IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB INC., UCB BIOPHARMA SRL, HANANJA EHF and UNIVERSITY OF ICELAND *Plaintiffs*, v. HIKMA PHARMACEUTICALS USA INC., *Defendant*.	C.A. No. 25-cv-0382-JLH

DEFENDANT HIKMA PHARMACEUTICALS USA INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT

Defendant Hikma Pharmaceuticals USA Inc. ("Hikma")[1], by and through the undersigned attorneys, submits its answer, affirmative defenses, and counterclaims to the Complaint for patent infringement of Plaintiffs UCB, Inc. and UCB Biopharma SRL (together, "UCB"), Hananja EHF ("Hananja"), and University of Iceland (the "University") (collectively, "Plaintiffs"). Hikma denies all allegations in Plaintiffs' Complaint except those admitted specifically below. This pleading is based upon Hikma's knowledge of its own activities, and upon information and belief as to the activities of others.

[1] The complaint uses "Hikma" and "Defendants" to collectively include Hikma USA and Hikma Pharmaceuticals PLC. However, Hikma Pharmaceuticals PLC is no longer a party to this case. Pursuant to the Stipulation submitted on April 15, 2025 (D.I. No. 9 in C.A. No. 25-cv-0382-JLH) ("the Stipulation") and so ordered on April 17, 2025, the parties have stipulated to dismissal of the action against Hikma Pharmaceuticals PLC. Accordingly, all responses herein are made solely on behalf of Hikma Pharmaceuticals USA, Inc.

NATURE OF THE ACTION

1. This action for patent infringement, brough pursuant to the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, arises from Hikma's recent submission to the United States to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 219736 (hereinafter "Hikma's ANDA"). Through Hikma's ANDA, Hikma seeks approval to market Midazolam nasal spray (5mg) (the "ANDA Product"), a generic version of UCB's pharmaceutical product, NAYZILAM®, prior to the expiration of patents listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for NAYZILAM®, namely U.S. Patent No. 8,217,033 ("the '033 Patent"); U.S. Patent No. 8,809,322 ("the '322 Patent"); U.S. Patent No. 9,289,432 ("the '432 Patent"); and U.S. Patent No. 9,687,495 ("the '495 Patent").

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma admits that Hikma submitted ANDA No. 219736 ("Hikma's ANDA") to the FDA seeking approval to commercially market a generic version of Midazolam nasal spray (5mg) (the "ANDA Product") prior to the expiration of U.S. Patent No. 8,217,033 ("the '033 Patent"); U.S. Patent No. 8,809,322 ("the '322 Patent"); U.S. Patent No. 9,289,432 ("the '432 Patent"); and U.S. Patent No. 9,687,495 ("the '495 Patent") (collectively, "the patents-in-suit"). Hikma further admits that Plaintiffs' Complaint purports to bring an action for patent infringement under 35 U.S.C. § 1 *et seq.*, but denies that Plaintiffs are entitled to any relief. Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore, denies them.

THE PARTIES

2. Plaintiff UCB Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 1950 Lake Park Drive, Building 2100, Smyrna, GA 30080. UCB, Inc. holds New Drug Application ("NDA") No. 211321 for NAYZILAM®.

ANSWER: According to the records of the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), Hikma admits that Plaintiff UCB Inc. is the holder of NDA No. 211321 for NAYZILAM®. Hikma lacks knowledge or information

sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies them.

3. Plaintiff UCB Biopharma SRL is a corporation organized and existing under the laws of Belgium, with a place of business at Allee de la Recherche 60 B-1070, Brussels, BE. UCB Biopharma SRL is the exclusive license of the '033, '322, '432, and '495 Patents for NAYZILAM®.

ANSWER: Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies them.

4. Plaintiff Hananja EHF is a corporation organized and existing under the laws of Iceland, with a place of business at Aflagrandi 7, 107 Reykjavik, Iceland. Hananja is an assignee and co-owner of the '033, '322, '432, and '495 Patents.

ANSWER: Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies them.

5. Plaintiff University of Iceland is an entity organized and existing under the laws of Iceland, with a principal place of business at Sæmundargata 2, 102 Reykjavik, Iceland. University of Iceland is an assignee and co-owner of the '033, '322, '432, and '495 Patents.

ANSWER: Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies them.

6. On information and belief, Defendant Hikma Pharmaceuticals PLC is a corporation organized and existing under the laws of the United Kingdom, with a principal place of business at 1 New Burlington Place, London W1S 2HR.

ANSWER: Pursuant to the Stipulation filed on April 15, 2025 (D.I. No. 9 in C.A. No. 25-cv-0382-JLH) ("the Stipulation"), the parties have stipulated the dismissal of Hikma PLC from this action; accordingly, no response to this paragraph is required. To the extent a response is required, Hikma admits that Hikma Pharmaceuticals PLC is a corporation organized and existing under the laws of the United Kingdom, with a principal place of business at 1 New Burlington Place, London W1S.

7. On information and belief, Defendant Hikma Pharmaceuticals USA Inc. is a corporation organized and existing under the laws of the state of Delaware with a principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

ANSWER: Hikma admits that Hikma is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

8. On information and belief, Hikma Pharmaceuticals USA Inc. is a wholly-owned subsidiary of Hikma Pharmaceuticals PLC.

ANSWER: Pursuant to the Stipulation, the parties have stipulated the dismissal of Hikma Pharmaceuticals PLC from this action; accordingly, no response to this paragraph is required. To the extent a response is required, Hikma admits that Hikma Pharmaceuticals USA Inc. is an indirect wholly-owned subsidiary of Hikma Pharmaceuticals PLC.

9. On information and belief, Hikma Pharmaceuticals USA Inc. acts at the direction, and for the benefit, of Hikma Pharmaceuticals PLC, and is controlled and dominated by Hikma Pharmaceuticals PLC.

