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Back in the Limelight: Innovation as Antitrust Violation

By Howard Morse and David Burns

Lawyers may not instinctively think about antitrust risk when their clients introduce new products. After all, innovation—building a better mousetrap—is a central aim of antitrust policy and new products are "essential to a dynamic economy" as the Supreme Court recently put it.[1]

But the intersection of innovation and antitrust is increasingly a hot issue in antitrust enforcement, most recently in the pharmaceutical sector, where so-called "product hopping" to new formulations of patent protected drugs has attracted mounting scrutiny.

This was the fact pattern earlier this year in *New York v. Actavis*, where the Second Circuit upheld an injunction requiring a pharmaceutical company to continue to make available an older generation drug until generic firms could enter the market, after the company introduced a new, admittedly improved version of the drug.[2]

While pharmaceutical product hopping has attracted attention over the last few years, the issues—and potential risks—are much broader than drug reformulations. In any industry where product innovation may be used as a tool for exclusion, counsel should remain up to speed with this evolving area of law, both to help formulate strategies to reduce antitrust risk and potentially as a tool for striking back against competitors' exclusionary conduct.

[1] *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877 (2007).

[2] *New York v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015). The defendants had petitioned for review by the Supreme Court but recently settled the suit.

Innovation as Antitrust Violation: What is the Issue?

That innovation may lead to an antitrust violation is counterintuitive. Innovation may at times harm rivals, but this sort of competition on the merits is ordinarily thought of as a good thing, providing variety and improved products to consumers and forcing rivals to improve their own products, all of which furthers the goals of antitrust policy.

Indeed, courts have long recognized the tenet, as the Second Circuit observed over three decades ago, that "any firm, even a monopolist, may generally bring its products to market whenever and however it chooses."[3] In assessing whether Microsoft's software changes violated the antitrust laws, for instance, the starting point for the D.C. Circuit was the deferential admonition that "courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes."[4]

Unilateral conduct by a firm with monopoly power can raise antitrust concerns, however, when used to maintain or extend such power and exclude rivals. While courts are reluctant to condemn innovation, this deference does not necessarily extend to accompanying exclusionary conduct. As the Second Circuit in *Berkey Photo* put it, "it is not the product introduction itself, but some associated conduct, that supplies the violation."

The current hot topic in this space is "product hopping" in the pharmaceutical sector, where efforts by pioneer drug companies to switch patients to new drug formulations as old versions are about to go off patent have increasingly come under attack. In *Actavis*, the all-important fact was that the product redesign was coupled with withdrawal of the legacy drug. The Second Circuit reasoned that while "neither product withdrawal nor product improvement alone is anticompetitive," the combination of the two can "cross the line."

Product redesign as a theory of antitrust liability has deep roots, with cases brought against IBM and AT&T in the 1970s alleging that the introduction of new products made interconnection more difficult or expensive.[5] While there is ample authority that a monopolist has no antitrust duty to help its competitors when introducing a new product, the deliberate creation of incompatibilities for the purpose of foreclosing competition can be exclusionary.

One of the most important precedents is another Second Circuit decision, *Berkey Photo v. Eastman Kodak*, decided in 1979. There, the court reversed a jury verdict in favor of the plaintiff, finding that Kodak's introduction of a redesigned photo system was lawful. It reasoned, however, that the case might have been "completely different" had Kodak coupled the introduction of its new camera system with the withdrawal of its legacy film product. In the court's eyes, such coercion of consumer choice to limit competition, rather than winning on the merits of the innovation, might have been problematic.

More recently, the D.C. Circuit in 2001 found that Microsoft violated the antitrust laws by integrating Internet Explorer into Windows 98, which had "the effect of significantly reducing usage of rival's products." The court acknowledged that the redesign alone was not a violation, noting that in "a competitive market, firms routinely innovate in the hope of appealing to consumers." Nevertheless, the court found the conduct anticompetitive because the change reduced rival share, not because it was "more attractive to consumers," but rather because it discouraged "OEMs from distributing rival products."

Cases alleging anticompetitive product redesign continue to be filed, both in and out of the pharmaceutical sector. Pending multi-district litigation against Keurig Green Mountain over its single serve coffee maker, for instance, includes allegations that as its K-Cup patents were expiring Keurig took steps to foreclose competition by introducing a redesigned coffee maker that only works with K-Cup coffee pods.[6]

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[3] *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979).

[4] *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001).

[5] *See, e.g., Cal. Computer Prods. v. IBM Corp.*, 613 F.2d 727 (9th Cir. 1979); *Ne. Tel. Co. v. AT&T*, 651 F.2d 76 (2d Cir. 1981).

[6] *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litigation*, No. 14-md-02542 (S.D.N.Y. 2014).

Customer Coercion as Guidepost?

