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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED, SALIX PHARMACEUTICALS, INC., and NORGINE B.V., Plaintiffs, v. LUPIN LTD., LUPIN ATLANTIS HOLDINGS SA, LUPIN INC. and LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No. 20-cv-11039-RMB-KMW **JURY TRIAL DEMANDED** *Document Filed Electronically*

LUPIN LIMITED, LUPIN ATLANTIS HOLDINGS SA, LUPIN INC., AND LUPIN PHARMACEUTICALS, INC.'S ANSWER, DEFENSES AND COUNTERCLAIMS

Defendants Lupin Limited, Lupin Atlantis Holdings SA, Lupin Inc. and Lupin Pharmaceuticals, Inc., (collectively, "the Lupin Defendants") hereby answer the Complaint of

Bausch Health Ireland Limited, Salix Pharmaceuticals, Inc., and Norgine B.V. (collectively, "Plaintiffs"), as follows.

GENERAL DENIAL

Pursuant to Federal Rule of Civil Procedure 8(b)(3), the Lupin Defendants deny all allegations in Plaintiffs' Complaint except those specifically admitted below.

THE PARTIES

1. Plaintiff Bausch Health Ireland Limited ("Bausch") is a company organized and existing under the laws of Ireland, having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations and, therefore, deny each and every allegation contained therein.

2. Plaintiff Salix Pharmaceuticals, Inc. ("Salix") is a corporation organized and existing under the laws of California, having its principle place of business at 400 Somerset Blvd., Bridgewater, NJ 08807. Salix is the registered holder of approved New Drug Application ("NDA") No. 209381, which covers Plenvu®.

ANSWER: Paragraph 2 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations and, therefore, deny each and every allegation contained therein.

3. Plaintiff Norgine B.V. ("Norgine") is a corporation organized and existing under the laws of the Netherlands, having a corporate headquarters at Antonio Vivaldistraat 150, 1083 HP Amsterdam, The Netherlands.

ANSWER: Paragraph 3 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations and, therefore, deny each and every allegation

contained therein.

4. Upon information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India, having a corporate headquarters at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited is an Indian corporation having a registered office at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India. The Lupin Defendants deny any and all remaining allegations of Paragraph 4. The Lupin Defendants further deny that Lupin Limited is a proper party to this action.

5. Upon information and belief, Defendant Lupin Atlantis Holdings SA ("Lupin Atlantis") is a corporation organized and existing under the laws of Switzerland, having a corporate headquarters at Landis & Gyr-Strasse 1, Zug, Switzerland 6300. Upon information and belief, Lupin Atlantis is a wholly-owned subsidiary of Lupin Ltd.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Atlantis Holdings SA is a Swiss corporation having its only place of business in Switzerland, including at Landis & Gyr-Strasse 1, Zug, Switzerland 6300. The Lupin Defendants further admit that Lupin Atlantis Holdings SA is a wholly owned subsidiary of Lupin Limited. The Lupin Defendants deny any and all remaining allegations of Paragraph 5. The Lupin Defendants further deny that Lupin Atlantis Holdings SA is a proper party to this action.

6. Upon information and belief, Defendant Lupin Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202. Upon information and belief, Lupin Inc. is a wholly-owned subsidiary of Lupin Atlantis.

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Inc. is a company

organized and existing under the laws of Delaware and having a place of business at 111 S. Calvert St., 21st Floor Baltimore, MD 21202. The Lupin Defendants further admit that Lupin Inc. is a wholly owned subsidiary of Lupin Atlantis Holdings S.A. The Lupin Defendants deny any and all remaining allegations of Paragraph 6.

7. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. ("Lupin Pharm.") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202. Upon information and belief, Lupin Pharm. is a subsidiary of Lupin Ltd. (3%) and Lupin Inc. (97%).

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Pharmaceuticals, Inc. is a Delaware corporation with a place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202. The Lupin Defendants further admit that Lupin Pharmaceuticals, Inc. is a subsidiary of Lupin Limited and Lupin Inc. The Lupin Defendants deny any and all remaining allegations of Paragraph 7. The Lupin Defendants further deny that Lupin Pharmaceuticals, Inc. is a proper party to this action.

NATURE OF THE ACTION

8. This is an action for infringement of United States Patent No. 10,646,512 B2 ("the '512 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Lupin's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market generic polyethylene glycol 3350 (140 g), sodium ascorbate (48.11 g), sodium sulfate (9 g), ascorbic acid (7.54 g), sodium chloride (5.2 g), and potassium chloride (2.2 g) for oral solution ("Lupin's ANDA Product").

