IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENZYME CORPORATION and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. GLAND PHARMA LIMITED, Defendant.	)	C.A. No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Genzyme Corporation ("Genzyme") and sanofi-aventis U.S. LLC ("Sanofi"), by their attorneys, for their complaint against Gland Pharma Limited ("Gland") hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent Nos. RE42,152 ("the '152 patent"), 7,897,590 ("the '590 patent"), and 6,987,102 ("the '102 patent") arising under the Patent Laws of the United States, Title 35, United States Code, Sections 100 *et seq*.

2. This action relates to the following Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA"): ANDA No. 206644 filed by Gland for approval to engage in the marketing, commercial manufacture, use, or sale of Plerixafor Injection, 24 mg /1.2mL, a proposed generic version of Genzyme's Mozobil® drug product ("Gland's ANDA product").

THE PARTIES

3. Plaintiff Genzyme is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, having its principal place of business at 50 Binney Street, Cambridge, Massachusetts 02142.

4. Plaintiff Sanofi is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

5. On information and belief, Gland is a corporation organized and existing under the laws of India having a principal place of business at Survey No: 143-148, 150 & 151, Near Gandimaisamma Cross Roads, D.P.Pally, Dundigal Post, Dundigal - Gandimaisamma Mandal, Medchal - Malkajgiri District, Hyderabad, Telangana 500 043, India.

6. On information and belief, Gland is in the business of, inter alia: (a) the development and manufacture of generic pharmaceutical products for sale and distribution throughout the world, including throughout the United States and, more specifically, throughout the State of Delaware; (b) the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (c) the distribution of generic pharmaceutical products for sale and use throughout the United States, including throughout the State of Delaware.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. On information and belief, this Court has personal jurisdiction over Gland pursuant to 10 Del. C. § 3104. Specifically, Gland's filing of ANDA No. 206644 has caused

tortious injury in Delaware, namely from the tort of patent infringement under 35 U.S.C. § 271(e)(2), and Gland intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in this District. For example, on information and belief, following approval of ANDA No. 206644, Gland will make, use, sell, offer for sale, and/or import its generic product at issue in this suit in/into the United States, including the State of Delaware, a product that infringes at least some claims of the '152 patent, the '590 patent, and the '102 patent. Moreover, Plaintiff Sanofi is a Delaware limited liability company, and so not only are the injuries and consequences suffered in Delaware, but Gland has purposefully directed its activities towards a Delaware entity. Because defending against a patent infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Gland reasonably anticipates being sued in Delaware. Further, Gland maintains substantial, systematic, and continuous contacts with the State of Delaware as it regularly does or solicits business in Delaware and this District through its marketing and distribution of generic products. Gland has engaged and continues to engage in a persistent course of conduct in Delaware and this District, and derives substantial revenue from things used or consumed in Delaware and this District.

9. On information and belief, this Court has personal jurisdiction over Gland because, *inter alia*: (a) Gland prepared, filed, and submitted ANDA No. 206644 for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Gland's ANDA Product throughout the United States, including in Delaware; (b) upon any approval of ANDA No. 206644, Gland will market, distribute, offer for sale, and/or sell Gland's ANDA Product throughout the United States, including Delaware, and will derive substantial revenue from the use or sale of Gland's ANDA Product in Delaware; (c) upon any

approval of ANDA No. 206644, Gland's ANDA Product would be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware; and (d) the resolution of this action will directly affect when ANDA No. 206644 can be approved to allow the marketing of Gland's ANDA Product in or directed at Delaware, and when such marketing can lawfully take place.

10. This Court also has personal jurisdiction over Gland because, *inter alia*: (a) Gland has purposefully directed its activities at corporate entities and residents within the State of Delaware; (b) the claims set forth herein arise out of or relate to those activities; (c) Gland's contacts with the State of Delaware are continuous and systematic; and (d) it is reasonable and fair for this Court to exercise personal jurisdiction over Gland.

