**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| AstraZeneca Pharmaceuticals LP,<br><br>Plaintiff,<br><br>v.<br><br>Palmetto Pharmaceuticals LLC,<br><br>Defendant. | C.A. No.: |

## COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff AstraZeneca Pharmaceuticals LP, for its Complaint against Defendant Palmetto Pharmaceuticals LLC, hereby states as follows:

## PARTIES

1. Plaintiff AstraZeneca Pharmaceuticals LP ("AstraZeneca") is a limited partnership operating and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

2. On information and belief, Defendant Palmetto Pharmaceuticals LLC ("Palmetto") is a limited liability corporation organized under the laws of Delaware with its principal place of business at 211 King Street, Charleston, South Carolina 29401.

## JURISDICTION AND VENUE

3. This action arises 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.

4. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

5. Palmetto is a limited liability corporation organized and existing under the laws of the State of Delaware. By virtue of its incorporation in Delaware, this Court has personal jurisdiction over Palmetto.

6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

## FACTS

7. On information and belief, Palmetto is the assignee of United States Patent No. 6,465,516 B1, entitled "Method of Stimulating Nitric Oxide Synthase," which issued on October 15, 2002, as amended by Reexamination Certificate No. 6,465,516 C1, which issued on April 5, 2011 (collectively, "the '516 patent"). A copy of United States Patent No. 6,465,516 B1 is attached as Exhibit A. A copy of Reexamination Certificate No. 6,465,516 C1 is attached as Exhibit B.

8. CRESTOR® (rosuvastatin calcium) is a prescription drug belonging to a group of medicines called "statins." Rosuvastatin calcium is the active ingredient in CRESTOR®.

9. AstraZeneca, among other things, manufactures and sells CRESTOR® Tablets in the United States.

10. Palmetto has alleged that sales of CRESTOR® Tablets and offers to sell CRESTOR® Tablets with its associated labeling induces infringement of the '516 patent and has threatened to sue and has sued AstraZeneca alleging such infringement.

## CAUSE OF ACTION

11. AstraZeneca realleges and incorporates paragraphs 1 to 10 as if fully set forth herein.

12. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties.

13. AstraZeneca's sale of CRESTOR® Tablets and offers to sell CRESTOR® Tablets do not induce infringement of any valid claim of the '516 patent.

14. On information and belief, the '516 patent is invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of 35 U.S.C. §§ 101 et seq.

15. AstraZeneca seeks and is entitled to a declaratory judgment that it does not induce infringement of any valid claim of the '516 patent.

16. AstraZeneca seeks and is entitled to a declaratory judgment that the claims of the '516 patent are invalid.

## PRAYER FOR RELIEF

WHEREFORE, AstraZeneca respectfully requests that this Court enter judgment in its favor as follows:

(1) For judgment that AstraZeneca's sale of CRESTOR® Tablets has not and does not induce infringement of any valid claim of the '516 patent;

(2) For judgment that the claims in the of the '516 patent are invalid;

(3) For a preliminary and permanent injunction precluding Palmetto, its officers, directors, employees, agents and all other persons acting in concert or participation with them from suing for infringement, maintaining a suit for infringement, or otherwise asserting infringement of the '516 patent against AstraZeneca for its sale of CRESTOR® Tablets;

(4) For costs and reasonable attorneys' fees incurred in connection with this action; and

(5) For such other and further relief as the Court deems just.

Respectfully submitted:

*/s/ Mary W. Bourke*

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