IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN PHARMACEUTICALS INC.,

Plaintiff,

v.

KATHLEEN SEBELIUS, *et al.*

Defendants,

TEVA PHARMACEUTICALS USA, INC.

and

CEPHALON, INC.

Defendant-Intervenors.

Civil Action No. 1:12-cv-00524-ESH

FEDERAL TRADE COMMISSION CORRECTED BRIEF AS *AMICUS CURIAE*

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This case presents an important issue of first impression: Can the Food and Drug Administration, consistent with the Hatch-Waxman Act, give a branded drug seller sole control of the 180-day generic exclusivity rights designed to create competition between the branded drug and its generic equivalents? The resolution of this question will likely have substantial effects on consumer welfare in the market for the sleep disorder drug Provigil and its generic equivalents, and on generic drug competition generally.

Mylan's primary attack on FDA's award of exclusivity to Teva is its contention that – due to Teva Pharmaceutical Industries Ltd.'s 2011 acquisition of Cephalon, which has owned and marketed Provigil since 1998 – Teva is disqualified from holding those exclusivity rights.[1] Mylan asserts that FDA's decision to grant exclusivity to the seller of the branded drug fundamentally contradicts the statutory framework that Congress enacted to speed low-cost generic drugs to market and is thus arbitrary and capricious. The FTC's concern is that giving the brand sole control over generic competition eviscerates the competitive incentives in the Hatch-Waxman Act. Various decisions in this Circuit[2] have warned against interpretations of

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[1] As used herein, "Teva" means Teva Pharmaceutical Industries Ltd. and all of its wholly-owned subsidiaries, including Teva Pharmaceuticals USA, Inc. ("Teva USA") and, since October 2011, Cephalon, Inc.

[2] *See, e.g., Mylan Pharms. Inc. v. Henney*, 94 F. Supp. 2d 36, 54 (D.D.C. 2000) (rejecting FDA interpretation that "places the decision as to whether a generic manufacturer will be entitled to exclusivity entirely in the hands of the patent holder"); *Inwood Labs. v. Young*, 723 F. Supp. 1523, 1527 (D.D.C. 1989) ("By subjecting the exclusivity entitlement to the caprices of the patent holder, FDA's interpretation would seem to affect adversely the incentives that Congress sought to create in providing for 180 days of exclusivity for the manufacturers of generic drugs."), *vacating as moot*, 43 F.3d 712 (D.C. Cir. 1989). *See also Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1317-18 (D.C. Cir. 2010) (noting the "incentives for the brand manufacturer" to take action "where its impact on Congress's scheme is most destructive").

the Hatch-Waxman Act that would place decisions about the exercise of generic exclusivity rights in the hands of branded drug firms. Even Teva has recognized this principle in the past.[3]

But no court has faced the precise question that Mylan's challenge poses. FDA has acknowledged not only that the situation presented here is without precedent, but also that putting the brand drug manufacturer in control of the generic exclusivity period "appears to thwart the Hatch-Waxman Amendments' goal of bringing more generic drugs to market faster."[4] Both FDA and Teva agree that the Act is silent on this novel question.[5] The FTC agrees that the situation is unprecedented. Teva, by virtue of its acquisition of Cephalon, is currently asserting its Provigil patents are valid and infringed in another federal court while simultaneously maintaining before FDA and this Court, by virtue of its Paragraph IV certification, that those same patents are invalid, unenforceable, or not infringed.

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[3] *See* Brief of Teva Pharms. USA, Inc. as *Amicus Curiae* Supporting Plaintiff, *Hi-Tech Pharmacal Co. v. FDA*, No. 08-1495-JDB (D.D.C. Oct. 24, 2008), Dkt. No. 25, *available at* http://www.fdalawblog.net/fda_law_blog_hyman_phelps/files/cosopt_teva_amicus.pdf ("Needless to say, Congress could not possibly have intended to put patent holders in charge of an incentive that rewards patent challengers, and the courts accordingly have rejected each of FDA's prior efforts to enable such manipulation." (citations omitted)).

