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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

LA JOLLA PHARMACEUTICAL COMPANY; LA JOLLA PHARMA, LLC and THE GEORGE WASHINGTON UNIVERSITY, Plaintiffs, v. GLAND PHARMA LIMITED, SHANGHAI FOSUN PHARMACEUTICAL (GROUP) CO., LTD. and FOSUN PHARMA USA INC. Defendants.	Civil Action No. _____ (Filed Electronically)

COMPLAINT

Plaintiffs La Jolla Pharmaceutical Company ("LJPC"), La Jolla Pharma, LLC ("LJP LLC," together with LJPC, "La Jolla") and The George Washington University ("GW") (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Gland Pharma Limited ("Gland"), Shanghai Fosun Pharmaceutical (Group) Co., Ltd. ("Fosun Shanghai"), and Fosun Pharma USA Inc. ("Fosun USA") (collectively, "Defendants"), allege:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, involving U.S. Patent Nos. 11,219,662 ("the '662 patent") (attached as Exhibit A), 9,220,745 ("the '745 patent") (attached as Exhibit B), 10,028,995 ("the '995 patent") (attached as Exhibit C), 10,493,124 ("the '124 patent") (attached as Exhibit D), 11,096,983 ("the '983 patent") (attached as Exhibit E), 9,572,856 ("the '856 patent") (attached as Exhibit F), 9,867,863 ("the '863 patent") (attached as Exhibit G), 10,335,451 ("the '451 patent") (attached as Exhibit H), 10,500,247 ("the '247 patent") (attached as Exhibit I), and 10,548,943 ("the '943 patent") (attached as Exhibit J) (collectively, "the patents-in-suit").

THE PARTIES

2. LJPC is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 201 Jones Road, Suite 400, Waltham, Massachusetts 02451.

3. LJP LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 201 Jones Road, Suite 400, Waltham, Massachusetts 02451.

4. LJP LLC is the owner of New Drug Application ("NDA") No. 209360, which was approved by the U.S. Food and Drug Administration ("FDA") for the manufacture and sale of Giapreza® (angiotensin II acetate), EQ 2.5 mg base/mL, solution for intravenous administration (hereinafter, "Giapreza®").

5. LJP LLC is the current owner and assignee of the '662 patent, which is listed in FDA's publication titled "Approved Drug Products with Therapeutics Equivalence Evaluations" (commonly known as the "Orange Book") as covering Giapreza®.

6. GW is a Congressionally-chartered institution of higher education, having a principal place of business at 1918 F St., N.W., Washington, D.C. 20052.

7. GW is the current owner and assignee of the '745 patent, the '995 patent, the '124 patent, the '983 patent, the '856 patent, the '863 patent, the '451 patent, the '247 patent, and the '943 patent, which are listed in FDA's Orange Book as covering Giapreza®.

8. GW granted La Jolla an exclusive, worldwide license under the '745 patent, the '995 patent, the '124 patent, the '983 patent, the '856 patent, the '863 patent, the '451 patent, the '247 patent, and the '943 patent to make, have made, use, import, offer for sale and sell Giapreza®.

9. Upon 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 'X' Roads, D.P. Pally, Dundigal- Gandimaisamma Mandal, Medchal-Malkajgiri District, Hyderabad, Telangana- 500 043, India.

10. Upon information and belief, Gland is in the business of, among other things: (i) alone or in concert with and/or through related entities (including Fosun Shanghai and Fosun USA), the development and manufacture of generic pharmaceutical products for sale throughout

the United States, including throughout the State of New Jersey; (ii) alone or in concert with and/or through related entities (including Fosun Shanghai and Fosun USA), the preparation, submission, and filing of Abbreviated New Drug Applications seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) alone or in concert with and/or through related entities (including Fosun Shanghai and Fosun USA), the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

11. Upon information and belief, Gland is the current owner of Abbreviated New Drug Application No. 216966 ("Gland's ANDA") and is seeking final approval of Gland's ANDA to engage in the commercial use, sale, and/or distribution of angiotensin II, 2.5 mg/mL vial ("Gland's ANDA Product") throughout the United States, including in New Jersey, before the expiration of the patents-in-suit. Upon information and belief, Gland's ANDA includes a paragraph IV certification under 21 U.S.C. § 355(j)(2) ("paragraph IV certification") to the patents-in-suit.

12. Upon information and belief, Fosun Shanghai is a Chinese corporation having a principal place of business at No. 1289 Yishan Road, 9th Floor, Building A, Shanghai, F4 200233, China.

13. Upon information and belief, Fosun Shanghai is in the business of, among other things: (i) alone or in concert with and/or through related entities (including Fosun USA and Gland), the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey; (ii) alone or in concert with and/or through related entities (including Fosun USA and Gland), the preparation, submission, and filing of Abbreviated New Drug Applications seeking FDA approval to market

generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) alone or in concert with and/or through related entities (including Fosun USA and Gland), the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

14. Upon information and belief, Gland is a subsidiary of Fosun Shanghai. Upon information and belief, Gland acts at the direction of, under the control of, and for the benefit of Fosun Shanghai, and is controlled and/or dominated by Fosun Shanghai. Upon information and belief, Gland and Fosun Shanghai have at least one officer and/or director in common.

15. Upon information and belief, on September 18, 2017, Fosun Shanghai and Gland "reached agreement that [Fosun Shanghai] will acquire an approximate 74% stake in Gland Pharma for no more than US$ 1,091.30 million." Fosun Shanghai publicly stated that "the agreement will establish a closer cooperation between the management teams of Fosun Pharma and Gland Pharma to jointly promote the sustainable and stable development of Gland Pharma" and noted that "[c]urrently, Gland Pharma's main business model is joint development of products and introduction of licenses to provide all global major pharmaceutical companies with the manufacturing services [sic] in relation to injectable generic drugs."[1]

16. Upon information and belief, Fosun USA is a Delaware corporation having a principal place of business at 104 Carnegie Center Drive, Suite 204, Princeton, New Jersey 08540.

17. Upon information and belief, Fosun USA is in the business of, among other things: (i) alone or in concert with and/or through related entities (including Fosun Shanghai and Gland), the development and manufacture of generic pharmaceutical products for sale

[1] https://www.fosunpharma.com/en/news/news-details-3700.html (last visited on Mar. 21, 2022).

throughout the United States, including throughout the State of New Jersey; (ii) alone or in concert with and/or through related entities (including Fosun Shanghai and Gland), the preparation, submission, and filing of Abbreviated New Drug Applications seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) alone or in concert with and/or through related entities (including Fosun Shanghai and Gland), the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

18. Upon information and belief, Fosun USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0101045291. Upon information and belief, Fosun USA is registered with the State of New Jersey's Department of Health as a drug & medical device "manufacturer and wholesaler" under Registration Number 5005532.

