UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PAR PHARMACEUTICAL, INC., Plaintiffs, v. SYLVIA MATHEWS BURWELL, Secretary of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201 ROBERT CALIFF, M.D., Commissioner of Food and Drugs Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, and U.S. FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue, Silver Spring, MD 20993 Defendants,	)	Civil Action No.

COMPLAINT

Plaintiff Par Pharmaceutical, Inc. ("Par") for its complaint against the defendants, Sylvia Mathews Burwell, Secretary of Health and Human Services; Robert Califf, M.D., Commissioner of Food and Drugs, and the United States Food and Drug Administration (collectively "FDA"), alleges as follows:

NATURE OF THE ACTION

1. This is an action for declaratory and injunctive relief for Defendants' violation of the 180-day exclusivity forfeiture provision of the Medicare Prescription Drug, Improvement,

and Modernization Act of 2003 ("MMA") (December 8, 2003) codified at 21 U.S.C. § 355(j)(5)(D)(i)(III).

2. On December 22, 2011, Par submitted to FDA Abbreviated New Drug Application ("ANDA") No. 203976 under the generic drug provisions of the Federal Food, Drug and Cosmetic Act ("FDCA"), seeking FDA approval to market generic version of the drug product Colcrys (Colchicine Tablets USP, 0.6 mg) prior to the expiration of U.S. Patent Nos. 7,601,758, 7,619,004, 7,820,681, 7,906,519, 7,915,269, 7,935,731, 7,964,647, 7,964,648, and 7,981,938.

3. On March 12, 2012, FDA informed Par that Par's ANDA had been received and was acceptable for filing with an effective date of December 23, 2011. This letter confirmed that Par's ANDA was substantially complete as of December 23, 2011.

4. Par and two other Colchicine Tablets USP, 0.6 mg ANDA applicants, Watson, Laboratories, Inc. ("Watson") and Amneal Pharmaceuticals, LLC ("Amneal") entered into protracted patent litigation with Takeda Pharmaceuticals USA, Inc.

5. On November 24, 2015, Takeda and Par reached a settlement agreement, and the court dismissed the lawsuit against Par on January 12, 2016.

6. On January 7, 2016, Takeda and Watson reached a settlement agreement, and the court dismissed the lawsuit against Watson on February 29, 2016.

7. On March 11, 2016, Takeda and Amneal reached a settlement agreement, and the court dismissed the lawsuit against Amneal on May 3, 2016.

8. Despite the fact that Par has maintained an uninterrupted paragraph IV certification with respect to at least claims 1 and 7 of the '648 patent, FDA sent a letter on

September 28, 2016, notifying Par that it had forfeited its eligibility for 180-day exclusivity for Colchicine Tablets USP, 0.6 mg (the "FDA Decision").

9. As set forth more fully herein, the FDA Decision is arbitrary, capricious, and contrary to law, and will cause Par harm for which Par is entitled to declaratory and injunctive relief, including but not limited to:

a. Issuance of judgment declaring that the FDA Decision is arbitrary, capricious, and contrary to law;

b. Issuance of an injunction directing FDA not to approve any other ANDA for Colchicine Tablets USP, 0.6 mg prior to the approval of Par's ANDA; and

c. Issuance of an injunction directing FDA to immediately stay the effective approval of any other ANDA that it has approved.

THE PARTIES

10. Plaintiff Par is a New York corporation, having a place of business at 1 Ram Ridge Rd., Chestnut Ridge, New York, 10977.

11. Defendant Sylvia Mathews Burwell ("Burwell") is a party in her official capacity as the Secretary of the United States Department of Health and Human Services ("HHS"). Defendant Burwell has been delegated the authority by the Congress of the United States to administer the FDCA. Defendant FDA is a major operating division of HHS. As Secretary of HHS, Secretary Burwell has supervisory authority for FDA. Secretary Burwell has delegated her authority under the FDCA to the Commissioner of Food and Drugs.

12. Defendant Robert Califf, M.D., ("Califf") is a party in his official capacity as the Commissioner of Food and Drugs. In that capacity, Dr. Califf has the authority and

responsibility for administering FDA and FDCA, including matters delegated by the Secretary of HHS relating to drug approvals as well as the statutes and regulations at issue in this case.

13. Defendant FDA is an agency within the Public Health Service, which is a part of Health and Human Services, that administers the FDCA.