11. Venue is proper in this judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS AND ACTS GIVING RISE TO THIS ACTION

12. Genzyme is the holder of New Drug Application ("NDA") No. 022311, which relates to plerixafor solution 20 mg/mL for subcutaneous injection (the "Mozobil® NDA"). On December 15, 2008, the FDA approved the marketing of the drug product described in NDA No. 022311 for use in combination with granulocyte-colony stimulating factor ("G-CSF") to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma and multiple myeloma (the "Approved Indication"). This drug product is prescribed and sold in the United States using the trademark Mozobil®. Usage of this drug product and the Approved Indication are described in the Mozobil® Prescribing Information (a true and accurate copy of which is attached hereto as Exhibit A). Genzyme and Sanofi both share in the profits from the sale of Mozobil®.

13. The ’152 patent (a true and accurate copy of which is attached hereto as Exhibit B) was duly and legally issued on February 15, 2011 to inventors Gary J. Bridger, Sreenivasan Padmanabhan, Renato Skerlj, and David M. Thornton. With patent term extension, the ’152 patent will expire on December 10, 2018. At all times from the issuance of the ’152 patent to the present, Genzyme has been the owner of the ’152 patent. Sanofi is Genzyme’s exclusive licensee under the ’152 patent.

14. The ’590 patent (a true and accurate copy of which is attached hereto as Exhibit C) was duly and legally issued on March 1, 2011 to inventors Gary J. Bridger, Michael J. Abrams, Geoffrey W. Henson, Ronald Trevor MacFarland, Gary B. Calandra, Hal E. Broxmeyer, and David C. Dale. With patent term adjustment, the ’590 patent will expire on July 22, 2023. At all times from the issuance of the ’590 patent to the present, Genzyme has been the owner of the ’590 patent. Sanofi is Genzyme’s exclusive licensee under the ’590 patent.

15. The ’102 patent (a true and accurate copy of which is attached hereto as Exhibit D) was duly and legally issued on January 17, 2006 to inventors Gary J. Bridger, Michael J. Abrams, Geoffrey W. Henson, Ronald Trevor MacFarland, Gary B. Calandra, Hal E. Broxmeyer, and David C. Dale. The ’102 patent was assigned to AnorMed, Inc., which then assigned the ’102 patent to Genzyme in 2008. With patent term adjustment, the ’102 patent will expire on July 22, 2023. Since 2008, Genzyme has been the owner of the ’102 patent. Sanofi is Genzyme’s exclusive licensee under the ’102 patent.

16. The ’152 patent, the ’590 patent, and the ’102 patent cover the use of Mozobil® according to its Approved Indication.

17. By letter dated June 6, 2018, purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B) (“Notice Letter”), Gland notified Genzyme that Gland had amended ANDA No.

206644 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) to seek approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product as a generic version of Genzyme's Mozobil® drug product prior to the expiration of the '152, '590, and '102 patents.

18. In addition to the information provided to Plaintiffs in the Notice Letter, counsel for Plaintiffs reviewed the portions of ANDA No. 206644 voluntarily provided by Gland under terms of a confidentiality agreement.

19. On information and belief, the active ingredient of Gland's ANDA Product is plerixafor, which is the same active ingredient in Mozobil® and the same active ingredient used in the claims of the '152 patent, the '590 patent, and 'the 102 patent, including, but not limited to Claim 37 of the '152 patent, Claims 8 and 19 of the '590 patent, and Claim 8 of the '102 patent.

20. On information and belief, Gland stated in its ANDA No. 206644 that Gland's ANDA Product is bioequivalent to Genzyme's Mozobil® drug product. On information and belief, Gland's ANDA No. 206644 refers to and relies upon the Mozobil® NDA and contains statements that, according to Gland, Gland's ANDA Product is a bioequivalent of Mozobil®.

21. On information and belief, Gland is seeking approval to market Gland's ANDA Product for the same Approved Indication as Genzyme's Mozobil® drug product.

