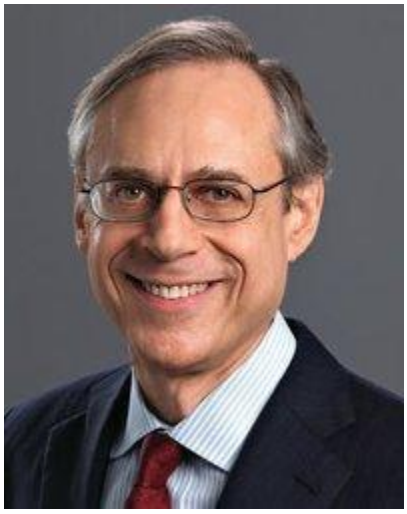
Portfolio Media. Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

8 Product-Hopping Takeaways From Namenda Ruling

Law360, New York (June 11, 2015, 9:18 AM ET) --



Robert Reznick

On May 22, 2015, in New York v. Actavis,[1] a panel of the U.S. Court of Appeals for the Second Circuit became the first appellate court to consider the legal limits attendant to "product-hopping" in the pharmaceutical industry, a term given by some to a variety of practices used by drug manufacturers to migrate patients from a medicine approaching the end of its patent life to a successor with much of its patent term remaining.

In affirming the district court's grant of a preliminary injunction, the panel held that pharmaceutical manufacturer Actavis PLC, and its wholly owned subsidiary Forest Laboratories LLC (the "drug manufacturers"), likely violated Section 2 of the Sherman Act by engaging in what has been termed a "hard" switch: withdrawing from the market a twice-daily pill used to treat Alzheimer's disease (and soon to face generic competition) so patients wishing to remain on the medicine's active ingredient would have to switch to the drug manufacturers' delayed-release successor, which enjoyed a considerable remaining patent term and would not have been subject to generic substitution laws. The court affirmed the lower court's order directing the drug manufacturers to keep the incumbent twice-daily pill on the market until 30 days after generics could enter, on unchanged terms of sale.

Drug manufacturers regularly develop successor medicines with enhanced exclusivity in an effort to protect their franchises, and they consider carefully how aggressively they may promote switches in advance of generic entry. The stakes are huge. The Second Circuit's decision in Actavis shrinks a number of the gray areas of the law relating to this question, but key issues concerning how aggressively drug manufacturers may seek to migrate patients to follow-on drugs remain open, largely because of the unusual characteristics of the market under review. This note seeks to identify aspects of Actavis that may prove inapplicable in other settings.

Background

"Product-hopping" refers to a range of practices by manufacturers of branded prescription drugs to try to ameliorate the financial impact of impending generic competition, specifically through the introduction of follow-on products that have a longer remaining period of patent protection and thus, unlike their predecessor products, will not be subject to generic substitution laws. The introduction of

product enhancements is generally encouraged by the law, but litigation has ensued where the "enhancement" has been challenged as insubstantial, or actions by drug manufacturers are seen as coercing consumers into bypassing a newly-available generic in favor of the new branded product. Under certain circumstances, such conduct has been found unlawful because it "injures" competition in a putative market made up of the existing product and its generic.

For a number of years, many have understood the line between lawful and unlawful conduct to have been that originally drawn by two district court cases: Walgreen Co. v. AstraZeneca Pharm. LP, 534 F. Supp. 2d 146, 151 (D.D.C. 2008), and Abbott Labs. v. Teva Pharms. USA Inc., 432 F. Supp. 2d 408, 430 (D. Del. 2006). To simplify a bit, the line generally distinguished a manufacturer's withdrawal of a branded incumbent product prior to generic entry in order to promote the switch of patients to a follow-on product (a so-called "hard" switch) from conduct seen as merely providing encouragement for the switch, with no withdrawal of the incumbent product (a "soft" switch). The "hard" switch has been considered to present substantial antitrust risk, while a "soft" switch has been thought to be pro-competitive. Until Actavis, this understanding had not received appellate review, and in any event did not come with guidance as to the many variables that a particular market presents.

