UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WATSON LABORATORIES, INC., Plaintiff,	)	
v.	)	Civil Action No. 12-1344 (ABJ)
KATHLEEN SEBELIUS, *Secretary of Health and Human Services, et al.*, Defendants.	)	**UNDER SEAL**

MEMORANDUM OPINION

Plaintiff Watson Laboratories, Inc. ("Watson") brings this action against defendants Kathleen Sebelius, Secretary of Health and Human Services; Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, U.S. Food and Drug Administration ("FDA"); and FDA (collectively "FDA") under the Administrative Procedure Act ("APA"), 5 U.S.C. § 551, *et seq.* (2006), and the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.* (2006),[1] for interpreting the FDCA's 180-day exclusivity provision to deny Watson shared exclusivity to market the generic drug pioglitazone. Watson maintains that FDA's decision is contrary to the express terms of the statute; that it is an unreasonable interpretation of the FDCA; and that it is arbitrary and capricious. Am. Compl. [Dkt. # 22]. On August 16, 2012, Mylan Pharmaceuticals, Inc. ("Mylan") filed a motion to intervene on behalf of FDA [Dkt. # 9], which was granted. On August 27, 2012, Watson filed a motion for summary judgment [Dkt. # 25],

[1] The FDCA was amended in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (codified at 21 U.S.C. § 355 (2006)). Because the relevant filings in this case pre-date the December 8, 2003 effective date of the MMA, the pre-MMA version of the FDCA controls in this case. Pl.'s Mem. of P. and A. in Support of Mot. for Summ. J. ("Pl.'s Mem.") [Dkt. # 25] at 3, citing *Ranbaxy Labs., Ltd. v. Leavitt*, 459 F. Supp. 2d 1, 2 n.2 (D.D.C. 2006).

and on September 5, 2012, FDA responded with a motion to dismiss Watson's complaint, or, in the alternative, for summary judgment. [Dkt. # 36]. The Court heard argument on the motions on September 14, 2012. [Dkt. # 50]. For the reasons stated below, the Court finds that FDA's decision to deny Watson shared exclusivity was contrary to the plain language of the statute, and that even if the statute is ambiguous and FDA's interpretation of the relevant provision is reasonable as a general matter, its decision was arbitrary and capricious under the unique factual circumstances of this case. Thus, the Court will overturn FDA's decision and order FDA to approve Watson's ANDA for generic pioglitazone effective immediately so that Watson may enjoy what remains of the shared exclusivity previously awarded to other filers.

I. BACKGROUND

A. Statutory Background

The FDCA requires all new drugs to be approved by the FDA before they are introduced into interstate commerce. 21 U.S.C. § 355(a) (2006). It provides two primary pathways for obtaining approval: (1) the new drug application ("NDA"), described in section 355(b); and (2) the abbreviated new drug application ("ANDA") for generic products, set forth in section 355(j).

A drug that follows the NDA pathway is referred to as a "pioneer" drug because it is the first drug of its kind to go through an approval process with the FDA. The NDA procedure requires the applicant to conduct a spectrum of safety and effectiveness tests and to inform the FDA of the results. *See* 21 U.S.C. § 355(b)(1). In addition, it requires the applicant to file information about "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged

in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). Once the drug is approved, it is referred to as a "listed" drug. *See* 21 C.F.R. § 314.3(b).

A drug that follows the ANDA pathway seeks to rely on research conducted by a third party – the maker of the listed drug – in order to meet the approval requirements. 21 U.S.C. § 355(b)(2), (j)(2)(A). Congress added the truncated ANDA approval process to the FDCA as part of the 1984 Hatch-Waxman amendments, which sought "to make available more low cost generic drugs" by providing a pathway that was less costly and time consuming than the NDA process. *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1316 (D.C. Cir. 1998), quoting H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647 (internal quotation marks omitted). ANDA applicants must file information showing that the conditions of use, active ingredient, dosage form, strength, route of administration, and labeling of the generic drug are "the same as" those of the reference listed drug that was previously approved. 21 U.S.C. § 355(j)(2)(A)(i)-(iii), (v). They are thereby relieved of the obligation to perform the extensive testing demonstrating safety and effectiveness that is the hallmark of the NDA process. *See* § 355(b)(1)(A).

To protect the patent rights of NDA holders, ANDA applicants must provide one of four "certifications" for "each patent which claims the listed drug . . . or which claims a use for such listed drug for which the application is seeking approval." § 355(j)(2)(A)(vii); *see also Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 802 (D.C. Cir. 2001). Thus, for each relevant patent, ANDA applicants must certify either:

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

§ 355(j)(2)(A)(vii)(I)–(IV). FDA may approve an ANDA containing either of the first two certifications effective immediately, § 355(j)(5)(B)(i), and it may approve an ANDA containing the third type of certification effective on the relevant patent's expiration date, § 355(j)(5)(B)(ii).

But the filing of the fourth type of certification – the certification referred to as a "paragraph IV certification" which is relevant here – is an act of patent infringement on the part of the ANDA applicant, 35 U.S.C. § 271(e)(2)(A), and it can delay the approval process in two different ways. First, the FDCA requires an ANDA applicant to notify the patent holder of the filing of a paragraph IV certification, 21 U.S.C. § 355(j)(2)(B), and the filing allows the patent owner to sue the ANDA filer. If the patent holder brings a suit within 45 days of receipt of the notice, the FDCA bars approval of the applicant's ANDA, or any other ANDA relating to the drug, for thirty months, unless the applicant wins the patent infringement suit earlier or the court hearing the suit shortens the period. § 355(j)(5)(B)(iii).

Second, approval of an ANDA containing a paragraph IV certification is delayed if FDA determines that "a previous application has been submitted . . . [containing] such a certification" for the drug. § 355(j)(5)(B)(iv); *see also* 21 C.F.R. § 314.107(c)(1). In such a situation, FDA may not approve the subsequent ANDA until 180 days from either the date of the "first commercial marketing of the drug" by the previous applicant or the date on which the previous applicant wins a patent infringement suit involving the relevant patent, whichever is earlier. § 355(j)(5)(B)(iv). This delay gives the earlier applicant what is referred to as a "180-day exclusivity period," during which the applicant has the right to sell its product and compete

against the brand without competition from other generic manufacturers. *See id.* It is this exclusivity grant that is at issue in this case.[2]

Patent certifications are not the only way to address a pioneer drug's patents. An applicant seeking approval for a use that is not claimed by a patent need only file a "statement that the method of use patent does not claim such a use" under 21 U.S.C. § 355(j)(2)(A)(viii). This is called a "section viii statement." For example, if a pioneer drug applicant's patent claims a use for treating depression, and an ANDA applicant seeks approval of the drug for treatment of any other condition, then only a section viii statement is required. *See Purepac Pharm. Co. v. Thomson*, 354 F.3d 877, 880 (D.C. Cir. 2004). "Thus, whereas applicants use paragraph IV certifications to challenge the validity of admittedly applicable patents, they use section viii statements to assert that patents do not apply." *Id.* If an applicant submits a section viii statement, the applicant must omit or "carve out" from the proposed labeling submitted with its application any information pertaining to the use or uses claimed by the patent. *See* 21 C.F.R. § 314.94(a)(12)(iii)(A) (providing that applicants may use a section viii statement when "the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use patent").

Section viii statements are not subject to either of the delays attendant to paragraph IV certifications. Filing a section viii statement is not an act of infringement, so it does not require applicants to provide notice to the pioneer applicant or wait thirty months for FDA approval. *See* 21 U.S.C. § 355(j)(2)(B); *Purepac*, 354 F.3d at 880. Further, section viii applications cannot be

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2 FDA indicates that prior to the 2003 amendments, it granted exclusivity on a patent-by-patent basis. A.R. at 7. This meant that a period of exclusivity could potentially arise for each patent claimed by a drug. *Id.* In the event that such a practice blocked applicants from getting to the market – i.e., each applicant is blocked by an exclusivity period held by another applicant as to one or more patents – FDA might decide that exclusivity should be shared among those applicants. *Id.*; *Apotex Inc. v. FDA*, 414 F. Supp. 2d 61, 75 (D.D.C. 2006)..

delayed by previous applicants awarded exclusivity, because previous filers of section viii statements are not eligible for an exclusivity period. *See* 21 U.S.C. § 355(j)(5); *Purepac*, 354 F.3d at 880. As this Circuit has explained, "the FDA may [thus] approve a section viii application immediately, making it an attractive route for generic manufacturers, even though a section viii statement does not entitle a successful applicant to the 180-day period of exclusivity bestowed on paragraph IV applicants." *Purepac*, 354 F.3d at 880 (internal quotation marks omitted).

