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Antitrust Scrutiny of Pharmaceutical "Product Hopping"

BY M. SEAN ROYALL, ASHLEY E. JOHNSON, AND JASON C. McKENNEY

PATENT AND ANTITRUST LAWS ALIKE are meant to encourage innovation, and for good reason. The U.S. Patent and Trademark Office estimates that innovation has accounted for fully three-quarters of post-World War II economic expansion in the United States.[1] Nonetheless, innovation in the form of new products and product enhancements has at times been attacked under the antitrust laws, and it appears we have reached such a moment in the pharmaceutical industry.

Branded and generic manufacturers compete on an annual basis for roughly $340 billion in U.S. sales and almost $1 trillion globally.[2] As one would hope and expect, this battle is waged in part through branded drug company efforts to develop and release new, improved (and often patent-protected) versions of existing medications. But not all stakeholders agree that this is an inherently good thing. Branded drug companies have increasingly been accused of violating the Sherman Act by using new drug formulations as a tactic to blunt competition from generic rivals.

Such claims have been framed in recent antitrust class action lawsuits and in private suits brought by generic competitors.[3] Likewise, the Federal Trade Commission, joining various antitrust commentators, has expressed concern that the practice of releasing new and improved versions of pre-existing drugs—"product hopping" or "product switching"—can, in certain circumstances, harm competition by complicating or delaying generic entry.[4]

All such claims, to some extent, are predicated upon the regulatory framework governing Food and Drug Administration (FDA) approval of generic drugs in the United States, a framework established by the Hatch-Waxman Act and related regulations, which define a process by which generic drug companies may seek expedited approval to manufacture and sell counterparts to previously approved branded medications.[5] Most product-hopping antitrust claims in effect assert that the branded manufacturer has gamed or manipulated the FDA's regulatory scheme by opportunistically shifting resources to a new FDA-approved drug formulation, while, at the same time, withdrawing support for the prior formulation that faces imminent or nascent competition from generics. The contention is that this type of "product shift" or "product hop" can have the effect of destroying demand for the generic and thus impeding an effective generic product launch. The branded manufacturer's move to a new drug formulation, the theory goes, serves to reset the product market, putting the generic essentially back to square one in its efforts to deliver FDA-approved equivalents to the marketplace.

A common contention in such cases is that the generic drug companies, which keep their costs low in part by not actively marketing their products, are largely at the mercy of their branded competitors, whose continued support for the branded version of the relevant drug is essentially a prerequisite for successful generic entry. Most theories of competitive harm in this area also depend to some extent on skepticism regarding the improved health benefits of new drug formulations—for instance, a change from a lower to a higher dosage, from a capsule to a tablet, or from immediate release to extended release.

This naturally leads to a complicated, and one might say troubling, balancing of the social welfare benefits of marginally improved pharmaceuticals, on the one hand, versus unchanged but somewhat less expensive ones on the other. The risks entailed by antitrust scrutiny of product innovation are well known and largely intuitive,[6] but this has not deterred courts from entertaining Sherman Act challenges based in significant part on product-hopping allegations. Indeed, in one recent case Abbott Laboratories and its co-defendants, after losing a motion for summary judgment, paid $250 million in part to settle such claims,[7] and Warner Chilcott is presently defending a similar case in which the plaintiffs are seeking treble damages potentially reaching into the billions.[8]

The very prospect of a branded drug maker being exposed to treble damages linked to the launch of an FDA-approved new product formulation would be enough to send chills down the spines of many pharmaceutical executives. But the present situation is worse still, considering that the courts have yet to reach any consensus regarding what standards should be applied in judging the merits of such claims.

