IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ZS PHARMA, INC. and ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, v. MACLEODS PHARMACEUTICALS LTD. and MACLEODS PHARMA USA, INC., Defendants.	)	C.A. No. 1:23-cv-01190

DEFENDANTS MACLEODS PHARMACEUTICALS LTD. AND MACLEODS PHARMA USA, INC.'S ANSWER AND COUNTERCLAIMS

Defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, "Macleods"), by and through their attorneys, answer the Complaint filed by Plaintiffs ZS Pharma, Inc. and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca" or "Plaintiffs") as follows:

AS TO THE NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 217541, filed by and for the benefit of Defendants with the United States Food and Drug Administration ("FDA"). Through ANDA No. 217541, Defendants seek approval to market generic versions of LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet (the "Proposed ANDA Product"), prior to the expiration of U.S. Patent No. 11,738,044 ("the '044 Patent").

ANSWER: Macleods admits that Plaintiffs purport to bring this action under the patent laws of the United States and under the Federal Declaratory Judgment Act. Macleods admits that

it has submitted ANDA No. 217541 seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of sodium zirconium cyclosilicate for oral suspension 5 g per packet and 10 g per packet (the "Proposed ANDA Product") prior to the expiration of the '044 Patent. Macleods lacks sufficient information to determine the truth or falsity of any remaining allegations in Paragraph 1 of the Complaint and on that basis denies them.

AS TO THE PARTIES

2. Plaintiff ZS Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business in Wilmington, Delaware.

ANSWER: Macleods lacks sufficient information to determine the truth or falsity of the allegations in Paragraph 2 of the Complaint and on that basis denies them.

3. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of Delaware, having a principal place of business in Wilmington, Delaware.

ANSWER: Macleods lacks sufficient information to determine the truth or falsity of the allegations in Paragraph 3 of the Complaint and on that basis denies them.

4. On information and belief, Defendant Macleods Ltd. is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai 400059, Maharashtra, India.

ANSWER: Admitted.

5. On information and belief, Defendant Macleods Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 103 College Road East (2nd Floor), Princeton, New Jersey, 08540.

ANSWER: Admitted.

6. On information and belief, Defendants collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group.

ANSWER: Denied.

7. On information and belief, Defendants acted in concert to develop the Proposed ANDA Product that is the subject of ANDA No. 217541 and to seek regulatory approval from the FDA to market and sell the Proposed ANDA Product throughout the United States, including within this District.

ANSWER: Denied.

8. Defendants' ANDA No. 217541 seeks approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of AstraZeneca's LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet prior to the expiration of the '044 Patent.

ANSWER: Macleods admits that it has submitted ANDA No. 217541 seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of sodium zirconium cyclosilicate for oral suspension 5 g per packet and 10 g per packet (the "Proposed ANDA Product") prior to the expiration of the '044 Patent. Macleods denies the remaining allegations in Paragraph 8 of the Complaint.

9. On information and belief, Defendants intend to act collaboratively to obtain approval for Defendants' ANDA No. 217541, and, in the event the FDA approves that ANDA,

to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product.

ANSWER: Denied.

JURISDICTION AND VENUE

10. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of the submission of Defendants' ANDA No. 217541 to the FDA.

ANSWER: Paragraph 10 contains legal conclusions that do not require a response. Macleods admits that this is an action for patent infringement and that it has submitted ANDA No. 217541 seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of sodium zirconium cyclosilicate for oral suspension 5 g per packet and 10 g per packet (the "Proposed ANDA Product") prior to the expiration of the '044 Patent. Macleods denies the remaining allegations in Paragraph 10 of the Complaint.

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 35 U.S.C. § 1, *et seq*.

ANSWER: Admitted.

12. This Court has personal jurisdiction over Macleods Ltd. because, inter alia, it has maintained continuous and systematic contacts with this District and availed itself of the privilege of doing business in this District. On information and belief, Macleods Ltd. has: (1) acted in concert with Macleods Inc. to file ANDA No. 217541 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product in the United States, including in this District; (2) regularly and continuously transacted business within this District, including by selling pharmaceutical products in this District either on its own or through its affiliates; and (3) derived substantial revenue from the sale of those products in this District.