It has been FDA's position that paragraph IV certifications and section viii statements are mutually exclusive, and neither party in this case challenges this proposition. *See* Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,347 (Oct. 3, 1994) ("[T]he two provisions . . . are not overlapping, and an applicant does not have the option of making a certification under [paragraph IV] in lieu of, or in addition to, a statement under [section viii]."); *see also, e.g.*, *Purepac*, 354 F.3d at 880. For example, where an applicant seeks approval of a drug for a use that is not claimed by a listed patent, only a section viii statement is appropriate; a paragraph IV certification may not be used.[3]

FDA's procedure for receiving all ANDA applications – whether they contain paragraph IV certifications, section viii statements, or both – is outlined in its regulations. Within sixty days of submission of an ANDA, FDA reviews the application to determine whether it "may be filed." 21 C.F.R. § 314.101(a)(1). Before an application may be filed, FDA must make "a

3 There are instances, however, where it may be appropriate to file both a paragraph IV certification and a section viii statement to address the same listed patent. *See* 59 Fed. Reg. at 50,347. FDA refers to this as a "split certification." FDA's Mem. in Support of Mot. to Dismiss or, in the alternative, for Summ. J. ("FDA's Mem.") [Dkt. # 36] at 7. This situation arises when a listed patent contains both product and method of use claims, such that a paragraph IV certification is needed to address the product claim and a section viii statement is needed to address the method of use claim. 59 Fed. Reg. at 50,347. In this case, both Watson and Mylan originally filed split certifications as to the drug composition/use patents. *See* A.R. at 10.

threshold determination that the application is sufficiently complete to permit a substantive review." *Id.* FDA's regulations provide various grounds on which FDA may refuse to receive an application. *See* § 314.101(d)–(e). For example, it may refuse to receive an application if it "is incomplete because it does not on its face contain information required under section 505(b), section 505(j), or section 507" of the FDCA or relevant regulations. § 314.101(d)(3). If FDA does not consider an application to be filed for any of these reasons, the regulations provide that FDA notify the applicant, "ordinarily by telephone," giving the applicant three options: (1) withdraw the application under [21 C.F.R.] § 314.99; (2) amend the application to cure the deficiencies; or (3) take no action, in which case FDA will refuse to receive the application. § 314.101(b)(3). According to FDA, if an applicant chooses the second option and FDA receives the amended application, agency practice is to consider the amended application to have been received on the date on which it was first submitted. *See* FDA's Mem. in Supp. of Mot. to Dismiss or, in the alternative, for Summ. J., and Opp. to Pl.'s Mot. for Summ. J. ("FDA's Opp.") [Dkt. # 36] at 4, citing A.R. at 3.

B. Factual Background

On July 15, 2003, Watson submitted an ANDA for approval to market a generic version of pioglitazone hydrochloride tablets. Brannan Decl. ¶ 9 [Dkt # 3-2]. Pioglitazone, originally developed and marketed by Takeda Pharmaceutical Company Ltd. ("Takeda") under the trade name Actos®, is widely prescribed for the treatment of type 2 diabetes. *Id.* ¶¶ 7–8. Watson filed its ANDA on the earliest date on which ANDAs could be filed with FDA for this particular drug. *Id.* ¶ 9. Watson submitted the ANDA with labeling for the use of the generic drug as a monotherapy, or as a therapy taken by itself, as opposed to a combination therapy, which involves using more than one medication or therapy. *Id.* ¶ 11; Pl.'s Mem. of P. and A. in

Support of Mot. for Summ. J. ("Pl.'s Mem.") [Dkt. # 25] at 7. A second applicant, Mylan, also submitted an ANDA on July 15, 2003. A.R. at 8.

Watson's ANDA included paragraph IV certifications for all of the patents covering the brand name drug. A.R. at 8. Ten of those patents are relevant to this case. *Id.* Eight of the ten patents are referred to as use-only patents,[4] which contain only method of use claims. *Id.* The remaining two patents are referred to as drug composition/use patents,[5] which contained two types of claims: drug composition claims and method of use claims. *Id.* Drug composition claims relate to use of pioglitazone as a monotherapy, while method of use claims relate to use of the drug as a combination therapy. *See* Am. Compl. ¶ 31.

On August 18, 2003, FDA contacted Watson by telephone to discuss its application. *See* A.R. at 37. And on August 27, 2003, Watson responded by filing a "telephone amendment" to its ANDA. *Id.* The administrative record does not contain any documents that memorialize the content of the telephone communication or the nature of FDA's objections to the original ANDA other than this statement in Watson's telephone amendment:

> As a result of conversations . . . , we understand that FDA will not accept Paragraph IV certifications against method of use patents for uses for which Watson is not seeking approval.

A.R. at 38; *see also* Brannan Decl. ¶ 12 ("On August 18, 2003, FDA communicated to Watson that, among other things, Watson should revise its labeling to include language regarding pioglitazone as a combination therapy because Watson had asserted Paragraph IV certifications to the Combination Therapy Patents.").

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4 The use-only patents are U.S. Patent Nos. 6,211,205; 6,271,243; 6,303,640; 6,166,042; 6,166,043; 6,172,090; 6,150,383; and 6,150,384. Brannan Decl. ¶ 11. Watson refers to these patents as "Combination Therapy" patents. *Id.*

5 The drug composition/use patents are U.S. Patent Nos. 5,965,584 and 6,329,404. *Id*.

FDA contends in its pleadings that the original ANDA was defective because Watson filed paragraph IV certifications for all of the patents when it also "sought to carve out (i.e., omit from its proposed labeling) the methods of use protected by the various patents." FDA's Opp. at 10. According to FDA, the FDCA prohibits an ANDA applicant from filing a paragraph IV certification challenging a patent for a use that it has carved out from its proposed labeling. *Id.* at 6–7, citing 59 Fed. Reg. at 50,347; *see also Purepac*, 354 F.3d at 880. Rather, an applicant must file section viii statements for a proposed carve-out of labeling referring to a patented method of use. FDA's Opp. at 6–7.

According to FDA, at that time, Watson was faced with four options. It could:

> (1) withdraw its ANDA; (2) maintain paragraph IV certifications to all the patents, but submit new labeling that included (i.e., did not carve out) the protected methods of use; (3) maintain paragraph IV certifications challenging only the drug composition claims contained in the two Drug Composition/Use Patents, and file section viii statements as to the method-of-use claims in the Drug Composition/Use Patents and to the Use-only patents . . . ; or (4) take no action, in which case FDA would refuse to receive the application due to the invalid certifications and Watson would lose any benefits associated with its original filing date.

A.R. at 9. Watson "amended its ANDA to change its certifications to the Combination Therapy Patents to Section viii statements, while maintaining its Paragraph IV certifications as to the composition claims of the Composition Patents." Brannan Decl. ¶ 13; A.R. at 38. According to FDA, choosing this option meant that Watson could maintain its carved-out labeling rather than submitting new labeling that included the protected methods of use. A.R. at 9; FDA's Opp. at 11.

But in making this amendment, Watson explicitly reserved its rights. The telephone amendment stated: "Watson does not agree with the Agency's position . . . . However, solely to facilitate ANDA review, and without prejudice to Watson's position, Watson is amending the

ANDA by changing Paragraph IV certifications . . . to section viii statements . . . ." A.R at 38. Watson went on:

> Watson makes this amendment without prejudice to its right to reinstate its original Paragraph IV Certifications with the effective date of original submission on July 15th, 2003, should a court or the Agency hold in the future that Paragraph IV Certifications should have been made and/or maintained.

Id.; Am. Compl. ¶ 36.

On September 4, 2003, FDA informed Watson that its ANDA was deemed acceptable for filing as of the original filing date of July 15, 2003.[6] A.R. at 33. On December 13, 2005, FDA informed Watson that its ANDA had been tentatively approved. Ex. C to Brannan Decl., Aug. 23, 2012 [Dkt. # 33] (FDA referencing "tentative approval letter issued by this office on December 13, 2005"); Pl.'s Mem. at 11.

On September 9, 2003, Watson sent the required letter to the patent holder Takeda notifying Takeda that its ANDA contained paragraph IV certifications to two of Takeda's patents. A.R. at 29. Takeda responded to the letter by filing a lawsuit against Watson and other ANDA filers, including intervenor defendant Mylan, in the U.S. District Court for the Southern District of New York for infringement of U.S. Patent Nos. 5,965,584 and 6,329,404 – the drug composition/use patents. A.R. at 30; *see Takeda Chemical Indus. Ltd. v. Watson Pharms., Inc.*, No. 03-cv-8254 (S.D.N.Y. filed Oct. 17, 2003) [Dkt. # 46-1]. This litigation settled in March 2010, and both Watson and Mylan entered into settlement agreements with Takeda, providing that they would receive non-exclusive licenses to the drug composition/use patents that were the subject of the paragraph IV certifications to be effective August 17, 2012. Brannan Decl. ¶ 16;

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6 On the same date, FDA filed Mylan's original ANDA, which also contained paragraph IV certifications to the drug composition/use-only patents and section viii statements to the remaining use-only patents. *See* A.R. at 10.

Sept. 14, 2012 Tr. [Dkt. # 50] at 17;[7] *see also* Ex. A to Brannan Decl. (Takeda press release announcing settlement of the patent litigation with Watson and Mylan). But the agreement also specified that Watson (and presumably Mylan, but the Court does not have any exhibits that specify the terms of its agreement) would withdraw the section viii statements in the ANDA and receive licenses for the use-only patents as well. Sept. 14, 2012 Tr. at 16–17; *see also* Watson Minor Amendment dated March 7, 2012 ("Watson Minor Amendment") [Dkt. 45].

