UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN PHARMACEUTICALS, INC. Plaintiff, **v.** **KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services, *et al*.,** Defendant, **and** **TEVA PHARMACEUTICALS USA, INC.,** Defendant-Intervenor, **and** **CEPHALON, INC.,** Defendant-Intervenor.	**Civil Action No. 12-524 (ESH)**

MEMORANDUM OPINION

On April 4, 2012, two days before Mylan Pharmaceuticals Inc.'s ("Mylan") anticipated launch, the Food and Drug Administration ("FDA") decided that Teva Pharmaceuticals U.S.A. Inc. ("Teva USA") was entitled to a 180-day period of exclusivity to market modafinil, the generic version of Provigil. The FDA rejected Mylan's request for final approval to sell modafinil and indicated that it would consider Mylan's request at the conclusion of Teva USA's period of exclusivity. Mylan brings this action pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq*., claiming that the FDA's decision conflicts with the Drug Price Competition and Patent Term Restoration Act of 1984 (known as the "Hatch-Waxman Act" or

the "Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984), and that it is entitled to a preliminary injunction requiring the FDA to revoke Teva USA's exclusivity and to issue a final approval of Mylan's ANDA.

BACKGROUND

I. STATUTORY FRAMEWORK

At issue in this case are a complex set of amendments to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, added by the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act amendments.[1] These amendments were designed to simplify and expedite the process by which generic drugs are brought to market. *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1316 (D.C. Cir. 1998).

Under the Act, a company seeking FDA approval to market a particular drug must file a lengthy document called a New Drug Application ("NDA"), which, among other things, includes detailed data establishing the drug's safety and effectiveness. 21 U.S.C. § 355(b)(1). The NDA must also contain information on each patent that claims the drug or a method of using the drug that is the subject of the application and with respect to which a patent infringement claim could reasonably be asserted against an unauthorized party. *Id*. The FDA lists such patent information in a publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, known in the industry as the "Orange Book." *See Am. Bioscience, Inc. v. Thompson*, 269 F.3d

[1] Although the FDCA has subsequently been amended on various occasions, including by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003), it is agreed that the instant dispute is governed by pre-MMA law. (*See* Teva USA and Cephalon's Opp'n to Mylan's Mot. for Preliminary Injunction ("Teva USA's Opp'n"), Ex. B (FDA letter decision dated Apr. 15, 2009)) (explaining that pre-MMA law applies if at least one ANDA was submitted prior to the enactment of the MMA)); Mylan's Reply Br. in Support of its Preliminary Injunction Mot. ("Mylan's Reply") at 24 n. 15; Teva USA's Opp'n at 4 n.1.) Therefore, all references to the statute relate to the pre-MMA version unless otherwise noted.

1077, 1079 (D.C. Cir. 2001); Terry G. Mahn, *Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process*, 54 Food Drug L.J. 245, 249-50 (1999).

Once an NDA has been filed, manufacturers seeking to market generic versions of the drug may file an Abbreviated New Drug Application ("ANDA"). *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998); 21 U.S.C. § 355(j). The ANDA is not required to include new safety and effectiveness data, but instead may rely on the safety and effectiveness data in the original NDA. *Id.* In this way, the Hatch-Waxman amendments were intended both to encourage the development of innovative new drugs and to permit the speedy marketing of lower cost generic drugs. *Tri-Bio Labs., Inc. v. FDA*, 836 F.2d 135, 139 (3d Cir. 1987).

An ANDA applicant must certify whether the generic drug would infringe any existing patents relied on and listed by the inventor of the pioneer drug and specify:

> (I) that such patent information has not been filed,
>
> (II) that such patent has expired,
>
> (III) [] the date on which such patent will expire, or
>
> (IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii).

By filing a paragraph IV certification (the only certification at issue in this case), the ANDA applicant challenges the validity of the patent or claims that the patent would not be infringed by the generic drug proposed in the ANDA. An applicant must provide notice of a paragraph IV certification to the patent holder. *Id.* § 355(j)(2)(B). The filing of a paragraph IV certification is deemed by statute to constitute an act of infringement under patent law, 35 U.S.C.

§ 271(e)(2)(A),[2] and the patent holder has 45 days to bring suit against the ANDA applicant. 21 U.S.C. § 355(j)(5)(B)(iii). If the patent holder brings such a suit, the FDA must delay approving the ANDA for 30 months. *Id.* This provision, known as the 30-month stay, allows the patent holder to assert its patent rights before the generic competitor is permitted to enter the market. *Mova Pharm. Corp.*, 140 F.3d at 1064. If no suit is filed within 45 days, the FDA may approve a paragraph IV ANDA, and the approval may be effective immediately even though the patent has not expired, provided that other conditions have been met. *Id.*[3]

As an incentive to generic manufacturers who take the risk of "sparking costly [patent infringement] litigation" and "to compensate [generic] manufacturers for research and development costs," the statute awards a 180-day period of market exclusivity to the first ANDA applicant to gain final FDA approval of its paragraph IV certification. *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010) (quotation marks and citation omitted) (second alternation in original); *see* 21 U.S.C. § 355(j)(5)(B)(iv). During this "Edenic moment of freedom from the pressures of the marketplace," *Mova Pharm. Corp.*, 140 F.3d at 1064, the FDA

[2] Under 35 U.S.C. § 271(e)(2)(A), it is considered to be an act of infringement to submit an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent." Thus, whenever a generic applicant includes a paragraph IV certification in its ANDA, this provision creates a "somewhat artificial" case or controversy for purposes of establishing federal jurisdiction and permits the brand manufacturer to initiate a patent infringement suit even though the generic manufacturer has not yet marketed the drug. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

[3] The FDA grants "tentative approval" to an ANDA when all scientific and procedural conditions have been met, but final approval is blocked by the 30-month stay, marketing exclusivity, or some other barrier arising from patent infringement litigation. *See* 21 U.S.C.§ 355(j)(5)(B)(iv)(II)(dd)(AA). An application that has been tentatively approved will not become final —and the generic may not be legally marketed—until the FDA issues a final approval letter. *See* 21 C.F.R. § 314.105(d); 21 C.F.R. § 314.107(b)(3)(v); s*ee also Ranbaxy Labs. Ltd. v. FDA*, 307 F. Supp. 2d 19, 19-21 (D.D.C. 2004) ("Approvals do not become effective by operation of law because the FDA has an ongoing health and safety responsibility to perform.").

may not allow any subsequent ANDAs for the drug in question to become effective, thus allowing the first mover to sell its generic drug without competition from other generic manufacturers. *Teva Pharms. USA, Inc.*, 595 F.3d at 1305. The statute is thus designed so that the promise of initial marketing exclusivity will lead to increased competition with brand manufacturers by incentivizing the filing of paragraph IV certifications, thereby expediting the availability of generic equivalents. *Id*.

Under pre-MMA law, the 180-day period of marketing exclusivity is triggered on the earlier of (1) the date on which the first applicant first begins to sell its approved ANDA product (the "commercial marketing trigger"), or (2) the date of a court decision holding that the NDA's patent is invalid or not infringed ("the court decision trigger"). 21 U.S.C. § 355(j)(5)(B)(iv). At the conclusion of the 180-day period, full competition among generics can commence.

II. FACTUAL BACKGROUND

The instant case centers on modafinil, a prescription drug used to treat sleep disorders, including narcolepsy and sleep apnea.

