MIDLIGE RICHTER, LLC
645 Martinsville Road
Basking Ridge, New Jersey 07920
(908) 626-0622
James S. Richter

Attorneys for Defendants,
Lupin, Ltd. and Lupin Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICALS U.S.A., INC. and VIROPHARMA BIOLOGICS LLC,	:	Honorable Robert Kirsch, U.S.D.J.
	:	Civil Action No. 25 CV 12574 (RK)(TJB)
Plaintiffs,	:	
v.	:	**DEFENDANTS' ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**
LUPIN, LTD. and LUPIN PHARMACEUTICALS, INC.,	:	
Defendants.	:	

Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Defendants") by and through the undersigned attorneys, answer the Complaint of Plainitffs, Takeda Pharmaceuticals U.S.A., Inc. ("TPUSA") and ViroPharma Biologics LLC ("ViroPharma") (collectively, "Plaintiffs"), and assert their separate defenses, and Lupin Ltd. asserts its separate counterclaims, as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Defendants deny all allegations in Plaintiffs' Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 11,260,064 ("the '064 patent") and 11,564,934 ("the '934 patent") (collectively, the "Patents-in-Suit") under the patent laws of the United States, 35 U.S.C. §100, *et seq*. This action arises from Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 220382 ("Lupin's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell a generic version of Plaintiffs' EOHILIA® drug product prior to the expiration of the Patents-in-Suit.

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Plaintiffs' Complaint purports to be a civil action alleging infringement pursuant to Title 35 of the United States Code. Defendants deny all remaining allegations of Paragraph 1.

THE PARTIES

2. TPUSA is a corporation organized and existing under the laws of the State of Delaware, having an office and place of business at 500 Kendall Street, Cambridge, Massachusetts 02142.

ANSWER: Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations contained in Paragraph 2 of the Complaint, and on that basis, deny them.

3. ViroPharma is a corporation organized and existing under the laws of the State of Delaware, having an office and place of business at 300 Shire Way, Lexington, Massachusetts 02421.

ANSWER: Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations contained in Paragraph 3 of the Complaint and, on that basis, deny them.

4. On information and belief, Lupin, Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Kalpataru Inspire, 3rd Floor, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd. is a

cooperation organized and existing under the laws of India, having a principal place of business at Kalpataru Inspire, 3rd Floor, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India. To the extent not expressly admitted, Defendants deny the remaining allegations contained in Paragraph 4 of the Complaint.

5. On information and belief, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having places of business at 15 Jensen Drive, Somerset, New Jersey 08873 and 400 Campus Drive, Somerset, New Jersey 08873.

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Pharmaceuticals, Inc. is a cooperation organized and existing under the laws of the State of Delaware, having places of business at 5801 Pelican Bay Blvd., Suite 500, Naples, FL 34108-273. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations in this paragraph.

6. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin, Ltd.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Ltd. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. To the extent not expressly admitted, Defendants deny the remaining allegations contained in Paragraph 6 of the Complaint.

THE PATENTS-IN-SUIT

7. On March 1, 2022, the United States Patent and Trademark Office duly and lawfully issued the ’064 patent, entitled “Stable Corticosteroid Compositions” to ViroPharma Biologics LLC as assignee of inventor Ramalingeswar Kasina. A copy of the ’064 patent is attached as Exhibit A.

ANSWER: Defendants admit that Plaintiffs purport to attach a copy of the ’064 patent to the Complaint as Exhibit A. Defendants further admit that on its face, the ’064 patent is titled

"Stable Corticosteroid Compositions," and indicates that it issued on March 1, 2022, to assignee ViroPharma Biologics LLC of inventor Ramalingeswar Kasina. Defendants deny the remaining allegations of this paragraph, including that the '064 patent was duly and lawfully issued.

8. On January 31, 2023, the United States Patent and Trademark Office duly and lawfully issued the '934 patent, entitled "Stable Corticosteroid Compositions" to ViroPharma Biologies LLC as assignee of inventor Ramalingeswar Kasina. A copy of the '934 patent is attached as Exhibit B.

ANSWER: Defendants admit that Plaintiffs purport to attach a copy of the '934 patent to the Complaint as Exhibit B. Defendants further admit that on its face, the '934 patent is titled "Stable Corticosteroid Compositions," and indicates that it issued on January 31, 2023, to assignee ViroPharma Biologics LLC of inventor Ramalingeswar Kasina. Defendants deny the remaining allegations of this paragraph, including that the '934 patent was duly and lawfully issued.

THE EOHILIA® DRUG PRODUCT

9. TPUSA holds approved New Drug Application No. 213976 for budesonide suspension for oral use, which is prescribed and sold under the trademark EOHILIA®. EOHILIA® is a corticosteroid indicated for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis.

ANSWER: Defendants admit that TPUSA is listed in the FDA's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as the holder of New Drug Application ("NDA") No. 213976 for EOHILIA®. Defendants lack sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in Paragraph 9 and, on that basis, deny them.

10. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the Patents-in-Suit are listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to EOHILIA®.

