NEW YORK V. ACTAVIS PLC, FOREST LABORATORIES, LLC, _____ (2D. CIR. 2015)

Before WALKER, RAGGI, and DRONEY, Circuit Judges.

Opinion
JOHN M. WALKER, JR., Circuit Judge:

*1 The State of New York brought this antitrust action against Defendant—Appellant Actavis plc and its wholly-owned subsidiary Forest Laboratories, LLC (collectively, "Defendants"). New York alleges that as Namenda IR, Defendants' twice-daily drug designed to treat moderate-to-severe Alzheimer's disease, neared the end of its patent exclusivity period in July 2015, Defendants introduced a new once-daily version called Namenda XR. The patents on XR ensure exclusivity, and thus prohibit generic versions of XR from entering the market, until 2029. Faced with the prospect of competition from generic IR, Defendants decided to withdraw virtually all Namenda IR from the market in order to force Alzheimer's patients who depend on Namenda IR to switch to XR before generic IR becomes available. Because generic competition depends heavily on state drug substitution laws that allow pharmacists to substitute generic IR for Namenda IR—but not for XR, New York alleges that Defendants' forced-switch scheme would likely impede generic competition for IR. Moreover, the substantial transaction costs of switching from once-daily XR back to twice-daily IR therapy would likely further ensure that Defendants would maintain their effective monopoly in the relevant drug market beyond the time granted by their IR patents.

The United States District Court for the Southern District of New York (Robert W. Sweet, Judge) issued a preliminary injunction barring Defendants from restricting access to Namenda IR prior to generic IR entry. ... [W]e affirm the district court's order issuing a preliminary injunction.

BACKGROUND

This case raises 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,"2 violate the Sherman Act, 15 U.S.C. §§ 1 and 2. This question is an issue of first impression in the circuit courts. Determining whether Defendants' actions are unlawfully anticompetitive requires some understanding of the idiosyncratic market characteristics of the complex and highly-regulated pharmaceutical industry, as well as some peculiar characteristics of treatment for Alzheimer's disease. We begin by describing several key features of the pharmaceutical industry.

I. FDA REQUIREMENTS, THE HATCH—WAXMAN ACT, AND STATE DRUG SUBSTITUTION LAWS

[1] [2] In compliance with the Federal Food, Drug, and Cosmetic Act, 21 U .S.C. §§ 301—399f, when a pharmaceutical manufacturer seeks to bring a new drug to market, it must submit a New Drug Application ("NDA") for approval by the U.S. Food and Drug Administration ("FDA"). 21 U.S.C. § 355. An NDA must contain scientific evidence that demonstrates the drug is safe and effective, which inevitably requires "a long, comprehensive, and costly testing process." F.T.C. v. Actavis, Inc., ——— U.S. ———, ———, 133 S.Ct. 2223, 2228, 186 L.Ed.2d 343 (2013). NDA-approved drugs are generally referred to as brand-name or brand drugs. An approved brand drug enjoys a period of patent exclusivity in the market at the end of which one or more generic drugs,3 exhibiting the same characteristics as the brand drug, may enter the market at a lower price to compete with the brand drug.

*2 In 1984, Congress amended the Federal Food, Drug, and Cosmetic Act by enacting the Drug

Price Competition and Patent Term Restoration Act (the "Hatch–Waxman Act" or "Hatch–Waxman"), Pub.L. No. 98–417, 98 Stat. 1585. [...]

[3] Hatch–Waxman also promotes competition from generic substitute drugs. It permits a manufacturer that seeks to market a generic version of an NDA-approved drug to file what is known as an Abbreviated New Drug Application ("ANDA"). See 21 U.S.C. § 355(j); see also In re Adderall XR Antitrust Litig., 754 F.3d 128, 130 (2d Cir.2014). An ANDA allows a generic manufacturer to rely on the studies submitted in connection with the already-approved brand drug's NDA to show that the generic is safe and effective, provided that the ANDA certifies that the generic drug has the same active ingredients as and is "biologically equivalent" or "bioequivalent" to the already-approved drug.4 21 U.S.C. § 355(j)(2)(A)(iv); [...]

[4] A generic drug is bioequivalent to a brand drug if "the rate and extent of absorption" of the active ingredient is the same as that of the brand drug. 21 U.S.C. § 355(j)(8)(B)(i). In other words, two drugs are bioequivalent if they deliver the same amount of the same active ingredient content into a patient's blood stream over the same amount of time. [...]