After the litigation and pursuant to their settlement agreements, both Mylan and Watson amended their ANDAs by changing their section viii statements to the use-only patents to paragraph IV certifications. Pl.'s Mem. at 10; A.R. at 9–10. Mylan did so first, on March 22, 2010. A.R. at 9; FDA's Opp. at 12. Two years later, Watson amended its application on March 7, 2012, via a letter entitled "Minor Amendment." Watson Minor Amendment; *see also* A.R. at 10. Watson characterizes its amendment as "reinstat[ing]" the paragraph IV certifications to the use-only patents in its original application. *See, e.g.*, Brannan Decl. ¶ 16; Pl.'s Mem. at 2, 10, 12, 23.

The following charts summarize Watson's and Mylan's relevant patent certifications:

7 At the motions hearing, Watson's counsel confirmed that Watson and Mylan have separate settlement agreements, and stated that that "the general understanding is that [the agreements] were the same or roughly the same at least in substance." Sept. 14, 2012 Tr. at 17.

	Patent Type	Watson's Original Application Submitted on 7/15/03	Watson's First Amended Application Accepted by FDA Effective 7/15/03	Watson's Second Amended Application Submitted on 3/7/12
5,965,584	Drug Composition/Use	IV	IV/viii	IV
6,329,404	Drug Composition/Use	IV	IV/viii	IV
6,150,383	Use-only	IV	viii	IV
6,150,384	Use-only	IV	viii	IV
6,166,042	Use-only	IV	viii	IV
6,166,043	Use-only	IV	viii	IV
6,172,090	Use-only	IV	viii	IV
6,211,205	Use-only	IV	viii	IV
6,271,243	Use-only	IV	viii	IV
6,303,640	Use-only	IV	viii	IV

	Patent Type	Mylan's Original Application Accepted by FDA Effective 7/15/03	Mylan's Amended Application Submitted on 3/22/10
5,965,584	Drug Composition/Use	IV/viii	IV
6,329,404	Drug Composition/Use	IV/viii	IV
6,150,383	Use-only	viii	IV
6,150,384	Use-only	viii	IV
6,166,042	Use-only	viii	IV
6,166,043	Use-only	viii	IV
6,172,090	Use-only	viii	IV
6,211,205	Use-only	viii	IV
6,271,243	Use-only	viii	IV
6,303,640	Use-only	viii	IV

A.R. at 10; Pl.'s Mem. at 11.

Pursuant to the settlement agreement with Takeda and in anticipation of FDA's acceptance of its ANDA, Watson planned to launch its generic drug on August 17, 2012, and it claims that it expended "significant resources," including "millions of dollars on materials,

studies and overhead, for its anticipated [] entry" into the market. Brannan Decl. ¶ 19. Watson states that as recently as July 6, 2012, FDA indicated to Watson that its ANDA "should be on track for full approval come August." *Id.* ¶ 20 (internal quotation marks omitted). But in August 2012, a representative from Watson spoke with an FDA representative, who told Watson that FDA no longer planned to approve Watson's ANDA on August 17, 2012. *Id.* ¶ 21. That is what prompted plaintiff's lawsuit.

On August 23, 2012, FDA sent Watson a letter confirming FDA's decision to delay approval of Watson's ANDA. A.R. at 1–15. The letter explained that Mylan's ANDA was the first application "with a paragraph IV certification for all of the patents" and was thus a previous application barring approval of Watson's ANDA for 180 days:

> FDA does not dispute that Watson is a first-applicant with respect to the drug composition claims within the Drug Composition/Use Patents. Because Watson's initial paragraph IV certifications on the remaining patent claims and patents were invalid . . . and because Watson so delayed in changing its section viii statements to paragraph IV certifications after the patent settlement, Watson was not a first application with respect to the method-of-use claims in the Drug Composition/Use Patents and the Use-only Patents. . . . Mylan . . . filed valid paragraph IV certifications to the method-of-use claims in the Drug Composition/Use Patents and the Use-only Patents . . . approximately two years before Watson did.

A.R. at 14. In the same letter, FDA notified Watson of its finding that Mylan and one or more other ANDA applicants (presumably Ranbaxy) were entitled to exclusivity instead. A.R. at 1. Sometime after August 17, 2012, Mylan (and presumably one or more other ANDA applicants) began marketing generic pioglitazone exclusively. Aug. 21, 2012 Tr. at 17 (Mylan's counsel stating that Mylan had already begun selling the drug).

C. Procedural History

On August 15, 2012, Watson filed this lawsuit against FDA, seeking a temporary restraining order and a preliminary injunction that would (1) enjoin FDA from granting final

approval to any ANDA for generic pioglitazone hydrochloride, or in the alternative, (2) if FDA granted final approval to any other ANDA for generic pioglitazone hydrochloride, that the Court also grant Watson's ANDA for the drug. [Dkt. # 3]. Soon after filing the lawsuit, FDA sent Watson a "Bioequivalence Deficiencies" letter regarding its ANDA. Brannan Decl. ¶ 22, Aug. 23, 2012. Based on this letter, the Court denied the motion for temporary restraining order without prejudice. Minute Order, Aug. 16, 2012.

Watson responded to the deficiencies letter and renewed its motion for temporary restraining order and preliminary injunction on August 16, 2012. Brannan Decl. ¶ 22, Aug. 23, 2012. The Court again denied the motion for temporary restraining order and issued the following minute order:

> For the reasons explained at the August 16, 2012 hearing, the Court finds that plaintiff did not show a substantial likelihood of success on the merits in its motion for a temporary restraining order concerning its [ANDA] . . . Specifically, plaintiff was told by the Food and Drug Administration ("FDA") on August 15, 2012 that its application was deficient and that it was required to submit additional information. The Court denied plaintiff's initial motion for a temporary restraining order without prejudice in view of the FDA's request. Plaintiff then responded to the FDA's request and renewed its motion. During the August 16 hearing on plaintiff's renewed motion, the FDA informed plaintiff that it had not submitted sufficient information in response to the August 15 request. Accordingly, at that time, plaintiff's application was still deemed deficient by the FDA and plaintiff was unable to demonstrate a likelihood of success on the merits; indeed, plaintiff's counsel conceded that the Court could not grant injunctive relief if its application was deemed deficient.
>
> Even if plaintiff had provided sufficient information to the FDA prior to the August 17, 2012 release date of Generic Pioglitazone, however, the Court finds that plaintiff did not present the Court with any case law or other legal authority that would persuade the Court that it has the authority to compel the FDA to immediately process and approve Watson's ANDA under the facts of this case. Plaintiff's alternative requests for relief also fail. Plaintiff requested, *inter alia*, that the Court enjoin the FDA from approving any other company's ANDA for Generic Pioglitazone if the FDA were not to approve Watson's ANDA on August 17, 2012. This request fails because such relief would plainly cause substantial injury to

> the other providers of Generic Pioglitazone who would have been approved on August 17, 2012. Furthermore, the public interest would not be furthered by an injunction that prevents approved companies from selling a generic drug. Accordingly, for the reasons stated by the Court on August 16, 2012 and for the reasons explained above, plaintiff's motion for a temporary restraining order is DENIED.

Minute Order, Aug. 17, 2012. At a status hearing on August 24, 2012, Watson withdrew its previously filed motions for preliminary injunction. Aug. 24, 2012 Tr. at 8.

On August 27, 2012, Watson filed a motion for summary judgment [Dkt. # 25], which is currently pending before the Court. In its motion, Watson asks the Court to order FDA to (1) "refrain from denying Watson's ANDA approval on the basis of FDA's determination that such approval is barred by exclusivity granted to any other ANDAs" and (2) grant final approval to Watson's ANDA. Proposed Order [Dkt. # 25-3].

II. STANDARD OF REVIEW

The APA establishes the scope of judicial review of agency action. *See Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 545–549 (1978).

A. Chevron Deference

Courts are required to analyze an agency's interpretation of a statute by following the two-step procedure set forth in *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). First, the court must determine "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842–43. Courts "use 'traditional tools of statutory construction' to determine whether Congress has unambiguously expressed its intent," *Serono Labs., Inc., v. Shalala*, 158 F.3d 1313, 1319 (D.C. Cir. 1998), including an examination of the statute's text, structure, purpose, and legislative history. *Bell Atl. Tel. Co. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997).

Thus, the *Chevron* step I exercise involves not only an analysis of the text, but a consideration of the provisions at issue in light of the statute's purpose. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1067–68 (D.C. Cir. 1998), quoting *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987) ("[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."). And, at the *Chevron* I stage, the Court must consider not only the provision in question, but also the statutory structure as a whole. *See United Savs. Ass'n of Tex. v. Timbers of Inwood Forest Assocs.*, 484 U.S. 365, 371 (1988) ("A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme – because the same terminology is used elsewhere in a context that makes its meaning clear, or because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law.") (internal citations omitted). *See also K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988) ("In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole."); *U.S. Nat. Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) (noting that courts "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"); *Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 574 F.3d 748, 771 (D.C. Cir. 2009) ("[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme."), quoting *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989); N. Singer & J. Singer, 2A Sutherland Statutes and Statutory Construction 189–90 (7th ed. 2007).

