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

MYLAN PHARMACEUTICALS, INC.,

Plaintiff,

v. **CIVIL ACTION NO. 1:04CV242**
(Judge Keeley)

FOOD AND DRUG ADMINISTRATION,
TOMMY G. THOMPSON, and LESTER M. CRAWFORD,

Defendants.

MEMORANDUM OPINION AND ORDER GRANTING FEDERAL DEFENDANTS' MOTION TO DISMISS

Before the Court is a Motion to Dismiss filed by the Federal Defendants ("FDA"), seeking to dismiss Mylan's lawsuit for failure to state a claim upon which relief may be granted under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Specifically, the FDA contends that the plain language of 21 U.S.C. §355(j)(5)(B)(iv) does not authorize it to prohibit brand companies from marketing "authorized generics" of their approved drugs during the 180-day exclusivity period provided by the statute to first filers of paragraph IV abbreviated new drug applications. In its Motion, the FDA also moves to dismiss Mylan's Complaint under Rule 12(b)(1) of the Federal Rules of Civil Procedure on the ground that Mylan lacks standing to bring this lawsuit and its claims are not ripe for adjudication by the Court. The FDA's motion is fully briefed and proper for review. For the following reasons, the Court **GRANTS** the FDA's Motion to Dismiss (dkt no. 24).

II. BACKGROUND

A. Brief Statutory Primer

A "pioneer drug" company seeking to sell a new drug must file a new drug application ("NDA") with the Food and Drug Administration ("FDA"). The NDA must contain assorted technical data about the drug and any patents encompassed by the drug or its administration. See 21 U.S.C. § 355(b)(1),(c)(2). After an NDA is approved, a generic drug company may submit an abbreviated new drug application ("ANDA") which must establish, among other things, that its product is bioequivalent to the approved NDA drug. See 21 U.S.C. § 355(j)(2)(A).

An ANDA must also contain a "certification" to each listed patent for the NDA drug. See 21 U.S.C. § 355(j)(2)(A)(vii). Of the four certification options, only one is relevant here: the paragraph IV certification. An ANDA applicant seeking approval to market a generic drug before expiration of the listed patent must submit a paragraph IV certification, asserting that the relevant patent is invalid and/or not infringed. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Paragraph IV certifications carry two significant legal consequences. First, submitting an ANDA containing a paragraph IV certification (or "paragraph IV ANDA") constitutes an act of patent

infringement, vesting district courts with subject matter jurisdiction before the ANDA drug is marketed. See 35 U.S.C. § 271(e)(2)(A); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 675, 678 (1990). If the patent holder brings suit for patent infringement within 45 days after receiving notice of the paragraph IV filing, Hatch-Waxman prevents FDA from approving the ANDA for 30 months, or such shorter or longer time as the court orders. 21 U.S.C. § 355(j)(5)(B)(iii).

Second, the first applicant who submits a paragraph IV ANDA enjoys the right to market its generic drug free from competition from subsequent paragraph IV ANDA applicants for 180 days. 21 U.S.C. § 355(j)(5)(B)(iv). The scope and meaning of the 180-day exclusivity period underlie the dispute in this case.

B. Brief Summary of Facts

On December 24, 1991, Proctor & Gamble ("P&G") obtained approval of its NDA for Macrobid(R) (Nitrofurantoin Monohydrate/Macrocrystals), an antimicrobial prescription drug for the treatment of urinary tract infections. On January 28, 2003, Mylan submitted an ANDA seeking immediate FDA approval to market generic nitrofurantoin capsules. Mylan's ANDA contained a paragraph IV certification for P&G's two Macrobid patents. As the first such

ANDA applicant, Mylan was eligible for 180-day marketing exclusivity.

On March 22, 2004, FDA approved Mylan's ANDA and confirmed its statutory right to a 180-day exclusivity period. Mylan launched its generic nitrofurantoin the next day, triggering the exclusivity period that would end on September 19, 2004. Meanwhile, Watson Pharmaceuticals, Inc. ("Watson") commercially launched an "authorized generic" verison of Macrobid on or about the same day. P&G manufactured the "authorized generic" and licensed Watson to distribute it under a different label and product name.