ANSWER: This paragraph contains legal conclusions to which no response is required. Further, pursuant to the Stipulation, the parties have stipulated the dismissal of Hikma Pharmaceuticals PLC from this action; accordingly, no response to this paragraph is required. To the extent a response is required, denied.

10. On information and belief, Hikma Pharmaceuticals PLC and Hikma Pharmaceuticals USA, Inc. hold themselves out as a single entity for the purpose of the manufacturing, selling, marketing, distribution, and importation of generic drug products.

ANSWER: This paragraph contains legal conclusions to which no response is required. Further, pursuant to the Stipulation, the parties have stipulated the dismissal of Hikma Pharmaceuticals PLC from this action; accordingly, no response to this paragraph is required. To the extent a response is required, Hikma admits that it manufactures, sells, distributes, and imports generic drug products. Hikma denies the remaining allegations of this paragraph.

11. On information and belief, Hikma Pharmaceuticals PLC and Hikma Pharmaceuticals USA Inc. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief,

Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are closer than arms' length.

ANSWER: This paragraph contains legal conclusions to which no response is required. Further, pursuant to the Stipulation, the parties have stipulated the dismissal of Hikma Pharmaceuticals PLC from this action; accordingly, no response to this allegation is required. To the extent a response is required, Hikma denies that Hikma Pharmaceuticals PLC is a "Defendant" to this action. Hikma denies the remaining allegations of this paragraph.

12. On information and belief, Hikma Pharmaceuticals PLC and Hikma Pharmaceuticals USA Inc. acted collaboratively in the preparation and submission of Hikma's ANDA and continue to act collaboratively in pursuing FDA approval of Hikma's ANDA and seeking to market the ANDA Product.

ANSWER: This paragraph contains legal conclusions to which no response is required. Further, pursuant to the Stipulation, the parties have stipulated the dismissal of Hikma Pharmaceuticals PLC from this action; accordingly, no response to this allegation is required. To the extent a response is required, Hikma denies that Hikma Pharmaceuticals PLC is a "Defendant" to this action. Hikma denies the remaining allegations of this paragraph.

ANSWER:

13. On information and belief, Hikma Pharmaceuticals USA Inc. acts as the U.S. agent for Hikma Pharmaceuticals PLC for purposes of regulatory submissions to the FDA in seeking approval for generic drugs, including for Hikma's ANDA.

ANSWER: This paragraph contains legal conclusions to which no response is required. Further, pursuant to the Stipulation, the parties have stipulated the dismissal of Hikma Pharmaceuticals PLC from this action; accordingly, no response to this allegation is required. To the extent a response is required, Hikma denies that Hikma Pharmaceuticals PLC is a "Defendant" to this action. Hikma denies the remaining allegations of this paragraph.

14. On information and belief, Hikma caused Hikma's ANDA to be submitted to the FDA and seeks FDA approval of Hikma's ANDA.

ANSWER: Hikma admits that it submitted ANDA No. 219736 to the FDA seeking approval of the ANDA. Hikma denies the remaining allegations of this paragraph.

15. On information and belief, Hikma intends to commercially manufacture, market, offer for sale, and sell the proposed ANDA Product throughout the United States, including in the State of Delaware, in the event FDA approves Hikma's ANDA.

ANSWER: Hikma admits that Hikma submitted ANDA No. 219736 seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Product throughout the United States, including in the State of Delaware. Hikma denies any remaining allegations in this paragraph.

16. On information and belief, Hikma Pharmaceuticals PLC relies on material assistance from Hikma Pharmaceuticals USA Inc. to market, distribute, offer for sale, and/or sell generic drugs in the market, including the State of Delaware. On information and belief, Hikma Pharmaceuticals PLC and Hikma Pharmaceuticals USA Inc. intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the ANDA Product, in the event FDA approves Hikma's ANDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further, pursuant to the Stipulation, the parties have stipulated the dismissal of Hikma Pharmaceuticals PLC from this action; accordingly, no response to this paragraph is required. To the extent a response is required, Hikma admits that Hikma prepared and submitted ANDA No. 219736 seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Product throughout the United States, including in the State of Delaware. Hikma otherwise denies the remaining allegations of this paragraph.

JURISDICTION AND VENUE

17. This is a civil action for patent infringement under the patent laws of the United States, including 35 U.S.C. § 271, alleging infringement of the '033, '322, '432, and '495 Patents.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma admits that the Complaint purports to bring an action for infringement under 35 U.S.C. § 271, alleging infringement of the '033, '322, '432, and '495 Patents. Hikma denies any remaining allegations in this paragraph.

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma does not contest subject matter jurisdiction for the purposes of this action only and expressly reserves the right to contest subject matter jurisdiction in any other case as to any party. Hikma denies any remaining allegations in this paragraph.

19. This Court has personal jurisdiction over Hikma Pharmaceuticals USA Inc. because it is a corporation organized and existing under the laws of Delaware. On information and belief, Hikma Pharmaceuticals USA Inc. is registered to do business as a domestic corporation in Delaware (File Number 2264775).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma denies the remaining allegations of this paragraph.

20. This Court has personal jurisdiction over Hikma Pharmaceuticals PLC because, on information and belief, it, inter alia, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more wholly-owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell the ANDA Product in the State of Delaware upon approval of Hikma's ANDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further, pursuant to the Stipulation, the parties have stipulated the dismissal of Hikma Pharmaceuticals PLC from this action; accordingly, no response to this paragraph is required. To the extent a response is required, Hikma denies that Hikma Pharmaceuticals PLC is a "Defendant" to this action. Hikma denies the remaining allegations of this paragraph.

21. On information and belief, Hikma is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter-egos, which Hikma manufactures, distributes, markets, and/or sells throughout the United States, including in this judicial district.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma denies the remaining allegations of this paragraph.

22. On information and belief, Hikma is licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more subsidiaries or agents.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma admits that it is licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more subsidiaries or agents. Hikma denies the remaining allegations of this paragraph.