[5] By the time Congress enacted the Hatch–Waxman Act, many states had enacted drug substitution laws to further encourage generic competition.5 ... [D]rug substitution laws 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 that the prescription must be dispensed as written.7 [...]

Hatch–Waxman and state substitution laws were enacted, in part, because the pharmaceutical market is not a well-functioning market. In a well-functioning market, a consumer selects and pays for a product after evaluating the price and quality of the product. In the prescription drug market, however, the party who selects the drug (the doctor) does not fully bear its costs, which creates a price disconnect. Moreover, a patient can only obtain a prescription drug if the doctor writes a prescription for that particular drug. The doctor selects the drug, but the patient, or in most cases a third-party payor such as a public or private health insurer, pays for the drug. As a result, the doctor may not know or even care about the price and generally has no incentive to take the price into account. See American Antitrust Institute Amicus Brief in Support of Appellee ("AAI Br.") at 6; see also Intellectual Property and Antitrust Professors Amicus Brief in Support of Appellee ("IP and Antitrust Prof. Br.") at 12. As the Federal Trade Commission has explained:

> The basic problem is that the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay. Patients have little influence in determining which products they will buy and what prices they must pay for prescription.
> Fed. Trade Comm'n Bureau of Consumer Prot., Drug Product Selection 2–3 (1979), available at http://bit.ly/1JqKd4G. ("FTC, Drug Product Selection").

State substitution laws are designed to correct for this price disconnect by shifting drug selection, between brand drugs and their corresponding generics from doctors, to pharmacists and patients, who have greater financial incentives to make price comparisons.11 See AAI Br. at 8–9.

II. THE RELEVANT MARKET

*4 The relevant market, undisputed on appeal, is the memantine-drug market in the United

States. [...]

Namenda IR and Namenda XR have the same active ingredient and the same therapeutic effect. The relevant medical difference between the two is that IR, which is released immediately into the bloodstream, is taken twice a day while XR, which is released gradually, is taken once a day.15 All other Alzheimer's disease treatments are administered once a day.

The non-medical difference between IR and XR relates to their patent protection. Defendants' patents on Namenda IR prohibit any manufacturer from marketing a generic version of IR until July 11, 2015 (Namenda IR's "exclusivity period").16 The exclusivity period for Namenda XR does not expire until 2029. A brand drug's exclusivity period is significant because when that period ends and generic versions enter the market, the brand drug often loses more than 80 to 90% of the market within six months. This period following the end of patent exclusivity has been referred to in this litigation and throughout the industry as the "patent cliff."

III. DEFENDANTS' INTRODUCTION OF NAMENDA XR AND WITHDRAWAL OF NAMENDA IR

Namenda IR and Namenda XR currently occupy the entire memantine-drug market. [...] Because Namenda XR has a different strength and daily dosage regimen—Namenda IR involves two immediate-release tablets of 10mg each and Namenda XR involves one 28mg extended-release capsule17—the generic IR versions that are poised to enter the market will be therapeutically equivalent under FDA regulations to Namenda IR, but not to Namenda XR. Therefore, pharmacists are prohibited from substituting generic IR for Namenda XR under most, if not all, state drug substitution laws.

When Defendants brought Namenda XR to market in July 2013 (approximately three years after it was approved), they adopted so-called "product extension" strategies to convert patients from Namenda IR to Namenda XR and, thus, to avoid the patent cliff. Initially, Defendants sold both Namenda IR and XR but stopped actively marketing IR. During that time, they spent substantial sums of money18 promoting XR to doctors, caregivers, patients, and pharmacists. They also sold XR at a discounted rate, making it considerably less expensive19 than Namenda IR tablets, and issued rebates to health plans to ensure that patients did not have to pay higher co-payments for XR than for IR. The parties have referred to Defendants' efforts to transition patients to XR while IR was still on the market as the "soft switch," and we will adopt that term.