New York v. Actavis

The Actavis decision solidifies the line that had been widely understood to have been drawn between soft and hard switches, but the extent to which it offers guidance for future situations is less clear.

Briefly, Forest Laboratories (subsequently acquired by Actavis PLC) sold a twice-daily drug, Namenda IR ("IR") indicated for use by moderate-to-severe sufferers of Alzheimer's disease. The drug, which had sales of approximately $1.5 billion, was one of Forest's best-selling drugs.[2] As IR neared the July 2015 end of its patent life, generics were poised to enter the market.[3] In anticipation of the usual 80-90 percent decline in sales after generic entry, Forest introduced a once-daily version of IR, Namenda XR ("XR"), whose patent protection does not expire until 2029.[4] IR and XR are the only drugs indicated for the treatment of Alzheimer's disease that contain the active ingredient memantine. Forest promoted, discounted and rebated XR heavily, but it concluded that only 30 percent of patients would respond to the soft switch prior to generic entry.[5] Accordingly — and most notably for present purposes — Forest decided to withdraw "virtually" all IR from the market prior to XR's introduction, leaving IR patients who wished to remain on memantine therapy no choice but to switch to XR.[6]

The state of New York sued to enjoin Forest from withdrawing IR from the market, basing its claim principally on Section 2 of the Sherman Act.[7] After a five-day hearing at which testimony was taken from 24 witnesses and 1,400 exhibits were admitted into evidence, the U.S. District Court for the Southern District of New York issued a preliminary injunction granting the state virtually all the relief it had requested: an order requiring Forest to keep IR on the market until August 2015 (when the first generic memantine drug will be available), on terms and conditions prevailing when XR was introduced in 2013.[8] Forest appealed and the Second Circuit granted expedited review, issuing its decision six weeks after argument.

The Second Circuit affirmed entry of the preliminary injunction. It found that New York had demonstrated a "substantial likelihood of success" on its Section 2 claim, and "a strong showing of irreparable harm to competition and consumers in the absence of a preliminary injunction."[9] The ruling was based on many agreed facts on appeal, including that the relevant market for antitrust purposes was the universe of Alzheimer's drugs having memantine as an active ingredient — 100 percent of which was comprised of IR and XR.[10]

The court found that Forest possessed monopoly power in the relevant market, and that its hard switch violated Section 2: "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."[11]

Among others, the court rejected Forest's argument that in withdrawing IR it was merely "exercise[ing] rights afforded by the Patent Act," explaining that "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.'"[12] By contrast, the court endorsed the soft switch as lawful: "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."[13]

The presence of drug substitution laws was critical to the court's analysis. These laws exist in one form or another in every state, and generally permit or require pharmacies to dispense generic products where a prescription has been written for the generic's branded counterpart. Because the generics had been approved by the U.S. Food and Drug Administration as substitutes for IR, the substitution laws would only allow generic memantine to be substituted for prescriptions written for IR; a prescription for XR would be free from generic competition until the patents covering XR expired in 2029.[14] The Second Circuit concluded that, despite other means by which generics could try to enter the market, drug substitution laws provided the only "cost-efficient" alternative, and therefore the only viable one.[15] The hard switch, in the court's view, thus had the effect of "coercing" patients to switch to XR, with the effect that the drug manufacturers' monopoly over memantine-based therapies would continue.[16]

The following points in the Second Circuit's opinion are the most notable for purposes of the guidance they offer (or, in some cases, the uncertainty they engender) regarding application of the Sherman Act to future instances of product-hopping. These are areas where drug manufacturers seeking to understand the risks attendant to hard and "semi-soft" switches might focus their analysis:

1. On appeal, the parties did not dispute the district court's finding that there was a relevant antitrust "market" of Alzheimer drug therapy based on the active ingredient, memantine. This ruling allowed the panel to conclude that the drug manufacturers possessed monopoly power and that the hard switch was a device for the maintenance of monopoly power (as opposed to merely retaining sales). It is well established, however, that a patent standing alone does not necessarily define a market or confer monopoly power.[17] While courts often (but not always) define relevant markets in Hatch-Waxman litigation to comprise a brand and its generic, the precedent is less clear where a third product, outside the realm of state generic-substitution laws, is present. In fact, the Second Circuit's conclusion that there is a memantine-therapy "market" was fact-specific.[18] Whether the incumbent drug, its generic and its successor collectively define a relevant market will be far from obvious in other circumstances.[19] Where the relevant market is broader than the incumbent drug and the generic, it may be difficult for a plaintiff to demonstrate sufficient market power to prevail under the rule of reason.

2. The court's description and endorsement of the soft switch seems to allow a wide range of lawful

competitive conduct that a drug manufacturer may engage in to defend its franchise. In addition to "promoting" its follow-on product, Forest sold the product at a discounted price that made it "considerably less expensive" than the incumbent.[20] The court was not more specific, and this vagueness may be significant. Nothing in Actavis suggests a limit on the extent to which a drug manufacturer may lawfully make its follow-on product "considerably less expensive" than the incumbent, thereby presenting to consumers an exceedingly powerful economic incentive to switch. In other contexts, where patients are not as switch-adverse as Alzheimer's patients are said to be, exceedingly high price differentials might make for a very effective soft switch. Time will tell whether the Federal Trade Commission or private litigants will attack heavy discounting as making a de facto hard switch.[21]

3. Although New York's case focused on Section 2 monopolization and attempted monopolization claims,[22] the Second Circuit does not say much about maintaining a monopoly or there being a "dangerous probability" of achieving one. Indeed, the court's selection of an analysis that asks whether a monopolist's conduct is "anti-competitive or exclusionary," and if so, whether "nonpretextual" pro-competitive justifications exist for it, seems more appropriate for a context in which the conduct in question deters the only competition capable of threatening the monopoly.[23] That certainly was the case in United States v. Microsoft Corp., 253 F.3d 34 (D.C. Cir. 2001) (en banc), from which the panel borrowed the standard, in which Microsoft's continuing monopoly position as a result of its conduct was not in dispute.[24] The court appears to support use of such a standard with its consideration and rejection of two potential means by which the market would defeat the anti-competitive effects of a hard switch, concluding (1) that moderate-to-severe Alzheimer's patients would be "very reluctant" to switch to generic IR after having been migrated to XR, and (2) that third-party payors could not "cost-efficient[ly]" drive switches.[25]

This is all well and good, but while dismissing these specific mechanisms for ending the drug manufacturers' monopoly, the Second Circuit assumes that other market factors will end the monopoly. The court itself cites and relies upon a statement by Forest's CEO that the goal of the hard switch was not to eliminate forever the loss of sales through generic substitution (referred to as the patent "cliff"), but to replace that immediate loss with a "prolonged decline."[26] The market forces leading to that loss of monopoly power, and the timeline on which it would be expected to occur are never discussed.

One obvious source of the "prolonged decline" in the drug manufacturers' share is no mystery: Even if "reverse commutes" or changes to medicines with other active ingredients are excluded, drug markets are notoriously subject to constant turnover of prescriptions.[27] Here, patients with prescriptions first written after the generic becomes available would have had no exposure to the hard switch, and could simply decide at the outset whether or not to elect the generic incumbent or the follow-on drug. Although the court considers two mechanisms by which the market might defeat a hard switch, it does not consider this one, or the implications of a "prolonged decline" that, at some point, would drop the drug manufacturers' share below monopoly levels.