If the Court concludes that the statute is either silent or ambiguous, the second step of the Court's review process is to determine whether the interpretation proffered by the agency is

"based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. Once a reviewing court reaches the second step, it must accord "considerable weight" to an executive agency's construction of a statutory scheme it has been "entrusted to administer." *Id.* at 844. Indeed, "under Chevron, courts are bound to uphold an agency interpretation as long as it is reasonable – regardless whether there may be other reasonable or, even more reasonable, views." *Serono*, 158 F.3d at 1321. And the Court must defer to an agency's reading of its own regulations unless it is "plainly erroneous or inconsistent with the regulation." *Id.* at 1320 (internal quotation marks omitted).

B. Arbitrary and Capricious Review

"Even where [an agency's] construction satisfies *Chevron*, [the court] must still ensure that its action is not otherwise arbitrary and capricious." *Nat'l Ass'n of Clean Air Agencies v. EPA*, 489 F.3d 1221, 1228 (D.C. Cir. 2007). The agency action will be upheld if it "has considered the relevant factors and articulated a 'rational connection between the facts found and the choice made.'" *Id.*, quoting *Allied Local & Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 68 (D.C. Cir. 2000). The review is "[h]ighly deferential" and "presumes the validity of agency action." *Id.*, citing *AT&T Corp. v. FCC*, 349 F.3d 692, 698 (D.C. Cir. 2003). "[The] court is not to substitute its judgment for that of the agency[,] . . . [but] the agency must examine the relevant data and articulate a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted).

III. ANALYSIS

A. Chevron Step One

The issue presented in this case is whether FDA correctly interpreted the 180-day exclusivity provision in 21 U.S.C. § 355(j)(5)(B)(iv) when it delayed approval of Watson's ANDA until the expiration of Mylan's 180-day exclusivity period. The statute provides that if an ANDA contains a paragraph IV certification "and is for a drug for which a previous application has been submitted . . . [containing] such a certification," approval of the ANDA must be delayed for 180 days. § 355(j)(5)(B)(iv). Watson challenges FDA's determination that because Mylan amended its ANDA after the litigation to include paragraph IV certifications as to all of the patents applicable to pioglitazone two years before Watson did, Mylan's application was a "previous" application requiring the 180-day delay in the approval of Watson's application.

The relevant chronology is as follows:

- 7/15/2003: Both Watson and Mylan submitted ANDAs to market generic pioglitazone hydrochloride tablets on the first day such applications could be submitted. Watson's ANDA contained paragraph IV certifications for *all* of the applicable patents. Mylan's ANDA contained paragraph IV certifications for only the drug composition/use patents, and contained section viii statements for the remaining patents.

- 8/18/2003: FDA informed Watson that it would not accept paragraph IV certifications against the use-only patents

- 8/27/2003: Watson filed a "telephone amendment" to its ANDA to change its paragraph IV certifications to section viii certifications for the use-only patents, and reserved its right to reinstate its original certifications with the effective date of its original submission of July 15, 2003. Watson did not change its paragraph IV certifications to the drug composition/use patents, so there were at least two ANDAs (Watson's and Mylan's) containing at least two paragraph IV certifications received by the FDA on July 15, 2003.

- 9/4/2003: FDA informed Watson that its amended ANDA had been deemed acceptable for filing and that its filing date would be July 15, 2003, the date of Watson's original ANDA submission.

- 9/9/2003: Watson notified Takeda, the patent holder, that it had filed paragraph IV certifications to two of Takeda's patents. Presumably Mylan also informed Takeda of its paragraph IV certifications.

- 10/17/2003: Takeda filed a patent infringement lawsuit against Watson, Mylan, and other ANDA filers in the U.S. District Court for the District of New York for infringement of U.S. Patent Nos. 5,965,584 and 6,329,404 – the drug composition/use patents.

- 12/13/2005: FDA informed Watson that its ANDA had been "tentatively approved."

- 3/2010: The patent infringement litigation settled and both Watson and Mylan entered agreements providing that they would each receive non-exclusive licenses to the drug composition/use and use-only patents effective on August 17, 2012. The agreements required both to amend their ANDAs to change their section viii statements to the use-only patents to paragraph IV certifications.

- 3/22/2010: Mylan amended its ANDA to change its section viii statements to the use-only patents to paragraph IV certifications.

- 3/7/2012: Watson, in a letter entitled "minor amendment," amended its ANDA to change its section viii statements to the use-only patents to paragraph IV certifications.

Based on that record, FDA decided the following:

> FDA does not dispute that Watson is a first-applicant with respect to the drug composition claims within the Drug Composition/Use Patents. Because Watson's initial paragraph IV certifications on the remaining patent claims and patents were invalid . . . and because Watson so delayed in changing its section viii statements to paragraph IV certifications after the patent settlement, Watson was not a first application with respect to the method-of-use claims in the Drug Composition/Use Patents and the Use-only Patents. . . . Mylan . . . filed valid paragraph IV certifications to the method-of-use claims in the Drug Composition/Use Patents and the Use-only Patents . . . approximately two years before Watson did.

A.R. at 14. FDA went on to conclude that Mylan was the first applicant "with a paragraph IV certification for all of the patents." *Id.*

Watson objects to FDA's first line of reasoning – that Watson was not the first because its initial application was invalid. It argues that it was in fact the first to "submit" an application with paragraph IV certifications for all of the patents, pointing to its original July 15, 2003 ANDA. A.R. at 47. There is not enough information in the record for the Court to accept FDA's representations in its briefs about why Watson's initial paragraph IV certifications were "invalid."[8] The administrative record reveals little more than the fact that there was a telephone conference and Watson amended its application, A.R. at 37–39, after which FDA accepted it and deemed it filed as of the original filing date. But the record also does not support Watson's assertion that it filed paragraph IV certifications for all of the patents first. Once it substituted the section viii statements, A.R. at 38, FDA accepted the revised application and deemed *that* application as having been filed on July 15, 2003, A.R. at 33. The original application was essentially nullified – not because it was inherently invalid, but because it was retroactively amended. So the Court is not inclined to find as a matter of law that Watson filed *before* Mylan, but the characterization in the chart contained on page 10 of the FDA decision letter stating that

8 The Court notes that FDA does provide authority for the proposition that paragraph IV certifications and section viii statements are mutually exclusive. *See, e.g.*, *Purepac*, 354 F.3d at 880. That potentially explains why FDA deemed Watson's initial paragraph IV certifications "invalid" for purposes of ultimate approval of its ANDA, but it does not explain why FDA deemed those certifications "invalid" for purposes of granting exclusivity. In other words, FDA does not explain why it reads a "previous application . . . [containing] a paragraph IV certification" as a "previous application . . . [containing] a *valid* paragraph IV certification." Watson argues that to be eligible for exclusivity, a first-filed ANDA need only include "a certification" and the results of the required bioequivalence studies. *See* Pl.'s Mem. at 18–19, citing 21 C.F.R. § 314.107(c)(2). It argues that its first-filed application was eligible because it contained both. *Id.* Watson goes on to cite a passage in the Federal Register that, while it relates to bioequivalence studies and not paragraph IV certifications, appears to support FDA's point: "In order for an ANDA to be considered substantially complete for purposes of exclusivity, the bioequivalence studies submitted in the ANDA at the time it is initially submitted must, upon review by the agency, meet the appropriate standards for approval. If the applicant must conduct a new bioequivalence study to obtain approval of the ANDA, the application will not be considered to be substantially complete and the applicant will not be eligible for exclusivity." 64 Fed. Reg. 42,873, 42, 875 (Aug. 6, 1999).

Watson's "valid certification" was filed on August 27, 2003 – *i.e.*, suggesting that Watson filed *after* Mylan – is not supported by the record either. As the decision letter to Watson stated on page 9:

> FDA determined that the ANDA as amended was sufficiently complete to begin substantive review, and, consistent with FDA practice, sent an acknowledgement letter on September 9, 2003, indicating the application as amended was received as of July 15, 2003 (the initial submission date).

A.R. at 9.

What we have then is a tie: both Watson and Mylan *filed* ANDAs with some paragraph IV certifications – the ones for the drug composition/use patents, but not the use-only patents – on July 13, 2003.[9]

So the question at *Chevron* step one is: does the FDCA exclusivity provision permit the FDA to use the date that Mylan changed its section viii statements for the use-only patents to paragraph IV certifications as the critical date instead? Is that when the exclusivity attached? The statute says that an ANDA applicant has to wait 180 days for approval "[i]f the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which **a previous application has been submitted** . . . **[containing] such a certification . . . .**" Thus, on its face, the statute refers to the date *an application is submitted containing a certification*, not the date of any later, additional certifications, and not the date of the *amendment* of an application (much less the "minor amendment" of an application) to substitute a paragraph IV certification for a section viii statement.[10]

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9 FDA does not dispute that Watson was a first-filer as to the drug composition/use patents. *See* A.R. at 14.

