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

JANSSEN PHARMACEUTICA NV, JANSSEN BIOTECH, INC., and ASTEX THERAPEUTICS LTD., Plaintiffs, v. NATCO PHARMA LTD., Defendant.	Civil Action No. _____ (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Pharmaceutica NV ("JPNV"), Janssen Biotech, Inc. ("JBI"), and Astex Therapeutics Ltd. ("Astex") (collectively, "Plaintiffs") for their Complaint against Defendant Natco Pharma Limited ("Natco" or "Defendant"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.* This action relates to Abbreviated New Drug Application ("ANDA") No. 218578 filed by Natco with the United States Food and Drug Administration ("FDA"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic copies of BALVERSA® (erdafitinib) Tablets prior to the expiration of U.S. Patent No. 12,037,644 ("the '644 Patent") and U.S. Patent No. 10,478,494 ("the '494 Patent").

PARTIES

2. Plaintiff JPNV is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, B-2340, Beerse, Belgium. JPNV researches, develops, and manufactures innovative pharmaceutical products. JPNV is a wholly owned subsidiary of Johnson & Johnson. JPNV is the assignee of and owns the '644 Patent. Additionally, JPNV is engaged in the development and commercialization of BALVERSA® (erdafitinib) Tablets, and JPNV participates in the flow of proceeds from U.S. sales of BALVERSA® (erdafitinib) Tablets.

3. Plaintiff JBI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 800/850 Ridgeview Drive, Horsham, Pennsylvania 19044. JBI harnesses innovations in large-molecule and small-molecule research to create important new therapeutic options. Like JPNV, JBI is a wholly owned subsidiary of Johnson & Johnson. JBI holds New Drug Application ("NDA") No. 212018 for BALVERSA® (erdafitinib) Tablets. Additionally, JBI is engaged in the distribution of BALVERSA® (erdafitinib) Tablets, and JBI participates in the flow of proceeds from U.S. sales

of BALVERSA® (erdafitinib) Tablets.

4. Plaintiff Astex is a company organized and existing under the laws of England and Wales, with its principal place of business at 436 Cambridge Science Park, Cambridge, CB4 0QA, United Kingdom. Astex is a leader in innovative drug discovery and development, committed to the fight against cancer and diseases of the central nervous system. Astex is a wholly owned subsidiary of Otsuka America, Inc., which is wholly owned by Otsuka Pharmaceutical Co., Ltd. Otsuka Holdings Co., Ltd. is the holding company of Otsuka Pharmaceutical Co., Ltd. Astex is the assignee of and owns the '494 Patent. Additionally, Astex participates in the flow of proceeds from U.S. sales of BALVERSA® (erdafitinib) Tablets.

5. On information and belief, Defendant Natco is a company organized and existing under the laws of the Republic of India with a principal place of business at Natco House Road No. 2, Banjara Hills, Hyderabad – 500 034, India. Natco has appointed Timothy G. Gearity, CPA, 185 Park Avenue, Rutherford, NJ 07070-2344 as its registered agent for service of process in New Jersey. On information and belief, Natco is in the business of, among other things, developing, manufacturing, importing, marketing, distributing, offering to sell, and/or selling generic copies of branded pharmaceutical products in New Jersey and throughout the United States, and obtaining regulatory approval for generic pharmaceutical products that it markets, distributes, offers to sell, and/or sells in New Jersey and throughout the United States.

JURISDICTION AND VENUE

6. This action for patent infringement arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq.*

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. *See also Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*,

887 F.3d 1117, 1123–25 (Fed. Cir. 2018); *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, No. 12-3289, 2013 WL 591976, at *3–4 (D.N.J. Feb. 14, 2013).

8. Venue is proper in this Court under 28 U.S.C. § 1391(c)(3) because Natco is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including this District.

