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,	) Civil Action No. _____
v.	)
CROSSMEDIKA S.A.,	)
Defendant.	)

COMPLAINT

Plaintiff Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. ("Plaintiff"), 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 CrossMedika S.A. ("CrossMedika"), of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial use or sale of a generic version of DESYREL® (trazodone hydrochloride) in tablet form in doses of 50, 100, 150, and 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. CrossMedika notified Plaintiff, by letter dated either February 4, 2021 or February 9, 2021 (the exact date is handwritten and ambiguous) ("CrossMedika's Notice Letter") that it

had submitted to the FDA ANDA No. 211116 ("CrossMedika's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of its generic "trazodone hydrochloride tablets USP, 50 mg, 100 mg, 150 mg, and 300 mg" ("CrossMedika's ANDA Product") prior to the expiration of the '893 patent.

4. Plaintiff received CrossMedika's Notice Letter on February 12, 2021.

5. Upon information and belief, CrossMedika'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 CrossMedika claims is bioequivalent to DESYREL®.

6. Upon information and belief, CrossMedika submitted its ANDA to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '893 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of CrossMedika's ANDA Product.

PARTIES

7. Plaintiff Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. ("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. Plaintiff'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 CrossMedika is a corporation organized and existing under the laws of the Switzerland with its principal place of business at Centro

Insema, Manno, TI, 6928, Switzerland. Upon information and belief, CrossMedika is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, CrossMedika does not reside or have a place of business in the United States.

JURISDICTION

11. 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 CrossMedika. CrossMedika is subject to personal jurisdiction in Delaware because, among other things, it has engaged in the costly and significant step of filing an ANDA for the purpose of engaging in injury-causing and wrongful marketing of the infringing CrossMedika ANDA Product in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 761 (Fed. Cir. 2016).

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

14. Upon information and belief, CrossMedika, with knowledge of the Hatch-Waxman Act process, directed CrossMedika's Notice Letter to, *inter alia*, Plaintiff, and alleged in CrossMedika's Notice Letter that the '893 patent is invalid and/or will not be infringed by the commercial manufacture, use or sale of the CrossMedika's ANDA Product. Upon information and belief, CrossMedika 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.

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

16. According to the Orange Book, CrossMedika has filed ANDAs with the FDA for the generic manufacture of at least mexiletine hydrochloride, moxifloxacin hydrochloride, trimipramine maleate, and vardenafil hydrochloride, and has received approval for the manufacture and sale of these drugs within the United States.

17. Upon information and belief, CrossMedika derives substantial revenue from at least mexiletine hydrochloride, moxifloxacin hydrochloride, trimipramine maleate, and vardenafil hydrochloride that are used and/or consumed within Delaware, and which are manufactured by CrossMedika and/or for which CrossMedika is the named applicant on approved ANDAs.

18. For the foregoing reasons, this Court has personal jurisdiction over CrossMedika.

VENUE

19. Venue is proper in this district for CrossMedika pursuant to 28 U.S.C. § 1391(c)(3) because, *inter alia*, as a nonresident of the United States, CrossMedika is properly subject to venue in any judicial district.

THE '893 PATENT

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

21. The '893 patent, entitled "Trazodone and Trazodone Hydrochloride in Purified Form," was duly and legally issued on March 12, 2012, to Angelini as assignee of the Named Inventors. A copy of the '893 patent is attached as **EXHIBIT A**.

22. 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.

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

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

25. 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."

26. 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 – CROSSMEDIKA'S INFRINGEMENT OF THE '893 PATENT

27. Plaintiff incorporates each of the preceding paragraphs 1–26 as if fully set forth herein.

I. Direct Infringement

28. In CrossMedika's Notice Letter, CrossMedika notified Plaintiff that it had submitted CrossMedika's 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 CrossMedika's ANDA Product in the United States prior to the expiration of the patent-in-suit.

29. In its Notice Letter, CrossMedika also notified Plaintiff that, as part of its ANDA, CrossMedika had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '893 patent.

30. CrossMedika's ANDA is an application for a drug claimed in one or more claims of the '893 patent, including at least claim 1.

31. CrossMedika has knowledge of the '893 patent.

32. CrossMedika's submission of its 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).

33. Upon information and belief, CrossMedika 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 ANDA and expiration of any other Orange Book-listed patent or relevant exclusivity for the DESYREL® product.

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

35. Upon information and belief, the manufacture, use, sale, offer for sale, and/or

importation of CrossMedika's ANDA Product in the United States in accordance with, and as directed by CrossMedika's proposed product labeling would infringe one or more claims of the '893 patent, including at least claim 1.

II. Indirect Infringement: Contributory Infringement

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

37. Upon information and belief, CrossMedika knows that CrossMedika's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '893 patent, that CrossMedika's ANDA Product is not a staple article or commodity of commerce, and that CrossMedika's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, CrossMedika plans and intends to, and will, contribute to infringement of the '893 patent immediately and imminently upon approval of CrossMedika's ANDA and expiration of any other Orange Book-listed patent or relevant exclusivity for the DESYREL® product.

38. Notwithstanding CrossMedika's knowledge of the claims of the '893 patent, CrossMedika has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import CrossMedika's ANDA Product with its product labeling upon FDA approval of CrossMedika's ANDA and prior to the expiration of the '893 patent.

III. Indirect Infringement: Inducement of Infringement

39. Upon information and belief, CrossMedika knows that CrossMedika's ANDA Product will induce the direct infringement of the '893 patent by a number of direct infringers, including, but not limited to CrossMedika's customers, distributors, affiliates, employees and

manufacturers. Upon information and belief, CrossMedika plans and intends to, and will, induce others to directly infringe the '893 patent immediately and imminently upon approval of CrossMedika's ANDA and expiration of any other Orange Book-listed patent or relevant exclusivity for the DESYREL® product.

40. Notwithstanding CrossMedika's knowledge of the claims of the '893 patent, CrossMedika has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import CrossMedika's ANDA Product in the United States with its product labeling upon FDA approval of CrossMedika's 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.

41. The foregoing actions by CrossMedika, with CrossMedika'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.

42. Upon information and belief, CrossMedika 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.

43. Unless CrossMedika 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 CROSSMEDIKA OF THE '893 PATENT

44. Plaintiff incorporates paragraphs 1–43 as if fully set forth herein.

45. 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 CrossMedika on the other regarding CrossMedika's infringement, active inducement of infringement, and contribution to the infringement by others of the '893 patent.

46. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of CrossMedika'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.

47. Plaintiff will be irreparably harmed by the sale of CrossMedika'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 CrossMedika's submission to the FDA of CrossMedika's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of CrossMedika'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 CrossMedika, and all persons acting in concert with CrossMedika, from the commercial manufacture, use, sale, offer for sale,

or importation into the United States of CrossMedika'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 CrossMedika'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.

Respectfully submitted,

Dated: March 26, 2021

YOUNG CONAWAY STARGATT & TAYLOR LLP

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