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DR. REDDY'S LABORATORIES LTD. and
DR. REDDY'S LABORATORIES INC.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH & LOMB INCORPORATED; BAUSCH & LOMB IRELAND LIMITED; and NICOX S.A., *Plaintiffs*, v. DR. REDDY'S LABORATORIES LTD. and DR. REDDY'S LABORATORIES INC., *Defendants.*	Civil Action No. 3-23-cv-03463-RK-RLS

DR. REDDY'S LABORATORIES LTD. AND DR. REDDY'S LABORATORIES INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO COMPLAINT FOR PATENT INFRINGEMENT

Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's Ltd.") and Dr. Reddy's Laboratories Inc. ("Dr. Reddy's Inc.") (collectively, "Defendants" or "DRL"), hereby provide their answer to the

Complaint for Patent Infringement of Bausch & Lomb Incorporated, Bausch & Lomb Ireland Limited, and Nicox, S.A. (collectively, "Plaintiffs"), as follows:

GENERAL DENIAL

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

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 7,273,946 ("the '946 patent"), 7,629,345 ("the '345 patent"), 7,910,767 ("the '767 patent"), and 8,058,467 ("the '467 patent") (collectively, "Asserted Patents") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to DRL's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration("FDA") approval to market its generic latanoprostene bunod ophthalmic solution, 0.024% ("DRL's generic latanoprostene bunod product") prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that Plaintiffs purport to state a claim for alleged patent infringement. DRL further admits that Dr. Reddy's Ltd. submitted an Abbreviated New Drug Application through its authorized U.S. Agent Dr. Reddy's Inc. ("DRL's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval for latanoprostene bunod ophthalmic solution, 0.024% ("DRL's ANDA Product") prior to the expiration of U.S. Patent Nos. 7,273,946 ("the '946 patent"), 7,629,345 ("the '345 patent"), 7,910,767 ("the '767 patent"), and 8,058,467 ("the '467 patent") (collectively, "Asserted Patents"). DRL denies any and all remaining allegations of Paragraph 1.

THE PARTIES

2. Plaintiff Bausch & Lomb Incorporated ("B+L") is a corporation organized and existing under the laws of New York with a place of business at 1400 N. Goodman St. Rochester, NY 14609.

ANSWER: Paragraph 2 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2, and therefore denies any and all allegations of Paragraph 2.

3. B+L is the registered holder of approved New Drug Application ("NDA") No. 207795, which FDA approved on November 2, 2017.

ANSWER: Paragraph 3 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the electronic version of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), identifies Bausch & Lomb Inc. as the purported "Applicant Holder" for NDA No. 207795 for VYZULTA® and the "Approval Date" as November 2, 2017. DRL denies any and all remaining allegations of Paragraph 3.

4. B+L manufactures and markets the product covered by NDA No. 207795 ("Vyzulta") in the United States. The product is marketed under the registered trade name Vyzulta®. Vyzulta, which has an active ingredient of latanoprostene bunod, is approved by FDA for the reduction of intraocular pressure ("IOP") in patients with open-angle glaucoma or ocular hypertension.

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book identifies Bausch & Lomb Inc. as the purported "Applicant Holder" for NDA No. 207795 and that the active ingredient in VYZULTA® is "latanoprostene bunod." DRL further admits that the VYZULTA® label (Revised 06/2018) states:

---------- **INDICATIONS AND USAGE** ----------
VYZULTA is a prostaglandin analog indicated for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension. (1)

DRL denies any and all remaining allegations of Paragraph 4.

5. Plaintiff Bausch & Lomb Ireland Limited ("B+L Ireland") is a company organized and existing under the laws of Ireland, having its registered office at 3013 Lake Drive, Citywest Business Park, Dublin, Ireland. B+L Ireland exclusively licenses the Asserted Patents.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 5, and therefore denies any and all allegations of Paragraph 5.

6. Plaintiff Nicox S.A. ("Nicox") is a company organized and existing under the laws of France, having its registered office at Drakkar 2 – Bât D, 2405 route des Dolines – CS 10313, Sophia Antipolis – 06560 Valbonne, France. Nicox is the owner of the Asserted Patents.