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that the Complaint purports to state an action for alleged infringement of United States Patent No. 10,646,512 B2 ("the '512 patent") under 35 U.S.C. §§ 271 and 281, and for Declaratory Judgment under 28 U.S.C. §§ 28 U.S.C. §§

2201 and 2202. The Lupin Defendants further admit that Lupin Inc. submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval for Polyethylene Glycol 3350, Sodium Ascorbate, Sodium Sulfate, Ascorbic Acid, Sodium Chloride, and Potassium Chloride for Oral Solution, 140 g, 48.11 g, 9 g, 7.54 g, 5.2 g, 2.2 g ("Lupin Inc.'s ANDA Product"). The Lupin Defendants deny any and all remaining allegations of Paragraph 8.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, the Lupin Defendants do not contest subject matter jurisdiction solely for claims directed against Lupin Inc. under 35 U.S.C. § 271(e)(2), and solely for the limited purposes of this action only. The Lupin Defendants deny that subject matter jurisdiction is proper for any and all claims under 35 U.S.C. § 271(a), (b) or (c) asserted against any of the Lupin Defendants, and for any and all claims whatsoever asserted against Lupin Limited, Lupin Atlantis Holdings SA, and Lupin Pharmaceuticals, Inc. The Lupin Defendants deny any and all remaining allegations of Paragraph 9.

10. Upon information and belief, this Court has jurisdiction over Lupin Ltd. Upon information and belief, Lupin Ltd. is in the business of, inter alia, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Lupin Ltd. directly or indirectly manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Lupin's ANDA Product. Upon information and belief, Lupin Ltd. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Lupin Ltd. operates a manufacturing and research facility at 400 Campus Drive, Somerset, New Jersey 08873. Upon information and belief, Lupin Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in

other civil actions initiated in this jurisdiction.

ANSWER: Paragraph 10 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

11. 11. Upon information and belief, this Court has jurisdiction over Lupin Atlantis. Upon information and belief, Lupin Atlantis directly or indirectly manufactures, markets, and sells generic drug products, including generic drug products manufactured by Lupin Ltd., throughout the United States and in this judicial district. Upon information and belief, Lupin Atlantis purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Lupin Atlantis operates a manufacturing and research facility at 400 Campus Drive, Somerset, New Jersey 08873. Upon information and belief, Lupin Atlantis has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

ANSWER: Paragraph 11 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

12. Upon information and belief, this Court has jurisdiction over Lupin Inc. Upon information and belief, Lupin Inc. directly or indirectly manufactures, markets, and sells generic drug products, including generic drug products manufactured by Lupin Ltd., throughout the United States and in this judicial district. Upon information and belief, Lupin Inc. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Lupin Inc. operates a manufacturing and research facility at 400 Campus Drive, Somerset, New Jersey 08873. Upon information and belief, Lupin Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

ANSWER: Paragraph 12 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, Lupin Inc. does not contest personal jurisdiction in this judicial District solely for the limited purposes of this action only.

13. Upon information and belief, this Court has jurisdiction over Lupin Pharm. Upon information and belief, Lupin Pharm. directly or indirectly manufactures, markets, and sells generic drug products, including generic drug products manufactured by Lupin Ltd., throughout the United States and in this judicial district. Upon information and belief, Lupin Pharm. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Lupin Pharm. operates a manufacturing and research

facility at 400 Campus Drive, Somerset, New Jersey 08873. Upon information and belief, Lupin Pharm. is registered to do business in New Jersey (business identification number 0101043376) and is registered with the State of New Jersey as a manufacturer and wholesale distributor of drugs under Registration Numbers 5004060 and 5005159. Upon information and belief, Lupin Pharm. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

ANSWER: Paragraph 13 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

14. Upon information and belief, Defendants have a regular and established place of business in this judicial district because, for example, they maintain a place of business in this judicial district at 400 Campus Drive, Somerset, New Jersey 08873.

ANSWER: Paragraph 14 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

15. Upon information and belief, Lupin Ltd., Lupin Atlantis, Lupin Inc., and Lupin Pharm. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products in the United States. Upon information and belief, Lupin employs "vertical integration in discovery research, process chemistry, active pharmaceutical ingredient production, formulation development and regulatory filings." (See http://www.lupinpharmaceuticals.com/about.htm, last accessed April 1, 2019.)

ANSWER: Paragraph 15 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

16. Lupin's ANDA No. 212934 is the subject of an ongoing infringement litigation in the District of New Jersey: *Bausch Health Ireland Limited v. Lupin Inc.*, Civil Action No. 19-cv-09178-RMB-KMW, in which Lupin has consented to personal jurisdiction and venue before this Court.

ANSWER: Paragraph 16 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Inc. is a named defendant in Civil Action No. 19-cv-09178. The Lupin Defendants further admit that Civil Action No. 19-cv-09178 is related to Lupin's ANDA No. 212934. The Lupin Defendants deny any and all remaining allegations of Paragraph 16.

17. Lupin Ltd. and Lupin Pharm. availed themselves of the rights, benefits, and privileges of this Court by filing a complaint in the District of New Jersey in at least the following action: *Lupin Ltd. v. Merck, Sharp & Dohme Corp.*, Civil Action No. 10-cv-00683.

ANSWER: Paragraph 17 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited and Lupin Pharmaceuticals, Inc. were the named plaintiffs in Civil Action No. 3:10-cv-00683. The Lupin Defendants deny any and all remaining allegations of Paragraph 17.