14. HHS and FDA are agencies within the meaning of the APA, 5 U.S.C. § 701(b)(1).

JURISDICTION AND VENUE

15. This case arises under the Administrative Procedure Act ("APA"), 5 U.S.C. § 551, et seq.; the FDCA, 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly referred to as the "Hatch-Waxman Act") (codified as amended in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271); and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

16. The FDA Decision is a final agency action, which presents an actual controversy for which Par is entitled to review and relief under 5 U.S.C. § 701 et seq.

17. Par has standing to maintain this action pursuant to the APA, as a legal entity that has suffered a legal wrong and has been adversely affected by final agency action, as complained of herein.

18. There exists an actual, justiciable case or controversy between Par and FDA regarding the FDA Decision as to which Par requires: (i) a declaration of rights by this Court; and (ii) injunctive relief against FDA.

19. This Court has jurisdiction over the subject matter of this action under, inter alia, 28 U.S.C. §§ 1331, 1361, 2201.

20. This Court has personal jurisdiction over Defendants Burwell, Secretary of Health and Human Services; Califf, Commissioner of Food and Drugs; and FDA, in that the agency and the individual Defendants conduct substantial business in the district.

21. Venue is proper in this judicial district by virtue of 28 U.S.C. § 1391.

FACTUAL BACKGROUND

New Drugs and Patent Listing Requirements

22. Before marketing a new drug in the United States, a manufacturer must submit an NDA to FDA, and FDA must approve it. Once approved, new drugs generally are referred to as brand name drugs because they are marketed under a trade name or trademark for the drug product rather than the chemical name for the active ingredient in the drug product.

23. In addition to the technical data submitted in an NDA, a brand name drug manufacturer is required to submit to FDA information on each patent that claims the drug or a method of using the drug that is the subject of the NDA with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, sale or importation of the drug product. A brand name drug manufacturer should submit patent information – the patent's number and its expiration date – in connection with its NDA if the patent claims a drug or claims a method of using the drug covered by the NDA. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53.

24. Once FDA approves an NDA, FDA lists the patent information submitted by the brand name drug manufacturer in its publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). 21 U.S.C. § 355(b)(1).

Generic Drug Applications and Patent Certification Requirements

25. A generic drug is a version of a brand name drug that is generally sold without a trade name or trademark for the drug product.

26. Generic drugs typically enjoy a significant price advantage over their brand name counterparts. Consequently, generic drugs are frequently prescribed in an effort to control healthcare costs. Generic drugs represent a substantial and increasing portion of the medicines used in the United States.

27. A generic drug manufacturer seeking FDA approval for a generic version of a brand name drug product must file one of four certifications with FDA: (i) that the brand name drug manufacturer has not filed patent information with FDA; or, for each patent listed in the Orange Book as claiming the brand name drug or a method of use for which the ANDA applicant is seeking approval, (ii) that the patent has expired; (iii) that the patent expires on a date before which the generic manufacturer is seeking to market its generic product; or (iv) that the patent claiming the brand name drug is invalid, unenforceable, or will not be infringed by the manufacturer, 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)(4). The final certification is commonly referred to as a Paragraph IV certification.

28. If an ANDA applicant submits an ANDA with a Paragraph IV certification to FDA, it is required to notify the patent owner and the holder of the approved NDA (both of which are usually the brand name drug manufacturer). The filing of an ANDA with a Paragraph IV certification is deemed to be an act of infringement, which can be grounds for a brand name drug manufacturer to commence an action for patent infringement against the ANDA applicant. See 35 U.S.C. § 271(e)(2).

29. As an alternative to certification under Paragraph IV, an ANDA filer may submit a "section viii" statement to the effect that it is not seeking approval for a use claimed by the listed patent. 22 U.S.C. § 505(j)(2)(A)(viii). FDA permits ANDA filers to submit a Paragraph IV certification and a Section viii statement to a single patent (referred to as "split certifications"), when a single patent contains method-of-use claims in addition to other claims related to the applicable drug product. Specifically, FDA permits such combinations of Paragraph IV certifications with Section viii statements, where a single patent contains claims either for a drug substance or drug product and a method of use or for multiple methods of use.

Generic Marketing Exclusivity

30. In order to encourage generic market entry, the first ANDA applicant to file a "substantially complete" ANDA with a Paragraph IV certification (the "First Filer") is given a 180-day period in which it is the only applicant allowed to market a generic version of the brand name product. This is commonly referred to as the 180-day exclusivity period.

