UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WATSON LABORATORIES, INCORPORATED,

Plaintiff,

v.

KATHLEEN SEBELIUS, Secretary of Health and Human Services,

MARGARET A. HAMBURG, M.D., Commissioner of Food and Drugs,

and

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants,

and

MYLAN PHARMACEUTICALS, INC.,

Intervenor-Defendant.

Civil Action No. 12-cv-01344 (ABJ)

EXPEDITED HEARING REQUESTED

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Federal Rule of Civil Procedure 56 and Local Civil Rule 7(h)(2), and upon the accompanying Memorandum of Points and Authorities, Declaration of Chad Landmon, and Declaration of Beth Brannan, Plaintiff Watson Laboratories, Inc. ("Watson") hereby moves this Court to grant summary judgment in its favor, declare that FDA's denial of shared exclusivity to Watson's pioglitazone hydrochloride ANDA was arbitrary, capricious and contrary to law, and enter an injunction ordering defendants Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services, Margaret A. Hamburg, M.D., in her official capacity as

Commissioner of Food and Drugs, and the United States Food and Drug Administration (collectively, "FDA"):

(i) to 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 for generic pioglitazone hydrochloride 15 mg, 30 mg, and 45 mg tablets; and

(ii) to grant final approval to Watson's ANDA.

Watson further moves for an expedited hearing on its motion. The grounds for this motion are fully set forth in the accompanying Memorandum of Points and Authorities. A proposed order is attached. Oral argument is requested.

Dated: August 27, 2012

Respectfully submitted,

AXINN, VELTROP & HARKRIDER LLP

By: /s/ Chad A. Landmon

Chad A. Landmon (DC Bar No. 990347)
M. Lily Woodland (DC Bar No. 985249)
950 F Street, N.W.
Washington, D.C. 20004
(202) 721-5415 (telephone)
(202) 912-4701 (facsimile)

Mark D. Alexander (pro hac vice)
Aaron J. Feigenbaum (pro hac vice)
114 West 47th Street, 22nd Floor
New York, NY 10036
(212) 728-2200 (telephone)
(212) 728-2201 (facsimile)

Attorneys for Watson Laboratories, Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WATSON LABORATORIES, INCORPORATED, Plaintiff, v. KATHLEEN SEBELIUS, Secretary of Health and Human Services, MARGARET A. HAMBURG, M.D., Commissioner of Food and Drugs, and UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants, and MYLAN PHARMACEUTICALS, INC., Intervenor-Defendant.	Civil Action No. 12-cv-01344-ABJ

PLAINTIFF'S MEMORANDUM OF POINTS AND
AUTHORITIES IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

INTRODUCTION 1

STATEMENT OF FACTS 3

A. Generic Drug Entry: The Statutory Framework 3

B. New Drugs and Generic Drug Application Requirements 3

C. First Filer Status and 180-Day Exclusivity 5

D. Watson's First-Filed Pioglitazone ANDA 7

E. Watson's FDA-Prompted Telephone Amendment 8

F. Watson's Takeda Settlement Acknowledges Watson's First Filer Status 9

G. Watson Has Always Maintained Paragraph IV Certifications To The Composition Patents 10

H. FDA's Eleventh-Hour About-Face 11

ARGUMENT 13

I. Legal Standards 13

II. The Court Can and Should Review FDA's Determination 14

III. FDA's Decision To Delay Approval Of Watson's ANDA Is Contrary to Law 16

A. FDA Must Ground Its Actions in The Text and Purpose of Governing Congressional Statutes 16

B. The Governing Statute Forecloses FDA's Ruling against Watson 17

C. FDA's Ruling Produces Absurd Results Contrary to Congressional Intent 22

D. FDA's Ruling Leads to Arbitrary and Capricious Results 23

IV. Any Exclusivity with Respect to The Combination Therapy Patents No Longer Exists 26

A. Watson's Conversion of Its Paragraph IV Certifications to Section viii Statements Extinguished Exclusivity as to The Combination Therapy Patents 26

B. FDA's Determination Cannot Be Upheld 29

V. The Court May Compel FDA to Approve Watson's ANDA 30

CONCLUSION 32

TABLE OF AUTHORITIES

Page(s)

CASES

*Alaska Prof'l Hunters Ass'n, Inc. v. Fed. Aviation Admin.,
177 F.3d 1030 (D.C. Cir. 1999) 29, 30

American Bioscience, Inc. v. Thompson,
269 F.3d 1077 (D.C. Cir. 2001) 14

Apotex Inc. v. FDA,
414 F. Supp. 2d 61 (D.D.C. 2006) 25

Bowen v. Massachusetts,
487 U.S. 879 (1988) 14

Bracco Diagnostics v. Shalala,
963 F. Supp. 20 (D.D.C. 1997) 6

Chevron U.S.A. Inc. v. Natural Resources Defense Council,
467 U.S. 837 (1984) 16

*Christensen v. Harris Cnty.,
529 U.S. 576 (2000) 29

County of Los Angeles v. Shalala,
192 F.3d 1005 (D.C. Cir. 1999) 30

*Indep. Petroleum Assoc. of Am. v. Babbitt,
92 F.3d 1248 (D.C. Cir. 1996) 30

*Mova Pharm. Corp. v. Shalala,
140 F.3d 1060 (D.C. Cir. 1998) 15, 18, 25, 26

Mova Pharm. Corp. v. Shalala,
955 F. Supp. 128 (D.D.C. 1997) 31

Mylan Pharms., Inc. v. Shalala,
81 F. Supp. 2d 30 (D.D.C. 2000) 22

Nat'l Ass'n of Home Builders v. United States Army Corps of Engineers,
440 F.3d 459 (D.C. Cir. 2006) 15

Paralyzed Veterans of America v. D.C. Arena,
117 F.3d 579 (D.C. Cir. 1997) 29

*Purepac Pharm. Co. v. Thompson,
238 F. Supp. 2d 191 (D.D.C. 2002) 16, 20, 23

*Ranbaxy Labs., Ltd. v. Leavitt,
459 F. Supp. 2d 1 (D.D.C. 2006) 3, 5, 17

Ranbaxy Labs. Ltd. v. Leavitt,
469 F.3d 120 (D.C. Cir. 2006) 16, 18, 22

Reckitt Benckiser Inc. v. Envtl. Prot. Agency,
613 F.3d 1131 (D.C. Cir. 2010) 15

Sabre, Inc. v. Dep't of Transp.,
429 F.3d 1113 (D.C. Cir. 2005) 15

SB Pharmco Puerto Rico, Inc. v. Mutual Pharm. Co.,
552 F. Supp. 2d 500 (E.D. Pa. 2008) 9, 19

Shays v. Fed. Election Comm'n,
414 F.3d 76 (D.C. Cir. 2005) 14

Stainback v. Mabus,
671 F. Supp. 2d 126 (D.D.C. 2009) 18, 21

Stuttering Found. of Am. v. Springer,
498 F. Supp. 2d 203 (D.D.C. 2007) 14

Teva Pharmaceuticals USA, Inc. v. U.S. Food & Drug Admin.,
No. 99-67, 1999 WL 1042743 (D.D.C. Aug. 19, 1999) 31

Teva Pharms., USA, Inc. v. FDA,
182 F.3d 1003 (D.C. Cir. 1999) 16

*Teva Pharms., USA, Inc. v. Sebelius,
595 F.3d 1303 (D.C. Cir. 2010) 15, 17, 21, 22

TorPharm, Inc. v. Shalala,
No. 97-1925, 1997 WL 33472411 (D.D.C. Sep. 15, 1997) 16