19. Upon information and belief, Fosun USA is a subsidiary of Fosun Shanghai. Upon information and belief, Fosun USA acts at the direction of, under the control of, and for the benefit of Fosun Shanghai, and is controlled and/or dominated by Fosun Shanghai. Upon information and belief, Fosun USA and Fosun Shanghai have at least one officer and/or director in common.

JURISDICTION AND VENUE

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

21. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1); (ii) Fed. R. Civ. P. 4(k)(2); and/or (iii) N.J. Ct. R. 4:4-4.

22. This Court has personal jurisdiction over Gland at least because, upon information and belief, Gland manufactures generic pharmaceutical products that are imported, distributed,

and sold throughout the United States—including in New Jersey—and thus avails itself of the privileges and benefits of the laws and commerce of the United States, including New Jersey.[2]

23. This Court has personal jurisdiction over Gland at least because, upon information and belief, Gland regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, thereby demonstrating that Gland has continuous and systematic contacts with New Jersey.

24. This Court has personal jurisdiction over Gland at least because, upon information and belief, Gland has purposefully directed its activities at residents and corporate entities within the State of New Jersey and the claims set forth herein as to Gland arise out of or relate to those activities.

25. This Court has personal jurisdiction over Gland at least because, upon information and belief, Gland, together with Fosun Shanghai and Fosun USA, has committed, induced, and/or contributed to acts of patent infringement in New Jersey.

26. This Court has personal jurisdiction over Gland at least because, upon information and belief, Gland has previously submitted to the jurisdiction of this Court and has availed itself of New Jersey's legal protections in prior litigations.[3]

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[2] *See, e.g.*, *Novartis Pharm. Corp. v. Actavis LLC*, No. 13-1028 (D.N.J. filed Feb. 20, 2013), ECF No. 241, Gland's Answer at ¶ 13 (admitting that Gland "manufactures products that are sold throughout the United States, including in New Jersey"); *Medicure Int'l., Inc. v. Gland Pharma Ltd.*, No. 18-16246 (D.N.J. filed November 16, 2018), ECF No. 13, Gland's Answer at ¶ 4 (admitting that Gland "develops, manufactures and/or distributes generic pharmaceutical products, and that certain generic pharmaceutical products developed, manufactured and/or distributed by Gland are ultimately sold in the United States, including in New Jersey.").

[3] *See, e.g.*, *Novartis Pharm. Corp. v. Gland Pharma Ltd.*, No. 14-1841 (D.N.J. filed Mar. 21, 2014); *Novartis Pharm. Corp. v. Actavis LLC*, No. 13-1028 (D.N.J. filed Feb. 20, 2013); *Novartis Pharm. Corp. v. Wockhardt USA LLC*, No. 12-3967 (D.N.J. filed June 27, 2012); *Medicure Int'l., Inc. v. Gland Pharma Ltd.*, No. 18-16246 (D.N.J. filed Nov. 16, 2018).

27. This Court has personal jurisdiction over Gland at least because, upon information and belief, Gland has previously invoked this Court's jurisdiction by asserting counterclaims in prior litigations.[4]

28. This Court has personal jurisdiction over Gland at least because, upon information and belief, it is reasonable and fair for this Court to exercise personal jurisdiction over Gland.

29. Upon information and belief, Gland "sells its products primarily under a business to business ('B2B') model in over 60 countries with its core markets being ***United States***, Europe, Canada, Australia and India."[5]

30. Upon information and belief, "[g]eographically, USA continues to be [Gland's] primary market."[6]

31. Upon information and belief, Gland's regulatory "team is ***constantly engaged with regulators including the USFDA***."[7]

32. Upon information and belief, Gland, "along with its partners has 284 ANDA filings in the United States, of which 234 were approved and 50 were pending approval."[8]

[4] *See Novartis Pharms. Corp. v. Actavis LLC*, No. 13-1028 (D.N.J. filed Feb. 20, 2013); *Novartis Pharma Corp. v. Wockhardt USA LLC*, No. 12-3967 (D.N.J. filed June 27, 2012); *Medicure Int'l., Inc. v. Gland Pharma Ltd.*, No. 18-16246 (D.N.J. filed Nov. 16, 2018).

[5] https://glandpharma.com/images/Annual%20Report%202020-21%20(Double%20Page).pdf (last visited Mar. 21, 2022) (emphasis added).

[6] https://glandpharma.com/images/Annual%20Report%202020-21%20(Double%20Page).pdf (last visited Mar. 21, 2022).

[7] https://glandpharma.com/images/Annual%20Report%202020-21%20(Double%20Page).pdf (last visited Mar. 21, 2022) (emphasis added).

[8] https://glandpharma.com/images/Annual%20Report%202020-21%20(Double%20Page).pdf (last visited Mar. 21, 2022).

33. Upon information and belief, "[a]s on March 31, 2021, [Gland] has filed 45 DMFs in the United States."[9]

34. Upon information and belief, Gland derives substantial revenue from the sale of generic pharmaceutical products throughout the United States, including in New Jersey.

35. This Court has personal jurisdiction over Fosun Shanghai at least because: (i) Fosun Shanghai is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (ii) Fosun Shanghai has purposefully directed its activities and the activities of Fosun USA and Gland, its subsidiaries, at residents and corporate entities within the State of New Jersey; (iii) the claims set forth herein as to Fosun Shanghai arise out of or relate to those activities; (iv) Fosun Shanghai, together with Gland and Fosun USA, its subsidiaries, is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (v) Fosun Shanghai, together with Gland and Fosun USA, its subsidiaries, has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (vi) Fosun Shanghai's contacts with the State of New Jersey (direct and/or indirect) are continuous and systematic; and (vii) it is reasonable and fair for this Court to exercise personal jurisdiction over Fosun Shanghai.

36. This Court has personal jurisdiction over Fosun USA at least because, upon information and belief: (i) Fosun USA maintains a principal place of business in New Jersey located at 104 Carnegie Center, Suite 204, Princeton, New Jersey 08540; (ii) Fosun USA is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) Fosun USA, together with Gland and its parent Fosun Shanghai, is in the

[9] https://glandpharma.com/images/Annual%20Report%202020-21%20(Double%20Page).pdf (last visited Mar. 21, 2022).

business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) Fosun USA, together with Gland and its parent Fosun Shanghai, has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (v) Fosun USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0101045291; and (vi) Fosun USA is registered with the State of New Jersey's Department of Health as a drug & medical device "manufacturer and wholesaler" under Registration Number 5005532.