31. Specifically, the exclusivity provisions, as revised by the MMA provide that the first ANDA applicant who submits a Paragraph IV certification with a 180-day exclusivity period during which it is entitled to market its ANDA product without competition from other generic applicants. 21 U.S.C. § 355(j)(5)(B)(iv).

32. A First Filer under the statute is "an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug."

33. The MMA added several "forfeiture triggers" under which the first applicant might lose its entitlement to 180-day exclusivity. One such trigger applies where the first generic applicant "amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period." 21 U.S.C. § 355(j)(5)(D)(i)(III).

Par's ANDA for Colchicine Tablets USP, 0.6 mg

34. Takeda is the holder of the patents for Colchicine Tablets USP, 0.6 mg, including patents relating to methods of using colchicine in the treatment or prophylaxis of gout flares; methods of using colchicine for the treatment of familial Mediterranean fever; or methods of treating a patient with colchicine employing a modified dosing regimen in view of co-administration with another drug for either disease.

35. Par's ANDA contained all necessary information under 21 U.S.C. § 355(j)(2)(A) and 21 C.F.R. § 314.94 to be considered "substantially complete."

36. On or about March 12, 2012, Par sent the required "notice letter" to Takeda, informing them of their Paragraph IV certification in respect of a subset of patents listed against the Colcrys® in the Orange Book, a section viii statement with respect to others, and a "split certification" as to U.S. 7,964,648 (hereinafter the "'648 Patent.") On April 4, 2012 Takeda filed its complaint in the United States District Court for the District of Delaware initiating a patent suit in light of Par's certification. That case was dismissed September 22, 2014 in view of a settlement and license agreement entered into by Takeda and Par.

37. During the pendency of the litigation, Takeda secured additional patents that were eventually listed in the Orange Book and to which Par, alternatively, submitted Paragraph IV certification, section viii statements, and split certifications, the lattermost of which was filed in

view of U.S. 8,093,297 (hereinafter the "'297 Patent"). On July 19, 2013, Par submitted a labelling amendment by which the gout indications were removed from its proposed label and replaced with the familial Mediterranean fever indication. At the same time, as required by FDA statute and regulations, Par submitted a corresponding patent amendment. Par's July 19, 2013 patent amendment changed the Paragraph IV certifications and section viii statements with respect to each Orange Book listed patent – except for the Paragraph IV certifications to the Orange Book patents and their claims that are directed to the treatment of both gout and familial Mediterranean fever. With respect to those patents—namely U.S. Patent Nos. 7,964,648 and 8,093,297—Par had maintained uninterrupted Paragraph IV certifications before and after submission of the July 19, 2013 patent amendment. Moreover, Par has maintained an uninterrupted Paragraph IV certification with respect to claims 1 and 7 of the '648 patent, which cover both gout and familial Mediterranean fever.

38. On or about February 12, 2015, the FDA informed Par that the Par ANDA had been tentatively approved.

FDA's Decision that Par Forfeited

Eligibility for 180-Day Exclusivity for Colchicine Tablets USP, 0.6 mg

39. On September 28, 2016, FDA informed Par for the first time that it had forfeited eligibility for 180-day exclusivity for Colchicine Tablets USP, 0.6 mg.

40. FDA informed Par that "[a]lthough Par has maintained a paragraph IV certification with respect to the '648 Patent and the '297 Patent, it has not maintained an uninterrupted paragraph IV certification with respect to *any claims* within these patents."

41. As discussed above in Paragraph 37, Par did maintain uninterrupted paragraph IV certification with respect to at least claims 1 and 7 of the '648 Patent.

42. While, as noted, Par changed its Paragraph IV certifications to section viii statements with respect to the gout-based claims, and section viii statements to Paragraph IV certifications with respect to the familial Mediterranean fever-based claims, it never changed its Paragraph IV certifications with respect to claims 1 and 7, which are directed solely to methods of treating a patient with colchicine which patient is also being administered ketoconazole. Inasmuch as the claim itself would embrace a method that is equally applicable to either disease, the initial Paragraph IV position was never altered, from submission to the present day.

43. FDA has therefore made a final decision that Par is not eligible for 180-day exclusivity period for Colchicine Tablets USP, 0.6 mg.