[4] Defendants' Opposition to Plaintiff's Motion for a Preliminary Injunction, at 11-12, *Mylan Pharms., Inc. v. Sebelius*, No. 12-0524 (Dkt. No. 21, filed Apr. 10, 2012) ("FDA Br."). *See* Mylan's Motion for a Preliminary Injunction, Ex. 15, at 2, *Mylan Pharms., Inc. v. Sebelius*, No. 12-0524 (Dkt. No. 5, filed Apr. 5, 2012) ("Mylan Br.") (Mar. 28, 2012 letter from FDA to Teva noting Teva's "unique posture" with Provigil and stating that "FDA has never previously made a 180-day exclusivity determination in a situation in which one of the ANDA applicants seeking exclusivity – which would block approval of other ANDAs – is also the NDA holder").

[5] FDA Br. at 11 (stating that the statutes and regulations "are silent regarding the corporate relationship between an NDA holder and an ANDA holder"); Memorandum of Points and Authorities in Support of Teva's Opposition to Plaintiff Mylan's Motion for Preliminary Injunction, at 2, *Mylan Pharms., Inc. v. Sebelius*, No. 12-0524,(Dkt. No. 23, filed Apr. 10, 2012) ("Teva Br.") ("Nothing in the Hatch-Waxman Act remotely hinges on the presence or absence of a relationship between the ANDA applicant and the NDA holder.").

The Commission takes no position here on FDA's interpretation and application of its governing statute and regulations. But the FTC has a substantial interest in the Court's resolution of this issue because it directly affects competition in light of Teva's acquisition of Cephalon, a merger that the Commission conditionally approved last year. Resolution of this unprecedented exclusivity issue is likely to determine the nature and extent of generic drug competition for Provigil and, consequently, the amount consumers will pay for this drug, perhaps well into the future. The FTC submits this brief for two purposes: first, to explain the Commission's enforcement actions relating to Provigil, particularly its approval of the acquisition at the heart of Mylan's challenge; and second, to explain why putting the branded drug manufacturer in control of the generic exclusivity period will impede rather than promote generic competition.

The Commission conditionally approved Teva's proposed acquisition of Cephalon in October 2011, based on the understanding that as many as four generic applicants would share exclusivity rights and be in a position to begin selling generic Provigil on April 6, 2012. Thus, it ordered certain limited relief designed to remedy what appeared at the time to be the loss of one of those generic competitors in the market for Provigil and its generic equivalents.

FDA's subsequent ruling that Teva holds sole exclusivity creates a dramatically different competitive landscape than the one the FTC expected. Instead of the robustly competitive market for Provigil and its generic equivalents that had long been anticipated to begin on April 6, 2012, consumers are left with a very different reality, one in which the sole first-filer and the brand are one and the same. To be sure, due to the FTC proposed consent order, generic entry has recently occurred: Teva and Par Pharmaceutical, Inc. ("Par") are now each selling an "authorized generic" Provigil (that is, they are marketing Provigil tablets in generic trade dress).

But this is a highly unusual scenario with two authorized generic sellers (linked directly through a supply agreement) ***and not a single independent competitor***. As discussed below, such a market is not likely to produce the same cost savings that consumers enjoy when multiple independent generic rivals compete. The Commission is also concerned that the award to Teva of sole exclusivity for generic Provigil could further delay entry by any independent generics until 2015, and perhaps longer.

Had the FTC been aware, when reviewing the acquisition, that Teva would have sole exclusivity rights, it would have sought a remedy suited to address the far greater threat to competition that the Teva-Cephalon acquisition poses under such circumstances. While the Commission may, if necessary, bring an antitrust enforcement action to resolve the competitive concerns raised by the acquisition as a result of FDA's awarding sole exclusivity to Teva, such a proceeding may not conclude before consumers suffer substantial harm. Provigil has annual U.S. sales well over $1 billion and can cost on the order of $1,000 for a one-month supply. The absence of independent generic competition to Provigil is an ongoing loss for consumers, the intended beneficiaries of the Hatch-Waxman Act.[6]