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the face of each of the Asserted Patents identifies Nicox S.A. as the purported "assignee." DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 6, and therefore denies any and all remaining allegations of Paragraph 6.

7. Upon information and belief, Dr. Reddy's Laboratories Inc. ("DRL Inc.") is a New Jersey corporation having a principal place of business at 107 College Road East, Princeton, NJ 08540.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Dr. Reddy's Inc. is an entity organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540. DRL denies any and all remaining allegations of Paragraph 7.

8. Upon information and belief, Dr. Reddy's Laboratories Ltd. ("DRL Ltd.") is an Indian corporation, with its principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Dr. Reddy's Ltd. is an entity organized and

existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500034, India, which is in the state of Telengana. DRL denies any and all remaining allegations of Paragraph 8.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that subject matter jurisdiction is proper solely for the claims against Dr. Reddy's Ltd. under 35 U.S.C. § 271(e)(2)(A). DRL denies any and all remaining allegations of Paragraph 9.

10. Upon information and belief, this court has jurisdiction over DRL Inc. Upon information and belief, DRL Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, DRL Inc. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for DRL's generic latanoprostene bunod product. Upon information and belief, DRL Inc. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, DRL Inc. has its principal place of business at 107 College Road East, Princeton, NJ 08540. Upon information and belief, DRL Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL does not contest personal jurisdiction solely for the limited purposes of this action only. DRL denies any and all remaining allegations of Paragraph 10.

11. Upon information and belief, this court has jurisdiction over DRL Ltd. Upon information and belief, DRL Ltd. is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, DRL Ltd. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for DRL's generic latanoprostene bunod product. Upon information and belief, DRL Ltd. purposefully has conducted and continues to conduct business in this judicial

district, including through its use of DRL Inc. as its agent, for example, related to the acts complained herein.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL does not contest personal jurisdiction solely for the limited purposes of this action only. DRL denies any and all remaining allegations of Paragraph 11.

12. Upon information and belief, DRL Inc. is a wholly owned subsidiary of DRL Ltd.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that Dr. Reddy's Ltd. is the ultimate parent company of Dr. Reddy's Inc. DRL denies any and all remaining allegations of Paragraph 12.

13. Upon information and belief, DRL Inc. is an agent of DRL Ltd., and DRL Inc. and DRL Ltd. have acted in concert with respect to the acts complained herein, including the preparation and filing of ANDA No. 218414 and in preparation to sell DRL's generic latanoprostene bunod product in the United States and in this judicial district. For example, DRL refers to their ANDA with Paragraph IV certifications and their product without differentiating between DRL Inc. and DRL Ltd., instead referring to "DRL."

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

14. DRL has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the State of New Jersey and elsewhere. DRL's ANDA filing constitutes formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, DRL intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, DRL will engage in marketing, sale, and offer for sale of its generic latanoprostene bunod product in New Jersey upon approval of its ANDA.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

15. DRL has designated in-house counsel for DRL Inc., Anjum Swaroop PhD, Esq., at 107 College Road East, Princeton, NJ 08540 as an agent in the United States authorized to accept service of process for DRL, with respect to DRL's ANDA seeking FDA approval for its generic latanoprostene bunod product.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL sent a letter, dated May 24, 2023 ("DRL's Notice Letter"), that identifies Anjum Swaroop as an agent in the United States authorized to accept service of process for DRL. DRL denies any and all remaining allegations of Paragraph 15.

16. Upon information and belief, DRL Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in.at least the following actions. *E.g., Eisai Management Co., Ltd., et al. v. Dr. Reddy's Laboratories Inc., et al.*, Civil Action No. 22-5950 (Jan. 6, 2023); *Celgene Corp. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 21-2111 (Apr. 23, 2021); *Horizon Medicines LLC, et al. v. Dr. Reddy's Laboratories Inc., et al.*, Civil Action No. 15-3324 (July 29, 2020); *Merck Sharp & Dohme B.V., et al. v. Dr. Reddy's Laboratories, Inc., et al.*, Civil Action No. 20-2909 (June 8, 2020).