On February 17, 2004, prior to the approval of its ANDA, Mylan filed a citizen petition with the FDA seeking to prohibit "authorized generic" marketing during its 180-day exclusivity period. Two other generic drug companies, Apotex Corp. and Teva, and the Generic Pharmaceutical Association submitted comments in support of the petition. In its July 2, 2004 ruling, the FDA denied the petition, holding that "[t]he marketing of authorized generics during the 180-day exclusivity period is a long-standing, pro-competitive practice, permissible under the Act." The FDA also stated that, in any event, it lacked authority to enforce such a prohibition.

On November 11, 2004, Mylan filed the present action against the FDA, Tommy G. Thompson, the then Secretary of Health and Human Services, Lester M. Crawford, Acting Commissioner of the Food and Drug Administration, Proctor & Gamble, and Watson Pharmaceuticals. In Paragraph 13 of its Complaint, Mylan alleges that "FDA's denial of Mylan's Petition violates the Federal Food, Drug and Cosmetic Act and the Administrative Procedures Act, 5 U.S.C. 706(2)(A)." In Paragraph 14 of its Complaint, Mylan seeks not only declaratory and injunctive relief, but also an award of damages. On January 18, 2005, Mylan filed a Notice of Voluntary Dismissal Without Prejudice as to the claims alleged against Proctor & Gamble and Watson Pharmaceuticals in its Complaint. Therefore, the only claims left for the Court to decide are Mylan's allegations against the FDA. On January 19, 2005, the FDA filed its Motion to Dismiss.

III. STANDARD OF LAW

A court should grant a Rule 12(b)(6) motion only if, "after accepting all well-pleaded allegations in the plaintiff's complaint as true and drawing all reasonable factual inferences from those facts in the plaintiff's favor, it appears certain that the plaintiff cannot prove any set of facts in support of his claim entitling him to relief." Edwards v. City of Goldsboro, 178 F.3d 231, 244 (4th Cir. 1999) (citation omitted). "When a federal court

reviews the sufficiency of a complaint, . . . [t]he issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." Scheuer v. Rhodes, 416 U.S. 232, 236 (1974), overruled on other grounds by Davis v. Sherer, 468 U.S. 183 (1984). Therefore, "a rule 12(b)(6) motion should be granted only in very limited circumstances." Rogers v. Jefferson-Pilot Life Ins. Co., 883 F.2d 324, 325 (4th Cir. 1989).

IV. DISCUSSION

A. Standing/Ripeness

Federal courts are confined to adjudicating actual cases and controversies. Allen v. Wright, 468 U.S. 737, 751 (1984). The doctrines of standing and ripeness both flow from this constitutional requirement. Id. at 750. Therefore, federal courts are under an independent obligation to examine their own jurisdiction, and standing is perhaps the most important of jurisdictional doctrines. Id. at 751. Accordingly, the Court must address the jurisdictional issues of standing and ripeness prior to resolving the substantive issue in this matter.

1. Standing

Standing is the threshold jurisdictional question for federal courts. Simply, the issue of standing is whether a party is

entitled to have the court decide the merits of a dispute. Id. To satisfy Article III's standing requirements, a plaintiff must show: (1) it has suffered an injury in fact that is concrete and particularized and is **actual or imminent**, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. Friends of the Earth, Inc. v. Laidlaw, 528 U.S. 167, 180 (2000)(emphasis added).

In Paragraph 14 of its Complaint, Mylan seeks not only declaratory and injunctive relief, but also an award of damages. Specifically, Mylan contends, that as a result of the FDA's ruling permitting P&G and Watson to market an "authorized generic" during its 180-day exclusivity period, Mylan not only lost its right to the exclusivity period, but also lost revenues of over $32 million. Therefore, the Court finds that Mylan has alleged an actual injury in fact.