I. Interest of the Federal Trade Commission

The FTC is an independent law enforcement agency charged by Congress with protecting the interests of consumers by enforcing competition and consumer protection laws. The FTC enforces, among other laws, Section 7 of the Clayton Act, 15 U.S.C. § 18, which prohibits

[6] Teva admits as much, estimating that it would lose $60 million per quarter should Mylan prevail in this case, including through additional price competition. Teva's Memorandum in Support of Motion for TRO and PI, at 29, *Teva Pharms. USA, Inc. v. Sebelius*, No. 12-0512 (Dkt. No. 3, filed Apr. 3, 2012) ("Teva TRO Br."). Consumers would be the beneficiaries of this price competition.

acquisitions that may substantially lessen competition, and Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, which prohibits unfair methods of competition.

A. FTC Actions Regarding Teva's Acquisition of Cephalon

The FTC reviewed Teva's proposed $6.8 billion acquisition of Cephalon and assessed the acquisition's impact on competition in the sale of Provigil and its generic alternatives. Available evidence at that time indicated that multiple firms, including Mylan, Teva, and Cephalon (through an authorized generic product), were positioned to launch generic Provigil products on April 6, 2012, because multiple generic firms had filed Abbreviated New Drug Applications ("ANDAs") on the same day and were likely to share in 180-day exclusivity rights.[7] Even under this scenario, however, the Commission concluded that Teva's acquisition of Cephalon was likely to substantially lessen competition in the market for Provigil and its generic equivalents, because Teva and Cephalon were two of a limited number of companies capable of marketing generic Provigil as of April 6, 2012.

On October 7, 2011, the Commission issued an administrative complaint and simultaneously entered a proposed consent order conditionally resolving the Commission's competitive concerns about the merger.[8] The terms of the Commission's proposed consent order concerning Provigil were tailored to address a scenario in which multiple generic firms would be in a position to obtain final FDA approval on April 6, 2012 (and the 180-day exclusivity period

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[7] Analysis of Agreement Containing Consent Orders to Aid Public Comment, *In re Teva Pharm. Indus. Ltd. and Cephalon, Inc.*, FTC File No. 111-0166, at 2 (Oct. 7, 2011), *available at* http://www.ftc.gov/os/caselist/1110166/111007tevacephalonanal.pdf. *See also FTC v. Bisaro*, 757 F. Supp. 2d 1, at 3-4 (D.D.C. 2010) (Kollar-Kotelly, J.) (referring in Provigil-related subpoena enforcement action, to shared exclusivity and referencing 2009 discussions among FTC and FDA staff).

[8] Analysis of Agreement Containing Consent Orders, *supra* note 7, at 2.

would commence on that date) – not one in which Teva held sole 180-day exclusivity rights and had the incentive to delay generic competition indefinitely.[9] Given these expectations, the FTC ordered limited relief as to Provigil, and did not impose the standard divestiture requirements used to remedy other competitive concerns raised by the transaction. For Provigil, the proposed FTC consent decree required only that Teva enter a supply agreement with Par under which Teva would supply Par with finished generic Provigil for a one-year period (renewable for a second year at Par's option), sufficient to enable Par to begin marketing the product by April 6, 2012. Teva completed its acquisition of Cephalon later in October 2011.

B. Other FTC Actions Concerning Generic Drug Competition

The FTC has filed an additional law enforcement action concerning Provigil, a February 2008 antitrust lawsuit against Cephalon awaiting trial in the United States District Court for the Eastern District of Pennsylvania. *FTC v. Cephalon, Inc.*, No. 08-2141 (E.D. Pa.). In that case, the FTC alleges that, in 2006, through a series of patent settlements, Cephalon paid Teva (years before Teva acquired Cephalon), Mylan, and two other generic applicants to delay competition from generic versions of Provigil for six years, until April 6, 2012. The complaint charges that, had Cephalon not paid its rivals to delay their entry, lower-cost generic versions of Provigil would likely have been available to consumers as early as 2006.[10] Indeed, Cephalon had provided the investment community earnings guidance in November 2005 that explicitly assumed that Provigil was "going away" because of generic entry in 2006. FTC Compl. ¶ 50.

