IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

MYLAN PHARMACEUTICALS, INC.,

Plaintiff,

v. Civil Action No. 1:01CV23
(STAMP)

TOMMY G. THOMPSON, Secretary,
United States Department
of Health and Human Services,
BERNARD A. SCHWETZ, D.V.M., Ph.D.,
Commissioner, U.S. Food
and Drug Administration and
U.S. FOOD AND DRUG ADMINISTRATION,

Defendants,

and

TEVA PHARMACEUTICALS USA, INC.,
BIOVAIL LABORATORIES, INC.,

Intervenors/Defendants.

**MEMORANDUM OPINION AND ORDER
DENYING PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION
AND TEMPORARY RESTRAINING ORDER,
DENYING MOTION TO DISMISS OF DEFENDANT
TEVA PHARMACEUTICALS USA, INC. AND
BIOVAIL LABORATORIES, INC. AND
DENYING MOTION OF TEVA PHARMACEUTICALS USA, INC.
AND BIOVAIL LABORATORIES, INC.
FOR EXPEDITED DOCUMENT PRODUCTION**

Pending before this Court is the motion of plaintiff Mylan Pharmaceuticals, Inc. ("Mylan") for a preliminary injunction and temporary restraining order filed pursuant to Federal Rule of Civil Procedure 65. For the reasons set forth below and following a hearing on the motion for preliminary injunction held on February 16, 2001, the motion for preliminary injunction and temporary restraining order is denied.

I. Procedural History

Mylan filed a complaint and separate motion for preliminary injunction on February 13, 2001. Following a transfer of this civil action to the undersigned judge, this matter, on February 14, 2001, was set for hearing on February 16, 2001.

On February 13, 2001, Mylan filed a Motion to Shorten Notice Period for Hearing on Temporary Restraining Order and Preliminary Injunction and a separate Motion for Extension of Page Limit, with regard to its Memorandum in Support of its Motion for Preliminary Injunction.

On February 16, 2001, this Court granted Mylan's motion for extension of page limit in regard to Mylan's memorandum in support of its motion for preliminary injunction and also granted the motion of the U.S. Food and Drug Administration ("FDA") for extension of the page limit.

On February 16, 2001, Mylan filed its Memorandum in Support of Motion for Preliminary Injunction, with attached exhibits. At the hearing on February 16, 2001, defendants and intervenors, Teva Pharmaceuticals, USA, Inc. ("Teva") and Biovail Laboratories, Inc. ("Biovail"), filed a joint motion to intervene as defendants which motion, being unopposed, was granted. Teva and Biovail on that date filed their opposition to plaintiff Mylan's motion for a temporary restraining order and preliminary injunction. On February 16, 2001, Teva and Biovail filed the declaration of William S. Marth, Vice

President of Sales and Marketing for Teva. On February 16, 2001, this Court conducted a hearing on the plaintiff's motion for temporary restraining order and preliminary injunction. In addition to the declarations filed by the parties, the Court heard and considered oral argument presented by counsel for all parties.

On February 20, 2001, defendant FDA, Tommy G. Thompson ("Thompson"), and Bernard A. Schwetz, D.V.M., Ph.D., Commissioner of U.S. Food and Drug Administration ("Schwetz"), filed a memorandum in opposition to Mylan's motion for a preliminary injunction. On February 21, 2001, FDA, Thompson, and Schwetz filed a Supplemental Memorandum in Opposition to Mylan's Motion for Preliminary Injunction. On February 21, 2001, Teva and Biovail filed Intervenor's Supplemental Brief Regarding the Adequacy of Any Potential Bond together with their Motion for Leave to File Under Seal Their Supplemental Brief Regarding the Adequacy of Any Potential Bond. On February 21, 2001, intervenors Teva and Biovail filed a motion to dismiss for failure to exhaust administrative remedies and a memorandum in support of that motion. Plaintiff Mylan, on February 21, 2001, filed its Supplementary Memorandum in Support of Its Motion for a Preliminary Injunction on the Issue of Exhaustion.

On February 21, 2001, intervenors Teva and Biovail filed a motion for expedited document production by Mylan. On February 22, 2001, this Court granted intervenors' motion for leave to

file their supplemental brief on the adequacy of any bond under seal.

On February 28, 2001, Teva and Biovail filed the declaration, under seal, of Rolf K. Reininghaus in support of the Intervenors' sealed supplemental brief regarding the adequacy of any potential bond. Also on February 28, 2001, Mylan filed the declarations of Dawn Beto and Robert Cunard in support of their motion to shorten the notice period for hearing on preliminary injunction and their motion for preliminary injunction.

