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Attorneys for Plaintiff
Azurity Pharmaceuticals, Inc.

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

Azurity Pharmaceuticals, Inc.,

Civil Action No.: _____

Plaintiff,

vs.

MSN Pharmaceuticals Inc. and
MSN Laboratories Pvt. Ltd.,

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Azurity Pharmaceuticals, Inc. (“Azurity”), by and through its attorneys, brings this Complaint for Patent Infringement against Defendants MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. (“Defendants”), and alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 11,324,696 (the “’696 Patent”) and 11,446,246 (the “’246 Patent”) (collectively, the “Patents-in-Suit”), arising under the patent laws of the United States, Title 35, United States Code.
2. By letter dated “June XX, 2025” (“Defendants’ Notice Letter”), Defendants notified Azurity that they submitted Abbreviated New Drug Application (“ANDA”) No. 220553 to the U.S. Food and Drug Administration (“FDA”) under § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act (“FDCA”) (21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1)) seeking approval to engage in the commercial manufacture, use, and sale of a generic version of Azurity’s FLEQSUVY® product (the “ANDA Product”) before the expiration of the ’696 and ’246 Patents.
3. This action arises out of the filing by Defendants of ANDA No. 220553 with FDA seeking approval to market a generic version of Azurity’s

oral suspension formulation that is the subject of New Drug Application (“NDA”) No. 215602, hereinafter referred to as Azurity’s FLEQSUVY® product. Azurity seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100 et. seq., and other applicable laws for Defendants’ infringement of the Patents-in-Suit.

THE PARTIES

4. Plaintiff Azurity is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn, Massachusetts 01801.

5. On information and belief, Defendant MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware and is registered to conduct business in the State of New Jersey, with a principal place of business at 20 Duke Road, Piscataway NJ 08854.

6. Upon information and belief, Defendant MSN Laboratories Pvt. Ltd. is a private limited company organized and existing under the laws of India, having a principal place of business at MSN House, Plot No. C 24, Industrial Estate, Sanath Nagar, Hyderabad, Telangana, 500018, IN.

7. Upon information and belief, Defendants are in the business of, among other things, developing, manufacturing, and selling generic copies of branded pharmaceutical products for the United States market.

8. On information and belief, MSN Pharmaceuticals Inc. is a wholly owned subsidiary of MSN Laboratories Pvt. Ltd. and is controlled and/or dominated by MSN Laboratories Pvt. Ltd. On information and belief, MSN Laboratories Pvt. Ltd. established MSN Pharmaceuticals Inc. for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district. On information and belief, MSN Pharmaceuticals Inc. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

9. Upon information and belief, MSN Pharmaceuticals Inc. is the U.S. agent for MSN Laboratories Pvt. Ltd.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq.* and from Defendants' submission of ANDA No. 220553.

11. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a). Relief is sought under 35 U.S.C. § 271(e)(2).

12. On information and belief, this Court has personal jurisdiction over MSN Pharmaceuticals Inc. under the New Jersey state long arm statute and

consistent with due process of law, because MSN Pharmaceuticals Inc. maintains its principal place of business in New Jersey.

13. On information and belief, this Court has personal jurisdiction over MSN Laboratories Pvt. Ltd. under the New Jersey state long arm statute and consistent with due process of law because MSN Laboratories Pvt. Ltd. has extensive contacts with the State of New Jersey and regularly does business in this judicial district, including through its subsidiary MSN Pharmaceuticals Inc.

14. Defendants have previously availed themselves of the legal protections of the State of New Jersey by, among other things, selecting the State of New Jersey as the principal place of business for MSN Pharmaceuticals Inc., consenting to jurisdiction in this judicial district, and/or pursuing counterclaims in this judicial district. *E.g., American Regent, Inc. v. MSN Laboratories Private Limited et al.*, Civil Action No. 24-10674 (D.N.J.) (MSN Laboratories Pvt. Ltd. and MSN Pharmaceuticals Inc. did not contest personal jurisdiction and asserted counterclaims); *Esperion Therapeutics, Inc. v. MSN Pharmaceuticals Inc. et al.*, Civil Action No. 24-06386 (D.N.J.) (same); *AbbVie Inc. et al. v. MSN Pharmaceuticals Inc. et al.*, Civil Action No. 24-04662 (D.N.J.) (same).

