EXHIBIT C

No. [illegible]

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

MYLAN PHARMACEUTICALS INC., Plaintiff-Appellant

[illegible]

TOMMY G. THOMPSON, Secretary of Health and Human Services and
BERNARD A. SCHWETZ, D.V.M., Ph.D., Commissioner of Food and Drugs
[illegible] FOOD AND DRUG ADMINISTRATION
Federal Defendants-Appellees

and

[illegible] CORPORATION and [illegible] PHARMACEUTICALS [illegible] INC.
[illegible] Defendants-Appellees

[illegible] Distrib[illegible] for the Northern District of West Virginia

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TABLE OF CONTENTS

Page(s)

TABLE OF AUTHORITIES iii

STATEMENT OF JURISDICTION 1

STATEMENT OF THE ISSUE 1

STATEMENT OF THE CASE 1

STATEMENT OF FACTS 5

I. Statutory And Regulatory Background 5

A. New Drug Applications 6

B. Abbreviated New Drug Applications 6

C. 180-Day Period Of Market Exclusivity 8

II. Factual Background 10

SUMMARY OF ARGUMENT 17

ARGUMENT 18

I. Standard Of Review 18

A. Chevron Analysis And Deference 19

B. Skidmore Deference 23

C. Principles Of Statutory Construction 24

D. FDA's Guidance Document 26

II. Discussion Of Issues 27

A. The District Court Correctly Determined That The Balance Of Harms Did Not Decidedly Tilt In Mylan's Favor 27

B. The District Court Properly Found That Mylan Was Unlikely To Succeed On The Merits Because FDA Properly Determined That Mylan's Exclusivity Had Expired 31

1. FDA's Statutory Construction Is Consistent With The Language And Purpose Of The FDCA, As Well As Precedent 33

2. The District Court Correctly Applied The Chevron Analysis 38

3. FDA Properly Considered The Purpose Of The Statutory Scheme 40

4. FDA's Decision Is Due Deference 41

C. Alternatively, The District Court's Judgment May Be Upheld Because Mylan No Longer Has Exclusivity 44

D. The Public Interest Weighs Against Injunctive Relief 55

CONCLUSION 56

CERTIFICATE OF COMPLIANCE 57

TABLE OF AUTHORITIES

FEDERAL CASES

Apotex, Inc. v. Shalala, 53 F. Supp. 2d 454 (D.D.C. 1999), aff'd, 1999 WL 956686 (D.C. Cir. Oct. 8, 1999) 34

Board of Governors v. Dimension Finance Corp., 474 U.S. 361 (1986) 41

Blackwelder Furniture Co. v. Seilig Manufacturing Co., 550 F.2d 189 (4th Cir. 1977) 29

Branch Banking & Trust Co. v. FDIC, 172 F.3d 317 (4th Cir. 1999) 23, 24

Bristol-Myers Squibb Co. v. Shalala, 923 F. Supp. 212 (D.D.C. 1996) 28

In re Cardizem CD Antitrust Litigation, 105 F. Supp. 2d 682 (E.D. Mich. 2000) 46

Chevron U.S.A. Inc. v. NRDC, 467 U.S. 837 (1984) 19, 21, 22

Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402 (1971) 18

Colautti v. Franklin, 439 U.S. 379 (1979) 45

Direx Israel, Ltd. v. Breakthrough Med. Corp., 952 F.2d 802 (4th Cir. 1992) 16, 30

First South Product Credit Association v. Farm Credit Admin., 926 F.2d 339 (4th Cir. 1991) 41

Genuten, Inc. v. Shalala, Nos. 97-1873 and 97-1874, 1998 U.S. App. LEXIS 6685 (4th Cir. Apr. 3, 1998) 26, 39

Inwood Laboratories, Inc. v. Young, 723 F. Supp. 1523 (D.D.C. 1989), vacated as moot, 43 F.3d 712 (D.C. Cir. 1989) 39

Keller v. Prince George's County, 923 F.2d 30 (4th Cir. 1991) 45

Massachusetts v. Morash, 490 U.S. 107 (1989) 24, 41

Mastro Plastics Corp. v. NLRB, 350 U.S. 270 (1956) 24

McCarthy v. Bronson, 500 U.S. 136 (1991) 24, 41

MicroStrategy Inc. v. Motorola, Inc., 245 F.3d 335 (4th Cir. 2001) 30

Mova Pharm. Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998) ..... *passim*

Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co., 22 F.3d 546 (4th Cir. 1994) 30

Mylan Pharm., Inc. v. Shalala, 94 F. Supp. 2d 36 (D.D.C. 2000) ..... *passim*

National Rifle Association v. Reno, 216 F.3d 122 (D.C. Cir. 2000) 23

Offshore Logistics, Inc. v. Tallentire, 477 U.S. 207 (1986) 24

Pilot Life Insurance Co. v. Dedeaux, 481 U.S. 41 (1987) 24, 41

Public Citizen v. U.S. Department of Justice, 491 U.S. 440 (1989) 25

Purepac Pharm. Co. v. Friedman, 162 F.3d 1201 (D.C. Cir. 1998) 26, 40

Rust v. Sullivan, 500 U.S. 173 (1991) 22, 43

Serono Laboratories, Inc. v. Shalala, 158 F.3d 1313 (D.C. Cir. 1998) 42

Skidmore v. Swift & Co., 323 U.S. 134 (1944) 23

Teva Pharm., USA, Inc. v. FDA, 182 F.3d 1003 (D.C. Cir. 1999) ..... *passim*

Teva Pharm., USA, Inc. v. FDA, 1999 WL 1042743 (D.D.C. Aug. 19, 1999), aff'd, 2000 WL 1838303 (D.C. Cir. Nov. 15, 2000) 35-37

Teva Pharm., USA, Inc. v. FDA, 2000 WL 1838303 (D.C. Cir. Nov. 15, 2000) 44

Thomas Jefferson University v. Shalala, 512 U.S. 504 (1994) 22

Tuttle v. Arlington County Sch. Board, 195 F.3d 698 (4th Cir. 1999) 18

United States v. Amer. Ry. Express, 265 U.S. 425 (1924) 45

United States v. Mead Corp., __ U.S. __, 121 S. Ct. 2164 (2001) . . . 19, 20, 22, 23

United States v. Raines, 362 U.S. 17 (1960) 45

WMATC v. Holiday Tours, Inc., 559 F.2d 841 (D.C. Cir. 1977) 28

Wetzel v. Edwards, 635 F.2d 283 (4th Cir. 1980) 18

Williams v. U.S. Merit System Prot. Board, 15 F.3d 46 (4th Cir. 1994) 18

Wisconsin Gas Co. v. FERC, 758 F.2d 669 (D.C. Cir. 1985) 28

DOCKETED CASES

Teva Pharmaceuticals USA, Inc. v. Shalala, Civ. No. 00-2592 (RMU) 12, 14

FEDERAL STATUTES

5 U.S.C. § 706(2)(A) 18

21 U.S.C. § 355 . . . . . *passim*

21 U.S.C. § 371(a) 20

28 U.S.C. § 1292(a)(1) 1

28 U.S.C. § 1331 1

FEDERAL REGULATIONS

21 C.F.R. § 10.30 . . . . . 11, 12, 21

21 C.F.R. § 314.53(e) 6

21 C.F.R. §314.94(a)(12) 9

21 C.F.R. § 314.94(a)(12)(viii) 10, 52

21 C.F.R. §314.94(a)(12)(viii)(A) 50

21 C.F.R. § 314.95 . . . . . 8, 46

21 C.F.R. § 314.107 46

21 C.F.R. § 314.107(c)(4) 32

21 C.F.R. § 314.107(f)(2) 8

OTHER

55 Food & Drug L.J. 321, 331 (2000) 47

64 Fed. Reg. 42,873 (Aug. 6, 1999) 26, 43, 44, 47

H.R. Rep. No. 857 (Part I), 98th Cong., 2d Sess. (1984), reprinted in 1984 U.S.C.C.A.N. 2647 5

Pub. L. No. 98-417, 98 Stat. 1585 (1984) 5

Wright, Miller & Cooper, Fed. Prac. and Proc., Jurisdiction 2d, § 3904 (1992) . 45

Wright & Miller, Fed. Prac. and Proc. § 5122 (1977) 51

STATEMENT OF JURISDICTION

The district court had jurisdiction over this case, which raises issues of statutory construction under the Federal Food, Drug, and Cosmetic Act, under 28 U.S.C. § 1331. This Court has jurisdiction over this appeal, filed April 20, 2001, of an interlocutory order of the U.S. District Court for the Northern District of West Virginia, entered April 18, 2001, under 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUE

Whether the district court correctly held that Mylan Pharmaceuticals, Inc. (Mylan) failed to satisfy its burden of proving an entitlement to preliminary injunctive relief?

STATEMENT OF THE CASE

This case involves the interpretation of statutory requirements governing approvals by the United States Food and Drug Administration (FDA) of generic drug products. Mylan, a manufacturer of generic drugs, filed this action for injunctive and declaratory relief against FDA, seeking to extend a period of marketing exclusivity for a drug product under the Federal Food, Drug, and Cosmetic Act (FDCA) in a way not intended by Congress and in a manner completely at odds with the statutory purposes of the FDCA. The provision of the statute at issue was designed to give one generic drug manufacturer a 180-day "head start" over other generic drug manufacturers. What Mylan seeks to do,

through an agreement it reached with the brand name drug manufacturer, Pfizer, Inc., is to prevent all generic drug competition for its 30 milligram (mg.) nifedipine product, not just defer such competition for 180 days.

