IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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 ivalents,09 tJ3 -2).98 – is its cder17.575qualifialefro(a)-.5er, Fhe "inoseusivity rights desi3 -2. 0 7

[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

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.").

[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);

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).

[20] Teva Br. at 7 (stating that exclusivity "begins to run on . . . the date on which the first

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).

[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

On the other hand, upholding FDA's position would preserve the status quo, a market

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.

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Respectfully submitted,

/s/ Markus H. Meier

RICHARD A. FEINSTEIN
Director
Bureau of Competition

PETER J. LEVITAS
Deputy Director
Bureau of Competition

WILLARD K. TOM
General Counsel
Federal Trade Commission

MARKUS H. MEIER (DC Bar # 459715)
BRADLEY S. ALBERT
ELIZABETH R. HILDER
MARK J. WOODWARD (DC Bar # 479537)
TIMOTHY J. SLATTERY
DOMINIC E. VOTE
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

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