9. Additionally, Natco has previously consented to venue in this jurisdiction in other patent actions brought against it based on its filing of an ANDA. *See, e.g.*, *Janssen Pharms. NV, et al. v. Natco Pharma Ltd.*, No. 2:23-cv-03959-JXN-JRA, at D.I. 17 (not contesting venue); *AstraZeneca Pharms. LP, et al. v. Natco Pharma Ltd.*, No. 3:23-cv-00796-RK-TJB, at D.I. 12 (same); *Janssen Prods., LP, et al. v. eVenus Pharms. Lab'ys Inc., et al.*, No. 1:20-cv-09369-FLW-ZNQ, at D.I. 23 (same); *Shire Dev. LLC, et al. v. Natco Pharma Ltd.*, No. 2:14-cv-07053-SRC-CLW, at D.I. 17 (same); *Celgene Corp. v. Natco Pharma Ltd., et al.*, No. 2:14-cv-03126-SDW-MCA, at D.I. 7 (same); *Celgene Corp. v. Natco Pharma Ltd., et al.*, No. 2:12-cv-04571-SDW-MCA, at D.I. 15 (same); *Gilead Scis., Inc., et al. v. Natco Pharma Ltd., et al.*, No. 2:11-cv-01455-SDW-MCA, at D.I. 24 (same); *Celgene Corp. v. Natco Pharma Ltd.*, No. 2:10-cv-05197-SDW-MCA, at D.I. 9 (same).

10. This Court has personal jurisdiction over Natco by virtue of its specific acts in, and its continuous and systematic contacts with, the State of New Jersey.

11. Specifically, this Court has personal jurisdiction over Natco by virtue of, among other things: (1) its substantial, continuous, and systematic contacts with New Jersey; (2) its acts of patent infringement that will result in foreseeable harm to Plaintiffs in New Jersey; (3) its sale of a substantial volume of pharmaceutical products in New Jersey; (4) its purposefully availing itself of the jurisdiction of this Court in the past; and (5) its appointment of a registered agent in

New Jersey for receipt of service of process.

12. Natco has purposefully availed itself of the benefits and protections of New Jersey's laws such that it would reasonably anticipate being haled into court here. On information and belief, Natco has sold a substantial volume of pharmaceutical products in New Jersey, including a substantial volume of generic pharmaceutical products. On information and belief, Natco conducts marketing and sales activities in the State of New Jersey, including but not limited to the systematic and continuous importation, distribution, marketing, offer for sale, and sale of pharmaceutical products, including generic pharmaceutical products, to New Jersey residents. On information and belief, Natco develops and manufactures pharmaceutical products, including generic pharmaceutical products, for importation into and marketing and sale within the United States, including the State of New Jersey. Therefore, Natco transacts business within the State of New Jersey and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

13. Further, Natco has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, including harm and injury in New Jersey. For example, on information and belief, Natco developed a generic copy of BALVERSA® (erdafitinib) Tablets, sought approval from the FDA to sell generic copies of BALVERSA® (erdafitinib) Tablets in New Jersey and throughout the United States, filed Natco's ANDA No. 218578, is actively preparing to make generic copies of BALVERSA® (erdafitinib) Tablets that are the subject of Natco's ANDA No. 218578, and is preparing to commercially manufacture, use, sell, offer to sell, and/or import such generic copies in this State and this Judicial District. Plaintiffs' claims for patent infringement arose as a result

of these acts and Natco sending the required notice of its ANDA filing.

14. Natco has previously submitted to the jurisdiction of this Court and asserted counterclaims in this jurisdiction. *See, e.g.*, *Janssen Pharms. NV, et al. v. Natco Pharma Ltd.*, No. 2:23-cv-03959-JXN-JRA, at D.I. 17 (asserting counterclaims and not contesting personal jurisdiction); *AstraZeneca Pharms. LP, et al. v. Natco Pharma Ltd.*, No. 3:23-cv-00796-RK-TJB, at D.I. 12 (same); *Janssen Prods., LP, et al. v. eVenus Pharms. Lab'ys Inc., et al.*, No. 1:20-cv-09369-FLW-ZNQ, at D.I. 23 (same); *Shire Dev. LLC, et al. v. Natco Pharma Ltd.*, No. 2:14-cv-07053-SRC-CLW, at D.I. 17 (same); *Celgene Corp. v. Natco Pharma Ltd., et al.*, No. 2:14-cv-03126-SDW-MCA, at D.I. 7 (same); *Celgene Corp. v. Natco Pharma Ltd., et al.*, No. 2:12-cv-04571-SDW-MCA, at D.I. 15 (same); *Gilead Scis., Inc., et al. v. Natco Pharma Ltd., et al.*, No. 2:11-cv-01455-SDW-MCA, at D.I. 24 (same); *Celgene Corp. v. Natco Pharma Ltd.*, No. 2:10-cv-05197-SDW-MCA, at D.I. 9 (same).

