IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC., et al.,	)	
Plaintiffs,	)	**Civil Action No. 12-3824**
	)	**CONSOLIDATED**
v.	)	
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,	)	
Defendants.	)	

FEDERAL TRADE COMMISSION BRIEF AS *AMICUS CURIAE*

RICHARD A. FEINSTEIN
Director
Bureau of Competition

PETER J. LEVITAS
Deputy Director
Bureau of Competition

DAVID C. SHONKA
Acting General Counsel
Federal Trade Commission

MARKUS H. MEIER
BRADLEY S. ALBERT
HEATHER M. JOHNSON
KARA LEE MONAHAN
Attorneys for *Amicus Curiae*
Federal Trade Commission
600 Pennsylvania Avenue N.W.
Washington, D.C. 20580
Telephone: (202) 326-3759
Facsimile: (202) 326-3384
mmeier@ftc.gov

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Competition from lower-priced generic drugs saves American consumers billions of dollars a year. These consumer savings, however, mean lower profits for brand drug companies. It is well-established that when generic entry occurs, the brand drug company suffers a rapid and steep decline in sales and profits. The threat of generic competition thus creates a powerful incentive for brand companies to protect their revenue streams. This incentive can prompt brand companies to create innovative new products that offer medical benefits to patients. But it may also drive brand companies to seek to obstruct generic drug competition by making modest product reformulations that offer patients little or no therapeutic advantages.

Such tactics, often referred to as product-switching or product-hopping, can be an effective way to game the regulatory structure that governs the approval and sale of generic drugs, thereby frustrating the efforts of federal and state policymakers to facilitate price competition in pharmaceutical markets. As discussed below, a brand company can interfere with the mechanism by which generic drugs compete by making modest non-therapeutic changes to its product, and effectively prevent generic competition, not because the reformulated product is preferred by consumers, but simply because it is different.

Plaintiffs allege that Warner Chilcott engaged in a pattern of product-switching, introducing three successive product reformulations that, according to their complaints, offered little or no apparent medical benefit to consumers. Each reformulation, plaintiffs allege, was designed to, and did, impede meaningful generic competition and preserve Warner Chilcott's monopoly profits not on the merits of the reformulations, but by manipulating the pharmaceutical regulatory system. Warner Chilcott has moved to dismiss the complaints, asserting that the introduction of a new product is essentially per se legal. While courts are properly cautious when confronting antitrust challenges to new product introductions, "[j]udicial deference to

product innovation. . . does not mean that a monopolist's product design decisions are per se lawful."[1]

A key issue raised by Warner Chilcott's motion to dismiss is whether plaintiffs have plausibly alleged exclusionary conduct sufficient to state a claim under Section 2 of the Sherman Act.[2] Assessing the plausibility of these allegations requires an understanding of the history and context of the federal and state regulations affecting generic drug competition in the pharmaceutical industry.[3] The Federal Trade Commission submits this brief as amicus curiae to assist the Court in this assessment. The Commission presents background and analysis on the role of generics in creating price competition in the pharmaceutical sector and the federal and state laws that promote generic competition. In addition, the Commission addresses the appropriate antitrust framework to apply when assessing allegations that a brand drug reformulation unlawfully delayed or inhibited generic competition.

I. Interest of the Federal Trade Commission

The FTC is an independent agency charged by Congress with protecting the interests of consumers by enforcing competition and consumer protection laws.[4] It exercises primary responsibility over federal antitrust enforcement in the pharmaceutical industry.[5] The Commission has substantial experience considering and analyzing the balance between antitrust

---

[1] *United States v. Microsoft*, 253 F.3d 34, 65 (D.C. Cir. 2001) (en banc).

[2] For purposes of this brief, we accept the allegations in Mylan's complaint as true, as is appropriate for a motion to dismiss. The FTC takes no position on the merits of Mylan's allegations.

[3] *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 567 (2007) (considering the history and context of the highly regulated telecommunications industry in assessing the plausibility of a complaint).

[4] 15 U.S.C.§§ 41-58.

