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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUN PHARMA GLOBAL FZE, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Defendants.	:	Honorable Civil Action No. **COMPLAINT FOR DECLARATORY JUDGMENT**

Plaintiff Sun Pharma Global FZE ("Sun") by way of Complaint against Defendants, Novartis Pharmaceuticals Corporation and Novartis AG (together, "Defendants"), states, upon knowledge with respect to its own acts, and upon information and belief as to other matters, as follows:

NATURE OF ACTION

1. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), 21 U.S.C. § 355(j)(5)(c)(i), and seeks a declaration that the claims of U.S. Patent No. 6,894,051 ("the '051 patent") are not infringed by

Sun's proposed generic drug products and/or are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

THE PARTIES

2. Plaintiff Sun is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Executive Suite #43, Block Y, SAIF-Zone, PO Box 122304, Sharjah, U.A.E.

3. Defendant Novartis Pharmaceuticals Corporation 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.

4. Defendant Novartis AG is a corporation organized and existing under the laws of Switzerland, having an office and a place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

U.S. PATENT NO. 6,894,051

5. The '051 patent, a copy of which is attached as Exhibit A, is owned by Defendant Novartis AG.

6. The '051 patent is scheduled to expire on November 23, 2019.

7. Defendant Novartis Pharmaceuticals is the exclusive licensee of the '051 patent and holds New Drug Application ("NDA") No. 21-588 to market the GLEEVEC® brand imatinib mesylate tablet products.

8. Defendants have standing under Article III of the U.S. Constitution to sue for any infringement of the '051 patent.

JURISDICTION AND VENUE

9. Substantial, present, genuine and justiciable controversies exist between Sun and Defendants regarding the ’051 patent.

10. This Court has subject matter jurisdiction over this action under 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 ’051 patent; and under the MMA, 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.

11. Sun has the statutory right to bring and maintain this declaratory judgment action under 21 U.S.C. § 355(j)(5)(C)(i). This Court can and should exercise its declaratory judgment jurisdiction over Sun’s claims pursuant to 35 U.S.C. § 271(e)(5).

12. This Court has personal jurisdiction over Defendants because, among other reasons, Defendants have continuous and systematic business contacts with the State of New Jersey and this District.

13. Defendants purposefully avail themselves of the privilege of doing business in the State of New Jersey and in this District.

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

BACKGROUND

I. Regulatory Framework

A. Approval Of Brand-Name Drugs

15. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, sets forth the rules that the U.S. Food and Drug Administration must follow when considering whether to approve the marketing of both brand-name and generic drugs.

16. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare an NDA for consideration by the FDA.

17. The NDA must include, among other things, the number of any patent that claims the drug or a method of using the drug for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2).

18. Upon approval of the NDA, the FDA publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

19. By filing an NDA and submitting a patent for listing in the Orange Book, the NDA holder or patent owner necessarily represents that the listed patent covers the approved drug described in the NDA, or a method of using that drug, and that the NDA holder or patent holder could reasonably assert a patent infringement suit against any company that seeks FDA approval to make a generic version of the drug before the listed patent expires.

20. Thus, the NDA holder or patent owner necessarily puts all prospective generic drug manufacturers on notice that a suit for infringement can and likely will be asserted against

any manufacturer that attempts to seek approval for, or to market, a generic version of the drug described in the NDA before the listed patent expires.

21. Such conduct by the NDA holder or patent owner gives rise to a real and concrete belief by the generic drug applicant that it will face a patent infringement suit, or the threat of one, if it attempts to seek approval for, or to market, a generic version of the drug described in the NDA before the listed patent expires.

B. Approval Of Generic Drugs Under The Hatch-Waxman Amendments

22. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). This statute created a pathway for approval by the FDA of generic prescription drugs, which are versions of brand-name prescription drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients, as previously-approved brand-name drugs.

23. The Hatch-Waxman Amendments simplified the procedures for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition and to expedite the marketing of lower-priced generic drug products.

24. Under the Hatch-Waxman Amendments, a manufacturer seeking approval to market a generic drug must submit what is called an Abbreviated New Drug Application ("ANDA"). To receive approval of its ANDA, an applicant must show, among other things, that its generic drug is "bioequivalent" to the reference listed drug. *See* 21 U.S.C. § 355(j)(4)(F).

25. An ANDA also must contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

26. A so-called "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic drug product prior to that patent's expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

27. An applicant submitting an ANDA containing a paragraph IV certification must notify both the NDA holder and patent owner of the paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

28. If the NDA holder or patent owner files a lawsuit for patent infringement within 45 days of receiving notice of the paragraph IV certification, the FDA is generally prevented from issuing final approval of the ANDA for a period of 30 months, or until the district court enters a judgment that the patent is invalid, not infringed or unenforceable—whichever is sooner. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

29. The submission of a paragraph IV certification constitutes an artificial act of patent infringement that enables an NDA holder or patent owner to file, and a district court to resolve, an action for patent infringement—before the generic drug is actually made, used, or sold—to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

30. The submission of a paragraph IV certification likewise creates a case or controversy that allows an ANDA applicant to file a declaratory judgment action against the NDA holder or patent owner if the ANDA applicant is not sued on the listed patent within the applicable 45-day period.