18. Lupin Ltd., Lupin Atlantis, Lupin Inc., and/or Lupin Pharm. consented to or did not contest jurisdiction of this Court, for example, in at least the following District of New Jersey actions: *Jazz Pharm., Inc. v. Lupin Ltd.*, Civil Action No. 13-cv-00391-ES-JAD (Lupin Inc.); *Otsuka Pharm. Co., Ltd. v. Lupin Ltd.*, Civil Action No. 14-cv-07105-JBS-KMW (Lupin Ltd., Lupin Atlantis, and Lupin Pharm.); *Horizon Pharma Ireland Ltd. v. Lupin Ltd.*, Civil Action No. 15-cv-06935-NLH-AMD (Lupin Ltd. and Lupin Pharm.); *Senju Pharm. Co., Ltd. v. Lupin Ltd.*, Civil Action No. 16-cv-01097-JBS-KMW (Lupin Ltd. and Lupin Pharm.); *Sun Pharma Global FZE v. Lupin Ltd.*, Civil Action No. 18-cv-02213-FLW-TJB (Lupin Ltd. and Lupin Pharm.); *Endo Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-10952-FLW-TJB (Lupin Atlantis and Lupin Inc.); *Boehringer Ingelheim Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-12663-BRM-TJB (Lupin Ltd. and Lupin Atlantis); *Valeant Pharm. N. Am. LLC v. Lupin Ltd.*, Civil Action No. 18-cv-13700-PGS-LHG (Lupin Ltd.); *Boehringer Ingelheim Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-16708-BRM-TJB (Lupin Ltd. and Lupin Atlantis).

ANSWER: Paragraph 18 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that certain Lupin Defendants were defendants in *Jazz Pharm., Inc. v. Lupin Ltd.*, Civil Action No. 13-cv-00391 (Lupin Inc.); *Otsuka Pharm. Co., Ltd. v. Lupin Ltd.*, Civil Action No. 14-cv-07105-JBS-KMW (Lupin Limited, Lupin Atlantis, and Lupin Pharm.); *Horizon Pharma Ireland Ltd. v. Lupin Ltd.*, Civil Action No. 15-cv-06935-NLH-AMD (Lupin Limited and Lupin Pharm.); *Senju Pharm. Co., Ltd. v. Lupin Ltd.*, Civil Action No. 16-cv-01097-JBS-KMW (Lupin Limited and Lupin Pharm.); *Sun Pharma Global FZE v. Lupin Ltd.*, Civil Action No. 18-cv-02213-FLW-TJB (Lupin Limited and Lupin Pharm.); *Endo Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-10952-FLW-TJB (Lupin Atlantis and Lupin Inc.); *Boehringer Ingelheim Pharm., Inc. v.*

Lupin Atlantis Holdings SA, Civil Action No. 18-cv-12663-BRM-TJB (Lupin Limited and Lupin Atlantis); *Valeant Pharm. N. Am. LLC v. Lupin Ltd.*, Civil Action No. 18-cv-13700-PGS-LHG (Lupin Limited); *Boehringer Ingelheim Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-16708-BRM-TJB (Lupin Limited and Lupin Atlantis). The Lupin Defendants deny any and all remaining allegations of Paragraph 18.

19. Lupin Ltd., Lupin Atlantis, Lupin Inc., and/or Lupin Pharm. availed themselves of the rights, benefits, and privileges of this Court by asserting counterclaims, for example, in at least the following District of New Jersey actions: *Jazz Pharm., Inc. v. Lupin Ltd.*, Civil Action No. 13- cv-00391-ES-JAD (Lupin Ltd., Lupin Inc., and Lupin Pharm.); *Horizon Pharma Ireland Ltd. v. Lupin Ltd.*, Civil Action No. 15-cv-06935-NLH-AMD (Lupin Ltd.); *Senju Pharm. Co., Ltd. v. Lupin Ltd.*, Civil Action No. 16-cv-01097-JBS-KMW (Lupin Ltd.); *Sun Pharma Global FZE v. Lupin Ltd.*, Civil Action No. 18-cv-02213-FLW-TJB (Lupin Ltd.); *Endo Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-10952-FLW-TJB (Lupin Atlantis and Lupin Inc.); *Boehringer Ingelheim Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-12663- BRM-TJB (Lupin Atlantis); *Valeant Pharm. N. Am. LLC v. Lupin Ltd.*, Civil Action No. 18-cv- 13700-PGS-LHG (Lupin Ltd.); *Boehringer Ingelheim Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-16708-BRM-TJB (Lupin Atlantis).