[5] For a summary of the FTC's antitrust actions in the pharmaceutical industry, *see Overview of FTC Antitrust Actions in Pharmaceutical Services and Products* (June 2012), available at http://www.ftc.gov/bc/healthcare/antitrust/rxupdate.pdf.

and intellectual property laws[6] and the impact of the Hatch-Waxman Act on competition in the pharmaceutical industry.[7]

In addition to its role as a law enforcement agency, the FTC has a congressionally-mandated role to conduct studies of industry-wide competition issues. To fulfill this role, Congress granted the agency broad authority to compel the production of data and information not directly related to any law enforcement investigation.[8] As an American Bar Association report observed, this authority gives the agency a unique capacity to conduct "systematic, institutional stud[ies] of real-world industries and activities" that "modern academic research in industrial organization rarely undertakes."[9] Courts, including the Supreme Court, have relied on FTC studies when resolving legal and policy issues.[10]

---

[6] *See, e.g.*, Federal Trade Commission, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* (2011) (http://www.ftc.gov/os/2011/03/110307patentreport.pdf); U.S. Department of Justice & Federal Trade Commission, *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition* (2007)(http://www.ftc.gov/reports/innovation/P040101PromotingInnovationandCompetitionrpt0704.pdf); Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) (www.ftc.gov/os/2003/10/innovationrpt.pdf); U.S. Department of Justice & Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995) (www.usdoj.gov/atr/public/guidelines/0558.htm).

[7] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (codified at various sections of Titles 15, 21, and 35 of the U.S. Code).

[8] The FTC has authority "[t]o require, by general or special orders, persons, partnerships, and corporations, engaged in or whose business affects commerce . . . to file with the Commission in such form as the Commission may prescribe . . . reports or answers in writing to specific questions, furnishing to the Commission such information as it may require as to the organization, business, conduct, practices, management, and relation to other corporations, partnerships, and individuals." 15 U.S.C. § 46(b).

[9] *Report of the American Bar Association Section of Antitrust Law Special Committee to Study the Role of the Federal Trade Commission*, 58 Antitrust L.J. 43, 103 (1989).

[10] *See, e.g., Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, — U.S. —, 132 S. Ct. 1670, 1678 (2012) (citing an FTC study on generic pharmaceuticals); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 396 (2006) (Kennedy, J. concurring) (citing an FTC study on the proper balance between competition and patent law); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer*

The Commission has conducted a variety of empirical studies covering the pharmaceutical industry generally and generic substitution for brand drug prescriptions in particular.[11] The FTC's 1979 "Drug Product Selection" report examined the effect of legislative barriers to generic market entry at the state level, which imposed significant costs on consumers by unnecessarily restricting pharmaceutical price competition.[12] In 1985, the FTC published a comprehensive report analyzing the impact of state legislative initiatives designed to expand generic competition and drive down overall prescription drug prices.[13] These reports reflect the Commission's long-standing interest in and study of generic drug competition and the legislative measures designed to encourage it.

II. Competition in the Pharmaceutical Industry

Today, generic drugs play a crucial role in containing rising prescription drug costs by offering consumers therapeutically identical alternatives to brand drugs at a significantly reduced cost.[14] This was not always the case, however. In the late 1970s, two legal barriers limited

---

Council, Inc., 425 U.S. 748, 754 n.11, 765 n.20 (1976) (referring to an FTC study concerning drug price advertising restrictions).

[11] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011), *available at* http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf (hereinafter AG Report); FTC, *Pay-For-Delay: How Drug Company Pay-offs Cost Consumers Billions* (2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf (hereinafter Pay for Delay); FTC, *Emerging Health Care Issues: Follow-on Biologic Drug Competition* (June 2009), available at http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf.

[12] *Drug Product Selection*, Staff Report to the FTC, Bureau of Consumer Protection (Jan. 1979) (hereinafter Drug Product Selection).

[13] Allison Masson & Robert L. Steiner, FTC, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* at 8-13 (September 1985) (hereinafter Masson & Steiner).

[14] *See e.g.*, KaiserEDU.org, *Prescription Drug Costs*, *available at* http://www.kaiseredu.org /Issue-Modules/Prescription-Drug-Costs/Background-Brief.aspx (explaining that "increases in prescription drug costs have outpaced other categories of health care spending" in the past two

generic competition: (1) the costly and lengthy FDA approval process and (2) state anti-substitution laws that restricted generic sales.[15] Congress remedied the first issue through the Hatch-Waxman Act; state legislatures remedied the second issue through drug substitution law reform.

