

**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 patent (“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 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% ("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 holds 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 1, 2014. The ’290 patent claims, inter alia, formulations of bromfenac for ophthalmic administration. Plaintiffs holds 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 holds 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 and ’290 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 an ANDA for a generic version of Prolensa<sup>®</sup> under Section 505(j) of the Act and 21 U.S.C. § 355(j) containing a Paragraph IV certification to the ’431 patent.

21. Upon information and belief, Metrics’ ANDA 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. Upon information and belief, Metrics’ actions relating to the ANDA complained of herein 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)**

23. Paragraphs 1-22 are incorporated herein as set forth above.

24. 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, an ANDA seeking approval for the

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