IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG	)	
Plaintiffs,	)	Civil Action No.
v.	)	
AMNEAL PHARMACEUTICALS LLC	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Novartis Pharmaceuticals Corporation and Novartis AG (collectively "Novartis"), by their attorneys, for their Complaint against Amneal Pharmaceuticals LLC ("Amneal") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.* This action relates to an Abbreviated New Drug Application ("ANDA") filed by Amneal with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Novartis' Gleevec® drug product.

THE PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

4. Upon information and belief, defendant Amneal is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd floor, Bridgewater, New Jersey 08807.

JURISDICTION AND VENUE

5. This action for patent infringement arises under 35 U.S.C. § 271.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Upon information and belief, Amneal is in the business of manufacturing, marketing, and selling pharmaceutical drug products, including generic pharmaceutical products. Upon information and belief, Amneal directly, or indirectly through its affiliates and/or distributors, markets, distributes, and sells its pharmaceutical products within and throughout the United States, including in the State of Delaware and throughout this judicial district.

8. Upon information and belief, this Court has personal jurisdiction over Amneal because it purposefully avails itself of the privilege of doing business in the State of Delaware by being formed and existing under the laws of Delaware and continuously and systematically placing goods in the stream of commerce for distribution throughout the United States, including the State of Delaware.

9. Upon information and belief, this Court also has personal jurisdiction over Amneal because it is registered to do business in the State of Delaware and has appointed as a

registered agent The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, Delaware 19801.

10. Upon information and belief, this Court also has personal jurisdiction over Amneal because it is registered pursuant to Del. Code Ann. Tit. 24, § 2540 to distribute its generic pharmaceutical products in Delaware and holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy.

11. Upon information and belief, Amneal has previously filed ANDAs and, using the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), has challenged branded pharmaceutical companies' patents by filing a certification under 35 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification"), sending notice of such certification to those companies, and engaging in patent litigation arising from this process.

12. Upon information and belief, with knowledge of the Hatch-Waxman process, pursuant to 21 U.S.C. § 355(j)(2)(B)(iii) Amneal directed a letter including a paragraph IV certification to Novartis, including NPC which is a Delaware corporation, and deliberately challenged Novartis' patent rights, knowing that such certification could trigger a patent infringement suit from Novartis under the Hatch-Waxman Act. Moreover, upon information and belief, Amneal knew that other Hatch-Waxman infringement actions relating to the same patents had been brought and litigated in Delaware.

13. Upon information and belief, this Court has personal jurisdiction over Amneal because Amneal has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and

injury to NPC, a Delaware corporation, such that Amneal should anticipate being haled into court in this judicial district.

14. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) & (c) and 1400(b).

THE PATENTS IN SUIT

15. United States Patent No. 6,894,051 (the "'051 Patent") duly and legally issued on May 17, 2005 to inventors Jürg Zimmermann, *et al*. A true and correct copy of the '051 Patent is attached hereto as Exhibit A.

16. The '051 Patent is assigned to Novartis AG, and NPC is an exclusive licensee under the '051 Patent.

17. United States Reissue Patent No. RE43,932 (the "RE932 Patent") duly and legally issued on January 15, 2013 to inventors Jürg Zimmermann, *et al*. A true and correct copy of the RE932 Patent is attached hereto as Exhibit B.

18. The RE932 Patent is assigned to Novartis AG, and NPC is an exclusive licensee under the RE932 Patent.

ACTS GIVING RISE TO THIS ACTION

19. Plaintiff NPC holds an approved New Drug Application ("NDA") No. 21588 for Gleevec® tablets containing 100 mg and 400 mg imatinib mesylate, which was approved by the FDA on April 18, 2003.

20. By letter dated September 17, 2015 ("Amneal's Notice Letter"), Amneal notified Novartis that it had submitted ANDA No. 207495 to the FDA under Section 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, offer to sell or sale of tablets containing 100 mg and 400 mg of

imatinib mesylate (the "Imatinib Mesylate ANDA Tablets"). Upon information and belief, Amneal stated in its ANDA that its Imatinib Mesylate ANDA Tablets are bioequivalent to Novartis' 100 mg and 400 mg imatinib mesylate Gleevec® tablets.

21. As stated in its Notice Letter, Amneal's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, use and/or sale of Amneal's Imatinib Mesylate ANDA Tablets prior to the expiration of the '051 Patent and the RE932 Patent which are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as being applicable to Novartis' Gleevec® tablets. Upon information and belief, Amneal intends to engage in the commercial manufacture, use and/or sale of Amneal's ANDA Imatinib Mesylate Tablets promptly upon receiving FDA approval to do so.

22. In its Notice Letter, Amneal notified Novartis that its ANDA contained a "paragraph IV certification" that in Amneal's opinion, the '051 Patent and the RE932 Patent are invalid, unenforceable or will not be infringed by the manufacture, use, sale, or offer to sell of Amneal's Imatinib Mesylate ANDA Tablets.

23. Amneal's filing of its ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell or sale of its Imatinib Mesylate ANDA Tablets, prior to the expiration of the '051 Patent and the RE932 Patent, constitutes infringement of one or more of the claims of those patents under 35 U.S.C. § 271(e)(2).

24. Amneal's commercial manufacture, use, offer to sell or sale of Amneal's Imatinib Mesylate ANDA Tablets, prior to the expiration of the '051 Patent and the RE932 Patent, would constitute infringement of the '051 Patent and the RE932 Patent under 35 U.S.C. § 271.

25. Upon FDA approval of Amneal's ANDA, Amneal will infringe the '051 Patent and the RE932 Patent by making, using, offering to sell, and/or selling Amneal's Imatinib Mesylate ANDA Tablets in the United States unless enjoined by this Court.

26. Amneal had notice of the '051 Patent and the RE932 Patent at the time of its infringement.

27. Novartis will be substantially and irreparably damaged and harmed if Amneal's infringement is not enjoined. Novartis does not have an adequate remedy at law.

WHEREFORE, Novartis respectfully requests the following relief:

(a) a judgment and decree that the '051 Patent and the RE932 Patent are valid and enforceable;

(b) a judgment and decree that Amneal has infringed one or more claims of the '051 Patent and the RE932 Patent in violation of 35 U.S.C. § 271;

(c) a judgment declaring that Amneal's making, using, selling, offering to sell or importing Amneal's Imatinib Mesylate ANDA Tablets will infringe the '051 Patent and the RE932 Patent;

(d) a judgment providing that the effective date of any FDA approval for Amneal to make, use or sell Amneal's Imatinib Mesylate ANDA Tablets be no earlier than the date on which last-expiring patent of the '051 Patent and the RE932 Patent expires, including any associated regulatory exclusivities;

(e) a judgment permanently enjoining Amneal from making, using, selling, offering to sell, or importing Amneal's Imatinib Mesylate ANDA Tablets until after expiration of the '051 Patent and the RE932 Patent, including any associated regulatory exclusivities;

(f) if Amneal engages in the commercial manufacture, use or sale of Amneal's Imatinib Mesylate ANDA Tablets prior to the expiration of the '051 Patent and the RE932 Patent, a judgment awarding Novartis damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(g) a judgment awarding Novartis attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(h) a judgment awarding Novartis costs and expenses in this action; and

(i) a judgment awarding Novartis such further and other relief as this Court may deem just and proper.

Dated: October 28, 2015

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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