Courts only rarely tangle with these thorny issues and, as a result, the line as to when new production introduction violates the law is not always clear. One trend that has emerged in the case law is whether the innovative conduct increases options to customers, or limits options and coerces consumer choice. While the former is ordinarily heralded under the antitrust laws, product development coupled with measures to coerce consumers to use the monopolist's new product at the expense of its legacy rivals can lead to trouble.

Berkey Photo—self-described as "one of the largest and most significant private antitrust suits in history"—usefully illustrates the distinction. The case involved Kodak's introduction of a new photography system, composed of a new "110" camera and Kodacolor II film. Kodak, which had a monopoly share of film sales but not camera sales, initially manufactured its new Kodacolor film to fit only its new 110 cameras and Berkey Photo, a rival producer of the legacy "126" cameras, challenged the conduct as exclusionary. One of its theories was that to enjoy the benefits of the new system, consumers would have to purchase a Kodak 110 camera and not a Berkey camera.

While the jury was sympathetic, awarding nearly $90 million in damages, the Second Circuit reversed, on the grounds that Kodak's "success was not based on any form of coercion." Critical to the court's reasoning was the fact that Kodak's legacy film offerings remained on the market, and consumers thus remained free to choose between the new system and the legacy options. If the new system was popular and generated increased sales at Berkey's expense, the court said, it was only because "some consumers regarded it as superior," and

> [i]f a monopolist's products gain acceptance in the market . . . it is of no importance that a judge or jury may later regard them as inferior, so long as that success was not based on any form of coercion.

The court noted, however, that the "situation might be completely different if . . . Kodak had ceased producing film in the 126 size, thereby compelling camera purchasers to buy a Kodak 110 camera."

This reservation has come to play a key role in later cases, including the recent *Actavis* decision. While recognizing that the introduction of the reformulated drug—a long-acting, extended release version—may well have been procompetitive, the Second Circuit fixated on treatment of the legacy product, finding that its withdrawal from the market would force patients to switch to the new formulation. Thus, unlike in *Berkey Photo*, the "overall effect" was "to coerce consumers rather than persuade them on the merits," which (in the absence of procompetitive justifications) it deemed unlawful.

Other courts have similarly focused on the effect of challenged conduct on consumer choice. Where coercion is lacking because the legacy product remains available, challenges have generally been unsuccessful. In one such case, AstraZeneca introduced and began promoting a newly-approved prescription heartburn medication, Nexium, marketed as "The Purple Pill," just as its long-marketed drug Prilosec, was beginning to face generic competition. The D.C. District Court granted a motion to dismiss, finding that, far from "deliberately limit[ing] . . . consumers' choices," AstraZeneca had actually "added choices" to the market, and thus there was no violation.[7]

Similarly, in 2010, in *Allied Orthopedic*, the Ninth Circuit rejected a claim that Tyco violated the antitrust laws by introducing a new patented pulse oximetry system that was incompatible with generic sensors, just as its legacy product was about to go off patent. Even though Tyco had discontinued its legacy product, the generic entrants were still free to enter the market, and in fact had done so, taking market share. Given the lack of any evidence that Tyco had coerced consumer choice, but in fact had increased it, the court was not at all impressed by the claim.[8]

On the other hand, antitrust challenges have found some success where the monopolist has coerced switching. The *Actavis* case, described above, offers one example. A more extreme example is *Abbott v. Teva*. There, after

[7] *Walgreen Co. v. AstraZeneca Pharms. LP*, 534 F. Supp. 2d 146 (D.D.C. 2008).

[8] *Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP*, 592 F.3d 991 (9th Cir. 2010).

introducing a new formulation, the defendant not only stopped selling the old drug, but also was alleged to have changed the National Drug Data File (NDDF) to obsolete, effectively blocking generic entry and thereby compelling consumers to switch to the new product.[9]

In *Mylan v. Warner Chilcott*, the trial court refused to condemn a pioneer drug company's withdrawing its prior formulation from the market—even where it did so "primarily to defeat generic competition." The judge in that case held that while the generic manufacturer would no longer be able to take advantage of state generic substitution laws, which permit pharmacists to substitute generic drugs even when prescriptions are written for a bioequivalent branded drug, the generic drug had not been excluded as it could still "reach consumers through, *inter alia*, advertising, promotion, cost competition, or superior product development."[10]

In September the FTC filed an *amicus* brief on appeal of *Mylan* to the Third Circuit, urging reversal under a broad standard that conduct by a monopolist to deprive rivals of their "most efficient distribution mechanisms" or to "damage the market for the original formulation" may be unlawful, at least in the absence of countervailing procompetitive justifications.[11]

The FTC's position goes further than the cases discussed above, which generally suggest that antitrust risk is lessened so long as the legacy product remains available. Under the FTC's proposed standard, conduct short of literal withdrawal of the legacy drug—such as raising price before generic entry, or ceasing marketing efforts to encourage switching to a new product—may technically "damage" the legacy market and be deemed unlawful, unless redeemed by proven procompetitive justifications.

