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. GRAVITI PHARMACEUTICALS PRIVATE LIMITED, Defendant.	Civil Action No. _____

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 Graviti Pharmaceuticals Private Limited ("Graviti"), 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. Graviti notified Plaintiff, by letter dated December 5, 2022 ("Graviti's Notice Letter") that it had submitted to the FDA ANDA No. 217740 ("Graviti'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" ("Graviti's ANDA Product") prior to the expiration of the '893 patent.

4. Graviti's Notice Letter was delivered to Plaintiff on December 7, 2022.

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

6. Upon information and belief, Graviti 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 Graviti'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 Graviti is a corporation organized under the laws of India, with an address of Survey No. 621/E & 621/EE, Isnapur Village, Patancheru Mandal, Sangareddy, Telangana 502307, India. Upon information and belief, Graviti's corporate office is located at Plot Number 64, Nagarjuna Hills, Panjagutta, Hyderabad -500 084. Telangana,

India. Upon information and belief, Graviti 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, Graviti does not reside or have a place of business in the United States, but does have a wholly owned subsidiary, Graviti Pharmaceuticals, Inc., which is a Delaware corporation.

JURISDICTION

12. Subject matter jurisdiction is proper in this district pursuant to at least 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

13. This Court has jurisdiction over Graviti under Rule 4(k)(2) of the Federal Rules of Civil Procedure because, upon information and belief, Graviti is organized under the laws of India.

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

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

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

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

18. According to the Orange Book, Graviti has filed ANDAs with the FDA for the generic manufacture of at least atorvastatin calcium, bupropion hydrochloride, fenofibric acid, clopidogrel bisulfate, escitalopram oxalate, esomeprazole magnesium, fenofibrate, furosemide, montelukast sodium, ranolazine, solifenacin succinate, tramadol hydrochloride and

acetaminophen, and tramadol hydrochloride ("Graviti Approved Drug Products"), and has received approval for the manufacture and sale of these drugs within the United States.

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

20. Upon information and belief, Graviti maintains continuous and systematic contacts with Delaware through its U.S. subsidiary Graviti Pharmaceuticals Inc., which is incorporated in Delaware.

21. For the foregoing reasons, this Court has personal jurisdiction over Graviti.

VENUE

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

THE '893 PATENT

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

24. 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**.

25. 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.

26. Angelini is assignee of the ’893 patent, and has the right to enforce the ’893 patent.

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

28. 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.”

29. 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 – GRAVITI’S INFRINGEMENT OF THE ’893 PATENT

30. Plaintiff incorporates each of the preceding paragraphs 1–29 as if fully set forth herein.

I. Direct Infringement

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

32. In its Notice Letter, Graviti also notified Plaintiff that, as part of its ANDA, Graviti 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.

33. Plaintiff has not been able to review Graviti’s ANDA because the terms of Graviti’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 Graviti "exceed [the terms and conditions] that usually apply under a protective order." *In re Cyclobensaprine Hydrochloride Extended-Releases Capsule Patent Litig.*, 893 F. Supp. 2d 409, 413 (D. Del. 2010).

34. Angelini provided Graviti with a Counter Proposal, containing terms similar to those agreed to in other ANDA litigations, but Graviti has not agreed to the terms contained in the Counter Proposal. Upon information and belief, Angelini nevertheless has a good faith belief that Graviti's ANDA product infringes the '893 patent, either literally or under the doctrine of equivalents.

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

36. Upon information and belief, Graviti has knowledge of the '893 patent.

37. Upon information and belief, Graviti'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).

38. Upon information and belief, Graviti 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.

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

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

II. Indirect Infringement: Contributory Infringement

41. Upon information and belief, for at least the following reasons, Graviti 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.

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

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

III. Indirect Infringement: Inducement of Infringement

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

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

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

46. Upon information and belief, the foregoing actions by Graviti, with Graviti'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.

47. Upon information and belief, Graviti 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.

48. Unless Graviti 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 GRAVITI OF THE '893 PATENT

49. Plaintiff incorporates paragraphs 1–48 as if fully set forth herein.

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

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

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

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Graviti'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 Graviti, and all persons acting in concert with Graviti, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Graviti'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 Graviti'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 20, 2023

YOUNG CONAWAY STARGATT & TAYLOR,LLP

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