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[9] The proposed consent order, on the public record for comment, is not final.

[10] *See King Drug Co. v. Cephalon, Inc.*, 702 F. Supp. 2d 514 (E.D. Pa. 2010) (denying Cephalon motions to dismiss and summarizing plaintiffs' allegations). *See also* First Am. Compl., *FTC v. Cephalon*, No. 08-2141 (E.D. Pa. Oct. 12, 2009), *available at* http://www.ftc.gov/os/caselist/ 0610182/090812cephaloncmpt.pdf ("FTC Compl.").

Because these four generic applicants at the time held potential rights to 180-day exclusivity for generic Provigil, their agreements with Cephalon effectively blocked generic entry from any competitor. Cephalon's CEO stated shortly after the settlements: "We were able to get six more years of patent protection. That's $4 billion in sales that no one expected." FTC Compl. ¶ 4.[11]

These Provigil-related enforcement actions are part of a long line of FTC law enforcement and policy initiatives related to competition in the pharmaceutical industry, generic drug entry, and the impact of provisions of the Hatch-Waxman Act on consumers. The FTC has focused substantial law enforcement and policy resources to prevent anticompetitive conduct that delays generic competition, and has filed enforcement actions[12] and amicus briefs[13] to address such conduct. The FTC has also conducted empirical research relating to generic drug

[11] A subsequent generic applicant, Apotex, Inc., has tried to gain market entry by seeking a court decision that might trigger the 180-day exclusivity for generic Provigil. Apotex's April 2006 declaratory judgment suit against Cephalon eventually resulted in a late 2011 ruling that the first of Cephalon's two patents relevant to this case (the "Particle Size Patent") is invalid. The court also held the patent unenforceable, finding that Cephalon had engaged in inequitable conduct before the Patent and Trademark Office by failing to disclose material information with an intent to deceive. *Apotex, Inc. v. Cephalon, Inc.*, No. 06-2768, 2011 WL 6090696 (E.D. Pa. Nov. 7, 2011). The court held in March 2012 that the Apotex product does not infringe the Particle Size Patent. *Apotex, Inc. v. Cephalon, Inc.*, No. 06-2768, 2012 WL 1080148 (E.D. Pa. Mar. 28, 2012). *See also* Order, *Apotex, Inc. v. Cephalon, Inc.*, No. 06-2768 (E.D. Pa. Mar. 15, 2011) (granting Apotex's motion for summary judgment of non-infringement of the second patent). The district court entered judgment on all of Apotex's declaratory judgment claims on April 9, 2012.

[12] *See, e.g., FTC v. Watson Pharms., Inc.*, No. 09-955 (N.D. Ga.); *FTC v. Warner Chilcott Holding Co., Ltd.*, No. 05-2179 (D.D.C.); *In the Matter of Bristol-Myers Squibb Co.*, 135 F.T.C. 444 (2003).

[13] *See, e.g., In re K-Dur Antitrust Litig.*, Nos. 10-2077, 10-2078, 10-2079 (3d Cir. argued Dec. 12, 2011); *Arkansas Carpenters v. Bayer AG*, No. 08-1097 (Fed. Cir. 2008); *In re Buspirone Antitrust Litig.*, MDL Dkt. No. 1410 (S.D.N.Y. Jan. 8, 2002).

competition[14] and testified before Congress on legislative proposals affecting pharmaceutical competition.[15] In addition, under a 2003 congressional mandate, the FTC reviews every brand-generic patent settlement agreement for potential antitrust violations.[16]

II. The Impact of Teva's Acquisition of Cephalon on Its Incentives to Compete and the Likely Effect on Consumer Access to Low-Cost Generic Drugs Are Relevant to the Court's Consideration of Mylan's Claim.