II. Factual Background

Plaintiff Mylan is a West Virginia corporation with its principal place of business in Morgantown, West Virginia. Mylan is engaged in the research, development, manufacturing, and distribution of generic pharmaceutical products. Defendant Thompson is Secretary of the U.S. Department of Health and Human Services ("HHS") and is responsible for supervising its activities. Defendant Schwetz is Commissioner of the FDA and is responsible for supervising the its activities. Both Thompson and Schwetz are sued in their official capacities. The FDA is an agency within the Public Health Service, which is a part of HHS.

In this civil action, Mylan challenges the FDA's February 6, 2001 decision to grant the Citizen Petition of Teva in which Teva requested that the FDA determine that the Abbreviated New

Drug Application ("ANDA") submitted by Mylan for a 30 milligram nifedipine extended release tablet for the treatment of hypertension and angina is not eligible for, or, alternatively, is no longer eligible for the 180-day exclusivity period provided by certain federal legislation known as the "Hatch-Waxman Amendments."

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman Amendments") amended the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., ("FFDCA"), which regulates the manufacture and distribution of pharmaceuticals. The stated purpose of the Hatch-Waxman Amendments was to "make available more low cost generic drugs[.]" H.R. Rep. No. 98-857, pt. 1, at 14 (1984). The Hatch-Waxman Amendments created § 505(j) of the FFDCA (21 U.S.C. § 355(j)), and established the Abbreviated New Drug Application ("ANDA") approval process which allows low-priced generic versions of previously approved innovator drugs to be approved and brought to market on an expedited basis. A generic drug contains the same active ingredients as the brand-name counterpart, but does not necessarily contain the same inactive ingredients. See Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060, 1063 (D.C. Cir. 1998). Under the Hatch-Waxman Amendments, generic drug makers were permitted to file an ANDA which incorporated data that the "pioneer" manufacturer had already submitted to the FDA regarding the pioneer drug safety

and efficacy. In order to obtain FDA approval, the ANDA must demonstrate, among other things, that the generic drug is "bioequivalent" to the pioneer drug. See Mylan v. Shalala, 81 F. Supp. 2d 30, 32 (D.D.C. 2000). As protection for pioneer drug makers, the applicant is also required to certify in one of four ways that the generic drug will not infringe upon any patent which claims the pioneer drug. See 21 U.S.C. § 355(j)(2)(A)(vii). As Judge Wald noted in Mova Pharmaceutical Corp. v. Shalala:

> The Hatch-Waxman Amendments specify the contents of an ANDA in detail. One requirement is that, for each of the patents applicable to the pioneer drug, the ANDA applicant must certify whether the proposed generic drug would infringe that patent, and, if not, why not. The statute provides ANDA applicants with four certification options: they may certify (I) that the required patent information has not been filed; (II) that the patent has expired; (III) that the patent has not expired, but will expire on a particular date; or (IV) that the patent is invalid or will not be infringed by the drug for which the ANDA applicant seeks approval. 21 U.S.C. § 355(j)(2)(A)(vii). We will call these paragraph I, II, III, and IV certifications respectively.

140 F.3d at 1063-64.

This case involves a "IV certification" initially and ultimately, at least according to the FDA, a "III certification."

The Court of Appeals for the Federal Circuit explained the consequences of a "IV certification" as follows:

> If the ANDA contains a paragraph IV certification, and all applicable scientific and regulatory requirements have been met, approval of the ANDA "shall be made effective immediately" unless the patent owner brings

> an action for infringement under 35 U.S.C.A. § 271(e)(2)(A) within forty-five days of receiving the notice required by 21 U.S.C. § 355(j)(2)(B). 21 U.S.C. § 355(j)(4)(B)(iii). The Hatch-Waxman Act further provides that, when a patent owner brings a section 271(e)(2)(A) infringement action, the FDA must suspend approval of the ANDA. Id. The suspension continues -- and the FDA cannot approve the ANDA -- until the earliest of three dates: (i) if the court decides that the patent is invalid or not infringed, the date of the court's decision; (ii) if the court decides that the patent has been infringed, the date that the patent expires; or (iii) subject to modification by the court, the date that is thirty months from the patent owner's receipt of the notice of the filing of the paragraph IV certification. 21 U.S.C. § 355(j)(4)(B)(iii)(I)-(III); 35 U.S.C.A. § 271(e)(4)(A).

Bristol-Myers Squibb Co. v. Royce Lab., 69 F.3d 1130, 1131-32 (Fed. Cir. 1995), cert. denied, 516 U.S. 1026 (1995); see also Mova, 140 F.3d at 1064.