23. Hikma has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture NAYZILAM® for sale and use throughout the United States, including in this judicial district. On information and belief and as indicated by a letter dated February 14, 2025, sent by Hikma to UCB, Inc., Hananja, and the University pursuant to 21 U.S.C. § 355(j)(2)(B) (hereinafter, the "Notice Letter"), Hikma's ANDA was prepared and submitted with the intention of seeking to market the ANDA Product nationwide, including within this judicial district.

ANSWER: This paragraph contains legal conclusions to which no answer is required. Hikma admits that Hikma submitted ANDA No. 219736 seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Product nationwide, including within this judicial district. Hikma otherwise denies the remaining allegations of this paragraph.

24. On information and belief, Hikma plans to sell the ANDA Product in the State of Delaware, list the ANDA Product on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the ANDA Product in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: This paragraph contains legal conclusions to which no answer is required. Hikma admits that Hikma submitted ANDA No. 219736 seeking approval to engage in the commercial

manufacture, use, or sale of the ANDA Product nationwide, including within this judicial district. Hikma denies the remaining allegations of this paragraph.

25. On information and belief, Hikma knows and intends that the proposed ANDA Product will be distributed and sold in Delaware and will thereby displace sales of NAYZILAM®, causing injury to Plaintiffs. On information and belief, Hikma intends to take advantage of their established channels of distribution in Delaware for the sale of the proposed ANDA Product.

ANSWER: ANSWER: This paragraph contains legal conclusions to which no answer is required. Hikma admits that Hikma submitted ANDA No. 219736 seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Product nationwide, including within this judicial district. Hikma denies the remaining allegations of this paragraph.

26. Hikma regularly engages in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction in this judicial district in such litigation, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Hikma Pharmaceuticals USA Inc. v. Cipla USA Inc.*, C.A. No. 23-1157-GBW, D.I. 1 (D. Del. Oct. 13, 2023); *Astellas US LLC v. Hikma Pharmaceuticals USA, Inc.*, C.A. No. 21-1785-CFC, D.I. 9 (D. Del. Feb. 28, 2022); *Novo Nordisk Inc. v. Hikma Pharmaceuticals USA Inc.*, C.A. No. 21-1783-CFC, D.I. 8 (D. Del. Jan. 12, 2022); *InfoRLife SA v. Hikma Pharmaceuticals USA Inc*., C.A. No. 21-1764-CFC, D.I. 20 (D. Del. Feb. 23, 2021).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma admits that Hikma was a party to the lawsuits identified in this paragraph. Hikma does not contest personal jurisdiction for the purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma denies the remaining allegations of this paragraph.

27. Alternatively, this Court has personal jurisdiction over Hikma Pharmaceuticals PLC under Federal Rule of Civil Procedure 4(k)(2)(A) as (a) Plaintiffs' claims arise under federal law; (b) Hikma Pharmaceuticals PLC is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Hikma Pharmaceuticals PLC has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Hikma's ANDA to FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Hikma Pharmaceuticals PLC satisfies due process.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further, pursuant to the Stipulation, the parties have stipulated the dismissal of Hikma Pharmaceuticals PLC from this action; accordingly, no response to this paragraph is required. To the extent a response is required, Hikma denies that Hikma Pharmaceuticals PLC is a "Defendant" to this action. Hikma does not contest personal jurisdiction for the purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma denies the remaining allegations of this paragraph.

28. Venue is proper in this district for Hikma Pharmaceuticals PLC pursuant to 28 U.S.C. § 1391 because, inter alia, Hikma Pharmaceuticals PLC is a corporation organized and existing under the laws of the United Kingdom and is subject to personal jurisdiction in this judicial district.

ANSWER: This paragraph contains conclusions of law for which no response is required. Further, pursuant to the Stipulation, the parties have stipulated the dismissal of Hikma Pharmaceuticals PLC from this action; accordingly, no response to this paragraph is required. To the extent a response is required, Hikma denies that Hikma Pharmaceuticals PLC is a "Defendant" to this action. Hikma does not contest venue for the purposes of this action only and expressly reserves the right to contest venue in any other case as to any party. Hikma otherwise denies the remaining allegations of this paragraph.

29. Venue is proper in this district for Hikma Pharmaceuticals USA Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, inter alia, Hikma Pharmaceuticals USA Inc. is a corporation organized and existing under the laws of the State of Delaware

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma does not contest venue for the purposes of this action only and expressly reserves the right to contest venue in any other case as to any party. Hikma otherwise denies the remaining allegations of this paragraph.

NAYZILAM®

30. UCB, Inc. is the holder of New Drug Application ("NDA") No. 211321 for NAYZILAM® nasal spray (5 mg). The active ingredient in NAYZILAM® is midazolam. FDA approved NDA No. 211321 on May 17, 2019.

ANSWER: Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies them. To the extent that a response is required, Hikma admits that the FDA's website indicates UCB, Inc. as the holder of New Drug Application ("NDA") No. 211321 for NAYZILAM® nasal spray (5 mg), which was approved by the FDA on May 17, 2019 and contains the active ingredient midazolam. Hikma denies any remaining allegations of this paragraph.

31. NAYZILAM® is a nasal spray indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.

ANSWER: Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies them. To the extent that a response is required, Hikma admits that the approved label for NAYZILAM® indicates NAYZILAM® for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older. Hikma denies any remaining allegations of this paragraph.

32. FDA granted NAYZILAM® orphan drug status. NAYZILAM®'s orphan drug exclusivity continues until May 17, 2026.

ANSWER: Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies them. To the extent that a response is required, Hikma admits that the FDA's website indicates NAYZILAM® was granted orphan drug status. Hikma denies any remaining allegations of this paragraph.

33. The ’033, ’322, ’432, and ’495 Patents are listed in the “Orange Book” for NAYZILAM®.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma admits that the patents-in-suit are listed in the “Orange Book” for NAYZILAM®.

