IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO A.C.R.A.F. S.p.A.,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
SUN PHARMACEUTICAL INDUSTRIES, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiff Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. ("Plaintiff" or "Angelini"), alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing, made by Sun Pharmaceutical Industries, Inc. ("Sun"), of an Abbreviated New Drug Application ("ANDA") supplement with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of a generic version of DESYREL® (trazodone hydrochloride) in tablet form in doses of 300 mg, before the expiration of U.S. Patent No. 8,133,893 ("the '893 patent"). The '893 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

2. DESYREL® is a selective serotonin reuptake inhibitor indicated for the treatment of major depressive disorder.

3. Sun notified Plaintiff, by letter dated February 1, 2023 ("Sun's Notice Letter") that it had submitted to the FDA a supplement to ANDA No. 073137 ("Sun's ANDA"), seeking approval from the FDA to engage in commercial manufacture, use, importation, offer for sale, or

sale of its generic Trazodone Hydrochloride tablets, 300 mg ("Sun's ANDA Product") prior to the expiration of the '893 patent.

4. Sun's Notice Letter was delivered to counsel for Plaintiff by email on February 1, 2023.

5. Upon information and belief, Sun's ANDA Product is a drug product that is a generic version of DESYREL®, containing the same or equivalent ingredients in the same or equivalent amounts, which Sun claims is bioequivalent to DESYREL®.

6. Upon information and belief, Sun submitted its ANDA supplement to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) asserting that the '893 patent is invalid or will not be infringed by the manufacture, use, or sale of Sun's ANDA Product.

PARTIES

7. Angelini is a company organized under the laws of Italy with its principal place of business at Viale Amelia 70, Rome 00181 Italy. Angelini is the assignee of the '893 patent.

8. Angelini's subsidiary, Angelini Pharma, Inc., is a Delaware corporation, operating and existing under the laws of Delaware, with a principal place of business in Maryland.

9. Angelini is a leader in healthcare, with a significant focus on researching and developing pharmaceuticals to treat nervous system diseases and disorders, mental health, pain and inflammation, and rare diseases.

10. Upon information and belief, defendant Sun is a company organized and existing under the laws of the State of Delaware, having its principal place of business at 2 Independence Way, Princeton, New Jersey 08540. Upon information and belief, Sun is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

JURISDICTION

11. This action arises under the patent laws of the United States, Title 35, United States Code. Subject matter jurisdiction is proper in this district pursuant to at least 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

12. This Court has personal jurisdiction over Sun. Sun is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Sun maintains continuous and systematic contacts with Delaware, including at least the following: Sun is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware at Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. It therefore has consented to general jurisdiction in Delaware. In addition, upon information and belief, Sun develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

13. Upon information and belief, this Court also has personal jurisdiction over Sun based on its generic drugs business activities. Sun "has taken the costly, significant step of applying to the FDA for approval to engage in future activities – including the marketing of its generic drugs – that will be purposefully directed at," on information and belief, the District of Delaware and elsewhere. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016). Upon information and belief, Sun's "ANDA filings constitute formal acts that reliably indicate

plans to engage in marketing of the proposed generic drugs." *Id.* at 760. Upon information and belief, Sun "intends to direct sales of its drugs into Delaware, among other places, once it has the requested FDA approval to market them." *Id.* at 758. Upon information and belief, Sun will engage in marketing of its proposed ANDA products in Delaware upon approval of its supplemental ANDA.

14. Upon information and belief, Sun intends that upon approval of Sun's supplemental ANDA, Sun will manufacture Sun's ANDA Product and will directly or indirectly market, sell, and distribute Sun's ANDA Product throughout the United States, including in Delaware.

15. Upon information and belief, Sun, with knowledge of the Hatch-Waxman Act process, directed Sun's Notice Letter to, *inter alia*, Plaintiff, and alleged in Sun's Notice Letter that the '893 patent is invalid and/or will not be infringed by the commercial manufacture, use, or sale of the Sun's ANDA Product. Upon information and belief, Sun knowingly and deliberately challenged the '893 patent knowing that when it did so that it was triggering a forty-five day period for Plaintiff to bring an action for patent infringement under the Hatch-Waxman Act.