22. On information and belief, Gland will knowingly accompany Gland's ANDA Product with prescribing information that is substantially similar to the Mozobil® Prescribing Information.

23. On information and belief, Gland's prescribing information for Gland's ANDA Product will instruct users to administer Gland's ANDA Product to human patients to mobilize

hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation.

24. On information and belief, Gland's prescribing information for Gland's ANDA Product will instruct users to administer Gland's ANDA Product to human patients after the patients have received granulocyte-colony stimulating factor (G-CSF).

25. On information and belief, Gland has knowledge and/or an expectation that Gland's ANDA Product will be used in accordance with its prescribing information.

26. On information and belief, Gland knows that the prescribing information for Gland's ANDA Product will induce and/or contribute to others using Gland's ANDA Product in the manner set forth in the prescribing information.

27. On information and belief, physicians, health care providers, and/or patients will directly infringe one or more claims of the '152 patent, the '590 patent, and/or the '102 patent, including, but not limited to, Claim 37 of the '152 patent, Claims 8 and 19 of the '590 patent, and Claim 8 of the '102 patent, by using Gland's ANDA Product in accordance with the prescribing information provided by Gland upon FDA approval of ANDA No. 206644.

28. On information and belief, Gland specifically intends that physicians, health care providers, and/or patients will use Gland's ANDA Product in accordance with the prescribing information provided by Gland to directly infringe one or more claims of the '152 patent, the '590 patent, and/or the '102 patent, including, but not limited to, Claim 37 of the '152 patent, Claims 8 and 19 of the '590 patent, and Claim 1 of the '102 patent.

29. On information and belief, Gland designed Gland's ANDA Product for use in a way that would infringe the '152 patent, the '590 patent, and the '102 patent and will instruct users of Gland's ANDA Product to use the Gland's ANDA Product in a way that would infringe

one or more claims of the ’152 patent, the ’590 patent, and/or the ’102 patent, including, but not limited to, Claim 37 of the ’152 patent, Claims 8 and 19 of the ’590 patent, and Claim 8 of the ’102 patent.

30. On information and belief, Gland’s ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

31. On information and belief, Gland knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using Gland’s ANDA Product in a manner that directly infringes one or more claims of the ’152 patent, ’590 patent, and the ’102 patent, including but not limited to by providing instructions for administering Gland’s ANDA Product as claimed in one or more claims of the ’152, the ’590 patent, and the ’102 patent, including, but not limited to, Claim 37 of the ’152 patent, Claims 8 and 19 of the ’590 patent, and Claim 8 of the ’102 patent.

32. Gland has knowledge of the ’152 patent, the ’590 patent, and the ’102 patent.

33. Gland amended its ANDA to obtain FDA approval to engage in the commercial manufacture, importation, use, and sale of the Gland ANDA Product prior to the expiration of the ’152 patent, the ’590 patent, and the ’102 patent, each of which is listed in the FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluation” (the “Orange Book”) as being applicable to Genzyme’s Mozobil® drug product.

34. On information and belief, Gland intends to engage in the commercial manufacture, importation, use, sale, and/or offering for sale of Gland’s ANDA Product in/into the United States and/or induce or contribute to such acts promptly upon receiving FDA approval to do so and during the terms of the ’152 patent, the ’590 patent, and the ’102 patent.

35. In the Notice Letter, Gland notified Genzyme that ANDA No. 206644 had been amended to include Paragraph IV certifications to the '152 patent, the '590 patent, and the '102 patent based on Gland's contention that the '152 patent, the '590 patent, and the '102 patent are invalid or will not be infringed by the manufacture, use, sale, offer to sell, or importation of Gland's ANDA Product in/into the United States.

36. On information and belief, Gland is aware of the Federal Circuit's affirmance of a previous decision from this District finding Claim 19 of the '590 patent not invalid. *Genzyme Corp. v. Dr. Reddy's Labs., Ltd*., 716 F. App'x 1006 (Fed. Cir. Dec. 18, 2017) affirming *Genzyme Corp. v. Dr. Reddy's Labs., Ltd*., 13-cv-1506-GMS, 2016 WL 2757689 (D. Del. May 11, 2016).