ANSWER: Defendants admit that the '064 patent and the '934 patent are listed in the Orange Book in connection with EOHILIA®. Defendants lack sufficient knowledge or

information to form a belief as to the truth of the remaining allegations contained in Paragraph 10 and, on that basis, deny them.

11. The claims of the '064 patent cover, *inter alia*, pharmaceutical compositions comprising budesonide for oral administration. The claims of the '934 patent cover, *inter alia*, methods of treating or alleviating the symptoms and inflammation associated with eosinophilic esophagitis comprising the administration of pharmaceutical compositions comprising budesonide.

ANSWER: This paragraph contains legal conclusions and allegations for which no response is required. To the extent an answer is deemed required, Defendants deny the allegations contained in Paragraph 11 of the Complaint.

12. The FDA-approved labeling for EOHILIA® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to orally administer EOHILIA® for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis.

ANSWER: Defendants lack sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in Paragraph 12 of the Complaint, and on that basis, denies them.

JURISDICTION AND VENUE

13. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: This paragraph contains legal conclusions and allegations for which no response is required. To the extent a response is required, Defendants admit that this action cites the patent laws of the United States generally. Defendants do not contest that this Court has jurisdiction over the subject matter of this action against Lupin Ltd. for the purposes of the asserted patents in this action only. Defendants deny any remaining allegations in this paragraph.

14. On information and belief, Lupin is in the business of, among other things, developing, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. Lupin's website states that "Lupin is [sic] leading global manufacturer of generic

medicines" and identifies the United States as among its "Key Markets."[1] Lupin's website also states that, since entering the "U.S. generic pharmaceutical market in 2003," it has "received more than 250 FDA approvals and market[s] a total of 180 generic products."[2]

ANSWER: This paragraph, and any footnote thereof, contains legal conclusions and allegations for which no response is required. To the extent a response is required, Defendants does not contest that this Court has jurisdiction over the subject matter of this action against Lupin Ltd. for the purposes of the asserted patents in this action only. Defendants deny any remaining allegations in Paragraph 14 of the Complaint.

15. On information and belief, Lupin, Ltd. and Lupin Pharmaceuticals, Inc. work in privity and/or concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District. With respect to the U.S. generic pharmaceutical market, Lupin's website states, "[w]e are vertically integrated, from process development of the API to the submission of the dossiers for finished dosages."[3] On information and belief, Lupin, Ltd. manufactures generic pharmaceutical products for Lupin Pharmaceuticals, Inc., which Lupin Pharmaceuticals, Inc. sells and/or distributes for sale throughout the United States, including in this Judicial District, for example: (1) Cefixime for oral suspension, 100 mg/5 mL, 200 mg/5 mL; (2) Cefprozil for oral suspension, 125 mg/5 mL, 250 mg/5 mL; (3) Doxycycline for oral suspension; (4) Famotidine for oral suspension; and (5) Budesonide inhalation suspension, 0.5 mg/2 mL single-dose ampules.

ANSWER: This paragraph, and any footnote thereof, contains legal conclusions and allegations for which no response is required. To the extent a response is required, Defendants do not contest that this Court has jurisdiction over the subject matter of this action against Lupin Ltd. for the purposes of the asserted patents in this action only. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations in Paragraph 15 of the Complaint.

---

[1] "Generics – Lupin," *available at* https://www.lupin.com/our-products/generics/ (last visited June 18, 2025).

[2] *Id.*

[3] *Id.*

16. On information and belief, Lupin, Ltd. and Lupin Pharmaceuticals, Inc. work in privity and/or concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to prepare and/or aid in the preparation and submission of ANDAs to the FDA, including Lupin's ANDA. FDA's Orange Book identifies "LUPIN LTD" as the holder of an ANDA for more than three hundred generic prescription products and "LUPIN PHARMACEUTICALS INC" as the holder of an ANDA for more than twenty generic prescription products. On information and belief, Lupin Ltd. is the ANDA holder for generic pharmaceutical products that Lupin Pharmaceuticals, Inc. sells and/or distributes throughout the United States, including in this Judicial District, for example: (1) Cefixime capsules, 400 mg; (2) Cefprozil for oral suspension, 125 mg/5 mL, 250 mg/5 mL; (3) Doxycycline for oral suspension; (4) Famotidine for oral suspension; and (5) Rufinamide for oral suspension. On information and belief, Lupin Pharmaceuticals, Inc. is the ANDA holder for generic pharmaceutical products that Lupin Ltd. manufactures for sale and/or distribution by Lupin Pharmaceuticals, Inc. throughout the United States, including in this Judicial District, for example: (1) Cefixime for oral suspension, 200 mg/5 mL; (2) Diclofenac sodium topical solution, 2% w/w, for topical use; (3) Meloxicam capsules, for oral use; and (4) Rifampin capsules.

ANSWER: This paragraph contains legal conclusions and allegations for which no response is required. To the extent a response is required, Defendants do not contest that this Court has jurisdiction over the subject matter of this action against Lupin Ltd. for the purposes of the asserted patents in this action only. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations in Paragraph 16 of the Complaint.