*5 In early 2014, Defendants decided on a more direct approach. They were concerned that they would be unable to convert a significant percentage of Alzheimer's patients dependent upon memantine therapy from IR to XR prior to the entry of generic IR. Defendants' internal projections estimated that only 30% of Namenda IR users would voluntarily switch prior to July 2015. On February 14, 2014, Defendants publicly announced that they would discontinue Namenda IR on August 15, 2014, notified the FDA of their plans to discontinue Namenda IR, and published letters on their websites urging caregivers and healthcare providers to "discuss switching to Namenda XR" with their patients. S.A. 51—52. [...]

The parties have referred to Defendants' efforts to withdraw Namenda IR from the market as the "hard switch" or "forced switch," terms we also adopt. [...]

IV. PROCEDURAL HISTORY

[...]

DISCUSSION

[...]

I. THE APPLICABLE PRELIMINARY INJUNCTION STANDARD

[...]

II. MONOPOLIZATION AND ATTEMPTED MONOPOLIZATION UNDER § 2 OF THE SHERMAN ACT

Section 2 of the Sherman Act makes it an offense to "monopolize, or attempt to monopolize ... any part of the trade or commerce among the several States." 15 U.S.C. § 2

[...]

Defendants' patents on Namenda IR indisputably grant them a legal monopoly in the U.S. memantine-drug market until July 11, 2015.21 The parties do not dispute the district court's factual findings that the relevant market is the memantine-drug market in the United States and that Namenda IR and XR represent 100% of that market. S.A. 108—10. Consequently, the parties do not dispute that Defendants possess monopoly power. [...]

Given that Defendants' monopoly power has been established, this case turns on whether Defendants willfully sought to maintain or attempted to maintain that monopoly in violation of § 2. In United States v. Microsoft Corp., 253 F.3d 34, 58—60 (D.C.Cir.2001) (en banc), the D.C. Circuit, sitting en banc, established a helpful framework for determining when a product change violates § 2 based on the rule-of-reason test articulated by the Supreme Court in Standard Oil Co. v. United States, 221 U.S. 1, 31 S.Ct. 502, 55 L.Ed. 619 (1911), and generally applied to antitrust claims. [...] Under the Microsoft framework, once a plaintiff establishes that a monopolist's conduct is anticompetitive or exclusionary, the monopolist may proffer "nonpretextual" procompetitive justifications for its conduct. 253 F.3d at 58—59. The plaintiff may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit. Id.

A. ANTICOMPETITIVE AND EXCLUSIONARY CONDUCT

"As a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes." Microsoft, 253 F.3d at 65; see also Foremost Pro Color, Inc. v. Eastman Kodak Co., 703 F.2d 534, 544—45 (9th Cir.1983). Product innovation generally benefits consumers and inflicts harm on competitors, so courts look for evidence of "exclusionary or anticompetitive effects" in order to "distinguish 'between conduct that defeats a competitor because of efficiency and consumer satisfaction' " and conduct that impedes competition through means other than competition on the merits. Trans Sport, Inc. v. Starter Sportswear, Inc., 964 F.2d 186, 188—89 (2d Cir.1992) (quoting U.S. Football League v. Nat'l Football League, 842 F.2d 1335, 1359 (2d Cir.1988)).

Well-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition.23

The leading case in our circuit for § 2 liability based on product redesign is Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263 (2d Cir.1979). In that case, Kodak simultaneously introduced its new Kodacolor II film and new Kodak 110 camera, which was designed so that it could only be used with the Kodacolor II film (the "110 system"). Id.

at 277—78. Kodak, which possessed a lawful monopoly in film but not in cameras, heavily advertised Kodacolor II film as "a remarkable new film," and for 18 months, Kodak made Kodacolor II film only for the 110 camera. Id. at 278. Berkey Photo, Inc. ("Berkey"), a smaller camera manufacturer, alleged that Kodak unlawfully used its monopoly in film to increase camera sales and monopolize the camera market. Id. We rejected that claim and held that the introduction of the 110 system and advertising of the Kodacolor II film did not violate the Sherman Act because "[Kodak's] success was not based on any form of coercion." Id. at 287. But, of significance to the case before us, we cautioned that "the situation might be completely different if, upon the introduction of the 110 system, Kodak had ceased producing film in the 126 size, thereby compelling camera purchasers to buy a Kodak 110 camera." Id. at 287 n. 39.24

*10 In this case, Defendants argue that withdrawing a product is not anticompetitive or exclusionary conduct, especially when the new product is superior to the old product.25 Certainly, neither product withdrawal nor product improvement alone is anticompetitive. But under Berkey Photo, 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, id. at 287, and to impede competition, id. at 274—75, its actions are anticompetitive under the Sherman Act. [...] Here, Defendants' hard switch—the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR—forced Alzheimer's patients who depend on memantine therapy to switch to XR (to which generic IR is not therapeutically equivalent) and would likely impede generic competition by precluding generic substitution through state drug substitution laws.

