

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

**CEPHALON, INC. and
ACUSPHERE, INC.,**

Plaintiffs,

v.

**CELGENE CORP., ABRAXIS BIOSCIENCE,
INC., and ABRAXIS BIOSCIENCE, LLC,**

Defendants.

Civil Action No.: 11-12226

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Cephalon, Inc. and Acusphere, Inc. (collectively, “Plaintiffs”) bring this Complaint for patent infringement against Celgene Corp., Abraxis Bioscience, Inc., and Abraxis Bioscience, LLC (collectively, “Defendants”), and hereby state as follows:

Nature of the Action

1. This is an action for patent infringement of United States Patent No. RE40,493, 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 Abraxane[®], Defendants have infringed U.S. Patent No. RE40,493.

Parties

2. Plaintiff Cephalon, Inc. (“Cephalon”) is a corporation operating and existing under the laws of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

3. Plaintiff Acusphere, Inc. (“Acusphere”) is a corporation operating and existing under the laws of Delaware, with its principal place of business at 99 Hayden Avenue, Suite 385, Lexington, MA 02421. Acusphere is specialty pharmaceutical company that develops new drugs and improved formulations of existing drugs using its proprietary porous microparticle technology.

4. On information and belief, Defendant Celgene Corp. (“Celgene”) is a corporation operating and existing under the laws of Delaware, with its principal place of business at 86 Morris Avenue, Summit, New Jersey 07901. On information and belief, Celgene and/or one of its subsidiaries has a facility located at One Broadway, Cambridge, Massachusetts 02142.

5. On information and belief, Defendant Abraxis Bioscience, Inc. (“Abraxis Inc.”) is a corporation operating and existing under the laws of Delaware, with its principal place of business at 11755 Wilshire Boulevard, 20th Floor, Los Angeles, California 90025.

6. On information and belief, Defendant Abraxis Bioscience, LLC (“Abraxis LLC”) is a corporation operating and existing under the laws of Delaware, with its principal place of business at 11755 Wilshire Boulevard, 20th Floor, Los Angeles, California 90025. On information and belief, Defendant Abraxis LLC is, among other things, the marketing arm of Abraxis Inc.

7. On information and belief, Abraxis Inc. and Abraxis LLC (collectively, “Abraxis”) are wholly-owned subsidiaries of Celgene.

Jurisdiction and Venue

8. 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.

9. On information and belief, Defendants, acting in concert, distribute, sell, and offer to sell drug products, including at least Abraxane[®], with substantial sales in this District.

10. On information and belief, Abraxis Inc., directly and/or through Defendants Abraxis LLC, Celgene, and/or others, has regularly done or solicited business, or engaged in a persistent course of conduct, in Massachusetts, has maintained continuous and systematic contacts with Massachusetts, and has purposefully availed itself of the privileges of doing business under the laws of Massachusetts. Thus, on information and belief, Abraxis Inc. is subject to personal jurisdiction in this judicial district.

11. On information and belief, Abraxis LLC, directly and/or through Defendants Abraxis Inc., Celgene, and/or others, has regularly done or solicited business, or engaged in a persistent course of conduct, in Massachusetts, has maintained continuous and systematic contacts with Massachusetts, and has purposefully availed itself of the privileges of doing business under the laws of Massachusetts. Thus, on information and belief, Abraxis LLC is subject to personal jurisdiction in this judicial district.

12. On information and belief, Celgene, directly and/or through Defendants Abraxis LLC, Abraxis Inc., and/or others, has regularly done or solicited business, or engaged in a persistent course of conduct, in Massachusetts, has maintained continuous and systematic contacts with Massachusetts, and has purposefully availed itself of the privileges of doing business under the laws of Massachusetts. Thus, on information and belief, Celgene is subject to personal jurisdiction in this judicial district.

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

BACKGROUND

14. United States Patent No. RE40,493 (“the ’493 patent”), entitled “Porous Paclitaxel Matrices and Methods of Manufacture Thereof,” was duly and legally reissued by the United States Patent and Trademark Office on September 9, 2008. A true and correct copy of the ’493 patent is attached as Exhibit A.

15. The ’493 patent is assigned to Acusphere and exclusively licensed to Cephalon. Acusphere and Cephalon hold all substantial rights in the ’493 patent and have the right to sue for infringement thereof.

16. In part, the ’493 patent covers pharmaceutical formulations of paclitaxel particles in a porous matrix and methods of administration thereof.

