Keith J. Miller
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, NJ 07102
Tel: (973) 690-5400
kmiller@rwmlegal.com

Attorneys for Plaintiffs

Of Counsel:

Irena Royzman
Christine Willgoos
Jonathan Pepin
KRAMER LEVIN NAFTALIS & FRANKEL LLP
1177 Avenue of the Americas
New York, New York 10036

Daniel Williams
KRAMER LEVIN NAFTALIS & FRANKEL LLP
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065

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

JANSSEN PHARMACEUTICALS, INC. and JANSSEN PHARMACEUTICA NV,

Plaintiffs,

v.

MACLEODS PHARMACEUTICALS, LTD. and MACLEODS PHARMA USA, INC.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Pharmaceuticals, Inc. ("JPI") and Janssen Pharmaceutica NV ("JNV") (collectively, "Janssen" or "Plaintiffs") for their Complaint against Defendants Macleods Pharmaceuticals, Ltd. ("Macleods India") and Macleods Pharma USA, Inc. ("Macleods USA") (collectively, "Macleods" or "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement by Defendants of United States Patent No. 11,576,894 (the "894 Patent") arising under the patent laws of the United States, 35 U.S.C.

§§ 1 et seq., and for a declaratory judgment of infringement of the 894 Patent under 35 U.S.C. §§ 1 et seq., 28 U.S.C. §§ 2201 and 2202.

2. This action arises out of Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 210380 (the "Macleods ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Janssen's highly successful 50 mg/500 mg; 50 mg/1000 mg; 150 mg/500 mg; and 150 mg/1000 mg INVOKAMET® (canagliflozin and metformin hydrochloride tablets) drug products (the "Macleods ANDA Products") prior to the expiration of the 894 Patent.

THE PARTIES

3. Plaintiff JPI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

4. Plaintiff JNV is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, 2340 Beerse, Belgium.

5. Janssen is an innovator pharmaceutical company that discovers, develops, and brings to market revolutionary pharmaceutical products in areas of unmet medical need, including treatments for mental illness, HIV/AIDS, and cancer. Janssen markets INVOKAMET® in this District and throughout the United States.

6. On information and belief, defendant Macleods India is a corporation organized and existing under the laws of India, having its principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, 400059, India. On information and belief, Macleods India is in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products for the United States market and/or manufacturing active pharmaceutical ingredients ("API") for generic copies of branded pharmaceutical products for the United States market. On information and belief, Macleods India is actively involved in the

commercial manufacture, use, marketing and/or sale of the Macleods ANDA Products in the United States, including in New Jersey.

7. On information and belief, Macleods India is the holder of the Macleods ANDA. On information and belief, Macleods India is the holder of Drug Master File 33198 for metformin hydrochloride and Drug Master File 30753 for canagliflozin, the APIs of INVOKAMET®.

8. On information and belief, defendant Macleods USA is a corporation organized under the laws of the State of Delaware, having its principal place of business at 103 College Road East, 2nd Floor, Princeton, New Jersey 08540. On information and belief, Macleods USA is a wholly-owned subsidiary of and is an authorized United States agent of Macleods India, including for the Macleods ANDA and Macleods ANDA Products.

9. On information and belief, Macleods USA is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing in the United States generic copies of branded pharmaceutical products for the United States market. On information and belief, Macleods USA will financially benefit in the event FDA approves the Macleods ANDA Products because Macleods USA is actively involved in the use, marketing, and/or sale of the Macleods ANDA Products in the United States, including in New Jersey.

10. On information and belief, Macleods prepared and submitted to FDA the Macleods ANDA seeking approval to commercially manufacture, import, market, and/or sell the Macleods ANDA Products in the United States, including in this District, if FDA approves the Macleods ANDA.

11. On information and belief, Macleods India will manufacture the Macleods ANDA Products for Macleods USA, which will market and distribute them. On information and belief, the acts of Macleods India complained of here were done with the cooperation, participation, and assistance of Macleods USA.

JURISDICTION

12. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 1 et seq., including §§ 271(e)(2), 271(a), 271(b), and/or 271(c). This Court has jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

13. The Court also has jurisdiction to adjudicate this action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and justiciable controversy exists between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the parties' adverse legal interests with respect to the 894 Patent.