15. On information and belief, MSN Pharmaceuticals Inc. is registered to do business in the State of New Jersey under Entity Identification Number 040062779 and registered as a “Manufacturer and Wholesaler” within New

Jersey's Department of Health under Registration No. 5006107. Moreover, on information and belief, MSN Pharmaceuticals Inc. has appointed a registered agent in New Jersey for the receipt of service of process. Defendants' Notice Letter fails to comply with 21 C.F.R. § 314.95(c)(9), which required MSN Laboratories Pvt. Ltd, an entity that does not reside or have a place of business in the United States, to include the name and address of an agent in the United States authorized to accept service of process.

16. On information and belief, Defendants are subject to personal jurisdiction in New Jersey because they regularly and continuously transact business in New Jersey, including by directly or indirectly through one or more agents, developing, manufacturing, marketing, and selling generic pharmaceutical products in New Jersey. On information and belief, Defendants derive substantial revenue from the sale of those products in New Jersey and have availed themselves of the privilege of conducting business within New Jersey.

17. On information and belief, consistent with their past practices, MSN Laboratories Pvt. Ltd. and MSN Pharmaceuticals Inc. acted collaboratively in the preparation and submission of ANDA No. 220553.

18. In the alternative, this Court has personal jurisdiction over MSN Laboratories Pvt. Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Azurity's claims arise under federal law; (b) MSN

Laboratories Pvt. Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) MSN Laboratories Pvt. Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to FDA and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over MSN Laboratories Pvt. Ltd. satisfies due process.

19. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because MSN Pharmaceuticals Inc. has its principal place of business in the State of New Jersey. MSN Laboratories Pvt. Ltd. is a foreign company not residing in any United States judicial district and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

AZURITY'S FLEQSUHVY® PRODUCT

20. Azurity's FLEQSUHVY® product is an FDA-approved gamma-aminobutyric acid (GABA-ergic) agonist indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. FLEQSUHVY® may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

21. Azurity owns NDA No. 215602.

PATENTS-IN-SUIT

22. The '696 Patent, entitled "Suspensions and Diluents for Metronidazole and Baclofen," was duly and legally issued on May 10, 2022. A true and correct copy of the '696 Patent is attached to the Complaint as Exhibit A. Azurity is the assignee of the '696 Patent.

23. Pursuant to 21 U.S.C. § 355, the '696 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), in connection with Azurity's FLEQSUVY® product. Azurity's FLEQSUVY® product is covered by at least one claim of the '696 Patent.

24. The '246 Patent, entitled "Suspensions and Diluents for Metronidazole and Baclofen," was duly and legally issued on September 20, 2022. A true and correct copy of the '246 Patent is attached to the Complaint as Exhibit B. Azurity is the assignee of the '246 Patent.

25. Pursuant to 21 U.S.C. § 355, the '246 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), in connection with Azurity's FLEQSUVY® product. Azurity's FLEQSUVY® product is covered by at least one claim of the '246 Patent.

INFRINGEMENT BY DEFENDANTS

26. Defendants notified Azurity by Defendants' Notice Letter that they had submitted ANDA No. 220553 to FDA under Section 505(j)(2)(B) of the

FDCA (21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. §314.95) seeking approval to engage in the commercial manufacture, use, and sale of the ANDA Product before expiration of the '696 and '246 Patents.

27. The '696 Patent expires on September 29, 2037 and the '246 Patent expires on September 8, 2037.

28. Upon information and belief, Defendants intend to engage in commercial manufacture, use, and sale of the ANDA Product promptly upon receiving FDA approval to do so.

29. Upon information and belief, Defendants are seeking approval to engage in the commercial manufacture, use, and sale of the ANDA Product before expiration of the Patents-in-Suit.

30. By filing ANDA No. 220553, Defendants have necessarily represented to FDA that the ANDA Product has the same active ingredients as Azurity's FLEQSUVY® product and is bioequivalent to Azurity's FLEQSUVY® product.