ANSWER: Paragraph 19 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that certain Lupin Defendants asserted counterclaims in *Jazz Pharm., Inc. v. Lupin Ltd.*, Civil Action No. 13-cv-00391 (Lupin Limited, Lupin Inc., and Lupin Pharm.); *Horizon Pharma Ireland Ltd. v. Lupin Ltd.*, Civil Action No. 15-cv-06935-NLH-AMD (Lupin Limited); *Senju Pharm. Co., Ltd. v. Lupin Ltd.*, Civil Action No. 16-cv-01097-JBS-KMW (Lupin Limited); *Sun Pharma Global FZE v. Lupin Ltd.*, Civil Action No. 18-cv-02213-FLW-TJB (Lupin Limited); *Endo Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-10952-FLW-TJB (Lupin Atlantis and Lupin Inc.); *Boehringer Ingelheim Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-12663-BRM-TJB (Lupin Atlantis); *Valeant Pharm. N. Am. LLC v. Lupin Ltd.*, Civil Action No. 18-cv-13700-PGS-LHG (Lupin Limited); *Boehringer Ingelheim Pharm., Inc. v. Lupin Atlantis Holdings*

SA, Civil Action No. 18-cv-16708-BRM-TJB (Lupin Atlantis). The Lupin Defendants deny any and all remaining allegations of Paragraph 19.

20. Lupin is subject to specific jurisdiction in this judicial district based on the filing of its ANDA for its generic polyethylene glycol 3350 (140 g), sodium ascorbate (48.11 g), sodium sulfate (9 g), ascorbic acid (7.54 g), sodium chloride (5.2 g), and potassium chloride (2.2 g) for oral solution.

ANSWER: Paragraph 20 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, Lupin Inc. does not contest personal jurisdiction in this judicial District solely for the limited purposes of this action only.

21. Lupin has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, this judicial district and elsewhere.

ANSWER: Paragraph 21 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

22. Lupin's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs.

ANSWER: Paragraph 22 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

23. Upon information and belief, Lupin intends to direct sales of its drugs into New Jersey, among other places, once it has requested FDA approval to market them.

ANSWER: Paragraph 23 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

24. Upon information and belief, Lupin will engage in marketing of Lupin's ANDA Product in New Jersey, upon approval of its ANDA.

ANSWER: Paragraph 24 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

25. Lupin's ANDA filing regarding the '512 patent at issue here is suit-related and has a substantial connection with this judicial district because it reliably, non-speculatively predicts activities by Lupin in this judicial district.

ANSWER: Paragraph 25 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

26. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and 1400(b).

ANSWER: Paragraph 26 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, Lupin Inc. does not contest venue in this judicial District solely for the limited purposes of this action only.

27. Lupin Ltd., Lupin Atlantis, Lupin Inc., and/or Lupin Pharm. did not contest venue in this judicial district in at least the following actions: *Jazz Pharm., Inc. v. Lupin Ltd.*, Civil Action No. 13-cv-00391-ES-SCM (Lupin Inc.); *Otsuka Pharm. Co., Ltd. v. Lupin Ltd.*, Civil Action No. 14-cv-07105-JBS-KMW (Lupin Ltd. and Lupin Pharm.); *Horizon Pharma Ireland Ltd. v. Lupin Ltd.*, Civil Action No. 15-cv-06935-NLH-AMD (Lupin Ltd. and Lupin Pharm.); *Senju Pharm. Co., Ltd. v. Lupin Ltd.*, Civil Action No. 16-cv-01097-JBS-KMW (Lupin Ltd. and Lupin Pharm.); *Sun Pharma Global FZE v. Lupin Ltd.*, Civil Action No. 18-cv-02213-FLW-TJB (Lupin Ltd. And Lupin Pharm.); *Endo Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-10952-FLW-TJB (Lupin Atlantis and Lupin Inc.); *Boehringer Ingelheim Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-12663-BRM-TJB (Lupin Ltd. and Lupin Atlantis); *Valeant Pharm. N. Am. LLC v. Lupin Ltd.*, Civil Action No. 18-cv-13700-PGS-LHG (Lupin Ltd.); *Boehringer Ingelheim Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-16708-BRM-TJB (Lupin Ltd. and Lupin Atlantis).

ANSWER: Paragraph 27 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that certain Lupin Defendants were defendants in *Jazz Pharm., Inc. v. Lupin Ltd.*, Civil Action No. 13-cv-00391 (Lupin Inc.); *Otsuka Pharm. Co., Ltd. v. Lupin Ltd.*, Civil Action No. 14-cv-07105-JBS-KMW (Lupin Limited and Lupin Pharm.); *Horizon Pharma Ireland Ltd. v. Lupin Ltd.*, Civil Action No. 15-cv-06935-NLH-AMD (Lupin Limited and Lupin Pharm.); *Senju Pharm. Co., Ltd. v. Lupin*

Ltd., Civil Action No. 16-cv-01097-JBS-KMW (Lupin Limited and Lupin Pharm.); *Sun Pharma Global FZE v. Lupin Ltd.*, Civil Action No. 18-cv-02213-FLW-TJB (Lupin Limited and Lupin Pharm.); *Endo Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-10952-FLW-TJB (Lupin Atlantis and Lupin Inc.); *Boehringer Ingelheim Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-12663-BRM-TJB (Lupin Limited and Lupin Atlantis); *Valeant Pharm. N. Am. LLC v. Lupin Ltd.*, Civil Action No. 18-cv-13700-PGS-LHG (Lupin Limited); *Boehringer Ingelheim Pharm., Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 18-cv-16708-BRM-TJB (Lupin Limited and Lupin Atlantis). The Lupin Defendants deny any and all remaining allegations of Paragraph 27.