15. Additionally, this Court will have personal jurisdiction over Natco under Federal Rule of Civil Procedure 4(k) once Plaintiffs either serve a summons or file a waiver of service.

16. Litigating in the District of New Jersey would not burden Natco unduly. Among other things, Natco has consented to personal jurisdiction in the District of New Jersey. The United States has a substantial interest in adjudicating the dispute and enforcing its patent laws. Plaintiffs have a substantial interest in obtaining convenient and effective relief for violations of their property interests. In addition, the State of New Jersey has an interest in furthering the fundamental substantive policy of the United States with respect to its intellectual property laws.

17. For the above reasons, it would not be unfair or unreasonable for Natco to litigate this action in this District, and the Court has personal jurisdiction over Natco here.

PLAINTIFFS' BALVERSA® (ERDAFITINIB) TABLETS

18. Plaintiff JBI is the holder of New Drug Application ("NDA") No. 212018 that has been approved by the FDA for the manufacture and sale of BALVERSA® (erdafitinib) Tablets for oral use ("BALVERSA®" or the "BALVERSA® drug product").

19. BALVERSA® is approved by the FDA for the treatment of locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 genetic alterations and progressed during or following at least one line of prior systemic therapy.

20. Under NDA No. 212018, BALVERSA® is marketed in 3 mg, 4 mg, and 5 mg tablets.

THE PATENTS-IN-SUIT

The '644 Patent

21. On July 16, 2024, the United States Patent and Trademark Office duly and legally issued the '644 Patent, titled "Use of FGFR Mutant Gene Panels in Identifying Cancer Patients That Will Be Responsive to Treatment With an FGFR Inhibitor," naming Suso Jesus Platero and Jayaprakash Karkera as the inventors. A copy of the '644 Patent, with a Certificate of Correction issued October 22, 2024, is attached as Exhibit 1.

22. Plaintiff JPNV is the owner, by assignment, of the '644 Patent, and JPNV has the full right to sue and to recover for infringement of the '644 Patent.

23. Pursuant to 21 U.S.C. § 355(b)(1)(viii), the '644 Patent is listed in the FDA's publication, *Approved Drug Products with Therapeutic Equivalent Evaluations* (the "Orange Book") as covering BALVERSA®, which is the subject of approved NDA No. 212018.

24. Natco knows that the '644 Patent is listed in the Orange Book as covering BALVERSA®.

The ’494 Patent

25. On November 19, 2019, the United States Patent and Trademark Office duly and legally issued the ’494 Patent, titled “FGFR/PD-1 Combination Therapy for the Treatment of Cancer,” naming Jayaprakash Karkera, Suso Jesus Platero, Raluca Verona, and Matthew V. Lorenzi as the inventors. A copy of the ’494 Patent is attached as Exhibit 2.

26. Plaintiff Astex is the owner, by assignment, of the ’494 Patent, and plaintiff JPNV is the exclusive licensee of the ’494 Patent. Together, plaintiffs Astex and JPNV have the full right to sue and to recover for infringement of the ’494 Patent.

27. Pursuant to 21 U.S.C. § 355(b)(1)(viii), the ’494 Patent is listed in the Orange Book as covering BALVERSA®, which is the subject of approved NDA No. 212018.

28. Natco knows that the ’494 Patent is listed in the Orange Book as covering BALVERSA®.

NATCO’S ANDA SUBMISSION AND THE RELATED LITIGATION

29. This is a civil action for infringement of the ’644 and ’494 Patents.

30. By letter dated June 12, 2023 (the “First Natco Notice Letter”), Natco notified Plaintiffs that it had submitted ANDA No. 218578 (“Natco’s ANDA”) to the FDA for Natco’s erdafitinib oral tablet, 3 mg, 4 mg, and 5 mg (the “ANDA Product” or “Natco’s ANDA Product”), a drug product that is a generic copy of BALVERSA® (erdafitinib) Tablets. In the First Natco Notice Letter, Natco notified Plaintiffs that, as part of Natco’s ANDA, Natco had filed certifications of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) with respect to U.S. Patent No. 9,902,714 (“the ’714 Patent”) and U.S. Patent No. 11,077,106 (“the ’106 Patent”). Natco filed or caused to be filed Natco’s ANDA with the FDA, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or

importation of Natco's ANDA Product prior to the expiration of the '714 and '106 Patents.