Alternatively, this Court has personal jurisdiction over Macleods Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2).

ANSWER: Macleods denies the allegations of Paragraph 12 of the Complaint. However, Macleods does not contest personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. in this Court for the purposes of this civil litigation only.

13. This Court has personal jurisdiction over Macleods Inc. because, on information and belief, Macleods Inc. is a corporation organized and existing under the laws of Delaware.

ANSWER: Macleods denies the allegations of Paragraph 13 of the Complaint. However, Macleods does not contest personal jurisdiction over Macleods Pharma USA, Inc. in this Court for the purposes of this civil litigation only.

14. On information and belief, if ANDA No. 217541 is approved, the Proposed ANDA Product accused of infringing the '044 Patent will be marketed, distributed, offered for sale, and/or sold in this District, prescribed by physicians practicing in this District, dispensed by pharmacies located within this District, and/or used by patients in this District, all of which would have a substantial effect on this District.

ANSWER: Macleods denies the allegations of patent infringement and denies the remaining allegations in Paragraph 14 of the Complaint. However, Macleods does not contest personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. in this Court for the purposes of this civil litigation only**.**

15. This Court also has personal jurisdiction over Defendants because they have affirmatively availed themselves of the jurisdiction of this Court through the assertion of counterclaims in suits brought in this District and/or by being sued in this District without challenging personal jurisdiction. For example, Defendants did not contest this Court's

jurisdiction in Plaintiffs' previously-filed civil action regarding Defendants' ANDA No. 217541, Civil Action No. 22-1100-GBW. *See ZS Pharma, Inc. et al. v. Macleods Pharmaceuticals Ltd. et al.,* Civil Action No. 22-1100-GBW, D.I. 18 at ¶¶ 8-12 (D. Del.).

ANSWER: Macleods denies the allegations of Paragraph 15 of the Complaint. However, Macleods does not contest personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. in this Court for the purposes of this civil litigation only.

16. For the reasons set forth above, and for additional reasons which will be supplied if Defendants challenge personal jurisdiction in this action, Defendants are subject to personal jurisdiction in this District.

ANSWER: Macleods denies the allegations of Paragraph 16 of the Complaint. However, Macleods does not contest personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. in this Court for the purposes of this civil litigation only.

17. Venue is proper in this District for Macleods Inc. pursuant to 28 U.S.C. § 1400(b) because Macleods Inc. is a corporation organized and existing under the laws of Delaware.

ANSWER: Paragraph 17 contains legal conclusions that do not require a response. Macleods does not contest that venue is proper in this Court for the purposes of this civil litigation only.

18. Venue is proper in this District for Macleods Ltd. pursuant to 28 U.S.C. § 1391(c) because, *inter alia*, Macleods Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this District.

ANSWER: Paragraph 18 contains legal conclusions that do not require a response. Macleods does not contest that venue is proper in this Court for the purposes of this civil litigation only.

THE '044 PATENT

19. The '044 Patent is assigned to ZS Pharma, Inc.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods admits that ZS Pharma, Inc. is identified as the assignee of the '044 Patent. Macleods denied the remaining allegations in Paragraph 19 of the Complaint.

20. The '044 Patent, entitled "Extended Use Zirconium Silicate Compositions and Methods of Use Thereof," was duly and legally issued on August 29, 2023. A copy of the '044 Patent is attached as Exhibit A.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods admits that the '044 Patent is entitled "Extended Use Zirconium Silicate Compositions and Methods of Use Thereof," that the '044 Patent states on its face that it issued on August 29, 2023 and that what appears to be a copy of the '044 Patent was attached as Exhibit A to the Complaint. Macleods denies that the '044 Patent was duly and legally issued and denies the remaining allegations in Paragraph 20 of the Complaint.

