

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

TEVA PHARMACEUTICALS USA, INC. and)	
MAYNE PHARMA INTERNATIONAL PTY)	
LTD.,)	
)	C.A. No. 13-2002-GMS
Plaintiffs,)	
)	JURY TRIAL DEMANDED
v.)	
)	
FOREST LABORATORIES, INC. and)	
FOREST PHARMACEUTICALS, INC.,)	
)	
Defendant.)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Teva Pharmaceuticals USA, Inc. and Mayne Pharma International Pty Ltd. (collectively, “Plaintiffs”), bring this First Amended Complaint for patent infringement against Forest Laboratories, Inc. (“Forest Laboratories”) and Forest Pharmaceuticals, Inc. (“Forest Pharmaceuticals”) and hereby state as follows:

Nature of the Action

1. This is an action for patent infringement of United States Patent No. 6,194,000, arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and seeking damages and other relief under 35 U.S.C. §§ 281 *et seq.* Herein, Plaintiffs allege that by making, using, selling, offering to sell, and/or importing the drug product Namenda XR®, Defendants infringe U.S. Patent No. 6,194,000.

Parties

2. Plaintiff, Teva Pharmaceuticals USA, Inc. (“Teva”), is a corporation operating and existing under the laws of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, PA 19454. Teva is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

3. Plaintiff, Mayne Pharma International Pty Ltd. (“Mayne”), is a corporation operating and existing under the laws of Australia, with its principal place of business at 1538 Main North Road, Salisbury South SA 5106. Mayne is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

4. On information and belief, Forest Laboratories is a corporation operating and existing under the laws of Delaware, with its principal place of business at 909 Third Avenue, New York, NY 10022.

5. On information and belief, Forest Pharmaceuticals is a corporation operating and existing under the laws of Delaware, with its principal place of business at 13600 Shoreline Drive, St. Louis, MO 63045.

Jurisdiction and Venue

6. This is a complaint for patent infringement under 35 U.S.C. § 271. Subject matter jurisdiction is proper under 28 U.S.C. § 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. On information and belief, Defendants are affiliated companies which make, use, sell, offer to sell and/or import drug products throughout the United States, with substantial sales in this District.

8. On information and belief, on or about June 6, 2013, Defendants launched a product, Namenda XR®, which is now for sale throughout the United States, including in this District.

9. On information and belief, Defendants have regularly done or solicited business, or engaged in a persistent course of conduct, in Delaware, have maintained continuous and systematic contacts with Delaware, and have purposefully availed itself of the privileges of doing

business under the laws of Delaware. Thus, on information and belief, Defendants are subject to personal jurisdiction in this judicial district.

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

BACKGROUND

11. United States Patent No. 6,194,000 (“the ’000 patent”), entitled “Analgesic Immediate and Controlled Release Pharmaceutical Composition,” was duly and legally issued by the United States Patent and Trademark Office on February 27, 2001. A true and correct copy of the ’000 patent is attached as Exhibit A.

12. The ’000 patent is assigned to Mayne and licensed to Teva. Mayne and Teva hold all substantial rights in the ’000 patent and have the right to sue for infringement thereof.

13. In part, the ’000 patent covers pharmaceutical formulations of NMDA receptor antagonists and methods of treatment of certain conditions, such as Alzheimer’s Disease, using NMDA receptor antagonists.

14. On information and belief, Forest Laboratories is the holder of approved New Drug Application (“NDA”) No. 022525 for Namenda XR®. The active pharmaceutical ingredient in Namenda XR® is memantine, which is a known NMDA receptor antagonist. Namenda XR® is indicated for the treatment of Alzheimer’s Disease.

15. On information and belief, Forest Pharmaceuticals imports Namenda XR® into the United States. On information and belief, Forest Pharmaceuticals is a wholly owned subsidiary of Forest Laboratories, and Forest Laboratories directs and controls the activities of Forest Pharmaceuticals as they relate to Namenda XR®.

16. On information and belief, Forest Laboratories sells and/or distributes Namenda XR® throughout the United States, including in this judicial either directly or through one or more corporate affiliates that it directs and/or controls.

17. On information and belief, working in concert, Defendants have made, used, offered to sell, sold, and/or imported, and continue to make, use, offer to sell, sell, and/or import, Namenda XR® in the United States, including in this judicial District.