THE ASSERTED PATENTS

34. The ’033 Patent, entitled “Methods and Compositions for the Delivery of a Therapeutic Agent,” was duly and lawfully issued by the USPTO on July 10, 2012. A true and correct copy of the ’033 Patent is attached hereto as Exhibit A.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, Hikma admits that on its face, the ’033 patent was issued on July 10, 2012, and is entitled “Methods and Compositions for the Delivery of a Therapeutic Agent.” Hikma admits that a purported copy of the ’033 patent is attached to the Complaint as Exhibit A. Hikma specifically denies that the ’033 patent was duly and legally issued. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

35. The ’322 Patent, entitled “Methods and Compositions for the Delivery of a Therapeutic Agent,” was duly and lawfully issued by the USPTO on August 19, 2014. A true and correct copy of the ’322 Patent is attached hereto as Exhibit B.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, Hikma admits that on its face, the ’322 patent was issued on August 19, 2014, and is entitled “Methods and Compositions for the Delivery of a Therapeutic Agent.” Hikma admits that a purported copy of the ’322 patent is attached to the Complaint as Exhibit B. Hikma specifically denies that the ’322 patent was duly and legally issued. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

36. The ’432 Patent, entitled “Methods and Compositions for the Delivery of a Therapeutic Agent,” was duly and lawfully issued by the USPTO on March 22, 2016. A true and correct copy of the ’432 Patent is attached hereto as Exhibit C.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, Hikma admits that on its face, the ’432 patent was issued on March 22, 2016, and is entitled “Methods and Compositions for the Delivery of a Therapeutic Agent.” Hikma admits that a purported copy of the ’432 patent is attached to the Complaint as Exhibit C. Hikma specifically denies that the ’432 patent was duly and legally issued. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

37. The ’495 Patent, entitled “Methods and Systems for the Delivery of a Therapeutic Agent,” was duly and lawfully issued by the USPTO on June 27, 2017. A true and correct copy of the ’495 Patent is attached hereto as Exhibit D.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, Hikma admits that on its face, the ’495 patent was issued on June 27, 2017, and is entitled “Methods and Systems for the Delivery of a Therapeutic Agent.” Hikma admits that a purported copy of the ’495 patent is attached to the Complaint as Exhibit D. Hikma specifically denies that the ’495 patent was duly and legally issued. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

38. UCB Biopharma SRL, Hananja, and the University own all rights to the ’033, ’322, ’432 and ’495 Patents, including the right to sue for infringement thereof.

ANSWER: Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies them.

HIKMA’S ANDA NO. 219736

39. On information and belief, Hikma has submitted Hikma’s ANDA to FDA, or caused Hikma’s ANDA to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to

engage in the commercial manufacture, use, offer to sell or sale of midazolam nasal spray as a generic version of NAYZILAM® nasal spray prior to the expiration of the '033, '322, '432, and '495 Patents.

ANSWER: Hikma admits that Hikma submitted ANDA No. 219736 ("Hikma's ANDA") to the FDA seeking approval to engage in the commercial manufacture, use, or sale of midazolam nasal spray as a generic version of NAYZILAM® nasal spray (the "ANDA Product") prior to the expiration of the patents-in-suit. Hikma denies the remaining allegations of this paragraph.

40. On information and belief, Hikma Pharmaceuticals PLC and Hikma Pharmaceuticals USA Inc. sent UCB, Inc., Hananja, and the University the Notice Letter dated February 14, 2025. The Notice Letter represented that Hikma had submitted to FDA Hikma's ANDA and a Paragraph IV certification for the '033, '322, '432, and '495 Patents.

ANSWER: Hikma admits that Hikma mailed a letter to UCB, Hananja, and University dated February 14, 2025 providing notice of Paragraph IV certification regarding ANDA No. 219736. Hikma further admits that the letter informed Plaintiffs that Hikma submitted ANDA No. 219736 seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the patents-in-suit. Hikma denies the remaining allegations of this paragraph.

41. On information and belief, the purpose of the submission of Hikma's ANDA and Paragraph IV certification was to obtain approval under section 505(j) of the Food, Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale and sale of the ANDA Product before expiration of the 033, '322, '432, and '495 Patents.

ANSWER: Hikma admits that Hikma filed ANDA No. 219736 seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the patents-in-suit. Hikma denies the remaining allegations of this paragraph.

42. On information and belief, if approved, the ANDA Product will have the same indication as NAYZILAM®. On further information and belief, the indication set forth in the proposed labeling submitted in Hikma's ANDA for the ANDA Product is the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.

ANSWER: Hikma admits that the indication set forth in the proposed labeling submitted in Hikma's ANDA for the ANDA Product is the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older. Hikma denies the remaining allegations of this paragraph.

43. In the Notice Letter, Hikma purported to offer confidential access to portions of Hikma's ANDA on terms and conditions set forth in the Notice Letter ("the Hikma Offer"). Hikma requested that UCB, Inc., Hananja, and the University accept the Hikma Offer before receiving access to Hikma's ANDA. The Hikma Offer contained unreasonable restrictions on who could view the ANDA, well beyond those that would apply under a protective order. For example, the Hikma Offer purported to allow access only to "certain information" from the ANDA. The Hikma Offer permitted access only to attorneys from a single law firm. The Hikma Offer did not permit any of UCB, Inc.'s, Hananja's, or the University's in-house attorneys to access Hikma's ANDA. Nor did it permit any scientific experts to access Hikma's ANDA. Nor did it permit any staff working under the supervision of UCB, Inc.'s, Hananja's, or the University's counsel or scientific experts to access Hikma's ANDA. Additionally, the Hikma Offer contained provisions that unreasonably restricted the ability of counsel receiving access to Hikma's ANDA to engage in any patent prosecution or work before or involving the FDA. The restrictions the Hikma Offer placed on access to Hikma's ANDA contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." Outside counsel for Plaintiffs proposed edits to the Hikma OCA on March 5, 2025. The parties met and conferred on March 11, 2025. As of the filing of this complaint, Plaintiffs have not received any follow up from Hikma, and the parties were unable to reach agreement as to reasonable terms governing confidential access to the Hikma ANDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, Hikma admits that the Notice Letter contained an offer of confidential access to portions of Hikma's ANDA on terms and conditions set forth in the Notice Letter ("the Hikma Offer"). Hikma further admits that Plaintiffs refused to accept the Hikma Offer and that outside counsel for Plaintiffs proposed edits to the Hikma Offer on March 5, 2025. Hikma admits that the parties met and conferred on March 11, 2025. Hikma specifically denies that the restrictions the Hikma Offer placed on access to Hikma's ANDA contravene 21 U.S.C. §