In one of the original cases alleging anticompetitive innovation, the Second Circuit in *Berkey Photo* held that the successful introduction of a new or improved product, even where it arguably undermines competition, should not give rise to an antitrust cause of action absent some element of

M. Sean Royall is a partner in Gibson Dunn & Crutcher LLP's Dallas and Washington, DC offices and co-chairs the firm's Antitrust and Trade Regulation Practice Group. Mr. Royall has represented branded drug manufacturers in a variety of competition disputes and presently represents Sanofi-Aventis and Allergan in such matters. Ashley E. Johnson and Jason C. McKenney are associates in the firm's Dallas office and have worked with Mr. Royall on various matters representing branded drug manufacturers.

what it meant by coercion, and confusion over this issue has persisted.[10]

Some years later, the D.C. Circuit in *Microsoft* held that product innovations challenged under the antitrust laws should be subjected to a form of rule-of-reason balancing, with the asserted procompetitive benefits of the product improvement being balanced against the alleged anticompetitive effects.[11] These seemingly conflicting standards have never been fully reconciled, and the resulting confusion can be seen in the small handful of court decisions that have addressed pharmaceutical product-hopping claims.

No matter where one stands on the broader issue of product hopping, most would agree that the risks of over-deterrence in this area could be serious, and that caution is warranted.[12] The benefits of generic drug competition are naturally quite significant, but the benefits of new and improved pharmaceutical product formulations are likewise important to our society and economy. The prospect of antitrust courts or agencies weighing these benefits against each other is, to the authors, an uncomfortable proposition. And such concerns are only heightened by the fact that, at present, there remains significant uncertainty in the law, a situation we hope will be corrected by future legal rulings.

The Regulatory Backdrop

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act,[13] attempts to strike a balance between two potentially countervailing public interests—inducing innovation by branded drug companies, and fostering the development of lower-cost generic versions of "innovative" or "pioneer" branded drugs.[14] Under FDA rules, a company seeking approval of a new pharmaceutical must file a New Drug Application (NDA), providing extensive data concerning the efficacy and safety of the product, which can be time-consuming and extremely expensive.[15] Before Hatch-Waxman, an NDA was required for all new drugs, including generic versions of previously approved branded drugs. But Hatch-Waxman enabled generic drug makers to obtain FDA approval through a more streamlined Abbreviated New Drug Application (ANDA) process that omits the need for clinical trials and other costly work required by the standard NDA. Under the FDA's ANDA process, generic drugs may be approved as long as they are shown to be "bioequivalent" to a previously approved branded drug.[16]

Once a generic drug company receives ANDA approval, it may commence marketing its product. Most generic drugs, however, are not marketed in a traditional sense. Generic drug manufacturers customarily do not advertise their products or employ sizable direct sales teams. The standard generic business model, rather than depending on sales and marketing efforts, relies heavily on requirements imposed by state "substitution" laws mandating that pharmacists dispense an available FDA-approved generic drug, unless other sales and marketing support, lower priced generic drugs, once available, typically attract a significant share of sales away from their branded equivalents.[18]

Congress recognized that the enactment of a regime facilitating swifter entry for generic drugs could reduce the incentives of branded drug makers to innovate, inasmuch as accelerated generic competition might prevent branded manufacturers from recouping their research, development, and marketing costs. To address this concern, the Hatch-Waxman Act, among other things, made it easier for branded manufacturers to enforce patents against generic rivals. If the ANDA filer wishes to sell its generic product before the expiration of patents that the branded manufacturer has listed on the FDA's "Orange Book," the ANDA filer must provide a "Paragraph IV certification," confirming that the ANDA product does not infringe or that the relevant patents are otherwise invalid.[19] If the branded manufacturer promptly initiates infringement litigation, this then triggers an automatic 30-month stay of final FDA approval for the generic drug.[20] Another feature of Hatch-Waxman is that the first ANDA filer, once it obtains final FDA approval, is generally entitled to 180 days of market exclusivity before any later ANDA filer with FDA approval is permitted to launch its generic product.[21]

By any measure, Hatch-Waxman has spawned an enormous amount of antitrust litigation and related agency enforcement activity. The most prevalent complaints to date have centered around claims that branded drug companies have improperly invoked Hatch-Waxman 30-month stays through "sham" patent litigation[22] and claims that branded and generic rivals have essentially "conspired" through "pay-for-delay" patent settlements to forestall the onset of generic competition, dividing the alleged gains between them—an issue recently addressed by the Supreme Court in *FTC v. Actavis*.[23] The law applicable to such patent-related antitrust claims has been developing for years, and the standards are now reasonably well settled. By contrast, product-hopping allegations—the latest antitrust outgrowth of Hatch-Waxman—are a relatively recent phenomenon, and the law remains very much in flux.

