

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

AMNEAL PHARMACEUTICALS LLC,

Plaintiff,

v.

PFIZER INC.,

Defendant.

C.A. No. \_\_\_\_\_

**COMPLAINT FOR DECLARATORY JUDGMENT**

Plaintiff Amneal Pharmaceuticals LLC (“Amneal”), by and through undersigned counsel, hereby brings its Complaint for Declaratory Judgment against Pfizer Inc. (“Pfizer”), and alleges as follows:

**Nature of the Action**

1. This is a declaratory judgment action under the Hatch-Waxman Act, the Declaratory Judgment Act, and the Patent Laws of the United States. 35 U.S.C. §1 *et seq.* Amneal seeks a declaration of non-infringement of United States Patent No. 6,268,489 (“the ’489 Patent” or “the patent-in-suit”). Amneal challenged the patent-in-suit as part of its Abbreviated New Drug Application (“ANDA”) No. 205666 filed under the Hatch-Waxman Act. Amneal’s ANDA No. 205666 seeks FDA approval of generic azithromycin for oral suspension USP, 100 mg/5 mL and 200 mg/5 mL (“Amneal’s ANDA product”). Amneal’s ANDA product will compete with Pfizer’s azithromycin for oral suspension sold under the tradename Zithromax®. The requested judgment of non-infringement is essential to prevent the potential indefinite delay of FDA approval of Amneal’s ANDA product and Amneal’s market entry, and

resultant competition with Pfizer's Zithromax® prior to expiration of the '489 Patent.

2. This case or controversy regarding infringement of the '489 Patent arises from the presumptive entitlement under the Hatch-Waxman Act of a prior ANDA filer to a 180-day marketing exclusivity period. The Hatch-Waxman Act prohibits the FDA from granting final FDA approval to Amneal's ANDA and any other subsequently-filed ANDA until after the first filer's 180-day period has run. With respect to Zithromax®, however, it is unclear when *or even if* that first filer will trigger the running of the 180-day period. Accordingly, Amneal may be blocked indefinitely from competing with Pfizer - notwithstanding an FDA determination in the meantime that Amneal's ANDA product meets the FDA's safety and efficacy requirements for final marketing approval.

3. In order to avoid this type of bottleneck to competition, the Hatch-Waxman Act contains several provisions under which the first ANDA filer forfeits its exclusivity - and thus frees the FDA to give final approval to subsequently-filed ANDAs. One such forfeiture event is keyed to another ANDA filer obtaining precisely the judgment Amneal seeks in this action - that is, a declaratory judgment that Amneal's subsequently-filed ANDA product does not infringe the patents challenged by the first filer. Upon occurrence of the statutory forfeiture, the FDA will be free to grant final approval to Amneal's ANDA product, and allow it to compete with Pfizer's Zithromax®.

4. Under the Hatch-Waxman Act, the Declaratory Judgment Act, and the Patent Laws of the United States, Amneal is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Amneal's ANDA product does not and will not infringe any valid and enforceable claim of the '489 Patent.

**The Parties**

5. Plaintiff Amneal Pharmaceuticals LLC is a privately held Delaware limited liability company having its principal place of business at 400 Crossing Boulevard, Bridgewater, New Jersey 08807-2863.

6. Upon information and belief, Defendant Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York, 10017.

**Jurisdiction and Venue**

7. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 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) (codified as amended at 21 U.S.C. § 355), and by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 17 Stat. 2066 (2003) (collectively herein the “Hatch-Waxman Act”), based upon an actual controversy between the parties for a final judgment declaring that Amneal is free, upon approval by the FDA, to manufacture, use, market, sell, offer to sell, and/or import its proposed ANDA product as described in ANDA No. 205666.

8. This Court has original jurisdiction over the subject matter of these claims pursuant to 28 U.S.C. §§ 1331 and 1338(a), because it involves substantial claims arising under the United States Patent Act, 35 U.S.C §§ 1 *et seq.*; under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because it is an actual controversy concerning the patents- in-suit; and under the Hatch-Waxman Act (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)), because Congress has directed that district courts maintain and exercise jurisdiction in such cases.

9. This Court has personal jurisdiction over Pfizer because Pfizer is incorporated under the laws of Delaware. On information and belief, this Court also has personal jurisdiction over Pfizer because of Pfizer's continuous and systematic contacts with the State of Delaware, including conducting of substantial and regular business therein through marketing and sales of pharmaceutical products in Delaware. Further, Pfizer has frequently subjected itself to the jurisdiction of this Court, including, but not limited to: *Pfizer Inc. v. Mylan Labs. Inc.*, No. 15-cv-0026-SLR (D. Del.); *Pfizer Inc. v. Teva Pharms. USA Inc.*, No. 08-cv-0237-JJF (D. Del.); *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, No. 08-cv-0164-GMS (D. Del.).

10. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c), and 1400(b).

#### **Patent-in-Suit**

11. On its face, the '489 Patent entitled "AZITHROMYCIN DIHYDRATE" indicates it was issued by the United States Patent and Trademark Office on July 31, 2001. A copy of the '489 patent is attached hereto as **Exhibit A**.

12. According to the Orange Book, the '489 Patent expires on July 31, 2018.

13. Upon information and belief, and according to records at the United States Patent and Trademark Office, Pfizer is the assignee of the '489 Patent.

#### **Statutory Background**

14. The Hatch-Waxman Act authorizes the submission of an Abbreviated New Drug Application ("ANDA") to seek approval of a generic version of any Reference Listed Drug ("RLD") in the *FDA's Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"). The Hatch-Waxman Act further authorizes the inclusion within an ANDA of a so-called "Paragraph IV" certification, in which the applicant certifies to the FDA that the proposed ANDA product will not infringe any valid and enforceable

claim of one or more patents in the Orange Book for the RLD. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

15. With respect to any such Paragraph IV certification, the ANDA applicant must provide notice of the certification to the patent holder and the holder of the New Drug Application (“NDA”) for the RLD (“the NDA Holder”), along with a statement of the factual and legal basis for its certification. The patent and NDA holder may commence a patent infringement action within 45 days of receiving that notice. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa) and 35 U.S.C. § 271(e)(2).

16. The Hatch-Waxman Act expressly authorizes the bringing of a declaratory judgment action under 28 U.S.C. § 2201 where the following conditions are met: (1) the 45-day period for the patent and NDA holder to bring suits has passed, without either entity having brought suit, and (2) the ANDA applicant claiming non-infringement included with its Paragraph IV certification notice a statutory offer of confidential access to the patent and NDA holders. *See* 21 U.S.C. § 355(j)(5)(C)(i).

17. The Hatch-Waxman Act also contains provisions for both the grant and forfeiture of a 180-day period of marketing exclusivity. This exclusivity is granted to the first applicant to file an ANDA with Paragraph IV certification(s) as to one or more patents listed in the Orange Book for an RLD. Until the expiration of the exclusivity period, the FDA cannot grant final approval to any subsequently filed ANDA. The Hatch-Waxman Act specifies, however, that such exclusivity may be forfeited in certain circumstances to prevent the exclusivity holder from blocking indefinitely the final approval and market entry of other generic challengers. Once the exclusivity period has run or been forfeited, the FDA may grant final approval to subsequently filed ANDAs.

18. In particular, first ANDA filer exclusivity for a given RLD is forfeited when (a) another generic challenger obtains “tentative approval” of a subsequently filed ANDA for the RLD, and (b) the other challenger obtains a final judgment, from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) is or may be taken, that all patents which are the subject of the Paragraph IV certification giving rise to exclusivity are not infringed or are invalid. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I). The Hatch-Waxman Act expressly provides that such a final judgment may come from a declaratory judgment action brought by a generic challenger. *Id.* Upon such a forfeiture, the FDA may grant final approval to subsequently filed ANDAs.

#### **Facts**

19. Pfizer, through its Pfizer Chemicals Division, is the holder of approved NDA No. 050710 for Zithromax®. Pfizer caused the '489 Patent to be listed in the Orange Book with respect to the RLD Zithromax® shortly after the '489 Patent date of issuance on July 31, 2001. The '489 Patent is the only patent currently listed in the Orange Book for Zithromax® suspension.

20. Amneal submitted ANDA No. 205666 to the FDA for proposed azithromycin for oral suspension USP, 100 mg/5 mL and 200 mg/5 mL. The RLD for Amneal's ANDA is Pfizer's Zithromax® (Azithromycin for Oral Suspension, 100 mg/5 mL and 200 mg/5 mL).

21. In its ANDA No. 205666, Amneal included a Paragraph IV certification that its product would not infringe any valid and enforceable claim of the '489 Patent. *See* 21 U.S.C. § 355 (j)(2)(A)(vii)(IV). Amneal served Pfizer with a Notice Letter informing Pfizer of Amneal's ANDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of Amneal's ANDA product before the expiration of the '489 Patent. Amneal's Notice Letter complied fully with 21 U.S.C. §§ 355(j)(2)(B) and 21 C.F.R. § 314.95. In addition,

Amneal's Notice Letter included an offer of access to confidential information within the meaning of 271 U.S.C. § 355(j)(5)(C)(i)(III). Pfizer did not bring an action for infringement of the '489 Patent within the 45-day statutory period.