355(j)(5)(C)(i)(III). Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore, denies them.

44. According to applicable regulations, Notice Letters such as Hikma's must contain a detailed statement of the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed that includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 CFR § 314.95(c)(7); *see also* 21 CFR § 314.52.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, Hikma denies the allegations of this paragraph.

45. For at least one claim of each of the '033, '322, '432, and '495 Patents, Hikma's Notice Letter does not contest that its ANDA Product or the proposed administration of that Product would infringe that claim, as set forth below

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, Hikma denies the allegations of this paragraph.

46. On information and belief, if FDA approves Hikma's ANDA, Hikma will manufacture, use, offer for sale, or sell the ANDA Product, within the United States, including within the State of Delaware, or will import the ANDA Product into the United States, including the State of Delaware.

ANSWER: Hikma admits that Hikma submitted ANDA No. 219736 seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Product nationwide, including within the State of Delaware. Hikma denies the remaining allegations of this paragraph.

47. On information and belief, if FDA approves Hikma's ANDA, Hikma will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Product in a manner that infringes the '033, '322, '432, and '495 Patents.

ANSWER: Hikma admits that Hikma submitted ANDA No. 219736 seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Product. Hikma otherwise denies the remaining allegations of this paragraph.

48. This action is being brought within forty-five days of Plaintiffs' receipt of the Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C).

ANSWER: Hikma admits that Plaintiffs filed the present action on March 28, 2025, which was within forty-five (45) days of receipt of the Notice Letter.

COUNT I
INFRINGEMENT OF THE '033 PATENT

49. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–48 as if fully set forth herein.

ANSWER: Hikma incorporates by reference its responses to paragraphs 1-48 as if fully set forth herein.

50. On information and belief, Hikma submitted or caused the submission of ANDA No. 219736 to FDA, and thereby seeks FDA approval of Hikma's ANDA.

ANSWER: Hikma admits that Hikma submitted ANDA No. 219736 seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Product. Hikma denies the remaining allegations of this paragraph.

51. The ANDA Product infringes claims of the '033 Patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

52. Hikma did not contest infringement of Claims 1–14 of the '033 Patent in the Notice Letter.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

53. Hikma has infringed claims of the '033 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Hikma's ANDA with a Paragraph IV certification and thereby seeking FDA approval of a generic version of NAYZILAM® prior to the expiration of the '033 Patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

54. Upon information and belief, Hikma's commercial manufacture, use, offer for sale or sale within the United States, or importation into the United States of the Hikma ANDA Product

would directly infringe, and would actively induce and contribute to infringement of the '033 Patent. See 35 U.S.C. § 271(a), (b) and (c).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

55. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will market and distribute the Hikma ANDA Product to resellers, pharmacies, health care professionals, and end users of the ANDA Product. Accompanying the ANDA Product, Hikma will also knowingly and intentionally include a product label and insert containing instructions for administering the ANDA Product. Accordingly, Hikma will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe the claims of the '033 Patent. In addition, on information and belief, Hikma will encourage acts of direct infringement with knowledge of the '033 Patent and knowledge that it is encouraging infringement.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

56. Hikma had actual knowledge of the '033 Patent prior to submission of Hikma's ANDA, and was aware that the submission of Hikma's ANDA with the request for FDA approval prior to the expiration of the '033 Patent would constitute an act of infringement of the '033 Patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

57. Hikma submitted Hikma's ANDA without adequate justification for asserting the '033 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Hikma's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '033 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

58. Plaintiffs will be irreparably harmed if Hikma is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '033 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Hikma, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

COUNT II
INFRINGEMENT OF THE '322 PATENT

59. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–58 as if fully set forth herein.

ANSWER: Hikma incorporates by reference its responses to paragraphs 1-58 as if fully set forth herein.

60. On information and belief, Hikma submitted or caused the submission of ANDA No. 219736 to FDA, and thereby seeks FDA approval of Hikma's ANDA.

ANSWER: Hikma admits that Hikma submitted ANDA No. 219736 seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Product. Hikma denies the remaining allegations of this paragraph.

61. The ANDA Product infringes claims of the '322 Patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

62. Hikma did not contest infringement of any claim of the '322 Patent in the Notice Letter.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

63. Hikma has infringed claims of the '322 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Hikma's ANDA with a Paragraph IV certification and thereby seeking FDA approval of a generic version of NAYZILAM® prior to the expiration of the '322 Patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

64. Upon information and belief, Hikma's commercial manufacture, use, offer for sale or sale within the United States, or importation into the United States of the Hikma ANDA Product

would directly infringe, and would actively induce and contribute to infringement of the '322 Patent. *See* 35 U.S.C. § 271(a), (b) and (c).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

65. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will market and distribute the Hikma ANDA Product to resellers, pharmacies, health care professionals, and end users of the ANDA Product. Accompanying the ANDA Product, Hikma will also knowingly and intentionally include a product label and insert containing instructions for administering the ANDA Product. Accordingly, Hikma will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe the claims of the '322 Patent. In addition, on information and belief, Hikma will encourage acts of direct infringement with knowledge of the '322 Patent and knowledge that it is encouraging infringement.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

66. Hikma had actual knowledge of the '322 Patent prior to submission of Hikma's ANDA, and was aware that the submission of Hikma's ANDA with the request for FDA approval prior to the expiration of the '322 Patent would constitute an act of infringement of the '322 Patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

67. Hikma submitted Hikma's ANDA without adequate justification for asserting the '322 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Hikma's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '322 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

68. Plaintiffs will be irreparably harmed if Hikma is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '322 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Hikma, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

COUNT III
INFRINGEMENT OF THE '432 PATENT

69. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–68 as if fully set forth herein.