10 The parties have pointed the Court to passages in the Federal Register related to the amendment of paragraph IV certifications, but none addresses whether an application amended to substitute paragraph IV certifications (*i.e.*, our use would infringe, but we have a license) for section viii statements (the method of use patent at issue does not claim the use for which we are

And did FDA properly interpret the statute as commanding it to award exclusivity to the first applicant with paragraph IV certifications for "all" of the patents? Again, such a decision is not mandated by the language of the provision: an applicant must wait 180 days for approval "if the application contains **a** certification described in subclause (IV) of paragraph (2)(A)(vii) and **is for a drug** for which a previous application has been submitted . . . [containing] such **a** certification . . . ." So the statute is written in terms of the drug, not one or all of the patents. It does not say that an applicant has to wait 180 days *if the application involves any patent that claims the drug for which a previous certification has been submitted*; it says if the application contains a paragraph IV certification and *is for a drug* for which a previous application has been submitted.[11] Nor does it say: "and is for a drug for which a previous application has been submitted containing paragraph IV certification**s** for **all** of the patents."

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seeking approval) may be deemed a "previous" application for purposes of exclusivity. Only one relates to the effect of such an amendment on the filing date of an ANDA: an amendment to a certification "cannot be read to suggest that the application will be considered to have contained only the changed certification retroactively to the date that the original certification was filed." 68 Fed. Reg. 36,676, 36,689 (June 18, 2003) (stating that the reason for prohibiting backdating in such a situation is that an "applicant could amend certifications to other patents and make them paragraph IV certifications. Among other difficulties, an applicant could then argue that, by virtue of relating back, such a paragraph IV certification was the 'first' application with a paragraph IV certification, potentially entitling the applicant to exclusivity under section 505(j)(5)(B)(iv) of the act."). The other Federal Register cites are not on point. *See, e.g.*, 59 Fed. Reg. at 50,350 (stating that FDA does not permit an applicant to notify a patent holder of its filing of a paragraph IV certification until FDA deems its application sufficiently complete for substantive review).

11 The court in *Apotex* found the statute to be silent and thus ambiguous as to whether more than one exclusivity period could arise for any given drug, but it ultimately upheld FDA's patent-based approach as reasonable and not arbitrary and capricious. *Apotex*, 414 F. Supp. 2d at 68–69. *But see Torpharm, Inc. v. FDA*, No. 03-2401, 2004 WL 64064 (D.D.C. Jan. 8, 2004) (finding that FDA's award of shared exclusivity to multiple applicants was contrary to the plain language of the statute and finding that Torpharm was entitled to sole exclusivity). The 2003 amendments under the MMA have since foreclosed FDA from granting exclusivity on a patent-by-patent basis, as they only permit one period of exclusivity to be awarded per drug to the first-filer as to any patent covered by the drug. *See* A.R. at 7 n.19.

But the provision cannot be interpreted standing alone. It does not say: if the application contains a paragraph IV certification . . . and is for a drug for which a previous application has been submitted containing a paragraph IV certification. It says: "if the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) . . ." and the previous application contains "such a certification." So what is "a certification described in subclause (IV) of paragraph (2)(A)(vii)?" Does looking at that provision resolve the question?

Unfortunately, no. Paragraph (2)(A) states that "an abbreviated application for a new drug shall contain" the items enumerated in eight subparagraphs. The seventh, subparagraph (2)(A)(vii), requires "**a** certification . . . **with respect to each patent** which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval . . . :

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

So, while it is clear that under paragraph (2)(A)(vii), before an application can be approved, there must be "a" certification" for "**each patent** which claims the listed drug," referring to that section does not shed any light on the decision this Court has to make: whether FDA can fairly say that Mylan was a "previous application . . . [containing] such a certification" – that is, a paragraph (2)(A)(vii)(IV) certification – when both Mylan and Watson submitted applications containing at least "a" certification on the same date in July of 2003. Thus, FDA's interpretation of the exclusivity provision in this case is not compelled by the statute. In other words, it is not *Chevron I* for the agency, as FDA contends.

The few authorities FDA provides in support of its position that Congress mandated its action in this case are not dispositive. FDA cites two authorities for the proposition that "[i]f one ANDA applicant is the first applicant to all of the listed patents, that applicant will have sole exclusivity." FDA's Opp. at 9. First, it cites its own decision letter to Watson. *See id.* Although the Watson decision letter sets out that principle on page 8, that letter merely cites two other decision letters issued by FDA. *See* A.R. at 8.[12] Second, it cites a footnote in another pharmaceutical case decided in this court, *Mylan Pharms., Inc. v. Sebelius*, 856 F. Supp. 2d 196 (D.D.C. 2012), which states that "when more than one patent relates to the brand drug, as became the case [in the action before the court], the FDA awards exclusivity to the company that is the first filer as to all of the patents referencing the brand drug." *Id.* at 204 n.12. This statement is simply the court's observation of what *does* happen in such a case; the court in *Mylan* was not deciding what the statute says *should* happen in such a case.

FDA's reliance upon *Mylan* is further misplaced because the situation in that case is different from the situation presented here. In *Mylan*, four generic manufacturers filed paragraph IV certifications with respect to the only applicable patent for the brand name drug on the same date, and their ANDAs were all tentatively approved by FDA. *Id.* at 202. Their certifications prompted the brand manufacturer to file a patent infringement action against them. Only after that litigation was resolved did the manufacturer obtain a second patent. On the first date that applicants could file certifications challenging the second patent, only one of the original four companies, Teva, and a company that had not been one of the original first filers, Watson, filed ANDAs with paragraph IV certifications to that patent. Mylan, also one of the original first filers, waited another three years to do so. In the meantime, Teva acquired the brand

12 One of the decision letters cited is FDA's decision letter issued to Mylan in *Mylan Pharm. v. Sebelius*, 856 F. Supp. 2d 196 (D.D.C. 2012).

manufacturer. So, the issue the court had to resolve was whether Teva's corporate (and non-adversarial) relationship with the brand manufacturer rendered its 180-day exclusivity period invalid.[13] But for the purposes of the preliminary injunction motion before it, the court did not have to resolve the issue posed in this case. It simply noted that it "proceeds on the basis that Teva USA was the only first filer as to both . . . patents and, therefore, was the only ANDA applicant entitled to 180-day exclusivity." *Id.* at 206–07. So, *Mylan* produced no holding that is authoritative here because the question was not presented. Moreover, there is something different in nature between a situation where a second patent comes along that was not originally involved and the situation we have here: where the list of patents remained constant from the beginning, and all of the parties put the manufacturer on notice from the start of their positions with respect to all of them.

Defendant Mylan cites several other cases for the proposition that 180-day exclusivity must be awarded solely to Mylan in this case. [Dkt. # 43]. However, those cases are also distinguishable. The analysis in the *Apotex* decision comes closest to the situation presented in this case, because it dealt with the same provision at issue here. But the question there was whether more than one exclusivity period could arise in connection with a given drug. The court found the statute to be silent on the issue, and it found FDA's position – that a separate 180-day exclusivity period arises in connection with each patent that is listed for the drug, for whichever ANDA applicant was first to file the paragraph IV certification *to that patent* – to be

13 The court also addressed whether Teva had abandoned its ANDA, an issue not presented in this case. *See Mylan*, 856 F. Supp. 2d at 213–15.

reasonable.[14] So the *Apotex* court did not reach the issue of whether FDA may deny exclusivity to an applicant in the circumstances presented in this case.

Other cases cited by Mylan deal with provisions of the statute that are only tangentially related to the 180-day exclusivity provision. The court in *Torpharm, Inc. v. Thompson*, 260 F. Supp. 2d 69 (D.D.C. 2003), for example, addressed FDA's interpretation of the notice provision in 355(j)(2)(B), specifically, the effect of an applicant's failure to simultaneously file its certification and its notice to the patent holder as required by the statute. *Id.* at 81. In that case, FDA established priority for the filing of the certifications based upon when the filer notified the patent holder. *Id.* (finding the statute silent on the issue in part because the notice provision "does not purport to govern when a paragraph IV amendment actually becomes effective for exclusivity purposes" and thus finding FDA's interpretation permissible). Here, even if Mylan filed its notification of the amended ANDA containing the new paragraph IV certifications before Watson did, FDA does not seem to be basing its decision on that circumstance. Instead, it is working from the date of the filing of the amendments. A.R. at 10–11. The court in *Purepac* also assessed FDA's interpretation of the effect of failure to follow the simultaneity requirement. *Purepac*, 354 F. 3d at 888–89 (concluding that statute was silent on the effect of an applicant's failure to simultaneously file and notify the patent holder), citing *Torpharm*, 260 F. Supp. 2d at 80.[15] The court in *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010),

14 Interestingly, in that case, FDA did not claim, as here, that the clock does not start ticking until someone has filed certifications for *all* of the patents.

15 The *Purepac* court also addressed several other issues under the arbitrary and capricious standard: (1) FDA's decision to change the use code for a patent in the Orange Book and thus reject Purepac's section viii statement as to that patent; (2) FDA's decision to delist a patent upon finding that no applicant was eligible for exclusivity for that patent; and (3) FDA's decision to deny an applicant an equitable exception the mutual exclusivity rule for section viii statements and paragraph IV certifications, where the applicant had filed both a statement and certification

addressed FDA's interpretation of a wholly different provision not present in the pre-MMA version of the statute – the "failure to market" forfeiture provision. *Id.* at 1317–18 (finding that FDA's interpretation of that provision as permitting a brand manufacturer to unilaterally trigger the forfeiture of an applicant's exclusivity period by delisting a patent failed *Chevron I* because it ran contrary to the incentive structure of the FDCA, which the MMA did not purport to change).