I. CONSUMER COERCION

Defendants' hard switch crosses the line from persuasion to coercion and is anticompetitive. As long as Defendants sought to persuade patients and their doctors to switch from Namenda IR to Namenda XR while both were on the market (the soft switch) and with generic IR drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives.

By effectively withdrawing Namenda IR prior to generic entry, Defendants forced patients to switch from Namenda IR to XR—the only other memantine drug on the market.27 S.A. 49; Tr. 183:22—184:17 (Stitt) ("So the unique thing [about the Namenda IR hard switch] I think is that there's really no place for prescribers to, to go with a drug to treat that condition."). In fact, the district court found that Defendants devised the hard switch because they projected that only 30% of memantine-therapy patients would voluntarily switch to Namenda XR prior to generic entry. S.A. 56—57. Defendants' hard switch was expected to transition 80 to 100% of Namenda IR patients to XR prior to generic entry, S.A. 81, and thereby impede generic competition.

Defendants argue that courts should not distinguish between hard and soft switches. But this argument ignores one of Berkey Photo 's basic tenets: the market can determine whether one product is superior to another only "so long as the free choice of consumers is preserved." 603 F.2d at 287. Had Defendants allowed Namenda IR to remain available until generic entry, doctors and Alzheimer's patients could have decided whether the benefits of switching to once-daily Namenda XR would outweigh the benefits of adhering to twice-daily therapy using less-expensive generic IR (or perhaps lower-priced Namenda IR). By removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of that choice. In this way, Defendants could avoid competing against lower-cost generics based on the merits of their redesigned drug by forcing Alzheimer's patients to take XR,28 with the knowledge that transaction costs would make the reverse commute by patients from XR to generic IR highly unlikely.

II. IMPEDES COMPETITION

*11 As the district court concluded, Defendants' hard switch would likely have anticompetitive and exclusionary effects on competition in the memantine market, creating a "dangerous probability" that Defendants would maintain their monopoly power after generics enter the market. [...]

We agree with the district court's analysis. Forcing patients to switch to XR would prevent generic substitution because generic versions of IR are not AB-rated to Namenda XR. And if, as Defendants' own internal predictions estimate, the hard switch successfully converted 80 to 100% of IR patients to XR prior to generic entry, there would be "few to no prescriptions" left for which generics would be eligible to compete. S.A. 82. Because Defendants' forced switch "through something other than competition on the merits[ ] has the effect of significantly reducing usage of rivals' products and hence protecting its own ... monopoly, it is anticompetitive." Microsoft, 253 F.3d at 65.

[...]

Although in theory, Alzheimer's patients would be free to switch back to IR therapy after generic entry, the district court found that, in practice, such a reverse commute would be a highly unlikely occurrence. As one of Defendants' own executives explained during a January 21, 2014 earnings call: "if we do the hard switch and we convert patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back." S.A. 51. [...]

B. PROCOMPETITIVE JUSTIFICATIONS

*13 All of Defendants' procompetitive justifications for withdrawing IR are pretextual. [...]

C. PROCOMPETITIVE BENEFITS V. ANTICOMPETITIVE HARMS

Because we have determined that Defendants' procompetitive justifications are pretextual, we need not weigh them against the anticompetitive harms. But in any event, New York has shown that whatever procompetitive benefits exist are outweighed by the anticompetitive harms. [...]

Defendants have presented no evidence to support their argument that antitrust scrutiny of the pharmaceutical industry will meaningfully deter innovation. To the contrary, as the American Antitrust Institute amici argue, immunizing product hopping from antitrust scrutiny may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations.

*14 In sum, we conclude that the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates § 2 of the Sherman Act.

III. PATENT RIGHTS AS A DEFENSE TO LIABILITY

Defendants argue that their patent rights under Namenda IR and Namenda XR shield them from

antitrust liability. [...]