The FDA Decision is Arbitrary, Capricious and Contrary to Law

44. FDA has failed to provide a lawful basis for the FDA Decision.

45. The FDA Decision is contrary to the plain language of the FDCA, under which eligibility for 180-day exclusivity is forfeited if the first applicant amends or withdraws the certification for all of the patents to which such applicant submitted certification qualifying the applicant for the 180-day exclusivity period.

46. Par submitted a substantially complete ANDA with Paragraph IV certifications on December 23, 2011. From the time of filing Par's ANDA through subsequent patent amendments, Par has maintained an uninterrupted paragraph IV certification with at respect to at least claims 1 and 7 of the '648 patent. As such, there is no basis in the law or regulations for FDA to determine that Par forfeited its eligibility for 180-day exclusivity for Colchicine Tablets USP, 0.6 mg.

47. Thus, FDA's Decision is arbitrary, capricious, and contrary to law.

Harm to Par Caused by FDA's Decision Regarding Par's ANDA

48. Unless it is immediately set aside and/or enjoined, FDA's decision to strip Par of its 180-day marketing exclusivity, and thereby allowing FDA to approve later-filed applications to market generic versions of Colchicine Tablets USP, 0.6 mg, will cause substantial and irreparable harm to Par.

49. Prior to receiving FDA's September 28, 2016 letter eliminating Par's 180-day marketing exclusivity, Par expected to enter the market as the sole generic supplier of Colchicine Tablets USP, 0.6 mg, for at least 180 days and to realize each of the economic benefits arising from that unique opportunity.

50. FDA's wrongful exclusivity determination will irreparably harm Par's business interests by eliminating, for example, Par's first-mover advantage. Par's 180-day marketing exclusivity would have allowed Par to generate goodwill with customers, maintain a significantly larger market share even after the expiration of the exclusivity period in comparison to other generic competitors that would be entering the market for the first time. Moreover, the 180-day marketing exclusivity affords Par an invaluable opportunity to enter into new or long-term relationships with key customers.

51. Par will also suffer substantial and unrecoverable economic losses in its first 180 days on the market. Even if Par were to enter the market at or around the same time as other generic drug competitors, Par could never replace the lost sales and market opportunity available to it with the 180-day marketing exclusivity. This harm is concrete and imminent, as Par was informed on September 29, 2016 that FDA granted final approval to another ANDA referencing Colcrys on September 28, 2016.

52. Without the requested preliminary relief, the direct economic value of the exclusivity period will be irretrievably lost.

53. Par has no adequate remedy at law.

CLAIM FOR RELIEF

54. Par repeats and realleges paragraphs 1 to 53 of the Complaint.

55. As set forth above, the FDA Decision improperly denies Par its eligibility for 180-day exclusivity to which it is entitled as a First Filer of a substantially complete ANDA containing a Paragraph IV certification, contrary to the plain meaning of the FDCA.

56. Because Par has maintained an uninterrupted paragraph IV certification with at respect to at least claims 1 and 7 of the ’648 patent, FDA’s Decision determining that Par forfeited its eligibility for 180-day exclusivity is arbitrary, capricious, and contrary to law within the meaning of 5 U.S.C. § 706(2)(A), in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C), and in violation of the FDCA.

57. The FDA Decision constitutes final agency action that is reviewable by this Court.

58. The FDA Decision will cause Par irreparable harm unless this Court issues immediate injunctive relief setting it aside, enjoining FDA from granting any other filer final approval, and compelling FDA to grant Par eligibility for 180-day exclusivity to which it is entitled as a First Filer. Par has exhausted its administrative remedies.

59. Par has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Par Pharmaceutical, Inc. respectfully requests this Court to enter judgment in its favor against Defendants Sylvia Mathews Burwell, Secretary of Health and

Human Services; Robert Califf, M.D., Commissioner of Food and Drugs, United States Food and Drug Administration; and the United States Food and Drug Administration as follows:

a. Entry of judgment declaring that the FDA Decision is arbitrary, capricious and contrary to law;

b. Entry of an injunction directing FDA not to approve any other ANDA for Colchicine Tablets USP, 0.6 mg prior to the approval of Par's ANDA;

c. Entry of an injunction directing FDA to immediately stay the effective approval of any other ANDA that it has approved.

d. Such other and further relief as the Court deems just and proper.

Date: September 29, 2016

Respectfully submitted,

/s/ Adam M. Acosta

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