14. On information and belief, Macleods India and Macleods USA operate and act in concert as an integrated, unitary business. On information and belief, Macleods India and Macleods USA work in concert with respect to the manufacturing, regulatory approval, marketing, sale, and distribution of generic pharmaceutical products throughout the United Sates, including in New Jersey.

15. This Court has personal jurisdiction over Macleods India because, *inter alia*, Macleods India 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 in New Jersey. For example, on information and belief, following approval of the Macleods ANDA, Macleods India will make, use, import, sell, and/or offer for sale the Macleods ANDA Products in the United States, including in New Jersey, prior to the expiration of the 894 Patent.

16. This Court also has personal jurisdiction over Macleods India because, *inter alia*, this action arises from actions of Macleods India directed toward New Jersey. For example, Macleods's counsel sent a letter dated February 20, 2024 to JPI, a corporation with its principal place of business in this District stating that Macleods had submitted ANDA No. 210380 seeking

approval to commercially manufacture, use, import, offer for sale, and sell the Macleods ANDA Products prior to the expiration of the 894 Patent. If Macleods succeeds in obtaining FDA approval, it would sell its Macleods ANDA Products in New Jersey and other states, causing injury to Plaintiffs in New Jersey.

17. On information and belief, Macleods India is subject to personal jurisdiction in New Jersey because, among other things, Macleods India itself and through its wholly-owned subsidiary Macleods USA has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

18. On information and belief, this Court has personal jurisdiction over Macleods India by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Macleods India regularly and continuously transacts business within New Jersey, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including New Jersey. Specifically, on information and belief, this Court has personal jurisdiction over Macleods India because, *inter alia*, it: (1) intends to market, sell, or distribute the Macleods ANDA Products to residents of New Jersey; (2) has continuous and systematic contacts with the State of New Jersey and regularly conducts business in the State of New Jersey, either directly or through one or more of its affiliates, agents, and/or alter egos; (3) exercises control over Defendant Macleods USA; (4) operates through its wholly-owned subsidiary Macleods USA, which has its principal place of business in New Jersey; (5) makes its generic pharmaceutical products available in New Jersey; (6) maintains a broad distributorship network within New Jersey; and (7) enjoys substantial income from sales of its generic pharmaceutical products in New Jersey.

19. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Macleods India received more than 100 FDA approvals to market and sell

pharmaceutical products throughout the United States, including in New Jersey. On information and belief, Macleods India derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

20. On information and belief, Macleods India markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates including Macleods USA, a Delaware corporation with its principal place of business in New Jersey. On information and belief, Macleods India, through Macleods USA, is licensed to sell generic pharmaceutical products in the State of New Jersey pursuant to 24 Del. C. § 2540.

21. This Court also has personal jurisdiction because Macleods India has prepared and submitted an ANDA for generic versions of Janssen's INVOKAMET® products, seeking approval from FDA to market and sell the Macleods ANDA Products throughout the United States, including in New Jersey. On information and belief, Macleods India and Macleods USA intend to commercially manufacture, import, use, sell and offer for sale the Macleods ANDA Products upon receiving FDA approval. On information and belief, if and when FDA approves the Macleods ANDA, the Macleods ANDA Products would, among other things, be marketed, distributed, and sold in New Jersey, and/or prescribed by physicians practicing and dispensed by pharmacies located within New Jersey, all of which would have a substantial effect on New Jersey. By submitting Defendants' ANDA, Macleods India has made clear that it intends to use its distribution channels to direct sales of the Macleods ANDA Products into New Jersey, displacing sales of INVOKAMET® in New Jersey and thus harming Plaintiffs in this District.

22. Further, Macleods India has previously been sued in this District and has not challenged personal jurisdiction. Macleods India also has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District, including in prior litigation between the parties with respect to INVOKAMET® and the Macleods ANDA. *See, e.g., Janssen Pharmaceuticals, Inc. et al. v. Macleods Pharmaceuticals, Ltd., et al.*, Civil Action No. 21-2309