Current State of the Law on Product Hopping

To the authors' knowledge, there have only been three pharmaceutical product-hopping cases to date that have resulted in substantive court decisions. The first two of these cases—one involving the cholesterol drug TriCor[24] and the other involving the heartburn medications Prilosec and Nexium[25]—dealt with mirror image facts and led to opposite conclusions, one denying a motion to dismiss and the other granting dismissal. From these two decisions alone, one might infer that the viability of product-hopping antitrust claims turns largely on the strength of the facts, including whether the branded manufacturer reinforced its switch to a new product formulation by withdrawing the

limiting consumer choice. But a third and more recent decision, in a case involving the prescription acne medication Doryx,[26] raises more fundamental questions about the merits of "novel"[27] product-hopping allegations and signals a fairly significant degree of skepticism concerning whether a branded drug maker's shift to a new product formulation should ever constitute an antitrust violation. As discussed below, these decisions taken as whole provide relatively little clarity and leave many questions unanswered.

Teva. *Abbott Labsoratories v. Teva Pharmaceuticals USA* appears to have been the first case to squarely frame an antitrust claim predicated on allegations of pharmaceutical product hopping, and it resulted in a somewhat detailed decision denying a motion to dismiss filed by the defendants, the principal defendant being Abbott Laboratories. The plaintiffs asserted that Abbott twice changed its formulation for TriCor (from a capsule to a tablet and later to a new tablet with lower dosage strengths), obtained NDA approval for the product changes, and completed two successive switches to new product formulations in a manner strategically timed, in both instances, to thwart imminent generic competition for the "obsolete" versions of the drug.[28] In both instances, the plaintiffs alleged that Abbott not only stopped selling the prior version of TriCor, but also took the further step of removing the prior formulation from the National Drug Data File (NDDF), a private database of FDA-approved drugs. This further step, plaintiffs alleged, literally prevented pharmacies from filling prescriptions for the superseded formulation or any generic equivalents, making generic substitution no longer possible.[29]

Abbott and its co-defendants, in their motion to dismiss, maintained that even the plaintiffs had acknowledged that the new formulations reflected improvements, however minor, over the prior formulations, and that any product change that introduces an improvement must be per se lawful under the antitrust laws.[30] The defendants also argued that they had no duty to aid competitor. Hence the withdrawal of old TriCor formulations, even if highly disruptive to generic rivals, cannot violate the Sherman Act.[31]

The court in *Teva* rejected these and other defense arguments and in so doing set forth what it deemed to be the appropriate standard for assessing claims of this nature. The starting point for the court's analysis was the Second Circuit's decision in *Berkey Photo, Inc. v. Eastman Kodak Co.*[32] As *Teva* explained, the outcome in *Berkey Photo* (which reversed a plaintiff's jury verdict) turned on one major logical underpinning—the observation that Kodak's challenged new product offerings (the Pocket Instamatic camera and related film cartridges) had gained "acceptance in the market" purely as a consequence of "free choice" by consumers.[33] Notably, in the view of the *Teva* court, it was clear from the facts in *Berkey Photo* that Kodak, upon introducing its new products, "did not remove any other films from the market"[34]; and even more notably, the Second Circuit in deciding *Berkey Photo*

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Kodak "ceased producing film in the [old] size, thereby *compelling* camera purchasers to buy [the new] camera."[35]