Pfizer has an approved new drug application for a 30 mg. nifedipine product, Procardia XL 30, which is used to treat hypertension and angina. Mylan submitted an abbreviated new drug application (ANDA) for a generic version of Procardia XL 30, and received FDA approval in December 1999. However, rather than immediately marketing its own product, Mylan began marketing Procardia XL 30 as a "generic" drug under a license from Pfizer.

Biovail Laboratories, Inc. (Biovail) also submitted an ANDA for a 30 mg. generic nifedipine product after Mylan submitted its ANDA. On February 6, 2001, FDA issued final approval for Biovail's ANDA.

In this lawsuit, Mylan challenges the approval of Biovail's ANDA. Mylan asserts that final approval for other generic versions of 30 mg. nifedipine may not be issued until the expiration of the statutory 180-day exclusivity period, which Mylan claims has not yet started. Mylan argues that this exclusivity period has not started to run because Mylan has not yet marketed its own generic product. Nevertheless, until FDA approved Biovail's ANDA in February 2001, Mylan was

the sole marketer of a "generic" 30 mg. nifedipine product (Pfizer's) for over ten months, far longer than the 180-day exclusivity period provided by the statute.

In response to an administrative petition submitted to FDA by Biovail's marketing partner, Teva Pharmaceuticals, USA, Inc. (Teva), FDA determined that Mylan no longer qualified for 180-day exclusivity, and, even if did, such period had expired. As explained in more detail below, the FDCA provides an exclusivity period for the first generic drug manufacturer who challenges an innovator's patent by filing a "paragraph IV certification" with FDA. The 180-day period is a statutory "reward" given to the first generic manufacturer who takes the risk of challenging the innovator's patent, and it gives the first generic a 180-day "head start" over other generics. The 180-day period starts, or is "triggered," when the first generic starts marketing or a court holds the patent in question to be invalid or not infringed.

Initially, Mylan filed a paragraph IV certification with its ANDA, and was sued by Pfizer for patent infringement. However, before a judgment was rendered in the infringement action, Mylan and Pfizer entered into a settlement agreement under which Mylan is marketing Pfizer's product as a "generic" drug. Based on these facts, FDA determined that Mylan was no longer challenging Pfizer's patent,

and therefore had effectively abandoned its paragraph IV certification and was no longer eligible for 180-day exclusivity.

Alternatively, FDA determined that Mylan's exclusivity had expired. Specifically, FDA concluded that by marketing Pfizer's product as a generic, Mylan triggered the 180-day period of exclusivity. Because Mylan had been marketing Pfizer's product as the sole generic competition for Procardia XL 30 for more than 180 days, FDA determined that any exclusivity period to which Mylan was entitled had expired. Under either theory, Biovail's ANDA was eligible for immediate approval, and FDA approved it on February 6, 2001.

Mylan challenged the approval of Biovail's ANDA. The district court did not agree with FDA's first rationale: that Mylan had effectively abandoned its paragraph IV certification. However, the court agreed that the marketing of Pfizer's product triggered Mylan's exclusivity period, which had since expired. Thus, the district court determined that Mylan was unlikely to prevail on the merits. The district court further found that the other factors in the preliminary injunction analysis did not weigh in Mylan's favor. Therefore, it denied Mylan's motion for preliminary injunction. Mylan appealed.

STATEMENT OF FACTS

I. Statutory And Regulatory Background

At issue in this case are provisions of the FDCA that apply to new drug applications and to generic drug approvals. 21 U.S.C. § 355(j). The statutory provisions were added to the FDCA through the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments. Pub. L. No. 98-417, 98 Stat. 1585 (1984). Title I of the Hatch-Waxman Amendments was intended "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." H.R. Rep. No. 857 (Part I), 98th Cong., 2d Sess. at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647. Title II of the Hatch-Waxman Amendments was intended to provide a new incentive for increased expenditures for research and development of pioneer drug products by "restoration of some of the time lost on patent life while the product is awaiting pre-market approval." H.R. Rep. No. 857 (Part I), 98th Cong., 2d Sess. at 15 (1984), reprinted in 1984 U.S.C.C.A.N. at 2648. The statutory scheme crafted by Congress represents a balancing of these two policy goals.

A. New Drug Applications

Under the FDCA, pharmaceutical companies seeking to market pioneer or innovator drugs must first obtain FDA approval by filing a new drug application (NDA). 21 U.S.C. § 355(a), (b). In addition to submitting data demonstrating the safety and effectiveness of the drug, an NDA applicant, also referred to as a sponsor, is required to submit information on any patent that claims the drug or a method of using the drug for which a claim of patent infringement could reasonably be asserted against an unauthorized party. 21 U.S.C. § 355(b)(1), (c)(2). FDA is required to publish patent information, and does so in Approved Drug Products With Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book." See 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.53(a).

B. Abbreviated New Drug Applications

The Hatch-Waxman Amendments permit the submission of abbreviated new drug applications (ANDAs) for generic versions of drugs listed in the Orange Book (listed drugs). 21 U.S.C. § 355(j). Under the abbreviated procedure, ANDA applicants may rely upon FDA's findings of safety and effectiveness for the listed drug that the generic application references. 21 U.S.C. § 355(j)(2). Thus, ANDA applicants do not need to submit data on those issues. The statute requires that an ANDA contain, among other data and information, a certification with respect to

each patent that claims the listed drug or the method of the drug's use for which patent information is required to be filed. 21 U.S.C. § 355(j)(2)(A)(vii). This certification must state one of the following:

(I) that the required patent information relating to such patent has not been filed;

(II) that such patent has expired;

(III) that the patent will expire on a particular date; or

(IV) that such patent is invalid or will not be infringed by the drug for which approval is being sought.

If a certification is made under paragraph I or II, indicating that patent information pertaining to the drug or its use has not been filed with FDA or the patent has expired, approval of the ANDA may be made effective immediately. 21 U.S.C. § 355(j)(5)(B)(i). A certification under paragraph III indicates that the ANDA applicant does not intend to market the generic drug until after the expiration date of the applicable patent, and approval of the ANDA may be made effective on such expiration date. 21 U.S.C. § 355(j)(5)(B)(ii).

A paragraph IV certification requires that the ANDA applicant give notice of the filing of the ANDA to the patent owner and the NDA holder for the listed drug, which notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be

infringed. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95. FDA may approve an ANDA with a paragraph IV certification and the approval may become effective immediately, despite the unexpired patent, unless an action for patent infringement is brought against the ANDA applicant within 45 days of the date the patent owner and NDA holder receive notice from the ANDA applicant of the paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2). Assuming a paragraph IV certification is made and the notice required by 21 U.S.C. § 355(j)(2)(B) is given, if a patent action is brought within 45 days, approval of the ANDA will not become effective until at least 30 months from the date that the patent owner and NDA holder received notice, unless a final decision is reached earlier in the patent case or the patent court otherwise orders a longer or shorter period. 21 U.S.C. § 355(j)(5)(B)(iii).

C. 180-Day Period Of Market Exclusivity

As an incentive to the first generic drug manufacturer to file an ANDA for a particular listed drug and to expose itself to the risk of costly patent litigation, the statute provides that the first manufacturer who files an ANDA containing a paragraph IV certification is eligible for a 180-day period of marketing exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv); see Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1064 (D.C. Cir. 1998); Mylan Pharm., Inc. v. Shalala, 94 F. Supp. 2d

36, 40 (D.D.C. 2000). The 180-day exclusivity period is triggered either by the generic manufacturer's first commercial marketing of the drug or by a decision of a court finding a patent covering the listed drug invalid, unenforceable, or not infringed, whichever is earlier. 21 U.S.C. § 355(j)(5)(B)(iv); 21 C.F.R. § 314.94(a)(12). The 180-day period precludes FDA approval of other generics, but has no effect on the innovator's product. Specifically, the statutory provision establishing this exclusivity reads:

> If the application contains a [paragraph IV certification] 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 eighty days after —
>
> > (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
> >
> > (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
>
> whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv).

Only an application containing a paragraph IV certification is eligible for 180-day exclusivity. See Mylan, 94 F. Supp. 2d at 40. An ANDA applicant is required to amend its patent certification from a paragraph IV to a paragraph III if

the patent is determined to be infringed or if the applicant discovers the submitted certification is no longer correct. 21 C.F.R. § 314.94(a)(12)(viii). If an applicant changes from a paragraph IV to a paragraph III certification, the ANDA applicant is no longer eligible for exclusivity. Mylan, 94 F. Supp. 2d at 56-58.

II. Factual Background

1. Pfizer has an approved NDA for a 30 mg. nifedipine product, and Bayer AG owns the applicable patents for the product. Joint Appendix (J.A.) at 99. In April 1997, Mylan submitted to FDA the first ANDA for a 30 mg. nifedipine product that contained a paragraph IV certification. Id. In July 1997, Pfizer and Bayer sued Mylan for patent infringement in the U.S. District Court for the Western District of Pennsylvania. Mylan notified FDA of the filing of this lawsuit, and final approval of the Mylan ANDA was delayed for 30 months. Id. The 30-month stay expired in December 1999, before a decision was rendered in the Mylan/Pfizer patent litigation. On December 17, 1999, FDA gave Mylan final approval to market its nifedipine product. Id. Despite this final approval, Mylan did not begin to market its product.