The statute provides that if an ANDA contains a "IV certification" and is for a drug for which a previous ANDA has been submitted containing such a certification, the later application shall be made effective not earlier than 180 days after the earlier of: (1) the date the FDA received notice from the first ANDA applicant of the first commercial marketing of the drug, or (2) the date of decision of a court in a patent infringement action holding the patent which is the subject of the certification to be invalid or not infringed. This particular provision provides an advantage to the first entity seeking to market a generic version of an already approved drug to undertake a challenge to the patent (or patents) blocking

generic competition with respect to that already approved drug. See Compl. at ¶¶ 11 and 12.

Pfizer, Inc. ("Pfizer") is the holder of an approved New Drug Application ("NDA") for nifedipine tablets, extended release, which it has sold since 1990 under the brand name Procardia® XL. Pfizer has patented this product and the patent was subsequently listed by the FDA in the Orange Book[1] under that product. Procardia® XL is sold exclusively by Pfizer for three available strengths (30, 60 and 90 mg). In April 1997, Mylan became the first generic manufacturer to file an ANDA directed towards a nifedipine table which is a generic bioequivalent of the 30 mg extended release Procardia® XL tablet. Mylan's ANDA contained a "IV certification" with respect to the Pfizer patent.

Thereafter, Pfizer filed a civil action against Mylan in the United States District Court for the Western District of Pennsylvania for infringement of its patent. On February 28, 2000, Pfizer and Mylan entered into a settlement agreement which, according to Mylan's complaint, (a) stipulated to the dismissal of the Pfizer-Mylan civil action, (b) granted Mylan a license to sell a private label version of 30, 60 and 90 milligram Procardia® XL nifedipine extended release tablet supplied by Pfizer, and (c) permitted Mylan to market its own 30

[1] Approved Drug Products with Therapeutic Equivalence Evaluations

milligram ANDA product. Mylan asserts that had the patent civil action in the Western District of Pennsylvania been tried and had Mylan prevailed in that civil action, then Mylan would only have been entitled to market the 30 milligram nifedipine extended release product covered by its own ANDA. Pursuant to the settlement agreement, the civil action in the Western District of Pennsylvania was dismissed without prejudice and Mylan maintained its "IV certification" for its ANDA. See Compl. at ¶¶ 14, 15, 16, 17, 18 and 19. The above-mentioned settlement agreement has not been attached to any papers filed by Mylan in this civil action and has not, as of this date, otherwise been submitted in this civil action, despite defendants' request that it do so.

On April 28, 2000, several months after the Pfizer-Mylan settlement, Mylan received a letter from Biovail asking that Mylan waive its 180-day exclusivity period under the Hatch-Waxman Amendments. On May 4, 2000, Mylan responded that it was prepared to entertain a reasonable offer from Biovail with respect to its exclusivity rights. Biovail responded to that letter on May 29, 2000 but did not make any offer with respect to Mylan's exclusivity. On July 21, 2000, Mylan wrote to Biovail to repeat its invitation to Biovail to submit an offer with respect to Mylan's exclusivity rights. Biovail did not respond to that letter. See Compl. at ¶¶ 20, 21, 22, 23 and 24.

On August 10, 2000, Teva, a licensee of Biovail, filed a Citizen Petition with the FDA in which Teva requested that the FDA determine that the ANDA submitted by Mylan for a 30 milligram nifedipine extended release tablet for the treatment of hypertension and angina was not eligible for or, alternatively, is no longer eligible for the 180-day exclusivity period provided by the Hatch-Waxman Amendments and that the FDA approve the ANDA of Biovail for a 30 milligram extended release nifedipine tablet. The FDA granted Teva's Citizen Petition on February 6, 2001. That decision is attached to and made a part of Biovail's opposition to plaintiff Mylan's motion for a temporary restraining order and preliminary injunction. By this decision, the FDA granted Teva's Citizen Petition on two grounds. First, the FDA held that as a result of the settlement that Mylan reached with Pfizer (the NDA holder and patent owner) whereby Pfizer dismissed its patent infringement suit in the Western District of Pennsylvania, and also whereby Mylan entered into a licensing agreement with Pfizer to market a private label generic version of Pfizer's Procardia® XL nifedipine extended release product, Mylan's "IV certification" under the statute was "effectively changed" from a "IV certification" to a "III certification." Therefore, because applicants who change from a "IV certification" to a "III certification" are no longer eligible for the 180-day exclusivity, the FDA held that Mylan lost its eligibility for exclusivity. Second, the FDA held that

Mylan, by marketing its private label generic version of Pfizer's Procardia® XL product, as opposed to its own 30 milligram ANDA product, triggered the "commercial marketing" provision of 21 U.S.C. § 355(j)(5)(B)(iv)(I) thereby commencing the running of the 180-day exclusivity period.