31. Defendants' Notice Letter contained an offer of confidential access ("Offer") to "certain information" (without specifying what information) in ANDA No. 220553. Defendants required that Azurity accept the Offer before receiving access to any portion of ANDA No. 220553.

32. The Offer contains unreasonable restrictions that differ materially from standard terms of protective orders entered in this jurisdiction. Under New Jersey Local Patent Rule 2.2, “Discovery cannot be withheld or delayed on the basis of confidentiality absent a Court order.” Moreover, Defendants’ Offer contains restrictions in excess of the use restriction contemplated by the Local Patent Rules for discovery prior to entry of a confidentiality order. *Id.*

33. For example, the Offer requires that any person that accesses the unspecified, partial ANDA information never “engage, formally or informally, in . . . any FDA counseling, litigation, regulatory approval, citizen petition, or other work before or involving the FDA relating to baclofen” for all time. Such unreasonable bars on FDA work as conditions of access to confidential information are routinely rejected by Courts. *E.g., Vivus, Inc. v. Actavis Lab’ys FL, Inc.*, No. 14-CV-3786 (SRC)(CLW), 2016 WL 590212, at *2, *5 (D.N.J. Feb. 11, 2016) (finding “[t]he general possibility of the unintentional use of confidential information in subsequent FDA-or patent-related proceedings is insufficient to overcome the real prejudice that Actavis’ bars impose upon Vivus,” and noting, *inter alia*, “duration of the bar,” must “reasonably reflect the risk presented by the disclosure of proprietary confidential information”); *Avion Pharms., LLC v. Granules Pharms., Inc.*, No. 20-898-LPS, 2021 WL 1785580, at *3 (D. Del. May 5, 2021) (explaining, “[b]ecause there is little risk of ‘inadvertent’ disclosure of

confidential materials to the FDA, requests for regulatory bars are routinely denied in this district”); *Ultragenyx Pharm. Inc. v. Navinta LLC*, No. 24-9483 (ES) (MAH), 2025 WL 1587961, at *4 (D.N.J. June 5, 2025) (“Following the Federal Circuit’s lead in *Deutsche Bank*, courts within the District of New Jersey and Third Circuit have consistently rejected patent-prosecution bars that pose such burdens on a patent litigant.”) (citing, *inter alia*, *Avion Pharms.*, 2021 WL 1785580 at *2).

34. As another example of similarly unreasonable restrictions, the Offer requires that any person that accesses the unspecified, partial ANDA information never “engage, formally or informally, in patent prosecution (including, without limitation, participation or consultation in prosecution of future or pending patent applications, reexaminations, reissues, or patent review proceedings) concerning baclofen” for all time. “[I]nformation designated to trigger the bar, the scope of activities prohibited by the bar, the duration of the bar, and the subject matter covered by the bar” must “reasonably reflect the risk presented by the disclosure of proprietary competitive information.” *Vivus, Inc.*, 2016 WL 590212 at *2 (citing *In re Deutsche Bank Tr. Co. Americas*, 605 F.3d 1373, 1381 (Fed. Cir. 2010); *see also Ultragenyx*, 2025 WL 1587961 at *4 (“[C]ourts within the District of New Jersey and Third Circuit have consistently rejected patent-prosecution bars that pose such burdens on a patent litigant.” (citing *In re Deutsche Bank*, 605 F.3d at 1380-81)).

35. In view of the unreasonable terms of Defendants' Offer, Azurity asked if Defendants were amenable to negotiating to reach reasonable terms regarding confidential access to Defendants' ANDA. As of the filing of this Complaint, the parties have not been able to reach an agreement.

36. To date, Defendants have not provided Azurity with access to any portion of ANDA No. 220553 or any information regarding the ANDA Product, beyond the sparse and incomplete information in Defendants' Notice Letter.

37. Defendants' Notice Letter provides no information about the content of the ANDA Product. Rather, Defendants' Notice Letter only states without support that the ANDA Product "does not meet . . . required limitations of the claims of the '696 and '246 patents." That conclusory statement does not demonstrate that the ANDA Product will not infringe at least one of the issued claims of the Patents-in-Suit.