Modafinil has been marketed by Cephalon Inc. ("Cephalon") under the brand name Provigil since 1998. (Teva USA's Opp'n, Ex. J. (Apr. 4, 2012 Letter from FDA to Teva USA [hereinafter "Modafinil Letter Decision"], at 2).) The FDA approved sale of this drug based on Cephalon's submission of NDA No. 020717 on December 24, 1998. (*Id.*) Currently, Cephalon has two patents in connection with Provigil: U.S. patents RE37,516 ("'516 patent") and 7,297,346 ("'346 patent"). (*Id*.) The '516 patent for Provigil was listed in the Orange Book in 2001[4] and the '346 patent, which covers a narrower class of modafinil products, was listed in 2007. (*Id*.) Unchallenged, the '516 patent would have blocked the sale of modafinil generics

[4] The '516 patent was a reissue of U.S. Patent No. 5,618,845, which was listed for Provigil in 1999. (*See id*. at 2 n.4.)

until October 6, 2014, and the '346 patent would have blocked the sale of generics until November 29, 2023. (Mylan's Mot. for Preliminary Injunction ("Mylan's Mot."), Ex. 2 ("Apr. 4, 2012 Letter from FDA to Mylan"), at 1.) Both patents for this profitable drug[5] were, however, challenged by generic manufacturers and these competing challenges have spawned the current litigation.

A. ANDAs Referencing the '516 Patent

The first date on which any ANDAs referencing the '516 patent could be filed was December 24, 2002. (Modafinil Letter Decision at 2.) On that date, four generic drug manufacturers—Mylan, Teva USA, Ranbaxy Laboratories, Inc. ("Ranbaxy"), and Barr Pharmaceuticals, Inc. ("Barr")—submitted ANDAs under paragraph IV declaring that the '516 patent was invalid, unenforceable, or not infringed by their generic versions of modafinil. (*Id*. at 3) The FDA tentatively approved all four ANDAs between 2004 and 2005 (*id*.); Mylan's was approved on February 9, 2005 (Apr. 4, 2012 Letter from FDA to Mylan at 1), and Teva USA's was approved on December 16, 2005. (Modafinil Letter Decision at 3.)

The filing of these paragraph IV certifications prompted Cephalon to file suit in New Jersey against all four generic manufacturers for patent infringement in February 2003. (*Id*; *see Cephalon, Inc. v. Mylan Pharms. Inc.*, No. 03-cv-1394 (D.N.J. Feb. 28. 2003).) This in turn triggered the automatic 30-month stay of final FDA approval of the tentatively approved ANDAs.

From late 2005 to early 2006, Cephalon settled with Mylan, along with Barr, Ranbaxy, and Teva. (*See* Modafinil Letter Decision at 3; Derkacz Decl. ¶ 13; Tr. 96-97.) As part of these settlements, Cephalon paid the generic companies a significant amount of money—hundreds of

[5] For example, Cephalon's sales totaled approximately $1.1 billion in 2011. (Teva USA's Opp'n, Ex. M. ("Derkacz Decl.") ¶ 6.)

millions of dollars, according to the Federal Trade Commission ("FTC")— to refrain from selling generic modafinil until April 6, 2012. (*See* Preliminary Injunction Hr'g Tr. 96, Apr. 18, 2012 ("Tr.").) In these agreements, the companies agreed not to sue each other in relation to the '516 patent or any other patents that referenced Provigil in the Orange Book. (Tr. 16, 23-24.)

Without these agreements, generic modafinil could have hit the market on June 24, 2005. However, by paying the ANDA applicants to delay, Cephalon bought itself almost seven years of market exclusivity during which time it sold, without any competition, Provigil at brand prices.[6]

B. ANDAs Referencing the '346 Patent

On November 20, 2007, Cephalon obtained the second patent related to Provigil, patent '346, which covers a specific and narrower formulation of the drug. (Derkacz Decl. ¶ 11) On the first day that the '346 patent could be challenged, December 14, 2007, two companies—Teva USA and Watson[7]— filed ANDAs with paragraph IV certifications. (Modafinil Letter Decision at 3; Derkacz Decl. ¶ 12.) Inexplicably, Mylan did not file a paragraph IV certification until over three years later, on February 2, 2011.[8] (Mylan's Mot., Ex. 6.) Cephalon did not file a patent infringement suit against any of these companies based on the paragraph IV certifications

[6] Unsurprisingly, this arrangement aroused significant concern on the part of the FTC and consumers. The FTC filed an antitrust suit, which is still pending, against Cephalon based on these "pay-for-delay" agreements, and this case was consolidated with a class action antitrust suit brought by "end-payers" in the Eastern District of Pennsylvania. *See King Drug Co.of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 517, 530-31 (E.D. Pa. 2010) (denying Cephalon's motions to dismiss and summarizing plaintiffs' allegations); *see also* First Am. Compl., *FTC v. Cephalon, Inc.*, No. 08-2141 (E.D. Pa. Aug. 12, 2009).

[7] "Watson" refers collectively to Watson Pharmaceuticals and its business partner Carlsbad Technologies. Watson had previously submitted a paragraph IV certification to the '516 patent, but not until January 10, 2005. (*Id.* ¶ 12.) Cephalon responded by filing a patent infringement suit, which triggered the 30-month stay. (*Id.*)

[8] Barr also filed a paragraph IV certification referencing the '346 patent at some point after December 14, 2007.

regarding patent '346.[9] Indeed, it had relinquished any right to do so in the settlement agreements signed with Teva USA and Mylan (and presumably Ranbaxy and Barr as well).

In the intervening years, Teva USA's parent company, Israel-based Teva Pharmaceuticals Industries Ltd. (Teva Ltd.), purchased Barr in 2008 and Cephalon in 2011. Teva Ltd.'s announcement that it planned to acquire Cephalon, which would mean that the two U.S. drug companies subsidiaries would become indirectly owned by the same parent (Teva Ltd.), sparked significant scrutiny from the Federal Trade Commission ("FTC") regarding the merger's impact on competition in the drug industry and, in particular, with regard to modafinil and two other drugs. (*See* FTC Corr. Br. as Amicus Curiae ("FTC Amicus") at 5-8; Derkacz Decl. ¶ 15.) The FTC's investigation culminated in a draft consent order imposing competition-preserving requirements on the acquisition. (*Id*. ¶¶ 15, 16.)[10] Specifically, Teva Ltd. was required to provide Par Pharmaceuticals ("Par"), a separate drug company, with supplies to market an

[9] Apotex, Inc., another generic manufacturer, initiated a separate round of litigation involving modafinil. *See Apotex, Inc. v. Cephalon, Inc*., No. 06-2768, 2012 U.S. Dist. LEXIS 43479, at *5 (E.D. Pa. Mar. 28, 2012). On March 30, 2005, it filed a paragraph IV certification claiming that patent '516 was invalid, unenforceable, or will not be infringed. *Id*. at *12. On June 26, 2006, Apotax filed suit in the District of New Jersey seeking a declaratory judgment. *Id*. at 5. Apotex subsequently added claims making the same challenges regarding patent '346. *Apotex, Inc. v. Cephalon, Inc*., No. 06-2768, 2010 U.S. Dist. LEXIS 107344 (Oct. 7, 2011). In late 2011, the court ruled that the '516 patent is invalid and 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 U.S. Dist. LEXIS 125859 (E.D. Pa. Oct. 31, 2011). In March 2012, the same court held that the Apotex product does not infringe the '516 patent. *See Apotex, Inc. v. Cephalon, Inc*. No. 06-2768, 2012 U.S. Dist. LEXIS 43479; *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 March 28, 2012. *See* Order (Dkt. No. 547), *Apotex, Inc. v. Cephalon, Inc*., No. 06-2768 (E.D. Pa. Mar. 29, 2011). According to counsel for Teva USA, an appeal to the Federal Circuit is "imminent." (Tr. 60.)

[10] *See also* Mylan's Reply, Ex. 19 (Redacted Decision & Consent Order in *In re Teva Pharm. Indus. Ltd. & Cephalon, Inc*., FTC File No. 1110166, at 2 (Oct. 7, 2011) ("FTC Consent Order")).

authorized generic version of modafinil for up to two years commencing on April 6, 2012. (*Id.* at 34-36.)

III. LAUNCH OF GENERIC MODAFINIL

As April 6, 2012 (the earliest launch date permitted by the modafinil settlement agreements) approached, there was growing confusion about which, if any, ANDA applicant would be permitted to sell generic modafinil.

Teva USA was the only ANDA applicant that was a "first filer" as to both Provigil patents[11] because it was the first and only company to file paragraph IV certifications on the first day permitted for both of the patents.[12] (Modafinil Letter Decision at 6.) Therefore, Teva USA was the only modafinil applicant eligible for the benefit of the 180-day period of exclusivity. (*Id.*)

In an effort to secure this right, Teva USA wrote to the FDA on February 29, 2012, to request confirmation that it was the only ANDA applicant entitled to a 180-day period of exclusivity because it was the only "first filer" in connection with both Provigil patents. (*See* Teva USA and Cephalon's Joint Mot. for a Temporary Restraining Order and Preliminary Injunction ("Teva USA's TRO/PI Mot."), Ex. L, *Teva USA, Inc. v. Sebelius*, 12-cv-512 (Apr. 3, 2012); *see also* Modafinil Letter Decision at 2.) Teva USA did not, however, request final

[11] For purposes of the preliminary injunction hearing, Mylan has chosen not to pursue its claim that it was the first filer as to the '516 patent since it was the first of the four generic companies to file ANDAs on December 24, 2002. It has, however, reserved the right to raise this argument at a later date. (*See* Mylan's Reply at 7 n.4.)

[12] If Provigil were only covered by the '516 patent, there would have been four "first filers" (Barr, Mylan, Ranbaxy, and Teva USA) and they would have shared the 180-day exclusivity period. (*Id.* at 5-6.) However, when more than one patent relates to the brand drug, as became the case with addition of the '346 patent, the FDA awards exclusivity to the company that is first filer as to all of the patents referencing the brand drug. (*See id.* at 5-6.) Since Barr, Mylan, and Ranbaxy were not first filers as to patent '346 and Watson was not a first filer as to patent '516, none of them qualified to share exclusivity with Teva USA. (*Id.*)

approval of its ANDA or indicate a desire to launch the generic; rather, it only sought to confirm that Teva USA—and no other company—was entitled to the 180-day exclusivity. (*Id.*) On March 28, 2012, the FDA responded to Teva USA that it could not make a decision at that time because of the complex nature of the inquiry, which raised the novel of question of what effect, if any, did Teva Ltd.'s acquisition of the NDA-holder (Cephalon) have where the ANDA-holder (Teva USA) was a wholly-owned subsidiary of the same corporate parent. (Mylan's Mot., Ex. 15 ("Mar. 28, 2012 Letter from FDA to Teva USA") at 2-3.) It also noted that it would need to consider the fact that Teva USA had not requested final approval of its ANDA, it had not filed a submission to its ANDA since 2009, and it had not provided the FDA with any indication that it ever intended to seek final approval. (*Id*. at 2.) Finally, the FDA acknowledged that Mylan was seeking exclusivity regarding the '516 patent. (*Id.* at 2.)

Two days later, on March 30, 2012, Teva USA wrote to the FDA, requesting final approval of its ANDA and submitting supplemental information. (Dkt. No. 26 ("Mar. 30, 2012 Letter from Teva USA to FDA").)

Mylan, meanwhile, remained focused on the April 6, 2012 date set forth in its settlement agreement with Cephalon, and it began preparations to sell the product. (Mylan's Mot., Ex. 22 ("Mauro Decl.") ¶¶ 3, 9, 10.) To that end, it requested that the FDA issue a final approval of its modafinil ANDA by a letter dated January 30, 2012 (Mylan's Mot., Ex.8), and when Mylan did not receive a response, it again wrote on March 30, 2012. (Mylan's Mot., Ex. 9.)

Before any ANDA-based generic hit the market, however, Cephalon launched an authorized generic version of modafinil under its NDA on March 30, 2012.[13] (Modafinil Letter

[13] "Authorized generic" refers to generic drugs that are put on the market by the NDA holder as opposed to a generic put on the market by the ANDA-holder. 21 C.F.R. § 314.3(b) (describing an authorized generic drug as "a listed drug . . . that has been approved under [an NDA] and is

Decision at 7.) As explained by Teva USA's counsel at the preliminary injunction hearing, Teva USA currently distributes Cephalon's authorized generic version pursuant to a distribution agreement with Cephalon signed on April 1, 2012, and for this reason, Teva USA's website lists modafinil as one of its generic products. (Tr. 9-11.)

Because the FDA had not answered the question of whether Mylan would be permitted to go to market on April 6, 2012, or whether it is barred by Teva USA's 180-day period of sole exclusivity, Teva USA and Cephalon filed suit against the FDA on April 3, 2012. (*See* Compl., *Teva USA, Inc. v. Sebelius*, 12-cv-512 (Apr. 3, 2012).) They immediately moved for a preliminary injunction and a temporary restraining order before the Honorable Richard W. Roberts to require the FDA to declare that it was the sole ANDA applicant entitled to the 180-day period of exclusivity. (*See* Teva USA's TRO/PI Mot.)

The FDA responded on April 4, 2012. (Apr. 4, 2012 Letter from FDA to Mylan.) On that date, it awarded exclusivity to Teva USA, which meant that Mylan could not begin marketing until at least the end of Teva's period of exclusivity. (*See id*. at 3; *see also* Modafinil Letter Decision at 8.) While it informed Teva USA of its entitlement, it stated that the 180-day period would commence on March 30, 2012, the day on which Cephalon began marketing its authorized generic version. (*Id*. at 7.) That same day, it sent another letter to Mylan which denied immediate final approval, explaining that Teva USA had earned market exclusivity because it was the only ANDA applicant who had been the first filer as to both the '516 patent and the '346 patent. (Apr. 4, 2012 Letter from FDA to Mylan; *see also* Modafinil Letter

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marketed, sold, or distributed directly or indirectly" for retail sale whose labeling, packaging, product code, labeler code, trade name, or trademark "differ[] from that of the listed drug."); *see also* FTC, *Authorized Generic Drugs, Short-Term Effects and Long-Term Impact* (Aug. 2011), *available at* http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf (discussing the interplay between authorized generics and the 180-day exclusivity granted to ANDA applicants).

Decision at 6.) Therefore, it refused to consider Mylan's request for final approval until the conclusion of Teva USA's period of exclusivity. (Apr. 4, 2012 Letter from FDA to Mylan.) [14]

Immediately thereafter, Teva USA and Cephalon withdrew their requests for injunctive relief, Judge Roberts *sua sponte* dismissed their suit as moot on April 5, 2012 (*see* Order, *Teva USA, Inc, v. Sebelius*, 12-cv-512 (Apr. 5, 2012)) and, several hours later, Mylan filed the instant suit seeking a preliminary injunction to require the FDA to retract the 180-day period of market exclusivity granted to Teva USA and immediately approve Mylan's ANDA so that it could begin selling modafinil. Teva USA and Cephalon have intervened and the FTC filed an amicus brief.[15]

The Court held a hearing on April 18, 2012, at which the parties, the defendant-intervenors, and the FTC appeared. At the hearing, counsel for Teva USA informed the Court, for the first time, that Teva USA intended to take advantage of its 180-day period of exclusivity and launch its own line of generic modafinil under its ANDA. (Tr. 3.) However, Teva USA was unable to say when it will launch, citing "manufacturing difficulties." (*Id*. 14-15.) Nor could the FDA predict when Teva USA's ANDA would receive final approval, without which Teva USA cannot launch even if it is ready. (*Id*. 92-93, 95.) Further, counsel for Teva USA has confirmed that Teva USA does not intend to challenge the FDA's determination that its exclusivity period began on March 30, 2012. (Tr. 88-89.)[16]

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[14] Also on April 4, 2012, the FDA responded to—and rejected—Mylan's July 31, 2005 letter asserting sole exclusivity based on a first-in-time theory of priority because this theory of priority was contrary to clear agency precedent. (*See* Dkt. No. 22, at 2-9.) As explained (*see supra* note 11), neither this theory nor this letter is at issue at this stage of proceedings.

[15] A group of modafinil consumers also sought to file an amicus brief. (*See* Dkt. No. 31.) Given the Court's resolution of this preliminary injunction motion, it will deny that motion as moot.

[16] In Mylan's latest pleading, it tries to discredit Teva USA's representation to the Court and suggests that Teva USA will not launch its own generic, but rather will block generics from launching until the Federal Circuit decides the *Apotex* case (*see supra* n. 9). (Mylan's Observations on Teva's Response to the Court's Post-Argument Questions at 2-3.) The Court

ANALYSIS

I. LEGAL STANDARD

A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Natural Res. Def. Council, Inc*., 555 U.S. 7, 22 (2008).

> On a motion for a preliminary injunction, the district court must balance four factors: (1) the movant's showing of a substantial likelihood of success on the merits, (2) irreparable harm to the movant, (3) substantial harm to the non-movant, and (4) public interest.

Davis v. Pension Benefit Guar. Corp., 571 F.3d 1288, 1291 (D.C. Cir. 2009). Historically, these four factors have been evaluated on a "sliding scale" in this Circuit, such that a stronger showing on one factor could make up for a weaker showing on another. *See Davenport v. Int'l Bhd. of Teamsters*, 166 F.3d 356, 360-61 (D.C. Cir. 1991).

Recently, the continuing vitality of the balancing approach has been called into question, as the Court of Appeals has suggested, without holding, that a likelihood of success on the merits is an independent, free-standing requirement for a preliminary injunction. *Greater New Orleans Fair Housing Action Ctr. v. U.S. Dep't of Housing and Urban Dev*., 639 F.3d 1078, 1089 (D.C. Cir. 2011) (explaining that likelihood of success is key and therefore, "when a plaintiff has not shown a likelihood of success on the merits, [the court] need not consider the other factors"); *see also Sherley v. Sebelius*, 644 F.3d 388, 392-93 (D.C. Cir. 2011). However, if a plaintiff cannot meet the less demanding "sliding scale" standard, it by definition cannot satisfy the more stringent standard alluded to by the Court of Appeals. *See Astrazeneca Pharms. LP v. FDA*, No. 12-cv-0388, 2012 U.S. Dist. LEXIS 39611, at **26-28 (D.D.C. Mar. 23, 2012).

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finds it difficult to accept this prognostication since it would be flatly contrary to a representation made by a member of the Bar to the Court.

II. LIKELIHOOD OF SUCCESS ON THE MERITS

For purposes of Mylan's motion, the Court proceeds on the basis that Teva USA was the only first filer as to both Provigil patents and, therefore, was the only ANDA applicant entitled to 180-day exclusivity. (*See supra* note 11.) Second, it is agreed that pre-MMA law governs. Therefore, the only question before the Court is whether Mylan has demonstrated a likelihood of success on the merits on either of its arguments that (1) Teva USA is disqualified from enjoying the 180-day period of exclusivity or (2) Teva USA has abandoned its ANDA. As to the first, Mylan argues that, following Cephalon's acquisition by Teva Ltd. in October 2011, Teva USA's paragraph IV certification became invalid due to the lack of an adversarial relationship between Teva USA and Cephalon, and therefore, Teva USA is ineligible for the exclusivity award that currently blocks Mylan from selling its product. (Mylan's Mot. at 6-9.) Second, Mylan argues that Teva USA was not "actively pursuing approval of [its ANDA]" as required by 21 CFR § 314.107(c)(3), and therefore, the FDA should have approved Mylan's application instead. (*Id*. at 12-13.) In its decision, the FDA considered these arguments and rejected both of them. Having reviewed the FDA's rationale for these decisions, the Court is persuaded that the agency has acted reasonably.

A. Effect of Common Corporate Parent

Mylan's first claim is based on the October 14, 2011 merger whereby Teva Ltd. acquired Cephalon, making the NDA-holder a corporate "sister" (as the FTC describes it) or "cousin" (as Teva USA describes it in its opposition). (Teva's Opp'n at 14.) Arguing that the Hatch-Waxman Act scheme relies upon adversarialism between the brand drug provider and the ANDA challengers, Mylan contends that Teva USA was rendered ineligible for the 180-day award because it was no longer adverse to Cephalon as of October 2011 given its common corporate parent. (*See* Mylan's Mot. at 6-7 (arguing that Teva USA's ANDA "ceased to have any legal

effect").) The parties agree that neither the statute nor any regulation addresses the question of what happens to a right to exclusivity when the ANDA applicant and NDA-holder/patent owner are owned and controlled by the same parent. Nevertheless, Mylan argues first that the statute requires that the NDA-holder/patent holder and the paragraph IV filer remain independent and adverse from the moment of filing the paragraph IV certification until the moment that exclusivity is awarded because, in its view, the purpose of the paragraph IV provision is to confer subject matter jurisdiction upon the Court. (Tr. 53, 104, 105, 108.) Second, Mylan contends that the FDA's grant of exclusivity to such an ANDA-holder violates the Act by conflicting with Congress' intent to bring more generics to market faster. (Mylan's Mot. at 7-8.)

As all agree, this is a matter of first impression. In deciding the case, since the FDA's decision turns upon its interpretation of a statute, the Court must apply the familiar framework set forth in *Chevron USA, Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984). FDA interpretations of the FDCA, as articulated in its letter decisions, are evaluated under the *Chevron* standard. *Mylan Labs, Inc. v. Thompson*, 389 F.3d 1272, 1279-80 (D.C. Cir. 2004); *see also Teva Pharms. USA, Inc.*, 595 F.3d at 1315 (analyzing the FDA's interpretations of the FDCA adopted in letter rulings under *Chevron*).

The first step is determining whether Congress has spoken directly to the "precise question at issue," for, if it has, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43; *New Jersey v. EPA*, 517 F.3d 574, 581 (D.C. Cir. 2008). When determining "whether Congress has spoken to the precise question at issue," courts "must first exhaust the 'traditional tools of statutory construction.'" *Natural Res. Def. Council v. Browner*, 57 F.3d 1122, 1125 (D.C. Cir. 1995) (quoting *Chevron*, 467 U.S. at 843 n.9). This typically includes an analysis of the text, structure,

and purpose of the statute. *See Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 124-26 (D.C. Cir. 2006). If, however, the statute is silent or ambiguous on the specific issue, the Court proceeds to step two of *Chevron* to determine if "the agency's answer is based on a permissible construction of the statute." 467 U.S. at 843. When the agency's construction of a statute is challenged at *Chevron* step two, its "interpretation need not be the best or most natural one by grammatical or other standards . . . . Rather [it] need be only reasonable to warrant deference." *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 702 (1991) (citations omitted).

The statutory provision at the center of this case is the 180-day exclusivity provision:

> If the application contains a certification described in subclause IV of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection [containing] such a certification, the application shall be made effective not earlier than one hundred and eighty days after—
>
> (I) the date the Secretary receives notice from the applicant under the previous application of first commercial marketing of the drug under the previous application, or
>
> (II) the date of a decision of a court in action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
>
> whichever is earlier.

Section 505(j)(5)(B)(iv).[17]

[17] The statute further states that an ANDA must contain:

> a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) . . . (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

Section 505(j)(2)(A)(vii).

While there is no dispute at this time that Teva USA was the first filer for both the '516 patent and the '346 patent and would otherwise be entitled to a 180-day period of exclusivity (*see supra* note 11), Mylan argues that such a result is impermissible because Teva USA's paragraph IV certification became invalid when adverseness was extinguished between Cephalon and Teva USA as a result of the October 2011 acquisition. (*See* Mylan's Mot. at 6-9; Mylan's Reply at 10-23.) Under its theory, since a common entity (Teva Ltd.) controls both sides of the fictional infringement dispute created by the paragraph IV certification, the Court lacks subject matter jurisdiction over the hypothetical suit and this conflicts with the purpose of paragraph IV. (Mylan's Reply at 15; Tr. 53, 104, 105, 108.) This argument is fatally flawed for several reasons.

The statute provides absolutely no guidance or limitations regarding the relationship between the ANDA-holder and the NDA-holder. But, even if one were to superimpose a requirement on the paragraph IV filer so that it could not be under the indirect or direct control of a parent who also has the ability to control the NDA-holder, that would not save Mylan's argument. Requiring litigation between the parties to be at least theoretically possible may be logical at the early stages of the paragraph IV challenge process where there is in fact an opportunity for that adversarial process to work, but at this stage of the proceeding, Mylan's argument makes no sense.

Initially, Teva USA and Cephalon were in fact distinct and in an adversarial posture. As contemplated by the statute, Teva USA filed two paragraph IV certifications; it was sued along with Mylan and the others by Cephalon with respect to the '516 patent in February 2003, thereby triggering a 30-month stay of FDA approval of any ANDA; and the cases were vigorously litigated for three years but were settled in 2005-2006. (*See* Modafinil Letter Decision at 2-3.)

Moreover, contrary to Mylan's argument (Mylan's Reply at 14 n.7, 20; *see also id*. at 15-21), any further litigation between Teva USA and Cephalon as to these two patents is foreclosed for reasons totally unrelated to the current corporate structure of Teva Ltd., Teva USA, and Cephalon. First, Cephalon's 45-day timeline for filing suit against Teva USA based on its paragraph IV certification to the '346 patent passed long before the acquisition. *See* 21 U.S.C. § 355(c)(3)(C). Second, the settlement agreement between Cephalon and Teva USA precludes litigation related to any modafinil patents. (Tr. 16, 23-24.) As a result, even if adverseness for purposes of subject matter jurisdiction was a requirement at one stage of the process, it is no longer a prerequisite under the statute or the agency's regulations for the FDA to issue a final approval as to Teva USA's ANDA and to award the 180-day period of exclusivity to Teva USA.

Second, the notion that exclusivity is predicated on the potential for litigation between adversaries is incorrect as a matter of law. On the contrary, paragraph IV certifications are, for example, not invalidated by licensing agreements between ANDA applicants and patent owners. *See* 21 C.F.R. § 314.94(a)(12)(v) (providing that ANDA applicants who have licensing agreements with the patent owner must indicate this relationship in their applications). Courts have recognized that covenants not to sue between the NDA-holder and the ANDA-holder, which obviously foreclose the adverseness that Mylan claims is essential, do not vitiate the ANDA applicant's exclusivity rights. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1296-97 (Fed. Cir. 2008); *see also Mova Pharm. Corp.*, 140 F.3d at 1072 (recognizing that ANDA applicants could collude with patent-owners to keep other generics off the market indefinitely).[18] And this makes perfect sense since the FDA's job is to administer the provisions

[18] Therefore, Mylan's recent attempt to distinguish the cases cited by intervenor-defendants is not persuasive. Contrary to Mylan's argument (*see* Mylan's Observations on Teva's Response to the Court's Post-Argument Questions at 3-4), these cases are relevant because they help to

of the FDCA and not "to get into the business of addressing the merits of patent litigation." (Tr. 64.)[19]

Third, Mylan reads too much into the fact that paragraph IV functions by creating a fictional controversy to give courts jurisdiction over patent suits and errs by conflating the way the provision works with its purpose. (Tr. 53, 104, 105, 108.) The purpose of the provision is not to propagate patent litigation, but instead to "facilitate the approval of generic drugs as soon as patents allow" by providing a mechanism for managing patent-holders' rights and challenges by generic companies who want to market competing drugs. *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. ___, 2012 U.S. LEXIS 3106, at **13, 16-18 (2012) (explaining paragraph IV filings in the context of the Hatch-Waxman scheme and the infringement suit that may be "trigger[ed]" as a *result*); *see also Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 106-07 (D.C. Cir. 2008). This provision is particularly important as a means to stake out areas of potential dispute since the FDA does not "independently assess the patent's scope" and views its "'role with respect to patent listing [as] 'ministerial.'" *Caraco Pharm. Labs., Ltd.*, 2012 U.S.

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demonstrate that pre-MMA law was silent on the question of whether a paragraph IV certification could be invalidated by subsequent events. This undermines Mylan's request that the Court invalidate a paragraph IV certification simply because Teva USA, by virtue of the corporate acquisition, may be less adverse to the NDA-holder. In addition, these cases show that Mylan's latest argument (*id*. at 2-3) regarding whether and when Teva USA will launch does not inform the decision on the merits.

[19] As the FDA's counsel further explained,

> [a]s soon as [the] FDA starts . . . evaluating the merits of whether someone is actually making a certification that there is a case with merit for patent infringement, they're no longer administering the statute that's committed to that agency that's an area of their expertise. So far as the settlement agreements in '05, the FDA is not going to look behind those to see whether or not the certifications are valid based upon the settlement agreements.

(*Id*. at 64-65.)

LEXIS 3106, at *15 (quoting 68 Fed. Reg. at 36,682-36,683 (2003).) Litigation arising from that filing—which is not even necessary for a paragraph IV certification to yield exclusivity, *Mova Pharm.*, 140 F.3d at 1069— is simply the result.

Finally, to accept Mylan's argument would require the Court to disregard the well-established principles of corporate law regarding the independence of Cephalon and Teva USA.[20] Although the Court shares Mylan's skepticism with respect to whether they are in fact distinct, it remains true that, in general, "'[c]orporations may bring actions against each other, even if . . . one corporation is the parent or subsidiary of the other." *Scandinavian Satellite Sys. v. Prime TV Ltd.*, 291 F.3d 839, 846 (D.C. Cir. 2002) (quoting 9 Victoria A. Braucher et al., *Fletcher Cyclopedia of the Law of Private Corporations* § 4229 (1999) (omission in original)). To be sure, corporate forms may be disregarded if, for example the corporate entities have a "complete unity of interest." *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 771 (1984). However, "[t]he unity of interest cannot be determined without an examination of the control exercised by the parent over the subsidiary," *Scandinavian Satellite Sys.*, 291 F.3d at 846, which has not yet occurred in this case. Therefore, there is no basis for the Court to assume that Teva USA is not adverse to Cephalon. *See id.*

Ultimately, it is not the province of the Court to rewrite the statute to create such an exemption where there is a corporate relationship between the entities. As the Supreme Court and this Circuit have consistently recognized, that sort of policymaking is not part of the judicial

[20] Significantly, Mylan does not seek to pierce the corporate veil or to disregard the corporate status of Teva USA and Cephalon, but instead, it asks the Court to find a lack of adverseness or the existence of collusion from the fact that the same parent controls both parties. (Mylan's Reply at 16-17.) Amicus FTC, on the other hand, argues based on antitrust concerns and contends that economic substance, and not corporate form, should control. (FTC Amicus at 11; *see also id.* at 8-12.) However, neither party cites any case law or statutory analysis that would support the imposition of antitrust principles onto an FDA matter.

role. *See, e.g.*, *Badaracco v. Comm'r of Internal Revenue*, 464 U.S. 386, 398 (1984) ("The relevant question is not whether, as an abstract matter, the rule advocated by petitioners accords with good policy . . . . Courts are not authorized to rewrite a statute because they might deem its effects susceptible of improvement."); *Blount v. Rizzi*, 400 U.S. 410, 419 (1971) ("[I]t is for Congress, not this Court, to rewrite the statute."); *Joseph v. U.S. Civil Serv. Comm'n*, 554 F.2d 1140, 1155 (D.C. Cir. 1977) ("[A]lthough a court should interpret the meaning of statutory language in light of the intent of its drafters, [it] cannot rewrite the statute to compensate for unforeseen circumstances. That power belongs to the legislature alone.").

Mylan next argues that it is contrary to the Act's broader aims to grant a period of exclusivity to an ANDA-holder who will refrain from launching its own product and simply use the exclusivity period to block other generics, or will not compete as vigorously as would an independent generic. (*See, e.g.*, Mylan's Mot. at 8; Mylan's Reply at 2, 4, 20, 22.) As Mylan correctly argues, and as recognized by the FDA,[21] either scenario would frustrate the Hatch-Waxman Act's goal of benefitting consumers by "get[ting] lower-cost, generic drugs to market." *Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005).

However, the facts elicited at the preliminary injunction hearing do not support Mylan's contentions: consumers have reported that the price of Provigil dropped substantially when Cephalon's authorized generic hit the market on March 30, 2012, and again when Par began selling its generic version on April 6, 2012. (Tr. 5.) If Teva USA launches its own generic product, as it avers that it will, it is anticipated that prices will drop again (Tr. 107; *see* First Am.

[21] In its April 4, 2012 letter to Teva USA, the FDA recognized "the potential for collusion between NDA-holders and captive first generics, and the subversion of the statutory scheme that could result." (Modafinil Letter Decision at 7 n.18.) Nevertheless, it did not deny Teva USA its 180-day exclusivity, but instead, it noted that "the agency may in the future provide guidance on the effect of such a relationship between NDA holder and first applicant upon any claim for 180-day exclusivity." (*Id.*)

Compl. ¶ 19, *FTC v. Cephalon, Inc*., No. 08-2141 (E.D. Pa. Aug. 12, 2009)), particularly since Cephalon does not control Par's pricing and there is no indication that it will limit Par's supply. (*See* Response of Teva USA and Cephalon to Br. Amicus Curiae of the FTC, Ex. 1 (Second Derkacz Decl.) ¶¶ 2-4). Regardless, while Mylan and the FTC have raised serious concerns about threats to competition, the solution to their concerns does not lie with the Court, but with the legislative or executive branch.

In fact, Congress has, as of 2003, attempted to address some of the problems identified by Mylan and the FTC. In the few years before the MMA was enacted, collusion between brand companies and generic companies was a matter of increasing concern within the FDA, the FTC, and Congress.[22] Under pre-MMA law, antitrust suits served as a vehicle to remedy such "pay-for-delay" agreements which aligned the interests of brand and generic companies in a way that, though anticompetitive, were not policed under the Hatch-Waxman Act. *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 813 (D.C. Cir. 2001). Indeed, both the FDA and FTC have long-recognized the potential for manipulation as a weakness of the pre-MMA statute, and in the months leading up to the MMA's enactment, both agencies advocated strenuously for the statute to be amended to include forfeiture triggers to counteract agreements between brand companies and generics whereby a party could use the period of exclusivity to block the flow of generic

[22] *See Examining the Senate and House Versions of the Greater Access to Affordable Pharmaceuticals Bill, Hearing before the S. Comm. on the Judiciary*, 108th Cong. 4 (2003) (statement of Timothy J. Muris, Chairman, FTC); *id*. at 9 (statement of Daniel E. Troy, Chief Counsel, FDA) (explaining goal of proposed forfeiture triggers); *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace, Hearing before the S. Comm. on the Judiciary*, 108th Cong. 45-46 (2003) ("Hearing on Barriers to Entry") (written submission of Timothy J. Muris, Chairman, FTC) (describing study of settlement agreements between NDA-holders and ANDA-holders that resulted in purposive delay on the part of the ANDA-holders entitled to 180-day exclusivity).

drugs to consumers.[23] *See Andrx. Pharms*, 256 F.3d at 815 n.16 (noting, in 2001, that the FDA had proposed a forfeiture trigger to guard against such collusive delay).

Specifically, the FDA, FTC, and Congress confronted the problem of private agreements between companies that had potential to thwart the Hatch-Waxman incentive system through "parking," an agency term for when ANDA applicants entitled to the 180-day period of exclusivity agree to avoid triggering that exclusivity and thereby stall the approval of any other pending ANDAs.[24] This was a growing problem, as companies were increasingly entering into agreements after the initial ANDA challenge, and this anticompetitive behavior sparked antitrust litigation. *See Hearing on Barriers to Entry*, at 2 (statement of Sen. Hatch.). To remedy this statutory loophole, Congress enacted a series of "forfeiture triggers" that required the forfeiture of an otherwise eligible paragraph IV exclusivity claim if, among other things, the generic company failed to commercially market the drug within a prescribed timeframe. 21 U.S.C. § 355(j)(5)(D). The remedy was explicitly made nonretroactive, *see* MMA, § 1102(b)(1), 117 Stat. at 2109, and therefore, it cannot be applied here.

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[23] The FTC, which has been fighting these "pay-for-delay" agreements for over thirteen years (Tr. 97), filed an amicus brief purporting to "take no position," but nevertheless portending grave consequences for the generics industry and the public if the Court refuses to revoke Teva USA's exclusivity. (*See* FTC Amicus at 1-4.) Allowing Teva USA's exclusivity to stand, it argues, would diminish the impact of the Teva Ltd.-Cephalon consent agreement which the FTC imposed to mitigate the damage of the lengthy delay that Cephalon had purchased through its modafinil settlement agreements. (*Id*. at 4.) At the time of the 2011 merger, the FTC understood that Teva USA would remain eligible for shared exclusivity with Cephalon and others even after Cephalon was acquired by Teva Ltd. (*See* Mylan's Reply, Ex. 20 (FTC Press Release) at 2.) Having been unaware of the FDA's determination, it now seeks to enlist the Court in its campaign against such collusion. While the mission is laudable, without a change in the statute, it is not the FDA's job under pre-MMA law or the Court's job to correct this situation.

[24] *See Hi-Tech Pharmacal Co. v. U.S. FDA*, 587 F. Supp. 2d 1, 4 (D.D.C. 2008) (explaining that Congress enacted the forfeiture provisions to "ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition") (quoting 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer)).

The MMA would have been unnecessary if the pre-MMA statute could be read to strip ANDA challengers of their statutory award if they are not sufficiently adverse to the NDA-holder at the time of final approval. *See Goldstein v. SEC*, 451 F.3d 873, 879 (D.C. Cir. 2006) (finding evidence of statutory meaning based on the fact that a subsequently added prohibition would have been unnecessary if the plaintiff's interpretation of the prior statute were correct); *Stone v. INS*, 514 U.S. 386, 397 (1995) ("When Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect."). And, if the pre-2003 statute had in fact required absolute adverseness from the point of filing a paragraph IV certification until the commercial launch of the generic, the drumbeat from the FDA and the FTC for forfeiture triggers would not have been necessary. Although the Court recognizes the hazards of attributing views of a subsequent Congress to a previously enacted statute, *see Mackey v. Lanier Collection Agency & Serv. Inc.*, 486 U.S. 825, 840 (1988), Congress' attempt to remedy collusive "parking" in 2003 weighs strongly against adopting the interpretation that Mylan proposes here.

In short, Mylan's position may well be sound as a policy matter. However, that is a matter that should be—and to a large degree has been—addressed by Congress. *See Sea-Land Service, Inc. v. Alaska R.R.*, 659 F.2d 243, 246 (D.C. Cir. 1981) (declining "to engraft on [the] statute additions . . . the legislature might or should have made") (quoting *United States v. Cooper Corp.*, 312 U.S. 600, 605 (1941) (alternation in original)); *see also United States* ex rel. *Long v. SCS Bus. & Tech. Inst., Inc*, 173 F.3d 870, 875 (D.C. Cir. 1999). At *Chevron*'s second step, the Court's role is limited. It need not find that the agency's interpretation is "the best or most natural one by grammatical or other standards," *Pauley*, 501 U.S. at 702, "the only one [the agency] permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." *Chevron*, 467

U.S. at 843 n.11. "*Chevron's* premise is that it is for agencies, not courts, to fill statutory gaps." *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 983 (2005). Therefore, if the agency's statutory construction is permissible, the Court must defer to it. *Id*. at 981; *Pauley*, 501 U.S. at 702 ("[It] need be only reasonable to warrant deference.").

For these reasons, the FDA's interpretation regarding Teva USA's 180-day exclusivity appears reasonable, and the Court cannot find it likely that Mylan will succeed on the merits.

B. "Actively Pursuing" Approval

In its second argument, Mylan contends that the FDA arbitrarily and capriciously violated its regulations because it did not disqualify Teva USA for failure to "actively pursu[e]" final approval. (Mylan's Mot. at 12.) This argument is based on 21 C.F.R. § 314.107(c)(3), which provides:

> if FDA concludes that the applicant submitting the first application is not actively pursuing approval of its abbreviated application, FDA will make the approval of subsequent abbreviated applications immediately effective if they are otherwise eligible for an immediately effective approval.

According to Mylan, the FDA should have found that Teva USA abandoned its ANDA. (Mylan's Mot. at 12.)

Of course, an agency is obligated to follow its own regulations, *Mine Reclamation Corp. v. FERC*, 30 F.3d 1519, 1524 (D.C. Cir. 1994), but the FDA argues that it has. (FDA's Opp'n at 13.) In its March 28, 2012 letter to Teva USA, the FDA itself raised the possibility that Teva USA could be rendered ineligible under this regulation, noting that it must consider the effect of the facts that

> (1) Teva has not filed a submission to its ANDA for modafinil tablets since 2009, (2) it has not requested final approval of its ANDA, and (3) it has not provided FDA with any indication that, in like of its purchase of the [NDA-holder], it ever intends to seek approval of its ANDA.

(*See* Mar. 28 Letter from FDA to Teva USA at 2.) Not surprisingly, two days later, Teva USA responded with a letter seeking final approval of its ANDA. (*See* Mar. 30, 2012 Letter from Teva USA to FDA.) Days later, the agency concluded that the follow-up letter was sufficient to demonstrate "active pursuit" of its ANDA and that it would not disqualify Teva USA. (*See* Apr. 4, 2012 Letter from FDA to Teva USA at 7 & n.21; FDA's Opp'n at 12-13.)

This claim must be considered in light of the "'substantial deference' [due] to an agency's interpretation of its own regulations." *Orion Reserves Ltd. P'ship v. Salazar*, 553 F.3d 697, 707 (D.C. Cir. 2009) (alteration in the original; some internal quotation marks omitted) (quoting *Fabri Constr. Co. v. Sec'y of Labor*, 508 F.3d 1077, 1080-81 (D.C. Cir. 2007)); *see Auer v. Robbins*, 519 U.S. 452, 461 (1997); *Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030, 1036 (D.C. Cir. 2008) ("An agency's determination of its own regulation is entitled to 'substantial deference,' unless 'plainly erroneous or inconsistent with the regulation.'" (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)).

Mylan contends that the FDA's application of the regulation does not warrant deference because Teva USA's March 30, 2012 letter is insufficient grounds for finding that Teva USA actively pursued its ANDA. (Mylan's Reply at 23-25.) Although the regulations do not define "actively pursuing approval," Mylan relies on the FDA's explanation when promulgating this rule:

> the phrase "actively pursuing approval" is intended to encompass a drug sponsor's good faith effort to pursue marketing approval in a timely manner. In determining whether a sponsor is actively pursuing marketing approval, FDA will consider all relevant factors, such as the sponsor's compliance with regulations and the timeliness of its responses to FDA's questions or application deficiencies during the review period.

Abbreviated New Drug Application Regulations; Patent and Exclusivity, 59 Fed. Reg. 50,338, 50,354 (Oct. 3, 1994).

Mylan does not claim that Teva USA failed to comply with the regulations, was not timely in responding to the FDA's questions, or that there were application deficiencies. Instead, Mylan argues that Teva USA intended to use its exclusivity to block other generic modafinil providers and that this motive, absent contradictory evidence, constitutes abandonment. (Mylan's Reply at 25.) First, the facts do not support the claim that Teva USA will use its period of exclusivity to block competition. Second, even if Mylan were correct, this type of "parking" was permitted under pre-MMA law. Third, although Teva USA has only recently announced an intention to actually sell generic modafinil (at the preliminary injunction hearing in this case), its eagerness to market is not one of the factors identified by the agency, nor does Mylan provide any legal support for its contention that a generic's lackadaisical attitude constitutes abandonment. There is no indication that the agency has deviated from its ordinary practice, particularly since the FDA's counsel informed the Court that, "to the best of [the] FDA's knowledge, no first applicant's ANDA has ever been deemed abandoned." (Tr. 54.) Finally, Teva USA further showed that, as a matter of fact, it had not abandoned its ANDA since it had communicated with the FDA at various points after 2009, which included emails asking about labeling requirements in anticipation of launching its ANDA-based modafinil. (*See* Tr. 81-84; *see also* Dkt No. 36 (communication from Teva USA to the FDA).)

In the absence of any legal authority or factual support for Mylan's position, the Court cannot conclude that the agency's interpretation in this case was unreasonable. While one is obviously skeptical of Teva USA's motives in pursuing final approval, the FDA's conclusion that neither the statute as it existed pre-MMA, nor the agency's regulations apply here is reasonable and entitled to deference. *See Devon Energy Corp.*, 551 F.3d at 1037. Therefore, Mylan has not established a likelihood of success on the merits of its claim of abandonment.

III. IRREPARABLE HARM

Without a likelihood of success on the merits of either claim, Mylan cannot obtain preliminary injunctive relief. *See Greater New Orleans Fair Housing Action Ctr.*, 639 F.3d at 1089. To demonstrate irreparable injury, a plaintiff must show that it will suffer harm that is "more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff." *Gulf Oil Corp. v. Dept. of Energy*, 514 F. Supp. 1019, 1026 (D.D.C. 1981). To warrant emergency injunctive relief, the alleged injury must be certain, great, actual, and imminent. *See Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). It is well established in this jurisdiction, that mere economic harm is insufficient, *see Wis. Gas*, 758 F.2d at 674; *Boivin v. US Airways, Inc.*, 297 F. Supp. 2d 110, 118 (D.D.C. 2003), unless a plaintiff can establish that the economic harm is so severe as to "cause extreme hardship to the business" or threaten its very existence. *Gulf Oil*, 514 F. Supp. at 1025; *see also Wis. Gas*, 758 F.2d at 674.

Mylan alleges that it will be irreparably harmed if its entry into the generic drug market is delayed. (Mylan's Mot. at 13-15.) This includes not only lost sales during the 180-day period and the costs sunk into its aborted April 2012 launch, but also the decreased ability to sell prospectively, including lost customers, distribution channels, and long-term agreements. (*See* Mauro Decl. ¶¶ 4-10.) Even if economic harms are not ordinarily enough, Mylan argues, it is sufficient here because sovereign immunity will prevent it from recovering from the FDA if it is ultimately successful. (Mylan's Mot. at 14-15.)

Mylan has, nevertheless, failed to show that the financial losses it faces satisfy the irreparability standard. In support of its allegations, it has submitted a declaration from President Anthony Mauro. (*See* Mauro Decl.) Although Mauro avers that Mylan's losses will be "significant" and "considerab[ly] disadvantage[]" Mylan (*id.* ¶¶ 5, 6), and that increased costs from delaying sales of ready-to-market inventory "may translate into an overall loss of revenue

and . . . share of sales" (*id.* ¶ 10), he makes no attempt at quantification. Such unquantified hardship had been found inadequate in similar cases, including one in which Mylan was denied injunctive relief for this same reason. *See Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 123 (D.D.C. 2007) (no irreparable injury where, although "the financial stakes [of allowing other ANDA applicants to enter the market] implicate millions of dollars," Mylan had not shown that its existence was threatened);[25] *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 32 (D.D.C. 2006) (even where plaintiff submitted that it "st[ood] to lose approximately $11 million in sales over 180 days . . . , [the injury] cannot be called anything other than 'merely economic'" and, since it did not threaten the existence of the plaintiff's business, it did not establish irreparable injury), *aff'd*, No. 06-5204, 2006 U.S. App. LEXIS 22342 (D.C. Cir. Aug. 30, 2006); *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 220-21 (D.D.C. 1996) (mere speculation about loss of 50-70 percent of its market share if the FDA approved a competitor's ANDA does not constitute irreparable injury, particularly where the business "will undoubtedly survive"); *Mead Johnson Pharm. Group v. Bowen*, 655 F. Supp. 53, 56 (D.D.C. 1986) (no irreparable injury based on patent-owner plaintiff's "pure[ly] specuti[ve]" loss of market share from the approval of ANDAs), *aff'd*, 838 F.2d 1332 (D.C. Cir. 1988).

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[25] Denying a second motion for a preliminary injunction in the same case, the court again found no irreparable injury and noted:

> [p]erhaps a showing that the financial wherewithal of the plaintiff had changed to such a degree that a dilution of its market share would likely lead to financial collapse would constitute a sufficient change in circumstances for the court to revisit (for the second time) its prior ruling. And perhaps such a showing would constitute a sufficient emergency for the court to issue a stay, though the D.C. Circuit denied that precise request.

Mylan Labs., Inc. v. Leavitt, 495 F. Supp. 2d 43, 48 n.7 (D.D.C. 2007).

Mylan argues that the defendant's immunity from damages makes the harm irreparable even if monetary loss alone is not sufficient. (*See* Mylan's Mot. at 14-15.) While it is true that at least one court has said as much, the plaintiff in that case, unlike Mylan, had demonstrated that the economic losses would jeopardize its business. *See, e.g., Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 28-29 (D.D.C. 1997).[26] Clearly, this cannot be the rule because every action claiming economic loss caused by the government would meet the standard. *See, e.g., Biovail Corp. v. U.S. FDA*, 519 F. Supp. 2d 39, 49 (D.D.C. 2007) (rejecting the argument that "the economic harm [plaintiff] will suffer is unrecoverable, and therefore irreparable, because the FDA is immune from suit for damages"); *Sandoz, Inc*., 439 F. Supp. 2d at 31-32; *cf. CollaGenex Pharms., Inc. v. Thompson*, No. 03-1405, 2003 U.S. Dist. LEXIS 12523, at **7, 31-34 (D.D.C. July 22, 2003) (finding irreparable harm established where a 150-person company depended on sales of the drug at issue for 80 percent of its income and faced competition by a much larger company if the challenged ANDA was approved).

Nor can Mylan's situation be compared to those of companies that stand to lose sole market exclusivity. While some courts have found that the loss of a statutory entitlement to the 180-day head start could be irreparable because, "[o]nce the statutory entitlement has been lost, it cannot be recaptured," *Apotex, Inc. v. FDA*, No. 06-0627, 2006 U.S. Dist. LEXIS 20894, at *57 (D.D.C. Apr. 19, 2006), *aff'd*, 449 F.3d 1249 (D.C. Cir. 2006); *Mova Pharm.Corp. v. Shalala*, 955 F. Supp. 128, 131 (D.D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998), that is not the case here since Mylan cannot enjoy sole market exclusivity. Furthermore, the cases cited by Mylan are inapposite since they involved smaller companies that lost their 180-day exclusivity and

[26] *CSX Transp. v. Williams*, 406 F.3d 667 (D.C. Cir. 2005), offers no support, as the Court of Appeals rejected this argument since the defendant was not protected by Eleventh Amendment immunity. *Id*. at 674 n.7.

therefore lost the opportunity to compete against larger ones and their claim was supported by evidence of a potentially debilitating loss. *See, e.g., CollaGenex Pharms., Inc.* 2003 U.S. Dist. LEXIS 12523, at *33 (noting the "David-and-Goliath size comparison" of the companies); *Mova Pharm. Corp.*, 955 F. Supp. at 131 (a small company may be irreparably injured by loss of 180-day marketing exclusivity if forced to compete against Mylan, a much larger company). Even if an injunction is granted, Mylan would still face competition from authorized generics sold by Cephalon and Par and, because it was not first filer as to both the '516 patent and the '346 patent, competition by several other ANDA applicants as well. At a minimum, Mylan could share the exclusivity period with Watson, who was a first filer on the '346 patent, as well as Barr (which is a wholly-owned subsidiary of Teva Ltd.), and Ranbaxy, the fellow first filers on the '516 patent. (Tr. 36.) This further diminishes the gains it could expect if multiple early entrants are permitted.

Thus, Mylan has not provided a sufficient factual or legal basis for a finding of irreparable harm.

IV. BALANCE OF EQUITIES

In considering whether the balance of equities favors granting a preliminary injunction, courts consider whether an injunction would "substantially injure other interested parties." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006); *see Winter*, 555 U.S. at 24 ("[C]ourts 'must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief.'" (quoting *Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 542 (1987)). Here, the balancing produces a somewhat murky picture since it is unknown whether Teva USA will avail itself of its 180-day head start or whether it will be prevented from doing so by manufacturing difficulties or the lack of final approval.

If the injunction were granted in theory and assuming it can take advantage of it, Teva USA would lose its statutorily granted right to *sole* exclusivity, which "cannot be recaptured," *Apotex, Inc.*, 2006 U.S. Dist. LEXIS 20894, at *57, as well as the profits from being one of only three generics in the modafinil market. (Tr. 35-36.) In contrast, if the injunction were not granted, Mylan would lose a *shared* head start and a smaller share of profits because it would be one of potentially five generics in the modafinil market. Cephalon, however, cannot claim to be harmed by the potential loss of sales. It has already delayed the introduction of competitive generics for almost seven years by virtue of its settlement agreements with the filers of paragraph IV certifications referencing the '516 patent, earning over a billion in sales of Provigil last year alone. (*See* Derkacz Decl. ¶ 6.) Given this, Cephalon's claim that it "will face competition in the market and may lose profits if the defendant approves [a generic drug company to enter the market] is insufficient to establish irreparable harm." *Biovail Corp.*, 448 F. Supp. 2d at 164. The FDA, for its part, claims to be harmed by the frustration of the Hatch-Waxman process if the Court were to enjoin its grant of exclusivity to Teva USA. (FDA's Opp'n at 16-17.)

Here, as "'often happens . . . . one party or the other will be injured whichever course is taken. A sound disposition … must [then] depend on a reflective and attentive appraisal as to the outcome on the merits.'" *Serono Labs., Inc*, 158 F.3d at1326 (quoting *Del. & Hudson Ry. Co. v. United Transp. Union*, 450 F.2d 603, 620 (D.C. Cir. 1971)). Ultimately, the balance of equities is not a particularly decisive factor.

V. PUBLIC INTEREST

As to the last relevant factor, the Court would be hard pressed to find that the result here promotes the public interest, both because it authorizes yet another delay in bringing generic modafinil to consumers and since it undercuts the FTC's work to combat such "pay-for-delay" schemes. (Tr. 95-98, 100-01.) Although the text of the statute compels the Court's decision, the

broader goals are clearly frustrated. *See Teva*, 595 F. 3d at 1318; *Apotex, Inc.*, 2006 U.S. Dist. LEXIS 20894, at *61. However, it is not for the Court to change the legislation so it can better achieve its objective. Mindful of the fact that "our polity would be very different indeed if the courts could decline to enforce clear laws merely because they thought them contrary to the public interest," *Mova Pharm. Corp*., 140 F.3d at 1067, the Court must recognize that the "public's interest in the rapid movement of generic drugs into the marketplace . . . . alone cannot support . . . an injunction." *Id*. at 1067 n. 6. Thus, "the operation of the statute on the facts of this case may appear to . . . be an invitation for abuse, but [the] remedy lies with Congress, not this Court." *Mova Pharm. Corp.*, 955 F. Supp. at 131.

CONCLUSION

Therefore, the Court will deny plaintiff's motion for a preliminary injunction. A separate order accompanies this Memorandum Opinion.

/s/
ELLEN SEGAL HUVELLE
United States District Judge

Date: April 23, 2012