The February 6, 2001 decision of the FDA was issued after Teva and Biovail had filed a civil action against the FDA in the United States District Court for the District of Columbia, and had moved for summary judgment. The FDA's February 6, 2001 decision was issued before its response to Teva's motion for summary judgment was due, thereby rendering moot the civil action filed by Teva. The Teva and Biovail-FDA civil action was then dismissed.

The FDA by its February 6, 2001 decision approved Biovail's ANDA thereby allowing Teva to market Biovail's 30 milligram extended release generic version of Procardia® XL. See Compl. at ¶¶ 1-4. As the FDA explained in its February 6, 2001 decision, existing FDA regulations did not cover the factual situation presented in the Citizen Petition. Instead, the FDA decision was governed by a what is termed a "guidance document" that provides that, until new FDA regulations are in place, the FDA will address any 180-day exclusivity issue not addressed by existing FDA regulations on a case-by-case basis. See "180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act" (1998 Guidance),

attached as Tab 1 to Memorandum in Opposition to Mylan's Motion for a preliminary Injunction filed by defendants FDA, Thompson and Schwetz. On February 9, 2000, Teva began shipping the Biovail 30 milligram generic nifedipine product to its wholesale and retail outlets.

In this civil action, Mylan contends that the FDA's granting of the Teva Citizens Petition was arbitrary and capricious. Mylan requests that this Court enjoin Biovail's approved status which would have the affect of reinstating Mylan as the sole generic drug on the market. Mylan contends that its 180-day exclusivity period under its ANDA has not yet been "triggered" by either provision of 21 U.S.C. § 355(j)(5)(B)(iv) so as to begin to run. Mylan further alleges that the FDA's conclusion that Mylan's ANDA certification was "effectively changed" from a "IV certification" to a "III certification" as a result of its settlement agreement with Pfizer and licensing for sale of a private level generic version of Procardia® XL products, thus rendering it ineligible for the 180-day exclusivity period, is contrary to law and is arbitrary and capricious because, according to Mylan, the FDA's conclusion is not based upon any reasonable construction of the language of the Hatch-Waxman Amendments or upon any specific factual findings with respect to the settlement agreement in terms of the license. Mylan also contends that the FDA ruling that the 180-day exclusivity period for Mylan's ANDA began to run from the date that Mylan began

marketing the private label generic version of Procardia® XL nifedipine products under a license with Pfizer is also contrary to law and is arbitrary and capricious because, as with the first ruling, the FDA's conclusion is not based on any reasonable construction of the language of the Hatch Waxman Amendments or on any specific factual findings with respect to the settlement agreement and terms of the license. Specifically, at this stage of the case, Mylan claims that it is entitled to injunctive relief that requires the defendants FDA, Thompson and Schwetz to withdraw approval of Biovail's ANDA and to notify Biovail that the approval of its ANDA cannot be made effective until the end of Mylan's 180-day exclusivity period.

III. Applicable Law

The Fourth Circuit recognizes that "preliminary injunctions are extraordinary remedies involving the exercise of a very far-reaching power to be granted only sparingly and in limited circumstances." MicroStrategy Inc. v. Motorola, Inc., No. 01-1289, 2001 WL 293602, at *2 (4th Cir. Mar. 28, 2001) (quoting Direx Israel, Ltd. v. Breakthrough Med. Corp., 952 F.2d 802, 816 (4th Cir. 1992)) (internal quotation marks omitted).

In Blackwelder Furniture Co. v. Seilig Mfg. Co., Inc., 550 F.2d 189 (4th Cir. 1977), Rum Creek Coal Sales, Inc. v. Caperton, 826 F.2d 353 (4th Cir. 1991) and Direx Israel, Ltd. v. Breakthrough Medical Corp., 952 F.2d 802 (4th Cir. 1991), the

Fourth Circuit has set forth the equitable factors that a district court must consider when determining whether a temporary restraining order or preliminary injunction should issue. See also C/R TV Cable, Inc. v. Shannondale, Inc., 792 F. Supp. 1018, 1021-22 (N.D. W. Va. 1992). The four factors which must be considered in granting the preliminary injunction under the Fourth Circuit test are:

> (1) the likelihood of irreparable harm to the plaintiff if the preliminary injunction is denied, (2) the likelihood of harm to the defendant if the requested relief is granted, (3) the likelihood that the plaintiff will succeed on the merits, and (4) the public interest.