17. On information and belief, Lupin, Ltd. and Lupin Pharmaceuticals, Inc. act, operate, and/or hold themselves out to the public as a single integrated business. Lupin's website states that, "[o]ver the past decades, Lupin has become a trusted leader in the U.S. generics market," and that "[o]ur success in this highly competitive market is underpinned by a multi-channel supply chain that includes a state-of-the-art commercial manufacturing facility in Somerset, a robust multi-national distribution network, and strategic partnerships with key stakeholders."[4]

ANSWER: This paragraph, and any footnote thereof, contains legal conclusions and allegations for which no response is required. To the extent a response is required, Defendants do not contest that this Court has jurisdiction over the subject matter of this action against Lupin Ltd. for the purposes of the asserted patents in this action only. Defendants deny that Lupin

[4] "Lupin US Corporate Overview | Advancing Healthcare Solutions," *available at* https://www.lupin.com/US/corporate-overview (last visited June 18, 2025).

Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations in Paragraph 17 of the Complaint.

18. On information and belief, Lupin Pharmaceuticals, Inc. acts at the direction, and for the benefit, of Lupin Ltd. and is controlled and/or dominated by Lupin, Ltd.

ANSWER: This paragraph contains legal conclusions and allegations for which no response is required. To the extent a response is required, Defendants do not contest that this Court has jurisdiction over the subject matter of this action against Lupin Ltd. for the purposes of the asserted patents in this action only. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations in Paragraph 18 of the Complaint.

19. On information and belief, Lupin derives substantial revenue, directly or indirectly, from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District. Lupin's Integrated Report/Annual Report (2023-2024) states that, "[a]s of March 2024, Lupin is the third-largest pharmaceutical company in the U.S. by filled prescriptions, with a 5.2% market share in generic scripts," and that "[d]uring the last fiscal year, the U.S. market contributed to 34% of the overall company sales."[5] Lupin's Integrated Report/Annual Report (2023-2024) includes Lupin Pharmaceuticals, Inc. in its consolidated financial statement and identifies Lupin Pharmaceuticals, Inc. as a material subsidiary.[6]

ANSWER: This paragraph, and any footnote thereof, contains legal conclusions and allegations for which no response is required. To the extent a response is required, Defendants do not contest that this Court has jurisdiction over the subject matter of this action against Lupin Ltd. for the purposes of the asserted patents in this action only. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations in Paragraph 19 of the Complaint.

20. On information and belief, each of Lupin, Ltd. and Lupin Pharmaceuticals, Inc. actively participated in the submission of Lupin's ANDA. On information and belief, Lupin, Ltd. and Lupin Pharmaceuticals, Inc. will work in privity and/or concert with one another and/or other related entities towards the regulatory approval, manufacturing, use, importation, marketing, offer

[5] Integrated Report/Annual Report (2023-2024) at 43.

[6] *Id.* at 203, 234, 359.

for sale, sale, and distribution of generic pharmaceutical products, including those described in Lupin's ANDA, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the Patents-in-Suit.

ANSWER: This paragraph contains legal conclusions and allegations for which no response is required. To the extent a response is required, Defendants do not contest that this Court has jurisdiction over the subject matter of this action against Lupin Ltd. for the purposes of the asserted patents in this action only. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations in Paragraph 20 of the Complaint.

21. On information and belief, Lupin intends to benefit directly if Lupin's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of Lupin's ANDA.

ANSWER: This paragraph contains legal conclusions and allegations for which no response is required. To the extent a response is required, Defendants do not contest that this Court has jurisdiction over the subject matter of this action against Lupin Ltd. for the purposes of the asserted patents in this action only. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations in Paragraph 21 of the Complaint.

22. On information and belief, this Judicial District is a likely destination for the generic drug products described in Lupin's ANDA.

ANSWER: This paragraph contains legal conclusions and allegations for which no response is required. To the extent a response is required, Defendants do not contest that this Court has jurisdiction over the subject matter of this action against Lupin Ltd. for the purposes of the asserted patents in this action only. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations in Paragraph 22 of the Complaint.

23. This Court has personal jurisdiction over Lupin, Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in the State of New Jersey, including directly or indirectly through its subsidiaries, agents, and/or alter egos, including Lupin Pharmaceuticals, Inc. a company with a regular and established place of business in New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including

through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Lupin Pharmaceuticals, Inc.

ANSWER: This paragraph contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, for purposes of this litigation only, Defendants do not contest personal jurisdiction in New Jersey. Defendants deny Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all remaining allegations of Paragraph 23.

24. In the alternative, this Court has personal jurisdiction over Lupin, Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met, as (a) Plaintiffs' claims arise under federal law; (b) Lupin, Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lupin, Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin, Ltd. satisfies due process.

ANSWER: This paragraph contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, for purposes of this litigation only, Lupin Ltd. does not contest personal jurisdiction in New Jersey. Defendants deny all remaining allegations of Paragraph 24.

25. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Lupin Pharmaceuticals, Inc. maintains a regular and established, physical places of business at 15 Jensen Drive, Somerset, New Jersey 08873 and 400 Campus Drive, Somerset, New Jersey 08873. On information and belief, Lupin Pharmaceuticals, Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0101043376. On information and belief, Lupin Pharmaceuticals, Inc. is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5005159. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. On information and belief, Lupin Pharmaceuticals, Inc. purposefully has conducted and continues to conduct business in this Judicial District.