37. On information and belief, Gland is aware that a second trial involving a challenge to the validity of the'590 patent has also already taken place in this District in Case No. 1:16-CV-0540-KAJ. On information and belief, the bases for Gland's opinion that the '590 patent and the '102 patent are invalid, as set forth in Gland's Notice Letter, are substantially similar to those presented in Case No. 1:16-CV-0540-KAJ.

38. Plaintiffs commenced this action within 45 days of receiving the Notice Letter.

COUNT I
INFRINGEMENT BY GLAND OF U.S. PATENT NO. RE42,152

39. Plaintiffs repeat and reallege the allegations of paragraphs 1-38 as if fully set forth herein.

40. Gland's submission of ANDA No. 206644 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of Gland's ANDA Product in/into the United States prior to the expiration of the '152 patent constitutes infringement of one

or more of the claims of the ’152 patent, including but not limited to Claim 37, under 35 U.S.C. § 271(e)(2).

41. Upon FDA approval of ANDA No. 206644, Gland’s commercial manufacture, importation, use, offer to sell, or sale of Gland’s ANDA Product in/into the United States prior to the expiration of the ’152 patent will infringe one or more claims of the ’152 patent, including but not limited to Claim 37, under 35 U.S.C. §§ 271(a), (b), and/or (c), unless enjoined by the Court.

42. Gland’s filing of ANDA No. 206644 and Gland’s intent to engage in the commercial manufacture, importation, use, sale, or offer for sale of Gland’s ANDA Product in/into the United States upon receiving FDA approval and prior to the expiration of the ’152 patent create an actual case or controversy with respect to infringement of one or more claims of the ’152 patent, including but not limited to Claim 37.

43. Upon FDA approval of ANDA No. 206644, use of Gland’s ANDA Product in accordance with the prescribing information to be provided by Gland will directly infringe one or more claims of the ’152 patent, including but not limited to Claim 37, under 35 U.S.C. § 271(a), unless enjoined by this Court.

44. Upon FDA approval of ANDA No. 206644, Gland will infringe one or more claims of the ’152 patent, including but not limited to Claim 37, under 35 U.S.C. § 271(b) and (c) by actively inducing and contributing to infringement by others, unless enjoined by this Court.

45. Gland has knowledge of the ’152 patent and, by the prescribing information Gland will include with Gland’s ANDA Product, Gland knows or should know that it will aid

and abet another's direct infringement of at least one of the claims of the '152 patent, including but not limited to Claim 37.

46. Gland's offering for sale, sale, and/or importation of Gland's ANDA Product in/into the United States with the prescribing information for Gland's ANDA Product will actively induce infringement of at least one of the claims of the '152 patent, including but not limited to Claim 37, under 35 U.S.C. § 271(b).

47. Use of Gland's ANDA Product constitutes a material part of at least one of the claims of the '152 patent; Gland knows that Gland's ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '152 patent, including but not limited to Claim 37; and Gland knows that Gland's ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

48. Gland's manufacture, use, offering for sale, sale, and/or importation of Gland's ANDA Product in/into the United States will contributorily infringe at least one of the claims of the '152 patent, including but not limited to Claim 37, under 35 U.S.C. § 271(c).

49. Gland had and will have notice of the '152 patent at the time of its infringement. Gland's infringement has been, continues to be, and will be deliberate and willful.

50. Plaintiffs will be substantially and irreparably harmed if Gland's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

51. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

COUNT II
INFRINGEMENT BY GLAND OF U.S. PATENT NO. 7,897,590

52. Plaintiffs repeat and reallege the allegations of paragraphs 1-51 as if fully set forth herein.

53. Gland's submission of ANDA 206644 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of Gland's ANDA Product in/into the United States prior to the expiration of the '590 patent constitutes infringement of one or more of the claims of the '590 patent, including but not limited to Claims 8 and 19, under 35 U.S.C. § 271(e)(2).