Direx Israel, 952 F.2d at 812 (citing Rum Creek, 926 F.2d at 859). Additionally, the "[p]laintiff bears the burden of establishing that each of these factors supports granting the injunction." Id. (quoting Technical Publishing Co. v. Lebhar-Friedman, Inc., 729 F.2d 1136, 1139 (7th Cir. 1984)).

The Direx Israel court emphasized that "[t]he 'likelihood of irreparable harm to the plaintiff' is the first factor to be considered in this connection." Id. If the plaintiff makes "a 'clear showing' of irreparable injury absent preliminary injunctive relief," a district court must then balance the likelihood of irreparable harm to the plaintiff without an injunction against the likelihood of harm to the defendant with an injunction. Id.; Blackwelder, 550 F.2d at 195. Then, if a decided imbalance of hardship appears in the plaintiff's favor, the plaintiff need not show a likelihood of success; plaintiff

need only show that grave or serious questions are presented by plaintiff's claim. Id. at 195-96; see also James A. Merritt & Sons v. Marsh, 791 F.2d 328, 330 (4th Cir. 1986) ("When the balance of harms decidedly favors the plaintiff, he is not required to make a strong showing of a likelihood of success . . . ."). The district court should also consider the public interest. Blackwelder, 550 F.2d at 196. However, as the Blackwelder court concluded "[t]he two more important factors are those of probable irreparable injury to plaintiff without a decree and of likely harm to the defendant with the decree." Id.

The issuance of a preliminary injunction is committed to the sound discretion of the district court. Conservation Council of North Carolina v. Costanzo, 550 F.2d 498, 502 (4th Cir. 1974). In deciding whether to issue a temporary restraining order, the factors to be weighed are the same as those to be weighed in deciding whether to enter a preliminary injunction, Commonwealth of Virginia v. Kelly, 29 F.3d 145, 147 (4th Cir. 1994). If a preliminary injunction is granted, the order granting same must "set forth the reasons for its issuance; shall be specific in terms; [and] shall describe in reasonable detail, and not by reference to the complaint or other document, the act or acts to be restrained." See Fed. R. Civ. P. 65(d); Fed. R. Civ. P. 52(a) ("[I]n granting or refusing interlocutory injunctions the

court shall . . . set forth the findings of fact and conclusions of law which constitute the grounds of its action.").

IV. Injunctive Relief

A. Irreparable Harm to Mylan

First, Mylan must establish that it is likely to suffer irreparable harm if injunctive relief is not granted. See Direx Israel, 952 F.2d at 812. Irreparable harm to Mylan must be actual and imminent, not remote and speculative. As the court noted in Direx Israel:

> The hardship balance and the likelihood of success determination are separate, sequential steps in the application of the hardship test. [Blackwelder Furniture Co. of Statesville, Inc. v. Seilig Mfg. Co., 550 F.2d 189 (4th Cir. 1977)] makes it plain that the balancing of hardship should proceed any consideration of the likelihood of success . . . . And the reason for this statement is easy to understand. The hardship test, by its very nature, is to proceed the consideration of the likelihood of success, since the outcome of the hardship test fixes the degree of proof required for establishing the likelihood of success by the plaintiff. If the hardship balance tilts sharply and clearly in the plaintiff's favor, the required proof of likelihood of success is substantively reduced. Similarly, if the hardship to plaintiff is minimal or nonexistent . . . then the burden on the plaintiff to establish likelihood of success on the merits becomes considerably greater. The likelihood of success determination is to proceed only after the hardship balance itself had been resolved. *It is obvious error to resolve the hardship test by including it in the likelihood-of-success test.*

Id. at 817 (emphasis added).

Mylan, referring to the Declaration of its Vice President of Marketing, Robert Cunard, asserts that if Mylan loses its 180-day exclusivity, Cunard "believe[s] Mylan will lose at least

30% of the generic 30 milligram nifedipine extended release market to Biovail." Cunard also "believe[s] that as a result of this lost market share and price competition with Biovail, Mylan will irretrievably lose over ten million dollars in sales revenues and several million dollars in profits over a 180-day period following the launch of Biovail's 30 milligram nifedipine extended release product." Cunard Declaration at ¶ 11.

Further, Cunard's Declaration states that "Mylan's irretrievable loses [sic] would not be limited to its 30 mg nifedipine product. Purchasers of pharmaceutical products generally prefer to buy pharmaceutical products from a company that can supply multiple strengths of a given product . . . . Because Biovail has been on a market with a generic 60 milligram nifedipine product since September 2000, Biovail will now be able to supply both the 30 and 60 milligram nifedipine extended release products, which are the two most popular strengths." Therefore, states Cunard, Mylan will lose significant market share not only for its 30 milligram nifedipine, but also on its 60 milligram nifedipine extended release product, and that "a significant number of Mylan's customers will likely switch" to purchasing Biovail's 30 and 60 milligram product because of "the preference to purchase different dosage strength versions of a pharmaceutical product from the same supplies." Cunard Declaration at ¶ 12.

