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Attorneys for Defendants
Padagis Israel Pharmaceuticals Ltd, Padagis US LLC, and Padagis LLC

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

BAUSCH HEALTH IRELAND
LIMITED, BAUSCH HEALTH US,
LLC; and BAUSCH HEALTH
AMERICAS INC.,

Plaintiffs,

v.

PADAGIS ISRAEL PHARMACEUTICALS
LTD; PADAGIS US LLC; and PADAGIS
LLC,

Defendants.

Civil Action No. 22-4248 (MCA) (AME)

Document Electronically Filed

**DEFENDANTS PADAGIS ISRAEL PHARMACEUTICALS LTD, PADAGIS US LLC,
AND PADAGIS LLC's ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES AND
COUNTERCLAIMS**

Defendants Padagis Israel Pharmaceuticals Ltd ("Padagis Israel"), Padagis US LLC ("Padagis US"), and Padagis LLC ("Padagis LLC") (collectively "Padagis" or "Defendants") through their undersigned counsel; hereby answer the Complaint of Plaintiffs Bausch Health Ireland Limited ("Bausch Ireland"), Bausch Health US, LLC ("Bausch US"); and Bausch Health Americas Inc. ("Bausch Americas") (collectively "Bausch" or "Plaintiffs") as follows:

The Parties¹

1. Padagis is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint, and therefore denies those allegations.

2. Padagis is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint, and therefore denies those allegations.

3. Padagis is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint, and therefore denies those allegations.

4. Padagis admits that Padagis Israel is an Israeli corporation with a place of business at 1 Rakefet St., Shoham 608500, Israel. Padagis admits that Padagis Israel is a wholly owned subsidiary of Padagis LLC. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 4 of the Complaint.

5. Padagis admits that Padagis US is a corporation having a place of business at 1251 Lincoln Road, Allegan, Michigan, 49010. Padagis admits that Padagis US is a wholly owned subsidiary of Padagis LLC. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 5 of the Complaint.

6. Padagis admits that Padagis LLC is a Delaware limited liability company having a place of business at 1251 Lincoln Road, Allegan, Michigan, 49010. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 6 of the Complaint.

7. Padagis admits that Padagis Israel filed ANDA No. 215393 with the FDA, seeking regulatory approval to engage in the commercial manufacture, use, or sale of a generic tazarotene

¹ For the Court's convenience, Padagis has incorporated the "Headings" that appear in the Complaint. It should be understood, however, that Padagis does not necessarily agree with the characterizations of these Headings and does not waive any right to object to those characterizations.

(0.045%) lotion in the United States. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 7 of the Complaint.

NATURE OF THE ACTION

8. Paragraph 8 of the Complaint contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Padagis admits that the Complaint filed by Plaintiffs purports to state a civil action for infringement of U.S. Patent No. 11,311,482 (“the ’482 patent) under the Patent Laws of the United States, 35 U.S.C. § 100 et seq. Padagis is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 8 of the Complaint, and therefore denies those allegations.

9. Paragraph 9 of the Complaint contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Padagis admits that Padagis Israel filed ANDA No. 215393 with the FDA, seeking regulatory approval to engage in the commercial manufacture, use, or sale of a generic tazarotene (0.045%) lotion product in the United States. Padagis admits that ANDA No. 215393 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Padagis’s opinion and to the best of its knowledge, no valid, enforceable claim of the ’482 patent will be infringed by the manufacture, use, or sale of the drug product for which ANDA No. 215393 was submitted. Padagis is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 9 of the Complaint, and therefore denies those allegations.

Jurisdiction and Venue

10. Paragraph 10 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) solely for the claims directed against Padagis

Israel under 35 U.S.C. § 271(e)(2). Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 10 of the Complaint.

11. Paragraph 11 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis Israel develops, formulates, and manufactures generic drug products that are sold throughout the United States. Padagis admits that Padagis Israel filed ANDA No. 215393 with the FDA, seeking regulatory approval to engage in the commercial manufacture, use, or sale of a generic tazarotene (0.045%) lotion product in the United States. Padagis further responds that Padagis Israel does not contest personal jurisdiction in this Court, solely for the limited purpose of this action only. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 11 of the Complaint.

12. Paragraph 12 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis Israel develops, formulates, and manufactures generic drug products that are sold throughout the United States. Padagis admits that Padagis Israel filed ANDA No. 215393 with the FDA, seeking regulatory approval to engage in the commercial manufacture, use, or sale of a generic tazarotene (0.045%) lotion product in the United States. Padagis further responds that Padagis Israel does not contest personal jurisdiction in this Court, solely for the limited purpose of this action only. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 12 of the Complaint.

13. Paragraph 13 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis responds that Padagis Israel does not contest personal jurisdiction in this Court, solely for the limited purpose of this action only. Except as

expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 13 of the Complaint.

14. Paragraph 14 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis responds that Padagis US does not contest personal jurisdiction in this Court, solely for the limited purpose of this action only. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 14 of the Complaint.

15. Paragraph 15 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis responds that Padagis LLC does not contest personal jurisdiction in this Court, solely for the limited purpose of this action only. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 15 of the Complaint.

16. Paragraph 16 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis responds that Padagis Israel, Padagis US, and Padagis LLC do not contest personal jurisdiction in this Court, solely for the limited purpose of this action only. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 16 of the Complaint.

17. Paragraph 17 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis responds that Padagis Israel, Padagis US, and Padagis LLC do not contest personal jurisdiction in this Court, solely for the limited purpose of this action only, consistent with the stipulation dated June 24, 2022. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 17 of the Complaint.

18. Paragraph 18 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis responds that Padagis Israel, Padagis US, and Padagis LLC do not contest venue, solely for the limited purpose of this action only. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 18 of the Complaint.

19. Paragraph 19 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis responds that Padagis Israel does not contest venue, solely for the limited purpose of this action only. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 19 of the Complaint.

20. Paragraph 20 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis responds that Padagis US and Padagis LLC do not contest venue, solely for the limited purpose of this action only. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 20 of the Complaint.

21. Paragraph 21 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis responds that Padagis Israel, Padagis US, and Padagis LLC do not contest venue, solely for the limited purpose of this action only, consistent with the stipulation dated June 24, 2022. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 21 of the Complaint.

THE PATENT-IN-SUIT

22. Padagis admits that U.S. Patent No. 11,311,482 (“the ’482 patent”) states on its face that it was issued on April 26, 2022 by the U.S. Patent and Trademark Office and is entitled “TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES.”

Padagis further admits that Exhibit A to the Complaint purports to be a copy of the '482 patent. Padagis is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 22 of the Complaint, and therefore denies those allegations.

23. Padagis admits that the '482 patent identifies Arturo Angel and Radhakrishnan Pillai as named inventors on the face of the patent. Padagis is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 23 of the Complaint, and therefore denies those allegations.

24. Padagis admits the allegations in Paragraph 24 of the Complaint.

25. Padagis is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 25 of the Complaint, and therefore denies those allegations.

ACTS GIVING RISE TO THIS ACTION

26. Padagis is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 26 of the Complaint, and therefore denies those allegations.

27. Padagis admits the allegations in Paragraph 27 of the Complaint.

28. Padagis admits that the '482 Patent is listed in the Orange Book for Arazlo® (tazarotene 0.045%). Padagis is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 28 of the Complaint, and therefore denies those allegations.

29. Padagis admits the allegations in Paragraph 29 of the Complaint.

30. Padagis admits that Padagis Israel notified each of Bausch Health Ireland Limited ("Bausch Ireland"), Bausch Health US, LLC ("Bausch US"), and Bausch Health Americas Inc.

(“Bausch Americas”) in a letter dated May 12, 2022 (“Padagis Israel’s Notice Letter”), signed by Joseph M. Reisman, that ANDA No. 215393 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Padagis’s opinion and to the best of its knowledge, no valid, enforceable claim of the ’482 patent will be infringed by the manufacture, use, or sale of the drug product for which ANDA No. 215393 was submitted. Padagis is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 30 of the Complaint, and therefore denies those allegations.

31. Padagis admits that Padagis Israel believes that the product that is the subject of ANDA No. 215393 is bioequivalent to Arazlo®. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 31 of the Complaint.

32. Padagis is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 32 of the Complaint, and therefore denies those allegations.

CLAIMS FOR RELIEF

COUNT I (Infringement of the ’482 Patent)

33. Padagis incorporates by reference its responses to the allegations in the preceding paragraphs as through fully set forth herein.

34. Padagis denies the allegations contained in Paragraph 34 of the Complaint.

35. Padagis denies the allegations contained in Paragraph 35 of the Complaint.

36. Padagis denies the allegations contained in Paragraph 36 of the Complaint.

37. Padagis denies the allegations contained in Paragraph 37 of the Complaint.

COUNT II (Declaratory Judgment of Infringement of the '482 Patent)

38. Padagis incorporates by reference its responses to the allegations in the preceding paragraphs as through fully set forth herein.

39. Padagis admits that the Complaint purports to state a claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Padagis is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations of Paragraph 39, and therefore denies those allegations.

40. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis is without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 40, and therefore denies those allegations.

41. Padagis admits that Padagis Israel filed ANDA No. 215393 with the FDA, seeking regulatory approval to engage in the commercial manufacture, use, or sale of a generic tazarotene (0.045%) lotion product in the United States. Padagis admits that ANDA No. 215393 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Padagis's opinion and to the best of its knowledge, no valid, enforceable claim of the '482 patent will be infringed by the importation, manufacture, use, offer for sale, or sale of the drug product for which ANDA No. 215393 was submitted. Except as expressly admitted, Padagis denies each and every remaining allegation contained in Paragraph 41 of the Complaint.

42. Padagis denies the allegations contained in Paragraph 42 of the Complaint.

43. Padagis denies the allegations contained in Paragraph 43 of the Complaint.

PRAYER FOR RELIEF

Padagis denies each and every allegation not specifically admitted herein, and further denies that Plaintiffs are entitled to the judgment and relief requested in Paragraphs 1-5 and 9 of

the Prayer for Relief in the Complaint or to any other relief. Padagis respectfully requests that the Court: (i) dismiss the Complaint with prejudice; (ii) enter judgment in favor of Padagis; (iii) award Padagis the reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and (iv) award Padagis such further relief as the Court deems just and appropriate.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its responses to Paragraphs 1 through 43 of the Complaint, Padagis asserts the following separate defenses to the Complaint. In doing so, Padagis does not intend to assume the burden of proof with respect to those matters for which Plaintiffs bear the burden of proof under the law. Padagis expressly reserves the right to allege additional defenses as they become known through the course of discovery.

First Affirmative Defense

The manufacture, use, sale, offer for sale, and/or importation of the product that is the subject of ANDA No. 215393 has not, does not, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the '482 patent.

Second Affirmative Defense

One or more claims of the '482 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112 and/or obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patents and/or defenses recognized in 35 U.S.C. § 282.

Third Affirmative Defense

To the extent the Complaint purports to seek an “exceptional case” determination, the Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285.

Fourth Affirmative Defense

Plaintiff has failed to state a claim for which relief can be granted because, *inter alia*, Padagis has not committed an act of infringement as prescribed in 35 U.S.C. § 271(e)(2).

Fifth Affirmative Defense

Padagis reserves the right to present any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendant/Counterclaimant Padagis Israel Pharmaceuticals Limited (“Padagis Israel”) brings the following Counterclaims against Plaintiffs/Counterdefendants Bausch Health Ireland Limited (“Bausch Ireland”), Bausch Health US, LLC (“Bausch US”), and Bausch Health Americas Inc. (“Bausch Americas”) (Bausch Ireland, Bausch US, and Bausch Americas are, collectively, “Bausch” or “Counterdefendants”) for a declaratory judgment that U.S. Patent No. 11,311,482 (“the ’482 patent”) is invalid and/or not infringed by Padagis Israel’s tazarotene (0.045%) lotion product that is the subject of ANDA No. 215393 (“ANDA Product”).

PARTIES

1. Counterclaimant Padagis Israel is a corporation organized and existing under the laws of Israel, and having a place of business at 1 Rakefet St., Shoham 608500, Israel.
2. Counterdefendants have averred that Bausch Ireland is a private company incorporated in Ireland with its office located at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

3. Counterdefendants have averred that Bausch US is a corporation organized and existing under the laws of Delaware with its headquarters located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

4. Counterdefendants have averred that Bausch Americas is a corporation organized and existing under the laws of Delaware with its headquarters located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

5. Counterdefendants have averred that Bausch Ireland is the assignee of the '482 patent and Counterdefendant Bausch US holds the approved New Drug Application ("NDA") No. 211882 for Arazlo® (tarazotene 0.045% strength).

JURISDICTION AND VENUE

6. Padagis Israel seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

7. The Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271(e)(2).

8. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by Counterdefendants' choice of forum.

9. Plaintiffs' assertions of patent infringement in this action (Civil Action No. 22-4248) give rise to an actual case or controversy between Padagis Israel and Plaintiffs concerning the invalidity and/or noninfringement of the '482 patent and Padagis Israel's right to continue to seek approval of ANDA No. 215393, and upon approval by the FDA, to manufacture, import, use, sell, or offer to sell its ANDA Product in the United States.

10. Padagis Israel has been and presently is engaged in the submission of documents for FDA approval to engage in the commercial manufacture, use, or sale of its ANDA Product.

Counterdefendants have alleged that Padagis Israel's ANDA Product has and will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '482 patent.

11. Counterdefendants have filed in this Court an infringement action to enforce the '482 patent.

12. Padagis Israel has denied that it has or will directly infringe, contributorily infringe, and/or induce infringement of any valid and enforceable claim of the '482 patent.

13. Padagis Israel has further asserted that the '482 patent is invalid for failure to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and in view of the defenses recognized in 35 U.S.C. § 282(b).

14. The '482 patent is listed in the FDA's electronic Orange Book with respect to Arazlo®.

15. Padagis Israel's ANDA No. 215393 includes a certification under FDCA § 505(j)(2)(A)(vii), Paragraph IV, that no valid, enforceable claim of the '482 patent will be infringed by the manufacture, importation, use, offer for sale, or sale of Padagis Israel's ANDA Product. On May 12, 2022, pursuant to § 505(j)(2)(B) of the FDCA, Padagis Israel notified Counterdefendants by letter ("Padagis Israel's Notice Letter") that Padagis Israel filed ANDA No. 215393 with the FDA containing certifications pursuant to FDCA § 505(j)(2)(A)(vii)(IV) that the claims of the '482 patent are invalid and/or would not be infringed by Padagis Israel's ANDA Product.

16. In view of the foregoing, a conflict of asserted rights has arisen between Padagis Israel and Counterdefendants with respect to the noninfringement and invalidity of the claims of the '482 patent, and as to Padagis Israel's right to obtain FDA approval to engage in the

commercial manufacture, importation, use, offer for sale, or sale of its ANDA Product. An actual controversy therefore exists between Counterdefendants and Padagis Israel.

FIRST COUNTERCLAIM
DECLARATION OF NONINFRINGEMENT OF THE '482 PATENT

17. Padagis Israel realleges Paragraphs 1-16 as though fully set forth herein.

18. Padagis Israel does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '482 patent.

19. The sale, offer for sale, manufacture, importation, and/or use of Padagis Israel's ANDA Product does not and will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid and enforceable claim of the '482 patent.

20. Padagis Israel's ANDA Product does not and will not infringe any claim of the '482 patent at least because Padagis Israel's ANDA Product does not satisfy the claims of the '482 patent.

21. Padagis Israel is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Padagis Israel's ANDA Product does not, and would not if marketed, infringe any valid and enforceable claim of the '482 patent.

SECOND COUNTERCLAIM
DECLARATION OF INVALIDITY OF THE '482 PATENT

22. Padagis Israel realleges Paragraphs 1-21 as though fully set forth herein.

23. The claims of the '482 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 101 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 102, 103, 112, and/or in view of the defenses recognized in 35 U.S.C. § 282(b).

24. The claims of the '482 patent are invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to International Patent Publication WO 2016/205001; U.S. Patent No. 6,517,847; U.S. Patent No. 8,808,716; International Patent Publication WO 2000/47211; International Patent Publication WO 1998/36753; US Patent Publication No. US 2012/0129824; ClinicalTrials.gov, "A Phase 2 Dosing Ranging, Evaluator-Blinded Study to Evaluate the Safety of Topical IDP-118"; U.S. Patent Publication No. US 2013/0310355; Highlights of Prescribing Information for TAZORAC® Cream; Ismail et al., Subchronic and Chronic Toxicity of Tazarotene Gel Following Topical Administration in Hanford Miniswine, 16 Int'l. J. Tox. 571 (1997); The Safety and Efficacy of Tazarotene Gel, a Topical Acetylenic Retinoid, in the Treatment of Psoriasis; U.S. Patent No. 6,730,308; Efficacy of Tazarotene 0.1% Cream and Adapalene 0.3% Gel in the Treatment of Patients with at Least Moderate Facial Acne Vulgaris; Meta-Analysis of Topical Tazarotene in the Treatment of Mild to Moderate Acne; Gennaro, A., Remington's Pharmaceutical Sciences (18th ed. 1990); Raymond C Rowe et al., Handbook of Pharmaceutical Excipients 110-114, 445- 449, 675-678 (6th ed. 2009); Lubrizol, Carbomer Homopolymer, Product Guide and Regulatory Overview 2011 Lubrizol Reference Information; TDS-114 2007 Pemulen Technical Data Sheet; International Patent Publication WO 2009/084020A2; U.S. Patent No. 8,962,028; U.S. Patent No. 8,071,578; U.S. Patent No. 4,244,942; U.S. Patent No. 5,326,566; and/or U.S. Patent No. 4,233,295.

25. Padagis Israel is entitled to a judicial declaration that the claims of the '482 patent are invalid.

DEMAND FOR JUDGMENT

WHEREFORE, Padagis Israel prays for the following relief:

A. That all claims against Padagis be dismissed with prejudice and that all relief

requested by Counterdefendants be denied;

B. That a judgment be entered declaring that Padagis has not, does not, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of U.S. Patent No. 11,311,482; that Padagis has a lawful right to obtain FDA approval of ANDA No. 215393; and further that Padagis has a lawful right to manufacture, import, use, sell, and/or offer to sell its ANDA Product in the United States once approved by the FDA;

C. That a judgment be entered declaring the claims of U.S. Patent No. 11,311,482 are invalid and/or unenforceable;

D. That Counterdefendants and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Padagis or any of its customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers of Padagis, or charging any of them either orally or in writing with infringement of U.S. Patent No. 11,311,482;

E. That a judgment be entered declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285 and that Padagis is therefore entitled to recover its reasonable attorneys' fees upon prevailing in this action;

F. That Padagis be awarded costs, attorney's fees, and other relief, both legal and equitable, to which it may be justly entitled; and

G. That Padagis be awarded such other and further relief as is just and proper.

Respectfully submitted,

Dated: August 26, 2022

/s/ Karen A. Confoy

Karen A. Confoy

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Defendants Padagis Israel Pharmaceuticals Ltd, Padagis US LLC, and Padagis LLC by their undersigned counsel, hereby certify that, the patent at issue in this action, U.S. Patent No. 11,311,482, has been asserted against Padagis by Plaintiffs Bausch Health Ireland Limited, Bausch Health US, LLC; and Bausch Health Americas Inc. (collectively “Bausch” or “Plaintiffs”) in this action (Civil Action No. 22-4248).

Padagis further certifies that, to the best of Padagis’s knowledge, the patent asserted by the Plaintiffs in this action is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: August 26, 2022

/s/ Karen A. Confoy

Karen A. Confoy

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Answer, Affirmative Defenses and Counterclaims and Local Rule 11.2 Certification were served on all counsel of record on this date via CM/ECF.

Dated: August 26, 2022

/s/ Karen A. Confoy
Karen A. Confoy