United States v. Hoyts Cinemas Corp.,
380 F.3d 558 (1st Cir. 2004) 29

*United States v. Mead Corp.,
533 U.S. 218 (2001) 29

STATUTES

5 U.S.C. § 701 13

5 U.S.C. §§ 701-706 1

5 U.S.C. § 704 14

*5 U.S.C. § 706 14

5 U.S.C. §706(1) 31

*5 U.S.C. § 706 (2)(A) 16, 26

5 U.S.C. § 706(2)(C). 16

21 U.S.C. § 355 3

21 U.S.C. § 355(a) 3

21 U.S.C. § 355(b) 4

21 U.S.C. § 355(j) 4

21 U.S.C. § 355(j)(2)(A) 4, 5, 7, 19

21 U.S.C. § 355(j)(4) 31

*21 U.S.C. § 355(j)(5)(B) 5, 6, 17, 18

35 U.S.C. § 156 3

35 U.S.C. § 271(e) 3

35 U.S.C. § 282 3

OTHER AUTHORITIES

21 C.F.R. § 314.53 4

21 C.F.R. § 314.94 7

21 C.F.R. § 314.94(a)(12)(i)(A) 4, 5

21 C.F.R. § 314.95(b) 9, 19

21 C.F.R. § 314.101 19

*21 C.F.R. § 314.107(c) ..... passim

59 Fed. Reg. 50338 ..... 5, 9, 19, 27

*64 Fed. Reg. 42873 28

67 Fed. Reg. 66593 28

68 Fed. Reg. 36676. 21

August 17, 2012 Letter from Gary Buehler to Mylan Pharmaceuticals Inc. re: ANDA No. 076801.....12

FDA, Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day (July 2003) 6

*Fed. Defendants' Memo. In Opp. To Pl.'s Mot. for Preliminary Injunction, Andrx Pharm., Inc. v. Thompson, No. 03-23171 (S.D. Fla. Dec. 11, 2003) 20, 27, 28

June 1, 2004 Letter from Gary Buehler to Kate C. Beardsley and Carmen M. Shepard re: Metformin Hydrochloride ER Tablets.....6, 27

Mar. 15,2010 Letter from Janet Woodcock to Stephen R. Auten re: Docket No. FDA-2009-P-0411.....5

Oct. 14, 2004 Letter. from Gary Buehler to James Veltrop re: Metformin Hydrochloride ER Tablets.....25

INTRODUCTION

Without this Court's immediate intervention pursuant to its judicial review authority under 5 U.S.C. §§ 701-706, FDA will continue to delay Watson Laboratories Inc.'s ("Watson's") entry into the market for the generic diabetes pharmaceutical product pioglitazone hydrochloride. This delay deprives Watson of its statutory right to enter as early as any other generic manufacturer, because FDA has already approved entry by Mylan Pharmaceuticals, Inc. ("Mylan") on August 17, 2012.

Watson filed its abbreviated new drug application ("ANDA") with FDA for its generic version of pioglitazone hydrochloride on the earliest possible day such applications were permitted – July 15, 2003. When it filed its ANDA, Watson filed Paragraph IV certifications with FDA, challenging patents owned by Takeda North America, Inc. (with its parent and affiliates, "Takeda"). FDA granted tentative approval to Watson's ANDA in 2005, indicating that Watson's product met the regulatory approval requirements.

Following six years of intensive litigation over the patents claiming pioglitazone and methods of its use, Takeda licensed them to Watson and two other generic drug companies, Ranbaxy Laboratories, Ltd. ("Ranbaxy") and Mylan. The license allows all three companies to launch their pioglitazone products on August 17, 2012, subject only to final FDA approval. Watson had been preparing to launch its product on that date, based on FDA assurances that it would be given final approval.

Now, in August 2012, FDA informed Watson that, despite previous assurances that approval of Watson's ANDA was on track for August 17, FDA would not grant Watson approval to launch its product on the date agreed to between Watson and Takeda. FDA subsequently granted approval to Mylan's ANDA on August 17, 2012, and again confirmed its decision in an August 23, 2012 letter to Watson. FDA made this determination not on the basis of the quality

of Watson's product or some sort of deficiency in Watson's ANDA, but because FDA has determined that Watson was blocked from launching its product by marketing exclusivity that FDA had awarded to Mylan and potentially another ANDA filer, such as Ranbaxy. FDA bases this determination on Paragraph IV certifications filed after the settlement with Takeda by at least Mylan (and possibly Ranbaxy) to certain of the patents that were litigated by and licensed to each of Watson, Ranbaxy and Mylan. FDA only informed Watson of this decision over nine years after Watson filed its ANDA, after numerous assurances that Watson's ANDA would be approved, after significant expenditures by Watson to prepare to launch its product and after supply arrangements for this critical diabetes treatment were in place.

FDA provides no acceptable explanation for its decision – and indeed cannot – because FDA's decision is contrary to statute, regulations and FDA's past practice. FDA's position is that Watson is blocked from receiving approval by an exclusivity period associated with these patents despite the fact that Watson filed Paragraph IV certifications to these patents on the earliest possible day and despite the fact that Watson has maintained Paragraph IV certifications at least to certain composition claims of certain patents from the first day pioglitazone ANDAs were filed. FDA has determined that at least Mylan is entitled to an exclusivity period that delays the approval of Watson's ANDA because, after Watson filed its ANDA, Watson amended its Paragraph IV certifications for the method of use claims in the patents and then reinstated its Paragraph IV certifications after Mylan and/or Ranbaxy filed their Paragraph IV certifications to the method of use claims. But FDA's decision: (i) contravenes the plain language of the statute and regulations, which only bars approval of *later* filed applications; and (ii) is contrary to FDA's regulations and past practice, which deny exclusivity to any ANDA applicant for patents

that are the subject of withdrawn or amended Paragraph IV certifications. Accordingly, Watson is entitled to the declaratory and injunctive relief requested in its complaint.

STATEMENT OF FACTS

A. Generic Drug Entry: The Statutory Framework

The Federal Food Drug & Cosmetic Act ("FDCA") establishes the requirements for marketing drugs in the United States. In 1984, Congress amended the FDCA to provide a streamlined process that manufacturers could use to obtain approval for a generic drug – a drug which contains the same active ingredient as, and is bioequivalent to, a brand name drug. Generic drugs are generally sold without a trademark and at lower prices than branded drugs. The FDCA amendments, which are codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e) and 282, are commonly referred to as the "Hatch-Waxman Amendments" or the "Hatch-Waxman Act." The FDCA was also amended more recently by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). The pending motion, however, is governed by the pre-MMA version of the FDCA ("pre-MMA FDCA") because the relevant filings by Watson pre-dated the December 8, 2003 effective date of the MMA. See MMA §1102(b), 21 U.S.C. § 355 (Amendments); Ranbaxy Labs., Ltd. v. Leavitt, 459 F. Supp. 2d 1, 2 n.2 (D.D.C. 2006) (because applications at issue were filed before MMA went into effect, pre-MMA FDCA governed issues).[1]

B. New Drugs and Generic Drug Application Requirements

Before marketing a new drug in the United States, the FDCA requires a drug company to submit a New Drug Application ("NDA") to FDA, and FDA must approve it. 21 U.S.C. § 355(a), (b). New drugs generally are referred to as "brand name" drugs because they are

[1] Because the pending motion is governed by the pre-MMA FDCA, all references herein to sections of the FDCA are to the pre-MMA versions effective in 2003.

marketed under a trademark for the drug product rather than the chemical name for the active ingredient in the drug product.

The NDA applicant must identify in its filing each patent that claims the drug or a method of using the drug that is the subject of the NDA, and that could reasonably be asserted in a patent infringement action against a person engaged in the unauthorized manufacture, use, sale or importation of the drug product. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53. Once FDA approves an NDA, FDA publishes the patent information submitted by the brand name drug company in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). 21 U.S.C. § 355(b)(1).

Drug companies cannot market generic drugs in the United States until they submit an ANDA to FDA that FDA approves. 21 U.S.C. § 355(a),(j). The ANDA approval process allows an applicant to rely on the data in an NDA for a brand name drug to show safety and effectiveness, so long as the ANDA drug product is bioequivalent to the branded drug in question (referred to as the "reference listed drug" or "RLD").