The defendants maintain that Mylan cannot show irreparable harm simply through its belief or expectation that it will or may sustain lost sales revenue. Courts in another jurisdiction in which Mylan has sought injunctive relief have held that purely economic injury and economic loss alone, however substantial, does not constitute irreparable harm. Mylan v. Henney, 94 F. Supp. 2d 36, 58 (D.D.C. 2000); Mylan v. Shalala, 81 F. Supp. 2d 30, 42 (D. D.C. 2000). In any event, the required "irreparable harm" must be "neither remote nor speculative, but actual and imminent." Direx Israel, Ltd., 952 F.2d at 812. The plaintiff must make a "clear showing" of irreparable harm. See id. (quoting ECRI v. McGraw Hill, Inc., 809 F.2d 223, 226 (3d Cir. 1987)) ("Establishing a risk of irreparable harm is not enough. A plaintiff has the burden of proving a 'clear showing of immediate irreparable injury.'") As any injury must be such that it cannot be fully remedied by an award of monetary damages, courts have been hesitant to award injunctive relief based on assertions of lost opportunities and market share. Mylan v. Henney, 94 F. Supp. 2d at 58; Mylan v. Shalala, 817 F. Supp. 2d at 42.

B. Irreparable Harm to Defendants

Looking at the second factor under the Blackwelder analysis, i.e., the likelihood of harm to the defendants if the request is granted, defendants Biovail and Teva contend that if injunctive relief is granted, and Biovail is not permitted to continue to

market its product, both Biovail and Teva will also lose substantial sums of money. In his Declaration, filed as Exhibit 6 to Teva and Biovail's Opposition to Mylan's Motion for a Temporary Restraining Order and a Preliminary Inunction, William S. Marth indicates that Teva, as of February 15, 2001, has pending orders worth $10 million which it is in the process of filling. Marth makes a "conservative" estimate that over the next several months, Teva will lose approximately $125,266.00 per day with lost revenues over a six-month period of $22,550,000.00

Hence, Mylan, Teva and Biovail allege similar economic injuries. However, "if 'the plight of the defendant [is] not substantially different from that of the plaintiffs; that is, if there is no imbalance of hardship in favor of the plaintiff, then 'the probability of success begins to assume real significance,' and interim relief is more likely to require a clear showing of a likelihood of success." Direx Israel, 952 F.2d at 808 (quoting Blackwelder, 550 F.2d at 195 n.3). Similarly, the FDA maintains that it would be harmed by "the Court's sanctioning of Mylan's continued monopoly and by the disruption of the FDA's generic drug program." Memorandum in Opposition to Mylan's Motion for a Preliminary Injunction at 29.

At this point, this Court believes that the balance of hardship to Mylan "does not tilt decidedly in plaintiff's

favor," and that, therefore, plaintiff 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. Direx Israel, Ltd., 952 F.2d at 818.

C. Likelihood of Success

Under the Administrative Procedures Act, the decisions of the FDA are subject to judicial review and will only be overturned if they are arbitrary and capricious. 5 U.S.C. § 706. The standard of review for courts examining agency decisions is set forth in Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). The Fourth Circuit recently discussed the test under Chevron in America Online v. AT&T Corp., No. 99-2138, 2001 WL 197818, at *24 (4th Cir. Feb. 28, 2001), as follows:

> Chevron . . . directs a court, when reviewing an agency's interpretation of a statute, to engage in a two-step process. First, it must determine "whether Congress has directly spoken to the precise question at issue." Only if the statutory language is silent or ambiguous with respect to the question posed does the court then proceed to the second step -- to determine "whether the agency's answer is based on a permissible construction of the statute." . . . Thus, Chevron deference is a tool of statutory construction whereby courts are instructed to defer to the reasonable interpretation of expert agencies charged by Congress "to fill any gap left, implicitly or explicitly," in the statutes they administer.

