

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

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

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Teva Pharmaceuticals USA, Inc. and Mayne Pharma International Pty Ltd. (collectively, “Plaintiffs”), bring this Complaint for patent infringement against Forest Laboratories, Inc. (“Defendant”), 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 injunctive and other relief under 35 U.S.C. §§ 281 *et seq.* Herein, Plaintiffs allege that by making, using, selling, offering to sell, or importing the drug product Namenda XR®, Defendant infringes 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, Defendant, Forest Laboratories, Inc. (“Forest”), 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.

Jurisdiction and Venue

5. 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.

6. On information and belief, Defendant distributes, sells, and offers to sell drug products throughout the United States, with substantial sales in this District.

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

8. On information and belief, Defendant has regularly done or solicited business, or engaged in a persistent course of conduct, in Delaware, has maintained continuous and systematic contacts with Delaware, and has purposefully availed itself of the privileges of doing business under the laws of Delaware. Thus, on information and belief, Defendant is subject to personal jurisdiction in this judicial district.

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

BACKGROUND

10. 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.

11. 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.

12. 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.

13. On information and belief, Defendant 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.

14. On information and belief, Defendant has made, used, offered to sell, sold, and/or imported, and continues to make, use, offer to sell, sell, and/or import, Namenda XR® in the United States, including in this judicial District.

15. On information and belief, the Defendant’s 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.

16. As a result of Defendant’s 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

17. Plaintiffs reallege and incorporate by reference paragraphs 1-16.

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

19. Defendant's actions constitute knowing and willful infringement of the '000 patent.

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

21. Plaintiffs will continue to be substantially and irreparably damaged and harmed as a consequence of Defendant's infringing activities unless those activities are preliminarily and permanently enjoined.

COUNT II - INDUCED PATENT INFRINGEMENT

Plaintiffs reallege and incorporate by reference paragraphs 1-21.

22. 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.

23. On information and belief, aware of Plaintiffs' patent rights, Defendant has actively and knowingly induced and is 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.

24. Defendant's actions constitute knowing and willful infringement of the '000 patent.

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

26. Plaintiffs will continue to be substantially and irreparably damaged and harmed as a consequence of Defendant's infringing activities unless those activities are preliminarily and permanently enjoined.

COUNT III - CONTRIBUTORY PATENT INFRINGEMENT

27. Plaintiffs reallege and incorporate by reference paragraphs 1-26.

28. Defendant has 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.

29. On information and belief, Defendant has 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.

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

31. Defendant has contributorily infringed and is continuing to contributorily infringe under 35 U.S.C. § 271(c) the '000 patent.

32. Defendant's actions constitute knowing and willful infringement of the '000 patent.

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

34. Plaintiffs will continue to be substantially and irreparably damaged and harmed as a consequence of Defendant's infringing activities unless those activities are preliminarily and permanently enjoined.

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, or importing the drug product Namenda XR®, Defendant has infringed one or more claims of the '000 patent under 35 U.S.C. § 271(a) and 271(g);
- 3) Holding and declaring that Defendant has induced infringement of one or more claims of the '000 patent under 35 U.S.C. § 271(b);
- 4) Holding and declaring that Defendant has contributorily infringed one or more claims of the '000 patent under 35 U.S.C. § 271(c);
- 5) Holding and declaring that Defendant has willfully infringed the '000 patent;
- 6) Holding and declaring that Defendant has no legal or equitable defense to Plaintiffs' allegations of infringement;
- 7) Accounting and awarding damages incurred by Plaintiffs as a result of Defendant's infringement;
- 8) Preliminarily and permanently enjoining Defendant, and its officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them,

from unauthorized making, using, offering to sell, or selling Namenda XR® within the United States or unauthorized importing Namenda XR® into the United States prior to the expiration of the '000 patent, or otherwise infringing any claims of the '000 patent;

- 9) Declaring this to be an exceptional case and awarding Plaintiffs their attorney fees under 35 U.S.C. § 285;
- 10) Awarding Plaintiffs their costs and expenses in this action; and
- 11) 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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1132169 / 40539

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