FACTUAL BACKGROUND

LOKELMA® (sodium zirconium cyclosilicate)

21. LOKELMA® (sodium zirconium cyclosilicate) is a drug used to treat hyperkalemia. Marked elevations in serum potassium can cause fatal heart arrhythmias and abnormalities in conduction (progression of electrical impulses through the heart) and muscle weakness and paralysis. LOKELMA® (sodium zirconium cyclosilicate) is a non-absorbed zirconium silicate that preferentially captures potassium in exchange for hydrogen and sodium, thereby lowering serum potassium levels.

ANSWER: Macleods admits that LOKELMA® (sodium zirconium cyclosilicate) is indicated for the treatment of hyperkalemia. Macleods denies the remaining allegations in Paragraph 21 of the Complaint.

22. AstraZeneca is the holder of approved New Drug Application ("NDA") No. 207078 for LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet. Pursuant to NDA No. 207078, AstraZeneca markets and distributes LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet in the United States.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods states that electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies New Drug Application ("NDA") No. 207078 in connection with LOKELMA®, and further identifies AstraZeneca as the holder of NDA No. 207078. As to any remaining factual allegations in Paragraph 22, Macleods is without sufficient information to form a belief as to the truth or falsity of the allegations and on that basis denies them.

23. LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet, the active pharmaceutical ingredient sodium zirconium cyclosilicate, the method of manufacture, and/or their use are covered by one or more claims of the '044 Patent. The '044 Patent has been listed for NDA No. 207078 in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is also known as the "Orange Book."

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods admits that the Orange Book identifies the active pharmaceutical ingredient of LOKELMA® as sodium zirconium cyclosilicate and that the '044

Patent is listed in connection with LOKELMA® in the Orange Book. Macleods denies the remaining allegations in Paragraph 23 of the Complaint.

Defendants' ANDA No. 217541

24. In a letter dated July 14, 2022 (the "Notice Letter"), Defendants stated that they had submitted ANDA No. 217541 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product. The Notice Letter further stated that ANDA No. 217541 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") that U.S. Patent Nos. 8,877,255 ("the '255 Patent"), 9,592,253 ("the '253 Patent"), 9,913,860 ("the '860 Patent"), 10,300,087 ("the '087 Patent"), and 10,695,365 ("the '365 Patent") are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product. Plaintiffs timely filed suit with respect to those patents on August 22, 2022. *See ZS Pharma, Inc. et al. v. Macleods Pharmaceuticals Ltd. et al.*, Civil Action No. 22-1100, D.I. 1 (D. Del.).

ANSWER: Macleods admits that it sent a notice letter dated July 14, 2022 for ANDA No. 217541 seeking approval from the FDA to engage in the commercial manufacture, use, and sale of the Proposed ANDA Product and that it filed a Paragraph IV Certification with respect to U.S. Patent Nos. 8,877,255, 9,592,253, 9,913,860, 10,300,087, and 10,695,365. Macleods denies the remaining allegations in Paragraph 24 of the Complaint.

25. On information and belief, Defendants have amended or will amend ANDA No.217541 to include a Paragraph IV Certification that the '044 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product.

ANSWER: Paragraph 25 contains hypothetical events that have not yet occurred and is therefore denied.

26. Defendants' submission of ANDA No. 217541 to the FDA constitutes infringement of one or more claims of the '044 Patent under 35 U.S.C. § 271(e)(2)(A). Although the '044 Patent did not issue until after ANDA No. 217541 was filed, this does not preclude Defendants from infringement liability under 35 U.S.C. § 271(e)(2). *See Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1127 (Fed. Cir. 2018).

ANSWER: Denied.

27. On information and belief, sodium zirconium cyclosilicate is the active ingredient in the Proposed ANDA Product.

ANSWER: Admitted.

28. On information and belief, the Proposed ANDA Product exhibits sodium zirconium cyclosilicate as patented by the '044 Patent.

ANSWER: Denied.