17. On information and belief, Defendant Abraxis Inc. is the holder of approved New Drug Application (“NDA”) No. 21-660 for Abraxane® injectable suspension of paclitaxel protein-bound particles. Abraxane® is indicated for the treatment of breast cancer.

18. On information and belief, Abraxane® is a pharmaceutical formulation of paclitaxel particles in a porous matrix.

19. On information and belief, Defendants have made, used, offered to sell, sold, and/or imported, and continue to make, use, offer to sell, sell, and/or import, Abraxane® in the United States, including in this judicial district.

20. On information and belief, the Defendants’ Abraxane product as currently formulated infringes, either literally or by equivalents, one or more claims of the ’493 patent, and/or will contribute to or induce such infringement, in violation of 35 U.S.C. § 271.

21. On information and belief, and according to the Abraxane® package insert, Abraxane® is indicated for the treatment of breast cancer.

22. As a result of Defendants' ongoing infringement of the '493 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

23. Plaintiffs reallege and incorporate by reference paragraphs 1-22.

24. Upon information and belief, Celgene has acted and is acting in concert with Abraxis Inc. and/or Abraxis LLC in the production, sale, offer for sale, and use of Abraxane[®].

25. Upon information and belief, Abraxis Inc. has acted and is acting in concert with Celgene and/or Abraxis LLC in the production, sale, offer for sale, and use of Abraxane[®].

26. Upon information and belief, Abraxis LLC has acted and is acting in concert with Celgene and/or Abraxis Inc. in the production, sale, offer for sale, and use of Abraxane[®].

27. By making, using, offering to sell, selling, and/or importing Abraxane[®], Defendants have directly infringed and are continuing to infringe under 35 U.S.C. § 271(a) one or more claims of the '493 patent, either literally or under the doctrine of equivalents.

28. Defendants' actions constitute knowing and willful infringement of the '493 patent.

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

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

COUNT II - INDUCED PATENT INFRINGEMENT

31. Plaintiffs reallege and incorporate by reference paragraphs 1-30.

32. On information and belief, doctors prescribing or administering Abraxane[®] according to the “Indications and Usage” section of the Abraxane[®] current package insert will be using Abraxane[®] in a manner that directly infringes one or more claims of the ’493 patent.

33. 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 ’493 patent by intentionally encouraging the administration of Abraxane[®] for the treatment of breast cancer.

34. Defendants’ actions constitute knowing and willful infringement of the ’493 patent.

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

36. Plaintiffs will continue to be substantially and irreparably damaged and harmed as a consequence of Defendants’ infringing activities unless those activities are preliminarily and permanently enjoined.

COUNT III - CONTRIBUTORY PATENT INFRINGEMENT

37. Plaintiffs reallege and incorporate by reference paragraphs 1-36.

38. Defendants have offered for sale and sold Abraxane[®] for use in practicing the patented methods claimed in the ’493 patent, which use constitutes a material part of the claimed inventions.

39. On information and belief, Defendants offered for sale and sold Abraxane[®] knowing that Abraxane[®] is especially made or adapted for use in infringing the ’493 patent, and

that Abraxane[®] is not a staple article or commodity of commerce suitable for substantial noninfringing use.

40. On information and belief, Defendants' customers have directly infringed and continue to infringe the '493 patent by using Abraxane[®] purchased from Defendants to treat breast cancer.

41. Defendants have contributorily infringed and are continuing to contributorily infringe under 35 U.S.C. § 271(c) the '493 patent.

42. Defendants' actions constitute knowing and willful infringement of the '493 patent.

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

44. Plaintiffs will continue to be substantially and irreparably damaged and harmed as a consequence of Defendants' 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 '493 patent are valid and enforceable;
- 2) Holding and declaring that by making, using, offering to sell, selling, or importing the drug product Abraxane[®], Defendants have infringed one or more claims of the '493 patent under 35 U.S.C. § 271(a);
- 3) Holding and declaring that Defendants have induced infringement of one or more claims of the '493 patent under 35 U.S.C. § 271(b);

- 4) Holding and declaring that Defendants have contributorily infringed one or more claims of the '493 patent under 35 U.S.C. § 271(c);
- 5) Holding and declaring that Defendants have willfully infringed the '493 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) Preliminarily and permanently enjoining Defendants Celgene, Abraxis Inc., and Abraxis LLC, and their 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 Abraxane[®] within the United States or unauthorized importing Abraxane[®] into the United States prior to the expiration of the '493 patent, or otherwise infringing any claims of the '493 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 Cephalon, Inc. and Acusphere, Inc. request a jury trial on all issues so triable.

Respectfully submitted,

/s/ John T. Bennett

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