**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF SOUTH CAROLINA**
**CHARLESTON DIVISION**

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| MEDICAL UNIVERSITY OF SOUTH CAROLINA FOUNDATION FOR RESEARCH DEVELOPMENT and<br><br>CHARLESTON MEDICAL THERAPEUTICS, INC.,<br><br>Plaintiffs,<br><br>v.<br><br>ASTRAZENECA PHARMACEUTICALS LP,<br><br>Defendant. | C/A No. 2:13-cv-2078-SB<br><br>PLAINTIFFS' ORIGINAL COMPLAINT AND DEMAND FOR JURY TRIAL |

**ORIGINAL COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Medical University of South Carolina Foundation for Research Development (the "Research Foundation") and Charleston Medical Therapeutics, Inc. ("CMT") (collectively, the "Plaintiffs") file this Original Complaint against Defendant AstraZeneca Pharmaceuticals LP ("AstraZeneca" or "Defendant") for infringement of U.S. Patent No. 6,511,800 (the "'800 Patent") under 35 U.S.C. § 271 and hereby allege as follows:

**PARTIES**

1. The Research Foundation is a not for profit entity affiliated with the Medical University of South Carolina ("MUSC") and serves as MUSC's technology transfer office. MUSC is a public institution of higher learning located in Charleston, South Carolina. MUSC was chartered by South Carolina in 1823 and is located at 171 Ashley Avenue, Charleston, South Carolina 29425. The Research Foundation is located at 19 Hagood Avenue, Suite 909, Charleston, South Carolina 29403.

2. CMT is a corporation organized under the laws of South Carolina, having a principal place of business at 2637 Anchor Watch Drive, Wadmalaw Island, South Carolina 29487.

3. Upon information and belief, AstraZeneca is a limited partnership organized under the laws of Delaware and conducts business throughout the United States, including within this District. AstraZeneca has a principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850. AstraZeneca's registered agent in South Carolina is CT Corporation System, 2 Office Park Court, Suite 103, Columbia, South Carolina 29223.

## JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This Court has exclusive subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1338.

5. This Court has personal jurisdiction over AstraZeneca. AstraZeneca does extensive business in South Carolina and has committed acts of infringement within the State, as herein alleged. As set forth in Paragraph 3, AstraZeneca maintains a registered agent for service of process in South Carolina. By virtue of these contacts, this Court has personal jurisdiction over AstraZeneca.

6. Venue in this district is proper under 28 U.S.C. §§ 1391(c) and 1400 because AstraZeneca has committed, and continues to commit, acts of infringement in this District and is subject to personal jurisdiction within this state. Additionally, AstraZeneca is currently involved in other litigation in this District related to Crestor®. *See Palmetto Pharms. LLC v. AstraZeneca Pharms. LP*, Civ. Action No. 2:11-CV-00807-SB-JDA (Apr. 5, 2011).

**INFRINGEMENT OF U.S. PATENT NO. 6,511,800**

7. Plaintiffs refer to and incorporate herein the allegations of Paragraphs 1-6 above.

8. On January 28, 2003, after a full and fair examination, the United States Patent and Trademark Office duly and legally issued the '800 Patent, entitled "Methods of Treating Nitric Oxide and Cytokine Mediated Disorders," naming Dr. Inderjit Singh as the sole inventor. Dr. Singh is currently, and has been for nearly three decades, a scientist at MUSC and has been awarded the title Distinguished University Professor. Plaintiffs are the assignees of all right, title, and interest in and to the '800 Patent and possess all rights of recovery under the '800 Patent. A copy of the '800 Patent is attached as Exhibit A.

9. AstraZeneca manufactures, uses, sells, and/or markets the drug rosuvastatin calcium throughout the United States and in this District under the trade name Crestor®. Rosuvastatin calcium belongs to a class of drugs called statins. There is currently no generic form of Crestor® available in the United States.

10. AstraZeneca sponsored a clinical trial known as the "JUPITER" Trial ("Justification for the Use of statins in Primary prevention: an Intervention Trial Evaluating Rosuvastatin") in order to obtain approval by the U.S. Food & Drug Administration ("FDA") for the use of Crestor® as a treatment to prevent or reduce the risk of cardiovascular disease or stroke.

11. The purpose of the JUPITER Trial was to evaluate whether patients who had an indication of vascular inflammation could benefit from taking Crestor® to prevent or reduce the risk of cardiovascular disease or stroke.

12. In approximately 2008, following the successful completion of the JUPITER Trial, AstraZeneca requested approval by the FDA to market Crestor® for the treatment of

cardiovascular disease and/or stroke in patients that possess an indication of vascular inflammation but who do not have high cholesterol (the "JUPITER Indications").

13. On December 15, 2009, an Advisory Committee of the FDA convened a meeting to consider AstraZeneca's request to market Crestor® for the JUPITER Indications. At that meeting, the Advisory Committee received presentations and public comments relating to the JUPITER Indications, including several presentations from AstraZeneca personnel or consultants urging the FDA Advisory Committee to approve the use of Crestor® for the Jupiter Indications.

14. Dr. Paul Ridker, a researcher at the Brigham and Women's Hospital in Boston, Massachusetts and consultant for AstraZeneca, served as the Principal Investigator of the JUPITER Trial and chaired the Independent Steering Committee of the JUPITER Trial. At the December 15, 2009 FDA Advisory Committee Meeting, Dr. Ridker made presentations in support of FDA approval to sell, market, and distribute Crestor® for the JUPITER Indications.