31. A separate patent infringement action relating to the '714 and '106 Patents is pending in this judicial district between Plaintiffs and Natco: *Janssen Pharms. NV, et al. v. Natco Pharma Ltd.*, No. 2:23-cv-03959-JXN-JRA ("*Natco I*"). *Natco I* also arises from the submission of Natco's ANDA seeking approval to market a generic version of BALVERSA®.

32. By letter dated September 3, 2025 (the "Second Natco Notice Letter"), Natco notified Plaintiffs that it had submitted to the FDA in connection with ANDA No. 218578 a Paragraph IV Certification for the '644 Patent and a recertification relating to other patents, including the '106 Patent that is at issue in *Natco I* and is currently being litigated in *Natco I*.

33. In the Second Natco Notice Letter, Natco notified Plaintiffs that, as part of its ANDA No. 218578, Natco had filed a Paragraph IV Certification with respect to the '644 Patent. On information and belief, ANDA No. 218578 contains certification(s) pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '644 Patent is invalid and/or will not be infringed by the commercial manufacture, use, or sale of Natco's ANDA Product. On information and belief, Natco intends to seek permission from FDA to market the ANDA Product prior to expiration of the '644 Patent.

34. On information and belief, Natco has not filed a Paragraph IV Certification or a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III Certification") with respect to the '494 Patent. However, the '494 Patent is listed in the Orange Book as covering BALVERSA®, which is the subject of approved NDA No. 212018. On information and belief, Natco intends to seek permission from FDA to market the ANDA Product prior to expiration of the '494 Patent. Given Natco's submission of ANDA No. 218578, a Paragraph IV certification is not a prerequisite for Plaintiffs to assert their claims in this action. *See Vanda Pharm. Inc. v. W.-*

Ward Pharm. Int'l Ltd., 887 F.3d 1117, 1123–25 (Fed. Cir. 2018); *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, No. 12-3289, 2013 WL 591976, at *3–4 (D.N.J. Feb. 14, 2013).

35. On information and belief, Natco filed or caused to be filed Natco's ANDA with the FDA, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Natco's ANDA product prior to the expirations of the '644 and '494 Patents.

36. By filing or causing to be filed Natco's ANDA, Natco necessarily represented to the FDA that the ANDA Product has the same active ingredient, the same method of administration, the same dosage form, and the same strength as BALVERSA® and is bioequivalent to BALVERSA®.

37. On information and belief, if Natco's ANDA is approved by the FDA, Natco will, prior to the expiration of the '644 and '494 Patents, begin commercially manufacturing, using, selling, offering to sell, and/or importing Natco's ANDA Product.

38. On information and belief, if Natco's ANDA is approved by the FDA, Natco will, prior to the expiration of the '644 and '494 Patents, begin marketing Natco's ANDA Product for the treatment of locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 genetic alterations and progressed during or following at least one line of prior systemic therapy, and doctors and patients will use Natco's ANDA Product for the indications marketed by Natco.

39. On information and belief, Natco had knowledge of the '644 and '494 Patents at least as of the date when Natco submitted its Paragraph IV Certification with respect to the '644 Patent to the FDA in connection with Natco's ANDA.

40. Natco's submission of ANDA No. 218578 to the FDA seeking approval to market Natco's ANDA Product is an act of infringement by Natco of one or more claims of each of the

'644 and '494 Patents under 35 U.S.C. § 271(e)(2). This infringement entitles Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 218578 be a date which is not earlier than the expiration date of the last expiring of the '644 and '494 Patents, including any extensions of that date.

41. Natco's anticipated commercial manufacture, use, sale, offer for sale, and/or importation of Natco's ANDA Product will infringe one or more claims of the '644 and '494 Patents under 35 U.S.C. §§ 271(a), (b), and/or (c).

42. This action is being commenced within forty-five days from the date Plaintiffs received the Second Natco Notice Letter.