ANSWER: This paragraph contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, for purposes of this litigation only, Lupin

Ltd. does not contest personal jurisdiction in New Jersey. Defendants deny Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all remaining allegations of Paragraph 25.

26. This Court also has personal jurisdiction over Lupin, Ltd. and Lupin Pharmaceuticals, Inc. because, *inter alia*, they have committed an act of patent infringement under 35 U.S.C. § 271(e)(2). On information and belief, Lupin, Ltd. and Lupin Pharmaceuticals, Inc. intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Plaintiffs in New Jersey and in this Judicial District.

ANSWER: This paragraph contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, for purposes of this litigation only, Lupin Ltd. does not contest personal jurisdiction in New Jersey. Defendants deny Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all remaining allegations of Paragraph 26.

27. On information and belief, Lupin, Ltd. and Lupin Pharmaceuticals, Inc. have previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases.

ANSWER: This paragraph contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, for purposes of this litigation only, Lupin Ltd. does not contest personal jurisdiction in New Jersey. Defendants deny Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all remaining allegations of Paragraph 27.

28. Lupin, Ltd. and Lupin Pharmaceuticals, Inc. have previously been sued in this Judicial District, have availed themselves of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey, and have not challenged personal jurisdiction in New Jersey. *See, e.g.*, *Bausch Health Ireland Ltd., et al. v. Lupin Ltd., et al.*, Civil Action No. 20-11039 (RMB) (KMW) (D.N.J.); *Boehringer Ingelheim Pharm., Inc., et al. v. Lupin Atlantis Holdings SA, et al.*, Civil Action No. 18-12663 (BRM)(TJB) (D.N.J.); *Bausch & Lomb Inc., et al. v. Lupin Ltd., et al.*, Civil Action No. 23-00790 (MEF)(JRA) (D.N.J.); *Merck Sharp & Dohme B.V., et al. v. Lupin Ltd., et al.*, Civil Action No. 20-02786 (CCC)(MF) (D.N.J.); *Mitsubishi Tanabe Pharm. Corp., et al. v. Lupin Ltd. and Lupin Pharma. Inc.*, Civil Action No. 19-07165 (RMB)(JS) (D.N.J.); *Teva Pharm. Indus. Ltd., et al. v. Lupin Ltd. and Lupin Pharma. Inc.*, Civil Action No. 07-00247 (WHW)(CCC) (D.N.J.); *Abbott Lab'ys., et al. v. Lupin Ltd., et al.*, Civil Action No. 09-01007 (GEB)(MCA) (D.N.J.); *Elan Pharm. Intern. Ltd., et al. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civil Action No. 09-01008 (GEB)(MCA) (D.N.J.); *AstraZeneca AB, et al. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 09-05404 (JAP) (TJB) (D.N.J.); *Abbott Labs and Laboratories Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 09-01007 (GEB)(MCA)

(D.N.J.); *Abbott Labs and Laboratories Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 10-01578 (DMC)(JAD) (D.N.J.).

ANSWER: This paragraph contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, for purposes of this litigation only, Lupin Ltd. does not contest personal jurisdiction in New Jersey. Defendants deny Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all remaining allegations of Paragraph 28.

29. Lupin, Ltd. has further availed itself of the jurisdiction of this Court by initiating litigation in this Judicial District. *See Lupin Ltd., et al. v. Merck, Sharp & Dohme Corp.*, Civil Action No. 10-00683 (D.N.J.).

ANSWER: This paragraph contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, for purposes of this litigation only, Lupin Ltd. does not contest personal jurisdiction in New Jersey. Defendants deny all remaining allegations of Paragraph 29.

30. Venue is proper in this Judicial District pursuant to U.S.C. §§ 1391 and/or 1400(b).

ANSWER: This paragraph contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Lupin Ltd. states that it does not contest venue for the purposes of this action only. Defendants deny Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all remaining allegations of Paragraph 30.

ACTS GIVING RISE TO THIS SUIT

31. Pursuant to Section 505 of the Federal Food, Drug, and Cosmetics Act ("FD&C Act"), Lupin submitted Lupin's ANDA seeking approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of budesonide suspension for oral use, 2 mg/10 mL (the "ANDA Product") before expiration of the Patents-in-Suit.

ANSWER: Defendants admit that Lupin Ltd. filed ANDA No. 220382 ("Lupin Ltd.'s ANDA") seeking FDA approval for budesonide suspension for oral use, 2 mg/10 mL. To the extent

not expressly admitted, Defendants deny the remaining allegations contained in Paragraph 31 of the Complaint.

32. On information and belief, following any FDA approval of Lupin's ANDA, Lupin will make, use, offer for sale, or sell Lupin's ANDA Product throughout the United States, or import such generic products into the United States.

ANSWER: Defendants admit that Lupin Ltd. filed ANDA No. 220382 seeking FDA approval for budesonide suspension for oral use, 2 mg/10 mL. To the extent not expressly admitted, Defendants deny the remaining allegations contained in Paragraph 32 of the Complaint.