A generic drug company seeking FDA approval for a generic version of a brand name drug product must file, in addition to technical data, one of four certifications with FDA: either (I) that no patent information for the RLD has been filed with FDA; or, for each patent listed in the Orange Book as claiming the RLD or a method of use for which the ANDA applicant is seeking approval, (II) that the patent has expired; (III) that the patent will expire on a particular date (until which time the generic company is not seeking to market its generic product); or (IV) that the patent claiming the RLD is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12)(i)(A). This final certification is commonly

referred to as a "Paragraph IV certification." 21 C.F.R. § 314.94(a)(12)(i)(A)(4). Alternatively, if a patent listed in the Orange Book claims a method of use for which the generic drug company is not seeking approval, the ANDA filer can submit a "Section viii statement." 21 U.S.C. § 355(j)(2)(A)(viii). FDA permits ANDAs to submit either a Paragraph IV certification or a Section viii statement, as appropriate, but not both.[2] FDA, Final Rule, Abbreviated new Drug Application Regulations; Patent and Exclusivity Provisions (59 Fed. Reg. 50338, 50347 (October 3, 1994)).

C. First Filer Status and 180-Day Exclusivity

In order to encourage generic companies to challenge patents and thereby bring to consumers the benefits of lower-priced generic drugs as quickly as possible, Congress provided that the first ANDA applicant to file an ANDA with a Paragraph IV certification (the "First Filer") is given a 180-day period in which it is the only ANDA applicant allowed to market a generic version of the brand name drug. 21 U.S.C. § 355(j)(5)(B)(iv). Specifically, Section 355(j)(5)(B)(iv) provides that, if an ANDA with a Paragraph IV certification "is for a drug for which a previous application has been submitted under this subsection [containing][3] such a certification, the application shall be made effective not earlier than one hundred and eighty days after" the earlier of one of two triggering events. Id. (the "exclusivity provision"). FDA's implementing rules similarly provide that First Filer status is conferred on the ANDA applicant that submits a substantially complete ANDA containing a Paragraph IV certification

[2] FDA does allow for "split certifications" in which an applicant files Paragraph IV certifications with respect to certain claims of a patent, but Section viii statements with respect to method of use claims. (See, e.g., Letter from Janet Woodcock to Stephen R. Auten re: Docket No. FDA-2009-P-0411 (Mar. 15, 2010) at 7 (split certifications proper for pioglitazone patents), available at http://www.regulations.gov/#!documentDetail;D=FDA-2009-P-0411-0010 .) A split certification still entitles the ANDA holder to exclusivity for a patent for which a Paragraph IV certification is filed.

[3] The statute uses the word "continuing," but "the D.C. Circuit has interpreted this word to be a typographical error meant to be 'containing'." Ranbaxy Labs., Ltd. v. Leavitt, 459 F. Supp. 2d 1, 3 n.3 (D.D.C. 2006).

before any other substantially complete ANDA containing the same certification is submitted.[4] 21 C.F.R. § 314.107(c)(2) (defining "first applicant"). If two substantially complete ANDAs containing the same Paragraph IV certification are submitted the same day, the ANDA filers share First Filer status.[5]

The 180-day exclusivity period begins to run on the earlier of: (1) the date of the first commercial marketing by the First Filer; or (2) the date of a decision by a court finding that the patent that is the subject of the Paragraph IV certification is invalid or not infringed ("triggering events"). 21 U.S.C. § 355(j)(5)(B)(iv). This exclusive marketing period has substantial commercial value. See, e.g., Bracco Diagnostics v. Shalala, 963 F. Supp. 20, 29 (D.D.C. 1997) ("[T]here is a significant economic advantage to receiving first approval and being the first company to enter the market, an advantage that can never be fully recouped through money damages or by 'playing catch-up.'").

In keeping with the statutory purpose of encouraging generic competition at the earliest possible date, FDA has long taken the position that changes by the First Filer to its patent certification that might render it ineligible for statutory exclusivity do not cause the benefits of statutory exclusivity to transfer to a subsequent ANDA applicant under a "rolling exclusivity" theory. (See, e.g., Letter from Gary Buehler (FDA) to Kate C. Beardsley and Carmen M. Shepard re: Metformin Hydrochloride ER Tablets (June 1, 2004) at p.6, available at http://www.regulations.gov/#!documentDetail;D=FDA-2010-P-0430-0010 (last visited Aug. 14, 2012).) Instead, exclusivity is enjoyed by the First Filer or not at all. In cases where several

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[4] FDA has provided that for the purposes of the "substantially complete" requirement, a "'substantially complete' application must contain the results of any required bioequivalence studies, or, if applicable, a request for a waiver of such studies." 21 C.F.R. § 314.107(c)(2).

[5] FDA, Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day (July 2003), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072851.pdf (last visited Aug. 14, 2012).

ANDAs are submitted but no party enjoys First Filer exclusivity, each ANDA may be approved when FDA has completed its review of the ANDA because no First Filer serves to block final approval of the ANDA. Similarly, in situations where parties share First Filer status, their generic products may each be sold during the exclusivity period.

D. Watson's First-Filed Pioglitazone ANDA

Takeda is the holder of NDA 21-073, pursuant to which it markets pioglitazone hydrochloride ("pioglitazone") in various dosage strengths under the brand name Actos®. (Declaration of Beth Brannan ("Brannan Decl.") ¶ 7.) Pioglitazone is widely prescribed for the treatment of type 2 diabetes and is among the highest-selling drugs in the United States. (Id. ¶ 8.)

On July 15, 2003, the first day on which ANDAs for generic pioglitazone could lawfully be filed, Watson submitted its ANDA No. 76-798 ("Watson's ANDA") to FDA, seeking approval for 15 mg, 30 mg and 45 mg dosage strengths of pioglitazone hydrochloride. (Id. ¶ 9.) Watson's ANDA contained Paragraph IV certifications to U.S. Patent Nos. 5,965,584 and 6,329,404 (collectively, "the Composition Patents") and to U.S. Patent Nos. 6,150,383, 6,150,384, 6,166,042, 6,166,043, 6,172,090, 6,211,205, 6,271,243 and 6,303,640 (collectively, the "Combination Therapy Patents"). (Id. ¶ 11.) The labeling submitted with the original ANDA was limited to an indication for the use of pioglitazone as a monotherapy (i.e., pioglitazone administered by itself) rather than as a combination therapy (i.e., pioglitazone administered in conjunction with other medications). (Id.)

Watson's ANDA contained all of the information required under 21 U.S.C. § 355(j)(2)(A) and 21 C.F.R. § 314.94, including, in particular, the results of bioequivalence studies that are the sole listed requirement for an ANDA to be considered "substantially complete" under FDA rules. See 21 C.F.R. § 314.107(c)(2); (Brannan Decl. ¶ 10). Because

Watson's filing (a) was substantially complete, (b) contained Paragraph IV certifications, and (c) was not preceded by other substantially complete ANDA filings that contained the same certifications, Watson earned First Filer status and thus anticipated that it would enjoy 180-day exclusivity (whether alone or shared with other ANDAs filed the same day) upon receiving approval from FDA.

E. Watson's FDA-Prompted Telephone Amendment

On August 18, 2003, FDA communicated various comments to Watson concerning Watson's ANDA, including that Watson should revise its proposed labeling to include language regarding the use of pioglitazone as a combination therapy.[6] (Brannan Decl. ¶ 12.) In essence, FDA took the position that because Watson filed Paragraph IV certifications to the Combination Therapy Patents and the method-of-use claims in the Composition Patents, its proposed labeling should also include combination therapy language.

In response, on August 27, 2003, Watson submitted a "telephone amendment" to its ANDA. (Id. ¶ 13.) Watson indicated that it disagreed with FDA's position that Watson could not maintain Paragraph IV certifications to the Combination Therapy Patents. (Id.) While reserving its rights as to that position,[7] Watson addressed FDA's concerns by amending its ANDA to change its certifications to the Combination Therapy Patents and to the method of use claims in the Composition Patents to Section viii statements, while maintaining its Paragraph IV certifications as to the composition claims of the Composition Patents. (Id.)

Shortly thereafter, on September 9, 2003, FDA provided notice to Watson that Watson's ANDA had been received and was "acceptable for filing" with an effective date of receipt of

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[6] Notably, FDA did not refuse to receive Watson's ANDA.

[7] Watson explicitly made its 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.)

July 15, 2003. (Id. ¶ 14.) Such "acceptable for filing" letters provide ANDA filers with notice that FDA considers their filings to be substantially complete.[8] FDA's letter thus acknowledged that Watson's ANDA had been substantially complete on July 15, 2003. Because Watson's ANDA also satisfied the other elements required for First Filer status (i.e., it contained Paragraph IV certifications and was not preceded by other ANDAs because it was filed on the earliest day on which pioglitazone ANDAs could be accepted), Watson considered FDA's letter to effectively confirm its First Filer status.