16. Upon information and belief, if Sun's supplemental ANDA is approved, Sun will directly or indirectly manufacture, market, sell, and/or distribute Sun's ANDA Product within the United States, including in Delaware, consistent with Sun's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Sun's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies in Delaware, and used by patients in Delaware. Upon information and belief, each of these activities would have a substantial effect within Delaware and would constitute infringement of the '893 patent in the event that Sun's supplemental ANDA is approved before the patent expires.

17. Sun has filed numerous ANDAs, with 464 entries for various products listed on the Orange Book ("Sun Approved Drug Products"), and has received approval for the manufacture and sale of these drugs within the United States, including within Delaware.

18. Upon information and belief, Sun derives substantial revenue from the Sun Approved Drug Products that are used and/or consumed within Delaware, and which are manufactured by Sun and/or for which Sun is the named applicant on approved ANDAs.

19. For the foregoing reasons, this Court has personal jurisdiction over Sun.

VENUE

20. Venue is proper in this district for Sun pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE '893 PATENT

21. The inventors named on the '893 patent are Marcello Marchetti, Tommaso Iacoangeli, Giovanni Battista Ciottoli and Giuseppe Biondi (collectively, "the Named Inventors").

22. The '893 patent, entitled "Trazodone and Trazodone Hydrochloride in Purified Form," was duly and legally issued on March 13, 2012, to Angelini as assignee of the Named Inventors. A copy of the '893 patent is attached as **EXHIBIT A**.

23. The '893 patent claims, *inter alia*, trazodone or trazodone hydrochloride comprising less than 15 parts per million of alkylating substances, a pharmaceutical composition of trazodone hydrochloride, and a process of production of trazodone or trazodone hydrochloride.

24. Angelini is assignee of the '893 patent, and has the right to enforce the '893 patent.

25. DESYREL®, and methods of producing DESYREL®, are covered by one or more claims of the '893 patent.

26. The ’893 patent has been listed in connection with DESYREL® in the FDA’s publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is referred to as the “Orange Book.”

27. Plaintiff will be substantially and irreparably damaged by infringement of the ’893 patent because Angelini is the exclusive supplier of the active pharmaceutical ingredient in DESYREL®.

COUNT I – SUN’S INFRINGEMENT OF THE ’893 PATENT

28. Plaintiff incorporates each of the preceding paragraphs 1–27 as if fully set forth herein.

I. Direct Infringement

29. In Sun’s Notice Letter, Sun notified Plaintiff that it had submitted Sun’s supplemental ANDA to the FDA. The purpose of the submission of the ANDA was to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sun’s ANDA Product in the United States prior to the expiration ofthe patent-in-suit.

30. In its Notice Letter, Sun also notified Plaintiff that, as part of its supplemental ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv)(II) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(iv)(II), with respect to the ’893 patent.

31. Plaintiff has not been able to review Sun’s ANDA because the terms of Sun’s Offer of Confidential Access were unreasonable, containing restrictions comparable to those at issue in *Novartis Pharms. Corp. v. Alkem Lab’ys Ltd. (In re Entresto (Sacubitril/Valsartan) Patent Litig.)*, Civ. No. 20-md-2930-RGA, 2022 U.S. Dist. LEXIS 112796, at *15 (D. Del. June 27, 2022). The terms proposed by Sun “exceed [the terms and conditions] that usually apply under a protective

order." *In re Cyclobenzaprine Hydrochloride Extended-Releases Capsule Patent Litig.*, 893 F. Supp. 2d 409, 413 (D. Del. 2010).

32. In its Notice Letter, Sun only asserts non-infringement as to Claims 9-27 of the '893 patent. Because Sun does not assert non-infringement as to Claims 1-8 of the '893 patent, upon information and belief, Angelini has a good faith belief that Sun's ANDA product infringes at least Claims 1-8 of the '893 patent, either literally or under the doctrine of equivalents.

33. Upon information and belief, Sun's supplemental ANDA is an application for a drug claimed in one or more claims of the '893 patent, including at least claim 1.

34. Upon information and belief, Sun has knowledge of the '893 patent.

35. Upon information and belief, Sun's submission of its supplemental ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product in the United States before the expiration of the '893 patent was an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its ANDA Product in the United States immediately and imminently upon approval of its supplemental ANDA.