Furthermore, in its Supplemental Memorandum in Opposition of the FDA's Motion to Dismiss, Mylan asserts that it is the first ANDA seeking to market a generic version of Alza Corporation's extended release Oxybutynin, 5 mg and 10mg. That patent infringement action has been pending before this Court, and Alza

recently filed two declarations in support of its Motion for Preliminary Injunction stating that its generic marketing partner is prepared to enter the market with an "authorized generic" version of Oxybutynin immediately upon launch of Mylan's products, and more importantly, at the start of Mylan's 180-day exclusivity period. The Court, therefore, finds nothing improbable about the proposition that the FDA's approval of the marketing of an "authorized generic" by NDA holders during the 180-day exclusivity period would curtail Mylan's regular practice of challenging suspect brand patents and, consequently, subject it to significant economic harm.[1] Therefore, the Court also finds that Mylan has also established an imminent injury in fact.[2]

Mylan's actual and imminent injuries with respect the marketing of "authorized generics" are fairly traceable to the challenged action of the FDA because without the FDA's ruling allowing NDA holders to market "authorized generics" during an ANDA

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[1] In Paragraph 15 of its Complaint, Mylan states that it is the first-filer on a number of other drug products that are currently in litigation, including Pfizer's Norvasc (amlodipine besylate) tablets, J&J's Levaquin (levofloxacin) tablets, and J&J's Ditropan XL (oxybutynin chloride) extended-release tablets, for which Mylan is eligible for the 180-day generic exclusivity period. It is clear that Mylan regularly files first Paragraph IV challenges to suspect brand patents and that the FDA's current interpretation of section 355 (j)(5)(b)(iv) will eliminate the generic exclusivity incentive which prompts Mylan to frequently make such challenges.

[2] On September 27, 2005, this Court declared Alza's '355 patent for extended release oxybutynin invalid.

holder's 180-day exclusivity period the NDA holders would have been prevented from marketing their generics during that time. Mylan's injuries will be redressed by a favorable decision by this Court because the FDA would no longer permit NDA holders to market "authorized generic" drugs during Mylan's exclusivity period. Therefore, the Court finds that Mylan has standing to assert the claims alleged against the FDA in its Complaint.

2. Ripeness

"The ripeness requirement serves to prevent the courts, through avoidance or premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." Abbott Labs. v. Gardner, 387 U.S. 136, 149 (1967). In order to determine whether a controversy is ripe a court must evaluate both the fitness of the issues of judicial decision and the hardship to the parties of withholding court consideration. Abbott Labs. v. Gardner, 387 U.S. at 148-49.

Here, the issue before the Court is a purely legal one: whether the FDA's interpretation of section 355 (j)(5)(B)(iv) is arbitrary, capricious, or contrary to the law. Clearly, this is a

case where both sides assert different interpretations of a statute and different views of the congressional intent behind such statute, but neither justifies its interpretation or view on factual terms. Furthermore, the FDA's interpretation of section 355(j)(5)(B)(iv) is a final agency action because the FDA has consistently ruled in light of various factual scenarios that section 355(j)(5)(B)(iv) applies only to first filers of Paragraph IV ANDA applications. There is no evidence that this ruling is informal or tentative, as demonstrated most recently by the D.C. Circuit Court's review of the FDA's interpretation of section 355 (j)(5)(B)(iv) in Teva v. Crawford, 410 F.3d 51 (D.C. Cir. 2005).

The present matter also involves an industry in which the impact of the FDA's interpretation is sufficiently direct and immediate on the actors within the industry as to require immediate judicial review. To require Mylan to challenge the interpretation only during the specific time period in which a NDA holder is manufacturing an "authorized generic" during a 180-exclusivity period held by Mylan would likely cause Mylan significant economic harm. Accordingly, the hardship on Mylan resulting from the Court withholding its consideration of the FDA's interpretation is great.