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL does not contest personal jurisdiction solely for the limited purposes of this action only. DRL denies any and all remaining allegations of Paragraph 16.

17. Defendants know or should know that Vyzulta® is manufactured and distributed by B+L, at least because that information is included in the label for Vyzulta® and is publicly available.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the VYZULTA® label (Revised 06/2018) states:

> Vyzulta is a trademark of Bausch & Lomb Incorporated or its affiliates.
>
> © Bausch & Lomb Incorporated
>
> **Distributed by:**
> Bausch + Lomb, a division of
> Valeant Pharmaceuticals North America LLC
> Bridgewater, NJ 08807 USA

DRL lacks knowledge or information sufficient to form a belief as to the truth of all remaining allegations of Paragraph 17, and therefore denies any and all remaining allegations of Paragraph 17.

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

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL does not contest venue solely for the limited purposes of this action only. DRL denies any and all remaining allegations of Paragraph 18.

19. Venue is proper against DRL Inc., a New Jersey corporation, which maintains a regular and established place of business in this judicial district.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL does not contest venue solely for the limited purposes of this action only. DRL denies any and all remaining allegations of Paragraph 19.

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

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL does not contest venue solely for the limited purposes of this action only. DRL denies any and all remaining allegations of Paragraph 20.

THE PATENTS-IN-SUIT

21. FDA issues a publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

ANSWER: Admitted.

22. In accordance with 21 U.S.C. § 355(b)(1), the Asserted Patents are listed in the Orange Book in connection with NDA No. 207795 as patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Vyzulta.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Asserted Patents are listed in the Orange Book for NDA No. 207795. DRL denies any and all remaining allegations of Paragraph 22.

23. The U.S. Patent and Trademark Office ("PTO") issued the '946 patent on September 25, 2007. The '946 patent discloses and claims, *inter alia*, novel prostaglandin nitroderivatives having improved pharmacological activity and enhanced tolerability, including compositions and uses thereof. Plaintiffs hold all substantial rights in the '946 patent and have the right to sue for infringement thereof. A copy of the '946 patent is attached hereto as Exhibit 1.

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the online records of the United States Patent and Trademark Office ("PTO"), the '946 patent, titled "Prostaglandin derivatives," issued on or about September 25, 2007. DRL further admits that what purports to be a copy of the '946 patent is attached to the Complaint as Exhibit 1. DRL denies any and all remaining allegations of Paragraph 23.

24. The PTO issued the '345 patent on December 8, 2009. The '345 patent discloses and claims, *inter alia*, novel prostaglandin nitroderivatives having improved pharmacological activity and enhanced tolerability, including compositions and uses thereof. Plaintiffs hold all substantial rights in the '345 patent and have the right to sue for infringement thereof. A copy of the '345 patent is attached hereto as Exhibit 2.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the online records of the PTO, the '345 patent, titled "Prostaglandin derivatives," issued on or about December 8, 2009. DRL further admits that what purports to be a copy of the '345 patent is attached to the Complaint as Exhibit 2. DRL denies any and all remaining allegations of Paragraph 24.

25. The PTO issued the '767 patent on March 22, 2011. The '767 patent discloses and claims, *inter alia*, novel prostaglandin nitroderivatives having improved pharmacological activity and enhanced tolerability, including compositions and uses thereof. Plaintiffs hold all substantial rights in the '767 patent and have the right to sue for infringement thereof. A copy of the '767 patent is attached hereto as Exhibit 3.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the online records of the PTO, the '767 patent, titled "Prostaglandin derivatives," issued on or about March 22, 2011. DRL further admits that what purports to be a copy of the '767 patent is attached to the Complaint as Exhibit 3. DRL denies any and all remaining allegations of Paragraph 25.

26. The PTO issued the '467 patent on November 15, 2011. The '467 patent discloses and claims, *inter alia*, novel prostaglandin nitroderivatives having improved pharmacological activity and enhanced tolerability, including compositions and uses thereof. Plaintiffs hold all substantial rights in the '467 patent and have the right to sue for infringement thereof. A copy of the '467 patent is attached hereto as Exhibit 4.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the online records of the PTO, the '467 patent, titled "Prostaglandin derivatives," issued on or about November 15, 2011. DRL further admits that what purports to be a copy of the '467 patent is attached to the Complaint as Exhibit 4. DRL denies any and all remaining allegations of Paragraph 26.