37. Upon information and belief, the manufacture, use, sale, offer for sale, and/or importation of Sun's ANDA Product in the United States would infringe one or more claims of the '893 patent, including at least claim 1.

38. Upon information and belief, the manufacture, use, sale, offer for sale, and/or importation of Sun's ANDA Product in the United States in accordance with, and as directed by Sun's proposed product labeling would infringe one or more claims of the '893 patent, including at least claim 1.

II. Indirect Infringement: Contributory Infringement

39. Upon information and belief, for at least the following reasons, Sun plans and intends to, and will, actively indirectly infringe the ’893 patent when its supplemental ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

40. Upon information and belief, Sun knows that Sun’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’893 patent, that Sun’s ANDA Product is not a staple article or commodity of commerce, and that Sun’s ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sun plans and intends to, and will, contribute to infringement of the ’893 patent immediately and imminently upon approval of Sun’s supplemental ANDA.

41. Notwithstanding Sun’s knowledge of the claims of the ’893 patent, upon information and belief, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun’s ANDA Product with its product labeling upon FDA approval of Sun’s supplemental ANDA and prior to the expiration of the ’893 patent. Upon information and belief, Sun plans and intends to, and will, contribute to infringement of the ’893 patent immediately and imminently upon approval of Sun’s supplemental ANDA.

III. Indirect Infringement: Inducement of Infringement

42. Upon information and belief, Sun knows that Sun’s ANDA Product will induce the direct infringement of the ’893 patent by a number of direct infringers, including, but not limited to Sun’s customers, distributors, affiliates, employees and manufacturers. Upon information and belief, Sun plans and intends to, and will, induce others to directly infringe the ’893 patent immediately and imminently upon approval of Sun’s supplemental ANDA and expiration of any other Orange Book-listed patent or relevant exclusivity for the DESYREL® product.

43. Upon information and belief, notwithstanding Sun's knowledge of the claims of the '893 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product in the United States with its product labeling upon FDA approval of Sun's supplemental ANDA and prior to the expiration of the '893 patent, with the knowledge that such activities will induce direct infringement of the '893 patent by others.

44. Upon information and belief, the foregoing actions by Sun, with Sun's knowledge detailed above, constitute and/or will constitute infringement of the '893 patent; active inducement of infringement of the '893 patent; and/or contribution to the infringement by others of the '893 patent.

45. Upon information and belief, Sun has acted with full knowledge of the '893 patent and without a reasonable basis for believing that it would not be liable for infringement of the '893 patent; active inducement of infringement of the '893 patent; and/or contribution to the infringement by others of the '893 patent.

46. Unless Sun is enjoined from infringing the '893 patent, actively inducing infringement of the '893 patent, and contributing to the infringement by others of the '893 patent, Plaintiff will suffer irreparable injury because Plaintiff is the exclusive supplier of the active pharmaceutical ingredient covered by the '893 patent. Plaintiff has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT

BY SUN OF THE '893 PATENT

47. Plaintiff incorporates paragraphs 1–46 as if fully set forth herein.

48. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the

one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '893 patent.

49. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Sun's ANDA Product, or any other drug product which is covered by, or use of which is covered by one or more claims of the '893 patent, will infringe, induce the infringement of, or contribute to the infringement by others of, that patent.

50. Plaintiff will be irreparably harmed by the sale of Sun's ANDA Product because Plaintiff is the exclusive supplier to third parties that sell or plan to sell pharmaceutical drugs containing of the active pharmaceutical ingredient covered by the '893 patent.

WHEREFORE, Plaintiff requests the following relief:

(a) A judgment that each claim of the '893 patent has been infringed under 35 U.S.C. § 271(e)(2) by Sun's submission to the FDA of Sun's supplemental ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Sun's ANDA Product, or any other drug product that infringes or the use of which infringes one or more claims of the '893 patent, be not earlier than the latest of the expiration dates of the '893 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Sun, and all persons acting in concert with Sun, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun's ANDA Product, or any other drug product covered by or whose use is covered by one or more of the claims of the '893 patent, prior to the expiration of said patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Sun's ANDA Product, or any other drug product which is covered by or whose use is covered by one or more of the claims of the '893 patent, prior to its expiration, will infringe, induce the infringement of, and contribute to the infringement by others of, the '893 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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