Teva fully embraced this dichotomy between "free choice" and "coercion," and largely on this basis the court determined that dismissal was inappropriate, given allegations that Abbott removed the prior drug formulations from the market and changed the NDDF codes. "[S]uch conduct," the court stated, "results in consumer coercion" and "is potentially anticompetitive."[36]

It appears that *Teva*, in line with *Berkey Photo*, would give "judicial deference" to pharmaceutical product shifts that do nothing to disrupt "free consumer choice,"[37] and in this sense the decision may signal an antitrust safe harbor of some sort.[38] But the borders of any such safe harbor, which would turn on distinctions between coercion and free choice, are hardly well defined. Under *Teva*, would a branded drug company have grounds for dismissal if the challenged formulation change was not accompanied by a change in NDDF codes? Would there at least be grounds for dismissal if the prior formulation of the product was not removed from the market? Could it be enough for a plaintiff to defeat dismissal if it alleged that the prior formulation, while still available, was no longer being actively marketed by the branded manufacturer? Is there some other form of alleged "coercion," besides withdrawing support for superseded product formulations that a plaintiff could argue interferes with "free choice" in this context? *Teva* provides no real answers to these questions, which is somewhat troubling, considering that it offers the most detailed judicial commentary to date on this subject.

Teva also plunged headlong down a path that the Second Circuit in *Berkey Photo* was cautious to avoid—the path of balancing the merits of new product innovations against the arguable competitive obstacles such innovations may erect. As *Teva* states, "[T]he Second Circuit refused to weigh the benefits from Kodak's introduction of a new camera model and film format against the alleged harm from the product introduction because that weighing had already occurred in the marketplace."[39] By contrast, the court in *Teva* concluded that an antitrust inquiry probing and comparing the "benefits" and "effects" of the defendants' formulation changes would be appropriate, given plaintiffs' assertion that consumers were deprived of an unfettered choice.[40]

The court in fact was very explicit in concluding that claims of this nature—at least claims that fall outside what-

be decided based on the type of rule-of-reason balancing approach adopted by the D.C. Circuit's decision in *United States v. Microsoft Corp.*[41] Hence, *Teva* (in what may well constitute dicta) suggested that the plaintiff in a pharmaceutical product-hopping case should have an initial burden to "show anticompetitive harm from the formulation changes" and then "that harm" will "be weighed against any benefits presented by" the defendant.[42]

Teva, of course, was a motion to dismiss decision and did not engage in any actual balancing. But to the extent *Teva*'s suggested approach was adopted by later cases, this too seems troubling. Are courts or juries truly in a position to sit in judgment on the merits, including potential therapeutic benefits, of one FDA-approved drug formulation versus another? And even to the extent courts have competence to delve into such questions, how, as a practical matter, does one balance the benefits of a new drug formulation against the arguable effects of reduced competition? As noted above, this could boil down to a choice between marginally improved pharmaceuticals and unchanged but somewhat less expensive ones, matters that arguably exceed the purview of traditional antitrust principles.

Walgreen. *Walgreen Co. v. AstraZeneca Pharmaceuticals*,[43] decided two years after *Teva*, was also a ruling on a motion to dismiss. The case involved allegations that AstraZeneca shifted its resources and began aggressively promoting a newly approved prescription heartburn medication, Nexium, just as its longstanding heartburn drug, Prilosec, was nearing the end of its patent protection and beginning to face generic competition. The plaintiffs alleged that when AstraZeneca began promoting and "detailing" Nexium to doctors, it ceased promoting and detailing Prilosec, but it did not withdraw Prilosec from the market; rather, Prilosec remained available as a prescription capsule, and, in a modified form, as an over-the-counter drug.[44] Nevertheless, the plaintiffs contended that AstraZeneca's efforts to "switch" the market from Prilosec, which faced generic competition, to "a virtually identical" and "no more effective" patent-protected drug, Nexium, constituted a Sherman Act violation.[45]