31. This right comes from the MMA, which was signed into law on December 8, 2003. Title XI of the MMA, labeled "Access to Affordable Pharmaceuticals," amended provisions of the FFDCA and, in particular, the Hatch-Waxman Amendments.

32. Under the MMA, an ANDA applicant that has filed a paragraph IV certification is statutorily entitled to institute and maintain an action for declaratory judgment against an NDA holder or patent owner if: (1) the 45-day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the NDA holder brought an action for infringement of the patent within the 45-day period; and (3) if the action seeks a declaration of non-infringement, the notice of paragraph IV certification contains an Offer of Confidential Access to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

33. The MMA provides that, once these three conditions are met, an ANDA applicant "may, in accordance with section 2201 of Title 28 [of the United States Code] bring a civil action under such section against the owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval." 21 U.S.C. § 355(j)(5)(C)(i)(II).

34. By enacting these provisions, Congress intended to allow ANDA applicants to obtain patent certainty before marketing their generic drug products in order to avoid a possible damages award in a patent infringement suit

II. Sun Has The Statutory Right To Seek A Declaration That Its Proposed Generic Products Will Not Infringe Any Valid Claim Of The '051 Patent.

35. On June 16, 2006, Sun Pharmaceutical Industries, Ltd. ("Sun India") filed ANDA No. 78-340 with the FDA seeking generic approval for 100 mg and 400 mg tablets of imatinib mesylate ("Sun's ANDA Products").

36. In 2012, ownership of ANDA 78-340 was transferred from Sun India to Sun.

37. Defendants listed the '051 patent, among others, in the Orange Book in connection with NDA No. 21-588 for the brand-name drug GLEEVEC®, which comprises the active ingredient imatinib mesylate.

38. By listing the '051 patent in the Orange Book, Defendants maintain, and have affirmatively represented, that the '051 patent claims GLEEVEC®, or a method of using that drug, and that an infringement suit could reasonably be asserted against a generic ANDA applicant, such as Sun, that attempts to seek approval for, and market, a generic version of GLEEVEC® before the expiration of the '051 patent.

39. Because Sun seeks FDA approval to market its ANDA Products before expiration of the '051 patent, Sun's ANDA includes a paragraph IV certification as to the '051 patent.

40. On or around August 25, 2007, Defendants received the statutorily-required notice of Sun's paragraph IV certification ("Sun's Notice Letter"), which contains a detailed factual and legal statement as to why the '051 patent is invalid, unenforceable, and/or not infringed by Sun's ANDA Products.

41. As required under 21 U.S.C. § 355(j)(5)(C), Sun's Notice Letter extended to Defendants an Offer of Confidential Access to Sun's ANDA.

42. Defendants did not file a lawsuit for infringement of the '051 patent within the 45-day time-period set forth in 21 U.S.C. § 355(j)(5)(b)(iii).

43. Because Defendants did not sue for infringement of the '051 patent within 45 days of receipt of Sun's Notice Letter, Sun is entitled to file and maintain this declaratory judgment action against Defendants under 28 U.S.C. §§ 2201 and 2202, pursuant to 21 U.S.C. § 355(j)(5)(C).

44. Sun has a reasonable apprehension that Defendants will initiate a patent infringement action against Sun, claiming that Sun's proposed ANDA Products infringe the '051 patent.

45. Until and unless Sun obtains a court decision of noninfringement and/or invalidity on the '051 patent, it faces the risk of incurring substantial damages for patent infringement if it commences marketing its ANDA Products before the '051 patent expires. Sun can alleviate this risk and obtain patent certainty through a declaratory judgment regarding the '051 patent.

COUNT I

Declaration Of Non-Infringement And/Or Invalidity Of The '051 Patent

46. Sun re-alleges and incorporates herein the allegations of paragraphs 1-45.

47. There is an actual, substantial, continuing and justiciable controversy between Sun and Defendants regarding whether Sun's ANDA Products infringe a valid claim of the '051 patent.

48. Defendants did not file a patent infringement suit as to the '051 patent within 45 days of receipt of Sun's Notice Letter, which included an Offer of Confidential Access. Accordingly, Sun has the right to file this declaratory judgment action against Defendants pursuant to the MMA, 21 U.S.C. § 355(j)(5)(c)(i).

49. Sun has not infringed, contributed to the infringement of, or induced the infringement of any valid claim of the '051 patent and is not liable for such infringement.

50. Sun is entitled to a declaration that all claims of the '051 patent are not infringed and/or are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Sun respectfully requests that this Court enter a Judgment and Order in its favor and against Defendants as follows:

A. declaring that all claims of the '051 patent are not infringed and/or are invalid;

B. awarding Sun its attorneys' fees, costs and/or expenses; and

C. awarding such other relief as the Court determines to be just and proper.

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Dated: June 7, 2013

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the within action is not the subject of any other action pending in any Court, or of any pending arbitration or administrative proceeding.

s/ James S. Richter
James S. Richter

Dated: June 7, 2013