F. Watson's Takeda Settlement Acknowledges Watson's First Filer Status

On September 9, 2003, the same day it received FDA's "acceptable for filing" letter, Watson provided a "notice letter" to Takeda as required under the FDCA. (Brannan Decl. ¶ 15); 21 C.F.R. § 314.95(b). Takeda responded by commencing patent litigation against Watson in the United States District Court for the Southern District of New York, asserting infringement of both the Composition Patents and the Combination Therapy Patents. (Brannan Decl. ¶ 15.) Takeda also sued each of the other pioglitazone ANDA applicants for patent infringement. (Id. ¶ 15.)

After extensive litigation in which Watson continued to assert, among other defenses, the non-infringement defense that was the basis for Watson's original Paragraph IV certifications, in March 2010 Takeda settled its litigation with Watson and the other ANDA filers. (Id. ¶ 16.) The settlement agreement between Watson and Takeda provided in relevant part that Takeda would grant Watson a non-exclusive license to the Composition Patents and the Combination Therapy Patents as of August 17, 2012. (Id.) Takeda announced that it had also reached settlements with the other pioglitazone ANDA applicants, explaining:

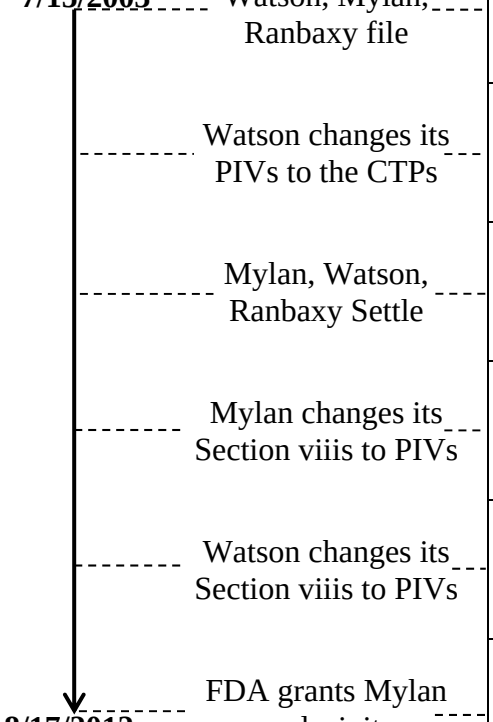
[8] FDA has specifically explained that 21 C.F.R. § 314.95(b) "requires the ANDA applicant to provide notice once FDA has determined that the ANDA is substantially complete." 59 Fed. Reg. 50338, 50350. See also SB Pharmco Puerto Rico, Inc. v. Mutual Pharm. Co., 552 F. Supp. 2d 500, 508 (E.D. Pa. 2008).

> Takeda has granted Mylan, Watson, and Ranbaxy licenses to enter the United States (U.S.) market with generic pioglitazone on August 17, 2012. The license date could be earlier than August 17, 2012 under certain circumstances. 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.

(Id. ¶ 17 (Press Release, Takeda Provides Update on Patent Litigation for ACTOS® (pioglitazone HCl) and ACTOplus met® (pioglitazone HCl and metformin HCl) in the U.S. (Apr. 28, 2010)).) Following the settlement, Watson amended its ANDA to reinstate its Paragraph IV certifications to the Combination Therapy Patents and the method of use claims of the Composition Patents and to include a full product label.

G. Watson Has Always Maintained Paragraph IV Certifications To The Composition Patents

Mylan incorrectly asserts that Watson did not maintain Paragraph IV certifications to "claims of the '404 and '584 patents at all times since the filing of its ANDA." ([DK No. 21], Memorandum by Mylan Pharms Inc. in Opp. to Pl. Watson Labs., Inc.'s Mot, for a Temporary Restraining Order and a Preliminary Injunction at 6.) In fact, Watson filed, and has consistently maintained, Paragraph IV certifications to the composition claims of these patents, the Composition Patents, from July 15, 2003 to date. Indeed, FDA agrees that Watson is entitled to exclusivity with respect to the composition claims of the Composition Patents. (See Letter from Gregory P. Geba to Chad A. Landmon re: ANDA 076798 (August 23, 2012) at p. 14. (Brannon Decl. Ex. D) ("FDA Decision Letter").) Watson and Mylan are in identical positions with regards to certifications to the composition claims of the Composition Patents – it is only the timeline for their certifications as to the Combination Therapy Patents and the method of use claims of the Composition Patents that differs, as shown in the below figure:



TIMELINE OF EVENTS	Combination Therapy Patents/Method of Use Claims of Composition Patents		Composition Claims of Composition Patents	
	Watson	Mylan	Watson	Mylan
Watson, Mylan, Ranbaxy file	IV	viii	IV	IV
Watson changes its PIVs to the CTPs	viii	viii	IV	IV
Mylan, Watson, Ranbaxy Settle	viii	viii	IV	IV
Mylan changes its Section viiis to PIVs	viii	IV	IV	IV
Watson changes its Section viiis to PIVs	IV	IV	IV	IV
FDA grants Mylan exclusivity	IV	IV	IV	IV

Under FDA's regulations, Watson is therefore entitled to exclusivity with respect to the Composition Patents.

H. FDA's Eleventh-Hour About-Face

Watson received tentative approval for its ANDA on December 13, 2005. This means that Watson's ANDA has been ready for approval, but was not approved because of the pending lawsuit and assertion of infringement by Takeda. Watson was actively preparing to launch its pioglitazone product on August 17, 2012, in keeping with the Takeda settlement, and with

Watson's communications with FDA that Watson's ANDA was moving toward approval. (Brannan Decl. ¶¶ 14, 16, 20.) As recently as July 6, 2012, FDA indicated that Watson's ANDA "should be on track for full approval come August." (Id. ¶ 20.)

But in August 2012, FDA informed Watson that its ANDA approval will be delayed because another ANDA (or ANDAs) has been granted exclusivity for pioglitazone. On August 17, 2012, FDA approved Mylan's ANDA for pioglitazone, confirming its decision in its approval letter to Mylan, which stated that Mylan was eligible for exclusivity for the Combination Therapy Patents. (See Letter from Gary Buehler (FDA) to Mylan Pharmaceuticals Inc. re: ANDA No. 076801 (August 17, 2012) at p. 2 available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/076801Orig1s000ltr.pdf (last visited Aug. 21, 2012) ("Mylan Approval Letter"). And on August 23, 2012, FDA provided Watson's counsel with a letter further confirming FDA's decision, explaining that Mylan and another ANDA filer are eligible for exclusivity because of Paragraph IV certifications to the Combination Therapy Patents filed on March 22, 2010, after Watson filed its original Paragraph IV certifications to the Combination Therapy Patents, but before Watson reinstated those certifications after the Takeda settlement. (See FDA Decision Letter at 14.) FDA acknowledged that Watson was a first-filer on the composition claims of the Composition Patents, but found that Mylan and the other ANDA filer's certifications to the Combination Therapy Patents blocked Watson from approval. (Id.) Further, on August 23, 2012, in a letter to Watson granting tentative approval, FDA confirmed that Watson's ANDA is in position for final approval, but for FDA's determination that Watson is blocked by Mylan and another ANDA holder's exclusivity. (Brannan Decl. at ¶ 23; Letter from Robert L. West to Watson Laboratories, Inc. re: ANDA 076798 (August 23, 2012) (Brannon Decl. Ex. C).)

As a First Filer, Watson is entitled to shared exclusivity as a matter of law. Moreover FDA's decision that Mylan and another ANDA filer are entitled to exclusivity because they submitted Paragraph IV certifications to the Combination Therapy Patents prior to Watson's amendment to convert back to Paragraph IV certifications following the Takeda settlement is contrary to law. As explained below, this theory, which would strip exclusivity from a party that took all necessary steps to achieve First Filer status on the first possible day and has maintained that status for nearly a decade, cannot be reconciled with the FDCA or FDA's own rules, much less principles of fairness and common sense.