37. Upon information and belief, Fosun USA or its affiliates, sell, offer for sale, and distribute generic pharmaceutical products for which Gland is the named ANDA applicant. Upon information and belief, Defendants each, directly or indirectly, derive substantial revenue from the sales of such generic pharmaceutical products in the United States, including in the State of New Jersey.

38. In its Notice Letter (*see* Paragraph 54, *infra)*, Gland represents that it prepared, submitted, and filed Gland's ANDA with FDA seeking approval to engage in the commercial manufacture, use, and/or sale of Gland's ANDA Product before the expiration of the patents-in-suit throughout the United States, including in this Judicial District.

39. This Court has personal jurisdiction over Defendants at least because, upon information and belief, if Gland's ANDA receives final FDA approval, Gland's ANDA Product will be manufactured by Defendants and offered for sale, sold, distributed, and/or used by Defendants in the United States, including in the State of New Jersey.

40. This Court has personal jurisdiction over Defendants at least because, upon information and belief, if Gland's ANDA receives final approval, Gland's ANDA Product will

be prescribed by physicians practicing in New Jersey and/or administered to patients in New Jersey.

41. Upon information and belief, Defendants' acts of preparing and filing Gland's ANDA and directing notice of the submission to Plaintiffs were performed at the direction of, with the authorization of, and with the cooperation, participation, assistance, and, at least in part, for the benefit of Gland, Fosun Shanghai, and Fosun USA. The acts giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, and/or sale of Gland's ANDA Product before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, will have real and injurious consequences for the State of New Jersey. Because defending against an infringement lawsuit such as this one is an essential and expected part of a generic pharmaceutical company's business, Defendants reasonably anticipated being sued in New Jersey.

42. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

43. Venue is further proper as to Gland, a foreign corporation, in any Judicial District that has personal jurisdiction, including this Judicial District.

44. Venue is further proper as to Fosun Shanghai, a foreign corporation, in any judicial district that has personal jurisdiction, including this Judicial District.

FACTS COMMON TO ALL COUNTS

45. Giapreza® is sold and marketed under NDA No. 209360, which was approved by FDA on December 21, 2017.

46. Giapreza® is a sterile, aqueous solution of synthetic human angiotensin II acetate for intravenous administration by infusion.

47. Giapreza® is supplied in a vial as a concentrated solution of 2.5 mg/mL angiotensin II that is diluted in 0.9% sodium chloride prior to use.

48. Each 1 mL of Giapreza® contains 2.5 mg angiotensin II equivalent to an average of 2.9 mg angiotensin II acetate, 25 mg mannitol, and water for injection adjusted with sodium hydroxide and/or hydrochloric acid to pH of 5.5.

49. The recommended starting dosage of Giapreza® is 20 ng/kg/min via continuous intravenous infusion.

50. Giapreza® is a vasoconstrictor that increases blood pressure in adults with septic or other distributive shock. Concomitant use of angiotensin converting enzyme (ACE) inhibitors may increase a patient's response to Giapreza®.

51. The safety of Giapreza® was evaluated in 321 adults with septic or other distributive shock in a randomized, double-blind, placebo-controlled study, ATHOS-3. Patients in the ATHOS-3 clinical study were receiving other vasopressors in addition to Giapreza® or placebo, which were titrated to effect on mean arterial pressure (MAP). The Giapreza® prescribing information provides the following additional information regarding the ATHOS-3 Clinical Study:

14.1. ATHOS-3

The Angiotensin II for the Treatment of High-Output Shock (ATHOS-3) trial was a double-blind study in which 321 adults with septic or other distributive shock who remained hypotensive despite fluid and vasopressor therapy were randomized 1:1 to GIAPREZA or placebo. Doses of GIAPREZA or placebo were titrated to a target mean arterial pressure (MAP) of ≥ 75 mmHg during the first 3 hours of treatment while doses of other vasopressors were maintained. From Hour 3 to Hour 48, GIAPREZA or placebo were titrated to maintain MAP between 65 and 70 mmHg while reducing doses of other vasopressors. The primary endpoint was the percentage of subjects who achieved either a MAP ≥ 75 mmHg or a ≥ 10 mmHg increase in MAP without an increase in baseline vasopressor therapy at 3 hours.

91% of subjects had septic shock; the remaining subjects had other forms of distributive shock such as neurogenic shock. At the time of study drug administration, 97% of subjects were receiving norepinephrine, 67% vasopressin, 15% phenylephrine, 13% epinephrine, and 2% dopamine. 83% of subjects had received two or more vasopressors and 47% three or more vasopressors prior to study drug administration. 61% of subjects were male, 80% were White, 10% were Black, and 10% were other races. The median age of subjects was 64 years (range: 22-89 years). Patients requiring high doses of steroids, patients with a history of asthma or bronchospasm, and patients with Raynaud's syndrome were not included.

The primary endpoint was achieved by 70% of patients randomized to GIAPREZA compared to 23% of placebo subjects; $p < 0.0001$ (a treatment effect of 47%). Figure 1 shows the results in all patients and in selected subgroups.

52. FDA's Orange Book lists the patents-in-suit as covering Giapreza®.

53. Under 21 U.S.C. § 355(j)(2)(B), the filer of an Abbreviated New Drug Application containing a paragraph IV certification must provide notice of the filing to each patent owner and each New Drug Application holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

54. Gland sent a letter regarding ANDA No. 216966 to "La Jolla Pharmaceutical Company [sic] LLC"[10] and GW dated February 14, 2022, purportedly pursuant to § 505(j)(2)(B)(ii) of the Federal Food Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(B)(ii) and § 314.95 of Title 21 of the Code of Federal Regulations (the "Notice Letter").

55. Plaintiffs received a copy of the Notice Letter on February 15, 2022.

56. The Notice Letter states that Gland's "ANDA was submitted under 21 U.S.C. § 355(j)(l) and 2(A) with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Angiotensin II injection for intravenous infusion 2.5

[10] The entity that owns New Drug Application NDA No. 209360 is "La Jolla Pharma, LLC," not "La Jolla Pharmaceutical Company LLC."

mg/mL in a vial, before the expiration of the [patents-in-suit], which are listed in Approved Drug Products with Therapeutic Equivalence Evaluation ('Orange Book') against Giapreza® (angiotensin II), Injection for Intravenous Infusion 2.5 mg/mL in a vial."

57. Upon information and belief, the reference listed drug for Gland's ANDA is Giapreza® (angiotensin II) 2.5 mg/mL Injection for Intravenous Infusion.