(D.N.J.) (consenting to personal jurisdiction and venue for the purposes of the action and asserting counterclaims in litigation involving INVOKANA®); *Mitsubishi Tanabe Pharma Corp. et al. v. Macleods Pharmaceuticals, Ltd. et al.*, Civil Action No. 21-697 (D.N.J.) (same in litigation involving INVOKAMET XR®); *Celgene Corp. v. Macleods Pharmaceuticals, Ltd.*, Civil Action No. 18-11212 (D.N.J.); *Mitsubishi Tanabe Pharma Corp. et al. v. Macleods Pharmaceuticals, Ltd. et al.*, Civil Action No. 17-13130 (D.N.J.) (same in litigation involving INVOKANA®); *Mitsubishi Tanabe Pharma Corp. et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 17-5005 (D.N.J.) (same in litigation involving INVOKAMET®); *AstraZeneca AB, et al. v. Macleods Pharmaceuticals, Ltd., et al.*, Civil Action No. 16-1682 (D.N.J); and *Otsuka Pharmaceutical Co., Ltd. v. Macleods Pharmaceuticals, Ltd., et al.*, Civil Action No. 15-5109 (D.N.J.).

23. Alternatively, this Court may exercise personal jurisdiction over Macleods India pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Macleods India is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Macleods India has sufficient contacts with the United States as a whole, including but not limited to participating in the preparation and submission of the Macleods ANDA, and/or marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, including in this District, such that this Court's exercise of jurisdiction Macleods India satisfies due process.

24. Litigating in the District of New Jersey would not burden Macleods India unduly. Among other things, on information and belief, Macleods India 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 states have a shared interest in furthering the fundamental substantive policy of the United States with respect to its intellectual property laws.

25. On information and belief, Macleods USA is a wholly owned subsidiary of Macleods India and is controlled and dominated by Macleods India.

26. On information and belief, this Court has personal jurisdiction over Macleods USA because Macleods USA has a principal place of business in Princeton, New Jersey.

27. On information and belief, Macleods USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business I.D. No. 0101021236.

28. On information and belief, Macleods USA is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5004370.

29. On information and belief, this Court has personal jurisdiction over Macleods USA because Macleods USA has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being subject to the jurisdiction of the Court in the District of New Jersey. For example, on information and belief, Macleods USA is licensed to sell generic pharmaceutical products in the State of New Jersey pursuant to 24 Del. C. § 2540.

30. On information and belief, Macleods USA directly and/or through its parent company Macleods India, markets, distributes, and sells generic pharmaceutical products throughout the United States, including in this District.

31. On information and belief, Macleods USA derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this District, directly and/or through its parent company Macleods India.

32. On information and belief, Macleods USA, directly and/or through its parent company Macleods India, has an extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, wholesalers, and distributors in this District.

33. Further, Macleods USA has previously been sued in this District and has not challenged personal jurisdiction. Macleods USA also has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District, including in prior litigation between the parties with respect to INVOKAMET® and Macleods ANDA. *See, e.g., Janssen Pharmaceuticals, Inc. et al. v. Macleods Pharmaceuticals, Ltd., et al.*, Civil Action No. 21-2309 (D.N.J.) (consenting to personal jurisdiction and venue for the purposes of the action and asserting counterclaims in litigation involving INVOKANA®); *Mitsubishi Tanabe Pharma Corp. et al. v. Macleods Pharmaceuticals, Ltd. et al.*, Civil Action No. 21-697 (D.N.J.) (same in litigation involving INVOKAMET XR®); *Mitsubishi Tanabe Pharma Corp. et al. v. Macleods Pharmaceuticals, Ltd. et al.*, Civil Action No. 17-13130 (D.N.J.) (same in litigation involving INVOKANA®); *Mitsubishi Tanabe Pharma Corp. et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 17-5005 (D.N.J.) (same in litigation involving INVOKAMET®); *AstraZeneca AB, et al. v. Macleods Pharmaceuticals, Ltd., et al.*, Civil Action No. 16-1682 (D.N.J); and *Otsuka Pharmaceutical Co., Ltd. v. Macleods Pharmaceuticals, Ltd., et al.*, Civil Action No. 15-5109 (D.N.J.).

VENUE

34. Venue is proper in this District for Macleods USA under 28 U.S.C. § 1400(b) because, *inter alia*, Macleods USA has a regular and established place of business in Princeton, New Jersey, located in this judicial district, and has committed and will commit acts of infringement in this District.

35. Venue is proper in this District for Macleods India under 28 U.S.C. § 1391(c)(3) and/or 1400(b) because, *inter alia*, Macleods India is a company organized and existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

THE ASSERTED PATENT

36. On February 14, 2023, the United States Patent and Trademark Office ("PTO") issued the 894 Patent, entitled "Combination Therapy For The Treatment Of Diabetes." A true

and correct copy of the 894 Patent is attached hereto as **Exhibit A**.