ARGUMENT

The Administrative Procedure Act ("APA") provides this Court the authority to review and overturn as unlawful FDA's determination to deny Watson shared exclusivity for pioglitazone. Under the standard of review provided in the APA, the Court should reverse FDA's decision and order FDA to immediately approve Watson's ANDA.

I. LEGAL STANDARDS

The APA provides that:

> [a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States.

5 U.S.C. § 701.

Under the APA, a court is directed to:

> decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall
>
> (1) compel agency action unlawfully withheld or unreasonably delayed; and

> (2) hold unlawful and set aside agency action, findings, and conclusions found to be -
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> * * *
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

5 U.S.C. § 706.

Under the APA, the entire case on review is a question of law. American Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1083-1084 (D.C. Cir. 2001). "Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." Stuttering Found. of Am. v. Springer, 498 F. Supp. 2d 203, 207 (D.D.C. 2007).

II. THE COURT CAN AND SHOULD REVIEW FDA'S DETERMINATION

The APA provides for review of "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. Because Congress has not "provided special and adequate review procedures" for FDA determinations under the FDCA, review under the APA is proper. Bowen v. Massachusetts, 487 U.S. 879, 922 (1988).

FDA's decision here is a final agency action that is the direct and only cause of FDA's refusal to approve Watson's ANDA. On August 23, 2012, FDA confirmed in writing that Watson's ANDA is in position for full approval (tentatively approved) and that FDA was delaying final approval on the basis of exclusivity that FDA had granted to Mylan and another ANDA filer. FDA cannot dispute that its action is final.

FDA cannot argue that Watson does not have standing to challenge FDA's determination that Watson is blocked from obtaining approval of its ANDA. Standing requires an actual or imminent injury that is fairly traceable to the defendant's challenged conduct and is redressable in judicial proceedings. See, e.g., Shays v. Fed. Election Comm'n, 414 F.3d 76, 83 (D.C. Cir.

2005). All three factors are met here. This determination directly implicates the interests the FDCA was designed to protect. See Section III.C below.

The Court of Appeals for the DC Circuit has repeatedly found that parties like Watson that are aggrieved by FDA denials of statutory exclusivity have standing to seek judicial review because such FDA determinations directly cause harm to the party whose ANDA approval is wrongfully delayed. Teva Pharms. USA, Inc. v. Sebelius, 595 F.3d 1303, 1312 (D.C. Cir. 2010) ("Any imminent deprivation of Teva's allegedly deserved exclusivity would be directly attributable to FDA's statutory interpretation."). And this harm can easily be redressed by this Court's rejection of FDA's determination. Id. .

Similarly, this issue is ripe for review. An agency determination is ripe if it is fit for judicial review and substantial hardship will result if such review is postponed. Nat'l Ass'n of Home Builders v. United States Army Corps of Engineers, 440 F.3d 459, 463-64 (D.C. Cir. 2006). Both elements are satisfied here. First, the facts that form the basis for the exclusivity determination are already established, and no further factual development is needed for this Court to assess the merits of Watson's arguments in its challenge to FDA's determination that its ANDA cannot be approved until 180 days after Mylan's ANDA. See, e.g., Reckitt Benckiser Inc. v. Envtl. Prot. Agency, 613 F.3d 1131, 1137-38 (D.C. Cir. 2010) (issue was ripe where EPA informed the plaintiff that its products "would be considered misbranded" after a specific date, determination was based on legal issues, and no further facts would be needed to review decision); Sabre, Inc. v. Dep't of Transp., 429 F.3d 1113, 1120 (D.C. Cir. 2005) (established facts of the case were sufficient for review and no further factual development was needed). Second, Watson will suffer substantial hardship for every day that FDA denies approval of Watson's ANDA. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1067 (D.C. Cir. 1998) (the

improper loss of exclusivity "suffices to show a severe economic impact"); TorPharm, Inc. v. Shalala, No. 97-1925, 1997 WL 33472411, at *4 (D.D.C. Sep. 15, 1997) (plaintiff would "be permanently disadvantaged in the market" because "timely entry into the market is critical for success").

III. FDA'S DECISION TO DELAY APPROVAL OF WATSON'S ANDA IS CONTRARY TO LAW

As the plain language of the FDCA makes clear, approval of an ANDA may be delayed only where another ANDA was filed previously with a Paragraph IV certification to the same set of patents. Here, when Watson filed its ANDA in July 2003, no other ANDA had been previously filed with Paragraph IV certifications to the same set of patents. FDA's decision to delay approval of Watson's ANDA runs afoul of the text and purpose of the governing law as well as FDA's own regulations. FDA's decision should therefore be set aside and enjoined under the APA as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and in excess of statutory authority or limitations. 5 U.S.C. § 706(2)(A) & (C).

A. FDA Must Ground Its Actions in The Text and Purpose of Governing Congressional Statutes

It is axiomatic that FDA must give effect to the intent of Congress as expressed in the plain meaning of the FDCA. See Chevron U.S.A. Inc. v. Natural Resources Defense Council, 467 U.S. 837, 842 (1984); Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120, 124 (D.C. Cir. 2006) (courts and FDA "must give effect to the unambiguously expressed intent of Congress"). Any analysis of FDA's decision-making under the APA, therefore, "must begin with the text" of the statute itself. See Purepac Pharm. Co. v. Thompson, 238 F. Supp. 2d 191, 204 (D.D.C. 2002). While FDA is granted some deference under the APA to the extent that the text of the FDCA does not reflect clear Congressional intent on an issue, it must always interpret the Act "to avoid absurd results and further congressional intent." Teva Pharms., USA, Inc. v. FDA, 182 F.3d

1003, 1011 (D.C. Cir. 1999). Even where Congress has not clearly expressed its intent through the statute, FDA must "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." Ranbaxy Labs., Ltd. v. Leavitt, 459 F. Supp. 2d at 8 (D.D.C. 2006).

B. The Governing Statute Forecloses FDA's Ruling against Watson

1. No Applicant Holds A Previously Submitted ANDA to Watson's ANDA

Under the pre-MMA FDCA, Congress expressed a clear intent that has been thwarted by FDA's decision to delay approval of Watson's ANDA. The plain language of the FDCA provides that an ANDA applicant, such as Watson, may be blocked from generic entry by another ANDA applicant only "[i]f the application contains a [Paragraph IV certification] and is for a drug for which a previous application has been submitted under this subsection [containing] such a certification . . . ." 21 U.S.C. § 355(j)(5)(B)(iv) (emphasis added). Thus, Congress authorized FDA to delay approval of an ANDA only when another ANDA was previously submitted with a Paragraph IV certification to the same set of patents. This reflects Congressional purpose that the exclusivity period is a reward and incentive for the First Filer who takes on the risk of patent litigation – here, Watson. See Teva Pharms., USA, Inc. v. Sebelius, 595 F.3d 1303, 1305 (D.C. Cir. 2010).

FDA's own regulations are in accord. Section 314.107(c)(1) provides that ANDA approval may be delayed when an ANDA covers a drug "for which one or more substantially complete [ANDAs] were previously submitted containing a [Paragraph IV certification]." 21 C.F.R. § 314.107(c)(1) (emphasis added). That same regulation grants exclusivity to the "applicant submitting the first application," which is defined as the "applicant that submits an application that is both substantially complete and contains a [Paragraph IV] certification . . .

prior to the submission of any other application for the same listed drug that is both substantially complete and contains the same certification." Id. § 314.107(c)(1)(i), (c)(2) (emphasis added). As with the FDCA, then, FDA's regulations make ANDA approval dependent on whether previous ANDAs have been filed. Thus, even if Congressional intent were less than clear (which it is not), FDA cannot lawfully depart from the text of its own regulations. See Stainback v. Mabus, 671 F. Supp. 2d 126, 138 (D.D.C. 2009) ("[A]gencies must follow their own regulations."). See also infra Section I.B.2.