So, the Court finds that neither the statute nor the case law compels the FDA's decision in this case. But is the FDA's decision precluded by the statute? In other words, does Watson prevail at the *Chevron* step one stage?

The Court concludes that FDA's decision is contrary to the plain language of the statute. As noted above, the FDCA says if the application contains **a** paragraph IV certificatio**n** and **it is for a drug** for which there was a previous application containing **such a certification**, approval of the application is delayed for 180 days. Here, when Watson filed its application containing a paragraph IV certification for the drug composition/use patents on July 15, 2003, there was no previous application containing such a certification on file for that drug. Mylan's application came in on the same day.

FDA regulations are also consistent with Watson's position. 21 C.F.R. § 314.107(c)(1) provides that approval is barred for 180 days:

> If an abbreviated new drug application contains **a** certification that **a** relevant patent is invalid, unenforceable, or will not be infringed and the application is for a generic copy of the same listed drug for which one or more substantially complete abbreviated new drug applications were previously submitted **containing a certification** that **the same patent** was invalid, unenforceable, or would not be infringed . . . .

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for the same patent. The court found the first decision arbitrary and capricious, and the second and third decisions not arbitrary and capricious.

More important, the meaning of the provision becomes clear in light of the entire statutory scheme and the purpose that the exclusivity provision is intended to serve. The cases that FDA and Mylan cite explain that the purpose of the paragraph IV certification is to put the patent holder on notice that its patent is about to be infringed by a generic manufacturer: the statute requires that the ANDA applicant notify the patent holder and then notify FDA that the notice was actually received. But the purpose of the 180-day exclusivity period is to reward the generic manufacturer who does this and thereby takes on the risk of being sued, and of being forced to participate in expensive patent litigation to earn the right to market the generic drug. In other words, to provide some incentive for manufacturers to take on the patent holders for the benefit of consumers, they get a pot at the end of the rainbow. The case law is clear and consistent about this. *See e.g.*, *Teva Pharms. ,* 595 F. 3d at 1304, citing *Mova Pharm. Corp. v. Shalala*, 140 F. 3d 1060, 1063–65 (D.C. Cir. 1998) (generic drug manufacturers earn the six month period of exclusivity "for successfully taking the risks and bearing the costs of showing the invalidity or inefficacy of a patent that a brand-name drug maker has said blocks competing products"), *id.* at 1305 ("In order . . . to compensate [generic] manufacturers for research and development costs as well as the risk of litigation from patent holders, . . . the statute provides that the first company to file an ANDA containing a paragraph IV certification earns an 'exclusivity' period . . . . This promise of initial marketing exclusivity is thus intended to increase competition by expediting the availability of generic equivalents.") (internal citations and quotation marks omitted). FDA was equally clear on this point in its decision letter to Watson, as well as in other decision letters it has issued in the past. *See* A.R. at 7 (stating that the "narrow purpose of the 180-day exclusivity provision [is] to reward the first ANDA applicant to challenge a listed patent" and rejecting the application of patent-based exclusivity in a

situation where the result "would be so at odds with . . . the narrow purpose of the 180-day exclusivity provision . . . as to defeat the purpose of the generic drug provisions").

Thus, looking at the plain terms of the statutory provision, and considering the purpose of the provision within the overall statutory scheme, *see Mova Pharm. Corp.*, 140 F.3d at 1067 ("[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.") (internal quotation marks omitted), it is the Court's view that FDA's interpretation of the exclusivity provision to deny shared exclusivity to Watson is inconsistent with the FDCA.[16]

B. Chevron Step Two

But the Court is aware of the prior decisions of this Court finding this and other provisions of the FDCA to be ambiguous. *See, e.g.*, *Apotex*, 414 F. Supp. 2d at 68–69 (concluding that "the provision lends itself to multiple interpretations, and hence is ambiguous under *Chevron* step one"). And certainly FDA and the parties have grappled with its terms, settling on different interpretations in different situations. *See, e.g.*, *id.* at 72–76 (FDA reading exclusivity provision to award an exclusivity period for each patent covered by a drug, but creating a shared exclusivity exception to that rule in exclusivity "standoff" situations); *Mylan*,

16 Although not a factor to be considered as part of the *Chevron* step one inquiry, it is worth noting that if the Court had to apply the current version of the statute, as it has been amended to more clearly implement Congress's intent, there is no question that Watson would enjoy shared exclusivity with Mylan. *See* A.R. at 7 n.19 (noting that the 2003 amendments under the MMA foreclosed granting exclusivity on a patent-by-patent basis, permitting only one period of exclusivity to be awarded per drug to the first-filer as to *any* patent covered by the drug). Here, FDA admits that Watson was a first-filer of paragraph IV certifications to the drug composition/use patents, and no other applicant filed a paragraph IV certification to any other patent before Watson filed its original ANDA. Only Mylan (and one or more other ANDA filers) filed applications containing certifications to the same patents on the same day. Moreover, FDA does not argue that Watson's original paragraph IV certifications to the drug composition/use patents were invalid, so it would have no basis for denying Watson shared exclusivity to market the drug.

856 F.Supp.2d at 207–09 (Mylan reading exclusivity provision to impose a requirement that ANDA filer and NDA holder must be adverse throughout the exclusivity period, in a situation where ANDA filer and NDA holder subsequently came under control of the same parent company). So the Court finds it prudent to go on to consider step two of the *Chevron* framework.

Assuming that the exclusivity provision is silent or ambiguous as to the issue presented in this case, the question under step two becomes whether FDA's interpretation is a reasonable one. FDA's interpretation could be viewed as unreasonable in light of the purpose of exclusivity provision and of the statute generally. However, at this stage of the *Chevron* analysis, the Court must accord deference to FDA's interpretation of the statute, *see, e.g.*, *Apotex*, 414 F. Supp. 2d at 72,[17] and it is difficult to conclude that the agency's reading of the statute to award exclusivity to the first-filer to file certifications as to all the patents is not based on a permissible reading of the statute, *see Chevron*, 467 U.S. at 843.

Watson argues that even if FDA's position in this case is based on a reasonable construction of the statute, that position need not be accorded deference because "it is . . . inconsistent with [FDA's] prior practice." Pl.'s Reply Mem. of P. and A. in Further Support of Mot. for Summ. J., and Pl.'s Opp. to FDA's Mot. to Dismiss, or, in the alternative, for Summ. J. ("Pl.'s Reply") [Dkt. # 41] at 3. It claims that FDA's prior practice commands against granting sole exclusivity to Mylan because that practice "makes clear that Watson's ANDA was substantially complete when filed, that Watson was a First Filer to the [Use-only] Patents and

17 This is not a situation, though, in which the Court must give heightened deference to an agency's decision because that decision falls within the agency's particular scientific expertise. *See, e.g.*, *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995) ("[C]ourts give a high level of deference to an agency's evaluations of scientific data within its area of expertise.").

that if Watson is not entitled to exclusivity for the [Use-only] Patents, it can only be because this exclusivity was rendered unavailable to any party when Watson amended its ANDA." *Id.*

It is true that "[a]n agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a consistently held agency view.'" *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987); *see also King Broad. Co. v. FCC*, 860 F.2d 465, 470 (D.C. Cir. 1988) (holding that "result reached by the agency is impermissible under the second prong of *Chevron* . . . [because it] is inconsistent with its prior analysis in similar situations without any acknowledgement of the fact, or cogent explanation as to why"). In *King*, the FCC had determined that the plaintiff's proposed radio program did not qualify for a statutory exemption, but it had failed to apply a two-part test that it previously found necessary to making such a determination. *Id.* at 470–71. Because the FCC did not offer a reasonable explanation for departing from its previous practice and not applying the test, the Court found its determination as to the plaintiff unreasonable under *Chevron* step two. *Id.* Watson argues that FDA acted inconsistently because it failed to apply two rules that it has applied to amended applications similar to Watson's in the past: (1) a rule against backdating the filing date of an amended application that was only deemed sufficiently complete upon amendment and (2) a rule against rolling exclusivity from a first filer to a subsequent filer.

Watson first argues that it is FDA's practice to "refus[e] to grant an ANDA applicant an 'acceptable for filing' date earlier than the date on which its amendment rendered the ANDA substantially complete." Pl.'s Mem. at 20. It therefore concludes that FDA acted inconsistently with that practice when it deemed Watson's amended ANDA to have been filed on the original submission date of July 15, 2003. It argues that if FDA did not deem Watson's application sufficiently complete until August 23, 2003, it was improper to give Watson's amended ANDA

an effective filing date any earlier than August 23. At first blush, this argument does not seem to advance Watson's position: there were reasons why deeming the amended ANDA to have been filed on the date of the original submission may have been in Watson's interest at the time. But at this juncture, Watson maintains that should never have happened. In short, Watson's position now is that its original ANDA – which contained the paragraph IV certifications as to all of the patents – was the application that was filed on July15, 2003. That would put it first in line for FDA's paragraph-IV-certifications-for-all-patents exclusivity period.