37. JNV holds title to the 894 Patent.

38. The claims of the 894 Patent are valid, enforceable, and not expired.

39. The 894 Patent expires on July 6, 2030.

40. The claims of the 894 Patent protect INVOKAMET®.

41. JPI holds approved New Drug Application ("NDA") No. 204353.

42. Janssen markets the tablets approved under NDA No. 204353 in the United States under the registered trademark INVOKAMET®.

43. INVOKAMET® (canagliflozin and metformin hydrochloride) is a sodium-glucose co-transporter (SGLT2) inhibitor and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

44. Canagliflozin is indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

45. Canagliflozin is also indicated to reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria.

46. INVOKAMET® is included in the FDA's list of *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"). Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under the provisions of 21 U.S.C. § 355(j).

47. The FDA's Orange Book also lists patents associated with approved drugs. The Orange Book identifies the 894 Patent, among other patents, for INVOKAMET®. The claims of the 894 Patent cover INVOKAMET®.

48. Defendants submitted to FDA the Macleods ANDA listing INVOKAMET® as the reference listed drug ("RLD").

49. By submitting their Macleods ANDA, Defendants have represented to FDA that their Macleods ANDA Products have the same active ingredients as INVOKAMET® in the same dosage forms and strengths as INVOKAMET® and are bioequivalent to INVOKAMET®.

DEFENDANTS' ANDA AND PARAGRAPH IV NOTICE LETTER

50. On information and belief, Defendants submitted to FDA the Macleods ANDA under Section 505(j) of the FDCA, seeking FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Macleods ANDA Products before the expiration of the 894 Patent. On information and belief, FDA assigned the ANDA number 210380.

51. On information and belief, Defendants sent a letter dated February 20, 2024 to Janssen (the "Macleods Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). The Macleods Notice Letter states that the Macleods ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the 894 Patent.

52. Janssen received the Macleods Notice Letter on or about February 22, 2024.

53. The Macleods Notice Letter included a purported Offer for Confidential Access ("OCA") to the Macleods ANDA on terms and conditions that were unreasonable and did not allow appropriate access to Janssen. Janssen proposed modifications to the purported OCA and requested the Macleods ANDA, DMF(s), and batch records under those terms. Macleods did not provide the requested Macleods ANDA, DMFs or batch records.

54. The Macleods Notice Letter does not contest infringement of any of the claims of the 894 Patent. In particular, Macleods does not dispute that the claims of the 894 Patent are infringed by the submission of the Macleods ANDA, including claims 1-4, 6-9 and 12 of the 894 Patent.

55. Macleods also does not dispute that the commercial manufacture, use, importation, offer for sale, and sale of its Macleods ANDA Products, if approved by FDA, would infringe at least claims 1-4, 6-9 and 12 of the 894 Patent.

56. This action is being commenced before the expiration of 45 days from the date Janssen received the Macleods Notice Letter containing a Paragraph IV certification as to the 894 Patent.

COUNT I

Infringement of the 894 Patent under 35 U.S.C. § 271(e)(2)(A)

57. Plaintiffs reallege each of the foregoing paragraphs as if fully set forth here.

58. Pursuant to 35 U.S.C. § 271(e)(2)(A), Defendants have committed an act of infringement of the 894 Patent by submitting to FDA the Macleods ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Macleods ANDA Products in the United States prior to the expiration of the 894 Patent.

59. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the Macleods ANDA Products prior to the expiration of the 894 Patent, and their inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the 894 Patent either literally or under the doctrine of equivalents, including but not limited to claims 1-4, 6-9 and 12 of the 894 Patent.

60. Defendants do not dispute that they infringe the claims of the 894 Patent, including claims 1-4, 6-9 and 12. The Macleods Notice Letter does not contest infringement of any claim.

61. Defendants had actual and constructive notice of the 894 Patent prior to submitting to FDA a Paragraph IV certification with respect to the 894 Patent and seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of the Macleods ANDA Products in the United States prior to the expiration of the 894 Patent.

62. On information and belief, Defendants became aware of the 894 Patent no later

than the date of the Macleods Notice Letter.

63. The commercial manufacture, importation, use, sale, or offer for sale of the Macleods ANDA Products in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

64. Plaintiffs have no adequate remedy at law to redress infringement by Defendants.

65. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the 894 Patent.