Watson satisfies all the statutory and regulatory criteria for earning ANDA approval without delay. When Watson submitted its ANDA on July 15, 2003 – with Paragraph IV certifications to the Composition Patents and the Combination Therapy Patents – no other applicant had previously submitted such an ANDA; indeed, Watson's application was filed the first day pioglitazone ANDAs were permitted to be filed. Watson, then, did not submit an ANDA "for a drug for which a previous application has been submitted" with a Paragraph IV certification, and there is thus no statutory restriction on FDA approving Watson's ANDA now. See 21 U.S.C. § 355(j)(5)(B)(iv). FDA's decision to block Watson reads a non-existent restriction into the clear text of the statute, which is not a proper exercise of discretion. See Ranbaxy, 469 F.3d at 124 (FDA must give effect to congressional intent as expressed in statute). As the Court of Appeals for the District of Columbia has held, FDA cannot graft onto Congress's chosen exclusivity regime a requirement that is "inconsistent with the unambiguously expressed intent of Congress." See Mova, 140 F.3d at 1069 (rejecting FDA's "successful defense" requirement because it was "gravely inconsistent with the text and structure of the statute").

2. Watson Is A First Filer

Watson also qualifies as the "applicant submitting the first application" under FDA regulations, thereby earning its entitlement to swift ANDA approval. A first applicant is one that

submits a substantially complete application containing a Paragraph IV certification. FDA's regulations specify only that a "substantially complete" application "must contain the results of any required bioequivalence studies, or, if applicable, a request for a waiver of such studies." 21 C.F.R. § 314.107(c)(2). Watson's ANDA contained such bioequivalence studies and additionally contained all the information required under the statutory and regulatory requirements for the contents of an ANDA, found in 21 U.S.C. § 355(j)(2)(A) and 21 C.F.R. § 314.94. See, e.g., 21 C.F.R. § 314.101(d)(3) (FDA may refuse to receive an abbreviated new drug application if it is "incomplete because it does not on its face contain information required" under these provisions).

Most importantly, however, FDA itself confirmed that Watson's ANDA was "substantially complete" by indicating that it was acceptable for filing as of July 15, 2003 – the day it was filed. Under FDA practice, this is therefore the date by which Watson's ANDA was "substantially complete." FDA's regulations provide that FDA will acknowledge that an ANDA is acceptable for filing when it is "sufficiently complete" such that an ANDA applicant may send notice to the patent holder that it has filed a Paragraph IV certification. 21 C.F.R. 314.95(b); see also id. at 314.101(a)(1) ("The filing of an application means that FDA has made a threshold determination that the application is sufficiently complete"). In promulgation of its own regulations, FDA explained that this provision acts precisely so that an applicant is not required to provide notice of its Paragraph IV certification to a patent holder until it is confirmed by FDA to be substantially complete. 59 Fed. Reg. 50338, 50350; see also SB Pharmco Puerto Rico, Inc. v. Mutual Pharm. Co., 552 F. Supp. 2d 500, 508 (E.D. Pa. 2008).

Watson's ANDA was "substantially complete" when filed on July 15, 2003. No other applicant submitted a "substantially complete" ANDA before Watson did. Nevertheless, FDA

apparently holds now that Watson was not an "applicant submitting the first application," and as a result, Watson must wait 180 days to bring its product to market. In its August 23, 2012 letter to Chad Landmon, FDA suggested that its practice is to consider ANDAs as received on the date on which they were first submitted, even when the ANDA was only brought into receivable status by an amendment correcting deficiencies. (FDA Decision Letter at 3.) To the extent that FDA's stated position can be said to be a practice at all, however, it is not a consistently observed practice – FDA has previously refused to grant an ANDA applicant an "acceptable for filing" date earlier than the date on which its amendment rendered the ANDA substantially complete. (See, e.g. Fed. Defendants' Memo. n Opp. to Pl.'s Mot. for Preliminary Injunction ("FDA Andrx Litigation Opp. Memo") at 10.) There, FDA had determined that Andrx's ANDA as first submitted on June 18, 1999 was not substantially complete because it lacked required information about the safety of the product's inactive ingredients, and required Andrx to submit an amendment to correct the deficiency. (Id. at 6-8.) After Andrx did so, "FDA notified Andrx that its ANDA was accepted for filing as of August 12, 1999 – the date its ANDA amendment was submitted." (Id. at 8-10.) This later filing date prevented Andrx from being eligible for exclusivity, as another applicant had filed a substantially complete ANDA after June 18 but before August 12. (Id. at 11, 18-19.) Thus, where FDA determined that an ANDA is not substantially complete when the ANDA is first submitted, its accepted for filing date reflects that determination.

"[C]onsistent with the requirement of reasoned decisionmaking," FDA may not "impose a requirement on [an ANDA applicant] wholly incompatible with the agency's own understanding of the facts" – but that is precisely what FDA has done here. See Purepac, 238 F.

Supp. 2d at 210. Nor is FDA entitled to any deference for a decision incompatible with the text of its own regulations. See Stainback, 671 F. Supp. 2d at 138. See also infra Section I.B.2.

3. That Watson Amended Some of Its Certifications Is Irrelevant

To the extent FDA argues that Watson forfeited its right to ANDA approval by amending some (but not all) of its Paragraph IV certifications to Section viii statements in 2003 – which Watson did only at FDA's insistence – that argument, too, is incompatible with the statutory text. Congress has made clear that approval of an ANDA and the corresponding grant of marketing exclusivity depend on the answers to two questions: (1) did the applicant submit an ANDA that "contains" a Paragraph IV certification; and (2) at the time, were there no other "previous application[s]" submitted with a Paragraph IV certification? If the answer to both questions is "yes," as it is here, then FDA is not authorized to withhold ANDA approval.

When Watson submitted its ANDA to FDA on July 15, 2003, the ANDA contained Paragraph IV certifications, and no other ANDA with such Paragraph IV certifications had been previously submitted.[9] Indeed, in the subsequent litigation with Takeda, Watson continued to assert a non-infringement defense, which was the basis for Watson's original Paragraph IV certifications. Despite Watson's conversion of some of its Paragraph IV certifications to Section viii statements, then, Watson's ANDA consistently contained Paragraph IV certifications – from the first possible date – and the amendments provide no reason to delay ANDA approval. FDA cannot unilaterally change the ANDA approval structure established by Congress when it proffers "not a single cogent reason" why Congress would have intended a different structure. Teva, 595 F.3d at 1317.

[9] FDA asserts that Watson's Paragraph IV certifications were invalid and therefore somehow did not count as Paragraph IV certifications. But Paragraph IV certifications are often amended or withdrawn prior to any assessment of their substantive merits, and FDA has stated that the provisions allowing amendment to certifications "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. 36676, 36689.

C. FDA's Ruling Produces Absurd Results Contrary to Congressional Intent

Even if the governing statutory and regulatory texts did not foreclose FDA's action here – which they do – sanctioning FDA's determination would lead to absurd results that are inconsistent with Congress's goal of encouraging generic companies to challenge brand manufacturers' patents promptly. As the court explained in Ranbaxy, by enacting the Hatch-Waxman Act, Congress intended to create an "incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book in the hope of bringing to market a generic competitor for an approved drug without waiting for the patent to expire." Ranbaxy, 469 F.3d at 126. Congress granted 180 days of marketing exclusivity to the "first company to file an ANDA containing a Paragraph IV certification" in order to encourage challenges to the Orange Book-listed patents as early as possible. See Teva, 595 F.3d at 1305; Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 33 (D.D.C. 2000). Even FDA recognizes that the "purpose of the 180-day exclusivity provision [is] to reward the first ANDA applicant to challenge a listed patent." (FDA Decision Letter at 7.)

This is precisely what Watson did: on the first possible day, Watson filed an ANDA challenging the patents with Paragraph IV certifications. After FDA deemed Watson's ANDA "received," Watson notified the patent holder and engaged in years of extensive litigation on the patents to be able to bring its product to market. After settling the litigation, Watson prepared to distribute the product, and is ready to do so starting this week. Despite this, and despite that FDA *admits* that Watson is eligible for exclusivity with respect to the composition claims of the Composition Patents (FDA Decision Letter at 14), FDA denies Watson the right to enter the market. Allowing another ANDA applicant to block Watson now turns Congressional intent on its head by discouraging prompt challenges to brand manufacturers' patents, and by discouraging

the use of company resources (financial, research and development, etc.) to bring generic products to market.

