William P. Deni, Jr.
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
(973) 596-4500

Attorneys for Plaintiffs
Bausch & Lomb Incorporated,
Bausch & Lomb Ireland Limited,
and Nicox S.A.

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. 23-3463 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch & Lomb Incorporated, Bausch & Lomb Ireland Limited, and Nicox, S.A. (collectively, "Plaintiffs") by way of Complaint against Defendants Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc. (collectively, "Defendants" or "DRL") allege as follows:

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.

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.

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

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.

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.

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.

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.

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.

JURISDICTION AND VENUE

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

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.

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.

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

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."

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.

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.

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).

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.

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

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

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

THE PATENTS-IN-SUIT

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

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.

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.

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.

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.

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.

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.

DRL'S INFRINGING 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).

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®.

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.

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®.

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.

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®.

COUNT I FOR PATENT INFRINGEMENT

Infringement of the '946 Patent Under § 271(e)(2)

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

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.

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.

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.

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.

COUNT II FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '946 Patent

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

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

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.

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.

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.

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.

COUNT III FOR PATENT INFRINGEMENT

Infringement of the ’345 Patent Under § 271(e)(2)

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

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.

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.

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.

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.

COUNT IV FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’345 Patent

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

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

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.

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.

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.

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.

COUNT V FOR PATENT INFRINGEMENT

Infringement of the ’767 Patent Under § 271(e)(2)

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

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.

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.

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.

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.

COUNT VI FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '767 Patent

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

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

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.

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.

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.

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.

COUNT VII FOR PATENT INFRINGEMENT

Infringement of the '467 Patent Under § 271(e)(2)

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

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.

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.

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.

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.

COUNT VIII FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '467 Patent

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

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

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.

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.

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.

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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against Defendants on the patent infringement claims set forth above and respectfully request that this Court:

1. Enter judgment that, 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 ANDA No. 218414 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of DRL’s generic latanoprostene bunod product before the expiration of the ’946 patent, including any PTE;

2. Enter judgment that, 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 ANDA No. 218414 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of DRL’s generic latanoprostene bunod product before the expiration of the ’345 patent, including any PTE;

3. Enter judgment that, 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 ANDA No. 218414 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of DRL’s generic latanoprostene bunod product before the expiration of the ’767 patent;

4. Enter judgment that, 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 ANDA No. 218414 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale

in the United States of DRL's generic latanoprostene bunod product before the expiration of the '467 patent, including any PTE;

5. Order that the effective date of any approval by the FDA of DRL's generic latanoprostene bunod product be a date that is not earlier than the expiration of the Asserted Patents, including any PTE, or such later date as the Court may determine;

6. Enjoin Defendants from the commercial manufacture, use, import, offer for sale, and/or sale of DRL's generic latanoprostene bunod product until expiration of the Asserted Patents, including any PTE, or such later date as the Court may determine;

7. Enjoin Defendants and all persons acting in concert with DRL from seeking, obtaining, or maintaining approval of DRL's ANDA No. 218414 until expiration of the Asserted Patents, including any PTE;

8. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees; and

9. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: June 27, 2023
Newark, New Jersey

s/ William P. Deni, Jr.
William P. Deni, Jr.
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
(973) 596-4500
wdeni@gibbonslaw.com
jlower@gibbonslaw.com

Bryan C. Diner
Justin J. Hasford
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Attorneys for Plaintiffs Bausch & Lomb Incorporated, Bausch & Lomb Ireland Limited, and Nicox S.A.