58. The Notice Letter further states that "[p]ursuant to 21 C.F.R. § 314.95(c)(6), we advise you that the [patents-in-suit] are alleged to be not infringed, invalid, and/or unenforceable in a paragraph IV certification submitted by Gland in connection with ANDA No. 216966."

59. The Notice Letter does not include any unenforceability contentions with respect to any of the patents-in-suit.

60. The FDA's Orange Book lists the "Patent Expiration" for the '745, '995, '124, and '983 patents as December 18, 2034; the "Patent Expiration" for the '856 patent as July 18, 2031; the "Patent Expiration" for the '863, '451, '247, and '943 patents as December 16, 2029; and the "Patent Expiration" for the '662 patent as January 6, 2037.

61. Gland's Notice Letter included an Offer of Confidential Access to "certain [unspecified] information" from Gland's ANDA, purportedly pursuant to 21 U.S.C. § 355(j)(5)(C). Gland demanded that Plaintiffs accept the Offer of Confidential Access before it would produce "certain [unspecified] information" from Gland's ANDA. Gland's Offer of Confidential Access contained numerous unreasonable and overly restrictive provisions. Plaintiffs proposed revisions comport with provisions that "would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." *See* 21 U.S.C. § 355. Plaintiffs and Defendants did not reach agreement on the

terms of an Offer of Confidential Access and, to date, Defendants have not produced a copy of Gland's ANDA to Plaintiffs.

62. In its Notice Letter, Gland stated that its proposed label states that Gland's ANDA Product "is indicated to increase blood pressure in adults with septic or other distributive shock."

63. In its Notice Letter, Gland stated that its proposed label "recommends starting angiotensin II injection intravenously at 20 nanograms (ng)/kg/min, and titrating by increments of up to 15 ng/kg/min as needed."

64. The '745 patent, titled, "Angiotensin II Alone or in Combination for the Treatment of Hypotension," was duly and legally issued by the U.S. Patent and Trademark Office on December 29, 2015. Inventor Lakhmir Chawla assigned all rights, title, and interest in the '745 patent to GW.

65. Pursuant to 21 U.S.C. § 355(b)(1), the '745 patent was submitted to FDA in connection with NDA No. 209360. The '745 patent was subsequently listed in the Orange Book as covering Giapreza®.

66. The '995 patent, titled, "Angiotensin II Alone or in Combination for the Treatment of Hypotension," was duly and legally issued by the U.S. Patent and Trademark Office on July 24, 2018. Inventor Lakhmir Chawla assigned all rights, title, and interest in the '995 patent to GW.

67. Pursuant to 21 U.S.C. § 355(b)(1), the '995 patent was submitted to FDA in connection with NDA No. 209360. The '995 patent was subsequently listed in the Orange Book as covering Giapreza®.

68. The '124 patent, titled, "Angiotensin II Alone or in Combination for the Treatment of Hypotension," was duly and legally issued by the U.S. Patent and Trademark

Office on December 3, 2019. Inventor Lakhmir Chawla assigned all rights, title, and interest in the '124 patent to GW.

69. Pursuant to 21 U.S.C. § 355(b)(1), the '124 patent was submitted to FDA in connection with NDA No. 209360. The '124 patent was subsequently listed in the Orange Book as covering Giapreza®.

70. The '983 patent, titled, "Angiotensin II Alone or in Combination for the Treatment of Hypotension," was duly and legally issued by the U.S. Patent and Trademark Office on August 24, 2021. Inventor Lakhmir Chawla assigned all rights, title, and interest in the '983 patent to GW.

71. Pursuant to 21 U.S.C. § 355(b)(1), the '983 patent was submitted to FDA in connection with NDA No. 209360. The '983 patent was subsequently listed in the Orange Book as covering Giapreza®.

72. The '856 patent, titled, "Method of Treating Low Blood Pressure," was duly and legally issued by the U.S. Patent and Trademark Office on February 21, 2017. Inventor Lakhmir Chawla assigned all rights, title, and interest in the '856 patent to GW.

73. Pursuant to 21 U.S.C. § 355(b)(1), the '856 patent was submitted to FDA in connection with NDA No. 209360. The '856 patent was subsequently listed in the Orange Book as covering Giapreza®.

74. The '863 patent, titled, "Method of Treating Low Blood Pressure," was duly and legally issued by the U.S. Patent and Trademark Office on January 16, 2018. Inventor Lakhmir Chawla assigned all rights, title, and interest in the '863 patent to GW.

75. Pursuant to 21 U.S.C. § 355(b)(1), the ’863 patent was submitted to FDA in connection with NDA No. 209360. The ’863 patent was subsequently listed in the Orange Book as covering Giapreza®.

76. The ’451 patent, titled, “Method of Treating Low Blood Pressure,” was duly and legally issued by the U.S. Patent and Trademark Office on July 2, 2019. Inventor Lakhmir Chawla assigned all rights, title, and interest in the ’451 patent to GW.

77. Pursuant to 21 U.S.C. § 355(b)(1), the ’451 patent was submitted to FDA in connection with NDA No. 209360. The ’451 patent was subsequently listed in the Orange Book as covering Giapreza®.

78. The ’247 patent, titled, “Method of Treating Low Blood Pressure,” was duly and legally issued by the U.S. Patent and Trademark Office on December 10, 2019. Inventor Lakhmir Chawla assigned all rights, title, and interest in the ’247 patent to GW.

79. Pursuant to 21 U.S.C. § 355(b)(1), the ’247 patent was submitted to FDA in connection with NDA No. 209360. The ’247 patent was subsequently listed in the Orange Book as covering Giapreza®.

80. The ’943 patent, titled, “Method of Treating Low Blood Pressure,” was duly and legally issued by the U.S. Patent and Trademark Office on February 4, 2020. Inventor Lakhmir Chawla assigned all rights, title, and interest in the ’943 patent to GW.

81. Pursuant to 21 U.S.C. § 355(b)(1), the ’943 patent was submitted to FDA in connection with NDA No. 209360. The ’943 patent was subsequently listed in the Orange Book as covering Giapreza®.

82. GW granted La Jolla an exclusive, worldwide license under the ’745 patent, the ’995 patent, the ’124 patent, the ’983 patent, the ’856 patent, the ’863 patent, the ’451 patent, the

'247 patent, and the '943 patent to make, have made, use, import, offer for sale and sell Giapreza®.

83. The '662 patent, titled, "Method for Treating Hypotension in a Patient that Has Received an ACE Inhibitor by Administering Angiotensin II," was duly and legally issued by the U.S. Patent and Trademark Office on January 11, 2022. Inventors Lakhmir Chawla and George Tidmarsh assigned all rights, title, and interest in the '662 patent to LJPC. LJPC subsequently assigned all rights, title, and interest in the '662 patent to LJP LLC.

84. Pursuant to 21 U.S.C. § 355(b)(1), the '662 patent was submitted to FDA in connection with NDA No. 209360. The '662 patent was subsequently listed in the Orange Book as covering Giapreza®.

85. Upon information and belief, Defendants intend to manufacture, import, use, sell, or offer to sell Gland's ANDA Product for uses that would infringe one or more of the claims of the patents-in-suit.

86. Upon information and belief, Defendants will market Gland's ANDA Product with labelling that substantially copies the FDA-approved label for Giapreza®. That labelling will induce, encourage, recommend, and promote direct infringement of the patents-in-suit by instructing physicians to administer Gland's ANDA Product to patients in a manner that will directly infringe the patents-in-suit.

FIRST COUNT
(Defendants' Infringement of the '662 patent)

87. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

88. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA to FDA pursuant to

§ 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the '662 patent.

89. Upon information and belief, Fosun Shanghai and Fosun USA provided material and significant support to Gland in the preparation of ANDA No. 216966.

90. Upon information and belief, Fosun Shanghai and Fosun USA are jointly and severally liable for Gland's infringement of one or more claims of the '662 patent.

91. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA with a paragraph IV certification to the '662 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '662 patent.

92. Upon information and belief, as of the Notice Letter, Defendants were aware of the statutory provisions and regulations in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

93. Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) sent the Notice Letter to "La Jolla Pharmaceutical Company [sic] LLC" and GW, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

94. Under 35 U.S.C. § 271(e)(2)(A), the submission of Gland's ANDA with a paragraph IV certification to the '662 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '662 patent is itself an act of infringement of the '662 patent.

95. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) will commercially manufacture, use, offer to

sell, sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

96. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more claims of the '662 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

97. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Gland ANDA Product prior to the expiration of the '662 patent will directly infringe the '662 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '662 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '662 patent under 35 U.S.C. § 271(c).

98. Upon information and belief, Gland's ANDA Product will be marketed with labeling that substantially copies the labeling for Giapreza®.

99. Upon information and belief, the label for Gland's ANDA Product that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Gland's ANDA will encourage such third parties to perform one or more of the methods claimed in the '662 patent.

100. Upon information and belief, the use of Gland's ANDA Product by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Gland's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '662 patent.

101. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Gland's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the '662 patent.

102. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement of claims of the '662 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

103. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Gland's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to the infringement of the '662 patent by third parties because: (i) Defendants' ANDA Product constitutes a material part of the methods of treatment claimed in the '662 patent; (ii) Defendants know or should know that Gland's ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the '662 patent; and (iii) Defendants' ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

104. Upon information and belief, Defendants have acted with full knowledge of the '662 patent and its claims and without a reasonable basis for believing that Defendants would not

be liable for infringement of the '662 patent. Defendants knew of the existence of the '662 patent, as evidenced by Defendants' filing of Gland's ANDA with a paragraph IV certification specifically referencing the '662 patent. Notwithstanding this knowledge, Defendants have continued to signal their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Gland ANDA Product before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendants specifically intend infringement of the '662 patent.

105. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

106. Unless Defendants are permanently enjoined by this Court, the acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

SECOND COUNT
(Defendants' Infringement of the '745 patent)

107. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

108. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the '745 patent.

109. Upon information and belief, Fosun Shanghai and Fosun USA provided material and significant support to Gland in the preparation of ANDA No. 216966.

110. Upon information and belief, Fosun Shanghai and Fosun USA are jointly and severally liable for Gland's infringement of one or more claims of the '745 patent.

111. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA with a paragraph IV certification to the '745 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '745 patent.

112. Upon information and belief, as of the Notice Letter, Defendants were aware of the statutory provisions and regulations in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

113. Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) sent the Notice Letter to "La Jolla Pharmaceutical Company [sic] LLC" and GW, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

114. Under 35 U.S.C. § 271(e)(2)(A), the submission of Gland's ANDA with a paragraph IV certification to the '745 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '745 patent is itself an act of infringement of the '745 patent.

115. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

116. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more claims of the '745 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

117. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Gland ANDA Product prior to the expiration of the '745 patent will directly infringe the '745 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '745 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '745 patent under 35 U.S.C. § 271(c).

118. Upon information and belief, Gland's ANDA Product will be marketed with labeling that substantially copies the labeling for Giapreza®.

119. Upon information and belief, the label for Gland's ANDA Product that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Gland's ANDA Product will encourage such third parties to perform one or more of the methods claimed in the '745 patent.

120. Upon information and belief, the use of Gland's ANDA Product by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Gland's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '745 patent.

121. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Gland's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make,

use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the ’745 patent.

122. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement of claims of the ’745 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

123. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Gland’s ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to the infringement of the ’745 patent by third parties because: (i) Defendants’ ANDA Product constitutes a material part of the methods of treatment claimed in the ’745 patent; (ii) Defendants know or should know that Gland’s ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’745 patent; and (iii) Defendants’ ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

124. Upon information and belief, Defendants have acted with full knowledge of the ’745 patent and its claims and without a reasonable basis for believing that Defendants would not be liable for infringement of the ’745 patent. Defendants knew of the existence of the ’745 patent, as evidenced by Defendants’ filing of Gland’s ANDA with a paragraph IV certification specifically referencing the ’745 patent. Notwithstanding this knowledge, Defendants have continued to signal their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Gland ANDA Product before the expiration of the patents-

in-suit. Upon information and belief, through such activities, Defendants specifically intend infringement of the '745 patent.

125. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

126. Unless Defendants are permanently enjoined by this Court, the acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

THIRD COUNT
(Defendants' Infringement of the '124 patent)

127. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

128. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the '124 patent.

129. Upon information and belief, Fosun Shanghai and Fosun USA provided material and significant support to Gland in the preparation of ANDA No. 216966.

130. Upon information and belief, Fosun Shanghai and Fosun USA are jointly and severally liable for Gland's infringement of one or more claims of the '124 patent.

131. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA with a paragraph IV certification to the '124 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '124 patent.

132. Upon information and belief, as of the Notice Letter, Defendants were aware of the statutory provisions and regulations in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

133. Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) sent the Notice Letter to "La Jolla Pharmaceutical Company [sic] LLC" and GW, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

134. Under 35 U.S.C. § 271(e)(2)(A), the submission of Gland's ANDA with a paragraph IV certification to the '124 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '124 patent is itself an act of infringement of the '124 patent.

135. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

136. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more claims of the '124 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

137. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Gland ANDA Product prior to the expiration of the '124 patent will directly infringe the '124 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '124 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '124 patent under 35 U.S.C. § 271(c).

138. Upon information and belief, Gland's ANDA Product will be marketed with labeling that substantially copies the labeling for Giapreza®.

139. Upon information and belief, the label for Gland's ANDA Product that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Gland's ANDA Product will encourage such third parties to perform one or more of the methods claimed in the '124 patent.

140. Upon information and belief, the use of Gland's ANDA Product by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Gland's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '124 patent.

141. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Gland's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the '124 patent.

142. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement

of claims of the ’124 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

143. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Gland’s ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to the infringement of the ’124 patent by third parties because: (i) Defendants’ ANDA Product constitutes a material part of the methods of treatment claimed in the ’124 patent; (ii) Defendants know or should know that Gland’s ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’124 patent; and (iii) Defendants’ ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

144. Upon information and belief, Defendants have acted with full knowledge of the ’124 patent and its claims and without a reasonable basis for believing that Defendants would not be liable for infringement of the ’124 patent. Defendants knew of the existence of the ’124 patent, as evidenced by Defendants’ filing of Gland’s ANDA with a paragraph IV certification specifically referencing the ’124 patent. Notwithstanding this knowledge, Defendants have continued to signal their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Gland ANDA Product before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendants specifically intend infringement of the ’124 patent.

145. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

146. Unless Defendants are permanently enjoined by this Court, the acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

FOURTH COUNT
(Defendants' Infringement of the '995 patent)

147. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

148. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the '995 patent.

149. Upon information and belief, Fosun Shanghai and Fosun USA provided material and significant support to Gland in the preparation of ANDA No. 216966.

150. Upon information and belief, Fosun Shanghai and Fosun USA are jointly and severally liable for Gland's infringement of one or more claims of the '995 patent.

151. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA with a paragraph IV certification to the '995 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '995 patent.

152. Upon information and belief, as of the Notice Letter, Defendants were aware of the statutory provisions and regulations in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

153. Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) sent the Notice Letter to "La Jolla Pharmaceutical Company [sic] LLC" and GW, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

154. Under 35 U.S.C. § 271(e)(2)(A), the submission of Gland's ANDA with a paragraph IV certification to the '995 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '995 patent is itself an act of infringement of the '995 patent.

155. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

156. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more claims of the '995 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

157. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Gland ANDA Product prior to the expiration of the '995 patent will directly infringe the '995 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '995 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '995 patent under 35 U.S.C. § 271(c).

158. Upon information and belief, Gland's ANDA Product will be marketed with labeling that substantially copies the labeling for Giapreza®.

159. Upon information and belief, the label for Gland's ANDA Product that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Gland's ANDA Product will encourage such third parties to perform one or more of the methods claimed in the '995 patent.

160. Upon information and belief, the use of Gland's ANDA Product by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Gland's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '995 patent.

161. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Gland's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the '995 patent.

162. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement of claims of the '995 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

163. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Gland's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to the infringement of the '995 patent by third parties because: (i) Defendants' ANDA Product constitutes a material part of the methods of treatment claimed in the '995 patent; (ii) Defendants know or should know that Gland's ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the '995 patent; and (iii) Defendants' ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

164. Upon information and belief, Defendants have acted with full knowledge of the '995 patent and its claims and without a reasonable basis for believing that Defendants would not be liable for infringement of the '995 patent. Defendants knew of the existence of the '995 patent, as evidenced by Defendants' filing of Gland's ANDA with a paragraph IV certification specifically referencing the '995 patent. Notwithstanding this knowledge, Defendants have continued to signal their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Gland ANDA Product before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendants specifically intend infringement of the '995 patent.

165. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

166. Unless Defendants are permanently enjoined by this Court, the acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

FIFTH COUNT
(Defendants' Infringement of the '983 patent)

167. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

168. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the '983 patent.

169. Upon information and belief, Fosun Shanghai and Fosun USA provided material and significant support to Gland in the preparation of ANDA No. 216966.

170. Upon information and belief, Fosun Shanghai and Fosun USA are jointly and severally liable for Gland's infringement of one or more claims of the '983 patent.

171. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA with a paragraph IV certification to the '983 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '983 patent.

172. Upon information and belief, as of the Notice Letter, Defendants were aware of the statutory provisions and regulations in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

173. Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) sent the Notice Letter to "La Jolla Pharmaceutical Company [sic] LLC" and GW, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

174. Under 35 U.S.C. § 271(e)(2)(A), the submission of Gland's ANDA with a paragraph IV certification to the '983 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '983 patent is itself an act of infringement of the '983 patent.

175. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

176. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more claims of the '983 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

177. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Gland ANDA Product prior to the expiration of the '983 patent will directly infringe the '983 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '983 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '983 patent under 35 U.S.C. § 271(c).

178. Upon information and belief, Gland's ANDA Product will be marketed with labeling that substantially copies the labeling for Giapreza®.

179. Upon information and belief, the label for Gland's ANDA Product that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Gland's

ANDA Product will encourage such third parties to perform one or more of the methods claimed in the ’983 patent.

180. Upon information and belief, the use of Gland’s ANDA Product by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Gland’s ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the ’983 patent.

181. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Gland’s ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the ’983 patent.

182. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement of claims of the ’983 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

183. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Gland’s ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to

the infringement of the ’983 patent by third parties because: (i) Defendants’ ANDA Product constitutes a material part of the methods of treatment claimed in the ’983 patent; (ii) Defendants know or should know that Gland’s ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’983 patent; and (iii) Defendants’ ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

184. Upon information and belief, Defendants have acted with full knowledge of the ’983 patent and its claims and without a reasonable basis for believing that Defendants would not be liable for infringement of the ’983 patent. Defendants knew of the existence of the ’983 patent, as evidenced by Defendants’ filing of Gland’s ANDA with a paragraph IV certification specifically referencing the ’983 patent. Notwithstanding this knowledge, Defendants have continued to signal their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Gland ANDA Product before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendants specifically intend infringement of the ’983 patent.

185. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

186. Unless Defendants are permanently enjoined by this Court, the acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

SIXTH COUNT

(Defendants’ Infringement of the ’856 patent)

187. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

188. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the '856 patent.

189. Upon information and belief, Fosun Shanghai and Fosun USA provided material and significant support to Gland in the preparation of ANDA No. 216966.

190. Upon information and belief, Fosun Shanghai and Fosun USA are jointly and severally liable for Gland's infringement of one or more claims of the '856 patent.

191. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA with a paragraph IV certification to the '856 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '856 patent.