1. FDA Conversion of "IV Certification" to "III Certification"

The FDA, in its February 6, 2001 ruling on the Citizen Petition of Teva, found that Mylan would no longer be eligible for the 180-day exclusivity. After reviewing the Pfizer-Mylan litigation, the FDA ruled that the settlement of that civil action "effectively changed" Mylan's patent certification from a paragraph IV to a paragraph III, and thus Mylan has lost its eligibility for exclusivity. The FDA acknowledges that it has "not yet published a final rule on the 180-day exclusivity and that since the Citizens Petition describes a situation not addressed by FDA's current regulations, the case must be resolved by the statute. The FDA further noted in its ruling that "Mylan has not amended its patent certification as a result of the settlement." See FDA Ruling at 2. The FDA then concluded that it should treat Mylan's "IV Certification" as though it had been changed to a "III Certification." See FDA Ruling at 6. The FDA noted that the details of the Mylan-Pfizer settlement had not been made public but that FDA could, at least, recognize that Mylan "is no longer participating in litigation intended to prove that its product will not infringe the listed patent." See FDA Ruling at 6. Also, the FDA stated that although Mylan's ANDA had been approved "for more than a year, Mylan has never marketed its own ANDA product." See FDA Ruling at 6. Consequently, the FDA determined:

> These facts lead FDA to presume that Mylan believes the product described in its ANDA may infringe the listed patent and is therefore waiting until patent expiring before marketing its own product. The

> appropriate certification for a company that has chosen to wait until a listed patent expires before marketing is a paragraph III certification stating the date of the patent expiration.

(emphasis added). See FDA Ruling at 6.

Therefore, the FDA concluded that it considered Mylan's settlement of the Pfizer civil action and its marketing of Pfizer's product to have "effectively changed Mylan's certification from a paragraph IV to a paragraph III," thus rendering it no longer eligible for 180-day exclusivity.

Chevron counsels that the court must first determine whether Congress has directly spoken to the precise question at issue. If Congress' interest is clear, then the court, as well as the agency, must give effect to the "unambiguously expressed intent of Congress." If, however, the statute is silent or ambiguous with respect to a specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute. The statute, while complex, is not in this Court's opinion, ambiguous. It is, however, silent on the question of Congress' intent to permit or require the agency change a "IV certification" to a "III certification," particularly where it is based upon a party's "presumed" conduct.

Further, an agency in administering a program created by Congress, must be allowed to formulate policy and make rules to fill a "gap" which has been left, implicitly or explicitly, by Congress. There is an express delegation of authority to an

agency to fill by regulation a gap explicitly left open by Congress. However, in this Court's opinion, there is no explicit gap in the statute on the subject of the change of a "IV certification" to a "III certification," particularly when one considers the somewhat severe results such a change by agency ruling can effect. Where there is a Congressional delegation to an agency that is implicit instead of explicit, a court still may not substitute its construction of a statutory provision for a "reasonable interpretation made by the administrator of an agency." Chevron at 844.

While this Court fully recognizes the "considerable weight" that "should be accorded" to the FDA construction of the Hatch-Waxman Amendments, which it is entrusted to administer and the principle of deferral to administrative interpretations, Chevron, 467 U.S. at 844, this Court finds after a careful analysis of the FDA ruling of February 6, 2001 and the relevant statute, that the FDA's interpretation is an unreasonable one. First, 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." Second, there is no FDA regulation that provides any basis for such a change. Third, the FDA ruling is based upon a presumption that is inadequately reached in this particular case. Finally, the sole precedent that the FDA relies upon, Mylan v. Henney, 94 F. Supp. 2d 36 (D.D.C. 2000), is clearly distinguishable because in that

case Barr Laboratories, an ANDA applicant with a "IV certification" by its own actions changed its "IV certification" to a "III certification" as part of its settlement with the NDA holder. In this case, Mylan has not effected a change to its certification and there is no evidence that its settlement agreement with Pfizer requires it to make such a certification change. The FDA ruling, at least on this subject, is therefore unreasonable, even if it possesses a right to make a ruling on this subject on a "case-by-case" basis. Therefore, there is, at least at this point, some likelihood of success by plaintiff Mylan on this feature of the FDA ruling.

2. FDA Ruling on the "First Commercial Marketing"

However, this does not end the analysis. The FDA also considered whether, even if Mylan were eligible for the 180-day exclusivity, that eligibility expired.

As noted by the FDA in its February 6, 2001 ruling, one of the ways that the 180-day exclusivity period can commence is that the Secretary receives notice from the applicant under the previous application of the "first commercial marketing" of the drug under the previous application. See 21 U.S.C. § 355(j)(5)(B)(iv). The FDA determined that Mylan's marketing of the Pfizer product following the settlement was "commercial marketing" that began the 180-day exclusivity period. The FDA explained its ruling:

> whether Mylan markets the produce approved in its ANDA or the product approved is Pfizer's NDA is of little

> import to the statutory scheme; Mylan has begun commercial marketing of genetic nifedipine, permitting Mylan to market nifedipine without triggering the beginning of exclusivity would be inconsistent with the intent of the statutory scheme.