22. Accordingly, both requirements are met for this declaratory judgment action expressly authorized by the Hatch-Waxman Act: (1) the 45-day period has passed without Pfizer bringing an action for infringement, and (2) Amneal made the statutory offer of confidential access in connection with the '489 Patent. *See* 21 U.S.C. § 355(j)(5)(C)(i).

23. The FDA granted Tentative Approval to Amneal's ANDA No. 205666 on March 17, 2017.

24. Publicly available FDA records reflect that Lupin Pharmaceuticals, Inc. ("Lupin") filed ANDA No. 065488 with a Paragraph IV certification as to the '489 Patent on April 6, 2007. The FDA granted approval to Lupin's ANDA No. 065488 on May 15, 2015. According to the FDA, Lupin was the first ANDA applicant for Azithromycin for Oral Suspension USP, 100 mg/5 mL and 200 mg/5 mL, to submit a substantially complete ANDA with a Paragraph IV certification. Under 21 U.S.C. § 355 (j)(5)(B)(iv), and as per the FDA's Tentative Approval letter to Amneal, Lupin is eligible for 180 days of generic drug exclusivity, which begins to run from the date Lupin begins commercial marketing of the ANDA drug. Lupin has not begun commercial marketing of azithromycin for oral suspension since receiving approval. It is uncertain when, or even if, that exclusivity period will begin. Accordingly, Amneal may be blocked indefinitely from competing with Pfizer.

25. In order to prevent such a bottleneck to market entry, the Hatch-Waxman Act expressly provides Amneal the right to attempt to trigger a forfeiture of the first filer's exclusivity period by obtaining a judgment that any listed patents are not infringed or are invalid.

*See* 21 U.S.C. § 355(j)(5)(D)(i)(I). Therefore, notwithstanding Pfizer's decision not to bring suit, Amneal's ability to obtain final FDA approval of its ANDA depends on Amneal's ability to obtain a final judgment that its proposed product does not infringe the '489 Patent.

## COUNT I

### **Declaratory Judgment of Noninfringement of the '489 Patent**

26. Amneal repeats and realleges each of the allegations in paragraphs 1-25, as if fully set forth herein.

27. There is a substantial and continuing controversy between Pfizer and Amneal, and a declaration of rights is both necessary and appropriate to establish that Amneal does not infringe any valid or enforceable claim of the '489 Patent.

28. But for Pfizer's decision to list the '489 Patent in the Orange Book, FDA approval of Amneal's ANDA would not have been independently delayed by the patent. Pfizer's actions of requesting the FDA to list the '489 Patent in the FDA Orange Book, continuing said listing in the FDA Orange Book, in combination with its subsequent failure to enforce the Orange Book listed '489 patent against Amneal, has created latent and ongoing liability for Amneal and, consequently, actual harm to Amneal. As intended by Congress, this Declaratory Judgment action under 21 U.S.C. § 355(j)(5)(D)(i) provides the means to address that latent liability and on-going harm.

29. Additionally, a declaratory judgment of noninfringement would trigger the forfeiture period under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) for Lupin's non-utilized exclusivity period, which otherwise threatens to block indefinitely final FDA marketing approval of Amneal's ANDA. If Amneal is blocked by the first filer's exclusivity, Amneal will be monetarily harmed, as it will lose sales of its ANDA product by virtue of not being able to enter

the market at the earliest possible date under the applicable statutory and FDA regulatory provisions, and it will be deprived of an economic opportunity to compete with Pfizer and others in the market for azithromycin for oral suspension.

**Prayer for Relief**

WHEREFORE, Amneal respectfully requests the Court enter judgment as follows:

A. Declaring that the claims of the '489 Patent have not been infringed by the filing of Amneal's ANDA 205666;

B. Declaring that the manufacture, marketing, use, offer for sale, sale and/or importation of the products that are the subject of Amneal's ANDA 205666 have not infringed, do not infringe, and would not, if marketed, infringe, or induce or contribute to the infringement by others of, any claims of the '489 Patent;

C. Declaring that the United States Food & Drug Administration may approve Amneal's ANDA No. 205666 whenever that application is otherwise in condition for approval, without awaiting any further order, judgment, or decree of this Court; that the judgment entered in this case is a judgment reflecting a decision that the patent-in-suit is not infringed pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa); and that any marketing exclusivity periods to which any other entity might otherwise be entitled (including any pediatric exclusivity) with respect to the '489 Patent is shortened to expire upon the date of entry of judgment in this case;

D. Awarding Amneal its costs, expenses and reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

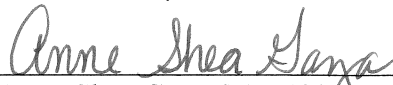
E. Awarding Amneal such other and further relief that the Court deems just and proper under the circumstances.

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