June 3, 2015

Second Circuit Applies Rule of Reason to Uphold Preliminary Injunction Preventing Manufacturer from Removing Alzheimer's Drug from Market

In *State of New York* v. *Actavis plc*, No. 14-4624-cv (2d Cir. May 22, 2015), the United States Court of Appeals for the Second Circuit addressed "a novel question" of antitrust law: "under what circumstances does conduct by a monopolist to perpetuate patent exclusivity through successive products, commonly known as 'product hopping,' violate the Sherman Act." Slip Op. at 6. The case involved a drug manufacturer[1] that planned to discontinue the manufacture and sale of a twice-daily immediate-release version of an Alzheimer's drug—for which the patent was about to expire—with the goal of switching patients to a once-daily extended-release version of the same drug covered by a patent that will not expire until 2029. By doing so, the manufacturer hoped to avoid losing substantial market share to generic manufacturers that would be able to begin selling the immediate-release version of the drug upon the expiration of its patent. The District Court issued a preliminary injunction that required the manufacturer to continue making the immediate-release version of the drug available to patients at the same price until thirty days after generic versions of the immediate-release drug become available. In an extensive 60-page decision, the Second Circuit—focusing its antitrust analysis on the "particular structure and circumstances" of the pharmaceutical industry—concluded that the District Court did not abuse its discretion and upheld the injunction.

As discussed below, the Second Circuit's decision is noteworthy because the standard for determining when this type of conduct violates the Sherman Act is evolving, and the remedy—requiring a patent holder to continue manufacturing a product for a period of time in order to facilitate competition in the product market once its patent expires—is unusual. Subsequent court decisions will need to determine the extent to which this decision is limited to the particular facts and circumstances presented by the regulation of the pharmaceutical industry, or whether it should be extended more broadly to similar conduct in other contexts.

Background

The Hatch-Waxman Act, which was intended to "serve the dual purposes of both encouraging generic drug competition in order to lower drug prices and incentivizing brand drug manufacturers to innovate

[1] Although there were two defendants in the case on appeal—Actavis plc and its subsidiary Forest Laboratories, LLC—these defendants are collectively referred to as the "drug manufacturer" for the sake of simplicity.

through patent extensions," slip op. at 8, provides important background for the court's decision. Of particular relevance here, the Hatch-Waxman Act permits a drug manufacturer that wants to market a generic version of an FDA approved branded drug to file an abbreviated application to expedite the FDA approval process for the generic version of the drug. *Id.* at 8-10. As the Second Circuit explained, "[b]y enabling generic manufacturers to 'piggy back' on a brand drug's scientific studies, Hatch-Waxman 'speeds the introduction of low-cost generic drugs to market, thereby furthering drug competition.'" *Id.* at 9-10 (quoting *F.T.C.* v. *Actavis, Inc.,* 133 S. Ct. 2223, 2228 (2013)).

The interplay between the Hatch-Waxman Act and state "drug substitution laws" is also important: All 50 states and the District of Columbia have enacted laws that "either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician." *Id.* at 10. Taken together, the Hatch-Waxman Act and state drug substitution laws mean that a brand drug manufacturer is forced to confront what is commonly known in the industry as the "patent cliff": when a brand drug's patent exclusivity ends and generic versions—supported by state drug substitution laws—enter the market, "the brand drug often loses more than 80 to 90% of the market within six months." *Id.* at 17.

In an attempt to avoid the patent cliff that it expected to face when the patent on its twice-daily immediate-release version of an Alzheimer's drug ("Namenda IR") would expire in July 2015, the brand drug manufacturer devised a so-called "product-hopping" strategy whereby it would stop manufacturing and selling Namenda IR before its patent expired, anticipating that physicians would switch their patients to the newer once-daily extended-release version of Namenda ("Namenda XR") that would remain on patent until 2029. According to the court, causing patients to make this switch to Namenda XR before the exclusivity period on Namenda IR expired would effectively "prevent generic substitution" of the generic version of Namenda IR after the patent on Namenda IR expired and therefore deprive generic manufacturers of "the only cost-efficient means of competing available to generic manufacturers." *Id.* at 39-41.[2] The court found that this was the case because, among other things, transaction costs would make it unlikely that patients having switched to Namenda XR would "reverse commute" and switch back to the generic version of Namenda IR. *Id.* at 23, 41-43.

On September 15, 2014, New York State filed a complaint that included monopolization and attempted monopolization claims under Section 2 of the Sherman Act and sought to enjoin the manufacturer from removing Namenda IR from the market. On December 15, 2014, after a five-day hearing, the district court issued a preliminary injunction ordering the manufacturer to make Namenda IR "available on the same terms and conditions applicable since July 21, 2013." *Id.* at 24. The manufacturer appealed.