2. On March 2, 2000, Mylan announced that it settled its patent infringement action with Pfizer. J.A. at 89. The settlement terminated the patent infringement litigation before the Pennsylvania court issued a decision. J.A. at 99.

Under the terms of the agreement, Mylan obtained a license to market three strengths of Pfizer's nifedipine product. J.A. at 89. Shortly after Pfizer and Mylan settled their patent dispute, Bayer and Mylan also settled their dispute. J.A. at 99.

3. In February 1998, after Mylan had submitted its ANDA, Biovail submitted an ANDA for a 30 mg. nifedipine product. J.A. at 176. On September 27, 2000, FDA issued a tentative approval to Biovail for its ANDA. Id. at 177. FDA explained that final approval could be issued only after the statutory 180-day exclusivity period given to the first generic filer, Mylan, had expired. Id.

4. On August 9, 2000, Teva, Biovail's marketing partner, filed a citizen petition with FDA, requesting that FDA determine that Mylan was no longer eligible for 180-day exclusivity for 30 mg. nifedipine or that such period had expired. J.A. at 341-46; 21 C.F.R. § 10.30. Teva asserted that because Mylan settled its litigation with Pfizer and was no longer challenging the patent, Mylan was no longer eligible for 180-day exclusivity. Id. In the alternative, Teva proposed that Mylan's exclusivity began to run either on the effective date of the Mylan/Pfizer settlement, or on the date that Mylan began to market Pfizer's licensed nifedipine product. Id. Under either rationale, there would no longer be a 180-day exclusivity bar to approval of Biovail's ANDA for 30 mg. nifedipine. See 21 U.S.C. § 355(j)(5)(B)(iv).

5. On October 27, 2000, Teva and Biovail filed a Complaint for Declaratory and Injunctive Relief against FDA in the U.S. District Court for the District of Columbia, seeking essentially the same relief as in the citizen petition. Teva Pharmaceuticals USA, Inc. v. Shalala, Civ. No. 00-2592 (RMU) (D.D.C.).

6. On February 6, 2001, consistent with its regulation requiring responses to citizen petitions within 180 days (see 21 C.F.R. § 10.30), FDA answered Teva's citizen petition and granted the relief requested. First, the agency explained that its existing regulations did not cover the factual situation presented. J.A. at 98-101. Instead, FDA's decision was governed by a guidance document that provides that, until new regulations are in place, FDA will address these 180-day exclusivity issues not addressed by the existing regulations on a case-by-case basis, by direct reference to the statute. Id. at 99, 101, 162-8. FDA explained that, in interpreting the statute and making decisions on a case-by-case basis, it has attempted to effectuate the purposes of the statute. Id. at 101-2.

7. As set forth in the citizen petition response, FDA determined that Mylan's actions rendered it ineligible for 180-day exclusivity. J.A. at 102-4. The Mylan/Pfizer settlement resulted in the dismissal of the patent infringement litigation, and in Mylan's marketing of a nifedipine product under a license from Pfizer. J.A. at 103. The appropriate certification for a company that is no longer

challenging a listed patent is a paragraph III certification. Id. By settling the litigation and marketing Pfizer's nifedipine product, Mylan effectively abandoned its paragraph IV certification. Because applicants who do not have a paragraph IV certification are no longer eligible for 180-day exclusivity, Mylan lost its eligibility for exclusivity. Id. at 102-4; Mylan, 94 F. Supp. 2d at 56-58.

8. Even if Mylan were eligible for 180-day exclusivity, however, FDA further determined that any 180-day period of exclusivity had already expired. J.A. at 104-5. One of two events that can start the running of exclusivity is "the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application." 21 U.S.C. § 355(j)(5)(B)(iv)(I). FDA explained that Mylan's marketing of the Pfizer drug was commercial marketing that began the exclusivity period because whether Mylan markets the product approved in its ANDA or the product approved in Pfizer's NDA is of little import to the statutory scheme. J.A. at 104. Permitting Mylan to market nifedipine without triggering the 180-day exclusivity period would harm the public by denying access to multiple safe and effective generic nifedipine products ready for final approval and give Mylan (and Pfizer) a windfall clearly not intended by Congress. Id. at 105. In addition, FDA determined that its interpretation gives Mylan exactly what the statute intends -

180 days to reap the economic benefits of being Pfizer's sole competition. Id. Because Mylan began marketing the 30 mg. nifedipine product under the license from Pfizer in approximately March 2000, FDA found that Mylan had received the full measure of the intended benefit under the Hatch-Waxman Amendments. Id.

9. Either ground alone -- that Mylan lost its entitlement to exclusivity or that the exclusivity period was triggered when Mylan began marketing nifedipine -- led to the same conclusion: there was no longer a 180-day exclusivity obstacle to approval of subsequent ANDAs for 30 mg. nifedipine products. See 21 U.S.C. § 355(j)(5)(B)(iv). Accordingly, on February 6, 2001, FDA gave final approval to Biovail's 30 mg. nifedipine product.

10. On February 12, 2001, the court dismissed Teva Pharmaceuticals USA, Inc. v. Shalala, Civ. No. 00-2592 (RMU) (D.D.C.).

11. On February 13, 2001, Mylan filed a Complaint and a Motion for a Temporary Restraining Order and for Preliminary Injunction against FDA in the U.S. District Court for the Northern District of West Virginia. J.A. at 4. The government and intervenors Teva and Biovail filed briefs in opposition to Mylan's motion, and the district court held a hearing on the motion on February 16, 2001. J.A. at 5.

12. On April 18, 2001, the district court issued a memorandum opinion and order denying Mylan's motion. J.A. at 388-414. After a comprehensive recounting of the facts, the district court set forth the standard for granting, and the analysis to be undertaken in considering, motions for temporary restraining order and preliminary injunction in the Fourth Circuit. Id. at 391-402.

13. As directed by the law of the Fourth Circuit, the district court began with an analysis of the harm Mylan alleged it would suffer in the absence of injunctive relief. The court observed that the harm must be "neither remote nor speculative, but actual and imminent." Id. at 404. The court noted that, while the declaration filed by Mylan contained "beliefs" about lost, the defendants maintained that Mylan "cannot show irreparable harm simply through its belief or expectation that it will or may sustain lost sales revenue." Id. at 403-4. The court then considered the harms claimed by Teva and Biovail, and FDA. Id. at 405-6. The court concluded that "the balance of hardship to Mylan does not tilt decidedly in plaintiff's favor." Id. at 406 (internal quotes omitted).

14. Because the district court determined that the balance of harms did not favor Mylan, it recognized that, under the law of the Fourth Circuit, Mylan must "demonstrate a 'strong showing of likelihood of success' or a 'substantial likelihood of success' by 'clear and convincing evidence' in order to obtain

injunctive relief." J.A. at 406 (quoting Direx Israel, Ltd. v. Breakthrough Med. Corp., 952 F.2d 802, 818 (4th Cir. 1992)). After setting forth the standard for review of agency decisions, the district court turned to the merits and considered both of the theories endorsed by FDA in its response to Teva's citizen petition. J.A. at 406-411.

15. With respect to the first basis for FDA's decision, the district court rejected FDA's determination that Mylan had effectively changed its paragraph IV certification to a paragraph III certification by entering into a settlement agreement with Pfizer and marketing Pfizer's product. Specifically, the district court found that "there is no statutory provision which grants to the FDA, either expressly or implicitly, the authority to change a 'IV certification' to a 'III certification,'" and that "the FDA ruling is based upon a presumption that is inadequately reached in this particular case." Id. at 409.

16. However, the district court determined that the second, independent basis for FDA's decision was grounded in a reasonable interpretation of the statute. J.A. at 410-11. The court quoted the relevant portion of FDA's citizen petition response, which reasoned that, by being the sole generic competitor to Pfizer for more than 180 days, Mylan had received the full measure of benefit intended by the statute, even though Mylan was marketing a generic version of

Pfizer's product rather than its own. Id. Because FDA's determination provided a second, independent basis for approving Biovail's nifedipine product, the district court determined that Mylan was unlikely to succeed on the merits. Id.

17. Finally, the district court determined that the public interest weighed against entry of a preliminary injunction, in that "Mylan's proposed interpretation of the 'commercial marketing' prong of the FDA ruling would bring about a result that could well work against the main purpose of the Hatch-Waxman Amendments which is to 'bring generic drugs onto the market as rapidly as possible.'" J.A. at 411 (quoting Mova, 140 F.3d at 1068).

18. On April 20, 2001, Mylan appealed the district court's decision of April 18, 2001. J.A. at 8.

SUMMARY OF ARGUMENT

1. The district court correctly denied Mylan's motion for preliminary injunction. The district court correctly balanced the four factors relevant to a preliminary injunction determination. All of the parties alleged injury from an outcome against them, and the court reasonably found that the balance of hardships did not decidedly tilt to Mylan's favor.

2. The district court also correctly found that Mylan was unlikely to succeed on the merits because the court found one of the two alternative

justifications offered by FDA for its administrative decision -- namely, that Mylan's marketing of Pfizer's nifedipine product triggered the exclusivity period -- to be reasonable.