Mylan's primary challenge to FDA's unprecedented decision rests on how Teva's acquisition of Cephalon affects Teva's rights to generic Provigil exclusivity. Teva's rights to the 180-day exclusivity period arise from its certification that the two Provigil patents are invalid, unenforceable, or not infringed. But since the acquisition, Teva has been litigating to defend those same patents in the *Apotex* patent litigation pending in the Eastern District of Pennsylvania. This incongruous result, Mylan asserts, cannot be reconciled with the Hatch-Waxman Act, given the legislative purpose to create the 180-day exclusivity period as a tool to promote generic drug competition.[17] The FTC agrees that giving the branded drug firm control of the generic drug exclusivity period creates clear competitive concerns. Indeed, absent the

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[14] *See, e.g.*, FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011), *available at* http://www.ftc.gov/os/2011/08/2011genericdrug report.pdf ("FTC AG Study"); FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

[15] *See, e.g., Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?: Hearing Before S. Comm. on the Judiciary*, 110th Cong. (2007); *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before S. Comm. on Commerce, Science, and Transportation*, 107th Cong. (2002).

[16] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461-63 (codified at 21 U.S.C. § 355) (requiring the filing of pharmaceutical patent settlement agreements with the FTC and the Department of Justice).

[17] *See, e.g., Teva Pharms. USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008).

limited relief the Commission ordered, there is no reason to think that any generic Provigil would be on the market today.

A. The Acquisition Changed Teva's Incentives Concerning Provigil

Before the acquisition, Teva and Cephalon were direct competitors in the market for Provigil and its generic equivalents. Teva had challenged Cephalon's patents and had strong incentives to manufacture and market generic Provigil as soon as possible after April 6, 2012. It also had strong incentives to price its product aggressively to win sales from both branded Provigil and the competing authorized generic product Cephalon would likely have launched in response. Teva's post-merger incentives are very different.

First, Teva now has substantial commercial incentives to protect its branded Provigil sales by limiting the total supply of generic Provigil product available in the market. Accordingly, it has an incentive to use its position as the supplier for Par's authorized generic to achieve that result and minimize Par's impact as a competitor, including using contract provisions to frustrate Par's attempts to obtain enough supply. While Teva has an obligation to comply with the terms of the FTC proposed consent decree that requires Teva to supply Par with generic product, those order provisions were designed for a market with multiple, independent generic competitors – competitors with both the incentive and the supply capacity to capture as many generic Provigil sales as possible, defeating any effort by Teva to raise market price by restricting supply to Par. The FTC order does not – and cannot – replicate the discipline that an independent generic competitor would exert on branded Provigil.

Second, FDA's decision to award sole exclusivity leaves a two-player market that increases the incentive for collusion. Because Par's supply agreement is at most two years long, and Par lacks the ability to independently increase supply to meet market demand, Par may not

have the incentive to price its product aggressively to win market share for the long term, as generic drug companies typically do.[18] The presence of one or more independent generic competitors, with the incentive and ability to compete for as large a share of the generic Provigil sales as possible, would be expected to discipline any collusive behavior. In the absence of such market discipline, however, consumers may not realize the savings typically associated with generic entry.

Third, as owner of branded Provigil, Teva now has an incentive to delay the entry of independent generic competition for as long as possible. While FDA has ruled that Teva's 180-day exclusivity period was triggered on March 30, 2012, Teva has given every indication that it rejects that decision. Indeed, just prior to FDA's decision, in papers filed in its own lawsuit against FDA, Teva stated that an appellate decision in the *Apotex* litigation might trigger the exclusivity period, provided that Teva "has not commenced commercial marketing of its exclusivity-entitled modafinil ***ANDA product under its ANDA*** by that point in time."[19] The language Teva chose is significant, because Teva has not commenced commercial marketing under its ***ANDA*** and it has little incentive to ever do so. Instead, Teva is marketing a generic product under Cephalon's NDA, prompted by the prospect of Par's April 6 entry. In its brief in

[18] *See, e.g.*, Teva Br. at 26 (first-to-launch generics are typically able to "secure distribution channels and access to customers; enter into long-term sales agreements; . . . and retain greater market share in the long-run"); *see also* FTC AG Study, supra note 14, at 93 ("early generic entrants . . . are able to retain a large portion of their market shares" over the long term), 75 (reporting that most authorized generics remain on the market for more than two years).