27. Applications for patent term extension ("PTE") under 35 U.S.C. § 156 are presently pending for each of the '946, '345, and '467 patents.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 27, and therefore denies any and all allegations of Paragraph 27.

DRL's ANDA SUBMISSION

28. Upon information and belief, DRL filed or caused to be filed with the FDA ANDA No. 218414, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that Dr. Reddy's Ltd., through its authorized

U.S. Agent Dr. Reddy's Inc., submitted DRL's ANDA to the FDA. DRL denies any and all remaining allegations of Paragraph 28.

29. Upon information and belief, DRL's ANDA No. 218414 seeks FDA approval to engage in commercial manufacture, use, and sale in the United States of DRL's generic latanoprostene bunod product, intended to be a generic version of Vyzulta®.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's ANDA seeks FDA approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 29.

30. On or about May 26, 2023, Plaintiffs received a letter from DRL dated May 24, 2023, purporting to be a Notice of Paragraph IV Certification regarding ANDA No. 218414 ("DRL's Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. DRL's Notice Letter was addressed to B+L and Nicox.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that it sent DRL's Notice Letter to Plaintiffs. DRL denies any and all remaining allegations of Paragraph 30.

31. DRL's Notice Letter alleges that DRL has submitted to the FDA ANDA No. 218414 seeking approval to engage in the commercial manufacture, use and/or sale of DRL's generic latanoprostene bunod product, intended to be generic versions of Vyzulta®.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter confirms that Dr. Reddy's Ltd. submitted DRL's ANDA seeking FDA approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 31.

32. DRL's Notice Letter states that DRL's ANDA No. 218414 contains "any required bioavailability or bioequivalence data or information with respect to latanoprostene bunod ophthalmic solution, 0.024%," for DRL's generic latanoprostene bunod product.

ANSWER: DRL admits that DRL's Notice Letter states that "[t]he U.S. Food and Drug Administration ('FDA') has received an ANDA submitted by DRL containing any required

bioavailability or bioequivalence data or information with respect to latanoprostene bunod ophthalmic solution, 0.024%[.]" DRL denies any and all remaining allegations of Paragraph 32 .

33. Upon information and belief, ANDA No. 218414 seeks approval of DRL's generic latanoprostene bunod product that is the same, or substantially the same, as Vyzulta®.

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

COUNT I

'946 Patent Under § 271(e)(2)

34. Paragraphs 1-33 are incorporated herein as set forth above.

ANSWER: DRL restates and incorporates by reference each of its responses to Paragraphs 1-33, as if fully set forth herein.

35. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '946 patent by submitting, or causing to be submitted to the FDA, ANDA No. 218414 seeking approval for the commercial marketing of DRL's generic latanoprostene bunod product before the expiration date of the '946 patent.

ANSWER: Denied.

36. Upon information and belief, DRL's generic latanoprostene bunod product will, if approved and marketed, infringe at least one claim of the '946 patent.

ANSWER: Denied.

37. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of DRL's generic latanoprostene bunod product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '946 patent.

ANSWER: Denied.

38. If Defendants' marketing and sale of DRL's generic latanoprostene bunod product prior to the expiration of the '946 patent, including any PTE, is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT II

Declaratory Judgment - '946 Patent

39. Paragraphs 1-38 are incorporated herein as set forth above.

ANSWER: DRL restates and incorporates by reference each of its responses to Paragraphs 1-38, as if fully set forth herein.

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

ANSWER: Denied.

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

ANSWER: Denied.

42. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import DRL's generic latanoprostene bunod product before the expiration date of the '946 patent, including DRL's filing of ANDA No. 218414.

ANSWER: Denied.

43. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of DRL's generic latanoprostene bunod product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '946 patent.

ANSWER: Denied.

44. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of DRL's generic latanoprostene bunod product will constitute infringement of at least one claim of the '946 patent.

ANSWER: Denied.

