

**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,	)	Civil Action No.:
	)	
v.	)	
	)	
METRICS, INC., COASTAL	)	
PHARMACEUTICALS, INC., MAYNE	)	
PHARMA GROUP LIMITED, and MAYNE	)	
PHARMA (USA), INC.,	)	

Defendants.

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Senju Pharmaceutical Co., Ltd., Bausch & Lomb Incorporated and Bausch & Lomb Pharma Holdings Corp. (collectively, "Plaintiffs") by way of Complaint against Defendants Metrics, Inc. ("Metrics"), Coastal Pharmaceuticals, Inc. ("Coastal"), Mayne Pharma Group Limited ("Mayne Pharma"), and Mayne Pharma (USA), Inc. ("Mayne Pharma USA") (collectively, "Defendants") allege 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.

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 No. 203168, which covers Prolensa<sup>®</sup>.

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

4. Upon information and belief, defendant Metrics is a corporation organized and existing under the laws of North Carolina, having a place of business at 1240 Sugg Parkway, Greenville, NC 27834. Upon information and belief, defendant Metrics, Inc. is a wholly-owned subsidiary of defendant Mayne Pharma.

5. Upon information and belief, defendant Coastal is a corporation organized and existing under the laws of North Carolina, having a place of business at 1240 Sugg Parkway, Greenville, NC 27834. Upon information and belief, defendant Coastal is a wholly-owned subsidiary of defendant Mayne Pharma.

6. Upon information and belief, defendant Mayne Pharma is a corporation organized and existing under the laws of Australia, having a place of business at Level 14, 474 Flinders Street, Melbourne VIC 3000, Australia.

7. Upon information and belief, defendant Mayne Pharma USA is a corporation organized and existing under the laws of New Jersey, having a place of business at 650 From Road, 2<sup>nd</sup> Floor, Mack Cali Centre, Paramus, NJ 07652. Upon information and belief, defendant Mayne Pharma USA is a wholly-owned subsidiary of defendant Mayne Pharma.

#### **NATURE OF THE ACTION**

8. This is an action for infringement of United States Patent Nos. 8,129,431 (“the ’431 patent”), 8,669,290 (“the ’290 patent”), and 8,754,131 (“the ’131 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement of the ’431 patent, the ’290 patent,

and the '131 patent under 28 U.S.C. §§ 2201 and 2202. This action relates to Metrics' filing of Abbreviated New Drug Application ("ANDA") No. 206257 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% ("Metrics' generic bromfenac ophthalmic solution").

### **JURISDICTION AND VENUE**

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

10. Upon information and belief, this Court has jurisdiction over Metrics. Upon information and belief, Metrics is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Metrics directly 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 Metrics' generic bromfenac ophthalmic solution. Upon information and belief, Metrics purposefully has conducted and continues to conduct business in this judicial district.

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

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

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

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

#### **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.

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.

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.

18. B+L is the holder of New Drug Application (“NDA”) No. 203168 for Prolensa<sup>®</sup>, which the FDA approved on April 5, 2013. In conjunction with NDA No. 203168, the ’431, ’290, and ’131 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

19. Bromfenac Ophthalmic Solution 0.07% is sold in the United States under the trademark Prolensa<sup>®</sup>.

**METRICS’ INFRINGING ANDA SUBMISSION**

20. Upon information and belief, Metrics filed with the FDA ANDA No. 206257, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

21. Upon information and belief, Metrics’ ANDA No. 206257 seeks FDA approval to sell in the United States Metrics’ generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa<sup>®</sup>.

22. Bausch & Lomb received a letter from Coastal dated June 26, 2014, purporting to be a Notice of Certification for ANDA No. 206257 (“Metrics’ 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).

23. Metrics’ notice letter alleges that Metrics has submitted to the FDA ANDA No. 206257 seeking FDA approval to sell generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa<sup>®</sup>.

24. Upon information and belief, ANDA No. 206257 seeks approval of Metrics’ generic bromfenac ophthalmic solution that is the same, or substantially the same, as Prolensa<sup>®</sup>.

25. Upon information and belief, Metrics' actions relating to ANDA No. 206257 were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Coastal, Mayne Pharma, and Mayne Pharma USA.

**COUNT I**

**Infringement of the '431 Patent Under 35 U.S.C. § 271(e)(2)**

26. Paragraphs 1-25 are incorporated herein as set forth above.

27. Under 35 U.S.C. § 271(e)(2), Metrics has infringed at least one claim of the '431 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206257 seeking approval for the commercial marketing of Metrics' generic bromfenac ophthalmic solution before the expiration date of the '431 patent.