29. On information and belief, ANDA No. 217541 refers to and relies upon the NDA for LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet and contains data that, according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Product and LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet. *See* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

ANSWER: Macleods admits that its Proposed ANDA Product is for sodium zirconium cyclosilicate for oral suspension 5 g per packet and 10 g per packet. Macleods denies the remaining allegations of Paragraph 29 of the Complaint.

30. On information and belief, Defendants intend to have healthcare providers use the Proposed ANDA Product, if approved, as set forth in the Proposed ANDA Product label.

ANSWER: Macleods states that the Proposed ANDA Product label speaks for itself. Macleods denies the remaining allegations in Paragraph 30 of the Complaint.

31. On information and belief, Defendants' Proposed ANDA Product label will instruct healthcare providers to prescribe the Proposed ANDA Product in the manner set forth in the label.

ANSWER: Macleods states that the Proposed ANDA Product label speaks for itself. Macleods denies the remaining allegations in Paragraph 31 of the Complaint.

32. On information and belief, the FDA has not yet approved ANDA No. 217541.

ANSWER: Admitted.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,738,044

33. Plaintiffs hereby reallege and incorporate the allegations of paragraphs 1 – 32 of this Complaint.

ANSWER: Macleods incorporates the answers to paragraphs 1-32 as if fully set forth herein.

34. On information and belief, the Proposed ANDA Product infringes one or more claims of the '044 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of a sodium zirconium silicate as covered by one or more of the claims of the '044 Patent.

ANSWER: Denied.

35. Defendants' submission of ANDA No. 217541 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale,

sell, and/or import the Proposed ANDA Product before the expiration of the '044 Patent constitutes infringement of the '044 Patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

36. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 217541 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

ANSWER: Denied.

37. On information and belief, upon FDA approval of ANDA No. 217541, Defendants will infringe the '044 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied.

38. On information and belief, Defendants have or will have knowledge that if they were to receive approval from the FDA to market the Proposed ANDA Product described in ANDA No. 217541 and make the Proposed ANDA Product available for sale and/or use by others, e.g., by doctors, pharmacists, healthcare providers and patients, according to the package insert and prescribing information during the proposed shelf life of the products before expiration of the '044 Patent, such activities would result in the sale and/or use of a product that itself infringes and/or is especially made for an infringing use. Upon information and belief, Defendants have or will have knowledge of such infringement and/or such infringing use and also knows or will know that the Proposed ANDA Product described in ANDA No. 217541 are not a staple article or commodity of commerce suitable for substantial non-infringing use, but

rather are especially made to infringe and/or are especially adapted for use in the direct infringement of the '044 Patent.

ANSWER: Denied.

39. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

RESPONSE TO PRAYER FOR RELIEF

Macleods denies that Plaintiffs are entitled to the judgment or other relief prayed for in the Complaint under the heading PRAYER FOR RELIEF.

AFFIRMATIVE DEFENSES

First Affirmative Defense

Plaintiffs fail to state a claim upon which relief may be granted.

Second Affirmative Defense

Plaintiffs fail to state any facts to support a claim upon which relief may be granted.

Third Affirmative Defense

Each asserted claim of the '044 Patent is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116 and/or is invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity.

Fourth Affirmative Defense

Macleods has not infringed, induced infringement of, or contributed to the infringement of, and Macleods will not infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable asserted claim of the '044 Patent, either literally or under the doctrine

of equivalents, through the submission of Macleods' ANDA No. 217541 and/or the importation, manufacture, use, offer for sale or sale of the product that is the subject of Macleods' ANDA No. 217541.

Fifth Affirmative Defense

Plaintiffs are not entitled to injunctive relief against Macleods because Plaintiffs' alleged damages are not immediate or irreparable, and therefore Plaintiffs have an adequate remedy at law. Moreover, considering the balance of hardships between the parties, and the public interest in fostering the prompt introduction of generic pharmaceuticals to the market, the equitable remedy of a permanent injunction is not warranted in any event.

