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and InnoPharma, LLC*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SENJU PHARMACEUTICAL CO., LTD.,
BAUSCH & LOMB, INC. and BAUSCH &
LOMB PHARMA HOLDINGS CORP.,

Plaintiffs,
v.

INNOPHARMA LICENSING, INC.,
INNOPHARMA LICENSING LLC,
INNOPHARMA, INC., and INNOPHARMA,
LLC,

Defendants.

Civil Action No.:
1:14-cv-06893-JBS-KMW

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**ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS OF
DEFENDANTS INNOPHARMA LICENSING, INC., INNOPHARMA LICENSING LLC,
INNOPHARMA, INC., AND INNOPHARMA LLC**

Defendants InnoPharma Licensing, Inc., InnoPharma Licensing LLC, InnoPharma, Inc.,
and InnoPharma, LLC (collectively “InnoPharma” or “Defendants”) by and through their

counsel, hereby answer the Complaint of Plaintiffs Senju Pharmaceutical Co., Ltd., Bausch & Lomb Incorporated, and Bausch & Lomb Pharma Holdings Corp., (collectively, “Plaintiffs”) and assert their separate defenses and counterclaims as follows:

THE PARTIES

1. Plaintiff Senju Pharmaceutical Co., Ltd. (“Senju”) is a corporation organized and existing under the laws of Japan, with a principal place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint and therefore deny them.

2. Plaintiff Bausch & Lomb Incorporated (“B+L”) is a corporation organized and existing under the laws of New York, with a place of business at 1400 North Goodman St., Rochester, New York 14609. B+L is the registered holder of approved New Drug Application (“NDA”) No. 203168, which covers Prolensa[®].

ANSWER: Defendants aver that the Orange Book as of the date of this answer currently lists B+L as the purported registered holder of New Drug Application (“NDA”) No. 203168, which purportedly covers Prolensa[®]. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 2 of the Complaint and therefore deny them.

3. Plaintiff Bausch & Lomb Pharma Holdings Corp. (“B+L Pharma Holdings”) is a corporation organized and existing under the laws of Delaware, with a place of business at 700 Route 202/206, Bridgewater, New Jersey 08807. B+L Pharma Holdings is a wholly-owned subsidiary of B+L.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint and therefore deny them.

4. Upon information and belief, defendant InnoPharma Licensing, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Picastaway (sic), New Jersey 08854.

ANSWER: Admitted.

5. Upon information and belief, defendant InnoPharma Licensing, LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Picastaway (sic), New Jersey 08854.

ANSWER: Admitted.

6. Upon information and belief, defendant InnoPharma Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Picastaway (sic), New Jersey 08854.

ANSWER: Admitted.

7. Upon information and belief, defendant InnoPharma, LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Picastaway (sic), New Jersey 08854.

ANSWER: Admitted.

NATURE OF THE ACTION

8. This is an action for infringement of United States Patent No. 8,129,431 (“the ’431 patent”), 8,669,290 (“the ’290 patent”), 8,754,131 (“the ’131 patent”), and 8,871,813 (“the ’813 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to InnoPharma Licensing, Inc.’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and

Drug Administration (“FDA”) approval to market generic Bromfenac Ophthalmic Solution 0.07% (“InnoPharma Licensing, Inc.’s generic bromfenac ophthalmic solution”).

ANSWER: Defendants admit that Plaintiffs’ Complaint purports to state an action for patent infringement. Defendants further admit that the Complaint filed by Plaintiffs purports to state an action relating to an Abbreviated New Drug Application (“ANDA”) No. 206326 purportedly filed by InnoPharma Licensing, Inc. with the United States Food and Drug Administration (“FDA”). To the extent an answer to any factual allegation not otherwise addressed herein is required, Defendants deny said allegation.

JURISDICTION AND VENUE

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

ANSWER: For the purposes of this action only, Defendants do not contest subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). To the extent an answer to any factual allegation not otherwise addressed herein is required, Defendants deny said allegation.

10. Upon information and belief, this Court has jurisdiction over InnoPharma Licensing, Inc. Upon information and belief, InnoPharma Licensing, Inc. is in the business of licensing, manufacturing, distributing and selling pharmaceutical products, including generic drug products. Upon information and belief, InnoPharma Licensing, Inc. directly licenses, manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for InnoPharma Licensing, Inc.’s generic bromfenac ophthalmic solution. Upon information and belief, InnoPharma Licensing, Inc. operates as a patent owner or lessor for InnoPharma, Inc., whose principal place of business is, on information and belief, at 10 Knightsbridge Road, Picastaway (sic), New Jersey 08854,

and has thereby purposefully and systematically conducted and continues to conduct business in this judicial district.

ANSWER: To conserve the resources of the parties and the Court, InnoPharma Licensing, Inc. does not contest personal jurisdiction in this judicial district for the limited purpose of this action only and for the limited purpose of the product covered by ANDA No. 206326 which is the subject of the Complaint. InnoPharma Licensing, Inc. denies the remaining allegations in Paragraph 10 of the Complaint.