COUNT III

'345 Patent Under § 271(e)(2)

45. Paragraphs 1-44 are incorporated herein as set forth above.

ANSWER: DRL restates and incorporates by reference each of its responses to Paragraphs 1-44, as if fully set forth herein.

46. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '345 patent by submitting, or causing to be submitted to the FDA, ANDA No. 218414 seeking approval for the commercial marketing of DRL's generic latanoprostene bunod product before the expiration date of the '345 patent.

ANSWER: Denied.

47. Upon information and belief, DRL's generic latanoprostene bunod product will, if approved and marketed, infringe at least one claim of the '345 patent.

ANSWER: Denied.

48. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of DRL's generic latanoprostene bunod product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '345 patent. Denied.

ANSWER: Denied.

49. If Defendants' marketing and sale of DRL's generic latanoprostene bunod product prior to the expiration of the '345 patent, including any PTE, is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT IV

Declaratory Judgment - '345 Patent

50. Paragraphs 1-49 are incorporated herein as set forth above.

ANSWER: DRL restates and incorporates by reference each of its responses to Paragraphs 1-49, as if fully set forth herein.

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

ANSWER: Denied.

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

ANSWER: Denied.

53. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import DRL's generic latanoprostene bunod product before the expiration date of the '345 patent, including DRL's filing of ANDA No. 218414.

ANSWER: Denied.

54. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of DRL's generic latanoprostene bunod product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '345 patent.

ANSWER: Denied.

55. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of DRL's generic latanoprostene bunod product will constitute infringement of at least one claim of the '345 patent.

ANSWER: Denied.

COUNT V

'767 Patent Under § 271(e)(2)

56. Paragraphs 1-55 are incorporated herein as set forth above.

ANSWER: DRL restates and incorporates by reference each of its responses to Paragraphs 1-55, as if fully set forth herein.

57. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '767 patent by submitting, or causing to be submitted to the FDA, ANDA No. 218414 seeking approval for the commercial marketing of DRL's generic latanoprostene bunod product before the expiration date of the '767 patent.

ANSWER: Denied.

58. Upon information and belief, DRL's generic latanoprostene bunod product will, if approved and marketed, infringe at least one claim of the '767 patent.

ANSWER: Denied.

59. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of DRL's generic latanoprostene bunod product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '767 patent.

ANSWER: Denied.

60. If Defendants' marketing and sale of DRL's generic latanoprostene bunod product prior to the expiration of the '767 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT VI

Declaratory Judgment - '767 Patent

61. Paragraphs 1-60 are incorporated herein as set forth above.

ANSWER: DRL restates and incorporates by reference each of its responses to Paragraphs 1-60, as if fully set forth herein.

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

ANSWER: Denied.

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

ANSWER: Denied.

64. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import DRL's generic latanoprostene bunod product before the expiration date of the '767 patent, including DRL's filing of ANDA No. 218414.

ANSWER: Denied.

65. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of DRL's generic latanoprostene bunod product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '767 patent.

ANSWER: Denied.

66. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of DRL's generic latanoprostene bunod product will constitute infringement of at least one claim of the '767 patent.

ANSWER: Denied.

COUNT VII

'467 Patent Under § 271(e)(2)

67. Paragraphs 1-66 are incorporated herein as set forth above.

ANSWER: DRL restates and incorporates by reference each of its responses to Paragraphs 1-66, as if fully set forth herein.

68. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '467 patent by submitting, or causing to be submitted to the FDA, ANDA No. 218414 seeking approval for the commercial marketing of DRL's generic latanoprostene bunod product before the expiration date of the '467 patent.

ANSWER: Denied.

69. Upon information and belief, DRL's generic latanoprostene bunod product will, if approved and marketed, infringe at least one claim of the '467 patent.

ANSWER: Denied.

70. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of DRL's generic latanoprostene bunod product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '467 patent.

ANSWER: Denied.

71. If Defendants' marketing and sale of DRL's generic latanoprostene bunod product prior to the expiration of the '467 patent, including any PTE, is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT VIII

Declaratory Judgment - '467 Patent

72. Paragraphs 1-71 are incorporated herein as set forth above.

ANSWER: DRL restates and incorporates by reference each of its responses to Paragraphs 1-71, as if fully set forth herein.