Furthermore, Mylan will not only be harmed economically, but the incentive created by the 180-day exclusivity period provided by

section 355(j)(5)(B)(iv)for generic drug manufacturers will effectively be defeated. Thus, the main purpose of the Hatch-Waxman Amendments, to bring generic drugs onto the market as rapidly as possible, will also be defeated. The public policy issues raised by this motion are substantial. The heart of this controversy is not whether a generic drug company should face competition from the pioneer drug company. Instead, the real dispute in this case lies in the means taken by the pioneer drug company to compete. The parties both identify essentially the same public interest: promotion of generic drug competition and providing low cost generic drugs to the public. The parties differ, however, as to the best means to vindicate this interest. There is significant interest in the Court quickly stating its role and authority in resolving this dispute so that the parties may seek further relief from the appropriate party, Congress. For all these reasons, the Court finds that Mylan's claims are ripe for consideration.

B. Administrative Procedure Act Claim

As noted, the sole substantive issue before this Court is whether the Food and Drug Administration's ("FDA's") interpretation of 21 U.S.C. § 355(j)(5)(B)(iv) (2000) is arbitrary, capricious, or contrary to law. Therefore, an evaluation of the merits of this case must be limited to a review of the FDA's interpretation of the

disputed statutory language. Under the Administrative Procedure Act ("APA"), this Court may only disturb an agency's decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A). When a court reviews an agency's construction of a statute which the agency administers, it is confronted with two questions: (1) Whether Congress has directly spoken on the precise question at issue, and if the statue is silent or ambiguous with respect to the specific issue, and (2) Whether agency's answer is based on a permissible construction of the statute. See Chevron, U.S.A., v. NRDC, 467 U.S. 837 (1984). Therefore, an agency's interpretation should be upheld unless the plaintiff establishes that the agency's interpretation is arbitrary, capricious or contrary to law. See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

1. The Statute at Issue

Mylan contends that the FDA incorrectly interpreted 21 U.S.C. §355(j)(5)(B)(iv), and thus should have prohibited P&G and Watson from marketing an "authorized generic" version of Macrobid(R) during Mylan's exclusivity period. The FDA asserts that 21 U.S.C. §355(j)(5)(B)(iv) applies only to the approval of ANDAs and does not, during an ANDA holder's exclusivity period, authorize it to

prohibit or delay the marketing of an "authorized generic" version of a brand-name drug already approved under an NDA. Because the parties take different positions on the correct interpretation of 21 U.S.C. §355(j)(5)(B)(iv), a brief discussion of Section 355(j)(5)(B)(iv) is necessary to explain the significance of the statutory language to this case.

The disputed statute in the case at bar, 21 U.S.C. §355(j)(5)(B)(iv), reads as follows:

> If **the application under paragraph 2** [i.e., an ANDA] contains a certification described in subclause (IV) of paragraph (2)(A)(vii) **and** is for a drug for which a previous application has been submitted under this subsection [containing] such a certification, **the application** shall be made effective not earlier than one hundred and eighty days after-
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> (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 infringed, whichever is earlier.

(emphasis added).

Mylan contends that section 355(j)(5)(B)(iv) prohibits the third-party marketing of an "authorized generic" version of the brand name drug during the 180-day exclusivity period applicable to the first filer of a paragraph IV ANDA. Accordingly, Mylan asserts that an ANDA generic and an "authorized generic" are functionally and legally equivalent for purposes of enforcing and applying the 180-day generic exclusivity provision. The FDA, however, rejected Mylan's interpretation, holding that paragraph (j)(5)(B)(iv) does not contemplate or countenance delaying the marketing of authorized generics as Section 355(j)(5)(B)(iv)does not address or apply to NDAs. Although the parties' interpretations may differ, the Court must determine whether Congress has expressly spoken on this issue within the plain and unambiguous terms of the statute. Here, the Court finds that the scope and purpose of the statute is clear.

2. <u>Teva v. Crawford</u>, 410 F.3d 51 (D.C. Cir. 2005).

Recently, the Circuit Court for the District of Columbia was presented with nearly identical facts to those here, and considered

the FDA's interpretation of the same statute under review in this matter.