[19] Teva TRO Br. at 37 n.8 (emphasis added).

this case, Teva reiterates its previously-expressed view about the trigger.[20] Of course, if Teva, as the sole exclusivity holder, does not trigger, then all other generic applicants are blocked, potentially until the 2015 expiration of the Particle Size Patent.

The Court may wish to consider these changes to Teva's incentives in resolving Mylan's claim that the acquisition eliminated Teva's right to the generic exclusivity period. Teva urges the Court to overlook Teva's common ownership of both Teva USA and Cephalon because "the corporate form is sacrosanct." Teva Br. at 2. But, as Teva and FDA both acknowledge, corporate law principles are not reflected in the language of the relevant Hatch-Waxman provisions.[21] The Supreme Court has emphasized that, in an antitrust analysis, economic substance, not corporate form, controls.[22] This reliance on economic substance appears relevant in the Hatch-Waxman context given the pro-competitive aim of the statute.[23]

The FTC suggests that the Court look to the economic realities of Teva's business: Teva USA and Cephalon are owned by the same parent company. Teva USA and Cephalon are run by the very same people. For example, Brian Shanahan, who submitted a declaration in his capacity

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[20] Teva Br. at 7 (stating that exclusivity "begins to run on . . . the date on which the first applicant first begins to sell its approved ANDA product (the 'commercial marketing trigger')"). *See also id.* at 6 ("sell its ANDA products"), 26 ("exclude . . . competitors . . . during the first six months after it begins selling its ANDA product").

[21] Teva and FDA agree that the statute does not address the relevance of the corporate relationship between the ANDA applicant and the NDA holder. *See supra* at n.4 & 5 and accompanying text.

[22] *See, e.g., Am. Needle, Inc. v. Nat'l Football League*, 130 S. Ct. 2201, 2209-10 (2010) ("[W]e have eschewed such formalistic distinctions [as whether the parties are legally distinct entities] in favor of a functional consideration of how the parties . . . actually operate.").

[23] FDA Br. at 11-12 (explaining that the goal of the Hatch-Waxman regime is to provide incentives for robust generic competition); *see also* Teva Br. at 29-30 (recognizing that the ultimate goal of the Hatch-Waxman regime is promoting generic competition).

as Assistant Secretary of Teva USA, serves in the exact same role for Cephalon.[24] In fact, Teva USA has benefitted from its unique connection with Cephalon. In its February 29, 2012 letter to FDA, Teva USA explained that it learned it was the sole first filer for both Cephalon patents only because of its access to Cephalon's internal documents.[25] And, as FDA notes, Teva has at times listed Provigil as one of its own branded products.[26] Despite their separate corporate structure, the economic realities are that Teva USA no longer competes with Cephalon and no longer faces the same competitive incentives with respect to generic Provigil as an independent generic firm.

B. Resolution of the Provigil Exclusivity Issues Will Significantly Affect Consumer Savings on Generic Provigil

1. Consumer savings from generic drugs depend on the extent of generic entry

Competition from generic drugs saves American consumers, including federal and state government purchasers, billions of dollars a year. The magnitude of cost savings from use of generics, however, depends on the nature and extent of generic drug competition. Empirical evidence demonstrates that generic drug prices fall as more generic competitors enter the market. For example, a recent study of the pricing of 25 pharmaceutical products with large sales shows "generic prices falling sharply" six months after generic entry, following the end of the 180-day

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[24] *See* Mylan Br. at Ex. 11.

[25] *See* Mylan Br. at Ex. 15; FDA Br. at Ex. 1.