28. Venue is proper against Lupin Ltd., a foreign corporation, in any judicial district that has personal jurisdiction, including this district.

ANSWER: Paragraph 28 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

29. Venue is proper against Lupin Ltd. because, *inter alia*, it maintains a regular and established place of business in this judicial district.

ANSWER: Paragraph 29 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

30. Venue is proper against Lupin Atlantis, a foreign corporation, in any judicial district that has personal jurisdiction, including this district.

ANSWER: Paragraph 30 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

31. Venue is proper against Lupin Atlantis because, *inter alia*, it maintains a regular and established place of business in this judicial district.

ANSWER: Paragraph 31 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

32. Venue is proper against Lupin Inc. because, *inter alia*, it maintains a regular and established place of business in this judicial district.

ANSWER: Paragraph 32 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, Lupin Inc. does not contest venue in this judicial District solely for the limited purposes of this action only.

33. Venue is proper against Lupin Pharm. because, *inter alia*, it maintains a regular and established place of business in this judicial district.

ANSWER: Paragraph 33 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

THE PATENT IN SUIT

34. The U.S. Patent and Trademark Office ("PTO") issued the '512 patent on May 12, 2020. The '512 patent claims, *inter alia*, compositions for admixture with water, compositions, and kits comprising compositions for the preparation of colon cleansing solutions. Plaintiffs hold all substantial rights in the '512 patent and have the right to sue for infringement thereof. Norgine is the assignee of the '512 patent. A copy of the '512 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, according to the electronic records of the U.S. Patent and Trademark Office, the '512 patent issued on or about May 12, 2020. The Lupin Defendants further admit that "Norgine BV" is listed as the "Assignee" on the face of the '512 patent. The Lupin Defendants further admit that what appears to be a copy of the '512 patent is attached to the Complaint as Exhibit A. The Lupin Defendants deny any and all remaining allegations of Paragraph 34.

35. Salix is the holder of NDA No. 209381 for Plenvu®, which the FDA approved on May 4, 2018. In conjunction with NDA No. 209381, the '512 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), together with U.S. Patent Nos. 8,999,313 B2; 9,326,969 B2; 9,592,252 B2; 9,707,297 B2; and 10,016,504 B2, which are the subject of an ongoing infringement litigation in the District of

New Jersey: *Bausch Health Ireland Limited v. Lupin Inc*., Civil Action No. 19-cv-09178-RMB-KMW.

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that the electronic version of FDA's Orange Book (i) identifies "SALIX PHARMACEUTICALS INC" as the holder of NDA No. 209381 and (ii) lists the "Approval Date" of NDA No. 209381 as May 4, 2018. The Lupin Defendants further admit that the '512 patent is listed in the electronic Orange Book in connection with NDA No. 209381. The Lupin Defendants further admit that U.S. Patent Nos. 8,999,313 B2; 9,326,969 B2; 9,592,252 B2; 9,707,297 B2; and 10,016,504 B2, are the subject of *Bausch Health Ireland Limited v. Lupin Inc*., Civil Action No. 19-cv-09178-RMB-KMW. The Lupin Defendants deny any and all remaining allegations of Paragraph 35.

36. Polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution is sold in the United States under the trademark Plenvu®.

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that the electronic version of FDA's Orange Book for NDA No. 209381 identifies polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride as "Active Ingredients" and PLENVU as the "Proprietary Name." The Lupin Defendants deny any and all remaining allegations of Paragraph 36.

LUPIN'S ANDA SUBMISSION

37. Upon information and belief, Lupin filed or cause to be filed with the FDA ANDA No. 212934, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Inc. submitted ANDA No. 212934 to the FDA. The Lupin Defendants deny all remaining allegations of Paragraph 37.

38. Upon information and belief, Lupin's ANDA No. 212934 seeks FDA approval to engage in commercial manufacture, use, and sale in the United States of Lupin's ANDA Product, which Lupin intends to be a generic version of Plenvu®.

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Inc. submitted ANDA No. 212934 seeking approval for Polyethylene Glycol 3350, Sodium Ascorbate, Sodium Sulfate, Ascorbic Acid, Sodium Chloride, and Potassium Chloride for Oral Solution, 140 g, 48.11 g, 9 g, 7.54 g, 5.2 g, 2.2 g. The Lupin Defendants deny all remaining allegations of Paragraph 38.

39. Plaintiffs received a letter from Lupin Inc. dated July 8, 2020, purporting to be a Notice of Certification for ANDA No. 212934 ("Lupin's Notice Letter") under Section 505(j)(2)(B)(ii)–(iv) of the Act and 21 § C.F.R. 314.95(c). Lupin's Notice Letter was addressed to Salix, Norgine, Bausch, and Bausch Health Companies Inc.

