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

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

FEDERAL TRADE COMMISSION'S BRIEF AS AMICUS CURIAE

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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 re

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

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].

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[6] See, e.g., FTC,

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.

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 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

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

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 to 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 inte

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]

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

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 thus has 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

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 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), and 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,

/s/ Markus H. Meier