28. Upon information and belief, Metrics' generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '431 patent.

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

**COUNT II**

**Declaratory Judgment of Infringement of the '431 Patent**

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

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

32. 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.

33. Metrics has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Metrics' generic bromfenac ophthalmic solution before the expiration date of the '431 patent, including Metrics' filing of ANDA No. 206257.

34. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Metrics' generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '431 patent.

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

### **COUNT III**

#### **Infringement of the '290 Patent Under 35 U.S.C. § 271(e)(2)**

36. Paragraphs 1-35 are incorporated herein as set forth above.

37. Under 35 U.S.C. § 271(e)(2), Metrics has infringed at least one claim of the '290 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206257 seeking approval for the commercial marketing of Metrics' generic bromfenac ophthalmic solution before the expiration date of the '290 patent.

38. Upon information and belief, Metrics' generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '290 patent.

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

**COUNT IV**

**Declaratory Judgment of Infringement of the '290 Patent**

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

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

42. 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.

43. Metrics has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Metrics' generic bromfenac ophthalmic solution before the expiration date of the '290 patent, including Metrics' filing of ANDA No. 206257.

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

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

**COUNT V**

**Infringement of the '131 Patent Under 35 U.S.C. § 271(e)(2)**

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

47. Under 35 U.S.C. § 271(e)(2), Metrics has infringed at least one claim of the '131 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206257 seeking

approval for the commercial marketing of Metrics' generic bromfenac ophthalmic solution before the expiration date of the '131 patent.

48. Upon information and belief, Metrics' generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '131 patent.

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

### **COUNT VI**

#### **Declaratory Judgment of Infringement of the '131 Patent**

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

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

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

53. Metrics has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Metrics' generic bromfenac ophthalmic solution before the expiration date of the '131 patent, including Metrics' filing of ANDA No. 206257.

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

55. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Metrics' generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '131 patent.

**PRAYER FOR RELIEF**

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

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '431 patent through Metrics' submission of ANDA No. 206257 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Metrics' generic bromfenac ophthalmic solution before the expiration of the '431 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '290 patent through Metrics' submission of ANDA No. 206257 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Metrics' generic bromfenac ophthalmic solution before the expiration of the '290 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '131 patent through Metrics' submission of ANDA No. 206257 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Metrics' generic bromfenac ophthalmic solution before the expiration of the '131 patent;

4. declare under 28 U.S.C. § 2201 that if Metrics or any person acting or attempting to act in concert with Metrics engages in the manufacture, use, offer for sale, sale and/or importation of Metrics' generic bromfenac ophthalmic solution, it will infringe at least one claim of the '431 patent.

5. declare under 28 U.S.C. § 2201 that if Metrics or any person acting or attempting to act in concert with Metrics engages in the manufacture, use, offer for sale, sale and/or importation of Metrics' generic bromfenac ophthalmic solution, it will infringe at least one claim of the '290 patent.

6. declare under 28 U.S.C. § 2201 that if Metrics or any person acting or attempting to act in concert with Metrics engages in the manufacture, use, offer for sale, sale and/or importation of Metrics' generic bromfenac ophthalmic solution, it will infringe at least one claim of the '131 patent.

7. order that the effective date of any approval by the FDA of Metrics' generic bromfenac ophthalmic solution be a date that is not earlier than the expiration of the '431 patent, '290 patent, and '131 patent or such later date as the Court may determine;

8. enjoin Defendants from the commercial manufacture, use, import, offer for sale and/or sale of Metrics' generic bromfenac ophthalmic solution until expiration of the '431 patent, '290 patent, and '131 patent or such later date as the Court may determine;

9. enjoin Metrics and all persons acting in concert with Metrics from seeking, obtaining or maintaining approval of Metrics' ANDA No. 206257 until expiration of the '431 patent, '290 patent, and '131 patent;

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

11. award Plaintiff such further and additional relief as this Court deems just and proper.

Dated: August 7, 2014

Respectfully submitted,

/s John F. Brenner

John F. Brenner  
PEPPER HAMILTON, LLP  
Suite 400  
301 Carnegie Center  
Princeton, New Jersey, 08543-5276  
(609) 951-4193  
brennerj@pepperlaw.com

*Attorneys for Plaintiffs*  
*SENJU PHARMACEUTICAL CO., LTD.,*  
*BAUSCH & LOMB, INC. and BAUSCH & LOMB*  
*PHARMA HOLDINGS CORP.*

**Of Counsel:**

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