D. FDA's Ruling Leads to Arbitrary and Capricious Results

FDA's decision to delay approval of Watson's ANDA is also impermissible because it arbitrarily and capriciously penalizes Watson. Watson is indisputably a first filer eligible for exclusivity for the Composition Patents, as it filed Paragraph IV certifications to the composition claims for those patents on the first day possible and has consistently maintained them from that point on. But instead of granting Watson an opportunity to share in the exclusivity that FDA has offered to other ANDA applicants – which would comport with Congressional intent by rewarding Watson's prompt challenge to the patents – FDA has chosen to single Watson out and force it to wait 180 days. There is no principled basis for treating Watson differently from the other applicants who filed their ANDAs on the same day as Watson.

If an agency's decision lacks a rational basis, "runs counter to the evidence before the agency," or "rests upon a factual premise that is unsupported by substantial evidence," the decision is "arbitrary and capricious" and "cannot stand." Purepac, 238 F. Supp. 2d at 204, 210, 211. FDA has decided to delay approval of Watson's ANDA because Watson reinstated its Paragraph IV certifications to the Combination Therapy Patents after settling the Takeda litigation and after other ANDA applicants had already done so. Nothing in the text of the Hatch-Waxman Act, of course, establishes this fact as a basis to deny approval of Watson's ANDA; on the contrary, the statute plainly provides that, because no other applicant had previously submitted Paragraph IV certifications when Watson did on July 15, 2003, Watson's ANDA is not blocked from approval due to any other applicant's ANDA. Moreover, denying Watson's right to exclusivity to the Composition Patents based on Watson's conduct after the Takeda litigation confuses Congress's objective in the FDCA, which was not to penalize ANDA

applicants for what they did (or did not do) at the conclusion of infringement litigation, but rather to reward applicants for what they did before such litigation began. Retracting a statutorily-created promise of exclusivity years after infringement litigation concludes does not incentivize generic companies to risk that infringement litigation in the first place, which was Congress's goal.

This problem is at the heart of why of FDA's reasons for denying Watson exclusivity cannot withstand scrutiny. In its Decision Letter, FDA repeatedly relies on the fact that Watson filed Section viii statements to the Combination Therapy Patents and thus "gained the benefit" of those statements as reason to deny Watson exclusivity. (FDA Decision Letter at 11, 12.) But Mylan and the other ANDA filer also "gained the benefit" of Section viii statements – they litigated the same patents, and the same accusations of infringement, that Watson did. FDA somehow has determined that Mylan and the other ANDA filer somehow took on different risks from Watson, that deserve reward, by filing Paragraph IV certifications after settling for the same license and launch date as Watson. These post-settlement certifications clearly did not result in the risks of a 30-month stay and patent infringement suit that FDA describes as the "cost" of filing Paragraph IV certifications. (Id. at 11.)

FDA has no reason to deny Watson the "shared exclusivity" that it has granted other applicants. Watson has exclusivity to at least the Composition Patents. In a shared exclusivity situation, FDA allows multiple applicants to share the 180-day period of exclusivity where otherwise, their independent exclusivity periods would block each other, leading to a situation

where neither applicant can bring its product to market.[10] FDA has decided, however, that it only grants shared exclusivity when applicant A's exclusivity period blocks applicant B on one patent, and applicant B's exclusivity period blocks applicant A on another patent. (FDA Decision Letter at 8; Letter from Gary Buehler (FDA) to James Veltrop re: Metformin Hydrochloride ER Tablets (Oct. 14, 2004) at pp. 2-3 (Ex. A to the Declaration of Chad Landmon).) Here, that is not the case, because Watson does not technically block Mylan or Ranbaxy on any patents: Watson filed its Paragraph IV certifications the same day as those applicants – not before them. FDA's decision is therefore to deny shared (or any) exclusivity to Watson despite the fact that it has exclusivity with respect to the composition claims of the Composition Patents. (FDA Decision Letter at 8, 14)

That decision, however, has no rational basis. Through the Hatch-Waxman Act, Congress intended to reward generics who file prompt Paragraph IV certifications by giving them 180 days of marketing exclusivity. See Mova, 140 F.3d at 1064. Watson was prompt. It filed its Paragraph IV certifications on the first legally permissible day. It could not have filed those certifications even a day earlier. FDA is nonetheless withholding from Watson the reward of exclusivity that Congress prescribed. FDA's decision arbitrarily confers a pure windfall to Mylan and Ranbaxy, who acted no differently from Watson in quickly filing their ANDAs in 2003, and who, like the entire industry, have understood and made arrangements for pioglitazone supplies based on the belief that Watson shared First Filer status with them.

[10] Such a situation could theoretically arise because of FDA's "patent-by-patent" approach to exclusivity, whereby a "separate 180-day exclusivity entitlement arises in connection with each patent that is listed for the drug product and as to which an ANDA applicant is the first to file a Paragraph IV certification." See Apotex Inc. v. FDA, 414 F. Supp. 2d 61, 68 (D.D.C. 2006). When multiple applicants obtain multiple exclusivity periods, those periods may lead to the applicants blocking each other's access to the market for 180 days.

Therefore, because FDA's decision to deny exclusivity to Watson leads to arbitrary, capricious and absurd results, contrary to Congressional intent, this Court should reverse FDA and order that Watson's ANDA be immediately approved. See Mova, 140 F.3d at 1067-69.

IV. ANY EXCLUSIVITY WITH RESPECT TO THE COMBINATION THERAPY PATENTS NO LONGER EXISTS

FDA's determination that Watson does not share exclusivity with other ANDA holders is based upon FDA's determination that Watson lost eligibility for that exclusivity by converting its original Paragraph IV certifications to the Combination Therapy Patents into Section viii statements. But if this is the case, no ANDA holder who subsequently filed Paragraph IV certifications to the Combination Therapy Patents would be entitled to exclusivity rights related to these patents. According to FDA's regulation and practice, when a First Filer to submit a substantially complete ANDA containing a Paragraph IV certification to a patent withdraws or amends the certification, the applicant loses eligibility for exclusivity. No other applicants (with later filed Paragraph IV certifications) will be given exclusivity for that patent. FDA's determination here is contrary to statute and regulation, and without proper reason, and thus must be reversed under the APA as arbitrary and capricious and not in accordance with law. 5 U.S.C. § 706 (2)(A).

A. Watson's Conversion of Its Paragraph IV Certifications to Section viii Statements Extinguished Exclusivity as to The Combination Therapy Patents

Because Watson's ANDA was both substantially complete when filed and contained Paragraph IV certifications to the Combination Therapy Patents, Watson was eligible for exclusivity with respect to the Combination Therapy Patents. FDA, however, has determined that Watson is not eligible for approval of its ANDA because other applicants (Mylan and presumably also Ranbaxy) have exclusivity to the Combination Therapy Patents from later filed

Paragraph IV certifications. But, under FDA's own regulations and practice, no exclusivity for the Combination Therapy Patents can exist.[11]

FDA has consistently stated that *only* First Filers can be eligible for 180-day exclusivity. 21 C.F.R. § 314.107(c); 59 Fed. Reg. 50338, 50350 (applicant must be the "first ANDA applicant"). FDA has long held that a later ANDA applicant does not "become a 'first' applicant to submit a patent challenge if the first applicant to actually do so . . . changes its patent certification." (Letter from Gary Buehler (FDA) to Kate C. Beardsley and Carmen M. Shepard re: Metformin Hydrochloride ER Tablets (June 1, 2004) at p. 6.)

FDA has applied this rule against "rolling exclusivity" to deny an ANDA applicant exclusivity where a previous applicant withdrew its Paragraph IV certification. In responding to Andrx Pharmaceutical's suit for exclusivity, for example, FDA explained that "Company X" had filed its substantially complete ANDA before Andrx remedied a deficiency necessary for FDA to accept its ANDA for filing. (FDA Andrx Litigation Opp. Memo at 11, 18-19, Andrx Pharm., Inc. v. Thompson, No. 03-23171 (S.D. Fla. Dec. 11, 2003) (Ex. B to the Declaration of Chad Landmon).) But "[w]hen Company X subsequently withdrew its Paragraph IV certification, FDA properly concluded that it was no longer eligible for exclusivity and that all other approvable ANDAs could therefore be made immediately effective." (Id. at 11.) Under FDA's reasoning, the exclusivity did not roll to Andrx or another ANDA filer.