ANSWER: Hikma incorporates by reference its responses to paragraphs 1-68 as if fully set forth herein.

70. On information and belief, Hikma submitted or caused the submission of ANDA No. 219736 to FDA, and thereby seeks FDA approval of Hikma's ANDA.

ANSWER: Hikma admits that Hikma submitted ANDA No. 219736 seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Product. Hikma otherwise denies the remaining allegations of this paragraph.

71. The ANDA Product infringes claims of the '432 Patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

72. Hikma did not contest infringement of claims 1-14 of the '432 Patent in the Notice Letter.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

73. Hikma has infringed claims of the '432 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Hikma's ANDA with a Paragraph IV certification and thereby seeking FDA approval of a generic version of NAYZILAM® prior to the expiration of the '432 Patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

74. Upon information and belief, Hikma's commercial manufacture, use, offer for sale or sale within the United States, or importation into the United States of the Hikma ANDA Product

would directly infringe, and would actively induce and contribute to infringement of the '432 Patent. *See* 35 U.S.C. § 271(a), (b) and (c).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

75. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will market and distribute the Hikma ANDA Product to resellers, pharmacies, health care professionals, and end users of the ANDA Product. Accompanying the ANDA Product, Hikma will also knowingly and intentionally include a product label and insert containing instructions for administering the ANDA Product. Accordingly, Hikma will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe the claims of the '432 Patent. In addition, on information and belief, Hikma will encourage acts of direct infringement with knowledge of the '432 Patent and knowledge that it is encouraging infringement.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

76. Hikma had actual knowledge of the '432 Patent prior to submission of Hikma's ANDA, and was aware that the submission of Hikma's ANDA with the request for FDA approval prior to the expiration of the '432 Patent would constitute an act of infringement of the '432 Patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

77. Hikma submitted Hikma's ANDA without adequate justification for asserting the '432 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Hikma's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '432 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

78. Plaintiffs will be irreparably harmed if Hikma is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '432 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Hikma, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

COUNT IV
INFRINGEMENT OF THE '495 PATENT

79. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–78 as if fully set forth herein.

ANSWER: Hikma incorporates by reference its responses to paragraphs 1-78 as if fully set forth herein.

80. On information and belief, Hikma submitted or caused the submission of ANDA No. 219736 to FDA, and thereby seeks FDA approval of Hikma's ANDA.

ANSWER: Hikma admits Hikma submitted ANDA No. 219736 seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Product. Hikma otherwise denies the remaining allegations of this paragraph.

81. The ANDA Product infringes claims of the '495 Patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

82. Hikma did not contest infringement of claims 1-14 of the '495 Patent in the Notice Letter.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

83. Hikma has infringed claims of the '495 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Hikma's ANDA with a Paragraph IV certification and thereby seeking FDA approval of a generic version of NAYZILAM® prior to the expiration of the '495 Patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

84. Upon information and belief, Hikma's commercial manufacture, use, offer for sale or sale within the United States, or importation into the United States of the Hikma ANDA Product

would directly infringe, and would actively induce and contribute to infringement of the '495 Patent. *See* 35 U.S.C. § 271(a), (b) and (c).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

85. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will market and distribute the Hikma ANDA Product to resellers, pharmacies, health care professionals, and end users of the ANDA Product. Accompanying the ANDA Product, Hikma will also knowingly and intentionally include a product label and insert containing instructions for administering the ANDA Product. Accordingly, Hikma will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe the claims of the '495 Patent. In addition, on information and belief, Hikma will encourage acts of direct infringement with knowledge of the '495 Patent and knowledge that it is encouraging infringement.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

86. Hikma had actual knowledge of the '495 Patent prior to submission of Hikma's ANDA, and was aware that the submission of Hikma's ANDA with the request for FDA approval prior to the expiration of the '495 Patent would constitute an act of infringement of the '495 Patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

87. Hikma submitted Hikma's ANDA without adequate justification for asserting the '495 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Hikma's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '495 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

88. Plaintiffs will be irreparably harmed if Hikma is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '495 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Hikma, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Hikma denies the allegations in this paragraph.

REQUEST FOR RELIEF

This section of Plaintiff's Complaint is a prayer for relief and does not require a response. To the extent any response is required, Hikma denies that Plaintiff is entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

Hikma hereby asserts the following defenses without undertaking or otherwise shifting any applicable burdens of proof. Hikma reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery. Hikma asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise denied.

First Affirmative Defense

The filing of Hikma's ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the Patents-in-Suit.

Second Affirmative Defense

The manufacture, use, sale, offer for sale, or importation of the ANDA Product has not, does not, and would not infringe, directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents.

Third Affirmative Defense

The claims of the patents-in-suit are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

Fourth Affirmative Defense

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

Fifth Affirmative Defense

Hikma's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Affirmative Defense

Hikma has not induced infringement of any claim of the patents-in-suit.

Seventh Affirmative Defense

Plaintiffs are estopped from asserting infringement by the doctrine of prosecution history estoppel, judicial estoppel, unclean hands and/or other equitable doctrines.

Eighth Affirmative Defense

Plaintiff cannot meet its burden of satisfying requirements for injunctive relief, whether preliminary or permanent.