11. Upon information and belief, this Court has jurisdiction over InnoPharma Licensing, LLC. Upon information and belief, InnoPharma Licensing, LLC is in the business of licensing, manufacturing, distributing and selling pharmaceutical products, including generic drug products. Upon information and belief, InnoPharma Licensing, LLC directly licenses, manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for InnoPharma Licensing, LLC's generic bromfenac ophthalmic solution. Upon information and belief, InnoPharma Licensing, LLC operates as a patent owner or lessor for InnoPharma, LLC, whose principal place of business is, on information and belief, at 10 Knightsbridge Road, Picastaway (sic), New Jersey 08854, and has thereby purposefully and systematically conducted and continues to conduct business in this judicial district.

ANSWER: To conserve the resources of the parties and the Court, InnoPharma Licensing, LLC does not contest personal jurisdiction in this judicial district for the limited purpose of this action only and for the limited purpose of the product covered by ANDA No. 206326 which is the subject of the Complaint. InnoPharma Licensing, LLC denies the remaining allegations in Paragraph 11 of the Complaint.

12. Upon information and belief, this court has jurisdiction over InnoPharma, Inc. Upon information and belief, InnoPharma, Inc. directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by InnoPharma Licensing, Inc. and InnoPharma Licensing, LLC, throughout the United States and in this judicial district. Upon information and belief, InnoPharma, Inc. purposefully has conducted and continues to conduct business in this judicial district.

ANSWER: To conserve the resources of the parties and the Court, InnoPharma, Inc. does not contest personal jurisdiction in this judicial district for the limited purpose of this action only and for the limited purpose of the product covered by ANDA No. 206326 which is the subject of the Complaint. InnoPharma, Inc. otherwise denies the remaining allegations in Paragraph 12 of the Complaint.

13. Upon information and belief, this court has jurisdiction over InnoPharma, LLC. Upon information and belief, InnoPharma, LLC directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by InnoPharma Licensing, Inc. and InnoPharma Licensing, LLC, throughout the United States and in this judicial district. Upon information and belief, InnoPharma, LLC purposefully has conducted and continues to conduct business in this judicial district.

ANSWER: To conserve the resources of the parties and the Court, InnoPharma, LLC does not contest personal jurisdiction in this judicial district for the limited purpose of this action only and for the limited purpose of the product covered by ANDA No. 206326 which is the subject of the Complaint. InnoPharma, LLC otherwise denies the remaining allegations in Paragraph 13 of the Complaint.

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

ANSWER: To conserve the resources of the parties and the Court, Defendants do not contest venue in this judicial district for the limited purpose of this action only. Defendants otherwise deny the remaining allegations of Paragraph 14 of the Complaint.

THE PATENTS IN SUIT

15. The U.S. Patent and Trademark Office (“PTO”) issued the ’431 patent on March 6, 2012. The ’431 patent claims, inter alia, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’431 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’431 patent. A copy of the ’431 patent is attached hereto as Exhibit A.

ANSWER: Defendants admit that the face of the ’431 patent purports the date of the issuance of the patent to be March 6, 2012. Defendants further admit that the face of the ’431 patent currently lists Senju as the assignee of the ’431 patent. Defendants admit that what purports to be a copy of the ’431 patent is attached to the Complaint as Exhibit A. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 15 of the Complaint and therefore deny them.

16. The U.S. Patent and Trademark Office (“PTO”) issued the ’290 patent on March 11, 2014. The ’290 patent claims, inter alia, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’290 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’290 patent. A copy of the ’290 patent is attached hereto as Exhibit B.

ANSWER: Defendants admit that the face of the ’290 patent purports the date of the issuance of the patent to be March 11, 2014. Defendants further admit that the face of the ’290

patent currently lists Senju as the assignee of the '290 patent. Defendants admit that what purports to be a copy of the '290 patent is attached to the Complaint as Exhibit B. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 16 of the Complaint and therefore deny them.

17. The U.S. Patent and Trademark Office ("PTO") issued the '131 patent on June 17, 2014. The '131 patent claims, inter alia, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '131 patent and have the right to sue for infringement thereof. Senju is the assignee of the '131 patent. A copy of the '131 patent is attached hereto as Exhibit C.

ANSWER: Defendants admit that the face of the '131 patent purports the date of the issuance of the patent to be June 17, 2014. Defendants further admit that the face of the '131 patent currently lists Senju as the assignee of the '131 patent. Defendants admit that what purports to be a copy of the '131 patent is attached to the Complaint as Exhibit C. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 17 of the Complaint and therefore deny them.

18. The U.S. Patent and Trademark Office ("PTO") issued the '813 patent on October 28, 2014. The '813 patent claims, inter alia, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '813 patent and have the right to sue for infringement thereof. Senju is the assignee of the '813 patent. A copy of the '813 patent is attached hereto as Exhibit D.

ANSWER: Defendants admit that the face of the '813 patent purports the date of the issuance of the patent to be October 28, 2014. Defendants further admit that the face of the '813 patent currently lists Senju as the assignee of the '813 patent. Defendants admit that what

purports to be a copy of the '813 patent is attached to the Complaint as Exhibit D. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 18 of the Complaint and therefore deny them.

19. B+L is the holder of New Drug Application ("NDA") No. 203168 for Prolensa[®], which the FDA approved on April 5, 2013. In conjunction with NDA No. 203168, the '431 patent, the '290, the '131, and the '813 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

ANSWER: Defendants admit that the Orange Book as of the date of this answer currently lists B+L as the purported registered holder of New Drug Application No. 203168. Defendants further admit that the Orange Book indicates that the FDA approved Prolensa[®] on April 5, 2013. Defendants lack knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 19 of the Complaint, including footnote 1 thereto, and therefore deny them.

20. Bromfenac Ophthalmic Solution 0.07% is sold in the United States under the trademark Prolensa[®].

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20 of the Complaint and therefore denies them.

**AS TO ALLEGED INNOPHARMA LICENSING, INC.'S INFRINGING ANDA
SUBMISSION**

21. Upon information and belief, InnoPharma Licensing, Inc. filed with the FDA ANDA No. 206326, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

ANSWER: Defendants admit that InnoPharma Licensing, Inc. caused submission of an Abbreviated New Drug Application ("ANDA") under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii)). Defendants further admit that the FDA assigned this

application ANDA No. 206326. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 21 of the Complaint and therefore deny them.

22. Upon information and belief, InnoPharma Licensing, Inc.'s ANDA No. 206326 seeks FDA approval to sell in the United States InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa[®].

ANSWER: Defendants aver that InnoPharma Licensing, Inc. caused submission of an Abbreviated New Drug Application ("ANDA") under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii)). Defendants further aver that the FDA assigned this application ANDA No. 206326. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 22 of the Complaint and therefore deny them.

23. B+L received a letter from InnoPharma Licensing, Inc. dated September 19, 2014, purporting to be a Notice of Certification for ANDA No. 206326 ("InnoPharma Licensing Inc.'s notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c).

ANSWER: Defendants aver that by letter dated September 19, 2014 InnoPharma Licensing, Inc. sent the requisite Notification pursuant to 21 U.S.C. § 355(j)(2)(B) to Senju Pharmaceutical, Co., Ltd. and Bausch & Lomb and, in that Notification, InnoPharma Licensing, Inc. advised, among other things, that it had submitted an ANDA seeking FDA approval for bromfenac ophthalmic solution. Defendants deny the remaining allegations of Paragraph 23 of the Complaint.

24. InnoPharma Licensing, Inc.'s notice letter alleges that InnoPharma Licensing, Inc. has submitted to the FDA ANDA No. 206326 seeking FDA approval to sell generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa[®].

ANSWER: Defendants aver that InnoPharma Licensing, Inc. caused submission of an Abbreviated New Drug Application ("ANDA") under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii)). Defendants further aver that the FDA assigned this application ANDA No. 206326. Defendants deny the remaining allegations of Paragraph 24 of the Complaint.

25. Upon information and belief, ANDA No. 206326 seeks approval of InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution that is the same, or substantially the same, as Prolensa[®].

ANSWER: Defendants aver that InnoPharma Licensing, Inc. caused submission of an Abbreviated New Drug Application ("ANDA") under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii)). Defendants further aver that the FDA assigned this application ANDA No. 206326. Defendants deny the remaining allegations of Paragraph 25 of the Complaint.

26. Upon information and belief, InnoPharma Licensing, Inc.'s actions relating to ANDA No. 206326 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of InnoPharma Licensing, LLC, InnoPharma, Inc., and InnoPharma LLC.

ANSWER: Defendants deny the allegations in Paragraph 26 of the Complaint.

COUNT I

Infringement of the '431 Patent under § 271(e)(2)

27. Paragraphs 1-26 are incorporated herein as set forth above.

ANSWER: Defendants repeat and incorporate by reference their responses contained in Paragraphs 1-26 as if fully set forth herein.

28. Under 35 U.S.C. § 271(e)(2), InnoPharma Licensing, Inc. has infringed at least one claim of the '431 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206326 seeking approval for the commercial marketing of InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '431 patent.

ANSWER: Defendants deny the allegations in Paragraph 28 of the Complaint.

29. Upon information and belief, InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '431 patent.

ANSWER: Defendants deny the allegations in Paragraph 29 of the Complaint.

30. Upon information and belief, InnoPharma Licensing, Inc. will, through the manufacture, use import, offer for sale and/or sale of InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '431 patent.

ANSWER: Defendants deny the allegations in Paragraph 30 of the Complaint.

COUNT II

Declaratory Judgment of Infringement of the '431 Patent

31. Paragraphs 1-30 are incorporated herein as set forth above.

ANSWER: Defendants repeat and incorporate by reference their responses contained in Paragraphs 1-30 as if fully set forth herein.

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

ANSWER: Paragraph 32 of the Complaint contains conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 32 of the Complaint.

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

ANSWER: Paragraph 33 of the Complaint contains conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 33 of the Complaint.

34. InnoPharma Licensing, Inc. has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import InnoPharma Licensing Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '431 patent, including InnoPharma Licensing Inc.'s filing of ANDA No. 206326.

ANSWER: Defendants aver that InnoPharma Licensing Inc. caused submission of an Abbreviated New Drug Application ("ANDA") under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii)). Defendants aver that the FDA assigned this application ANDA No. 206326. Defendants deny the remaining allegations of Paragraph 34 of the Complaint.

35. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of InnoPharma Licensing Inc.'s generic bromfenac ophthalmic solution

will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '431 patent.

ANSWER: Defendants deny the allegations in Paragraph 35 of the Complaint.

36. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, and/or importation of InnoPharma Licensing Inc.'s generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '431 patent.

ANSWER: Defendants deny the allegations contained in Paragraph 36 of the Complaint.

COUNT III

Infringement of the '290 Patent under § 271(e)(2)

37. Paragraphs 1-36 are incorporated herein as set forth above.

ANSWER: Defendants repeat and incorporate by reference their responses contained in Paragraphs 1-36 as if fully set forth herein.

38. Under 35 U.S.C. § 271(e)(2), InnoPharma Licensing, Inc. has infringed at least one claim of the '290 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206326 seeking approval for the commercial marketing of InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '290 patent.

ANSWER: Defendants deny the allegations in Paragraph 38 of the Complaint.

39. Upon information and belief, InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '290 patent.

ANSWER: Defendants deny the allegations in Paragraph 39 of the Complaint.

40. Upon information and belief, InnoPharma Licensing, Inc. will, through the manufacture, use import, offer for sale and/or sale of InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '290 patent.

ANSWER: Defendants deny the allegations in Paragraph 40 of the Complaint.

COUNT IV

Declaratory Judgment of Infringement of the '290 Patent

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

ANSWER: Defendants repeat and incorporate by reference their responses contained in Paragraphs 1-40 as if fully set forth herein.

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

ANSWER: Paragraph 42 of the Complaint contains conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 42 of the Complaint.

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

ANSWER: Paragraph 43 of the Complaint contains conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 43 of the Complaint.

44. InnoPharma Licensing, Inc. has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import InnoPharma

Licensing Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '290 patent, including InnoPharma Licensing Inc.'s filing of ANDA No. 206326.

ANSWER: Defendants aver that InnoPharma Licensing Inc. caused submission of an Abbreviated New Drug Application ("ANDA") under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii)). Defendants aver that the FDA assigned this application ANDA No. 206326. Defendants deny the remaining allegations of Paragraph 44 of the Complaint.

45. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of InnoPharma Licensing Inc.'s generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '290 patent.

ANSWER: Defendants deny the allegations in Paragraph 45 of the Complaint.

46. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, and/or importation of InnoPharma Licensing Inc.'s generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '290 patent.

ANSWER: Defendants deny the allegations contained in Paragraph 46 of the Complaint.

COUNT V

Infringement of the '131 Patent under § 271(e)(2)

47. Paragraphs 1-46 are incorporated herein as set forth above.

ANSWER: Defendants repeat and incorporate by reference their responses contained in Paragraphs 1-46 as if fully set forth herein.

48. Under 35 U.S.C. § 271(e)(2), InnoPharma Licensing, Inc. has infringed at least one claim of the '131 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206326 seeking approval for the commercial marketing of InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '131 patent.

ANSWER: Defendants deny the allegations in Paragraph 48 of the Complaint.

49. Upon information and belief, InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '131 patent.

ANSWER: Defendants deny the allegations in Paragraph 49 of the Complaint.

50. Upon information and belief, InnoPharma Licensing, Inc. will, through the manufacture, use import, offer for sale and/or sale of InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '131 patent.

ANSWER: Defendants deny the allegations in Paragraph 50 of the Complaint.

COUNT VI

Declaratory Judgment of Infringement of the '131 Patent

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

ANSWER: Defendants repeat and incorporate by reference their responses contained in Paragraphs 1-50 as if fully set forth herein.

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

ANSWER: Paragraph 52 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 52 of the Complaint.

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

ANSWER: Paragraph 53 of the Complaint contains conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 53 of the Complaint.

54. InnoPharma Licensing, Inc. has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import InnoPharma Licensing Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '131 patent, including InnoPharma Licensing Inc.'s filing of ANDA No. 206326.

ANSWER: Defendants aver that InnoPharma Licensing Inc. caused submission of an Abbreviated New Drug Application ("ANDA") under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii)). Defendants aver that the FDA assigned this application ANDA No. 206326. Defendants deny the remaining allegations of Paragraph 54 of the Complaint.

55. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of InnoPharma Licensing Inc.'s generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '131 patent.

ANSWER: Defendants deny the allegations in Paragraph 55 of the Complaint.

56. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, and/or importation of InnoPharma Licensing Inc.'s generic

bromfenac ophthalmic solution will constitute infringement of at least one claim of the '131 patent.

ANSWER: Defendants deny the allegations contained in Paragraph 56 of the Complaint.

COUNT VII

Infringement of the '813 Patent under § 271(e)(2)

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

ANSWER: Defendants repeat and incorporate by reference their responses contained in Paragraphs 1-56 as if fully set forth herein.

58. Under 35 U.S.C. § 271(e)(2), InnoPharma Licensing, Inc. has infringed at least one claim of the '131 (sic) patent by submitting, or causing to be submitted to the FDA, ANDA No. 206326 seeking approval for the commercial marketing of InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '813 patent.

ANSWER: Defendants deny the allegations in Paragraph 58 of the Complaint.

59. Upon information and belief, InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '813 patent.

ANSWER: Defendants deny the allegations in Paragraph 59 of the Complaint.

60. Upon information and belief, InnoPharma Licensing, Inc. will, through the manufacture, use import, offer for sale and/or sale of InnoPharma Licensing, Inc.'s generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '813 patent.

ANSWER: Defendants deny the allegations in Paragraph 60 of the Complaint.

COUNT VIII

Declaratory Judgment of Infringement of the '813 Patent

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

ANSWER: Defendants repeat and incorporate by reference their responses contained in Paragraphs 1-60 as if fully set forth herein.

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

ANSWER: Paragraph 62 of the Complaint contains conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 62 of the Complaint.

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

ANSWER: Paragraph 63 of the Complaint contains conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 63 of the Complaint.

64. InnoPharma Licensing, Inc. has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import InnoPharma Licensing Inc.'s generic bromfenac ophthalmic solution before the expiration date of the '813 patent, including InnoPharma Licensing Inc.'s filing of ANDA No. 206326.

ANSWER: Defendants aver that InnoPharma Licensing Inc. caused submission of an Abbreviated New Drug Application ("ANDA") under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii)). Defendants aver that the FDA assigned this

application ANDA No. 206326. Defendants deny the remaining allegations of Paragraph 64 of the Complaint.

65. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of InnoPharma Licensing Inc.'s generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '813 patent.

ANSWER: Defendants deny the allegations in Paragraph 65 of the Complaint.

66. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, and/or importation of InnoPharma Licensing Inc.'s generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '813 patent.

ANSWER: Defendants deny the allegations contained in Paragraph 66 of the Complaint.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief requested in Paragraphs 1-9 of the Prayer for Relief in Plaintiffs' Complaint or otherwise.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting any averments of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Defendants aver and assert the following Separate Defenses to the Complaint:

FIRST SEPARATE DEFENSE
(Invalidity)

67. On information and belief, the claims of the '431, '290, '131, and '813 patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of the Patent Laws of the United States, 35 U.S.C. § 1 et seq., including but not limited to §§ 101, 102, 103, and 112.

SECOND SEPARATE DEFENSE
(Non-Infringement)

68. The manufacture, sale, use, offer for sale, or importation of Defendants' proposed bromfenac product that is the subject of ANDA No. 206326, would not infringe, either directly or indirectly, any valid and enforceable claim of the '431, '290, '131, or '813 patents, either literally or under the doctrine of equivalents.

THIRD SEPARATE DEFENSE
(Prosecution History Estoppel)

69. Plaintiffs are estopped and/or precluded from asserting that any proposed bromfenac product that is the subject of ANDA No. 206326 infringes or will infringe the '431, '290, '131, or '813 patents by reason of actions taken and statements made by the applicants of those patents to the United States Patent and Trademark Office ("PTO") during prosecution of the applications which led to the patent.

FOURTH SEPARATE DEFENSE
(Failure to State a Claim)

70. Plaintiffs' Complaint fails to state a claim upon which relief can be granted within the meaning of Rule 12(b)(6) of the Federal Rules of Civil Procedure.

**FIFTH SEPARATE DEFENSE
(No Exceptional Case)**

71. Defendants' actions in defending this case do not give rise to an exceptional case under 35 U.S.C. §§ 271(e)(4) and 285.

**SIXTH SEPARATE DEFENSE
(Unenforceability)**

72. Any additional defenses or counterclaims that discovery may reveal, including unenforceability of the '431, '290, '131, or '813 patents.

**SEVENTH SEPARATE DEFENSE
(Injunctive Relief)**

73. Plaintiffs are not entitled to injunctive relief because Plaintiffs cannot prove (1) that they have suffered irreparable injury; (2) that there is no adequate remedy at law; (3) that a remedy in equity is warranted; and (4) that the public interest warrants an injunction.

COUNTERCLAIMS OF DEFENDANTS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendants/Counterclaim-Plaintiffs InnoPharma Licensing, Inc., InnoPharma Licensing LLC, InnoPharma, Inc., and InnoPharma, LLC (collectively "InnoPharma" or "Defendants/Counterclaim-Plaintiffs"), aver and assert the following Counterclaims against Plaintiffs/Counterclaim-Defendants Senju Pharmaceutical Co., Ltd., Bausch & Lomb Incorporated, and Bausch & Lomb Pharma Holdings Corp., (collectively, "Senju *et al.*") for a declaratory judgment of patent non-infringement and invalidity (or unenforceability), and allege as follows:

THE PARTIES

74. Upon information and belief, and based on Plaintiffs/Counterclaim-Defendants' allegations, Senju Pharmaceutical Co., Ltd. ("Senju") is a corporation organized and existing under the laws of Japan, with a principal place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.

75. Upon information and belief, and based on Plaintiffs/Counterclaim-Defendants' allegations, Bausch & Lomb Incorporated ("B+L") is a corporation organized and existing under the laws of New York, with a place of business at 1400 North Goodman St., Rochester, New York 14609. Upon information and belief, B+L is the current registered holder of approved New Drug Application ("NDA") No. 203168.

76. Upon information and belief, and based on Plaintiffs/Counterclaim-Defendants' allegations, Bausch & Lomb Pharma Holdings Corp. ("B+L Pharma Holdings") is a corporation organized and existing under the laws of Delaware, with a place of business at 700 Route 202/206, Bridgewater, New Jersey 08807. Upon information and belief, and based on Plaintiffs/Counterclaim-Defendants' allegations, B+L Pharma Holdings is a wholly-owned subsidiary of B+L.

77. Defendants/Counterclaim Plaintiffs are corporations organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Piscataway, New Jersey 08854.

JURISDICTION AND VENUE

78. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

79. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

80. This Court has personal jurisdiction over Senju *et al.* because Senju *et al.* has subjected itself to this jurisdiction by suing InnoPharma in this District.

81. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

FACTUAL BACKGROUND

82. Upon information and belief, and based on Plaintiffs/Counterclaim-Defendants' allegations, Counterclaim-defendant B+L is the current holder of New Drug Application No. 203168 ("NDA") for the manufacture and sale of Prolensa®.

83. Upon information and belief, and based on Plaintiffs/Counterclaim-Defendants' allegations, Counterclaim-defendant B+L sells bromfenac ophthalmic solution in the United States under the trade name the Prolensa® which was approved by the United States Food and Drug Administration ("FDA") on April 5, 2013.

84. Upon information and belief, and based on Counterclaim-Defendants' allegations, Counterclaim-Defendant Senju is the purported owner of record and the purported assignee of U.S. Patent Nos. 8,129,431 ("the '431 patent"), 8,669,290 ("the '290 patent"), 8,754,131 ("the '131 patent"), and 8,871,813 ("the '813 patent") (collectively "the patents-in-suit").

85. Counterclaim-Defendants have informed the United States Food and Drug Administration ("FDA") of the unexpired patents-in-suit with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use of sale of bromfenac ophthalmic solution. This patent is listed by the FDA in its publication "*Approved Drug Products with Therapeutic Equivalence Evaluations*," commonly referred to as the "Orange Book" for the NDA. *See* 21 U.S.C. § 355(j)(7).

86. By listing the patents-in-suit in the Orange Book, B+L is purportedly representing to the world that the patents-in-suit covers bromfenac, and that an infringement suit could be alleged against any generic ANDA applicant, InnoPharma, that attempts to seek approval for, and market, a generic version of bromfenac before the patent's expiration.

87. InnoPharma Licensing Inc. holds Abbreviated New Drug Application ("ANDA") No. 206326 for bromfenac ophthalmic solution.

88. InnoPharma Licensing, Inc. filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") certifying that the patents-in-suit listed in the Orange Book are either invalid, unenforceable, or will not be infringed by the manufacture, use, offer for sale, importation, or sale of bromfenac ("Proposed Product"). In accordance with 35 U.S.C. § 355(j)(2)(B)(i) and (ii), InnoPharma Licensing, Inc. mailed a notice dated September 19, 2014 to Senju Pharmaceutical, Co., Ltd. and Bausch & Lomb that it had filed such a Paragraph IV Certification and provided the factual and legal bases for that Certification.

89. On November 3, 2014, Senju *et al.* sued InnoPharma in this district alleging infringement of the patents-in-suit on InnoPharma's ANDA No. 206326. Accordingly, an actual, substantial and continuing justiciable case and controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between Senju *et al.* and InnoPharma regarding the patents-in-suit, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

90. Defendants/Counterclaim-Plaintiffs are statutorily entitled to bring and maintain this action for declaratory judgment pursuant to the Medical Modernization Act in order to obtain patent certainty. 21 U.S.C. § 355(j)(5)(C); *see also* 35 U.S.C. § 271(e)(5).

91. As a result of any exclusion of Defendants/Counterclaim-Plaintiffs from the marketplace, Defendants/Counterclaim-Plaintiffs and the public will be irreparably harmed by the potential indefinite delay in the market entry and availability of a lower-priced bromfenac product.

92. This case is exceptional pursuant to 35 U.S.C. § 285 and Defendants/Counterclaim-Plaintiffs are entitled to reasonable attorney fees pursuant to that statute.

FIRST COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '431 PATENT

93. Defendants/Counterclaim-Plaintiffs re-assert, re-allege, and incorporate by reference each of the foregoing Paragraphs of its Separate Defenses and Counterclaims, above, as if fully set forth herein.

94. The manufacture, use, sale, offer for sale, or importation of bromfenac ophthalmic solution that is the subject of InnoPharma Licensing, Inc.'s ANDA No. 206326 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '431 patent.

95. Defendants/Counterclaim-Plaintiffs and Senju *et al.* have adverse legal interests, and there is a substantial controversy between Defendants/Counterclaim-Plaintiffs and Senju *et al.* of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the '431 patent. Therefore, an actual, substantial and continuing justiciable case and controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between Defendants/Counterclaim-Plaintiffs and Senju *et al.* regarding, *inter alia*, the infringement of any valid or enforceable claim of the '431 patent.

96. Defendants/Counterclaim-Plaintiffs are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the bromfenac ophthalmic solution that is the subject of InnoPharma Licensing, Inc.'s ANDA No. 206326 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '431 patent.

SECOND COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '431 PATENT

97. Defendants/Counterclaim-Plaintiffs re-assert, re-allege, and incorporate by reference each of the foregoing Paragraphs of its Separate Defenses and Counterclaims, above, as if fully set forth herein.

98. An actual and justiciable case or controversy exists between Defendants/Counterclaim-Plaintiffs and Senju *et al.* as to invalidity of the '431 patent.

99. The claims of the '431 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and 112.

100. As a direct and proximate result of Senju *et al.*'s assertion of '431 patent, Defendants/Counterclaim-Plaintiffs have suffered, and are suffering, irreparable injury to their reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

101. Defendants/Counterclaim-Plaintiffs are entitled to a judicial declaration that the claims of the '431 patent is invalid.

THIRD COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '290 PATENT

102. Defendants/Counterclaim-Plaintiffs re-assert, re-allege, and incorporate by reference each of the foregoing Paragraphs of its Separate Defenses and Counterclaims, above, as if fully set forth herein.

103. The manufacture, use, sale, offer for sale, or importation of bromfenac ophthalmic solution that is the subject of InnoPharma Licensing Inc.'s ANDA No. 206326 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '290 patent.

104. Defendants/Counterclaim-Plaintiffs and Senju *et al.* have adverse legal interests, and there is a substantial controversy between Defendants/Counterclaim-Plaintiffs and Senju *et al.* of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the '290 patent. Therefore, an actual, substantial and continuing justiciable case and controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between Defendants/Counterclaim-Plaintiffs and Senju *et al.* regarding, *inter alia*, the infringement of any valid or enforceable claim of the '290 patent.

105. Defendants/Counterclaim-Plaintiffs are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the bromfenac ophthalmic solution that is the subject of InnoPharma Licensing, Inc.'s ANDA No. 206326 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '290 patent.

FOURTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '290 PATENT

106. Defendants/Counterclaim-Plaintiffs re-assert, re-allege, and incorporate by reference each of the foregoing Paragraphs of its Separate Defenses and Counterclaims, above, as if fully set forth herein.

107. An actual and justiciable case or controversy exists between Defendants/Counterclaim-Plaintiffs and Senju *et al.* as to invalidity of the '290 patent.

108. The claims of the '290 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and 112.

109. As a direct and proximate result of Senju *et al.*'s assertion of '290 patent, Defendants/Counterclaim-Plaintiffs have suffered, and are suffering, irreparable injury to their reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

110. Defendants/Counterclaim-Plaintiffs are entitled to a judicial declaration that the claims of the '290 patent is invalid.

FIFTH COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '131 PATENT

111. Defendants/Counterclaim-Plaintiffs re-assert, re-allege, and incorporate by reference each of the foregoing Paragraphs of its Separate Defenses and Counterclaims, above, as if fully set forth herein.

112. The manufacture, use, sale, offer for sale, or importation of bromfenac ophthalmic solution that is the subject of InnoPharma Licensing Inc.'s ANDA No. 206326 has not infringed,

does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '131 patent.

113. Defendants/Counterclaim-Plaintiffs and Senju *et al.* have adverse legal interests, and there is a substantial controversy between Defendants/Counterclaim-Plaintiffs and Senju *et al.* of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the '131 patent. Therefore, an actual, substantial and continuing justiciable case and controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between Defendants/Counterclaim-Plaintiffs and Senju *et al.* regarding, *inter alia*, the infringement of any valid or enforceable claim of the '131 patent.

114. Defendants/Counterclaim-Plaintiffs are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the bromfenac ophthalmic solution that is the subject of InnoPharma Licensing Inc.'s ANDA No. 206326 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '131 patent.

SIXTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '131 PATENT

115. Defendants/Counterclaim-Plaintiffs re-assert, re-allege, and incorporate by reference each of the foregoing Paragraphs of its Separate Defenses and Counterclaims, above, as if fully set forth herein.

116. An actual and justiciable case or controversy exists between Defendants/Counterclaim-Plaintiffs and Senju *et al.* as to invalidity of the '131 patent.

117. The claims of the '131 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and 112.

118. As a direct and proximate result of Senju *et al.*'s assertion of '131 patent, Defendants/Counterclaim-Plaintiffs have suffered, and are suffering, irreparable injury to their reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

119. Defendants/Counterclaim-Plaintiffs are entitled to a judicial declaration that the claims of the '131 patent is invalid.

SEVENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '813 PATENT

120. Defendants/Counterclaim-Plaintiffs re-assert, re-allege, and incorporate by reference each of the foregoing Paragraphs of its Separate Defenses and Counterclaims, above, as if fully set forth herein.

121. The manufacture, use, sale, offer for sale, or importation of bromfenac ophthalmic solution that is the subject of InnoPharma Licensing Inc.'s ANDA No. 206326 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '813 patent.

122. Defendants/Counterclaim-Plaintiffs and Senju *et al.* have adverse legal interests, and there is a substantial controversy between Defendants/Counterclaim-Plaintiffs and Senju *et al.* of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the '813 patent. Therefore, an actual, substantial and

continuing justiciable case and controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between Defendants/Counterclaim-Plaintiffs and Senju *et al.* regarding, *inter alia*, the infringement of any valid or enforceable claim of the '813 patent.

123. Defendants/Counterclaim-Plaintiffs are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the bromfenac ophthalmic solution that is the subject of InnoPharma Licensing Inc.'s ANDA No. 206326 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '813 patent.

EIGHTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '813 PATENT

124. Defendants/Counterclaim-Plaintiffs re-assert, re-allege, and incorporate by reference each of the foregoing Paragraphs of its Separate Defenses and Counterclaims, above, as if fully set forth herein.

125. An actual and justiciable case or controversy exists between Defendants/Counterclaim-Plaintiffs and Senju *et al.* as to invalidity of the '813 patent.

126. The claims of the '813 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and 112.

127. As a direct and proximate result of Senju *et al.*'s assertion of '813 patent, Defendants/Counterclaim-Plaintiffs have suffered, and are suffering, irreparable injury to their reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real

and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

128. Defendants/Counterclaim-Plaintiffs are entitled to a judicial declaration that the claims of the '813 patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully pray for judgment in its favor and against Plaintiffs:

- (a) Dismissing with prejudice Plaintiffs' Complaint against Defendants;
- (b) Denying Plaintiffs the relief requested in the Complaint;
- (c) Declaring that the manufacture, use, sale, offer for sale, or importation into the United States of the bromfenac ophthalmic solution that is the subject of InnoPharma Licensing Inc.'s ANDA No. 206326 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '431 patent;
- (d) Declaring that the claims of the '431 patent are invalid;
- (e) Declaring that the manufacture, use, sale, offer for sale, or importation into the United States of the bromfenac ophthalmic solution that is the subject of InnoPharma Licensing Inc.'s ANDA No. 206326 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '290 patent;
- (f) Declaring that the claims of the '290 patent are invalid;
- (g) Declaring that the manufacture, use, sale, offer for sale, or importation into the United States of the bromfenac ophthalmic solution that is the subject of InnoPharma Licensing Inc.'s ANDA No. 206326 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '131 patent;

- (h) Declaring that the claims of the '131 patent are invalid;
- (i) Declaring that the manufacture, use, sale, offer for sale, or importation into the United States of the bromfenac ophthalmic solution that is the subject of InnoPharma Licensing Inc.'s ANDA No. 206326 has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '813 patent;
- (j) Declaring that the claims of the '813 patent are invalid;
- (k) Declaring this case exceptional and awarding Defendants reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and
- (l) Awarding Defendants such other and further relief as the Court may deem just and proper

Dated: January 23, 2015

Respectfully submitted,

SAIBER LLC

*Attorneys for Defendants InnoPharma
Licensing, Inc., InnoPharma Licensing LLC,
InnoPharma, Inc., and InnoPharma, LLC*

s/ Arnold B. Calmann

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Defendants InnoPharma Licensing, Inc., InnoPharma Licensing LLC, InnoPharma, Inc., and InnoPharma, LLC, by their undersigned counsel, hereby certify on information and belief that the matters in controversy are the subject of other actions pending in court based upon the Local Civil Rule 11.2 Certification filed by Plaintiffs' counsel (Melissa A. Chuderewicz, Esq. of Pepper Hamilton LLP) at ECF No. 1-6, as well as a recently filed matter, *Senju Pharmaceutical Co., Ltd. v. Paddock Laboratories, LLC*, 1:15-cv-00337-JBS-KMW.

Dated: January 23, 2015

s/ Arnold B. Calmann
Arnold B. Calmann

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Defendants InnoPharma Licensing, Inc., InnoPharma Licensing LLC, InnoPharma, Inc., and InnoPharma, LLC (“Defendants”), hereby certifies that Defendants seek declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: January 23, 2015

s/ Arnold B. Calmann
Arnold B. Calmann