ANSWER: Paragraph 39 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that in a Notification dated July 8, 2020 ("the July 8, 2020 Notification"), Lupin Inc. provided the requisite notice to Salix Pharmaceuticals, Inc., Norgine B.V., and Bausch Health Companies Inc. that Lupin Inc. filed an ANDA with FDA seeking approval for Polyethylene Glycol 3350, Sodium Ascorbate, Sodium Sulfate, Ascorbic Acid, Sodium Chloride, and Potassium Chloride for Oral Solution, 140 g, 48.11 g, 9 g, 7.54 g, 5.2 g, 2.2 g. The Lupin Defendants deny any and all remaining allegations of Paragraph 39.

40. Lupin's Notice Letter alleges that Lupin Inc. has submitted to the FDA ANDA No. 212934 seeking to engage in the manufacture, use, and sale of Lupin's ANDA Product.

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that the July 8, 2020 Notification stated "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(l) and (2)(A), and contains paragraph IV certifications to obtain approval to engage in the commercial manufacture, use or

sale of Polyethylene Glycol 3350, Sodium Ascorbate, Sodium Sulfate, Ascorbic Acid, Sodium Chloride, and Potassium Chloride for Oral Solution, 140 g, 48.11 g, 9 g, 7.54 g, 5.2 g, 2.2 g." The Lupin Defendants deny any and all remaining allegations of Paragraph 40.

41. Lupin's Notice Letter states that Lupin's ANDA No. 212934 "contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver" for Lupin's ANDA Product.

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that the July 8, 2020 Notification stated "[t]he ANDA contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver." The Lupin Defendants deny any and all remaining allegations of Paragraph 41.

42. Lupin's Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defense, does not set forth any noninfringement defense related to claims 1–16 of the '512 patent.

ANSWER: Paragraph 42 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

43. The '512 patent is listed in the Orange Book in conjunction with NDA No. 209381 for Plenvu®.

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that the '512 patent is listed in the electronic Orange Book in connection with NDA No. 209381. The Lupin Defendants deny any and all remaining allegations of Paragraph 43.

44. Upon information and belief, ANDA No. 212934 seeks approval of Lupin's ANDA Product that is the same, or substantially the same, as Plenvu®.

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that ANDA No. 212934 seeks

approval for Polyethylene Glycol 3350, Sodium Ascorbate, Sodium Sulfate, Ascorbic Acid, Sodium Chloride, and Potassium Chloride for Oral Solution, 140 g, 48.11 g, 9 g, 7.54 g, 5.2 g, 2.2 g. The Lupin Defendants deny any and all remaining allegations of Paragraph 44.

45. Upon information and belief, Lupin Inc.'s actions related to ANDA No. 212934 complained of herein were done at the direction of, with the authorization of, or with the cooperation, the participation, the assistance of, or at least in part for the benefit of Lupin Ltd., Lupin Atlantis, and Lupin Pharm.

ANSWER: Paragraph 45 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

COUNT I
'512 Patent

46. Paragraphs 1–45 are incorporated herein as set forth above.

ANSWER: The Lupin Defendants restate and incorporate by reference their responses to the preceding Paragraphs 1 through 45 of the Complaint as if fully set forth herein.

47. Under 35 U.S.C. § 271(e)(2), Lupin has infringed at least one claim of the '512 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212934 seeking approval for the commercial marketing of Lupin's ANDA Product before the expiration date of the '512 patent.

ANSWER: Denied.

48. Upon information and belief, Lupin's ANDA Product will, if approved and marketed, infringe at least one claim of the '512 patent.

ANSWER: Denied.

49. Upon information and belief, Lupin will, through the manufacture, use, import, offer for sale, and/or sale of Lupin's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '512 patent.

ANSWER: Denied.

50. If Lupin's marketing and sale of Lupin's ANDA Product prior to the expiration of the '512 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT II
'512 Patent

51. Paragraphs 1–50 are incorporated herein as set forth above.

ANSWER: The Lupin Defendants restate and incorporate by reference their responses to the preceding Paragraphs 1 through 50 of the Complaint as if fully set forth herein.

52. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 52 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

53. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 53 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

54. Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Lupin's ANDA Product before the expiration date of the '512 patent, including Lupin's filing of ANDA No. 212934.

ANSWER: Paragraph 54 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

55. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '512 patent.

ANSWER: Denied.

56. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Lupin's ANDA Product will constitute infringement of at least one claim of the '512 patent.

ANSWER: Denied.

* * *

The Lupin Defendants deny that Plaintiffs are entitled to any of the relief prayed for in the Complaint or to any relief whatsoever, and further request that judgment be entered in favor of the Lupin Defendants, dismissing Plaintiffs' Complaint with prejudice, awarding the Lupin Defendants attorneys' fees and costs incurred defending this action under 35 U.S.C. § 285, and granting such further relief as this Court may deem just and proper.

SEPARATE DEFENSES

Without prejudice to the denials set forth in their Answer, without admitting any averments of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, the Lupin Defendants aver and assert the following defenses to the Complaint:

First Defense

The claims of the ’512 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability, including double-patenting.