38. This action was commenced within 45 days of Azurity receiving Defendants' Notice Letter.

CLAIMS FOR RELIEF

Count I — Infringement of the '696 Patent Under U.S.C. § 271 (e)(2)(A)

39. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

40. Defendants' submission of ANDA No. 220553 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the ANDA Product throughout the United States. By submitting the ANDA, Defendants have committed an act of infringement of the '696 Patent under 35 U.S.C. § 271(e)(2)(A).

41. On information and belief, if Defendants' ANDA is approved by FDA, the commercial manufacture, use (in accordance with and as directed by Defendants' proposed labeling for the ANDA Product), offer to sell, or sale within the United States, and/or importation into the United States of the ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '696 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

42. Upon information and belief, Defendants had actual and constructive knowledge of the '696 Patent prior to filing ANDA No. 220553 and was aware that filing this ANDA with FDA constituted an act of infringement of the '696 Patent. In addition, upon information and belief, Defendants had specific intent to infringe the '696 Patent when they filed ANDA No. 220553. Moreover, there are no substantial non-infringing uses for the ANDA Product other than as the pharmaceutical composition claimed in the '696 Patent.

43. The commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product in violation of Azurity's patent rights will cause irreparable harm to Azurity for which damages are inadequate.

Count II — Infringement by Defendants of U.S. Patent No. 11,446,246

44. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

45. Defendants' submission of ANDA No. 220553 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the ANDA Product throughout the United States. By submitting the ANDA, Defendants have committed an act of infringement of the '246 Patent under 35 U.S.C. § 271(e)(2)(A).

46. On information and belief, if Defendants' ANDA is approved by FDA, the commercial manufacture, use (in accordance with and as directed by Defendants' proposed labeling for the ANDA Product), offer to sell, or sale within the United States, and/or importation into the United States of the ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '246 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

47. Upon information and belief, Defendants had actual and constructive knowledge of the '246 Patent prior to filing ANDA No. 220553 and were aware

that filing this ANDA with FDA constituted an act of infringement of the '246 Patent. In addition, upon information and belief, Defendants had specific intent to infringe the '246 Patent when they filed ANDA No. 220553. Moreover, there are no substantial non-infringing uses for the ANDA Product other than the method of treatment using the pharmaceutical composition claimed in the '246 Patent.

48. The commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product in violation of Azurity's patent rights will cause irreparable harm to Azurity for which damages are inadequate.

PRAYER FOR RELIEF

Azurity respectfully requests the following relief:

- A. A judgment that Defendants have infringed one or more claims of the '696 and '246 Patents;
- B. A judgment ordering that the effective date of any FDA approval of ANDA No. 220553 shall be a date which is not earlier than the latest expiration date of the '696 and '246 Patents, as extended by any applicable periods of exclusivity;
- C. A preliminary and permanent injunction enjoining Defendants, their subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting

on their behalf, from engaging in the commercial manufacture, use, offer to sell, or importation into the United States, of any drug product covered by, or any drug product for which the use of the drug product is covered by the '696 and '246 Patents, including the ANDA Product;

- D. A judgment that the '696 and '246 Patents are valid and enforceable;
- E. A finding that this is an exceptional case under 35 U.S.C. § 285, and that Azurity be awarded reasonable attorneys' fees and costs; and
- F. An award of any such other and further relief as the Court may deem just and proper.

DATED: July 25, 2025

Respectfully submitted,

/s/ Wendi Opper Uzar

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Plaintiff Azurity Pharmaceuticals, Inc. hereby certify that this matter in controversy is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

DATED: July 25, 2025

Respectfully submitted,

/s/ Wendi Opper Uzar

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LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Plaintiff Azurity Pharmaceuticals, Inc. hereby certify that they seek both monetary damages greater than \$150,000 and injunctive and other equitable relief, and therefore this action is not appropriate for compulsory arbitration.

DATED: July 25, 2025

Respectfully submitted,

/s/ Wendi Opper Uzar

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CERTIFICATE OF SERVICE

I, Wendi Opper Uzar, hereby certify that on July 25, 2025, I caused a true and correct copy of the above document to be filed electronically and served as follows:

Via E-Mail

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DATED: July 25, 2025

Respectfully submitted,

/s/ Wendi Opper Uzar

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