Sixth Affirmative Defense

Plaintiffs are not entitled to attorney's fees against Macleods because Plaintiffs have not sufficiently alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285.

Seventh Affirmative Defense

35 U.S.C. § 288 prevents Plaintiffs from recovering any costs associated with this action.

Eighth Affirmative Defense

Plaintiffs' allegations are barred, in whole or in part, by the doctrines of waiver, estoppel and/or prosecution history estoppel.

Ninth Affirmative Defense

Macleods reserves the right to assert additional affirmative defenses that may be developed or revealed during discovery.

COUNTERCLAIMS

In further response to the Complaint, Macleods alleges the following counterclaims, without prejudice to any denial in its Answer, and without admission to any allegation in the Complaint, unless otherwise explicitly admitted above, and without assuming any burden when such burden would otherwise belong to Plaintiffs.

PARTIES

1. Counterclaimant Macleods Pharmaceuticals Limited is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at Atlanta Arcade, Marol Church, Andheri (East), Mumbai, India 400059.

2. Counterclaimant Macleods Pharma USA, Inc. (collectively, both entities are referred to herein as "Macleods") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 103 College Road East (2nd Floor), Princeton, New Jersey, 08540.

3. Upon information and belief, Counterclaim Defendant ZS Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business in Wilmington, Delaware.

4. Upon information and belief, Counterclaim Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of Delaware, having a principal place of business in Wilmington, Delaware.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367, 2201, and 2202. Macleods' counterclaims relate to the claims made by Counterclaim Defendants for patent infringement and arise under the patent laws of the United States, Title 35, United States Code.

6. This Court has personal jurisdiction over Counterclaim Defendants because they are organized under the law of the State of Delaware, conduct business in the State of Delaware, have availed themselves of the rights and benefits of Delaware law, and have engaged in substantial and continuing contacts with Delaware.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) and by Counterclaim Defendants' filing of their action against Macleods. This Court may declare the rights and legal relation of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(5).

THE CONTROVERSY

8. Macleods holds Abbreviated New Drug Application ("ANDA") No. 217541 for sodium zirconium cyclosilicate for oral suspension 5 g per packet and 10 g per packet.

9. On or about October 20, 2023, Counterclaim Defendants filed the present action against Macleods alleging infringement of United States Patent No. 11,738,044 ("the '044 Patent"). Accordingly, there is a real, substantial, and continuing justiciable controversy between the parties concerning the '044 Patent.

10. Macleods and Counterclaim Defendants have adverse legal interests with respect to the '044 Patent of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

COUNT I
DECLARATORY JUDGMENT OF INVALIDITY OF THE '044 PATENT

11. Macleods repeats and incorporates by reference the previous paragraphs of their Counterclaims as if fully set forth herein.

12. Each and every asserted claim of United States Patent No. 11,738,044 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States

Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT II
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '044 PATENT

13. Macleods repeats and incorporates by reference the previous paragraphs of their Counterclaims as if fully set forth herein.

14. Macleods has not infringed, induced infringement, or contributed to the infringement, and Macleods will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 11,738,044.

Macleods' Request for Relief

WHEREFORE, Macleods respectfully requests that:

(a) Judgment be entered that the Complaint against Macleods is dismissed with prejudice and that Plaintiffs/Counterclaim Defendants take nothing thereby;

(b) Judgment be entered that each claim of United States Patent No. 11,738,044 is invalid;

(c) The Court permanently enjoin Plaintiffs/Counterclaim Defendants or any of their assigns or successors from asserting that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Macleods' ANDA No. 217541 infringe or will infringe any valid claim of U.S. Patent No. 11,738,044.

(d) This case be deemed an exceptional case within the meaning of 35 U.S.C. § 285.

(e) Macleods be awarded its reasonable costs and attorney fees; and

(f) The Court award Macleods such other and further relief as this Court may deem necessary, just and proper.

Respectfully submitted,

/s/ G. Mason Thomson

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