In granting AstraZeneca's motion to dismiss, the court in *Walgreen* relied heavily on the reasoning in *Teva* and its emphasis on the "critical factor" of consumer choice.[46] In the court's view, this factor distinguished the two cases entirely. Whereas in *Teva* there were allegations that Abbott "sought to defeat competition from generic substitutes" by "deliberately limit[ing] . . . consumers' choices,"[47] based on the facts as alleged in the complaint AstraZeneca had "added choices" by introducing a new drug to compete with its alternative drug, Prilosec, with generic substitutes to Prilosec, and with heartburn medications offered by other manufacturers.[48] Even if, as the plaintiffs claimed, patent-protected Nexium was in no way superior to Prilosec, *Walgreen* stressed that nothing about antitrust law "requires a product new on the market—with or without a patent—to be superior to existing products in the marketplace."[50] And as for the impact of this product switch on the generic competition, the court stated, "The fact that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action."[51]

Taken in combination, *Teva* and *Walgreen* suggest that the introduction of a new FDA-approved prescription drug formulation, and the contemporaneous shift in marketing support from a prior formulation to the new formulation, likely is not enough, taken alone, to support a monopolization complaint, even if the consequence of such a shift is that generic competitors achieve a smaller overall share of sales. To survive a motion to dismiss, there would need to be, in addition, some basis for the plaintiff to credibly allege an actual reduction in consumer choice. In *Walgreen*, there were two reasons why this condition was not met. First, AstraZeneca did not remove Prilosec from the market; the drug continued to be sold, albeit primarily as an over-the-counter drug that was not heavily marketed. But secondly and importantly, there was no allegation that AstraZeneca's actions eliminated the consumer's option to choose a generic alternative. Indeed, the court's decision, citing to the complaint, suggests that generic manufacturers had collectively achieved a 30 percent share of sales.[52]

Teva and *Walgreen* therefore deal with somewhat polar extremes. In the former case, the asserted facts suggest that the defendants effectively eliminated both the prior NDA formulation of TriCor and any generic equivalents. In the latter case, there was no dispute that both the prior formulation and its generic equivalents remained readily available for purchase. Yet there are a number of alternative fact scenarios one could envision. For instance, the branded manufacturer, after launching a new formulation, may choose to cease actively marketing the prior formulation but not immediately remove it from the market, and generic entrants in response might choose to discontinue their efforts to enter. How courts might view this and other potential scenarios is not at all clear based on the combined holdings in *Teva* and *Walgreen*.

Mylan. In another ongoing product-hopping antitrust suit, *Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Limited Co.*, the district court recently denied a motion to dismiss.[53] Interestingly the court's order placed no reliance on either *Teva* or *Walgreen*, and seemed to signal views at odds with the approaches adopted by those prior decisions.

The asserted facts in *Mylan* fall somewhere between the fact patterns presented in *Teva* and *Walgreen*. The complaint alleges that Warner Chilcott and its co-defendants engaged in a conscious strategy to prevent or delay generic competition for the company's branded Doryx medication by executing at least three distinct product switches—first from a capsule to a tablet, then from 75mg and 100mg tablets to a single 150mg dosage strength, and finally from a single-scored version of the 150mg tablet to a dual-scored version.[54] "[T]hese

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apeutic benefit to consumers," but "devastated the market for the prior versions of Doryx," which Warner Chilcott ceased promoting and eventually withdrew from the market, thereby "forc[ing] generic manufacturers such as Mylan to change their products in development" in an effort to align their generic offerings with the currently promoted version of the branded drug.[55] Unlike *Teva*, however, there is no allegation in *Mylan* that Warner Chilcott changed NDDF codes in a manner that might preclude generic substitution. In fact, the complaint appears to acknowledge that Mylan successfully developed and at least initially launched several generic formulations.[56]