Ninth Affirmative Defense

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

For its Counterclaims against Plaintiff/Counterclaim-Defendants UCB Inc., UCB Biopharma SRL, Hananja EHF and University of Iceland (collectively "Plaintiffs" or "Counterclaim-Defendants"), Defendant/Counterclaim-Plaintiff Hikma Pharmaceuticals USA Inc. ("Hikma") states as follows:

PARTIES

1. Hikma is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

2. On information and belief, UCB Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 1950 Lake Park Drive, Building 2100, Smyrna, GA 30080.

3. On information and belief, UCB, Inc. holds New Drug Application ("NDA") No. 211321 for NAYZILAM®.

4. On information and belief, UCB Biopharma SRL is a corporation organized and existing under the laws of Belgium, with a place of business at Allee de la Recherche 60 B-1070, Brussels, BE.

5. On information and belief, UCB Biopharma SRL is the exclusive license of the '033, '322, '432, and '495 Patents for NAYZILAM®.

6. On information and belief, Hananja EHF is a corporation organized and existing under the laws of Iceland, with a place of business at Aflagrandi 7, 107 Reykjavik, Iceland.

7. On information and belief, Hananja EHF is an assignee and co-owner of the '033, '322, '432, and '495 Patents.

8. On information and belief, Plaintiff University of Iceland is an entity organized and existing under the laws of Iceland, with a principal place of business at Sæmundargata 2, 102 Reykjavik, Iceland.

9. On information and belief, University of Iceland is an assignee and co-owner of the '033, '322, '432, and '495 Patents.

JURISDICTION AND VENUE

10. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over Counterclaim Defendants/Plaintiffs on the

basis of, inter alia, its contacts with Delaware relating to the subject matter of this action, including having filed suit.

12. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

13. On information and belief, UCB, Inc. is the holder of New Drug Application ("NDA") No. 211321 for NAYZILAM® nasal spray (5 mg).

14. An NDA must include, among others, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2).

15. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

16. U.S. Patent No. 8,217,033 ("the '033 Patent"), entitled "Methods and Compositions for the Delivery of a Therapeutic Agent," issued on July 10, 2012.

17. U.S. Patent No. 8,809,322 ("the '322 Patent"), entitled "Methods and Compositions for the Delivery of a Therapeutic Agent," issued on August 19, 2014.

18. U.S. Patent No. 9,289,432 ("the '432 Patent"), entitled "Methods and Compositions for the Delivery of a Therapeutic Agent," issued on March 22, 2016.

19. U.S. Patent No. 9,687,495 ("the '495 Patent"), entitled "Methods and Systems for Delivery of a Therapeutic Agent," issued on June 27, 2017.

20. Upon information and belief, Plaintiffs caused the '033, '322, '432, and '495 Patents (collectively, "the patents-in-suit") to be listed in the Orange Book in connection with

NAYZILAM®.

21. Hikma submitted its ANDA No. 219736 ("Hikma's ANDA") seeking approval to engage in the commercial use, sale, offer for sale or importation into the United States of a Midazolam nasal spray (5mg) ("the ANDA Product") prior to the expiration of the patents-in-suit.

22. Hikma's ANDA contains "Paragraph IV" certifications under 21 U.S.C. § 355 5(j)(2)(A)(vii)(IV) that the claims of the patents-in-suit patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

23. On February 14, 2025, Hikma mailed a written notice of Hikma's Paragraph IV Certifications pursuant to 21 U.S.C. § 355(j)(2)(B) ("the Notice Letter"). The Notice Letter asserted that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by Hikma's ANDA or the product or activities described therein.

24. On March 28, 2025, Counterclaim-Defendants filed the present action alleging infringement of the patents-in-suit.

25. As a consequence of the foregoing, there is an actual and justiciable controversy between Hikma, on the one hand, and Counterclaim-Defendants, on the other hand, as to whether the claims of the patents-in-suit are invalid and/or unenforceable, and whether those claims are being infringed by the products described in Hikma's ANDA No. 219736.

COUNT I
(Declaration of Noninfringement of the '033 Patent)

26. Hikma re-alleges and incorporates the allegations of paragraphs 1-25 as if fully set forth herein.

27. Counterclaim-Defendants allege ownership, title, and/or interest to the '033 patent and have brought claims against Hikma alleging infringement of the '033 patent.

28. The manufacture, use, or sale of Hikma's ANDA Product would not infringe any

valid or enforceable claim of the '033 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

29. An actual, present, genuine, and justiciable controversy exists between Hikma, on the one hand, and Counterclaim-Defendants, on the other hand, regarding, *inter alia*, the issue of whether the filing of Hikma's ANDA and/or the manufacture, use, or sale of Hikma's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '033 patent.

30. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma's Product has not, does not, and will not infringe any valid or enforceable claim of the '033 patent.

31. This case is an exceptional one, and Hikma is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
(Declaration of Invalidity of the '033 Patent)

32. Hikma re-alleges and incorporates the allegations of paragraphs 1-31 as if fully set forth herein.

33. Counterclaim-Defendants allege ownership, title, and/or interest to the '033 patent and have brought claims against Hikma alleging infringement of the '033 patent.

34. One or more of the claims of the '033 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

35. An actual, present, genuine, and justiciable controversy exists between Hikma and Plaintiffs regarding, *inter alia*, the validity of all claims of the '033 patent.

36. Hikma is entitled to a declaration that all claims of the '033 patent are invalid.

37. This case is an exceptional one, and Hikma is entitled to an award of its reasonable

attorneys' fees under 35 U.S.C. § 285.

COUNT III
(Declaration of Noninfringement of the '322 Patent)

38. Hikma re-alleges and incorporates the allegations of paragraphs 1-37 as if fully set forth herein.

39. Counterclaim-Defendants allege ownership, title, and/or interest to the '322 Patent and have brought claims against Hikma alleging infringement of the '322 Patent.