[I]n its recent landmark antitrust case, F.T.C. v. Actavis, Inc., the Supreme Court made clear that "patent and antitrust policies are both relevant in determining the scope of the patent monopoly—and consequently antitrust law immunity—that is conferred by a patent." 133 S.Ct. at 2231. [...]

The Court's decision in Actavis reaffirmed the conclusions of circuit courts that a patent does not confer upon the patent holder an "absolute and unfettered right to use its intellectual property as it wishes," Microsoft, 253 F.3d at 63, and "[i]ntellectual property rights do not confer a privilege to violate the antitrust laws," In re Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1325 (Fed.Cir.2000). [...]

[20] Defendants argue that their conduct does not violate antitrust law because they have merely "exercised rights afforded by the Patent Act." Defs. Br. at 34. But patent law gives Defendants a temporary monopoly on individual drugs—not a right to use their patents as part of a scheme to interfere with competition "beyond the limits of the patent monopoly." United States v. Line Material Co., 333 U.S. 287, 308, 68 S.Ct. 550, 92 L.Ed. 701 (1948). Defendants have essentially tried to use their patent rights on Namenda XR to extend the exclusivity period for all of their memantine-therapy drugs. As explained above, it is the combination of Defendants' withdrawal of IR and introduction of XR in the context of generic substitution laws that places their conduct beyond the scope of their patent rights for IR or XR individually.

IV. THE SHERMAN ACT § 1 AND THE DONNELLY ACT [...]

V. IRREPARABLE HARM [...]

VI. THE PRELIMINARY INJUNCTION [...]

FOOTNOTES

23

Our emphasis on consumer coercion in evaluating a monopolist's product redesign is in accord with several of our sister circuits. See Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 994 (9th Cir.2010) ("A monopolist's discontinuation of [an old product] may violate § 2 if it effectively forces customers to adopt its new [product]."); Microsoft, 253 F.3d at 65 (explaining that Microsoft's redesign of its operating system was anticompetitive because the redesign impeded competition "not by making Microsoft's own browser more attractive to consumers but, rather, by discouraging [manufacturers] from distributing rival products"); cf. Multistate Legal Studies, Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc., 63 F.3d 1540, 1550 (10th Cir.1995) (noting that illegal tie-ins under Section 1 may "qualify as anticompetitive conduct for Section 2 purposes"). Similarly, the other district courts that have considered product hopping cases also examined consumer coercion. And those district courts that have ruled in favor of plaintiffs alleging antitrust violations stemming from product hopping have found consumer coercion. See In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., No. 13–MD–2445, 2014 WL 6792663, at *12 (E.D.Pa. Dec.3, 2014) (plaintiffs alleged exclusionary conduct under § 2 where the brand manufacturer coerced patients into switching from the tablet form of a drug—for which their patent was set to expire—to a new film version of the drug by raising allegedly false safety concerns about the tablet and announcing that it would soon be withdrawn from the market); Abbott Labs. v. Teva Pharm. USA, Inc., 432 F.Supp.2d 408, 430 (D.Del.2006) (plaintiffs alleged antitrust violations where the defendants introduced new drug formulations and withdrew

the prior versions whose exclusivity period would soon expire). In contrast, in cases in which there is no evidence of coercion, district courts have rejected such claims. See Mylan Pharm. Inc. v. Warner Chilcott PLC et al., No. Civ. 12—3824, 2015 WL 1736957, at *13 (E.D.Pa. Apr.16, 2015) (noting that because generics had already entered the market at the time of defendants' product reformulation, "doctors remained free to prescribe generic Doryx; pharmacists remained free to substitute generics when medically appropriate; and patients remained free to ask their doctors and pharmacists for generic versions of the drug"); Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F.Supp.2d 146, 151 (D.D.C.2008) (dismissing a case alleging attempted market monopolization because unlike in Abbott Labs, "there is no allegation that AstraZeneca eliminated any consumer choices. Rather, AstraZeneca ... introduced a new drug to compete with already-established drugs—both its own and others'—and with the generic substitutes for at least one of the established drugs").

25 Whether XR is superior to IR is not significant in this case. When there is coercion, "the technological desirability of the product change ... bear[s] on the question of monopolistic intent," id. at 287 n. 39, rather than the permissibility of the defendant's conduct. Here, there is no genuine dispute that Defendants intended to avoid the patent cliff. See, e.g., J.A. 132, 155.