In Teva v. Crawford, 410 F.3d 51 (D.C. Cir. 2005)[3], Teva Pharmaceutical Industries filed an action to overturn the FDA's denial of its citizen petition asking the FDA to prohibit Pfizer, the holder of the NDA for gabapetin, from marketing that drug in a generic form during Teva's 180-day exclusivity period. Teva had entered into an agreement by which Purepac Pharmaceutical Co., the first paragraph IV ANDA filer, agreed to share its exclusivity period with Teva in exchange for a portion of Teva's revenues. Id. at 52. During the exclusivity period, however, Pfizer marketed its own "authorized generic" version of gabapentin directly in competition with Teva's "generic" verison of the drug. Id.

In an effort to prohibit competition from Pfizer's "authorized generic," Teva petitioned the FDA to prohibit the marketing and distribution of "authorized generic" versions of brand-name products until after the expiration of any 180-day exclusivity

[3] Its holding in Teva v. Crawford was not the first case in which the Court of Appeals for the District of Columbia reviewed the plain and unambiguous meaning of Section 21 U.S.C. 355(j)(5)(B)(iv). Seven years earlier in Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1064 (D.C. Cir. 1998), the Court observed: "This provision on its face appears to provide an advantage to the **first party who files a paragraph IV ANDA** . . ., by granting a party a 180-day period in which to market its generic drug without competition **from other ANDA applicants**." (emphasis added). That court, thus, has consistently held that 21 U.S.C. §355(j)(5)(B)(iv) applies only to ANDAs containing a paragraph IV certification.

period applicable to an ANDA for the drug product. Id. at 52-53. On July 2, 2004, the same day as the FDA's denial of Mylan's petition in this case, the FDA also denied Teva's petition, stating in both cases that Section 355(j)(5)(B)(iv) does not contemplate or countenance delaying the marketing of authorized generic versions of a drug. Id. at 53.

Following a route similar to that followed by Mylan, Teva filed an action in the United States District Court for the District of Columbia, seeking review of the FDA's interpretation of §355(j)(5)(B)(iv). Id. Ultimately, the district court agreed with the FDA and entered summary judgment in favor of the agency, finding that the exclusivity provision did not apply to the holder of an approved NDA. Id. On June 3, 2005, the D.C. Court of Appeals affirmed the district court's decision.[4] Id.

In Teva, the circuit court reviewed the FDA's interpretation of the statute under the two-step framework of Chevron, U.S.A., Inc. v. NRDC, 467 U.S. 837 (1984), and found that Congress had an intention on the precise question at issue, and, because that

[4] Mylan filed a Motion to Stay in this case on February 25, 2005, stating that the administrative ruling under review and the statutory construction issue before the Court here were identical to the issues on appeal in Teva v. Crawford. Accordingly, to promote judicial economy, Mylan requested that the Court grant a temporary stay of this action pending the resolution of the Teva appeal. The fact that Mylan requested a stay of this action in light of the appeal in Teva indicates that it recognized the disposition in Teva would impact the resolution of the matter here.

intention is law, it must be given effect. Id. at 53-54. The court also recognized the "cardinal canon" that a court must presume that a legislature says what it means and means what it says in a statute. Id. at 53. Simply, when the words of a statute are unambiguous,"judicial inquiry is complete." Id.

Accordingly, the Teva court held that section 355(j)(5)(B)(iv) is silent about how the holder of an approved NDA may market its drug. It recognized the FDA's reasoning that "other provisions of the Act 'establish numerous express grounds for refusal to approve [a NDA], and ... grounds for compelling withdrawal of previously approved products ... [but none] addresses marketing arrangements in any manner." Id. at 53. The circuit court, therefore, stated that Teva was simply asking the Court to declare a previously lawful practice to be unlawful under a statute that does not address that practice. Id. at 53. It refused to do so.

This Court finds the analysis in Teva v. Crawford to be persuasive and adopts its holding in resolving the issue presently before it.