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

ANSWER: Denied.

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

ANSWER: Denied.

75. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import DRL's generic latanoprostene bunod product before the expiration date of the '467 patent, including DRL's filing of ANDA No. 218414.

ANSWER: Denied.

76. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of DRL's generic latanoprostene bunod product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '467 patent.

ANSWER: Denied.

77. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of DRL's generic latanoprostene bunod product will constitute infringement of at least one claim of the '467 patent.

ANSWER: Denied.

[PLAINTIFFS'] PRAYER FOR RELIEF

DRL denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief, or to any relief whatsoever, and further requests that Plaintiffs' Complaint be dismissed with prejudice and that DRL be awarded its attorney fees and costs incurred in defending this suit under 35 U.S.C. § 285.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted (and, for purposes of clarity, those allegations not specifically admitted are denied), and without undertaking any of the burdens imposed by law on

Plaintiffs, DRL asserts the following defenses to the Complaint:

FIRST DEFENSE

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

SECOND DEFENSE

The proposed manufacture, use, sale, offer for sale, importation, and/or marketing of Dr. DRL's ANDA Product has not infringed, does not infringe, and will not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the Asserted Patents, either literally or under the doctrine of equivalents.

THIRD DEFENSE

DRL has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the Asserted Patents.

FOURTH DEFENSE

DRL has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the Asserted Patents.

FIFTH DEFENSE

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

SIXTH DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendants/Counterclaim-Plaintiffs Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's Ltd.") and Dr. Reddy's Laboratories Inc. ("Dr. Reddy's Inc.") (collectively, "DRL"), for their Counterclaims against Bausch & Lomb Incorporated, Bausch & Lomb Ireland Limited, and Nicox, S.A. (collectively, "Plaintiffs/Counterclaim-Defendants"), allege:

THE PARTIES

1. Dr. Reddy's Laboratories Ltd. is an entity organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India.

2. Dr. Reddy's Laboratories Inc. is an entity organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

3. On information and belief, Plaintiff/Counterclaim-Defendant Bausch & Lomb Incorporated ("B+L") purports and claims to be a corporation organized and existing under the laws of New York with a place of business at 1400 N. Goodman St. Rochester, NY 14609.

4. On information and belief, Plaintiff/Counterclaim-Defendant Bausch & Lomb Ireland Limited ("B+L Ireland") purports and claims to be a company organized and existing under the laws of Ireland, having its registered office at 3013 Lake Drive, Citywest Business Park, Dublin, Ireland.

5. On information and belief, Plaintiff/Counterclaim-Defendant Nicox S.A. ("Nicox") purports and claims to be a company organized and existing under the laws of France, having its registered office at Drakkar 2 – Bât D, 2405 route des Dolines – CS 10313, Sophia Antipolis – 06560 Valbonne, France.

JURISDICTION

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

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

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

FACTUAL BACKGROUND

Patents-In-Suit

9. On or about September 25, 2007, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 7,273,946 ("the '946 patent"), titled "Prostaglandin derivatives," to Eninnio Ongini, Valerio Chiroli, Francesca Benedini, and Piero Del Soldato.

10. On or about December 8, 2009, the PTO issued U.S. Patent No. 7,629,345 ("the '345 patent"), titled "Prostaglandin derivatives," to Eninnio Ongini, Valerio Chiroli, Francesca Benedini, and Piero Del Soldato.

11. On or about March 22, 2011, the PTO issued U.S. Patent No. 7,910,767 ("the '767 patent"), titled "Prostaglandin derivatives," to Eninnio Ongini, Valerio Chiroli, Francesca

Benedini, and Piero Del Soldato.

12. On or about November 15, 2011, the PTO issued U.S. Patent No. 8,058,467 ("the '467 patent"), titled "Prostaglandin derivatives," to Eninnio Ongini, Valerio Chiroli, Francesca Benedini, and Piero Del Soldato.

13. On information and belief, Plaintiffs/Counterclaim-Defendants purport to own, license and/or have the right to enforce the '946 patent, the '345 patent, the '767 patent, and the '467 patent (collectively, the "Patents-In-Suit").