18. On information and belief, the Defendants' Namenda XR® product as currently formulated and made, infringes, either literally or by equivalents, one or more claims of the '000 patent, and/or will contribute to or induce such infringement, in violation of 35 U.S.C. § 271.

19. As a result of Defendants' ongoing infringement of the '000 patent, there is a substantial controversy between parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

CLAIMS FOR RELIEF

COUNT I - DIRECT PATENT INFRINGEMENT

20. Plaintiffs reallege and incorporate by reference paragraphs 1-19.

21. By making, using, offering to sell, selling, and/or importing Namenda XR®, Defendants have directly infringed and are continuing to infringe under 35 U.S.C. §§ 271(a) and/or 271(g) one or more claims of the '000 patent, either literally or under the doctrine of equivalents.

22. Defendants' actions constitute knowing and willful infringement of the '000 patent.

23. As a consequence of these infringing activities, Plaintiffs have been damaged in an amount not yet determined.

COUNT II - INDUCED PATENT INFRINGEMENT

24. Plaintiffs reallege and incorporate by reference paragraphs 1-23.

25. On information and belief, doctors prescribing or administering Namenda XR® according to the “Indications and Usage” section of the Namenda XR® current package insert will be using Namenda XR® in a manner that directly infringes one or more claims of the ’000 patent.

26. On information and belief, aware of Plaintiffs’ patent rights, Defendants have actively and knowingly induced and are continuing to induce infringement under 35 U.S.C. § 271(b) of the ’000 patent by intentionally encouraging the administration of Namenda XR® for the treatment of medical conditions including Alzheimer’s Disease.

27. Defendants’ actions constitute knowing and willful infringement of the ’000 patent.

28. As a consequence of these infringing activities, Plaintiffs have been damaged in an amount not yet determined.

COUNT III - CONTRIBUTORY PATENT INFRINGEMENT

29. Plaintiffs reallege and incorporate by reference paragraphs 1-28.

30. Defendants have offered for sale and sold Namenda XR® for use in practicing the patented methods claimed in the ’000 patent, which use constitutes a material part of the claimed inventions.

31. On information and belief, Defendants have offered for sale and sold Namenda XR® knowing that Namenda XR® is especially made or adapted for use in infringing the ’000 patent, and that Namenda XR® is not a staple article or commodity of commerce suitable for substantial noninfringing use.

32. On information and belief, Defendants' customers have directly infringed and continue to infringe the '000 patent by using Namenda XR® purchased from Defendants to treat medical conditions, including Alzheimer's Disease.

33. Defendants have contributorily infringed and are continuing to contributorily infringe under 35 U.S.C. § 271(c) the '000 patent.

34. Defendants' actions constitute knowing and willful infringement of the '000 patent.

35. As a consequence of these infringing activities, Plaintiffs have been damaged in an amount not yet determined.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

- 1) Declaring that the claims of the '000 patent are valid and enforceable;
- 2) Holding and declaring that by making, using, offering to sell, selling, and/or importing the drug product Namenda XR®, Defendants have infringed one or more claims of the '000 patent under 35 U.S.C. § 271(a) and/or 271(g);
- 3) Holding and declaring that Defendants have induced infringement of one or more claims of the '000 patent under 35 U.S.C. § 271(b);
- 4) Holding and declaring that Defendants have contributorily infringed one or more claims of the '000 patent under 35 U.S.C. § 271(c);
- 5) Holding and declaring that Defendants have willfully infringed the '000 patent;
- 6) Holding and declaring that Defendants have no legal or equitable defense to Plaintiffs' allegations of infringement;

- 7) Accounting and awarding damages incurred by Plaintiffs as a result of Defendants' infringement;
- 8) Declaring this to be an exceptional case and awarding Plaintiffs their attorney fees under 35 U.S.C. § 285;
- 9) Awarding Plaintiffs their costs and expenses in this action; and
- 10) Awarding Plaintiffs any further and additional relief as this Court deems just and proper.

JURY DEMAND

Plaintiffs Teva Pharmaceuticals USA, Inc. and Mayne Pharma International Pty Ltd.
request a jury trial on all issues so triable.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

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