33. On information and belief, in connection with the submission of Lupin's ANDA as described above, Lupin provided written certification to the FDA pursuant to Section 505 of the FD&C Act and 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), alleging that the claims of the Patents-in-Suit are invalid and/or will not be infringed by the activities described in Lupin's ANDA.

ANSWER: Defendants admit that Lupin Ltd. filed ANDA No. 220382 seeking FDA approval for budesonide suspension for oral use, 2 mg/10 mL. To the extent not expressly admitted, Defendants deny the remaining allegations contained in Paragraph 33 of the Complaint.

34. By letter dated May 19, 2025, Lupin purported to provide notice pursuant to Section 505(j)(2)(B)(iv) of the FD&C Act and 21 C.F.R. § 314.95 to Takeda Pharmaceuticals U.S.A., Inc.; Takeda Pharmaceuticals America, Inc.; ViroPharma Biologics LLC; Takeda Pharmaceuticals Company Ltd.; and Takeda Pharmaceuticals U.S.A., Inc. ("Lupin's Notice Letter") that Lupin had submitted its ANDA to the FDA with a Paragraph IV Certification, seeking approval to commercially manufacture, use, sell, offer for sale, or import Lupin's ANDA Product before expiration of the Patents-in-Suit.

ANSWER: Defendants admit that Lupin Ltd. mailed a Notice Letter on May 19, 2025 ("Lupin Ltd.'s Notice Letter), notifying Plaintiffs that it had submitted ANDA No. 220382 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Defendants admit that the May 19, 2025, Notice Letter included a Notice of Certification for ANDA No. 220382 under 37 C.F.R. § 314.95(c)(6) as to the EOHILIA® Patents. To the extent not expressly admitted, Defendants deny the remaining allegations contained in Paragraph 34 of the Complaint.

35. Lupin's ANDA Product is intended to be a generic version of EOHILIA®.

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations contained in Paragraph 35.

36. Exhibit A to Lupin's Notice Letter purports to provide, pursuant to Section 505(j)(2)(B)(iv) of the FD&C Act and 21 C.F.R. § 314.95(c)(7), a detailed statement of the factual and legal bases for its Paragraph IV Certification.

ANSWER: Defendants admit that Lupin Ltd. mailed a Notice Letter on May 19, 2025, notifying Plaintiffs that it had submitted ANDA No. 220382 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Defendants admit that the May 19, 2025, Notice Letter included a Notice of Certification for ANDA No. 220382 under 37 C.F.R. § 314.95(c)(6) as to the EOHILIA® Patents. To the extent not expressly admitted, Defendants deny the remaining allegations contained in Paragraph 36 of the Complaint.

37. This action is being commenced before the expiration of 45 days from the date that Plaintiffs received the Lupin Notice Letter.

ANSWER: Admitted.

COUNT I
Infringement of U.S. Patent No. 11,260,064

38. Plaintiffs repeat and reallege the preceding paragraphs above as if fully set forth herein.

ANSWER: Defendants incorporate their Answer to paragraphs 1-37 as if fully set forth herein.

39. Lupin's submission of ANDA No. 220382 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's ANDA Product before the expiration of the '064 patent constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

40. There is a justiciable controversy between the parties hereto as to infringement of the '064 patent.

ANSWER: Denied.

41. On information and belief, following FDA approval, Lupin intends to provide labeling with Lupin's ANDA Product that instructs and encourages infringement, literally or under the doctrine of equivalents, of one or more claims of the '064 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied

42. For example, claim 1 of the '064 patent recites:

> A pharmaceutical composition comprising budesonide, an antioxidant in an amount of from about 0.05% to about 0.5% w/w of the composition, wherein the antioxidant comprises a combination of ascorbic acid and a pharmaceutically acceptable salt of ascorbate, and a flavoring agent, a sweetener, or a combination thereof, wherein the pharmaceutical composition comprises less than 0.3% impurities formed by oxidative degradation, and wherein the pharmaceutical composition is for oral administration.

ANSWER: To the extent an answer is deemed required, Defendants admit that Plaintiffs purport that claim 1 of the '064 patent recites "[a] pharmaceutical composition comprising budesonide, an antioxidant in an amount of from about 0.05% to about 0.5% w/w of the composition, wherein the antioxidant comprises a combination of ascorbic acid and a pharmaceutically acceptable salt of ascorbate, and a flavoring agent, a sweetener, or a combination thereof, wherein the pharmaceutical composition comprises less than 0.3% impurities formed by oxidative degradation, and wherein the pharmaceutical composition is for oral administration." To the extent not expressly admitted, Defendants deny the remaining allegations contained in Paragraph 42 of the Complaint.

43. On information and belief, Lupin's ANDA Product meets each element of claim 1 of the '064 patent, literally or under the doctrine of equivalents.

ANSWER: Denied

44. On information and belief, upon FDA approval of Lupin's ANDA, the labeling for Lupin's ANDA Product will instruct and encourage physicians, pharmacists, other healthcare workers, and patients to directly infringe one or more claims of the '064 patent under 35 U.S.C. § 271(a).

ANSWER: Denied

45. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '064 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Product in or for the United States.

