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Attorneys for Defendants Metrics, Inc., Coastal Pharmaceuticals, Inc., Mayne Pharma Group Limited, and Mayne Pharma (USA), Inc.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

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

Plaintiffs, CIVIL ACTION NO. 1:14-CV-03962-

JBS-KMW

V.

METRICS, INC., COASTAL

PHARMACEUTICALS, INC., MAYNE

PHARMA GROUP LIMITED, and MAYNE

PHARMA (USA), INC.,

Defendants.

DECLARATION OF STEFAN J. CROSS



- I, Stefan J. Cross, hereby declare as follows:
- 1. I am currently the President of Mayne Pharma Group Ltd.'s ("Mayne Pharma's") operations in the USA, and have held this position since November 2013. Prior to assuming my current role, I was Vice President, Business and Corporate Development for Mayne Pharma. My responsibilities include leading Mayne Pharma operations in the USA, including the development and manufacture of U.S. generic and specialty pharmaceutical products, Metrics' contract services business, as well as other related U.S. business development initiatives.
- 2. I have reviewed the Complaint filed by Senju Pharmaceutical Co., Ltd., Bausch & Lomb, Inc., and Bausch & Lomb Pharma Holdings
 Corporation in the District of New Jersey on June 20, 2014. I submit this declaration in support of Defendants Metrics, Inc.'s ("Metrics"), Coastal Pharmaceuticals, Inc.'s ("Coastal"), Mayne Pharma Group Limited's ("Mayne Pharma"), and Mayne Pharma (USA), Inc.'s Motion to Dismiss the Complaint.
- 3. The information in this declaration is based on my personal knowledge and information made available to me in the course of performing my duties as President of Mayne Pharma's operations in the USA. If called as a witness, I could and would testify competently to the matters discussed below.



- 4. Mayne Pharma is a specialty pharmaceutical company that specializes in the development and manufacture of specialty and generic pharmaceutical products.
- 5. Mayne Pharma does not have any offices, facilities or other real property in the State of New Jersey. Rather, it is an Australian-based company, with its primary place of business in Melbourne, Australia. It comprises three operating segments:
- (i) Mayne Pharma International, where revenues and gross profits are derived principally from Australian manufacture and sale of specialty and generic pharmaceutical product globally and provision of contract manufacturing services to third party customers within Australia;
- (ii) US Products, where revenues and gross profits are derived principally from the manufacture and distribution of generic and specialty pharmaceutical products in the US; and
- (iii) Metrics Contract Services, where revenues and gross profits are derived principally from the provision of contract pharmaceutical development services to third-party customers principally in the USA.
- 6. The first and third business segments are not relevant to the ANDA which is the subject of the Complaint.



- 7. The second business segment is carried out in part by Metrics and in part by Libertas Pharma Inc. ("Libertas"), an entity incorporated in Georgia which is a wholly owned subsidiary of Mayne Pharma. Libertas has no interest in, or involvement with the ANDA which is the subject of the Complaint.
- 8. Metrics, a wholly owned subsidiary of Mayne Pharma, is organized under the laws of North Carolina, with a principal place of business in Greenville, North Carolina. *See,* Ex 1, Metrics Cert. of Assumed Name, 7/28/2014. Metrics does not have any offices, facilities or other real property in the State of New Jersey.
- 9. Mayne Pharma has no interest in, or involvement with, the ANDA which is the subject of the Complaint, other than indirectly as the parent of Metrics.
- 10. Mayne Pharma USA is not a recognized separate legal entity.

 Rather, it is a d/b/a entity of Metrics. Metrics is registered in certain states in the US (excluding New Jersey) to do business as Mayne Pharma.
- 11. I am aware of a non-related company that once traded in New Jersey under the legal name of Mayne Pharma (USA), Inc., which had a place of business in Paramus, NJ. I do not know if this entity still exists. It if does exist, it is not under common ownership or control with Mayne Pharma or Metrics. It does



not have any interest in, or involvement with, the ANDA which is the subject of the Complaint.

- 12. Coastal is also not a recognized separate legal entity. Rather, Coastal is a trading name ("assumed name") of Metrics, Inc., used in the marketplace to distinguish Metric Contract Services business segment from its pharmaceutical products business. *See*, Exhibit 2, Coastal Corp. Cert. of Assumed Name, 4/2/2007.
- 13. I am aware that Metrics, by and through its assumed name, Coastal, submitted to the FDA ANDA No. 206257, seeking approval to market a generic bromfenac sodium opthalmic solution 0.07% in the United States. The ANDA was prepared in North Carolina and filed in Maryland. No part of the ANDA product was developed, tested, or prepared in the State of New Jersey.
- 14. Metrics, has only one New Jersey employee, who is based out of a home office and is solely associated with the Metrics Contract Services business segment and has no association with the development and manufacturing of pharmaceutical products to be marketed or sold by any entity in the Mayne Pharma group.
- 15. There have been no sales of generic bromfenac opthalmic solutions that are the subject of ANDA No. 206257 in the State of New Jersey.

 Further, there have been no direct sales of products or services by Mayne Pharma



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