15. Also presenting at the FDA Advisory Committee Meeting on behalf of AstraZeneca were the following individuals: (a) Dr. Jonathan Fox, Vice President of Clinical Development for Cardiovascular and Gastrointestinal Diseases at AstraZeneca; (b) Dr. Michael Cressman, Medical Science Director for the rosuvastatin calcium (i.e., Crestor®) clinical development program at AstraZeneca; and (c) Dr. Antonio Gotto, who served on the steering committee of the JUPITER Trial and as a consultant to AstraZeneca.

16. The FDA approved the use of Crestor® for the JUPITER Indications on February 8, 2010. The FDA announced on its website: "This is the first time Crestor® has been approved for use in the prevention of heart disease in individuals with 'normal' low-density lipoprotein (LDL) cholesterol levels and no clinically evident heart disease."

**COUNT ONE: DIRECT INFRINGEMENT OF THE '800 PATENT**

17. The allegations of Paragraphs 1-16 are realleged and incorporated as if fully alleged herein.

18. During the course of the JUPITER Trial, AstraZeneca infringed the claims of the '800 Patent, at least by using Crestor® to treat patients who had an indication of inflammation.

19. As part of the JUPITER Trial, physicians and other health care professionals infringed the claims of the '800 Patent, at least by using Crestor® to treat patients who had an indication of inflammation.

20. AstraZeneca's acts constitute infringement of the claims of the '800 Patent.

21. In addition, the administration of Crestor® by physicians or other medical professionals constitute acts of direct infringement of the claims of the '800 Patent.

**COUNT TWO: INDUCED INFRINGEMENT OF THE '800 PATENT**

22. The allegations of Paragraphs 1-21 are realleged and incorporated as if fully alleged herein.

23. Through its marketing materials, label/package insert, website, and other promotional materials, AstraZeneca encourages, aids, instructs, and causes the public, including doctors and other health care professionals, to use Crestor® in a manner that infringes the claims of the '800 Patent.

24. Through its marketing materials, label/package insert, website, and funded publications related to Crestor®, AstraZeneca encourages, aids, instructs, and causes doctors and/or other medical professionals to prescribe and/or provide Crestor® in a manner that infringes the claims of the '800 Patent.

25. In addition, AstraZeneca employs pharmaceutical sales specialists in South Carolina, and throughout this country, who encourage, *inter alia*, doctors and/or other medical

professionals to prescribe and/or provide Crestor® in a manner that infringes the claims of the '800 Patent.

26. AstraZeneca has had knowledge of the '800 Patent since before the start of the JUPITER Trial and was previously informed that the manufacture, use, sale, and/or provision of Crestor® for the Jupiter Indications would infringe the claims of the '800 Patent. Nevertheless, AstraZeneca continues to intentionally encourage, aid, instruct, or otherwise cause others (including physicians and other healthcare professionals) to infringe the claims of the '800 Patent.

27. Since AstraZeneca first received notice that its conduct would unlawfully infringe the '800 Patent, AstraZeneca did not provide Plaintiffs with any defense to the alleged infringement.

28. AstraZeneca's acts constitute active inducement of infringement of the MUSC patent, and it is liable as an infringer.

**COUNT THREE: WILLFUL INFRINGEMENT OF THE '800 PATENT**

29. The allegations of Paragraphs 1-28 are realleged and incorporated as if fully alleged herein.

30. Prior to this lawsuit, AstraZeneca was notified that Plaintiffs owned the '800 Patent, which covered the use of statins, such as Crestor®, to treat inflammatory diseases, such as cardiovascular disease.

31. Prior to this lawsuit, Plaintiffs specifically indicated to AstraZenica that the JUPITER Trial would infringe the claims of the '800 Patent.

32. Despite this notice, AstraZeneca refused to license the '800 Patent, and continued to infringe the claims of the '800 Patent by directly infringing as well as encouraging, aiding, promoting, and otherwise causing others to infringe the '800 Patent.

33. At least as of the date of this filing, AstraZeneca has never indicated to Plaintiffs that it had a good faith defense to Plaintiffs' intellectual property claims.

34. AstraZeneca's infringement of the '800 Patent is intentional and willful.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek judgment against AstraZeneca as follows:

1. A judgment that AstraZeneca has infringed the '800 Patent directly and/or indirectly by way of inducing infringement of the '800 Patent, as alleged herein;
2. A judgment and order requiring AstraZeneca to pay Plaintiffs' monetary damages sufficient to compensate Plaintiffs for AstraZeneca's infringement of the '800 Patent, including treble damages for willful infringement;
3. A judgment and order requiring AstraZeneca to pay Plaintiffs' pre-judgment and post-judgment interest on the damages awarded;
4. A judgment and order finding this to be an exceptional case under 35 U.S.C. § 285 and requiring AstraZeneca to pay costs of this action (including all disbursements) and attorneys' fees;
5. A permanent injunction prohibiting AstraZeneca, its officers, agents, servants, employees, and those persons in active concert or participation with any of them, from infringing Plaintiffs' '800 Patent in the future; and
6. For such further relief as to which Plaintiffs may be entitled.

## JURY DEMAND

Plaintiffs hereby demand a trial by jury as to all issues so triable.

Dated: July 31, 2013

Respectfully submitted,

By: s/ *Joseph F. Rice*

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