VYZULTA®(Latanoprostene Bunod)

14. On information and belief, Plaintiff/Counterclaim-Defendant B+L purports to be the holder of approved New Drug Application ("NDA") No. 207795 for VYZULTA® (Latanoprostene Bunod) Ophthalmic Solution.

15. On information and belief, Plaintiffs/Counterclaim-Defendants listed, and/or caused to be listed, the Patents-In-Suit in the electronic version of the U.S. Food and Drug Administration's ("FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), in connection with VYZULTA® (Latanoprostene Bunod) Ophthalmic Solution.

16. By listing the Patents-In-Suit in the Orange Book, Plaintiffs/Counterclaim-Defendants maintain that an infringement suit could be asserted against any applicant, including Dr. Reddy's Ltd., that submits Abbreviated New Drug Application ("ANDA") seeking approval for Latanoprostene Bunod Ophthalmic Solution.

DRL's ANDA

17. Dr. Reddy's Ltd., through its authorized U.S. Agent, Dr. Reddy's Inc., submitted an ANDA ("DRL's ANDA") to FDA seeking approval for Latanoprostene Bunod Ophthalmic

Solution, 0.024% ("DRL's ANDA Product").

18. DRL's ANDA contains so-called "Paragraph IV Certifications," under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to the Patents-In-Suit, stating that such patents are invalid, unenforceable and/or not infringed.

19. Dr. Reddy's Ltd. provided timely notice ("DRL's Notice Letter") of DRL's ANDA and Paragraph IV Certifications to Plaintiffs/Counterclaim-Defendants.

20. DRL's Notice Letter included an offer of confidential access to DRL's ANDA.

21. In response to DRL's Notice Letter, Plaintiffs/Counterclaim-Defendants filed suit against DRL alleging infringement of the Patents-In-Suit.

COUNT I

(Declaratory Judgment of Non-Infringement of the '946 Patent)

22. DRL realleges and incorporates by reference the allegations of paragraphs 1-21 as though fully set forth herein.

23. A present, genuine, and justiciable controversy exists between DRL and Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of DRL's ANDA Product would infringe any valid or enforceable claim of the '946 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

24. The manufacture, use, offer for sale, sale, importation, and/or marketing of DRL's ANDA Product would not infringe any valid or enforceable claim of the '946 patent, either directly or indirectly.

25. DRL is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of DRL's ANDA Product would not infringe, directly or

indirectly, any valid or enforceable claim of the '946 patent, either literally or under the doctrine of equivalents.

COUNT II

(Declaratory Judgment of Invalidity of the '946 Patent)

26. DRL realleges and incorporates by reference the allegations of paragraphs 1-25 as though fully set forth herein.

27. A present, genuine, and justiciable controversy exists between DRL and Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, the invalidity of the '946 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

28. The '946 patent is invalid for failure to comply with one or more of the requirements in 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for obviousness-type double patenting.

29. DRL is entitled to a judicial declaration that the '946 patent is invalid for failure to comply with one or more of the requirements in 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for obviousness-type double patenting.

COUNT III

(Declaratory Judgment of Non-Infringement of the '345 Patent)

30. DRL realleges and incorporates by reference the allegations of paragraphs 1-29 as though fully set forth herein.

31. A present, genuine, and justiciable controversy exists between DRL and Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of DRL's ANDA Product would infringe any valid or enforceable claim of the '345 patent, either directly or indirectly, that is of sufficient immediacy

and reality to warrant the issuance of a Declaratory Judgment.

32. The manufacture, use, offer for sale, sale, importation, and/or marketing of DRL's ANDA Product would not infringe any valid or enforceable claim of the '345 patent, either directly or indirectly.

33. DRL is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of DRL's ANDA Product would not infringe, directly or indirectly, any valid or enforceable claim of the '345 patent, either literally or under the doctrine of equivalents.

COUNT IV

(Declaratory Judgment of Invalidity of the '345 Patent)

34. DRL realleges and incorporates by reference the allegations of paragraphs 1-33 as though fully set forth herein.

35. A present, genuine, and justiciable controversy exists between DRL and Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, the invalidity of the '345 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

36. The '345 patent is invalid for failure to comply with one or more of the requirements in 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for obviousness-type double patenting.