COUNT I: INFRINGEMENT OF THE '644 PATENT

43. Plaintiffs incorporate by reference each of the preceding paragraphs of this Complaint as if fully set forth herein.

44. On information and belief, the use and/or administration of Natco's ANDA Product is covered by one or more claims of the '644 Patent, including but not limited to claims 1-16, 19-21, and 23-25.

45. By filing or causing to be filed ANDA No. 218578 under 21 U.S.C. § 355(j) and submitting a Paragraph IV Certification regarding the '644 Patent in order to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Natco's ANDA Product before the expiration of the '644 Patent, Natco committed an act of infringement of one or more claims of the '644 Patent under 35 U.S.C. § 271(e)(2)(A).

46. If Natco commercially manufactures, uses, sells, and/or offers to sell the ANDA Product in the United States, and/or imports the ANDA Product into the United States, or

induces or contributes to any such conduct during the term of the ’644 Patent, Natco would further infringe the ’644 Patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

47. On information and belief, the use and/or administration of Natco’s ANDA Product, in accordance with and as directed by the proposed labeling for that product, before the expiration of the ’644 Patent, would infringe one or more claims of the ’644 Patent under 35 U.S.C. § 271(a), and if used or administered by another, Natco would be liable for inducing that infringement under 35 U.S.C. § 271(b).

48. By seeking approval to distribute the ANDA Product with, on information and belief, its proposed labeling, Natco intends to cause others, specifically medical professionals, to perform acts that Natco knows will infringe the ’644 Patent.

49. Unless enjoined by this Court, Natco intends to, and will, engage in the infringing commercial manufacture, use, sale, offer for sale, and/or importation of Natco’s ANDA Product immediately and imminently upon approval of Natco’s ANDA.

50. Unless enjoined by this Court, Natco intends to, and will, actively induce infringement of the ’644 Patent when Natco’s ANDA is approved, and intends to, and will do so, immediately and imminently upon approval of Natco’s ANDA.

51. Natco knows that Natco’s ANDA Product and, on information and belief, its proposed labeling are especially made or adapted for use in infringing the ’644 Patent, and that Natco’s ANDA Product and, on information and belief, its proposed labeling, are not suitable for substantial non-infringing use. Unless enjoined by this Court, Natco intends to, and will, contribute to the infringement of the ’644 Patent immediately and imminently upon approval of Natco’s ANDA.

52. Natco had knowledge of the ’644 Patent at least as of the date Natco submitted a

Paragraph IV Certification regarding the ’644 Patent and is knowingly infringing the ’644 Patent.

53. Natco acted without a reasonable basis for believing that it would not be liable for infringing the ’644 Patent, actively inducing infringement of the ’644 Patent, and/or contributing to the infringement of the ’644 Patent.

54. Unless Natco is enjoined from infringing the ’644 Patent, actively inducing infringement of the ’644 Patent, and/or contributing to the infringement of the ’644 Patent, Plaintiffs will suffer irreparable harm for which they have no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

55. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 218578 to be a date which is not earlier than the expiration date of the ’644 Patent, including any extensions of that date.

56. This case is “exceptional,” as that term is used in 35 U.S.C. § 285, and Plaintiffs are entitled to an award of their reasonable attorneys’ fees and expenses.

COUNT II: INFRINGEMENT OF THE ’494 PATENT

57. Plaintiffs incorporate by reference each of the preceding paragraphs of this Complaint as if fully set forth herein.

58. On information and belief, the use and/or administration of Natco’s ANDA Product is covered by one or more claims of the ’494 Patent, including but not limited to claims 1, 3–4, 6–7, 12, and 14–15.

59. By filing or causing to be filed ANDA No. 218578 under 21 U.S.C. § 355(j) in order to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of

Natco's ANDA Product before the expiration of the '494 Patent, which is listed in the Orange Book as covering BALVERSA®, Natco committed an act of infringement of one or more claims of the '494 Patent under 35 U.S.C. § 271(e)(2)(A). *See also Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1123–25 (Fed. Cir. 2018); *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, No. 12-3289, 2013 WL 591976, at *3–4 (D.N.J. Feb. 14, 2013).

60. If Natco commercially manufactures, uses, sells, or offers to sell the ANDA Product in the United States, or imports the ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '494 Patent, Natco would further infringe the '494 Patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

61. On information and belief, the use and/or administration of Natco's ANDA Product in accordance with and as directed by the proposed labeling for that product, before the expiration of the '494 Patent, would infringe one or more claims of the '494 Patent under 35 U.S.C. § 271(a), and if used or administered by another, Natco would be liable for inducing that infringement under 35 U.S.C. § 271(b).