[26] *See* FDA Br. at 7 n.6; *see also* Teva Fact Sheet, Third Quarter 2011 (Nov. 2, 2011), *available at* http://ir.tevapharm.com/phoenix.zhtml?c=73925&p=irol-qfactsheets (last visited Apr. 11, 2012) (listing Provigil with other Teva products).

exclusivity period and the entry of multiple generic competitors.[27] A recent FTC study of a broader universe of drugs similarly observed large price declines around the end of the 180-day exclusivity period, as generic competition increases.[28] The impact on consumer savings of entry by multiple generic drug competitors is well-documented in the economic literature and well-understood by drug companies and the parties in this case.

2. Resolution of Mylan's claim will determine the extent of competition and consumer savings from generic Provigil

The Court's decision here can be expected to result in one of two alternative market scenarios. If the Court upholds Mylan's claim that Teva's right to generic Provigil exclusivity was extinguished by the Cephalon acquisition, then FDA would be free to grant final approval to other generic applicants. At least seven companies (in addition to Teva and Barr, now owned by Teva) have filed applications to market generic Provigil.[29] As the economic literature discussed above reflects, the robust competition that would arise from multiple independent generic entrants would produce significant consumer savings. For example, Teva itself projected, in anticipation of generic Provigil entry in 2006, that robust generic competition would lower generic prices 90% relative to the branded price within a year of generic entry.[30]

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[27] Ernst R. Berndt et al., *A Primer on the Economics of Prescription Pharmaceutical Pricing in Health Insurance Markets* 19 (Nat'l Bureau of Econ. Research, Working Paper No. 16879, 2011), *available at* http://www.nber.org/papers/w16879.pdf.

[28] FTC AG Study, *supra* note 14, at 97-98.

[29] Center for Drug Evaluation and Research, Modafinil, Drugs@FDA, *available at* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName= MODAFINIL (listing companies that have received tentative FDA approval).

[30] FTC Complaint, *supra* note 10, at ¶ 42.

On the other hand, upholding FDA's position would preserve the status quo, a market with two authorized generic sellers, Teva and Par, and no independent generic competitor – at least for six months and potentially much longer. Because it is highly unusual for a brand to launch an authorized generic without the threat of imminent entry by an independent generic applicant, there is no body of empirical data to demonstrate the likely effect on price of this scenario. But as discussed above, what is clear is that Teva has every incentive to minimize competition to branded Provigil during its period of sole first-filer exclusivity. Because the terms of the Commission's proposed consent order assumed that Teva would face competition from independent generic entrants, the proposed consent likely is inadequate to protect consumers from the combined impact of FDA's award of sole exclusivity to Teva and the Teva-Cephalon merger. Even if Par is able, in the short term, to market some volume of generic Provigil at a discount to branded Provigil, over the long term, this market structure is likely to inhibit robust competition. And it certainly will not replicate the competition that multiple independent generic entrants would provide, which, even if limited to an incremental discount of only 5-10% off the price of branded Provigil, would save consumers tens of millions of dollars over a six-month period.

In addition, if Teva is able to use its exclusivity rights to block independent generic entry even after October 2012, then consumers would experience dramatically steeper losses. This scenario was expressly not contemplated by the Commission's proposed (but not finalized) consent. Moreover, the proposed consent order only provides for Teva to supply Par for two years. At that point, if Par is no longer selling generic Provigil, Teva will have no incentive to do so either, with the likely result that generic Provigil would cease to be available.

Conclusion

The framework established in the Hatch-Waxman Act to encourage firms to challenge weak patents has resulted in significant benefits for consumers. But the integrity and continued success of this landmark legislation is in jeopardy if, as Teva contends, the 180-day exclusivity period is available to a company without regard to its relationship with the branded manufacturer. If Teva is correct, then brand drug manufacturers can simply use a corporate subsidiary to file a Paragraph IV certification to its own product and secure exclusivity to block generic entry. This result would surely do violence to "the incentive structure adopted by the Congress."[31]

The FTC respectfully requests that the Court carefully consider the impact on consumers of the exclusivity questions before it. The FTC would be pleased to address any questions the Court may have, including participation at the April 18th hearing, should the Court find it useful.

Dated: April 12, 2012

Respectfully submitted,

/s/ Markus H. Meier

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[31] *Teva v. Sebelius*, 595 F.2d at 1316.