But FDA responds that it has no such practice. In fact, it represents that it backdates applications that were only deemed sufficiently complete upon amendment "all the time." Sept. 14, 2012 Tr. at 51 ("[FDA] does this all the time. It does a preliminary review of an ANDA to decide if it's sufficient. If there are deficiencies, they make calls, and they are corrected. And it deems [the corrected ANDA] substantially complete as of the day it was submitted."); *see also* FDA's Opp. at 18 ("[W]hen such corrections are made to errors in applications before the filing decision is made, FDA will deem the application to be received, as amended, as of the date it was originally filed, which can give the applicant the benefit of an original filing date."), citing 21 C.F.R. § 314.101.[18] So, FDA argues that its decision to backdate Watson's amended

18 The Court notes that neither party has pointed to sufficient evidence in the record to allow the Court to find whether such a practice does or does not exist. Both parties cite to 21 C.F.R. § 314.101 for support, but that regulation, which addresses the filing and receipt of ANDAs, does not contain any provisions governing the date of corrected or amended applications. It does suggest, though, that there is a difference between the date when an ANDA is "received," which triggers an FDA review to determine whether it "may be filed," and when it is "filed," which "means that FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.101(a)(1). Under the terms of that regulation, then, Watson's ANDA was "filed" only after it had been amended. But the FDCA does not use the word "received" or "filed" when it discusses the previous application that will delay a subsequent application's approval. Section 355(j)(5)(B)(iv) requires that an ANDA applicant must wait 180 days for approval if a previous application containing paragraph IV certification has been "**submitted**." 21 U.S.C. § 355(j)(5)(B)(iv). But at most, this lack of

application – the first Watson application that was actually accepted for filing -- was in fact consistent with its regulations and past practices, and indeed, it was that action that supplied the grounds for an award of shared exclusivity with Mylan.

Watson goes on to argue that FDA's decision to grant Mylan exclusivity in this case contradicts a second FDA policy against permitting exclusivity to "roll" from one applicant to the next.[19] Watson submits that "[b]ecause Watson's ANDA was both substantially complete when filed and contained Paragraph IV certifications to the [Use-only Patents], Watson was eligible for exclusivity with respect to the Use-only Patents" as a "first filer." Pl.'s Mem. at 26. So, according to Watson, when it withdrew its paragraph IV certifications on August 23, 2003, it destroyed eligibility for itself and all other applicants, because "*only* First Filers can be eligible for 180-day exclusivity." *Id.* at 27–28 (arguing that "FDA cannot justify why it has decided that the facts of this situation differ so that somehow the exclusivity with respect to the [Use-only Patents] has rolled to another applicant"). This time, FDA does not dispute that the policy

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clarity would lend more support to the argument that the provision is ambiguous, and that this Court must defer to the agency's interpretation that a previously submitted application is one that was accepted for filing.

Watson also cites 21 C.F.R. § 314.94, which speaks to the content and form of an abbreviated application. In particular, it points to subsection (a)(12)(viii)(A), which it claims is "directed to the amendment of certifications in cases like this where an original paragraph IV certification was later found to be incorrect." Pl.'s Reply at 4. However, § 314.94(a)(12)(viii)(A) governs only a situation where an applicant is required to change its paragraph IV certifications to paragraph III certifications after a court has found that the applicant has infringed the patent holder's patents. Upon the applicant making such a change, "the application will no longer be considered to be one containing a [paragraph IV] certification." That is not the situation presented here.

19 The rule against rolling exclusivity is described in the Federal Register: "[O]nly the applicant submitting the first substantially complete ANDA for a listed drug with a paragraph IV certification to [a] patent . . . for the listed drug . . .would be eligible for exclusivity." So, "if the first applicant subsequently withdraws its application or changes or withdraws its paragraph IV certification, either voluntarily or as a result of a settlement or defeat in patent litigation, no ANDA applicant will be eligible for 180-day exclusivity." 59 Fed. Reg. at 50, 350; s*ee also* 21 C.F.R. § 314.07(c).

against rolling exclusivity exists. But it argues that the policy does not apply in this case. FDA's Opp. at 20–21 (arguing that Watson was never a "first filer" eligible for exclusivity as to the use-only patents because its invalid paragraph IV certifications rendered its original application insufficient for filing). And it is true that FDA regulations confer the authority on the agency to review an application and deem it to be acceptable before it can ever be acknowledged as filed.

In any event, in this case, on these specific facts, as will be discussed below, the Court finds that FDA's decision to deny shared exclusivity to Watson is arbitrary and capricious. It thus finds that the proper remedy is awarding Watson shared exclusivity, and it need not reach the question of whether FDA should have applied the rolling exclusivity rule and denied exclusivity to everyone.

So, while the Court is troubled by the fairness of the agency action in this particular case, given the deference that must be accorded the agency at step two of the *Chevron* analysis, the Court finds that FDA's reading of the exclusivity provision is reasonable, and that the points made by Watson in its *Chevron* argument support the Court's finding that the agency decision was arbitrary and capricious in this case.[20]

C. Arbitrary and Capricious Review

Watson asserts that, even if FDA's denial of shared exclusivity to Watson survives *Chevron*, it nevertheless must be overturned in this case because it is arbitrary and capricious. Pl.'s Mem. at 23–26. The Court agrees. The FDA's decision is contrary to the purpose underlying the exclusivity provision and not supported by the proffered explanations.

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20 To the extent that Watson further argues that FDA's decision is unreasonable because it produced results contrary to the purpose of the statute, the Court will address that argument in its analysis under the arbitrary and capricious standard. *See, e.g., Gen. Instrument Corp. v. FCC*, 213 F.3d 724, 732 (D.C. Cir. 2000) ("[W]e have recognized that an arbitrary and capricious claim and a Chevron step two argument overlap . . . ."); *see also Nat'l Treasury Employees Union v. Chertoff*, 385 F. Supp. 2d 1 (D.D.C. 2005).

The Court finds that FDA's decision to deny Watson shared exclusivity in this circumstance is arbitrary and capricious because it produces absurd results that are contrary to the purpose of the Hatch-Waxman Amendments and the exclusivity provision in particular.[21] *See Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1011 (D.C. Cir. 1993) ("FDA must interpret the [FDCA] to avoid absurd results and further congressional intent."). In *Teva*, the court found that FDA's narrow interpretation of the court-decision trigger for 180-day exclusivity was arbitrary and capricious because it meant that the generic drug was "not available for a number of months despite the fact that appellants both stood ready to market them" – an absurd result that contradicted the Act's purpose of expediting the approval of generic drugs. *Id.* Here, although denial of shared exclusivity to Watson does not mean that generic pioglitazone cannot be marketed at all – Mylan and presumably Ranbaxy can still market the drug[22] – the result is still at odds with the sole purpose of the exclusivity provision: to encourage generic applicants to file paragraph IV certifications and incur the risks and costs of patent litigation necessary to clear the patents out of the way and facilitate the entry of generics into the market. *See* A.R. at 7 (stating that the "narrow purpose of the 180-day exclusivity provision [is] to reward the first ANDA applicant to challenge a listed patent, and the broader purpose of the

21 Watson further argues that "[b]ecause FDA's own regulations and past practice show that, if Watson is not entitled to exclusivity for the [Use-only Patents], no ANDA holder is entitled to such exclusivity, FDA's decision to deny Watson approval of its ANDA must be reversed as arbitrary and capricious." Pl.'s Mem. at 29. But, because the Court finds granting shared exclusivity to Watson is the appropriate remedy in this case, its analysis focuses on FDA's decision to deny shared exclusivity.

22 Watson argues in its summary judgment motion that granting exclusivity to Mylan does in fact lead to the absurd result of keeping generics off the market because Mylan agreed to delay market entry as part of its settlement with Takeda. Pl.'s Reply at 9. But, at the motions hearing, Watson conceded that "the general understanding is that [Watson's and Mylan's agreements] were the same or roughly the same at least in substance." Sept. 14, 2012 Tr. at 17. So, presumably Watson agreed to delay entry into the market, as well. But, at this stage in the process, it appears that any delay in market entry agreed to has since expired. *See* Aug. 21, 2012 Tr. at 17 (Mylan's counsel stating that Mylan had already begun selling the drug).

[Hatch-Waxman Act is] to encourage generic competition."). As Watson argues, FDA's decision produces the absurd result of denying Watson the reward it earned just as Mylan did: by instigating and participating in costly patent litigation against Takeda. Pl.'s Reply at 9.

It is true that after the litigation was resolved, Mylan amended its original ANDA to include the relevant paragraph IV certifications first, but that was nothing more than a formality. Filing those certifications did not put the patent holder on notice of anything it did not already know. Moreover, it did not require Mylan to risk patent litigation. The litigation was over. It is thus unfair and inconsistent with the sole purpose of the 180-day exclusivity provision to reward Mylan with sole exclusivity simply because it accomplished the final housekeeping task of amending its ANDA to reflect the results of the litigation first. Such a decision elevates form over substance.

It is important to note that the need to substitute paragraph IV certifications for the section viii statements in the Watson and Mylan ANDAs was not required by any decision of the court in the patent case, and it was not prompted because of any deficiency identified in the ANDAs by the FDA. It was simply a term of the settlement of the Takeda litigation negotiated by private parties. *See* Watson Minor Amendment at 3. The lawsuit alleged patent infringement as to the drug composition/use patents that were the subject of Watson's and Mylan's simultaneously filed July 2003 paragraph IV certifications. *See* Takeda Am. Compl. [Dkt. # 46-3]; *see also* A.R. at 12. Had the parties resolved the case with licenses for those patents alone, there would be no question that Watson and Mylan would be entitled to shared exclusivity.