ANSWER: Denied

46. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '064 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Product in or for the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '064 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied

47. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '064 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Product in or for the United States. On information and belief, Lupin has had and continues to have knowledge that Lupin's ANDA Product is especially adapted for a use that infringes one or more claims of the '064 patent and that there is no substantial non-infringing use for Lupin's ANDA Product.

ANSWER: Denied

48. Lupin has had knowledge of the '064 patent since at least the date of Lupin's ANDA submission.

ANSWER: Denied

49. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '064 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

50. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: This paragraph contains legal conclusions and allegations for which no response is required. To the extent an answer is deemed required, Defendants deny the allegations contained in Paragraph 50 of the Complaint.

COUNT II
Infringement of U.S. Patent No. 11,564,934

51. Plaintiffs repeat and reallege the preceding paragraphs above as if fully set forth herein.

ANSWER: Defendants incorporate their Answer to paragraphs 1-50 as if fully set forth herein.

52. Lupin's submission of ANDA No. 220382 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's ANDA Product before the expiration of the '934 patent constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

53. There is a justiciable controversy between the parties hereto as to infringement of the '934 patent.

ANSWER: Denied.

54. On information and belief, following FDA approval, Lupin intends to provide labeling with Lupin's ANDA Product that instructs and encourages infringement, literally or under the doctrine of equivalents, of one or more claims of the '934 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

55. For example, claim 1 of the '934 patent recites:

> A method of treating, or alleviating the symptoms of and inflammation associated with eosinophilic esophagitis in a subject in need thereof comprising administering to the subject a pharmaceutical composition comprising budesonide, and an antioxidant in an amount of from about 0.05% to about 0.5% w/w of the composition, wherein the antioxidant comprises a combination of ascorbic acid and a pharmaceutically acceptable salt of ascorbate, wherein the pharmaceutical composition comprises less than 0.3% impurities formed by oxidative degradation.

ANSWER: To the extent an answer is deemed required, Defendants admit that Plaintiffs purport that claim 1 of the '934 patent recites "[a] method of treating, or alleviating the symptoms of and inflammation associated with eosinophilic esophagitis in a subject in need thereof comprising administering to the subject a pharmaceutical composition comprising budesonide, and

an antioxidant in an amount of from about 0.05% to about 0.5% w/w of the composition, wherein the antioxidant comprises a combination of ascorbic acid and a pharmaceutically acceptable salt of ascorbate, wherein the pharmaceutical composition comprises less than 0.3% impurities formed by oxidative degradation." To the extent not expressly admitted, Defendants deny the remaining allegations contained in Paragraph 55 of the Complaint.

56. On information and belief, Lupin's ANDA Product meets each element of claim 1 of the '934 patent, literally or under the doctrine of equivalents.

ANSWER: Denied.

57. On information and belief, upon FDA approval of Lupin's ANDA, the labeling for Lupin's ANDA Product will instruct and encourage physicians, pharmacists, other healthcare workers, and patients to directly infringe one or more claims of the '934 patent under 35 U.S.C. § 271(a).

ANSWER: Denied.

58. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '934 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Product in or for the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '934 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

59. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '934 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Product in or for the United States. On information and belief, Lupin has had and continues to have knowledge that Lupin's ANDA Product is especially adapted for a use that infringes one or more claims of the '934 patent and that there is no substantial non-infringing use for Lupin's ANDA Product.

ANSWER: Denied.

60. Lupin has had knowledge of the '934 patent since at least the date of Lupin's ANDA submission.

ANSWER: Denied.

61. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '934 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

62. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: This paragraph contains legal conclusions and allegations for which no response is required. To the extent an answer is deemed required, Defendants deny the allegations contained in Paragraph 62 of the Complaint.

RESPONSE TO PLAINTIFFS' PRAYER FOR RELIEF

All remaining allegations not specifically admitted are herein denied. It is further denied that Plaintiffs are entitled to the relief requested in the Complaint or to any other relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, Defendants assert the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiffs.

FIRST SEPARATE DEFENSE

The Complaint fails to state a cause of action under 35 U.S.C. § 271(a), (b), (c) and/or (g) against Defendants because Plaintiffs have not pleaded with particularity facts regarding any post ANDA approval activities.

SECOND SEPARATE DEFENSE

The Court does not have subject matter jurisdiction over Plaintiffs' claims against Defendants under 35 U.S.C. § 271(a), (b), (c) and/or (g).

THIRD SEPARATE DEFENSE

The Court does not have subject matter jurisdiction over Plaintiffs' judgment claims against Defendants because there is no real and immediate case or controversy because Lupin Ltd.'s ANDA No. 220382 has not been approved.

FOURTH SEPARATE DEFENSE

Plaintiffs have failed to state a claim upon which relief can be granted.

FIFTH SEPARATE DEFENSE

The claims of the EOHILIA® Patents are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103, 112 and/or double patenting at least for the reasons set forth in the Detailed Statement of the factual and legal bases included with Lupin Ltd.'s May 19, 2025, Notice Letter to Plaintiffs.

