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. GRANULES INDIA LIMITED, Defendant.	Civil Action No. _____

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 Granules India Limited ("Granules India"), 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. Granules India notified Plaintiff, by letter dated Friday, December 8, 2023 ("Granules India's Notice Letter") that it had submitted to the FDA ANDA No. 218988 ("Granules India's ANDA"), seeking approval from the FDA to engage in the commercial

manufacture, use and/or sale of its generic Trazodone Hydrochloride tablets, 50 mg, 100 mg, 150 mg, and 300 mg ("Granule India's ANDA Product") prior to the expiration of the '893 patent.

4. Granule India's Notice Letter was delivered to Plaintiff's representative on Monday, December 11, 2023.

5. Upon information and belief, Granule India'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 Granules India claims is bioequivalent to DESYREL®.

6. Upon information and belief, Granules India 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 or will not be infringed by the manufacture, use, or sale of Granules India's ANDA Product.

7. This action was commenced by Plaintiff within 45 days of the date of receipt of the Granules India Notice Letter.

PARTIES

8. 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.

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 Granules India is a corporation organized under the laws of India, with an address and principal place of business of 2nd Floor, 3rd Block, My Home Hub, Madhapur, Hyderabad 500 081(TG), India. Upon information and belief,

Granules India is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

11. Upon information and belief, Granules does not reside or have a place of business in the United States, but does have two subsidiaries located in the United States, Granules USA, Inc. ("GUSA"), and Granules Pharmaceuticals, Inc. ("Granules Pharma").

12. Upon information and belief, GUSA is incorporated in Delaware, with a principal place of business located at 35 Waterview Blvd., Parsippany, NJ 07054.

13. Upon information and belief, Granules Pharma is incorporated in Delaware, with a principal place of business located at 3701 Concorde Parkway, Chantilly, VA 20151.

JURISDICTION

14. This is a litigation arising under the Patent Laws of the United States, 35 U.S.C. § 101, *et seq.*, seeking a finding of and declaratory judgment of patent infringement pursuant to 35 U.S.C. § 271(e)(2). Subject matter jurisdiction is proper in this district pursuant to at least 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

15. Upon information and belief, this Court has personal jurisdiction over Granules India. Granules India "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, Granules India'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, Granules India "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, Granules India will engage in marketing of its proposed ANDA products in Delaware upon approval of its ANDA.

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

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

18. Upon information and belief, if Granules India's ANDA is approved, Granules India will directly or indirectly manufacture, market, sell, and/or distribute Granules India's ANDA Product within the United States, including in Delaware, consistent with Granules India's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Granules India'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 Granules India's ANDA is approved before the patent expires.

19. According to the Orange Book, Granules India has filed ANDAs with the FDA for the generic manufacture of at least esomeprazole magnesium, gabapentin, losartan potassium and hydrochlorothiazide, ibuprofen, levetiracetam, losartan potassium, metformin hydrochloride, methocarbamol, metoprolol succinate, naproxen, pantoprazole sodium, potassium chloride, sertraline hydrochloride, venlafaxine hydrochloride, zonisamide, and acetaminophen ("Granules India Approved Drug Products"), and has received approval for the manufacture and sale of these drugs within the United States.

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

21. Upon information and belief, Granules India maintains continuous and systematic contacts with Delaware through its U.S. subsidiaries, GUSA and Granules Pharma, which are both incorporated in Delaware.

22. 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. Because Angelini Pharma, Inc. is a Delaware corporation, Angelini experienced legally cognizable injuries in Delaware upon the filing of Granules India's ANDA.

23. In the alternative, this Court has jurisdiction over Granules India under Rule 4(k)(2) of the Federal Rules of Civil Procedure because, upon information and belief, Plaintiff's claims arise under federal law; Granules India is organized under the laws of India and is therefore a foreign defendant and therefore not subject to personal jurisdiction in the courts of any state; and Granules India has sufficient contacts with the United States as a whole, including, but not

limited to, filing ANDAs with the FDA, selling generic pharmaceuticals throughout the United States, and maintaining its United States-based subsidiaries, GUSA and Granules Pharma.

24. For the foregoing reasons, this Court has personal jurisdiction over Granules India.

VENUE

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

THE '893 PATENT

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

27. 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**.

28. 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.

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

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

31. 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."

32. 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 – GRANULES INDIA'S INFRINGEMENT OF THE '893 PATENT

33. Plaintiff incorporates each of the preceding paragraphs 1–32 as if fully set forth herein.

I. Direct Infringement

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

35. In its Notice Letter, Granules India also notified Plaintiff that, as part of its ANDA, Granules India 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.

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

37. Upon information and belief, Granules India has knowledge of the '893 patent.

38. Upon information and belief, Granules India'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).

39. Upon information and belief, Granules India 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 prior to the expiration of any other Orange Book-listed patent or relevant exclusivity for the DESYREL® product.

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

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

II. Indirect Infringement: Contributory Infringement

42. Upon information and belief, for at least the following reasons, Granules India 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.

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

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

III. Indirect Infringement: Inducement of Infringement

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

46. Upon information and belief, notwithstanding Granules India's knowledge of the claims of the '893 patent, Granules India has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Granules India's ANDA Product in the United States with its product labeling upon FDA approval of Granules India'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.

47. Upon information and belief, the foregoing actions by Granules India, with Granule India'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.

48. Upon information and belief, Granules India 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.

49. Unless Granules India 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 GRANULES INDIA OF THE '893 PATENT

50. Plaintiff incorporates paragraphs 1–49 as if fully set forth herein.

51. 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 Granules India on the other regarding Granules India's infringement, active inducement of infringement, and contribution to the infringement by others of the '893 patent.

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

53. Plaintiff will be irreparably harmed by the sale of Granules India'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 Granules India's submission to the FDA of Granules India's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Granules India'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 Granules India, and all persons acting in concert with Granules India, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Granules India 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 Granules India'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.

DATED: January 22, 2024

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