COUNT II

Declaratory Judgment of Infringement of the 894 Patent under 35 U.S.C. § 271(a), (b) and/or (c)

66. Plaintiffs reallege each of the foregoing paragraphs as if fully set forth here.

67. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

68. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Defendants regarding infringement of the 894 Patent.

69. On information and belief, Defendants have made and will continue to make substantial and meaningful preparations to import into the United States and/or to offer to sell, sell and/or use within the United States the proposed Macleods ANDA Products prior to the expiration of the 894 Patent.

70. Defendants admit that they will sell and distribute the proposed Macleods ANDA Products if approved by FDA.

71. Defendants' actions, including, but not limited to, the filing of a Paragraph IV certification with respect to the 894 Patent for ANDA No. 210380 and Defendants' systematic attempts to meet the applicable regulatory requirements of approval of ANDA No. 210380 indicate a refusal to change their course of action.

72. Defendants' commercial manufacture, importation, use, sale and/or offer for sale of the proposed Macleods ANDA Products prior to the expiration of the 894 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the 894 Patent either literally or under the doctrine of equivalents under 35 U.S.C. §§ 271(a), (b), and/or (c).

73. The Macleods Notice Letter does not dispute that the proposed Macleods ANDA Products would infringe the claims of the 894 Patent, including claims 1-4, 6-9 and 12.

74. Plaintiffs should be granted a judicial declaration that the commercial manufacture, importation, use, offer for sale, and/or sale in the United States of the proposed Macleods ANDA Products will constitute infringement of the claims of the 894 Patent under §§ 271(a), (b) and/or (c).

75. Plaintiffs have no adequate remedy at law to redress infringement by Defendants.

76. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the 894 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

a) A judgment that Defendants have infringed the 894 Patent under 35 U.S.C. § 271(e)(2)(A);

b) A judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Macleods ANDA shall be a date which is not earlier than the day after the expiration of the 894 Patent as extended by any applicable periods of exclusivity to which Plaintiffs are or will be entitled;

c) A judgment declaring that Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the Macleods ANDA Products into the United States prior to the expiration of the 894 Patent (including such actions by its officers, agents, servants, employees,

licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with Defendants or acting on Defendants' behalf) will constitute infringement of the 894 Patent under 35 U.S.C. §§ 271 (a), (b), and/or (c) and providing any further necessary or proper relief based on the Court's declaratory judgment or decree;

d) An order under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from commercially manufacturing, using, offering to sell, and/or selling in the United States, and/or importing into the United States the Macleods ANDA Products, or any colorable variations thereof, until the day after the expiration of the 894 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or will be entitled, and from otherwise infringing one or more claims of the 894 Patent;

e) A declaration that this case is exceptional;

f) An award of Plaintiffs' costs, expenses, reasonable attorneys' fees and such other relief as the Court deems proper and just pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

g) Such other and further relief as this Court deems just and proper.

Of Counsel:

Irena Royzman
Christine Willgoos
Jonathan Pepin
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
1177 Avenue of the Americas
New York, New York 10036
Tel: (212) 715-9100
iroyzman@kramerlevin.com
cwillgoos@kramerlevin.com
jpepin@kramerlevin.com

Daniel Williams
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065
Tel: (650) 752-1700
ddwilliams@kramerlevin.com

April 4, 2024

Respectfully submitted,

/s/ Keith J. Miller
Keith J. Miller
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, NJ 07102
Tel: (973) 690-5400
kmiller@rwmlegal.com

Attorneys for Plaintiffs

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Respectfully submitted,

/s/ Keith J. Miller

Keith J. Miller
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, NJ 07102
Tel: (973) 690-5400
kmiller@rwmlegal.com

Attorneys for Plaintiffs

Of Counsel:
Irena Royzman
Christine Willgoos
Jonathan Pepin
KRAMER LEVIN NAFTALIS & FRANKEL LLP
1177 Avenue of the Americas
New York, New York 10036
Tel: (212) 715-9100
iroyzman@kramerlevin.com
cwillgoos@kramerlevin.com
jpepin@kramerlevin.com

Daniel Williams
KRAMER LEVIN NAFTALIS & FRANKEL LLP
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065
Tel: (650) 752-1700
ddwilliams@kramerlevin.com

April 4, 2024