In 1999, in a proposed regulation, FDA explained that it was maintaining its "current" interpretation of the FDCA, rather than adopting rolling exclusivity, and thus:

> only the applicant submitting the first substantially complete ANDA for a listed drug with a Paragraph IV certification . . . would be eligible for exclusivity. If the first applicant subsequently withdraws its application or changes or withdraws its

[11] To the extent that FDA is taking the position that separate exclusivity rights somehow exist with respect to the method claims of the Composition Patents, that exclusivity also cannot exist for the same reason as with respect to the Combination Therapy Patents.

> Paragraph IV certification . . . no ANDA applicant will be eligible for 180-day exclusivity.

64 Fed. Reg. 42873, 42875.[12] This proposed regulation was withdrawn for reasons unrelated to this statement, but FDA confirmed that it would "continue to regulate directly from the statute and applicable FDA regulations." 67 Fed. Reg. 66593, 66594. And FDA itself has cited to this regulation as confirmation of its current interpretation. (FDA Andrx Litigation Opp. Memo at 19.)

FDA cannot justify why it has decided that the facts of this situation differ so that somehow the exclusivity with respect to the Combination Therapy Patents has rolled to another applicant. Despite FDA's long-held prohibition on rolling exclusivity, FDA has held here that another applicant is entitled to exclusivity because of *later* filed Paragraph IV certifications. FDA is thus ignoring its own precedent to effectively pretend that Watson's Paragraph IV certifications were never made. FDA can point to no regulatory or statutory support for its current decision, and in fact that decision is contrary to both its own regulations and previous position.

FDA asserts that declining rolling exclusivity here would "permit any applicant to file an ANDA with a paragraph IV certification to a listed patent – and then extinguish the related 180-day exclusivity for all other ANDA applicants simply by amending its ANDA" by changing those certifications and "eviscerate" exclusivity. (FDA Decision Letter at 13-14.) But even under FDA's decision here, an ANDA applicant could file an ANDA with a Paragraph IV certification and a full label, and shortly amend its application to include a Section viii statement

[12] FDA further explained that its original promulgation of its regulation described the only exception to this rule – where an applicant with an already submitted ANDA voluntarily adds, and then withdraws, a Paragraph IV certification to an untimely listed patent. Id. ("The agency believes that in this situation it is appropriate to grant exclusivity to [the later applicant] because the applicant filed its ANDA after the NDA holder submitted the patent information.").

and a carve-out. This would similarly result in no exclusivity. FDA's practice of denying rolling exclusivity, which it does not dispute, is what "eviscerates" exclusivity – FDA cannot provide a rational explanation as to why it makes this one exception here.

B. FDA's Determination Cannot Be Upheld

Because FDA's own regulations and past practice show that, if Watson is not entitled to exclusivity for the Combination Therapy 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. This is especially the case here, where FDA is accorded little to no deference for an informal adjudication without notice and comment rulemaking. United States v. Mead Corp., 533 U.S. 218, 228-29 (2001) (informal decision without notice and comment rulemaking was only given deference to the extent it had the power to persuade the court).

FDA cannot effectively alter its current regulations without notice and comment rule-making. See, e.g., Christensen v. Harris Cnty., 529 U.S. 576, 588 (2000) (forbidding agency to, "under the guise of interpreting a regulation, . . . create de facto a new regulation"); United States v. Hoyts Cinemas Corp., 380 F.3d 558, 569 (1st Cir. 2004) ("where . . . the [agency's] interpretation has the practical effect of altering the regulation, a formal amendment . . . is the proper course"). Moreover, FDA cannot offer a new interpretation of its regulations contrary to its consistently stated previous interpretations, without formal adjudication. Alaska Prof'l Hunters Ass'n, Inc. v. Fed. Aviation Admin., 177 F.3d 1030, 1035 (D.C. Cir. 1999) (agency could not depart from consistently applied interpretation of regulation); Paralyzed Veterans of America v. D.C. Arena L.P., 117 F.3d 579, 586 (D.C. Cir. 1997) ("Once an agency gives its regulation an interpretation, it can only change the interpretation as it would formally modify the regulation itself . . . .").

FDA "must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so." Indep. Petroleum Assoc. of Am. v. Babbitt, 92 F.3d 1248, 1258 (D.C. Cir. 1996) (citing Nat'l Assoc. of Broadcasters v. FCC, 740 F.2d 1190, 1201 (D.C. Cir. 1984)); County of Los Angeles v. Shalala, 192 F.3d 1005, 1022 (D.C. Cir. 1999) (When "the agency offers insufficient reasons for treating similar situations differently," the agency action is arbitrary.) Thus FDA cannot change course from its past practice without an acceptable reason, especially where past action misleads a party to detrimentally rely on such action, as Watson has done in preparing to launch its ANDA product. See, e.g., Alaska Prof'l Hunters Ass'n, 177 F.3d at 1035 (change in interpretation of rules was improper without notice and comment despite a proferred explanation).

FDA has not offered (and in fact cannot offer) any explanation of its determination that would allow it to stand. Any determination that Watson was not a first applicant to file a substantially complete ANDA with Paragraph IV certifications is contrary to FDA regulations, FDA's stated interpretation of its regulations and FDA practice. And any determination that exclusivity to the Combination Therapy Patents can be passed from Watson to a party who filed later Paragraph IV certifications is again contrary to FDA's stated interpretation of its regulations and FDA practice. For these reasons, FDA's decision to deny Watson approval of its ANDA must be rejected.

V. THE COURT MAY COMPEL FDA TO APPROVE WATSON'S ANDA

For the reasons stated above, this Court should declare FDA's determination to deny Watson shared exclusivity for pioglitazone is arbitrary, capricious, contrary to law, and in excess of FDA's statutory authority or limitations. Additionally, this court should order FDA to immediately approve Watson's ANDA. The District of Columbia has previously found such

type of relief the proper remedy under the APA for an arbitrary, capricious, or unlawful decision, and the D.C. Circuit has affirmed such rulings. See, e.g., Teva Pharmaceuticals USA, Inc. v. U.S. Food & Drug Admin., Civ. A. 99-67 (CKK), 1999 WL 1042743 (D.D.C. Aug. 19, 1999) aff'd, 254 F.3d 316 (D.C. Cir. 2000) (because FDA's interpretation of statute governing exclusivity was arbitrary and capricious, ANDA holder was entitled to immediate final effective approval); Mova Pharm. Corp. v. Shalala, 955 F. Supp. 128, 132 (D.D.C. 1997) aff'd, 140 F.3d 1060 (D.C. Cir. 1998) (preliminary injunction remedy under APA was suspension of an already-approved ANDA). Additionally, Section (j)(4) of the FDCA requires FDA to approve ANDAs, subject to the limitations regarding exclusivity in Section (j)(5) unless the Secretary finds that the ANDA does not comply with the requirements of the FDCA regarding ANDAs. 21 U.S.C. § 355(j)(4). Because FDA practice and governing statute require FDA to approve ANDAs not blocked by exclusivity where FDA has not found them deficient, any delay of approval by FDA constitutes agency action unlawfully withheld, and this court may compel FDA action under the APA. 5 U.S.C. §706(1).

CONCLUSION

For the foregoing reasons, this Court should grant Watson's motion for summary judgment and order the relief requested as set forth in the Proposed Order attached hereto.

Dated: August 27, 2012

Respectfully submitted,

AXINN, VELTROP & HARKRIDER LLP

/s/ Chad Landmon
Chad A. Landmon (DC Bar No. 990347)
M. Lily Woodland (DC Bar No. 985249)
950 F Street, N.W.
Washington, D.C. 20004
(202) 912-4700 (telephone)
(202) 912-4701 (facsimile)

Mark D. Alexander (pro hac vice)
Nicholas E.O. Gaglio (pro hac vice)
Aaron J. Feigenbaum (pro hac vice)
114 West 47th Street, 22nd Floor
New York, NY 10036
(212) 728-2200 (telephone)
(212) 728-2201 (facsimile)

Attorneys for Watson Laboratories, Inc.