See FDA Ruling at 7-8.

Therefore, because more than 180 days had passed since March 28, 2000, the date the FDA determined Mylan began the commercial marketing, the exclusivity period had expired. At this point, this Court believes that the FDA's interpretation of the phrase "commercial marketing of the drug under the previous application" is a reasonable one. See Teva Pharmaceuticals USA, Inc. v. FDA, 182 F.3d 1003 (D.C. Cir. 1999). On the basis of this part of the FDA ruling, which this Court believes is a reasonable interpretation of the statute, Mylan must be deemed unlikely to succeed on the merits and, therefore, the defendants would prevail.

D. The Public Interest

This Court feels that the final factor, the public interest, must be resolved at this stage in favor of defendants and, therefore, in favor of denying injunctive relief to the plaintiff Mylan. 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." Mova Pharmaceutical Corp. v. Shalala, 140 F.3d at 1068 (D.C. Cir. 1998). The public interest

favors promoting competition in the pharmaceutical industry which would, hopefully, have the desired effect of providing a market for affordable and attainable drugs.

V. Exhaustion of Remedies

On the eve of and during the February 16, 2001 hearing on the motion for injunctive relief, an issue arose as to the effect, if any, to be given to the fact that Mylan did not intervene, or otherwise participate, in the Citizens Petition filed by defendant Teva with the FDA. The Court requested briefing on this issue. Defendants Teva and Biovail then filed a motion to dismiss the complaint for failure by Mylan to exhaust its administrative remedies and a brief in support of that motion. Mylan filed a supplementary memorandum in support of its motion for preliminary injunction concerning the issues of exhaustion of remedies. The defendants, FDA, Thompson, and Schwetz, also filed a supplemental memorandum. While the FDA, Thompson and Schwetz do not contend that exhaustion of remedies with the FDA is a jurisdictional prerequisite of this case, they contend that Mylan's failure to avail itself of the opportunity to participate in the FDA proceeding is further grounds for denying injunctive relief.

This Court can find no related statute or regulation that requires Mylan as an "interested party" to submit any opposition to a Citizen Petition or be precluded from having standing to contest the final agency action of the FDA in this Court.

Further, while the FDA might have been assisted by a filing by Mylan in the Teva Citizen Petition, the defendants have not presented satisfactory evidence to this Court that Mylan's failure to join those proceedings constituted bad faith sufficient, in itself, to constitute a bar to injunctive relief. This Court has determined that, based on the other evidence presented at the hearing on Mylan's motion for injunctive relief, Mylan's motion must be denied. Consequently, the motion to dismiss of Teva and Biovail must be denied.

VI. Motion of Defendants Teva and Biovail for Expedited Document Production by Mylan

Following the February 16, 2001 hearing on Mylan's motion for injunctive relief, defendants Teva and Biovail filed their First Request for Production of Documents seeking (1) a copy of the settlement agreement between Mylan and Pfizer; (2) any notes or correspondence between Mylan, Pfizer, Bayer AG and/or Bayer Corporation relating to the settlement agreement; (3) any documents concerning the obligation of Mylan, Pfizer and/or Bayer's right, obligation, privileges or interest after the dismissal of any claim in the Mylan-Pfizer-Bayer civil action; and (4) any marketing or licensing agreement or related notes or correspondence concerning Mylan's sale of Pfizer's Procardia® XL product or any related version of that product.

Teva and Biovail then moved, on February 21, 2001, for expedited production of the above documents because these documents bear directly on the factors to be considered by the

Court in deciding whether to grant injunctive relief to Mylan. Mylan filed no response to this motion.

Because this Court believes that it has been able to sufficiently consider and decide the motion for injunctive relief on the basis of the record presented by all parties to date and because this Court believes that the documents requested should be handled under the usual discovery procedures set forth under Federal Rule of Civil Procedure 34, the motion is DENIED.

VII. Conclusion

Accordingly, based upon the above findings of fact and conclusions of law, a preliminary injunction and temporary restraining order sought by Mylan pursuant to Federal Rule of Civil Procedure 65 is DENIED; defendants Teva and Biovail's motion to dismiss for failure by Mylan to exhaust its administrative remedies is DENIED and defendants Teva and Biovail's motion for expedited document production by Mylan is DENIED.

IT IS SO ORDERED.

The Clerk is directed to transmit copies of this order to counsel of record herein.

DATED: April 18, 2001

/s/
FREDERICK P. STAMP, JR.
UNITED STATES DISTRICT JUDGE