54. Upon FDA approval of ANDA No. 206644, Gland's commercial manufacture, importation, use, offer to sell, or sale of Gland's ANDA Product in/into the United States prior to the expiration of the '590 patent will infringe one or more claims of the '590 patent, including but not limited to Claims 8 and 19, under 35 U.S.C. §§ 271(a), (b), and/or (c), unless enjoined by the Court.

55. Gland's filing of ANDA No. 206644 and Gland's intent to engage in the commercial manufacture, importation, use, sale, or offer for sale of Gland's ANDA Product in/into the United States upon receiving FDA approval and prior to the expiration of the '590 patent create an actual case or controversy with respect to infringement of one or more claims of the '590 patent, including but not limited to Claims 8 and 19.

56. Upon FDA approval of ANDA No. 206644, use of Gland's ANDA Product in accordance with the prescribing information to be provided by Gland will directly infringe one or more claims of the '590 patent, including but not limited to Claims 8 and 19, under 35 U.S.C. § 271(a), unless enjoined by this Court.

57. Upon FDA approval of ANDA No. 206644, Gland will infringe one or more claims of the '590 patent, including but not limited to Claims 8 and 19, under 35 U.S.C. § 271(b) and (c) by actively inducing and contributing to infringement by others, unless enjoined by this Court.

58. Gland has knowledge of the ’590 patent and, by the prescribing information Gland will include with Gland’s ANDA Product, Gland knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’590 patent, including but not limited to Claims 8 and 19.

59. Gland’s offering for sale, sale, and/or importation of Gland’s ANDA Product in/into the United States with the prescribing information for Gland’s ANDA Product will actively induce infringement of at least one of the claims of the ’590 patent, including but not limited to Claims 8 and 19, under 35 U.S.C. § 271(b).

60. Use of Gland’s ANDA Product constitutes a material part of at least one of the claims of the ’590 patent; Gland knows that Gland’s ANDA Product is especially made or adapted for use in infringing at least one of the claims of the ’590 patent, including but not limited to Claims 8 and 19; and Gland knows that Gland’s ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

61. Gland’s manufacture, use, offering for sale, sale, and/or importation of Gland’s ANDA Product in/into the United States will contributorily infringe at least one of the claims of the ’590 patent, including but not limited to Claims 8 and 19, under 35 U.S.C. § 271(c).

62. Gland had and will have notice of the ’590 patent at the time of its infringement. Gland also has notice of the decision by this Court in 1:13-CV-1506-GMS and affirmed by the Federal Circuit, holding that Claim 19 of the ’590 patent is not invalid. Gland also has notice that this Court is already considering in 1:16-CV-540-KAJ the same invalidity arguments that Gland made in its Notice Letter with respect to Claims 8 and 19 of the ’590 patent. Gland’s infringement has been, continues to be, and will be deliberate and willful.

63. Plaintiffs will be substantially and irreparably harmed if Gland's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

64. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

COUNT III
INFRINGEMENT BY GLAND OF U.S. PATENT NO. 6,897,102

65. Plaintiffs repeat and reallege the allegations of paragraphs 1-64 as if fully set forth herein.

66. Gland's submission of ANDA 206644 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of Gland's ANDA Product in/into the United States prior to the expiration of the '102 patent constitutes infringement of one or more of the claims of the '102 patent, including but not limited to Claim 8, under 35 U.S.C. § 271(e)(2).

67. Upon FDA approval of ANDA No. 206644, Gland's commercial manufacture, importation, use, offer to sell, or sale of Gland's ANDA Product in/into the United States prior to the expiration of the '102 patent will infringe one or more claims of the '102 patent, including but not limited to Claim 8, under 35 U.S.C. §§ 271(a), (b), and/or (c), unless enjoined by the Court.