40. The manufacture, use, or sale of Hikma's ANDA Product would not infringe any valid or enforceable claim of the '322 Patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

41. An actual, present, genuine, and justiciable controversy exists between Hikma, on the one hand, and Counterclaim-Defendants, on the other hand, regarding, *inter alia*, the issue of whether the filing of Hikma's ANDA and/or the manufacture, use, or sale of Hikma's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '322 Patent.

42. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma's Product has not, does not, and will not infringe any valid or enforceable claim of the '322 Patent.

43. This case is an exceptional one, and Hikma is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VI
(Declaration of Invalidity of the '322 Patent)

44. Hikma re-alleges and incorporates the allegations of paragraphs 1-43 as if fully set forth herein.

45. Counterclaim-Defendants allege ownership, title, and/or interest to the '322 Patent and have brought claims against Hikma alleging infringement of the '322 Patent.

46. One or more of the claims of the ’322 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

47. An actual, present, genuine, and justiciable controversy exists between Hikma and Plaintiffs regarding, *inter alia*, the validity of all claims of the ’322 Patent.

48. Hikma is entitled to a declaration that all claims of the ’322 Patent are invalid.

49. This case is an exceptional one, and Hikma is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT V
(Declaration of Noninfringement of the ’432 Patent)

50. Hikma re-alleges and incorporates the allegations of paragraphs 1-49 as if fully set forth herein.

51. Counterclaim-Defendants allege ownership, title, and/or interest to the ’432 Patent and have brought claims against Hikma alleging infringement of the ’432 Patent.

52. The manufacture, use, or sale of Hikma’s ANDA Product would not infringe any valid or enforceable claim of the ’432 Patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

53. An actual, present, genuine, and justiciable controversy exists between Hikma, on the one hand, and Counterclaim-Defendants, on the other hand, regarding, *inter alia*, the issue of whether the filing of Hikma’s ANDA and/or the manufacture, use, or sale of Hikma’s ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the ’432 Patent.

54. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma’s Product has not, does not, and will not infringe any valid or enforceable claim of the ’432 Patent.

55. This case is an exceptional one, and Hikma is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VI
(Declaration of Invalidity of the '432 Patent)

56. Hikma re-alleges and incorporates the allegations of paragraphs 1-55 as if fully set forth herein.

57. Counterclaim-Defendants allege ownership, title, and/or interest to the '432 Patent and have brought claims against Hikma alleging infringement of the '432 Patent.

58. One or more of the claims of the '432 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

59. An actual, present, genuine, and justiciable controversy exists between Hikma and Plaintiffs regarding, *inter alia*, the validity of all claims of the '432 Patent.

60. Hikma is entitled to a declaration that all claims of the '432 Patent are invalid.

61. This case is an exceptional one, and Hikma is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VII
(Declaration of Noninfringement of the '495 Patent)

62. Hikma re-alleges and incorporates the allegations of paragraphs 1-61 as if fully set forth herein.

63. Counterclaim-Defendants allege ownership, title, and/or interest to the '495 Patent and have brought claims against Hikma alleging infringement of the '495 Patent.

64. The manufacture, use, or sale of Hikma's ANDA Product would not infringe any valid or enforceable claim of the '495 Patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

65. An actual, present, genuine, and justiciable controversy exists between Hikma, on the one hand, and Counterclaim-Defendants, on the other hand, regarding, *inter alia*, the issue of whether the filing of Hikma's ANDA and/or the manufacture, use, or sale of Hikma's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '495 Patent.

66. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma's Product has not, does not, and will not infringe any valid or enforceable claim of the '495 Patent.

67. This case is an exceptional one, and Hikma is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VIII
(Declaration of Invalidity of the '495 Patent)

68. Hikma re-alleges and incorporates the allegations of paragraphs 1-67 as if fully set forth herein.

69. Counterclaim-Defendants allege ownership, title, and/or interest to the '495 Patent and have brought claims against Hikma alleging infringement of the '495 patent.

70. One or more of the claims of the '495 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

71. An actual, present, genuine, and justiciable controversy exists between Hikma and Plaintiffs regarding, *inter alia*, the validity of all claims of the '495 Patent.

72. Hikma is entitled to a declaration that all claims of the '495 Patent are invalid.

73. This case is an exceptional one, and Hikma is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Hikma Pharmaceuticals USA Inc. ("Hikma") respectfully requests judgement in its favor and against Counterclaim Defendants/Plaintiffs as follows:

1. Declaring that Hikma has not infringed, does not infringe, and will not infringe, directly or indirectly, either literally or under the doctrine of equivalents, any valid and enforceable claim of the U.S. Patent No. 8,217,033;

2. Declaring that all claims of U.S. Patent No. 8,217,033 are invalid;

3. Declaring that Hikma has not infringed, does not infringe, and will not infringe, directly or indirectly, either literally or under the doctrine of equivalents, any valid and enforceable claim of the U.S. Patent No. 8,809,322;

4. Declaring that all claims of U.S. Patent No. 8,809,322 are invalid;

5. Declaring that Hikma has not infringed, does not infringe, and will not infringe, directly or indirectly, either literally or under the doctrine of equivalents, any valid and enforceable claim of the U.S. Patent No. 9,289,432;

6. Declaring that all claims of U.S. Patent No. 9,289,432 are invalid;

8. Declaring that Hikma has not infringed, does not infringe, and will not infringe, directly or indirectly, either literally or under the doctrine of equivalents, any valid and enforceable claim of the U.S. Patent No. 9,687,495;

9. Declaring that all claims of U.S. Patent No. 9,687,495 are invalid;

10. Declaring this to be an exceptional case pursuant to 35 U.S.C. § 285 and awarding Hikma its costs, expenses, and reasonable attorneys' fees in this action; and

11. Awarding Hikma any further and additional relief as the Court deems just and proper.

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Dated: May 29, 2025

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