37. DRL is entitled to a judicial declaration that the '345 patent is invalid for failure to comply with one or more of the requirements in 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for obviousness-type double patenting.

COUNT V

(Declaratory Judgment of Non-Infringement of the '767 Patent)

38. DRL realleges and incorporates by reference the allegations of paragraphs 1-37 as though fully set forth herein.

39. A present, genuine, and justiciable controversy exists between DRL and Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of DRL's ANDA Product would infringe any valid or enforceable claim of the '767 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

40. The manufacture, use, offer for sale, sale, importation, and/or marketing of DRL's ANDA Product would not infringe any valid or enforceable claim of the '767 patent, either directly or indirectly.

41. DRL is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of DRL's ANDA Product would not infringe, directly or indirectly, any valid or enforceable claim of the '767 patent, either literally or under the doctrine of equivalents.

COUNT VI

(Declaratory Judgment of Invalidity of the '767 Patent)

42. DRL realleges and incorporates by reference the allegations of paragraphs 1-41 as though fully set forth herein.

43. A present, genuine, and justiciable controversy exists between DRL and Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, the invalidity of the '767 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

44. The ’767 patent is invalid for failure to comply with one or more of the requirements in 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for obviousness-type double patenting.

45. DRL is entitled to a judicial declaration that the ’767 patent is invalid for failure to comply with one or more of the requirements in 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for obviousness-type double patenting.

COUNT VII

(Declaratory Judgment of Non-Infringement of the ’467 Patent)

46. DRL realleges and incorporates by reference the allegations of paragraphs 1-45 as though fully set forth herein.

47. A present, genuine, and justiciable controversy exists between DRL and Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of DRL’s ANDA Product would infringe any valid or enforceable claim of the ’467 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

48. The manufacture, use, offer for sale, sale, importation, and/or marketing of DRL’s ANDA Product would not infringe any valid or enforceable claim of the ’467 patent, either directly or indirectly.

49. DRL is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of DRL’s ANDA Product would not infringe, directly or indirectly, any valid or enforceable claim of the ’467 patent, either literally or under the doctrine of equivalents.

COUNT VIII

(Declaratory Judgment of Invalidity of the '467 Patent)

50. DRL realleges and incorporates by reference the allegations of paragraphs 1-49 as though fully set forth herein.

51. A present, genuine, and justiciable controversy exists between DRL and Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, the invalidity of the '467 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

52. The '467 patent is invalid for failure to comply with one or more of the requirements in 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for obviousness-type double patenting.

53. DRL is entitled to a judicial declaration that the '467 patent is invalid for failure to comply with one or more of the requirements in 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for obviousness-type double patenting.

PRAYER FOR RELIEF

WHEREFORE, DRL respectfully prays for judgment in its favor and against Plaintiffs/Counterclaim-Defendants:

(a) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's ANDA Product has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the Patents-In-Suit, either literally or under the doctrine of equivalents;

(b) Declaring that the claims of the Patents-In-Suit are invalid;

(c) Ordering that Plaintiffs'/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of DRL;

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

(e) Awarding DRL such other and further relief as the Court may deem just and proper

Dated: November 1, 2023

Respectfully submitted,

/s/ Rebekah Conroy

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DR. REDDY'S LABORATORIES LTD. and
DR. REDDY'S LABORATORIES INC.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, Defendants/Counterclaim-Plaintiffs Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc., by their undersigned counsel, hereby certify that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding, but it appears, at the time of this certification, that the Patents-in-Suit in this matter are also the subject of the following action:

- *Bausch and Lomb Incorporated et al. v. Gland Pharma Limited*, C.A. No. 22-4345 (D.N.J.)

Dated: November 1, 2023

Respectfully submitted,

/s/ Rebekah Conroy

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Attorneys for Defendants,
DR. REDDY'S LABORATORIES LTD. and
DR. REDDY'S LABORATORIES INC.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendants/Counterclaim Plaintiffs Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc., by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: November 1, 2023

Respectfully submitted,

/s/ Rebekah Conroy

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