SIXTH SEPARATE DEFENSE

Defendants have not directly or indirectly infringed any claims of the EOHILIA® Patents. The filing of Lupin Ltd.'s ANDA No. 220382, and the manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of Lupin Ltd.'s ANDA No. 220382 does not and would not infringe any valid or enforceable claim of the EOHILIA® Patents, either literally or under the doctrine of equivalents.

SEVENTH SEPARATE DEFENSE

The Complaint fails to state a claim for an exceptional case.

EIGHT SEPARATE DEFENSE

Lupin Pharmaceuticals, Inc., is not a proper party to this action.

NINTH SEPARATE DEFENSE

Defendants reserve all defenses, at law or equity, which may now exist or in the future be available on discovery and further factual investigation in this case.

COUNTERCLAIMS

For its counterclaims against Plaintiffs Takeda Pharmaceuticals U.S.A., Inc. ("TPUSA") and ViroPharma Biologics LLC ("ViroPharma") (collectively, "Counterclaim Defendants"), Lupin Ltd. states as follows:

NATURE OF THE ACTION

1. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1 et seq., the Hatch-Waxman Act, 21 U.S.C. §§ 355(j) et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

2. These counterclaims are for declaratory judgment of noninfringement and invalidity of U.S. Patent Nos. 11,260,064 ("the '064 patent") and 11,564,934 ("the '934 patent") (collectively, the "Counterclaim Patents").

3. The Counterclaim Patents are listed in the electronic version of the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for EOHILIA®.

PARTIES

4. Lupin Ltd. is a cooperation organized and existing under the laws of India, having a principal place of business at Kalpataru Inspire, 3rd Floor, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

5. Upon information and belief, TPUSA is a corporation organized and existing under the laws of the State of Delaware, having an office and place of business at 500 Kendall Street, Cambridge, Massachusetts 02142.

6. Upon information and belief, ViroPharma is a corporation organized and existing under the laws of the State of Delaware, having an office and place of business at 300 Shire Way, Lexington, Massachusetts 02421.

JURISDICTION AND VENUE

7. This action is for declaratory judgment that Lupin Ltd. has not, does not, and will not infringe any valid and enforceable claim of the Counterclaim Patents.

8. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, the Hatch-Waxman Act, 21 U.S.C. §§ 355(j) *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. The Court has subject matter jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a) because these counterclaims involve substantial claims arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq*.

10. This Court may declare the rights and other legal relations of the parties pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, 21 U.S.C. § 355(j)(5)(C), and 35 U.S.C. § 271(e)(5) because this is a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment that the Counterclaim Patents are not and will not be infringed by Lupin Ltd. and/or are invalid.

11. The Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants have commenced and continue to maintain this action against Lupin Ltd. in this judicial district.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) because Counterclaim Defendants commenced and continue to maintain this action against Lupin Ltd. in this judicial district.

FACTUAL BACKGROUND

13. Upon information and belief, on March 1, 2022, the'064 patent, entitled "Stable Corticosteroid Compositions" was issued to ViroPharma as assignee of inventor Ramalingeswar Kasina. A copy of the '064 patent is attached to the Complaint as Exhibit A.

14. Upon information and belief, on January 31, 2023, the '934 patent, entitled "Stable Corticosteroid Compositions" was issued to ViroPharma as assignee of inventor Ramalingeswar Kasina. A copy of the '934 patent is attached to the Complaint as Exhibit B.

15. Upon information and belief, and based on the allegations in the Complaint, TPUSA is the holder of New Drug Application ("NDA") No. 213976 for budesonide suspension for oral use, which is prescribed and sold under the trademark EOHILIA®.

16. Lupin Ltd. filed Abbreviated New Drug Application ("ANDA") No. 220382 seeking FDA approval for budesonide suspension for oral use, 2 mg/10 mL ("Lupin Ltd.'s ANDA Product").

17. By letter dated May 19, 2025 ("Lupin Ltd.'s Notice Letter"), Lupin Ltd. notified Counterclaim Defendants in writing that it had filed ANDA No. 220382 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the Counterclaim Patents are invalid, unenforceable, and/or will not be infringed by the products that are the subject of ANDA No. 220382.

18. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), Lupin Ltd.'s Notice Letter was accompanied by a detailed statement of the factual and legal bases for Lupin Ltd.'s Paragraph IV Certification that the Counterclaim Patents are invalid, unenforceable, and/or will not be infringed.

19. Counterclaim Defendants have accused Lupin Ltd. of infringing claims of the Counterclaim Patents in connection with ANDA No. 220382.

COUNT I: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE COUNTERCLAIM PATENTS

20. Lupin Ltd. repeats and realleges the allegations in paragraphs 1-21 of its counterclaims as if fully set forth herein.

21. Lupin Ltd. has not, and does not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the Counterclaim Patents, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

22. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.'s ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), or any valid, enforceable, properly construed claim of the Counterclaim Patents

23. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the Counterclaim Patents.

24. Unless Counterclaim Defendants are enjoined, Counterclaim Defendants will continue to assert that Lupin Ltd.'s ANDA Product is infringing the claims of the Counterclaim Patents and will continue to interfere with Lupin Ltd.'s business with respect to Lupin Ltd.'s ANDA Product and its manufacture, use, offer for sale and sale.