In 1984, Congress passed the Hatch-Waxman Act, which was designed to foster the entry of low-cost generic drugs without sacrificing the incentives for pharmaceutical companies to invest in developing new drugs.[16] This Act provides for accelerated approval of generic drugs by the FDA through an Abbreviated New Drug Application (ANDA), upon a showing that the generic drug is bioequivalent to its brand drug counterpart. 21 U.S.C. § 355(j). A generic drug is considered bioequivalent or "AB-rated" if it contains the same active pharmaceutical ingredient as the brand drug, is the same dosage and form, and exhibits a similar rate and extent of absorption as the brand product.[17] Allowing generic manufacturers to rely on brands' safety and efficacy studies significantly reduced generic drug development costs and expedited the FDA approval process.[18]

---

decades and that prescription drug costs are "projected to exceed the growth rates for hospital care and other professional services in 2010 and through 2019") (last visited Nov. 14, 2012).

[15] In the early 1980s, 150 drugs whose patent terms had expired did not face generic competition. Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 Fla. L. Rev. 1009, 1013 (Sept. 2010).

[16] H.R. Rep. No. 98-857, Pt. 1, p. 14-17 (1984). The Act safeguards brand patent rights by affording a patent holder the opportunity to trigger a 30-month stay on FDA approval of a generic drug so that it may attempt to enforce its patents through litigation. 21 U.S.C. § 355(j)(5)(B)(iii).

[17] FDA Center for Drug Evaluation and Research, Approved Drug Products with Therapeutic Equivalence Evaluations (32d ed.), http://www.fda.gov/drugs/developmentapprovalprocess /ucm079068.htm (last visited October 11, 2012).

[18] 21 U.S.C. §§ 355 (j)(2)(A)(ii), (iii), (iv).

As to the second barrier, anti-substitution laws in effect in most states in the 1970s prohibited pharmacists from substituting a generic version of a brand drug at the pharmacy counter. These laws reinforced an existing feature of prescription drug markets that already significantly limited price competition: The physician – who selects the drug product but does not pay for it – has little incentive to consider price when deciding which drug to prescribe. In its Drug Product Selection Report, the FTC explained this basic problem:

> [T]he 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 prescriptions.[19]

Given this feature, it is not surprising that studies have consistently shown that physicians are not well-informed about the price of existing products or the availability of cheaper alternatives.[20]

In 1979, the FTC and FDA published a model state drug substitution law to allow pharmacy substitution among bioequivalent products. State legislatures responded with legal reforms to promote access to generic drugs. Today, all states facilitate competition through laws that allow a pharmacist to substitute an AB-rated generic drug when presented with a prescription for its brand equivalent, unless a physician directs or the patient requests otherwise. These state substitution laws "foster price competition by allowing the only principals who have financial incentives to make price comparisons – the pharmacist and the patient – to select drug

[19] Drug Product Selection, *supra* note 12, at 2-3.

[20] Fiona M. Scott Morton, *Barriers to Entry, Brand Advertising, and Generic Entry in the US Pharmaceutical Industry*, 18 Int'l J. Indus. Org. 1085, 1086-87 (2000); *see also, e.g.*, G. Michael Allen et al., *Physician Awareness of Drugs Cost: A Systematic Review*, 4 PLOS Med. 1486, 1486 (2007) (reviewing studies over the last ten years and concluding the doctors overestimated prices of inexpensive products and underestimate the prices of expensive ones).

products on the basis of price."[21] Together, the Hatch-Waxman Act and the state substitution laws create a regulatory framework designed to reduce costs for consumers by lowering generic costs and increasing the role of price at the retail pharmacy counter. Whatever "free-riding" occurs (Defs. Br. Mot. Dismiss 23-24) is the intended result of the legislative framework of the Hatch-Waxman Act and the state substitution laws.

The Hatch-Waxman Act and state substitution law reforms have been remarkably successful in facilitating generic competition and generating large savings for patients, health care plans, and federal and state governments. The first generic competitor's product is typically offered at a 20% to 30% discount to the brand product.[22] Subsequent generic entry creates greater price competition, with discounts of 85% or more off the price of the brand name drug.[23] A recent study of 5.6 million prescriptions revealed that patients and their insurance plans respectively paid an average of $17.90 and $26.67 for generic drugs and an average of $49.50 and $158.25 for brand drugs where no generic existed.[24] In 2011 alone, the use of generic drugs generated $192 billion in total consumer savings.[25]

While generic alternatives save consumers billions of dollars, these savings come at the expense of additional profits to brand companies. As a result of lower prices and ease of substitution, many consumers routinely switch from the brand drug to a bioequivalent generic

---

[21] Drug Product Selection, *supra* note 12, at 7.

[22] AG Report, *supra* note 11, at ii-iii.

[23] Pay for Delay, *supra* note 11, at 8 ("in a mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug price"); *see also* FDA, Facts About Generic Drugs, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm (last visited Nov. 14, 2012).

[24] William H. Shrank et al., *The Consequences of Requesting "Dispense as Written,"* 124 Am. J. Med. 309, 311 (2011).

[25] Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.* (4th ed. 2012) at 2.

drug upon its introduction. Consequently, bioequivalent generic drugs typically capture over 80% of a brand drug's sales within six months of market entry.[26] As just one example, the brand osteoporosis drug Fosamax, which had over $1.5 billion in annual sales prior to generic entry, lost 84% of its retail market share just 30 days after generic entry.[27]

The threat posed to existing brand drugs by generic competition can incentivize the brand company facing dramatic loss of sales to develop new and innovative drugs that benefit consumers. This threat can also incentivize the brand company to engage in a strategy known as "product switching," or "product hopping" to impede generic substitution and thus meaningful generic competition. Product-hopping can work in the following way: first, the brand manufacturer makes minor non-therapeutic changes to the brand product, such as a dosage or form change. Next, prior to generic entry, it removes the original product from the marketplace, or accomplishes this indirectly, such as by recalling supply of the original product or raising the price of the original product by a meaningful amount above the reformulated one.[28] Such conduct can push patients and physicians to abandon the original product. In this way, a brand manufacturer can convert existing market demand for the original product to its reformulated product – not because physicians and patients prefer it, but simply because the original product is no longer as available or is more costly.[29] Once the original version of the brand product is less

---

[26] AG Report, *supra* note 11, Ch. 4, n. 6; *see also The Use of Medicines in the United States: Review of 2010*, IMS Institute for Healthcare Informatics, at 3 (April 2011), available at http://www.imshealth.com/imshealth/Global/Content/IMS%20Institute/Documents/IHII_UseOfMed_report%20.pdf.

[27] AG Report, *supra* note 11, Ch. 4, n.7.

[28] Carrier, *supra* note 15, at 1025-27, 1035.

[29] While it is true that physicians are typically uninformed about drug prices and do not price compare between products, they may be persuaded by the claim made by brand companies: that the reformulated product is equal to or better than the original version at a lower price to the consumer. *See id*.

available or more expensive, physicians will stop writing prescriptions for it. Because the prescription must contain, among other things, the same dosage and form as the generic for a pharmacist to substitute it for the brand, a product-switch will effectively eliminate substitution at the pharmacy counter and thus meaningful generic competition. As the author of the leading antitrust treatise put it: "Product-hopping seems clearly to be an effort to game the rather intricate FDA rules. . . . The patentee is making a product change with no technological benefit solely in order to delay competition."[30]

As a practical matter, if a generic cannot be substituted at the pharmacy counter, the economically meaningful market for the generic product disappears. Generic substitution is based, in part, on the premise that generic products will not be promoted like brand drugs. While the generic can attempt to market a non-substitutable generic product directly to prescribing physicians, such a costly undertaking undermines the ability of generic companies to offer the lower price benefits that the federal and state regulatory framework was intended to foster.[31] Moreover, such marketing, even if effective in causing physicians to prescribe the particular company's generic product, does not guarantee the sale of that product when the patient goes to the pharmacy. The pharmacy may stock a different company's generic and unless the physician has ordered "dispense as written" the pharmacy can fill the prescription with the alternative generic. Indeed, a company that does not bear the cost of such marketing to physicians is likely

[30] Hovenkamp et al, *IP and Antitrust*, 2d. Ed. (2010) § 15.3 at 15-75.

[31] Indeed, the promotional budgets for brand pharmaceutical companies are large and can be double the research and development budgets. *See e.g.*, Marc-André Gagnon, Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLoS Med 32 (Jan. 2008).

to offer a lower-priced generic product.[32] Thus, by definition and design generic drugs are lower-cost substitutes that do not compete with the promotional efforts of brand drug firms. If the brand manufacturer reformulates its product before a generic receives FDA approval, the generic's only practical option is to go back to the drawing board and reformulate its own product to be bioequivalent to the brand reformulation and thus substitutable at the pharmacy.

III. Pharmaceutical Product Redesigns Can Constitute Exclusionary Conduct

Plaintiffs allege, among other things, that Warner Chilcott maintained its monopoly in the Doryx market by suppressing competition from lower-priced generic versions of the drug in violation of Section 2 of the Sherman Act. A monopolization offense has two basic elements: "(1) the possession of monopoly power in the relevant market, and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). A central issue raised by Warner Chilcott's motion to dismiss is whether plaintiffs have adequately alleged that Warner Chilcott maintained its monopoly power through exclusionary conduct.[33]

Generally speaking, "[a] monopolist willfully acquires or maintains monopoly power when it competes on some basis other than the merits." *LePage's Inc., v. 3M*, 324 F.3d 141, 147 (3d Cir. 2003). Specifically, exclusionary conduct involves "behavior that not only (1) tends to impair the opportunities of rivals, but also (2) either does not further competition on the merits or does so in an unnecessarily restrictive way." *Aspen Skiing Co. v. Aspen Highlands Corp.*, 472

[32] Under the drug substitution laws, a pharmacy has the incentive to stock only the lowest priced generic drug to increase the pharmacy's own margins. Masson & Steiner, *supra* note 13, at 7, 35-39.

[33] The FTC does not address Warner Chilcott's additional contention that plaintiffs have failed adequately to allege monopoly power.

U.S. 585, 605 n.32 (1985). Such conduct is condemned under Section 2 of the Sherman Act when its anticompetitive effects outweigh its procompetitive benefits. *See United States v. Microsoft Corp.*, 253 F.3d 34, 58-59 (D.C. Cir 2001) (en banc). Traditional Section 2 analysis therefore involves a balancing test that is inherently fact-intensive and depends on the specific context of the conduct involved. *LePage's*, 324 F.3d at 152. It also must be guided by the "economic realities" of the industry at issue. *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005). Applying this fact-intensive analysis, the Third Circuit has found a broad range of conduct to be unlawfully exclusionary.[34]

The basic premise of Warner Chilcott's motion to dismiss is that product changes or redesigns can never constitute exclusionary conduct. According to Warner Chilcott, "such conduct is either competition-enhancing (if the new version represented an improvement) or at worst competition-neutral because one version was replaced by another." (Defs.' Br. Mot. Dismiss 21.) To be sure, product changes are often procompetitive. As the Second Circuit explained in *Berkey Photo, Inc. v. Eastman Kodak Co.*, "a monopolist is permitted, and indeed encouraged . . . to compete aggressively on the merits, [and] any success that it may achieve through the process of invention and innovation is clearly tolerated by the antitrust laws." 603 F.2d 263, 281 (2d Cir. 1979). Accordingly, "[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.

[34] *See Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297 (3d Cir. 2007) (patent holder engaging in deceptive conduct before standard-setting organization); *Dentsply*, 399 F.3d at 181 (exclusive contracts denying access to a particular distribution channel); *LePage's*, 324 F.3d at 141 (exclusive dealing and bundled rebates); *Mannington Mills, Inc. v. Congoleum Indus., Inc.*, 610 F.2d 1059 (3d Cir. 1979) (patent licensing practices); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978) (bundling of pharmaceutical products).

Nonetheless, it is well-established that a monopolist's product change can violate the antitrust laws. "Judicial deference to product innovation . . . does not mean that a monopolist's product design decisions are per se lawful." *Id.* For example, in *Microsoft*, the *en banc* D.C. Circuit unanimously affirmed the holding that two design changes by Microsoft to its software violated the Sherman Act because they had no "procompetitive justification," and served no purpose "other than protecting [Microsoft's] operating system monopoly." *Id.* at 59, 66-67. And in *C.R. Bard*, the Federal Circuit similarly affirmed a monopolization verdict based on the jury's finding that Bard modified its product to injure competitors rather than to improve the product. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1382 (Fed. Cir. 1988).[35]

The potential for anticompetitive product redesign is particularly acute in the pharmaceutical industry. In most other industries, the success of a new product in the marketplace reflects consumer choice. Courts are properly reluctant to question the innovative value of a new product in those circumstances. *See Berkey Photo*, 603 F.2d at 286-87 ("If 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"). In the pharmaceutical industry, however, the success of a product-switching scheme does not depend on whether consumers prefer the reformulated version of the product over the original, or whether the reformulated version provides any medical benefit. Instead, as the district court in *Abbott Labs v. Teva (Tricor)* explained, "[t]he