3. The Statute's Plain and Unambiguous Language

The statute in issue is, without question, unambiguous. Simply, section 355(j)(5)(B)(iv) says nothing about how the holder of an approved NDA may market its drug. As the court observed in

Teva, "[t]here is simply no way to read that limitation upon what the FDA may do in such a way as to prevent the holder of an approved NDA, which does not need to file an ANDA and certainly would not challenge its own patent, from marketing a brand-generic product." Teva v. Crawford, 410 F.3d at 54. Mylan, nevertheless, urges the Court to apply the 180-day exclusivity provision to "authorized generic" distributors, irrespective of whether they file a paragraph IV ANDA and not withstanding that the explicit, unequivocal language of the statutory provision applies only to paragraph IV ANDA applicants.

Accordingly, licensees of the brand name company, including "authorized generic" distributors, are neither eligible for nor subject to the 180-day exclusivity. Indeed, in the history of the Hatch Waxman Amendments, no court has ever applied section 355(j)(5)(B)(iv) to "authorized generic" distributors who had not also filed a paragraph IV ANDA. Therefore, the Court holds that the plain and unambiguous language of section 355(j)(5)(B)(iv) does not prohibit the holder of an approved NDA from marketing an "authorized generic" during the 180-day exclusivity period given to a paragraph IV ANDA holder.

4. The Nifedipine Litigation

Mylan relies on a February 6, 2001 FDA ruling that was affirmed by this Court (per Judge Frederick P. Stamp, Jr.) in the Nifedipine litigation to assert that ANDA generics and authorized generics must be treated the same for purposes of 180-day generic exclusivity.

In 1997, Mylan filed the first ANDA seeking FDA approval to market a generic version of Pfizer's branded drug Procardia (R) (nifedipine). The ANDA contained a paragraph IV certification with respect to the Pfizer patent. Pfizer subsequently filed an infringement suit against Mylan in the Western District of Pennsylvania. On February 28, 2000, Pfizer and Mylan entered into a settlement agreement which(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(R) XL nifedipine extended release tablet[s] supplied by Pfizer, and (c) permitted Mylan to market its own 30 milligram ANDA product." Mylan Pharmaceuticals, Inc. v. Thompson, 207 F. Supp. 2d 476, 481 (N.D. W. Va. 2001) (Stamp, J.).

On August 10, 2000, Teva filed a citizen petition with the FDA, seeking a determination of whether Mylan was either ineligible or, alternatively, no longer eligible for the 180-day exclusivity

period with respect to the 30 milligram nifedipine tablets described in its ANDA. The FDA held, among other things, that "Mylan, by marketing its private label generic version of Pfizer's Procardia(R) 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." Id. at 482. Without extensive discussion, Judge Stamp concluded that "FDA's interpretation of the phrase 'commercial marketing of the drug under the previous application' is a reasonable one." Id. at 488 (citing Teva Pharms. USA, Inc. v. FDA, 182 F.3d 1003 (D.C. 1999)).

Mylan asserts, erroneously in this Court's view, that, as a result of the Nifedipine decision, "authorized generics are the legal and functional equivalents of ANDA generics for purposes of the 180-day generic exclusivity provision." To the contrary, that case did not equate authorized generics and ANDA generics. Instead, it yielded the following rule: If the first company to file a paragraph IV ANDA later distributes authorized generic versions of the same drug covered in its ANDA, it thereby triggers the 180-exclusivity period. Thus, both the FDA's position and Judge Stamp's ruling were contingent on the fact that Mylan was a paragraph IV ANDA applicant; had Mylan merely been a licensee, as

Watson, it would not have been eligible for exclusivity in the first place. Accordingly, the Nifedipine litigation did not extend exclusivity to authorized generics distributors per se.[5]

The FDA's position in the Nifedipine litigation is also consistent with its position in this case. In both cases, it advocated a pro-competitive result that, in its view, would ultimately lower generic drug prices for consumers. By contrast, Mylan's position arguably seeks to eliminate competition. Had Mylan prevailed in the Nifedipine litigation, for example, it could have reaped the benefit of being the sole generic distributor on the market indefinitely by delaying the initiation of the exclusivity period and thus blocking the entry of other ANDA applicants. Here, Mylan attempts to preclude third party licensees from selling the brand-name drug at lower prices-despite the fact that 1) P&G is free to sell its drug at any price, and 2) the NDA holder has absolute control over when the "authorized generic" begins to be marketed to the public.