68. Gland's filing of ANDA No. 206644 and Gland's intent to engage in the commercial manufacture, importation, use, sale, or offer for sale of Gland's ANDA Product in/into the United States upon receiving FDA approval and prior to the expiration of the '102 patent create an actual case or controversy with respect to infringement of one or more claims of the '102 patent, including but not limited to Claim 8.

69. Upon FDA approval of ANDA No. 206644, use of Gland's ANDA Product in accordance with the prescribing information to be provided by Gland will directly infringe one or

more claims of the ’102 patent, including but not limited to Claim 8, under 35 U.S.C. § 271(a), unless enjoined by this Court.

70. Upon FDA approval of ANDA No. 206644, Gland will infringe one or more claims of the ’102 patent, including but not limited to Claim 8, under 35 U.S.C. § 271(b) and (c) by actively inducing and contributing to infringement by others, unless enjoined by this Court.

71. Gland has knowledge of the ’102 patent and, by the prescribing information Gland will include with Gland’s ANDA Product, Gland knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’102 patent, including but not limited to Claim 8.

72. Gland’s offering for sale, sale, and/or importation of Gland’s ANDA Product in/into the United States with the prescribing information for Gland’s ANDA Product will actively induce infringement of at least one of the claims of the ’102 patent, including but not limited to Claim 8, under 35 U.S.C. § 271(b).

73. Use of Gland’s ANDA Product constitutes a material part of at least one of the claims of the ’102 patent; Gland knows that Gland’s ANDA Product is especially made or adapted for use in infringing at least one of the claims of the ’102 patent, including but not limited to Claim 8; and Gland knows that Gland’s ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

74. Gland’s manufacture, use, offering for sale, sale, and/or importation of Gland’s ANDA Product in/into the United States will contributorily infringe at least one of the claims of the ’102 patent, including but not limited to Claim 8, under 35 U.S.C. § 271(c).

75. Gland had and will have notice of the ’102 patent at the time of its infringement. Gland also has notice of the decision by this Court in 1:13-CV-1506-GMS and affirmed by the

Federal Circuit, holding that Claim 19 of the '590 patent is not invalid. Gland also has notice that this Court is already considering in 1:16-CV-540-KAJ the same invalidity arguments that Gland made in its Notice Letter with respect to Claim 8 of the '102 patent. Gland's infringement has been, continues to be, and will be deliberate and willful.

76. Plaintiffs will be substantially and irreparably harmed if Gland's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

77. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that Gland has infringed, and that Gland's making, using, selling, offering to sell, or importing of Gland's ANDA Product in/into the United States will infringe one or more claims of the '152 patent;

(b) A judgment declaring that Gland has infringed, and that Gland's making, using, selling, offering to sell, or importing of Gland's ANDA Product in/into the United States will infringe one or more claims of the '590 patent;

(c) A judgment declaring that Gland has infringed, and that Gland's making, using, selling, offering to sell, or importing of Gland's ANDA Product in/into the United States will infringe one or more claims of the '102 patent;

(d) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Gland's ANDA No. 206644 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date no earlier than July 22, 2023, the date on which the '590 patent and the '102 patent expire, or the expiration

of any other exclusivity to which Plaintiffs become entitled;

(e) Injunctive relief under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Gland from making, using, selling, offering to sell, or importing Gland's ANDA Product in/into the United States until after July 22, 2023, the date on which the '590 patent and the '102 patent expire, or the expiration of any other exclusivity to which Plaintiffs become entitled;

(f) Damages under 35 U.S.C. § 271(e)(4)(C), which this Court should treble pursuant to 35 U.S.C. § 284, if Gland infringes the '152 patent, the '590 patent, or the '102 patent by engaging in the commercial manufacture, importation, use, offer to sell, or sale of Gland's ANDA Product in/into the United States prior to the expiration of the '152 patent, the '590 patent, and the '102 patent, or the expiration of any other exclusivity to which Plaintiffs become entitled;

(g) A determination that Gland's infringement is deliberate and willful;

(h) An award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

Respectfully submitted,

RATNERPRESTIA

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