[35] *See also Xerox Corp. v. Media Scis. Int'l, Inc.*, 511 F. Supp. 2d 372, 387 (S.D.N.Y 2007) ("several courts have found that product redesign, when it suppresses competition and is without other justification, can be violative of the antitrust laws"); *Berkey Photo*, 603 F.2d at 286 n.30 ("This is not to say, of course that new product introductions are ipso facto immune from antitrust scrutiny . . . . [I]n all such cases, however, it is not the product introduction itself but some associated conduct that supplies the violation."); Hovenkamp, *supra* note 30, § 15.3 at 15-75.

nature of the pharmaceutical drug market" does not always permit "the merits of any new product [to] be tested by unfettered consumer choice."[36]

For example, prior to facing generic competition, a brand company can introduce a reformulated product, and simply withdraw the original product, as the plaintiffs alleged in *Tricor*. In such a situation, consumers do not choose the reformulated product based on its merits; instead, the brand forces the switch by removing the product from the market and preventing consumers from weighing the relative merits of competing products. A brand company can achieve the same result through indirect means (such as by raising the price of the original product by a meaningful amount or by creating supply shortages of the original product prior to facing generic competition) so that there is effectively no longer a market for the original product when a generic would be ready to enter.

In *Tricor*, the district court denied a motion to dismiss where the brand company argued that its product changes were per se lawful – the same argument Warner Chilcott advances here. Instead, the court held that the relevant antitrust inquiry should assess whether the consumer harm created by lost generic competition outweighed the procompetitive benefit of the product reformulation.[37] The court further rejected the suggestion that plaintiffs were required to prove that the "new formulations were absolutely no better than the prior version or that the only purpose of the innovation was to eliminate the complementary product of a rival."[38] Instead, the court explained, "as in *Microsoft*, if plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by defendants."[39]

---

[36] *Abbott Labs v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 422 (D. Del. 2006).

[37] *Id.*

[38] *Id.*

[39] *Id.*

The FTC respectfully submits that, like the plaintiffs in *Tricor,* plaintiffs in this case have stated a plausible claim that defendants' product reformulations constitute an unlawful means of preserving monopoly power in violation of Section 2 of the Sherman Act. Plaintiffs allege that Warner Chilcott effectuated three successive product reformulations to impede generic substitution (Mylan's Compl. ¶¶ 2, 52-56, 61-72); that Warner Chilcott effectively converted the market from the prior Doryx version to the reformulated version in advance of generic entry by, among other things, discontinuing the sale of the prior version (Mylan's Compl. ¶¶ 49, 54), asking its major customers to return inventory of the prior version (Mylan's Compl. ¶ 67) or otherwise making the prior versions less available (Mylan's Compl. ¶ 63); that the reformulated products "provided little or no benefit other than to exclude generic competition from the market" (Mylan's Compl. ¶¶ 55, 75); and that Warner Chilcott's conduct "precluded and/or reduced, rather than expanded consumer choice." (Mylan's Compl. ¶ 82). The allegations that defendants used product reformulations to manipulate the pharmaceutical regulatory system and thereby suppress generic competition are sufficient to state a claim of exclusionary conduct. Applying a per se legal standard, as Warner Chilcott effectively advances here, would entitle brand pharmaceutical companies, as a matter of law, to manipulate the FDA regulatory process and undermine state and federal laws that encourage generic competition.

IV. Conclusion

The FTC respectfully requests that the Court carefully consider the history and context of the federal and state regulations affecting generic drug competition in the pharmaceutical industry when considering the allegations in plaintiffs' complaints. The FTC would be pleased to address any questions the Court may have, including by participation at any hearing, should the Court find it useful.

Dated: November 21, 2012

Respectfully submitted,

RICHARD A. FEINSTEIN
Director
Bureau of Competition

PETER J. LEVITAS
Deputy Director
Bureau of Competition

DAVID C. SHONKA
Acting General Counsel
Federal Trade Commission

MARKUS H. MEIER
BRADLEY S. ALBERT
HEATHER M. JOHNSON
KARA LEE MONAHAN
Attorneys for *Amicus Curiae*
Federal Trade Commission
600 Pennsylvania Avenue N.W.
Washington, D.C. 20580
Telephone: (202) 326-3759
Facsimile: (202) 326-3384
mmeier@ftc.gov