Furthermore, the decision is particularly arbitrary and capricious in this instance because it was Watson, and not Mylan, that intended to file an application with paragraph IV certifications as to all of the patents from the start. And it was FDA, and not Watson, that was

the moving force behind the amendment of the July 15, 2003 ANDA to substitute section viii statements for the use-only patents. Indeed, in the very document that effectuated the change – the telephone amendment – Watson specifically reserved its rights and sought to preserve its position. "Watson does not agree with the Agency's position . . . . However, solely to facilitate ANDA review, and without prejudice to Watson's position, Watson is amending . . . ." A.R. at 38. Watson reiterated: "Watson makes this amendment without prejudice to its right to reinstate its original Paragraph IV Certifications with the effective date of original submission on July 15, 2003, should a court or the Agency hold in the future that Paragraph IV Certifications should have been made and/or maintained." *Id.*

The FDA said nothing in response. And in the years leading up to its decision, FDA did nothing to lead Watson or any other party to believe that it would not grant shared exclusivity. As recently as July 6, 2010, FDA indicated to Watson that its ANDA "should be on track for full approval come August." Brannan Decl. ¶ 20.

In its decision letter, FDA took the position that Watson derived some benefit from FDA's insistence that the paragraph IV certifications be removed from the original ANDA:

> You fail to acknowledge the critical impact of Watson's amendment to its application that removed the paragraph IV certifications and substituted section viii statements regarding the method-of-use claims in the Drug Composition/Use Patents and the Use-only Patents. As a result of this amendment, Watson gained the benefits that flow from filing a section viii statement to a patent rather than a[] paragraph IV certification, including, among other things, not having to provide the detailed notice required for paragraph IV certifications to the NDA sponsor and patent holder describing why these patents were invalid and not infringed, and not running the attendant risk of a 30-month stay of approval of its ANDA while validity and infringement was litigated. These are not small benefits. . . . Watson gained the benefit of its section viii statements, and cannot now seek to essentially gain the benefit of 180-day exclusivity . . . .

A.R. at 11–12. But the notion that a generic manufacturer faces fewer risks and delays when it files section viii statements as a general matter is a completely irrelevant point in this case. Because Watson *did* file paragraph IV certifications with respect to two patents, it *did* have to file the detailed notice to the NDA sponsor and patent holder, and it *did* run the risk of a stay of approval while the costly litigation ensued. So that cannot be a reason for denying Watson exclusivity. And the fact that Watson bowed to FDA's request that it file section viii statements at the outset cannot be the reason for granting exclusivity to Mylan instead, since Mylan filed section viii statements for the exact same patents and received the very same "not small benefits" that the FDA saw fit to highlight in its decision.

Further, FDA fails to provide an adequate explanation for why it did not apply shared exclusivity in this particular situation. *See* Pl.'s Reply at 9–10. FDA's stated rationale for applying shared exclusivity in mutually-blocking situations – to avoid a result that is "so at odds with both the narrow purpose of the 180-day exclusivity provision to reward the first ANDA applicant to challenge a listed patent, and the broader purpose of the [Hatch-Waxman Act] to encourage generic competition, as to defeat the purpose of the generic drug provisions," *see* A.R. at 7 – certainly applies in this case.[23]

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23 FDA states that it did not award shared exclusivity in this case because shared exclusivity is reserved for "mutually blocking" situations, and it was not presented with such a situation here. FDA describes a "mutually blocking" situation as a situation where "two or more applicants are each eligible for exclusivity based upon paragraph IV certifications to different listed patents, and each is blocked by previous paragraph IV certifications on another patent to which it was not first to certify." A.R. at 7–8. From this, FDA concludes that Watson's case "is not . . . a situation in which shared exclusivity applies [because] Mylan and one or more other ANDA applicants block Watson [as to the use-only patents] but Watson does not block Mylan and the one or more other applicants [as to the drug composition/use patents]." A.R. at 14.

Watson asserts that this *is* the sort of blocking situation for which shared exclusivity is the remedy because as things stand, Watson is being blocked by the FDA's decision to give Mylan exclusivity for the use-only patents. It further asserts that FDA provides "no case law, no statute and no regulatory support for its position that shared exclusivity can only exist in a

Finally, FDA's decision to delay Watson's approval cannot be deemed rational when viewed in the context of parties' understanding all along that Mylan and Watson would share exclusivity.[24] *See, e.g.*, Brannan Decl. ¶ 20 (stating that "as recently as July 6, 2012, FDA indicated that Watson's ANDA 'should be on track for full approval come August"). Watson filed suit when it learned that its ANDA might not be approved by the time that Mylan was scheduled to launch, and it initially sought to block the FDA's ability to approve Mylan first. But those claims fell by the wayside once Mylan's ANDA was approved. Thereafter, at the status conference before the Court on August 21, 2012, everyone seemed clear that shared exclusivity was what was left at stake. Mylan's counsel began expressing her point of view before she ever took to the lectern. Aug. 21, 2012 Tr. at 15 ("The Court: I was very interested in the vigorous shaking of heads going on at the defense table when plaintiff said the [Mylan] approval letter issued on Friday is inherently denying shared exclusivity."). Counsel for Mylan then informed the court that the approval letter it received allowed for the possibility of shared exclusivity, and that Mylan was intervening in the case simply to protect its right to go to market

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'multiple [or mutually]-blocking' situation," and so that position should not govern here. Pl.'s Reply at 8 (quoting FDA's Opp. at 9, 20). The Court disagrees that there is no precedent for FDA's position, and finds that there does exist at least some support that FDA's practice has been to limit shared exclusivity to "multiple blocking" situations. In *Apotex*, the court noted that FDA had limited the application of shared exclusivity to "true blocking situation[s]" since at least March 2002. *See Apotex*, 414 F. Supp. 2d at 76 (upholding FDA's decision to deny shared exclusivity where plaintiff was blocked from marketing its product not by another applicant's exclusivity period but by a court decision). So, FDA's decision to refuse to apply shared exclusivity in the absence of a true blocking situation is not on its face inconsistent with its past practices, and it is not what drives the Court's determination that its action is arbitrary and capricious.

24 A press release issued by Takeda on April 28, 2010, attached as an exhibit to the Brannan declaration, states that the entire "industry," including Takeda, also expected Mylan and Watson to share exclusivity as well. *See* Ex. A to Brannan Decl. (stating that "Mylan, Watson and Ranbaxy are first-filers of ANDAs with paragraph IV certifications for generic ACTOS, and it is anticipated that the U.S. Food and Drug Administration (FDA) will grant them 180-day marketing exclusivity").

at all, not to go alone. Aug. 21, 2012 Tr. at 16–17 (suggesting that Mylan's only interest at the hearing was in making sure that Watson was only pursuing shared exclusivity and not sole exclusivity: "Under shared exclusivity, we weren't wrong, so . . . my interest and purpose here today . . . is whether or not Watson is making the argument that Mylan should be enjoined from continuing its sales or . . . should the final approval be rescinded."). Watson also clarified that what it was seeking was shared exclusivity. Aug. 21, 2012 Tr. at 18. The Court then expressed its understanding of the state of the matter at that time:

> Well the only thing I understand is at issue anymore is shared exclusivity. There's no ability – they're not asking to divest [Mylan] of your approved [ANDA]; they were trying to keep you from getting it, but you've gotten it, so that part of the lawsuit according to both sides, I believe, is moot. So the only question on the table is whether they can be approved in time to get what they believe they are entitled to which is to share this 180 day period with [Mylan], and you may not like that, but I think that was . . . what they were asking for all along.

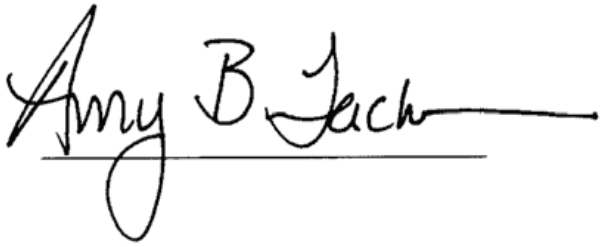
Aug. 21, 2012 Tr. at 17. No one from FDA spoke up to suggest that the Court was operating under a misimpression.

Therefore, in light of this unique combination of facts and circumstances, the Court finds that it was arbitrary and capricious for the FDA to deny Watson – which filed paragraph IV certifications and risked patent litigation at the same time as Mylan, and indeed, delivered paragraph IV certifications for all of the patents to the FDA years *before* Mylan – the right to share in the 180-day marketing opportunity prescribed by the statute.

IV. CONCLUSION

For the reasons stated above, the Court finds that FDA's interpretation of the exclusivity provision is at odds with the statute, but that even if the statute is ambiguous and FDA's interpretation is entitled to deference, its decision is arbitrary and capricious under the unique

circumstances of this case. Thus, the Court will grant Watson's motion for summary judgment and deny FDA's motion to dismiss.



AMY BERMAN JACKSON
United States District Judge

DATE: October 22, 2012