3. Alternatively, the district court's judgment can be upheld based on FDA's determination that Mylan lost its eligibility for exclusivity altogether when it settled its lawsuit with Pfizer and began marketing Pfizer's product.

ARGUMENT

I. Standard Of Review

This Court reviews preliminary injunction determinations for abuse of discretion. Tuttle v. Arlington County Sch. Bd., 195 F.3d 698, 703 (4th Cir. 1999); Wetzel v. Edwards, 635 F.2d 283, 286 (4th Cir. 1980). However, the Court reviews the district court's interpretations of law *de novo*. See, e.g., Williams v. U.S. Merit Sys. Prot. Bd., 15 F.3d 45, 48 (4th Cir. 1994).

The underlying agency decision in this case is reviewed by the Court pursuant to the Administrative Procedure Act ("APA"), and may be disturbed only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard is highly deferential to the agency. Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971).

A week before appellant Mylan's brief was due, the Supreme Court decided United States v. Mead Corp., __ U.S. __, 121 S. Ct. 2164 (2001), which addressed the level of deference to be given to certain types of agency decisions. As set forth below, however, Mead does not change the standard in this case.

A. Chevron Analysis And Deference

In this case, Mylan challenges several interpretations of law made by FDA in its response to a citizen petition filed by Teva. In reviewing FDA's interpretations of provisions of the FDCA, the Court first must examine whether "Congress has directly spoken to the precise question at issue" (Chevron step 1). Chevron U.S.A. Inc. v. NRDC, 467 U.S. 837, 842-43 (1984). If the statute does not answer the precise question, the Court must determine whether the agency's statutory interpretation is "based on a permissible construction of the statute" (Chevron step 2). Id.

In making the assessment of whether FDA's construction of ambiguous statutory provisions is reasonable, the Court must determine the level of deference to accord to the agency's interpretation. Mead, 121 S. Ct. 2164. Where "Congress delegated authority to the agency generally to make rules carrying the force of law," the Court must accord Chevron deference to the agency's statutory interpretation. Id. at 2171. This delegation may be express or it may "be apparent

from the agency's generally conferred authority and other statutory circumstances that Congress would expect the agency to be able to speak with the force of law when it addresses ambiguity in the statute or fills a space in the enacted law." Id. at 2172. Such a delegation may even arise in circumstances in which "Congress did not actually have an intent as to a particular result." Id. at 2172 (citations omitted). The agency interpretations may take the form of rules promulgated pursuant to notice-and-comment rulemaking or individual adjudications. Id. at 2171-73.

The agency ruling in this case is entitled to Chevron deference under the standards set forth in Mead. Congress has delegated to FDA the "authority to promulgate regulations for the efficient enforcement of" the FDCA. 21 U.S.C. § 371(a). Moreover, in the Hatch-Waxman Amendments themselves, Congress specifically authorized FDA to engage in notice-and-comment rulemaking "necessary for the administration of section 505 of the FDCA [21 U.S.C. § 355]." See 21 U.S.C. § 355 note, Pub. L. No. 98-417, § 105, 98 Stat. 1585, 1597 (1984). Thus, with respect to the Hatch-Waxman Amendments, Congress delegated to the agency the authority to "make rules carrying the force of law." Mead, 121 S. Ct. at 2171.

While the interpretations at issue in this case were not promulgated through notice-and-comment rulemaking, they are embodied in a response to a citizen petition submitted pursuant to a formal, administrative process prescribed in detail in FDA's regulations. See 21 C.F.R. § 10.30 (providing the format, content, and procedures relating to citizen petitions). The citizen petition process is an open, public process. Id. Pending petitions are listed on FDA's website, see J.A. at 194-199, and available for viewing and copying in FDA's docket management room. Interested parties have an opportunity to participate in the process, and regularly do, by submitting comments on pending petitions. Often, the petitioner responds to comments submitted regarding its petition, leading to a robust debate of the disputed issues. While not the product of notice-and-comment rulemaking, FDA's decision is nonetheless of the type entitled to Chevron deference under the Mead analysis because the agency was delegated authority to act with the force of law with respect to the Hatch-Waxman Amendments and the decision was arrived at through a structured, administrative process, which provided the opportunity for public input and debate.

Chevron deference means that the Court must defer to the agency's interpretation, so long as it is reasonable. Chevron, 467 U.S. at 843. The agency's construction need not be the one the Court itself would adopt or the one that the

Court believes would best implement Congressional policy. Id. at 844-45; see also Mead, 121 S. Ct. at 2172 (where Chevron deference is applicable, "reviewing court has no business rejecting an agency's exercise of its generally conferred authority to resolve a particular statutory ambiguity simply because the agency's chosen resolution seems unwise, but is obliged to accept the agency's position if Congress has not previously spoken to the point at issue and the agency's interpretation is reasonable") (citations omitted); Thomas Jefferson University v. Shalala, 512 U.S. 504, 512 (1994) ("agency's interpretation must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation") (citations omitted); Rust v. Sullivan, 500 U.S. 173, 184 (1991) (agency's statutory construction will not be disturbed if it "reflects a plausible construction of the plain language of the statute and does not otherwise conflict with Congress' expressed intent").

The D.C. Circuit has recently elaborated on the deference to be given an agency's statutory construction as follows:

> Such deference, the Supreme Court recently explained, is justified because the responsibilities for assessing the wisdom of policy choices and resolving the struggle between competing views of the public interest are not judicial ones, and because of the agency's greater familiarity with the ever-changing facts and circumstances surrounding the subjects regulated.

Nat'l Rifle Assn. v. Reno, 216 F.3d 122, 132 (D.C. Cir. 2000) (quoting, in part, FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 131 (2000) (citations and internal punctuation omitted)); see also Branch Banking & Trust Co. v. FDIC, 172 F.3d 317, 326 (4th Cir. 1999).

B. Skidmore Deference

Even if the Court determines that Chevron deference does not extend to the agency ruling in this case, FDA's decision is still entitled to deference under Skidmore v. Swift & Co., 323 U.S. 134 (1944). See Mead, 121 S. Ct. at 2168, 2175-76. Under Skidmore, the Court may give "considerable and in some cases decisive weight" to administrative decisions "made in pursuance of official duty, [and] based upon more specialized experience and broader investigations and information" than a court is likely to have, provided that the administrative decision is carefully and thoughtfully made. Skidmore, 323 U.S. at 139-40. Indeed, this case presents precisely the circumstance in which the Court should accord weight to the agency's interpretation because it involves a "highly detailed" regulatory scheme to which FDA has brought its "specialized experience" to bear. Mead, 121 S. Ct. at 2175. The agency decision "claim[s] the merit of its writer's thoroughness, logic and expertness," and, as such, is entitled to deference. Id. at 2176.

C. Principles Of Statutory Construction

Whether operating under the analysis set forth in Chevron or Skidmore, the Court must apply the familiar rules of statutory construction in reviewing FDA's decision. The Court must look to the entire purpose of the Hatch-Waxman Amendments in interpreting its provisions. "[I]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 51 (1987) (internal quotes omitted). Accord McCarthy v. Bronson, 500 U.S. 136, 139 (1991) (agreeing that, read in isolation, petitioner's reading was the most natural one but stating that "statutory language must always be read in its proper context"); Massachusetts v. Morash, 490 U.S. 107, 115 (1989); Offshore Logistics, Inc. v. Tallentire, 477 U.S. 207, 221 (1986); Morton Plastics Corp. v. NLRB, 350 U.S. 270, 285 (1956) (rejecting literal interpretation of words in "complete isolation from their context in the Act"); Branch Banking, 172 F.3d at 327-28 ("we look to the provisions of the whole law, and to its object and policy to determine whether [the agency's] interpretation is a permissible construction") (citation and internal punctuation omitted).

"Where the literal reading of a statutory term would 'compel an odd result,' we must search for other evidence of congressional intent to lend the term its

proper scope." Public Citizen v. U.S. Dep't of Justice, 491 U.S. 440, 454 (1989) (quoting in part Green v. Bock Laundry Mach. Co., 490 U.S. 504, 509 (1989)). In the context of construing the Hatch-Waxman Amendments, the D.C. Circuit has directed that "FDA must interpret the statute to avoid absurd results and further congressional intent." Teva Pharm. USA, Inc. v. FDA, 182 F.3d 1003, 1011 (D.C. Cir. 1999).

In another case brought by Mylan, the U.S. District Court for the District of Columbia elaborated on the purposes of the Hatch-Waxman Amendments, which should guide construction of the statute. Mylan, 94 F. Supp. 2d at 52-54. Specifically, the Mylan court identified three factors to consider in interpreting the 180-day exclusivity provision of Hatch-Waxman. First, the statute is to be interpreted in a manner consistent with "the statute's interest in affording market access and incentives for both generic and non-generic makers," and to maintain an incentive for the parties to fulfill the purposes of Hatch-Waxman. Id. at 53. Second, FDA should avoid an interpretation that excessively favors the first generic and the innovator parties' "anti-competitive hold" over the drug. The court observed that "Hatch-Waxman intended to provide an incentive for drug companies to explore new drugs, not a market 'windfall' for crafty, albeit industrious, market players." Id. at 54. Finally, the court directed FDA to avoid

interpreting the Hatch-Waxman Amendments so the decision on whether a generic applicant is entitled to exclusivity rests entirely in the patent holder's hands. Id.