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[5] The recent changes to the Hatch-Waxman Amendments in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("the MMA") codify the Nifedipine decision. As such, the statute now confirms that the "first commercial marketing" of the ANDA drug "includ[es] the commercial marketing of the listed [NDA] drug[] by any first applicant." 21 U.S.C. §355(j)(5)(B)(iv)(I) (2004). By its plain language, however, the amended statute still does not apply to "authorized generic" distributors (or licensees generally) who have not filed an ANDA with a paragraph IV certification.

5. Congress's Role in Striking the Balance

In Teva v. Crawford, 410 F.3d at 53-54, the circuit court recognized that, in the ANDA legislation, Congress had attempted to strike a balance between incentives for innovation and for quickly getting lower-cost generic drugs to market. Mylan's interpretation of section 355(j)(5)(B)(iv) in this case does not comport with the balance sought by Congress. Further, in Teva, the plaintiff had argued that Congress could not have anticipated brand-generic competition during the exclusivity period, and, thus, adhering to the express terms of the statute would lead to an absurd result. The D.C. Court of Appeals, however, found it absurd that Congress, having intended to create an incentive to challenge brand-drug patents, would create an incentive without limitation. See Teva v. Crawford, 410 F.3d at 53-54.

Here, the Court does not find that the FDA's interpretation would produce a manifestly absurd result. Specifically, Paragraph IV ANDA applicants always face competition from the pioneer company. The statute clearly contemplated such competition. Pioneer companies, for example, are free to lower their prices without violating § 355(j)(5)(B)(iv). Moreover, no provision of the Federal Food, Drug, and Cosmetic Act regulates marketing arrangements by NDAs. Thus, this Court cannot say that the exclusivity period was

intended to prohibit competition from an NDA holder. Rather, the clear intent of Congress was to provide an ANDA holder with 180 days within which to market its drug free from competition from subsequent paragraph IV ANDA applicants.

Furthermore, were the Court to accept Mylan's presuppositions and follow its logic, all authorized generic distributors would also be able to take advantage of the 180-day exclusivity periods. After all, as Mylan vigorously asserts, if "authorized generics" and ANDA generics are equivalent for one portion of the statutory provision then the same must be true for the remainder of the provision, unless Congress clearly and unambiguously indicated otherwise. Thus, in fairness, Mylan's strained interpretation would necessarily allow "authorized generic" distributors to enjoy 180 days of exclusivity if they were the first to market a particular generic drug. The effect of this, of course, would be devastating to the generic drug industry. Pioneer drug companies could begin licensing authorized generics well before ANDAs could be filed. Since the 180 exclusivity period cannot roll over, generic drug companies could be easily precluded from ever enjoying exclusivity. Consequently, Mylan's interpretation that ANDA generics and "authorized generics" are equivalents under the Act would tend to lead to an absurd result.

The holding in Teva v. Crawford recognized that the balance of these competing goals is a matter for legislative judgment and courts must stick closely to the terms in which Congress expressed that judgment. Id. at 55.

V. CONCLUSION

The Court concludes that the FDA's interpretation of 21 U.S.C. §355(j)(5)(B)(iv) is not arbitrary, capricious, or contrary to law because the plain and unambiguous language of the statute does not prohibit the holder of an approved NDA from marketing an "authorized generic" during the 180-day exclusivity period given to a paragraph IV ANDA holder by its express terms. The FDA has faithfully applied the law consistent with the intent of Congress. Whether that application ultimately vindicates the public interest in promoting generic competition is a question for Congress, not this Court, to resolve.

Accordingly, the Court **GRANTS** the Federal Defendants' Motion to Dismiss (dkt. no. 24). The Court also **ORDERS** that the case be stricken from the docket.

It is so **ORDERED.**

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

DATED: September 29, 2005.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE