claims cognizable under Section 2. *Image Technical*, the Court explained, involved a refusal to deal whereas no such refusal had been alleged in *Doe*: "Read in that context and in light of *linkLine*, *Image Technical* does not save Does' claim."[28] Although the Court stopped short of overruling *Image Technical*, the holding in *Doe* significantly limited the reach of that decision with respect to monopoly leveraging claims. Not only did the Court make clear that after *linkLine* a claim of monopoly leveraging would not be recognized outside the context of a refusal to deal, but after *Trinko* (as reaffirmed in *linkLine*) plaintiffs face significant hurdles in demonstrating that a monopolist's unilateral refusal to deal is actually anticompetitive.

The tenuousness of monopoly leveraging theory is underscored by the Seventh Circuit's 2006 decision in *Schor* v. *Abbott Laboratories*.[29] In that case, decided prior to *linkLine*, plaintiff had leveled virtually identical allegations of monopoly leveraging against Abbott in the same product markets at issue in *Doe*. Observing that Schor had alleged neither a refusal to deal nor predatory pricing, Judge Easterbrook's opinion rejected the argument that a free-standing theory of monopoly leveraging was sufficient to state a claim under Section 2. "The problem with 'monopoly leveraging' as an antitrust theory," the Court held, "is that the practice cannot increase a monopolist's profits."[30] The Court went on to note that in *Image Technical*, the Ninth Circuit had "adopted just such an undisciplined monopoly-leveraging principle."[31] Furthermore, the Court indicated that although it "would be possible to cabin *Image Technical* by observing that, despite the opinion's language, the case arose from a refusal to deal"—as the Ninth Circuit did in *Doe*—the Seventh Circuit's opinion was that "*Image Technical* just got it wrong."[32]

By limiting its holding in *Image Technical*, the Ninth Circuit avoided a direct split with the Seventh Circuit's holding in *Schor* and also kept the theory of monopoly leveraging alive to some extent. Nevertheless, the circumstances in which such a theory might be supported, after *Doe* and *linkLine*, are extremely narrow. As a result, plaintiffs—including government agencies and private parties alike—who seek to challenge the unilateral pricing practices of pharmaceutical patent holders in the Ninth Circuit and elsewhere will face significantly higher standards going forward.

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[27] *Id.* at 1120.
[28] 571 F.3d at 935.
[29] 457 F.3d 608 (7th Cir. 2006).
[30] *Id.* at 611.
[31] *Id.* at 613.
[32] *Id.*