D. FDA's Guidance Document

The situation presented by this case is not addressed by FDA's current regulations and thus must be resolved by direct interpretation of the statute. After certain of FDA's regulations regarding the generic drug approval process were struck down by the D.C. Circuit and this Court (see Mova, 140 F.3d 1060; Granutec, Inc. v. Shalala, Nos. 97-1873 and 97-1874, 1998 U.S. App. LEXIS 6685 (4th Cir. Apr. 3, 1998) (attached to appellant Mylan's brief as addendum 1)), FDA proposed new regulations in August 1999 to implement the 180-day exclusivity provision. See 64 Fed. Reg. 42,873 (Aug. 6, 1999). The proposed regulations have not been finalized. In the interim, FDA issued an explanatory and procedural guidance document, in which it announced that it planned to address 180-day exclusivity issues not covered by existing regulations on a case-by-case basis by direct reference to the statute. J.A. at 162-68.

The D.C. Circuit has upheld the approach taken by FDA in that guidance document. See Barr Pharm. Co. v. Friedman, 162 F.3d 1201, 1204 (D.C. Cir. 1998); Teva, 182 F.3d at 1007.

II. Discussion Of Issues

As the district court correctly explained, preliminary injunctions are extraordinary remedies only sparingly granted after the court weighs the following equitable factors: likelihood of irreparable harm to the plaintiff if relief is denied; likelihood of harm to the defendants if relief is granted; the plaintiff's likelihood of success on the merits; and the public interest. See J.A. at 400-02. Mylan challenges the district court's conclusions with respect to balance of harms and likelihood of success on the merits. However, the district court correctly balanced these factors, and did not abuse its discretion, in determining that Mylan was not entitled to a preliminary injunction.

A. The District Court Correctly Determined That The Balance Of Harms Did Not Decidedly Tilt In Mylan's Favor

The district court correctly determined that the balance of harms did not decidedly tilt in Mylan's favor. Thus, Mylan was required to show a likelihood of success on the merits by "clear and convincing evidence," which Mylan could not do. See J.A. at 406 (quoting Direx Israel, 952 F.2d at 818).

Mylan challenges the district court's irreparable harm determination for two reasons: (1) Mylan claims the court ignored the availability of a bond to protect Teva and Biovail from harm; and (2) the court discounted Mylan's claim that the

absence of a preliminary injunction could lead to a permanent loss of customers. Mylan Brief at 38-42. Mylan is wrong as a matter of law and fact in terms of the weight to be given to these to arguments in balancing the injunction factors.

With respect to its first argument, Mylan begins by asserting that the court should have recognized unrecoverable loss of sales as a basis for a finding of irreparable harm. Id. at 39. However, courts have held that simple allegations of economic loss in and of themselves do not constitute irreparable injury. Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985). Rather, the alleged injury must be significant in relation to the business of the party seeking relief. See WMATC v. Holiday Tours, Inc., 559 F.2d 841, 843 n.3 (D.C. Cir. 1977); Mylan, 94 F. Supp. 2d at 58-59.

Before the district court, Mylan alleged "lost sales revenues [of] ... over ten million dollars (with several million dollars in lost profits)." J.A. at 40. The 2000 annual report for Mylan Laboratories Inc., of which Mylan Pharmaceuticals is a division, records annual sales revenues of over 790 million dollars. J.A. at 157 (citing www.mylan.com/shareholder/2000annual/financial-highlights.htm). Thus, the harm alleged by Mylan falls far short of the type of economic loss that would significantly damage Mylan's business above and beyond a simple diminution in profits. See Mylan, 94 F. Supp. 2d at 59; Bristol-Myers Squibb Co. v. Shalala,

923 F. Supp. 212, 220 (D.D.C. 1996) (holding potential loss of $97 million did not amount to irreparable harm in light of company's revenues).

Mylan is also mistaken in the significance it ascribes to the possibility of indemnification from a bond. First, the authority for requiring a bond to be posted by the party who obtains a preliminary injunction is Rule 65(c) of the Federal Rules of Civil Procedure, which provides that "[n]o restraining order or preliminary injunction shall issue except upon the giving of security by the applicant." The rule itself says nothing to suggest that the bond should be part of the decision of whether to issue a preliminary injunction.

Second, the case law cited by Mylan suggests only that the possibility of indemnification from a bond is one of multiple considerations within the four part balancing test for preliminary injunction. The Fourth Circuit case upon which Mylan primarily relies, Blackwelder, expressly states that the decision on a preliminary injunction "depends upon a flexible interplay among all the factors considered." Blackwelder Furniture Co. v. Seilig Mfg. Co., 550 F.2d 189, 196 (4th Cir. 1977). Mylan cites no authority that states that failure to consider the possibility of indemnification from a bond is by itself reversible error. Indeed, recent Fourth Circuit precedent discussing the standards for issuing preliminary injunctions makes no mention of the possibility of indemnification from a bond as

one of the factors to consider. See, e.g., MicroStrategy Inc. v. Motorola, Inc., 245 F.3d 335, 339 (4th Cir. 2001); Direx Israel, 952 F.2d at 811-14.

Nor can Mylan persuasively argue that failure to enter a preliminary injunction in this case could lead to a permanent loss of customers. Mylan relies on Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co., 22 F.3d 546 (4th Cir. 1994), which stands for the proposition that irreparable harm may be established when "failure to grant preliminary relief creates the possibility of permanent loss of customers to a competitor." Multi-Channel, 22 F.3d at 552. See Mylan Brief at 42. In this case, however, if Mylan were to prevail on a motion for summary judgment, Mylan's customers would presumably return to Mylan. Its only other "competitor" would be Pfizer, an entity with which it has a business arrangement. Moreover, Mylan sells its product for less than Pfizer sells Procardia XL 30 (see J.A. at 52); there is no reason to believe Mylan would lose customers even to Pfizer. Thus, failure to grant preliminary relief does not mean a permanent loss of customers for Mylan, and Multi-Channel does not support a finding of irreparable harm for Mylan.

Finally, nowhere in its critique of the balance of the harms does Mylan mention the harm that would ensue to FDA if an injunction were entered. As the district court noted, FDA would be harmed by "the Court's sanctioning of Mylan's

continued monopoly and by the disruption of the FDA's generic drug program." J.A. at 405-06.[*]

Thus, the district court correctly balanced the competing harms and properly arrived at the conclusion that they did not decidedly tip in Mylan's favor. The district court's careful balancing, and its conclusion that Mylan, therefore, had to establish a likelihood of success on the merits by clear and convincing evidence should be sustained.

B. The District Court Properly Found That Mylan Was Unlikely To Succeed On The Merits Because FDA Properly Determined That Mylan's Exclusivity Had Expired

In determining that Mylan was not likely to succeed on the merits, the district court correctly upheld FDA's determination that Mylan's marketing of Pfizer's nifedipine product satisfied the "commercial marketing" trigger that begins the running of exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv)(I), and, thus, that Mylan's 180-day period of exclusivity has already expired. See J.A. at 410-

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[*] Also weighing against any argument of irreparable harm to Mylan is Mylan's failure to participate in the administrative citizen petition process initiated by Teva. That process is public and anyone can submit information into the record. While Mylan challenges certain of FDA's conclusions, it did not avail itself of the opportunity to provide FDA with information, including its settlement agreement with Pfizer, during the administrative proceeding. Should this Court determine that the factual conclusions challenged by Mylan are pivotal to the decision under review, Mylan should be required to submit its agreement with Pfizer to FDA for consideration in the first instance.

411. The district court quoted the portion of FDA's administrative ruling on this point:

> whether Mylan markets the [product] approved in its ANDA or the product approved [in] Pfizer's NDA is of little import to the statutory scheme; Mylan had begun commercial marketing of generic nifedipine, permitting Mylan to market nifedipine without triggering the beginning of exclusivity would be inconsistent with the intent of the statutory scheme.

Id. The court noted that more than 180 days had elapsed since Mylan began marketing generic nifedipine in March 2000. Following the reasoning of the D.C. Court of Appeal's in Teva, 182 F.3d 1003, the court determined that FDA's interpretation of the FDCA, specifically of the phrase "commercial marketing of the drug under the previous application," was reasonable. Id. The district court's determination is consistent with the purposes of the Hatch Waxman Amendments and existing precedent, and therefore should be upheld.[7]

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[7] In its opening brief on appeal, Mylan reveals for the first time that it manufactured and distributed several batches of its own product. Mylan Brief at 19 n. 4. FDA cannot determine, based on the few details provided by Mylan, whether this distribution constitutes "commercial marketing" under 21 U.S.C. § 355(j)(5)(B)(iv)(I), such that it would trigger the start of any exclusivity to which the Court may determine Mylan is or was entitled. See 21 C.F.R. § 314.107(c)(4). Mylan's late disclosure weighs against issuing an injunction in this case. If the Court determines that the facts relating to Mylan's distribution of its own product are potentially significant, the correct course of action would be to remand with directions that FDA be permitted to consider, in the first instance, the significance of the newly-revealed facts. Any other result would reward Mylan for its inexcusable failure to provide this information at an earlier juncture.

1. FDA's Statutory Construction Is Consistent With The Language And Purpose Of The FDCA, As Well As Precedent

The statute provides:

> If the [ANDA] contains a [paragraph IV certification] and is for a drug for which a previous [ANDA containing a paragraph IV certification] has been submitted, the application shall be made effective not earlier than one hundred and eighty days after ... the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application.