Second Defense

The manufacture, use, sale, offer for sale or importation of Lupin Inc.’s proposed Polyethylene Glycol 3350, Sodium Ascorbate, Sodium Sulfate, Ascorbic Acid, Sodium Chloride, and Potassium Chloride for Oral Solution, 140 g, 48.11 g, 9 g, 7.54 g, 5.2 g, 2.2 g, does not and would not infringe, either directly or indirectly, any valid and/or enforceable claim of the ’512 patent, either literally or under the doctrine of equivalents.

Third Defense

The Lupin Defendants have not induced, do not induce, and will not induce infringement of any valid and/or enforceable claim of the ’512 patent.

Fourth Defense

The Lupin Defendants have not contributed, do not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ’512 patent.

Fifth Defense

Plaintiffs' claims are barred in whole or in part by the doctrine of prosecution history estoppel. Under the doctrine of prosecution history estoppel, Plaintiffs cannot use the doctrine of equivalents to reclaim claim scope surrendered during prosecution.

Sixth Defense

Lupin Limited, Lupin Atlantis Holdings SA, and Lupin Pharmaceuticals, Inc. are not proper parties to this action under 35 U.S.C. § 271(e)(2)(A).

Seventh Defense

The Court lacks personal jurisdiction over Lupin Limited, Lupin Atlantis Holdings SA, and Lupin Pharmaceuticals, Inc.

Eighth Defense

Venue is improper for Lupin Limited, Lupin Atlantis Holdings SA, and Lupin Pharmaceuticals, Inc.

Ninth Defense

The Court lacks subject matter jurisdiction over any and all claims under 35 U.S.C. § 271(a), (b) or (c) asserted against any of the Lupin Defendants, and for any and all claims whatsoever asserted against Lupin Limited, Lupin Atlantis Holdings SA, and Lupin Pharmaceuticals, Inc.

Tenth Defense

The Lupin Defendants are exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e)(1).

Eleventh Defense

The Complaint fails to state a claim for exceptional case or willful infringement.

Twelfth Defense

The Complaint fails to state a claim upon which relief can be granted.

Thirteenth Defense

Any defense asserted in any other action in which the ’512 patent are asserted.

Fourteenth Defense

Any additional defenses or counterclaims that discovery may reveal, including unenforceability.

COUNTERCLAIMS

Defendant Lupin Inc., for its Counterclaims against Plaintiffs Bausch Health Ireland Limited, Salix Pharmaceuticals, Inc., and Norgine B.V. ("Plaintiffs/Counterclaim-Defendants"), alleges as follows:

Parties

1. Lupin Inc. is a corporation organized and existing under the laws of Delaware and having a place of business at 111 S. Calvert St., 21st Floor Baltimore, MD 21202.

2. Plaintiff Bausch Health Ireland Limited purports and claims to be a corporation organized and existing under the laws of Ireland, having a place of business at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

3. Plaintiff Salix Pharmaceuticals, Inc. purports and claims to be a corporation organized and existing under the laws of California, having a place of business at 400 Somerset Blvd., Bridgewater, NJ 08807.

4. Plaintiff Norgine B.V. purports and claims to be a corporation organized and existing under the laws of the Netherlands, having a place of business at Antonio Vivaldistraat 150, 1083 HP Amsterdam, the Netherlands.

Jurisdiction and Venue

5. These Counterclaims arise under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Lupin Inc. in this District, and/or because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular systematic contacts with, this District.

8. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and 1400(b).

The Patent-in-Suit

9. On or about May 12, 2020, the United States Patent and Trademark Office issued U.S. Patent No. 10,646,512 B2 ("the '512 patent"), entitled "Colonoscopy—Preparation" to Marc Halphen, Hans-Jurgen Gruss, Ian Cox, Alasdair Cockett, Peter Stein, and Alex Ungar.

10. On information and belief, Plaintiffs/Counterclaim-Defendants purport and claim to own, and/or to have the right to enforce, the '512 patent.

11. On or about August 21, 2020, Plaintiffs/Counterclaim-Defendants filed a Complaint against Lupin Inc., Lupin Limited, Lupin Atlantis Holdings SA, and Lupin Pharmaceuticals, Inc. in this District alleging infringement of the '512 patent.

Lupin Inc.'s ANDA Product

12. Lupin Inc. filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval for Polyethylene Glycol 3350, Sodium Ascorbate, Sodium Sulfate, Ascorbic Acid, Sodium Chloride, and Potassium Chloride for Oral Solution, 140 g, 48.11 g, 9 g, 7.54 g, 5.2 g, 2.2 g ("Lupin Inc.'s ANDA Product").

13. FDA assigned Lupin Inc.'s ANDA No. 212934.

14. Because Lupin Inc. seeks approval to market its ANDA Product prior to the expiration of the '512 patent, Lupin Inc. included paragraph IV certifications in its ANDA.

15. Lupin Inc. provided proper and timely notice of its paragraph IV certifications to

Salix Pharmaceuticals, Inc., Norgine B.V., and Bausch Health Companies Inc., as required under 21 U.S.C. § 355(j)(2)(B), by a Notification dated July 8, 2020 ("the July 8, 2020 Notification"), which included an offer of confidential access to Lupin Inc.'s ANDA No. 212934.