Adopting such an expansive view of antitrust liability could have significant ramifications, not only in the pharmaceutical sector, but for product redesigns in any industry. Company antitrust counsel should remain attuned to these developments.

Assessing Superiority and Procompetitive Justifications

Even where product innovation raises the specter of excluding rivals and impeding choice, courts remain highly sensitive to the procompetitive merits of new products and the grave error costs of chilling innovation. As a result, courts are generally unwilling to assess whether a product redesign reflects an improvement over the status quo, instead leaving that to the market.

As the Ninth Circuit observed in *Allied Orthopedic*, there "are no criteria that courts can use to calculate the right amount of innovation" as a "seemingly minor technological improvement today can lead to much greater advances in the future." The Ninth Circuit has thus concluded that "there is no room . . . for balancing the benefits or worth of a product improvement against its anticompetitive effects. If a monopolist's design change is an improvement, it is necessarily tolerated by the antitrust laws, unless the monopolist abuses or leverages its monopoly power in some other way when introducing the product."

On the other hand, in the rare case where the evidence demonstrates that a product redesign had no benefit and was aimed merely at exclusion, the ordinary deference afforded to innovative behavior is likely to evaporate. While, as the D.C. Circuit observed in *Microsoft*, the "focus is upon the effect of that conduct, not upon the intent behind it," corporate counsel should understand that courts may consider intent evidence in evaluating whether the monopolist's conduct likely benefits or harms competition.

The Federal Circuit's decision in *C.R. Bard v. M3 Systems* provides one such example. There, M3 alleged that Bard had modified a biopsy gun, a medical device used to extract body tissue, for the purpose of excluding rival needle manufacturers, such as M3, from the market. The Federal Circuit held that to prevail, M3 was required to prove the modification was made "for predatory reasons, i.e., for the purpose of injuring competitors in the replacement needle market, rather than for improving the operation of the gun."

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[9] *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006).

[10] *Mylan Pharms. v. Warner Chilcott PLC*, No. 12-3824 (E.D. Pa. April 16, 2015).

[11] Brief for the FTC as Amicus Curiae, *Mylan Pharms., Inc. v. Warner Chilcott PLC*, No. 15-2236 (3d Cir. Sept. 30, 2015).

Although Bard claimed that it had modified the gun to make it easier to load and unload, in the court's eyes this was belied by the company's internal documents, which indicated that the modifications "had no effect on gun or needle performance." Given the "substantial evidence" that the "real reasons" for the modification were to increase the cost of entry and exclude rival suppliers of replacement needles, the court found the modifications to constitute "restrictive or exclusionary conduct," in violation of the antitrust laws.

In *Microsoft*, the D.C. Circuit similarly condemned Microsoft's integration of Internet Explorer, finding that Microsoft failed to demonstrate the redesign achieved "any integrative benefit" or served any "purpose other than protecting its operating system monopoly." At the same time, the court reversed the district court's finding of an antitrust violation based on Microsoft's introduction of a modified Java Virtual Machine, finding that while Microsoft may have created incompatibilities, it also allowed applications to run more swiftly.[12]

More frequently, courts consider the benefits not of the challenged innovation itself, but of the associated conduct—for instance, in product hopping cases, the treatment of the legacy drug. In *Actavis*, the court rejected the asserted justifications for pulling the older product—such as supply chain and marketing savings, permitting the company to focus on newer innovations—finding them pretextual in light of the evidence that the withdrawal was actually done to force patients to switch to the new formulation.

The court also relied on other indicators of predatory conduct, including that by withdrawing the legacy product the company had allegedly forsaken short-term profits for an anticompetitive end. This type of evidence could become an even more important factor in future cases.

Key Considerations Going Forward

Innovation as a tool for exclusion has once again become a hot topic in antitrust, and with the New York Attorney General's recent high-profile win in the Second Circuit, additional litigation is likely.

One key piece of guidance that emerges from the case law is that so long as the legacy product remains available to consumers, either from the monopolist or its rivals, the antitrust risk is lessened. Keeping older products on the market may not always be required, but as the cases discussed above demonstrate, doing so may help defeat an antitrust claim.

Prudent companies should also make it a point to emphasize the benefits to customers of new and improved products. While courts are reluctant to condemn innovative conduct, documents extolling the exclusionary effect of proposed new products are at the forefront in those cases where the plaintiff has prevailed.

Counsel with clients outside the pharmaceutical industry, as well as those in the industry would be wise to keep future developments regarding product hopping on their radars, whether to guide strategies to shield against antitrust challenges or as a potential sword to strike out against competitors' conduct.

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[12] *CR Bard v. M3 Systems, Inc.*, 157 F.3d 1340 (Fed. Cir. 1998).