In moving to dismiss, the defendants argued, among other things, that Mylan's claims boiled down to a contention that branded drug companies have a duty to continue promoting outdated formulations to permit generic competitors to take advantage of automatic substitution laws. But, the defendants maintained, nothing in the antitrust laws suggests that such a duty either does or should exist.[57] On the contrary, the defendants argued, antitrust law suggests that this type of "free riding" is "'the antithesis of competition.'"[58]

The defendants also used their motion to dismiss to make a pointed attack against Mylan and its generic business model. In the opening paragraphs of their motion, the defendants contend that Mylan is one of the world's largest pharmaceutical companies, fully twice the size of Warner Chilcott, and that the company has ample resources to actively promote its generic products without relying entirely on state substitution laws, if it so chose.[59]

Had the court in *Mylan* followed the approach of *Teva* and *Walgreen*, it might have focused on Warner Chilcott's alleged decisions to phase out prior formulations and the extent to which this deprived consumers of choices. But there is no mention of such concepts in the *Mylan* dismissal order. The court instead summarized the defendants' principal grounds for dismissal, and commented that "[d]efendants' contentions, if correct, *appear compelling*."[60] This included the defendants' claims that "their product changes . . . did nothing to block generic firms from competing" but "merely precluded generic firms from taking advantage of automatic substitution laws"; the defendants' contention that if "generic firms cannot advertise their products to compete successfully with Doryx" this may simply "reveal a problem with the generics' business models" or with the relevant "regulatory regimes"; and the defendants' overarching claim that Mylan's "'novel' at best," fails to state "an antitrust injury."[61] In closing, the court's order stated, "Although I am skeptical that the 'product hopping' alleged here constitutes anticompetitive conduct under the Sherman Act, I cannot definitively address that question without going beyond the pleadings."[62] This was, to say the least, a marked departure from *Walgreen* and *Teva*.

The *Mylan* court's dismissal decision, while perhaps sending a promising sign to those who oppose antitrust scrutiny of product hopping, does little to clarify the law. Indeed, if anything, the dramatically different tone struck by the court's decision in comparison to *Teva* and *Walgreen* underscores how far we are at present from anything approaching a judicial consensus.

The FTC's Stance on Product Hopping

FTC interest in the product-hopping issue dates back to at least 2006. In that year, the FTC filed a preliminary injunction motion in federal court seeking to bar Warner Chilcott from following through with an apparent plan to withdraw an existing tablet formulation of its birth control product Ovcon coinciding with the launch of a new chewable version of the same product.[63] The issue arose in connection with an already pending suit in which the FTC's complaint alleged that Warner Chilcott and generic manufacturer Barr Pharmaceuticals had entered an agreement that would serve to delay generic competition for Ovcon. And the final order by which the litigation was settled included additional terms that in essence required Warner Chilcott to continue supporting the non-chewable tablet form of Ovcon, including requirements that Warner Chilcott not change the relevant NDDF codes or, for a period of three months, destroy inventory or buy back product already distributed to customers.[64]

The product-hopping issue has also surfaced at times in statements by various FTC commissioners. In 2007, then-FTC Chairman Deborah Platt Majoras, in a carefully worded statement, flagged the issue as one the Commission was "following."[65] A year later, then-FTC Commissioner and former FTC Chairman Jon Leibowitz signaled a potentially greater degree of FTC concern, mentioning product hopping as one example of "strategies used in connection with launching a new [pharmaceutical] product" that "seem to serve no purpose other than to undermine the ability of a generic to compete."[66] Leibowitz also suggested, consistent with the general subject of his remarks, that this could be an area where it might "make sense to apply" the FTC's expanded Section 5 enforcement authority.[67]

Most recently, in late 2012 the agency took the unusual step of filing a fairly lengthy amicus brief in connection with the district court's consideration of Warner Chilcott's motion to dismiss in the *Mylan* case.[68] The stated purposes of the brief were to present "background and analysis" on the nature and importance of generic competition and to address "the appropriate antitrust framework" for evaluating claims that

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