4. In a similar vein, Actavis leaves open the question whether some limitation on access to an incumbent product may suffice to allay competitive concerns. The mail-order pharmacy option for "medically necessary" prescriptions of IR that Forest established after New York sued was derided by the Second Circuit as insufficient, although a citation to Forest's internal estimate that only about 3 percent of then-current IR users would be able to take advantage of the option addresses market share issues more directly than the question whether "coercion" of patients though still exists.[28] Keeping in mind, again, that monopolization claims are of most direct significance, drug manufacturers may have lawful means less restrictive than Forest's mail order option but far short of open access to help promote their

successor products.

5. The court's conclusion that the drug manufacturer's justifications for the switch were pretextual short-circuited a discussion of the balancing of competitive pros and cons that the Microsoft opinion prescribes.[29]

6. The preliminary injunction is sweeping, requiring Actavis to continue to sell IR on the "same terms and conditions" as existed in 2013, immediately prior to the introduction of XR.[30] That is, Actavis appears to have less flexibility now in setting the "terms and conditions" for selling IR than it would have had in the absence of introducing XR. Notably, however, the injunction is effective until 30 days after generics are allowed to enter the market, at which point Actavis is free to withdraw IR if the injunction is not modified. In other words, the Second Circuit has provided doctors with a bridge to maintain IR's twice-daily treatment without interruption, but is not requiring Actavis to sell IR longer than 30 days after expiration of the patent.

7. Actavis contains one of the most express statements yet by a court of appeals that conduct contrary to what is later thought to be the "spirit" of a law — i.e., "gaming" the system — can be a basis for finding that conduct is exclusionary within the meaning of the antitrust laws. One of the drug manufacturers' principal arguments is that their decision to stop manufacturing a patented product is unqualified, and that no principle of antitrust law requires them to continue selling a patented product so that their competitors might profit from state substitution laws — to "free rid[e]."[31] The panel's response is to state that generic substitution ("free riding") is not only lawful but advances the goals of both state substitution laws as well as the Hatch-Waxman amendments.[32] The idea that taking advantage of arguable "loopholes" in the law is an occasion for liability rather than a call to arms to close the loophole is of relatively recent vintage (some have traced its modern incarnation to litigation following the collapse of Enron). Relying on such fluid principles can be problematic, especially in cases where legislation is a compromise between competing goals, as is the case with the Hatch-Waxman Amendments. Equally notable, the Second Circuit does not analyze the case through the lens of a substantial body of law limiting the circumstances in which monopolists are required to assist their competitors.[33] The court's failure to discuss this fundamental principle suggests unresolved conflicts that will need to be addressed on another occasion.

8. Finally, the court summarily dismissed the question whether XR represents an improvement over IR. It characterized the question as going to the drug manufacturers' "intent," and stated that their intent "to avoid the patent cliff" was undisputed.[34] The benefits to treatment of a daily as opposed to twice-daily dosage form would not appear difficult to show. Yet, the drug manufacturers' intent, as reflected in the company documents cited by the court, was described as one-dimensionally focused on the retention of sales. If drug manufacturers have striven to develop improved products so as better to compete with alternative therapies, they would be well advised to ensure that this intent was captured in planning documents.

Conclusion

The Second Circuit's decision in New York v. Actavis is sweeping and yet still limited by its stark facts and the distinctive characteristics of the patient population at issue. While soft switches may now safely be made, and hard switches may now confidently be understood to come with significant antitrust risk, there remains a commercially significant body of "semi-soft" switches whose legality remains very much open to question.

—By Robert P. Reznick, David M. Goldstein, Richard S. Goldstein and Howard M. Ullman, Orrick Herrington & Sutcliffe LLP

Robert Reznick is a partner in Orrick's Washington, D.C., office and co-chairman of the firm's life sciences practice. David Goldstein is a partner in the firm's San Francisco office. Richard Goldstein is a partner in the firm's New York office. and former in-house counsel at Merck & Co. Inc. and DoubleClick Inc. Howard Ullman is of counsel in the firm's San Francisco office.