16. The manufacture, use, sale, offer for sale or importation of Lupin Inc.'s ANDA Product does not and will not infringe any valid and/or enforceable claim of the '512 patent.

17. The claims of the '512 patent are invalid.

Count I
(Declaratory Judgment of Non-Infringement of the '512 Patent)

18. Lupin Inc. adopts by reference, repeats, and realleges its specific allegations and averments in the preceding paragraphs above as if fully set forth herein.

19. There is an actual, substantial, and continuing justiciable case or controversy between Lupin Inc. and Plaintiffs/Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding, *inter alia*, non-infringement of the '512 patent.

20. The manufacture, use, offer for sale, sale or importation of Lupin Inc.'s ANDA Product has not infringed, does not infringe, and will not infringe any valid and/or enforceable claim of the '512 patent, either literally or under the doctrine of equivalents, for at least the reasons set forth in the July 8, 2019 Notification, including, by example only, because the claims of the '512 patent are invalid and/or unenforceable, *see Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971) for proposition that "invalidity operates as a complete defense to infringement for any product, forever").

21. Lupin Inc. is entitled to a declaration that the manufacture, use, offer for sale, sale or importation of Lupin Inc.'s ANDA Product has not infringed, does not infringe, and will not

infringe any valid and/or enforceable claim of the '512 patent, either literally or under the doctrine of equivalents.

Count II
(Declaratory Judgment of Invalidity of the '512 Patent)

22. Lupin Inc. adopts by reference, repeats, and realleges its specific allegations and averments in the preceding paragraphs above as if fully set forth herein.

23. There is an actual, substantial, and continuing justiciable case or controversy between Lupin Inc. and Plaintiffs/Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding, *inter alia*, the invalidity of the '512 patent.

24. Each of the claims of the '512 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation, such as double-patenting, or unenforceability, for at least the reasons set forth in the July 8, 2020 Notification.

25. For example, and not by way of limitation, one or more claims of the '512 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the '512 patent, including in view of at least (but not limited to) the following: International Application Publication No. WO 2011/007153 A1, which published on January 20, 2011 ("Attwell"); German Patent Publication No. DE 20 2010 010 312 U1 (and EPO English translation thereof), which published on December 09, 2010 ("DE '312"); U.S. Patent No. 5,858,403, which issued on January 12, 1999 ("Borody"); Stéphane Mouly et al., *Effects of the Addition of High-Dose Vitamin C to Polyethylene Glycol Solution for Colonic Cleansing: A Pilot Study in Healthy Volunteers*, 66 CURRENT THERAPEUTIC RES. 486 (2005)

("Mouly"); MoviPrep® Prescribing Information, PHYSICIANS' DESK REFERENCE 2905 (64th ed. 2010) ("MoviPrep PI"); U.S. Patent Application Publication No. 2009/0324736 A1, which published on December 31, 2009 ("Johnson"); International Application Publication No. WO 2009/052256 A2, which published on April 23, 2009 ("Kastenberg"); and U.S. Patent Application Publication No. 2010/0255122 A1, which published on October 7, 2010 ("Garren").

26. There is no objective evidence of non-obviousness of the claims of the '512 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the '512 patent or outweigh the evidence in support of obviousness.

27. For example, and not by way of limitation, one or more claims of the '512 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement; (2) failing to comply with the "enablement" requirement; and/or (3) failing to comply with the "definiteness" requirement. The '512 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the '512 patent can conclude that the inventors were in possession of the claimed invention as of the filing date. The '512 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the '512 patent how to make and how to use the full scope of the claimed invention without undue experimentation. The '512 patent claims do not satisfy the definiteness requirement at least because those of ordinary skill in the art as relevant to the '512 patent would not understand the full scope of the '512 patent claims with reasonable certainty when read in light of the specification.

28. Lupin Inc. is entitled to a declaration that the claims of the '512 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Lupin Inc. respectfully prays for judgment in its favor and against

Plaintiffs/Counterclaim-Defendants:

(a) declaring that the manufacture, use, sale, offer for sale or importation of Lupin Inc.'s ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '512 patent;

(b) declaring that the claims of the '512 patent are invalid;

(c) ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Lupin Inc.;

(d) declaring this case exceptional and awarding Lupin Inc. its reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and

(e) awarding Lupin Inc. such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Lupin Inc. hereby demands a jury trial on all issues so triable.

Dated: December 30, 2020

Respectfully submitted,

By: */s/ Melissa E. Flax*

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Defendants hereby certifies that this matter is not the subject of any other action asserted by Defendants in any court, or of any pending arbitration or administrative proceeding, with the exception that the above-captioned action concerns the same ANDA that is at issue in the following action pending in this District before the Honorable Renée Marie Bumb, U.S.D.J. and the Honorable Karen M. Williams, U.S.M.J.: *Bausch Health Ireland Limited, et al. v. Lupin Ltd.*, Civil Action No. 19-9178 (RMB) (KMW).

Dated: December 30, 2020

Respectfully submitted,

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LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Defendants hereby certifies that Defendants seek declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: December 30, 2020

Respectfully submitted,

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