25. Lupin Ltd. will be irreparably harmed if Counterclaim Defendants are not enjoined from continuing to assert the Counterclaim Patents and from interfering with Lupin Ltd.'s business.

26. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the non-infringement of the Counterclaim Patents that is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

COUNT II: DECLARATORY JUDGMENT OF INVALIDITY OF THE COUNTERCLAIM PATENTS

27. Lupin Ltd. repeats and realleges the allegations in paragraphs 1-28 of its counterclaims as if fully set forth herein.

28. Lupin Ltd. does not infringe the Counterclaim Patents and the claims of the Counterclaim Patents are invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq*., including without limitation §§ 101, 102, 103, 112, and/or double patenting, and including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

23. The alleged inventions of the Counterclaim Patents were patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the Counterclaim Patents in the United States.

29. The alleged inventions of the Counterclaim Patents do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the Counterclaim Patents is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the Counterclaim Patents and would have had a reasonable expectation of success in doing so.

30. The claims of the Counterclaim Patents are invalid at least under 35 U.S.C. § 103 in view of the prior art. The differences between the subject matter claimed in the Counterclaim Patents and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

31. Unless Counterclaim Defendants are enjoined, Counterclaim Defendants will continue to assert that Lupin Ltd.'s ANDA Product is infringing the claims of the Counterclaim Patents and will continue to interfere with Lupin Ltd.'s business with respect to Lupin Ltd.'s ANDA Product and its manufacture, use, offer for sale and sale.

32. Lupin Ltd. will be irreparably harmed if Counterclaim Defendants are not enjoined from continuing to assert the Counterclaim Patents and from interfering with Lupin Ltd.'s business.

33. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the Counterclaim Patents that is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

34. Lupin Ltd. is entitled to a declaratory judgment that the claims of the Counterclaim Patents are invalid.

PRAYER FOR RELIEF

WHEREFORE, Lupin Ltd. respectfully requests entry of judgment in its favor and against Counterclaim Defendants providing the following relief:

a. Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is the subject of ANDA No. 220382 has not infringed, does not infringe

and would not infringe any valid or enforceable claim of the Counterclaim Patents, either literally or under the doctrine of equivalents;

b. Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is the subject of ANDA No. 220382 has not infringed, does not infringe and would not induce the infringement of any valid or enforceable claim of the Counterclaim Patents;

c. Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is the subject of ANDA No. 220382 has not infringed, does not infringe and would not contributorily infringe any valid or enforceable claim of the Counterclaim Patents;

d. Declaring that the claims of the Counterclaim Patents are invalid;

e. Ordering Counterclaim Defendants, their officers, agents, servants, employees, attorneys, successors, and any person who acts in concert or participation with Counterclaim Defendants be preliminarily and permanently enjoined from using the Counterclaim Patents to block, hamper, hinder, or obstruct FDA approval of ANDA No. 220382;

f. Ordering that Counterclaim Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Lupin Ltd.;

g. Declaring that Counterclaim Defendants are not entitled to any declaratory or injunctive relief or any alleged damages for alleged patent infringement by Lupin Ltd.;

h. Declaring this case exceptional and awarding Lupin Ltd. its reasonable attorney's fees and costs pursuant to 35 U.S.C. § 285; and

i. Awarding Lupin Ltd. such other and further relief as the Court may deem just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendants,
Lupin, Ltd. and Lupin Pharmaceuticals, Inc.

By: *s/ James S. Richter*
James S. Richter
jrichter@midlige-richter.com

Dated: September 22, 2025

OF COUNSEL:

Deepro R. Mukerjee (admitted *pro hac vice*)
Lance A. Soderstrom (admitted *pro hac vice*)
KATTEN MUCHIN ROSENMAN LLP
50 Rockefeller Plaza
New York, NY 10020-1605

Jitendra ("Jitty") Malik Ph.D. (admitted *pro hac vice*)
KATTEN MUCHIN ROSENMAN LLP
615 South College Street, Suite 1700
Charlotte, NC 28202-3354

Sara M. Pistilli (admitted *pro hac vice*)
KATTEN MUCHIN ROSENMAN LLP
2121 North Pearl Street, Suite 1100
Dallas, TX 75201-2591

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rules 11.2, the undersigned counsel for Defendants certifies that, to the best of his knowledge, information and belief, the matter in controversy is not the subject of any other action or proceeding.

s/ James S. Richter
James S. Richter

Dated: September 22, 2025

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel hereby certifies that to my knowledge, Plaintiffs' Complaint and Defendants' Counterclaims seeks injunctive and other equitable relief, and therefore this action is not appropriate for compulsory arbitration.

s/ James S. Richter
James S. Richter

Dated: September 22, 2025

CERTIFICATE OF SERVICE

I hereby certify that on September 22, 2025, copies of the foregoing Answer, Affirmative Defenses and Counterclaims were served by ECF and email on all counsel of record.

I certify that the foregoing statements made by are true. I am aware that if any of the foregoing statements are willfully false, I am subject to punishment.

s/ James S. Richter
James S. Richter

Dated: September 22, 2025