[1] No. 14-4624 (2d Cir. May 22, 2015) (opinion available here). As of this writing, Actavis's motion for rehearing and rehearing en banc remains pending.

[2] Slip op. at 16.

[3] Id. at 17.

[4] Id.

[5] Id. at 37.

[6] The Court discussed access to IR that Forest made available through a mail order pharmacy and dismissed it as offering a significant supply because of its restrictions. Id. at 20.

[7] A claim under Section 1 and a related claim under New York's antitrust statute, the Donnelly Act, was described as challenging only Forest's relationship with the mail order pharmacy. Id. at 53.

[8] Id. at 22, 24.

[9] Id. at 3.

[10] Id. at 30.

[11] Id. at 36.

[12] Id. at 52 (quoting United States v. Line Material Co., 333 U.S. 287, 308 (1948).

[13] Id. at 37.

[14] The Second Circuit rejected the Drug Manufacturers' argument that the drug substitution laws of at least 20 states would permit generic memantine to be substituted for XR as both untimely and incorrect. Id. at 43.

[15] Id. at 40-41.

[16] Id. at 37.

[17] Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28 (2006); see also 35 U.S.C. § 271(d)(5)

[18] See Slip op. at 15 n.12.

[19] See, e.g., Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co., 2015 U.S. Dist. LEXIS 50026, at *25 (E.D. Pa. Apr. 16, 2015) (concluding that branded Doryx® and its generic do not constitute a relevant product market because other oral tetracycline products prescribed for acne are "interchangeable."

[20] Slip op. at 18.

[21] In an interview following issuance of the Actavis decision, Eric Stock, Chief of the Antitrust Bureau of the New York Attorney General's Office, stated that the Court's opinion "absolutely leaves open the possibility for antitrust challenge to a product switch that does not involve a complete withdrawal of the prior drug from the market." Melissa Lipman, Nameda Isn't End of NY AG's Pharma Work: Antitrust Chief, Law360, May 29, 2015.

[22] The Section 1 claim, involving a side agreement with a mail order pharmacy presented as mitigating the hard switch, was not central to the liability finding. See slip op. at 53.

[23] Slip op. at 32.

[24] The most realistic practical loss of monopoly addressed by the Court of Appeals in Microsoft was that the software market was "uniquely dynamic in the long term," and it dismissed this potential as irrelevant because it would not work "soon," "promptly," or in the "short term" to dissipate any Microsoft monopoly. United States v. Microsoft Corp., 253 F.3d 34, 57 (D.C. Cir. 2001).

[25] Slip op. at 39-42. The Court's conclusion as to the unlikelihood of "reverse commuting" was notably fact-specific. Many pharmaceutical markets, by contrast, reflect quite a bit of fluidity, even as among drugs with different active ingredients. The statin segment may be a good example, in which Lipitor®'s loss of exclusivity profoundly reduced sales of other branded products. The regular changes to preferred drug status in formularies provide other examples. The Second Circuit's conclusion that third-party payors and pharmacy benefit managers are unable to drive the use of generics through formulary placement may thus come as a surprise to the many plans that contain exactly that feature.

[26] Id. at 48.

[27] This market characteristic is so pronounced, industry market research typically tabulates shares separately in terms of total prescriptions during a period and "new" prescriptions.

[28] See id.at 20.

[29] The Microsoft decision is notably pro-enforcement in this regard. The Ninth Circuit has rejected a need for (or the practicality of) trying to balance pro- and anti-competitive effects where non-pretextual justifications have been offered. See Allied Orthopedic Appliances, Inc. v. Tyco Health Care Group, LP., 592 F.3d 991, 1000 (9th Cir. 2010).

[30] Slip op. at 24.

[31] Id. at 45.

[32] Id. at 45-47.

[33] See, e.g., Verizon Communs. Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 (2004).

[34] Slip op. at 35 n.25.
