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*Bausch & Lomb Incorporated,*
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*and Nicox S.A.*

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| BAUSCH & LOMB INCORPORATED; BAUSCH & LOMB IRELAND LIMITED; and NICOX S.A.,<br><br>Plaintiffs,<br><br>v.<br><br>GLAND PHARMA LIMITED,<br><br>Defendant. | Civil Action No. 22-4345<br><br>*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 Defendant Gland Pharma Limited ("Defendant" or "Gland") 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 Gland'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% ("Gland's generic latanoprostene bunod product") prior to the expiration of the Asserted Patents.

**THE PARTIES**

2. Plaintiff Bausch & Lomb Incoporated ("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, Gland is a company organized under the laws of India, having a place of business at Survey No. 143-148, 150 & 151 Near Gandimaisamma 'X' Roads D.P. Pally, Dundigal Gandimaisamma Mandal Medchal-Malkjgiri District, Hyderabad 500043, Telangana, India.

## JURISDICTION AND VENUE

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

9. Upon information and belief, this court has jurisdiction over Gland. Upon information and belief, Gland is in the business of, inter alia, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, Gland 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 Gland's generic latanoprostene bunod product. Upon information and belief, Gland purposefully has conducted and continues to conduct business in this judicial district.

10. Gland 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. Gland's ANDA filing constitutes formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Gland 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, Gland will engage in marketing, sale, and offer for sale of its generic latanoprostene bunod product in New Jersey upon approval of its ANDA.

11. Upon information and belief, Gland has designated its outside counsel, Andrew J. Miller, Esq. at Windels Marx Lane & Mittendorf, LLP at 1 Giralda Farms, Suite 100, Madison, NJ 07940, as an agent in the United States authorized to accept service of process for Gland, with respect to Gland's ANDA seeking FDA approval for its generic latanoprostene bunod product.

12. Upon information and belief, Gland 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: *Fresenius Kabi Deutschland GmbH et al v. Gland Pharma Limited*, No. 3:20-cv-12347 (D.N.J.) (Sept. 4, 2020); *Merck Sharp & Dohme B.V. et al v. Gland Pharma Limited*, No. 2:20-cv-02750 (D.N.J.) (Mar. 12, 2020); *Chiesi USA Inc. et al v. Gland Pharma Limited*, No. 2:19-cv-18565 (D.N.J.) (Sept. 30, 2019); *Medicure Int'l, Inc. v. Gland Pharma Limited*, No. 2:18-cv-16246 (D.N.J.) (Nov. 16, 2018).

13. Gland 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.

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

15. Venue is proper against Gland, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

## THE PATENTS-IN-SUIT

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

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

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

## GLAND'S INFRINGING ANDA SUBMISSION

23. Upon information and belief, Gland filed or caused to be filed with the FDA ANDA No. 217387, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

24. Upon information and belief, Gland's ANDA No. 217387 seeks FDA approval to engage in commercial manufacture, use, and sale in the United States of Gland's generic latanoprostene bunod product, intended to be a generic version of Vyzulta®.

25. On or about May 19, 2022, Plaintiffs received a letter from Gland dated August May 17, 2022, purporting to be a Notice of Paragraph IV Certification regarding ANDA No. 217387 ("Gland's Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. Gland's Notice Letter was addressed to B+L and Nicox.

26. Gland's Notice Letter alleges that Gland has submitted to the FDA ANDA No. 217387 seeking approval to engage in the commercial manufacture, use and/or sale of Gland's generic latanoprostene bunod product, intended to be generic versions of Vyzulta®.

27. Gland's Notice Letter states that Gland's ANDA No. 217387 contains "any required bioavailability or bioequivalence data or information with respect to latanoprostene bunod ophthalmic solution, 0.024%," for Gland's generic latanoprostene bunod product.

28. Upon information and belief, ANDA No. 217387 seeks approval of Gland'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)

29. Paragraphs 1-28 are incorporated herein as set forth above.

30. Under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the '946 patent by submitting, or causing to be submitted to the FDA, ANDA No. 217387 seeking approval for the commercial marketing of Gland's generic latanoprostene bunod product before the expiration date of the '946 patent.

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

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

33. If Defendant's marketing and sale of Gland'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

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

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

36. 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.

37. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's generic latanoprostene

bunod product before the expiration date of the ’946 patent, including Gland’s filing of ANDA No. 217387.

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

39. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Gland’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)**

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

41. Under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the ’345 patent by submitting, or causing to be submitted to the FDA, ANDA No. 217387 seeking approval for the commercial marketing of Gland’s generic latanoprostene bunod product before the expiration date of the ’345 patent.

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

43. Upon information and belief, Defendant will, through the manufacture, use, import, offer for sale, and/or sale of Gland’s generic latanoprostene bunod product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’345 patent.

44. If Defendant’s marketing and sale of Gland’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

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

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

47. 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.

48. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland’s generic latanoprostene bunod product before the expiration date of the ’345 patent, including Gland’s filing of ANDA No. 217387.

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

50. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Gland’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)

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

52. Under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the ’767 patent by submitting, or causing to be submitted to the FDA, ANDA No. 217387 seeking approval

for the commercial marketing of Gland's generic latanoprostene bunod product before the expiration date of the '767 patent.

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

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

55. If Defendant's marketing and sale of Gland'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**

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

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

58. 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.

59. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's generic latanoprostene bunod product before the expiration date of the '767 patent, including Gland's filing of ANDA No. 217387.

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

61. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Gland'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)**

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

63. Under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the '467 patent by submitting, or causing to be submitted to the FDA, ANDA No. 217387 seeking approval for the commercial marketing of Gland's generic latanoprostene bunod product before the expiration date of the '467 patent.

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

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

66. If Defendant's marketing and sale of Gland'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**

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

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

69. 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.

70. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's generic latanoprostene bunod product before the expiration date of the '467 patent, including Gland's filing of ANDA No. 217387.

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

72. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Gland'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 Defendant 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), Defendant has infringed at least one claim of the ’946 patent by submitting or causing to be submitted ANDA No. 217387 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland’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), Defendant has infringed at least one claim of the ’345 patent by submitting or causing to be submitted ANDA No. 217387 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland’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), Defendant has infringed at least one claim of the ’767 patent by submitting or causing to be submitted ANDA No. 217387 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland’s generic latanoprostene bunod product before the expiration of the ’767 patent;

4. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendant has infringed at least one claim of the ’467 patent by submitting or causing to be submitted ANDA No. 217387 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in

the United States of Gland'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 Gland'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 Defendant from the commercial manufacture, use, import, offer for sale, and/or sale of Gland'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 Defendant and all persons acting in concert with Gland from seeking, obtaining, or maintaining approval of Gland's ANDA No. 217387 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 30, 2022
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.
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**CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)**

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: June 30, 2022
Newark, New Jersey

s/ William P. Deni, Jr.
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