192. Upon information and belief, as of the Notice Letter, Defendants were aware of the statutory provisions and regulations in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

193. Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) sent the Notice Letter to "La Jolla Pharmaceutical Company [sic] LLC" and GW, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

194. Under 35 U.S.C. § 271(e)(2)(A), the submission of Gland's ANDA with a paragraph IV certification to the '856 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '856 patent is itself an act of infringement of the '856 patent.

195. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

196. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more claims of the '856 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

197. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Gland ANDA Product prior to the expiration of the '856 patent will directly infringe the '856 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '856 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '856 patent under 35 U.S.C. § 271(c).

198. Upon information and belief, Gland's ANDA Product will be marketed with labeling that substantially copies the labeling for Giapreza®.

199. Upon information and belief, the label for Gland's ANDA Product that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Gland's ANDA Product will encourage such third parties to perform one or more of the methods claimed in the '856 patent.

200. Upon information and belief, the use of Gland's ANDA Product by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Gland's ANDA

Product will constitute an act of direct infringement of one or more of the methods claimed in the '856 patent.

201. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Gland's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the '856 patent.

202. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement of claims of the '856 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

203. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Gland's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to the infringement of the '856 patent by third parties because: (i) Defendants' ANDA Product constitutes a material part of the methods of treatment claimed in the '856 patent; (ii) Defendants know or should know that Gland's ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the '856 patent; and (iii) Defendants' ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

204. Upon information and belief, Defendants have acted with full knowledge of the '856 patent and its claims and without a reasonable basis for believing that Defendants would not be liable for infringement of the '856 patent. Defendants knew of the existence of the '856 patent, as evidenced by Defendants' filing of Gland's ANDA with a paragraph IV certification specifically referencing the '856 patent. Notwithstanding this knowledge, Defendants have continued to signal their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Gland ANDA Product before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendants specifically intend infringement of the '856 patent.

205. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

206. Unless Defendants are permanently enjoined by this Court, the acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

SEVENTH COUNT
(Defendants' Infringement of the '863 patent)

207. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

208. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the '863 patent.

209. Upon information and belief, Fosun Shanghai and Fosun USA provided material and significant support to Gland in the preparation of ANDA No. 216966.

210. Upon information and belief, Fosun Shanghai and Fosun USA are jointly and severally liable for Gland's infringement of one or more claims of the '863 patent.

211. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA with a paragraph IV certification to the '863 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '863 patent.

212. Upon information and belief, as of the Notice Letter, Defendants were aware of the statutory provisions and regulations in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

213. Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) sent the Notice Letter to "La Jolla Pharmaceutical Company [sic] LLC" and GW, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

214. Under 35 U.S.C. § 271(e)(2)(A), the submission of Gland's ANDA with a paragraph IV certification to the '863 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '863 patent is itself an act of infringement of the '863 patent.

215. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

216. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Gland's ANDA Product would

infringe, directly and/or indirectly, one or more claims of the '863 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

217. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Gland ANDA Product prior to the expiration of the '863 patent will directly infringe the '863 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '863 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '863 patent under 35 U.S.C. § 271(c).

218. Upon information and belief, Gland's ANDA Product will be marketed with labeling that substantially copies the labeling for Giapreza®.

219. Upon information and belief, the label for Gland's ANDA Product that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Gland's ANDA Product will encourage such third parties to perform one or more of the methods claimed in the '863 patent.

220. Upon information and belief, the use of Gland's ANDA Product by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Gland's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '863 patent.

221. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Gland's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers,

subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the ’863 patent.

222. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement of claims of the ’863 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

223. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Gland’s ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to the infringement of the ’863 patent by third parties because: (i) Defendants’ ANDA Product constitutes a material part of the methods of treatment claimed in the ’863 patent; (ii) Defendants know or should know that Gland’s ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’863 patent; and (iii) Defendants’ ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

224. Upon information and belief, Defendants have acted with full knowledge of the ’863 patent and its claims and without a reasonable basis for believing that Defendants would not be liable for infringement of the ’863 patent. Defendants knew of the existence of the ’863 patent, as evidenced by Defendants’ filing of Gland’s ANDA with a paragraph IV certification specifically referencing the ’863 patent. Notwithstanding this knowledge, Defendants have continued to signal their intent to engage in the manufacture, use, offer for sale, sale, marketing,

distribution, and/or importation of the Gland ANDA Product before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendants specifically intend infringement of the '863 patent.

225. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

226. Unless Defendants are permanently enjoined by this Court, the acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

EIGHTH COUNT
(Defendants' Infringement of the '451 patent)

227. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

228. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the '451 patent.

229. Upon information and belief, Fosun Shanghai and Fosun USA provided material and significant support to Gland in the preparation of ANDA No. 216966.

230. Upon information and belief, Fosun Shanghai and Fosun USA are jointly and severally liable for Gland's infringement of one or more claims of the '451 patent.

231. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA with a paragraph IV certification to the '451 patent for the purpose of obtaining FDA approval to engage in the

commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '451 patent.

232. Upon information and belief, as of the Notice Letter, Defendants were aware of the statutory provisions and regulations in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

233. Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) sent the Notice Letter to "La Jolla Pharmaceutical Company [sic] LLC" and GW, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

234. Under 35 U.S.C. § 271(e)(2)(A), the submission of Gland's ANDA with a paragraph IV certification to the '451 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '451 patent is itself an act of infringement of the '451 patent.

235. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

236. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more claims of the '451 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

237. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Gland ANDA Product prior to the expiration of the '451 patent will directly infringe the '451 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '451

patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '451 patent under 35 U.S.C. § 271(c).

238. Upon information and belief, Gland's ANDA Product will be marketed with labeling that substantially copies the labeling for Giapreza®.

239. Upon information and belief, the label for Gland's ANDA Product that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Gland's ANDA Product will encourage such third parties to perform one or more of the methods claimed in the '451 patent.

240. Upon information and belief, the use of Gland's ANDA Product by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Gland's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '451 patent.

241. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Gland's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the '451 patent.

242. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and

distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement of claims of the '451 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

243. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Gland's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to the infringement of the '451 patent by third parties because: (i) Defendants' ANDA Product constitutes a material part of the methods of treatment claimed in the '451 patent; (ii) Defendants know or should know that Gland's ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the '451 patent; and (iii) Defendants' ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

244. Upon information and belief, Defendants have acted with full knowledge of the '451 patent and its claims and without a reasonable basis for believing that Defendants would not be liable for infringement of the '451 patent. Defendants knew of the existence of the '451 patent, as evidenced by Defendants' filing of Gland's ANDA with a paragraph IV certification specifically referencing the '451 patent. Notwithstanding this knowledge, Defendants have continued to signal their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Gland ANDA Product before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendants specifically intend infringement of the '451 patent.

245. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

246. Unless Defendants are permanently enjoined by this Court, the acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

NINTH COUNT
(Defendants' Infringement of the '247 patent)

247. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

248. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the '247 patent.

249. Upon information and belief, Fosun Shanghai and Fosun USA provided material and significant support to Gland in the preparation of ANDA No. 216966.

250. Upon information and belief, Fosun Shanghai and Fosun USA are jointly and severally liable for Gland's infringement of one or more claims of the '247 patent.

251. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA with a paragraph IV certification to the '247 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '247 patent.

252. Upon information and belief, as of the Notice Letter, Defendants were aware of the statutory provisions and regulations in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

253. Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) sent the Notice Letter to "La Jolla Pharmaceutical Company [sic] LLC" and GW, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

254. Under 35 U.S.C. § 271(e)(2)(A), the submission of Gland's ANDA with a paragraph IV certification to the '247 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '247 patent is itself an act of infringement of the '247 patent.

255. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

256. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more claims of the '247 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

257. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Gland ANDA Product prior to the expiration of the '247 patent will directly infringe the '247 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '247 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '247 patent under 35 U.S.C. § 271(c).

258. Upon information and belief, Gland's ANDA Product will be marketed with labeling that substantially copies the labeling for Giapreza®.

259. Upon information and belief, the label for Gland's ANDA Product that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Gland's ANDA Product will encourage such third parties to perform one or more of the methods claimed in the '247 patent.

260. Upon information and belief, the use of Gland's ANDA Product by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Gland's ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the '247 patent.

261. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Gland's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the '247 patent.

262. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement of claims of the '247 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

263. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Gland's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to the infringement of the '247 patent by third parties because: (i) Defendants' ANDA Product constitutes a material part of the methods of treatment claimed in the '247 patent; (ii) Defendants know or should know that Gland's ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the '247 patent; and (iii) Defendants' ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

264. Upon information and belief, Defendants have acted with full knowledge of the '247 patent and its claims and without a reasonable basis for believing that Defendants would not be liable for infringement of the '247 patent. Defendants knew of the existence of the '247 patent, as evidenced by Defendants' filing of Gland's ANDA with a paragraph IV certification specifically referencing the '247 patent. Notwithstanding this knowledge, Defendants have continued to signal their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Gland ANDA Product before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendants specifically intend infringement of the '247 patent.

265. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

266. Unless Defendants are permanently enjoined by this Court, the acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

TENTH COUNT
(Defendants' Infringement of the '943 patent)

267. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

268. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Gland's ANDA Product prior to the expiration of the '943 patent.

269. Upon information and belief, Fosun Shanghai and Fosun USA provided material and significant support to Gland in the preparation of ANDA No. 216966.

270. Upon information and belief, Fosun Shanghai and Fosun USA are jointly and severally liable for Gland's infringement of one or more claims of the '943 patent.

271. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) submitted Gland's ANDA with a paragraph IV certification to the '943 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '943 patent.

272. Upon information and belief, as of the Notice Letter, Defendants were aware of the statutory provisions and regulations in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

273. Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) sent the Notice Letter to "La Jolla Pharmaceutical Company [sic] LLC" and GW, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

274. Under 35 U.S.C. § 271(e)(2)(A), the submission of Gland's ANDA with a paragraph IV certification to the '943 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '943 patent is itself an act of infringement of the '943 patent.

275. Upon information and belief, Gland (together with, at the direction of, and under the control of Fosun Shanghai and Fosun USA) will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

276. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more claims of the '943 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

277. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Gland ANDA Product prior to the expiration of the '943 patent will directly infringe the '943 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '943 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '943 patent under 35 U.S.C. § 271(c).

278. Upon information and belief, Gland's ANDA Product will be marketed with labeling that substantially copies the labeling for Giapreza®.

279. Upon information and belief, the label for Gland's ANDA Product that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Gland's

ANDA Product will encourage such third parties to perform one or more of the methods claimed in the ’943 patent.

280. Upon information and belief, the use of Gland’s ANDA Product by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Gland’s ANDA Product will constitute an act of direct infringement of one or more of the methods claimed in the ’943 patent.

281. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Gland’s ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the ’943 patent.

282. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement of claims of the ’943 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

283. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Gland’s ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to

the infringement of the ’943 patent by third parties because: (i) Defendants’ ANDA Product constitutes a material part of the methods of treatment claimed in the ’943 patent; (ii) Defendants know or should know that Gland’s ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the ’943 patent; and (iii) Defendants’ ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

284. Upon information and belief, Defendants have acted with full knowledge of the ’943 patent and its claims and without a reasonable basis for believing that Defendants would not be liable for infringement of the ’943 patent. Defendants knew of the existence of the ’943 patent, as evidenced by Defendants’ filing of Gland’s ANDA with a paragraph IV certification specifically referencing the ’943 patent. Notwithstanding this knowledge, Defendants have continued to signal their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Gland ANDA Product before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendants specifically intend infringement of the ’943 patent.

285. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

286. Unless Defendants are permanently enjoined by this Court, the acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment declaring that the patents-in-suit are valid and enforceable;

B. A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the patents-in-suit by submitting to FDA ANDA No. 216966 with a paragraph IV

certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the patents-in-suit;

C. A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, sale within the United States, and/or importation into the United States, of Gland's ANDA Product before the expiration of the patents-in-suit (including any regulatory extension) would directly and/or indirectly infringe the patents-in-suit;

D. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 216966 shall be no earlier than the date on which the last of the patents-in-suit expire (including any regulatory extension);

E. An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, attorneys, and any person in active concert or participation or privity with Defendants, from engaging in the commercial manufacture, use, offering to sell, sale within the United States, and/or importation into the United States, of Gland's ANDA Product until the expiration of the patents-in-suit (including any regulatory extension);

F. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Plaintiffs damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 216966, prior to the expiration of the patents-in-suit (including any regulatory extension);

G. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the patents-in-suit is willful and awarding Plaintiffs enhanced damages if Defendants commercially manufacture, use, offer to sell, sell within the United

States, and/or import into the United States any product that is the subject of ANDA No. 216966, prior to the expiration of the patents-in-suit (including any regulatory extension);

H. A judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Plaintiffs their attorneys' fees and costs; and

I. Such other and further relief as this Court may deem just and proper.

Dated: March 29, 2022

Respectfully submitted,

By: s/ Charles H. Chevalier

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