---

[2] Differences between Namenda IR and Namenda XR would be sufficient to prevent pharmacists from substituting the generic version of Namenda IR for Namenda XR under "most, if not all," states' drug substitution laws. *See id.* at 16-18 & n.15.

Second Circuit Opinion

The Second Circuit, applying a heightened standard requiring New York to show a "substantial likelihood of success on the merits," determined that the district court had not abused its discretion in entering the injunction. After concluding that it was appropriate for the district court to apply a "rule of reason" analysis to New York's claim under Section 2 of the Sherman Act, the court stated that "[w]ell-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition." *Id.* at 33-35.[3] Citing its 1979 decision in *Berkey Photo, Inc.* v. *Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979), the court declared that that "when a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive under the Sherman Act." Slip Op. at 35-36 (emphasis in original) (citations omitted).

Applying that principle, the court determined that the withdrawal of Namenda IR from the market constituted coercion of consumers: given the "transaction costs" of switching Alzheimer's patients from one medication to another, the drug manufacturer had functionally deprived consumers of the ability to choose between the generic version of Namenda IR and Namenda XR once the generic version of Namenda IR entered the market. *Id.* at 37-39; *see also id.* at 41-43. The court also found that the conduct was likely to be exclusionary because the chief means of competition in the pharmaceutical market consisted of "[p]rice competition at the pharmacy, facilitated by state substitution laws," and by preventing those substitution laws from operating, the drug manufacturer had deprived generic manufacturers of "the only cost-efficient means of competing available" to them. *Id.* at 39-47.

The court next rejected as pretextual the drug manufacturer's proffered procompetitive justifications for withdrawing Namenda IR, citing evidence that withdrawing Namenda IR made economic sense only because of the "benefit derived from eliminating generic competition." *Id.* at 49. The court also forcefully rejected an argument that the drug manufacturer's "patent rights under Namenda IR and Namenda XR shield [it] from antitrust liability," concluding that the manufacturer's actions had gone beyond the scope of what its patent rights allowed it. *Id.* at 51-53.

Finally, the court determined that New York had established irreparable harm to consumers based on higher prices they would have to pay if the drug manufacturer could compel patients to use Namenda XR before the generic version of Namenda IR became available. The court concluded that some of this harm might not be recoverable in damages (*e.g.*, harm to indirect purchasers) and that, regardless, calculating

---

[3] It was uncontested on appeal that the relevant product market was the market for memantine-based products, of which the drug manufacturer was the sole manufacturer. *Id.* at 14-15 & n.11. As a result, the parties also did not dispute that the drug manufacturer possessed monopoly power. *Id.* at 30.

the economic damage to consumers would be a sufficiently complex task that the damage could be viewed as irreparable. *Id.* at 54-59.

Implications

As the Second Circuit noted, the question of whether "product hopping" violates the Sherman Act is one of first impression in the circuit courts. *Id.* at 6. The court's decision is therefore likely to have significant influence in this evolving area of antitrust law. Although the conduct at issue in this appeal and the Second Circuit's analysis were clearly shaped by the unique regulatory structure created by the Hatch-Waxman Act and state drug substitution laws, it remains to be seen whether courts will apply a similar analysis outside the pharmaceutical regulatory context. Courts will in the future likely have to answer difficult questions about the extent to which an actual or potential monopolist may have a duty to refrain from introducing product improvements or other modifications if the effect would be to increase transaction costs for rivals and potentially discourage competition, and if so, what the appropriate remedy should be. Until courts have had an opportunity to address those questions, it remains to be seen whether the Second Circuit's decision will become mainstream Section 2 doctrine, or will instead be considered "at or near the outer boundary of [Section 2] liability." *Verizon Comms. Inc.* v. *Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004) (describing *Aspen Skiing Co.* v. *Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), and discussing the extent to which the duty to deal with competitors recognized in *Aspen Skiing* was at or near the limits of liability under Section 2 of the Sherman Act).

* * *

This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

Robert A. Atkins
212-373-3183
ratkins@paulweiss.com

Craig A. Benson
202-223-7343
cbenson@paulweiss.com

Andrew C. Finch
212-373-3460
afinch@paulweiss.com

Kenneth A. Gallo
202-223-7356
kgallo@paulweiss.com

William Michael
212-373-3648
wmichael@paulweiss.com

Jacqueline P. Rubin
212-373-3056
jrubin@paulweiss.com

Moses Silverman
212-373-3355
msilverman@paulweiss.com

Joseph J. Simons
202-223-7370
jsimons@paulweiss.com

Aidan Synnott
212-373-3213
asynnott@paulweiss.com

Associate Noam Lerer contributed to this memorandum.