62. By seeking approval to distribute the ANDA Product with, on information and belief, its proposed labeling, Natco intends to cause others, specifically medical professionals, to perform acts that Natco knows will infringe the '494 Patent.

63. Unless enjoined by this Court, Natco intends to, and will, engage in the infringing commercial manufacture, use, sale, offer for sale, and/or importation of Natco's ANDA Product immediately and imminently upon approval of Natco's ANDA.

64. Unless enjoined by this Court, Natco intends to, and will, actively induce infringement of the '494 Patent when Natco's ANDA is approved, and intends to, and will do so, immediately and imminently upon approval of Natco's ANDA.

65. Natco knows that Natco's ANDA Product and, on information and belief, its proposed labeling are especially made or adapted for use in infringing the '494 Patent, and that Natco's ANDA Product and, on information and belief, its proposed labeling are not suitable for substantial non-infringing use. Unless enjoined by this Court, Natco intends to, and will, contribute to the infringement of the '494 Patent immediately and imminently upon approval of Natco's ANDA.

66. On information and belief, Natco had knowledge of the '494 Patent at least as of the date it submitted a Paragraph IV Certification regarding the '644 Patent and is knowingly infringing the '494 Patent.

67. On information and belief, Natco is acting without a reasonable basis for believing that it would not be liable for infringing the '494 Patent, actively inducing infringement of the '494 Patent, and/or contributing to the infringement of the '494 Patent.

68. Unless Natco is enjoined from infringing the '494 Patent, actively inducing infringement of the '494 Patent, and/or contributing to the infringement of the '494 Patent, Plaintiffs will suffer irreparable harm for which they have no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

69. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 218578 to be a date which is not earlier than the expiration date of the '494 Patent, including any extensions of that date.

70. This case is "exceptional," as that term is used in 35 U.S.C. § 285, and Plaintiffs are entitled to an award of their reasonable attorneys' fees and expenses.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment in favor of Plaintiffs and against Defendant;

B. Judgment that Defendant has infringed, literally or by the doctrine of equivalents, the ’644 and ’494 Patents under 35 U.S.C. § 271(e)(2) by the submission of ANDA No. 218578;

C. Judgment declaring that commercial manufacturing, using, selling, offering to sell, and/or importing Natco’s ANDA Product, or inducing or contributing to such conduct, will constitute infringement, active inducement of infringement, and/or contributory infringement of the ’644 and ’494 Patents by Defendant under 35 U.S.C. §§ 271(a), (b) and/or (c);

D. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 218578 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date no earlier than the date of expiration of the last expiring of the ’644 and ’494 Patents plus any additional periods of exclusivity to which the Patents are or become entitled;

E. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65 enjoining Defendant, and its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, sale, offer to sell, and/or importation within or into the United States of any drug product described in ANDA No. 218578, and any product that is similar to or only colorably different from those products,

before the date of expiration of the last expiring of the ’644 and ’494 Patents plus any additional periods of exclusivity to which those Patents are or become entitled;

F. Damages or other monetary relief, including prejudgment and postjudgment interest, if Defendant engages in the commercial manufacture, use, sale, offer to sell, or importation of Natco’s ANDA Product, or any other products that infringe the ’644 or ’494 Patents, or that induce or contribute to the infringement of the ’644 and ’494 Patents, prior to the expiration of the last expiring of the ’644 and ’494 Patents plus any additional periods of exclusivity to which those Patents are or become entitled;

G. A declaration that this an exceptional case and an award to Plaintiffs of their reasonable attorneys’ fees and expenses, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

H. Such other and further relief as this Court may deem just and proper.

Dated: October 15, 2025

Respectfully submitted,

By: *s/ Keith J. Miller*

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that, to the best of my knowledge, this matter is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding, except for *Janssen Pharms. NV, et al. v. Natco Pharma Ltd.*, No. 2:23-cv-03959-JXN-JRA, which also relates to allegations of patent infringement arising from Natco's submission of ANDA No. 218578.

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Respectfully submitted,

By: *s/ Keith J. Miller*

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