21 U.S.C. § 355(j)(5)(B)(iv). FDA determined, and the district court agreed, that the phrase "first commercial marketing of the drug under the previous application" should be construed to apply to Mylan's marketing of a generic 30 mg. nifedipine product manufactured by Pfizer.

Mylan maintains that "drug under the previous application" must mean its own 30 mg. nifedipine product. Mylan Brief at 23. However, Mylan's interpretation is unduly narrow. The phrase can also be read to mean simply "30 mg. nifedipine product;" the reference to "previous application" is descriptive, rather than restrictive.

In fact, for the term "drug" in the introductory statutory language to make sense, it must mean something other than "Mylan's drug." The statute refers to a second "application ... for a drug for which a previous application has been

submitted." 21 U.S.C. § 355(j)(5)(B)(iv). If "drug" meant "Mylan's drug," as opposed to 30 mg. nifedipine product, the statute would only apply when the second applicant filed an application for the *exact same drug* (e.g., same active ingredient, same inactive ingredients, same manufacturing practices, etc.) as the first applicant. Rather than adopting that impossible standard, FDA, consistent with its interpretation of the rest of § 355(j), interprets "drug" to mean a product with the same active ingredient, same dosage form, and same strength, but not necessarily the same inactive ingredients and manufacturing practices. See, e.g., Apotex, Inc. v. Shalala, 53 F. Supp. 2d 454 (D.D.C. 1999), aff'd 1999 WL 956686 (D.C. Cir. Oct. 8, 1999).

This statutory construction is consistent with the purposes of the statute. The 180-day exclusivity period is intended to give the first ANDA applicant with a paragraph IV certification the opportunity to market with limited competition for 180 days. Mylan, 94 F. Supp. 2d at 40. Like the rest of the Hatch-Waxman Amendments, this provision strikes a balance: it creates an economic incentive and reward for a finite period of time, followed by market access for other generic products.

In effectuating this balance, it makes no difference whether Mylan markets the product approved in its ANDA or Pfizer's product as a generic drug. Mylan

has begun commercial marketing of a nifedipine product and has already obtained 180 days to reap the economic benefit of being Pfizer's sole competitor. Permitting Mylan to market nifedipine without triggering exclusivity would give Mylan an indefinite period, over which it would have complete control, during which other generic products would be excluded from the market. This result would harm the consuming public by denying access to multiple safe and effective generic nifedipine products that are ready for final approval and would give Mylan and Pfizer a windfall.

In construing the "commercial marketing" trigger of the 180-day exclusivity provision, both the district court and FDA relied on the analysis in Teva, 182 F.3d 1003. In that case, the D.C. Court of Appeals was construing the companion "court decision" trigger under 21 U.S.C. § 355(j)(5)(B)(iv)(II), which provides that 180-day exclusivity can also be triggered by a "decision of a court ... holding the patent ... invalid or not infringed." The plaintiff, Teva, had filed an ANDA containing a paragraph IV certification, challenging a patent held by Syntex. Teva was not the first company to file a paragraph IV ANDA; it was in line behind Torpharm, who was eligible for 180-day exclusivity. Teva, 1999 WL 1042743, *3 (D.D.C. Aug. 19, 1999), aff'd, 2000 WL 1838303 (D.C. Cir. Nov. 15, 2000) (attached as Addendum 1).

Torpharm did not yet have final approval, and, thus, did not trigger its 180-day exclusivity by commercially marketing the drug. Also, because Syntex did not sue either Teva or Torpharm for patent infringement, there was no court decision to start Torpharm's exclusivity. Generic manufacturers, such as Teva, who filed paragraph IV ANDAs after Torpharm, were unable to begin marketing their products because they could not receive final approval until the expiration of Torpharm's 180-day exclusivity, which at that point had not yet been triggered by commercial marketing or by a decision of a court holding the patent at issue to be invalid or not infringed. See 21 U.S.C. § 355(j)(5)(B)(iv).

In an effort to begin Torpharm's exclusivity and open the door for its own approval, Teva filed an action for a declaratory judgment against Syntex in California, seeking a judgment that its product did not infringe Syntex's patent. Teva, 1999 WL 1042743, *3. In response to the lawsuit, Syntex informed Teva that it did not believe Teva's product infringed Syntex's patent, and Syntex moved to dismiss Teva's case for lack of subject matter jurisdiction. Id. The California court granted Syntex's motion and dismissed Teva's action for lack of subject matter jurisdiction, finding that Teva lacked a reasonable apprehension of a patent infringement suit. Id.

Based on the above facts, FDA initially concluded that the California court's order of dismissal did not satisfy the statutory "court decision" trigger because it was not, on its face, a "decision of a court ... holding the patent ... to be invalid or not infringed." Id. at *4. The district court agreed with FDA. Id. However, the D.C. Court of Appeals reversed. Teva, 182 F.3d 1003. Rather than focusing on the literal language of the statute, the court examined the practical effect of the statutory terms. Id. at 1008. The court explained that the purpose of the provision was for 180-day exclusivity to begin when there was a court action that had preclusive effect on the innovator's right to pursue a patent infringement action. Id. Therefore, although the court found that "the dismissal was not a judgment on the merits after consideration of evidence presented by the parties," the court construed "decision of a court holding the patent ... invalid or not infringed" to include a dismissal for lack of subject matter jurisdiction because the dismissal had that same preclusive effect as a holding on the merits. Id. at 1009. The court explained that this interpretation was consistent with the purposes of Hatch-Waxman, and recognized that a narrower construction would mean "that the patent holder could manipulate the system in order to block or delay generic competition." Id.

Here, as in Teva, it is appropriate to examine the practical effect of the statutory provision in applying it to a factual situation not expressly contemplated by the statute. The 180-day exclusivity period was intended to allow a generic manufacturer 180 days of marketing a drug without competition from other generic drugs. Mylan, 94 F. Supp. 2d at 40. That occurred here when Mylan began marketing Pfizer's product. Therefore, the district court correctly held that the 180-day exclusivity period was triggered when Mylan began marketing Pfizer's product.

2. The District Court Correctly Applied The Chevron Analysis

Mylan challenges the district court's Chevron analysis. First, Mylan asserts that the district court's analysis fails because the court did not explicitly work through step 1 of the two-step analysis in Chevron in reviewing this part of FDA's decision. Mylan Brief at 19-21. Mylan's hyper-technical argument is without merit.

Mylan concedes that the district court "correctly explained" the analytical framework for review of agency interpretations of statutes. Mylan Brief at 18.[y] In its discussion of the "commercial marketing" trigger, the district court cited the

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[y] As explained above, the recent Supreme Court decision in Mead does not change that framework of analysis for this case.

correct statutory provision, referenced the relevant portion of FDA's administrative decision, and quoted the operative statutory language. J.A. at 410-11. Consistent with Chevron step 2, the court then determined that FDA's interpretation of the statute was "reasonable." Thus, the district court was clearly operating under the correct analytical framework and implicitly found that the language of the statute by itself (Chevron step 1) was insufficiently clear to resolve the issue. Contrary to Mylan's suggestion, the district court need not utter particular magic words in conducting the Chevron analysis.

Second, Mylan contends that FDA's decision falls under Chevron step 1 because the language is clear and unambiguous. Mylan Brief at 22-24. The relevant statutory provision prohibits FDA from approving a second generic drug, that is "a drug for which a previous [paragraph IV] application has been submitted," until 180 days after the "first commercial marketing of the drug under the previous application." See 21 U.S.C. § 355(j)(5)(B)(iv). As explained above, the phrase "first commercial marketing of the drug under the previous application" does not specify who the manufacturer of the drug must be.[#] Accordingly, the

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[#] Contrary to its assertions, Mylan gains no support from Genentec, 1998 U.S. App. LEXIS 6685, or Inwood Labs., Inc. v. Young, 723 F. Supp. 1523 (D.D.C. 1989), vacated as moot, 45 F.3d 712 (D.C. Cir. 1989), because neither case dealt with statutory construction issues presented here. See Mylan Brief at 23-24.

district court correctly determined that the language was ambiguous and it should defer to FDA's reasonable interpretation under Chevron step 2.

3. FDA Properly Considered The Purpose Of The Statutory Scheme

Mylan challenges FDA's consideration of the purpose behind the statutory scheme in its administrative decision. Mylan Brief at 25-32. Mylan's argument runs counter to long-established canons of statutory construction, and to specific instruction that FDA has received from the D.C. Court of Appeals in interpreting this very statutory provision.

As an initial matter, Mylan seems to fault FDA for following the procedures it established in a guidance document "that it itself issued." Mylan Brief at 25. However, as set forth above, the D.C. Court of Appeals has specifically approved of the approach set forth by FDA in the guidance document of regulating directly from the statute prior to the issuance of new regulations, and rejected a procedural challenge to the issuance of the guidance. See Purepac, 162 F.3d 1201. Mylan has no valid cause for complaint with respect to the approach taken by FDA.

Mylan next criticizes FDA's characterization of the marketing of Pfizer's product as a generic drug as being the "functional equivalent" of Mylan's marketing of its own product. Mylan Brief at 25-27. However, "functional

equivalence" is exactly what was upheld by the D.C. Court of Appeals. See Teva, 182 F.3d at 1006.

Mylan cites case law that it says rejects the approach to statutory construction taken by FDA in this case. Mylan Brief at 28-32. However, contrary to Mylan's assertion, FDA's effectuation of the statutory purpose is not at the expense of the language of the statute. Thus, Bd. of Governors v. Dimension Fin. Corp., 474 U.S. 361 (1986) and First South Prod. Credit Ass'n v. Farm Credit Admin., 926 F.2d 339 (4th Cir. 1991) are distinguishable. Here, FDA interpreted the Hatch-Waxman Amendments in a manner consistent with the language of the Amendments, to give effect to their clearly-intended purpose, in accord with canons of statutory construction approved by the Supreme Court. See Pilot Life Ins., 481 U.S. at 51; McCarthy v. Bronson, 500 U.S. at 139; Massachusetts v. Morash, 490 U.S. at 115.

4. FDA's Decision Is Due Deference

Finally, Mylan urges that the district court erred in according deference to the agency's decision. Mylan Brief at 32-37. Mylan claims FDA's administrative decision is suspect because it was issued after Teva and Biovail sued FDA in the

D.C. district court. Id. at 33.[#] The fact that the response to Teva's citizen petition was issued after litigation was commenced does not diminish the deference to which it is entitled. See Serono Labs., Inc. v. Shalala, 158 F.3d 1313, 1325 (D.C. Cir. 1998) (FDA decision issued after district court action was filed was not improper *post hoc* decision: "There is simply no reason to suspect that the interpretation does not reflect the agency's fair and considered judgment on the matter in question." (citing Auer v. Robbins, 519 U.S. 452, 462 (1997))).

Mylan also asserts that FDA's decision is not due deference because it represents a change in the agency's position. Mylan Brief at 33-37. There are at least two problems with Mylan's argument. First, while this is the first time that FDA has made the decisions at issue in this case, this is the first time that these precise questions have been posed to the agency since the invalidation of the agency's successful defense regulation in Mova and Granutec.[#] Also, in a March 1999 citizen petition discussed in Mylan's brief, FDA took the position that a

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[#] Ironically, Mylan seems to fault FDA for following the proper course of making an administrative decision before taking a position in the litigation. See Mylan Brief at 33.

[#] Prior to Mova and Granutec, the first generic drug applicant to submit a paragraph IV ANDA would only have been eligible for 180-day exclusivity if it successfully defended an action for patent infringement. Settlement of a patent infringement suit would have meant the applicant was no longer entitled to exclusivity. See J.A. 166-67.

similar agreement did not divest the first generic applicant of 180-day exclusivity. See Mylan Brief at 36-37. FDA's position was reversed by the district court that heard that action, in part because the court found that FDA's ruling did not effectuate the purposes of the Hatch-Waxman Amendments. See Mylan, 94 F. Supp. 2d at 52-54.[7] In any case, contrary to Mylan's assertion (see Mylan Brief at 36-37), FDA is not suddenly reversing course on its view that "drug" means "drug product" in 21 U.S.C. § 355(j)(5)(B)(iv); rather, the question is whether "drug" means "Mylan's 30 mg. nifedipine product" or "30 mg. nifedipine product," and FDA determined it means the latter.

Finally, Mylan points out that the "fix" proposed by FDA in its August 1999 proposed rule is different than the action taken by FDA in this case. See Mylan Brief at 35. In the rule proposed to implement Mova and Granutec, FDA suggested a 180-day "triggering period" within which exclusivity must be triggered or it is lost. See 64 Fed. Reg. 42,873. The proposed regulation follows an approach suggested by the D.C. Court of Appeals in Mova. See Mova, 140

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[7] Also, any change in an agency's statutory interpretation is entitled to deference where, as here, it is supported by reasoned analysis. See Rust v. Sullivan, 500 U.S. at 186-87 ("An agency is not required to establish rules of conduct to last forever, but rather must be given ample latitude to adapt its rules and policies to the demands of changing circumstances") (citations and internal quotation marks omitted).

F.3d at 1071 n. 11. Under that approach, settlement agreements of the type at issue in this case could not lead to lengthy delays in the introduction of generic drugs; for that reason, FDA proposed not to scrutinize settlement agreements. 64 Fed. Reg. at 42,880. In any event, the regulation proposed by FDA is not yet, and may never be, final and has no bearing on whether FDA's actions in this case are supportable under the statute. See Teva, 2000 WL 1838303 (attached as Addendum 3).

C. Alternatively, The District Court's Judgment May Be Upheld Because Mylan No Longer Has Exclusivity

In the underlying administrative action, FDA offered two reasons for finding that Mylan's exclusivity no longer barred approval of Biovail's ANDA for 30 mg. nifedipine: that Mylan lost its entitlement to exclusivity through its settlement with Pfizer, and that the exclusivity period was triggered when Mylan began marketing nifedipine. While the district court upheld FDA's determination that Mylan's exclusivity period has expired, it improperly rejected FDA's view that Mylan lost its entitlement to exclusivity through its settlement. J.A. at 407-10. As set forth below, this alternative basis for FDA's decision also supports the district court's judgment.

As a preliminary matter, Mylan's suggestion that FDA had to file a cross-appeal to urge an alternative basis for upholding the district court's judgment (Mylan Brief at 13 n. 6, 20) is wrong. It is well-established that "arguments that support the judgment as entered can be made without a cross-appeal." Wright, Miller & Cooper, Fed. Prac. and Proc., Jurisdiction 2d, § 3904 (1992); see also United States v. Amer. Ry. Express, 265 U.S. 425, 435 (1924) ("[I]t is likewise settled that the appellee may, without taking a cross-appeal, urge in support of a decree any matter appearing in the record, although his argument may involve an attack upon the reasoning of the lower court or an insistence upon matter overlooked or ignored by it."); Colautti v. Franklin, 439 U.S. 379, 397 n. 16 (1979) ("Appellees, as the prevailing parties, may of course assert any ground in support of that judgment, 'whether or not that ground was relied on or even considered by the trial court.'") (citing Dandridge v. Williams, 397 U.S. 471, 475 n.6 (1970)); United States v. Raines, 362 U.S. 17, 27 n.7 (1960); Keller v. Prince George's County, 923 F.2d 30, 32 (4th Cir. 1991) (although the district court entered judgment for the defendants on the basis of issue preclusion, the judgment could be affirmed on the alternate ground of immunity).

FDA determined that the settlement between Mylan and Pfizer effectively changed Mylan's patent certification from a paragraph IV to a paragraph III, and,

thus, Mylan lost its eligibility for exclusivity. A paragraph III certification means that the ANDA applicant intends to wait for the patent to expire before marketing its generic. A paragraph IV certification indicates that the generic manufacturer is requesting immediate approval, and is willing to litigate the validity of the innovator's patent. See 21 U.S.C. § 355(j)(2)(A)(vII), 355(j)(2)(B), 355(j)(5)(B)(ii) & (iii); 21 C.F.R. §§ 314.95, 314.107.

The 180-day exclusivity reward provided by 21 U.S.C. § 355(j)(5)(B)(iv) was designed to "encourage competitors to bring cheaper generic drugs to market, [given] that they will likely incur potentially substantial litigation cost associated with challenging pioneer drug makers' patents." In re Cardizem CD Antitrust Litigation, 105 F. Supp. 2d 682, 686 (E.D. Mich. 2000); see also Mylan, 94 F. Supp. 2d at 40. In other words, the Hatch-Waxman Amendments encourage generic companies to challenge innovator patents in order to free up the marketplace to generic competition. The reward for that challenge for the generic manufacturer is an "Edenic moment of freedom from the pressures of the marketplace." Mova, 140 F.3d at 1064. That reward is not available to those who hold paragraph III certifications because they do not risk costly patent litigation that may open the marketplace to generic competition.

Nevertheless, exclusivity can be misused to prolong market power contrary to the intent of the Hatch-Waxman Amendments. David A. Balto, "Pharmaceutical Patent Settlements: The Antitrust Risks," 55 Food & Drug L.J. 321, 331 (2000). The innovator and first generic filer may enter into commercial agreements to "put the cork in the bottle" to prevent other generic competition for an indefinite period by, for example, preventing the exclusivity period from being triggered. Id. at 332. As FDA explained in the preamble to the proposed rules issued in the wake of Mova and Granutec:

> [T]he first generic applicant to file a ... paragraph IV certification can delay generic competition by entering into certain commercial arrangements with an innovator company. The result may be that, notwithstanding the intent of the Hatch-Waxman Amendments, rewards are directed to generic companies for hindering rather than speeding generic competition. ... [I]t can be mutually beneficial for the innovator and the generic company that is awarded 180 days of generic exclusivity to enter into agreements that block generic competition for extended periods. This delayed competition harms consumers by slowing the introduction of lower priced products into the market and thwarts the intent of the Hatch-Waxman Amendments.

64 Fed. Reg. at 42,882-83.

In this case, Mylan was the first generic manufacturer to file a paragraph IV certification for 30 mg. nifedipine. However, Mylan entered into a settlement agreement with Pfizer that resulted in the dismissal of the patent infringement litigation and in Mylan marketing Pfizer's nifedipine product. Mylan is no longer

challenging the validity of the patent claiming Pfizer's drug. And, despite the fact that its ANDA has been approved for some time, Mylan has never marketed its own ANDA product beyond certain charitable distributions. See supra n. 2. Mylan's conduct in abiding by the patent on Pfizer's drug is consistent with a paragraph III certification, not a paragraph IV certification. FDA therefore determined that Mylan's certification should have been changed from a IV to a III in keeping with its conduct. As FDA explained in its citizen petition response, this statutory interpretation is consistent with the principles that guide construction of the Hatch-Waxman Amendments: it avoids perpetuating the first generic and innovator parties' "anti-competitive hold" over the drug and allows market access to other generic manufacturers. J.A. at 104.

The district court erred in construing the statute too rigidly. The court articulated the appropriate principles regarding deference to be given to an agency interpreting a statute to fill in the gaps left by Congress, but then did not apply those principles. The court recognized that under Chevron when a statute is "silent or ambiguous" with respect to a specific issue, *the court should defer to the agency's reasonable interpretation.* J.A. at 408. It further recognized that the agency must be allowed to formulate policy and make rules to fill a "gap" left in the statute. It nevertheless concluded that, because the statute was "silent" on the

issue of changing from a paragraph IV to a paragraph III certification, FDA lacked authority for its interpretation. Id. at 407-10.

The court failed to recognize the "gap" in the statutory scheme. While the statute provides for a variety of scenarios regarding paragraph IV certifications, it does not identify what to do if the patent litigation is settled without a court decision on the patent. For example, once an ANDA applicant notifies the NDA holder and patent owner that it is challenging a listed patent, one of two things can happen: either the 45-day period lapses without the filing of a lawsuit and the ANDA can be approved immediately under 21 U.S.C. § 355(j)(5)(B)(iii), or the ANDA applicant is sued for patent infringement and the 30-month stay described in 21 U.S.C. § 355(j)(5)(B)(iii) goes into effect. The statute describes the patent litigation as having two possible results: the court decides the patent is invalid or not infringed, or the court decides the patent has been infringed. 21 U.S.C. § 355(j)(5)(B)(iii)(I)-(III). The statute, however, does not explain what to do if the patent litigation is settled without a court decision, and therein lies the gap. FDA therefore had to determine the effect of this settlement on Mylan's patent certification in the absence of controlling statutory language. FDA attempted to fill that gap by providing an interpretation consistent with the structure and

purpose of the statute. By contrast, Mylan is urging the Court to adopt an interpretation that would thwart the purpose of the statute.

The district court also found that there was no FDA regulation on point. J.A. at 409. However, as FDA explained in the citizen petition response, there is analogous authority in FDA's regulations. J.A. at 102. 21 C.F.R. § 314.94(a)(12)(viii)(A) provides that, if an ANDA applicant submits a paragraph IV certification but subsequently loses the patent litigation with the innovator, the ANDA applicant "shall amend the certification" to change it from a paragraph IV to a paragraph III. If the applicant failed to submit the amendment, FDA would be justified in considering the certification amended as required. The facts here are only a slight variation on the scenario in the regulation -- Mylan did not lose the litigation but settled before the court issued a judgment. The effect of the settlement and losing the patent litigation are essentially the same: the patent litigation ended without opening the door to approval of competing ANDAs. Thus, Mylan, like the ANDA applicant in the above regulation, should be considered to have amended its certification.

The district court also faulted FDA for using the term "presumed," and stated that the "presumption ... [was] inadequately reached in this particular case." J.A. at 407-9. It appears that the district court may have misinterpreted what FDA

intended to convey in its citizen petition response. FDA was not using the term "presume" in the evidentiary sense of assuming a certain fact to be true unless and until contrary evidence is shown. Rather, FDA was using the term "presume" more in line with what FDA "considered" or "deemed" under the circumstances. See generally 21 Wright & Miller, Fed. Prac. and Proc. § 5122 (1977) (distinction between rebuttable and conclusive presumptions: for both types of presumptions, "the proof of one fact is taken as establishing another; but in the case of the conclusive presumption, no evidence is admissible to contradict the presumed fact"). FDA was not presuming that Mylan wanted to give up the exclusivity reward behind a paragraph IV certification; instead, FDA deemed that Mylan's conduct was no longer consistent with a paragraph IV certification so it should be treated as if it had changed its certification.

Finally, the district court faulted FDA's reliance on Mylan, 94 F. Supp. 2d at 40-42. J.A. at 409-10. Mylan presented a factual scenario very similar to the instant case, in which Mylan took essentially the opposite position. In Mylan, Barr Laboratories submitted the first ANDA with a paragraph IV certification for the drug tamoxifen. The innovator sued Barr as a result of its paragraph IV certification, and Barr won the case at the district court level. Before an appeal was complete, Barr and the innovator entered into an agreement under which Barr

obtained a payment from the innovator and a license to market the innovator's tamoxifen product. The patent infringement litigation was dismissed, and Barr amended its patent certification from a paragraph IV to a paragraph III so that Barr's ANDA was not eligible for approval until the patent expired in August 2002. Barr then petitioned FDA requesting a determination that its 180-day exclusivity be preserved until it began marketing its own generic product. FDA granted the petition, Mylan challenged FDA's decision, and the court vacated FDA's decision.

The court explained that collusion by the innovator and the first generic applicant to eliminate generic competition by delaying the start of the 180-day period (thereby holding up all subsequent applicants) conflicts with the purposes of Hatch-Waxman. Mylan, 94 F. Supp. 2d at 53-54. The court found two grounds for immediate approval of tamoxifen ANDAs filed after Barr's ANDA. First, the court held that the district court decision on the patent, although later vacated, began the running of Barr's exclusivity under 21 U.S.C. § 355(j)(5)(B). Id. at 54. Second, the court found that, under FDA's regulation at 21 C.F.R. § 314.94(a)(12)(viii), governing amendments to patent certifications, Barr's change from a paragraph IV certification to a paragraph III certification rendered it ineligible for exclusivity. Id. at 56-57.

The present case is similar to Mylan in that the first generic filer is marketing the innovator's product under a license agreement. Like Mylan, this agreement has resulted in delaying the date on which the first applicant begins to market its generic product and preventing other generic drugs from entering the market. But there are differences as well: in Mylan, the parties settled the patent litigation after the district court issued an opinion but before the appeal was completed; here, the parties settled the patent litigation before the court issued a decision. In Mylan, the first generic changed its certification from a IV to a III; here, the first generic did not amend its paragraph IV certification.

Perhaps some of the factual differences exist because the parties to the instant case read the Mylan decision and altered their conduct in an attempt to avoid the Mylan result. However, these factual differences are not significant in terms of the statutory scheme and the purposes of the statute, and should not lead to a different result. To find otherwise would allow these companies to manipulate the statute to obtain a market windfall contrary to the purposes of Hatch-Waxman. Thus, while the district court is correct that there are some factual distinctions between this case and Mylan, the similarities in terms of what the innovator and first generic filer are trying to do are striking. Moreover, the principle behind the holding of Mylan -- that the statute should be construed to

further its purposes rather than to enable anti-competitive schemes -- applies equally here.

In its opening brief before this Court, Mylan noted FDA's finding that Mylan lost its eligibility for exclusivity, but did not present argument on that issue. Mylan Brief at 13 n.6. However, Mylan did make several arguments to the court below, all of which are meritless. Mylan argued that its arrangement with Pfizer was not anti-competitive because Mylan would have been willing to sell its exclusivity for a reasonable price. J.A. at 24, 39. However, there was no guarantee that Mylan would actually culminate that deal or agree to a sum that was reasonable, and Mylan's refusal to do so could mean a prolonged delay in any other generic reaching the market. In any event, the practical effect of the Mylan/Pfizer settlement is that Mylan has been the sole "competition" for Pfizer's product for more than 180 days. In interpreting the FDCA, FDA need not speculate about potential financial arrangements between private parties that never culminated.

Similarly, Mylan's argument that its settlement arrangement with Pfizer allowed it to market two other strengths of Pfizer's nifedipine product for which it had not even filed ANDAs (see J.A. at 24, 30) is simply irrelevant to whether its arrangement for 30 mg. nifedipine is anti-competitive.

Finally, Mylan relied on Mova, but that reliance was misplaced. See J.A. at 36-7. In Mova, the D.C. Circuit found that the regulation promulgated by FDA that created a new requirement for exclusivity was "gravely inconsistent with the text and structure of the statute." Mova, 140 F.3d at 1069. The court explained that FDA adopted a broad rule where a more narrow solution could have corrected the statutory anomaly. Id. By contrast, FDA here is construing the statute on a case-by-case basis to apply it to a set of facts not contemplated by the statute.

In sum, FDA properly determined that the effect of Mylan's decision to no longer challenge the patent, Mylan's marketing of Pfizer's product, and Mylan's attempt to delay the market entry of other generic drugs, was to divest Mylan of continuing eligibility for the reward for originally challenging the innovator's patent. The Court should uphold FDA's determination that Mylan was no longer entitled to an exclusivity period because its certification had effectively changed from a paragraph IV to a paragraph III.

D. The Public Interest Weighs Against Injunctive Relief

Mylan does not challenge the district court's determination that the public interest weighed in favor of denying injunctive relief because the relief Mylan seeks is contrary to the purpose of the Hatch-Waxman Amendments. See J.A. at 411. This additional factor supports the district court's judgment.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned counsel certifies that the BRIEF OF FEDERAL DEFENDANTS-APPELLEES complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B), as follows:

1. Exclusive of portions of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii), the brief contains 12,565 words, based upon the word count of the word processing system used to prepare the brief.

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CERTIFICATE OF SERVICE

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