IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ÉLAN PHARMACEUTICAL INTERNATIONAL LIMITED))
Plaintiff) C. A. No
v.)) JURY TRIAL DEMANDED
ABRAXIS BIOSCIENCE, INC.) JOKI IRIAL DEMANDED)
Defendant.)

COMPLAINT

Plaintiff Élan Pharmaceutical International Limited complains as follows against Defendant Abraxis BioScience, Inc.

THE PARTIES

- Plaintiff Élan Pharmaceutical International Limited ("Élan") is a company organized and existing under the laws of Ireland, having a business address at Monksland, Athlone, Co. Westmeath, Ireland.
- 2. On information and belief, defendant Abraxis BioScience, Inc.

 ("Abraxis") is a corporation organized and existing under the laws of the State of

 Delaware, with its principal place of business at 11777 San Vincente Boulevard, Suite

 550, Los Angeles, CA 90049.

JURISDICTION AND VENUE

- This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338.
- 4. On information and belief, defendant Abraxis resides in this Judicial District, conducts business in this Judicial District, and has committed acts of patent infringement in this Judicial District including, *inter alia*, making, using, offering for sale, or selling an infringing product in this Judicial District.
- 5. On information and belief, defendant Abraxis has knowingly and actively contributed to infringement and/or has induced others to commit such acts of infringement in this Judicial District.
- 6. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

- 7. Plaintiff Élan is the owner by assignment of all right, title, and interest in and to United States Patent No. 5,399,363 ("the '363 patent") entitled "Surface Modified Anticancer Particles", which duly and legally issued in the names of Gary G. Liversidge, Elaine Liversidge, and Pramod P. Sarpotdar on March 21, 1995. A copy of the '363 patent is attached hereto as Exhibit A.
- 8. Plaintiff Élan is the owner by assignment of all right, title, and interest in and to United States Patent No. 5,834,025 ("the '025 patent") entitled "Reduction of Intravenously Administered Nanoparticulate-Formulation-Induced Adverse Physiological Reactions", which duly and legally issued in the names of Lawrence de Garavilla, Elaine

- M. Liversidge, and Gary G. Liversidge on November 10, 1998. A copy of the '025 patent is attached hereto has Exhibit B.
- 9. On information and belief, on March 29, 2005 the United States Food and Drug Administration ("FDA") approved the sale of Abraxane® in the United States for treatment of metastatic breast cancer.
- On information and belief, Abraxane® is a nanoparticle formulation of paclitaxel that is intravenously administered to patients for the treatment of breast cancer.
- On information and belief, Abraxane® is a product owned, manufactured, offered for sale, or sold by the defendant Abraxis within this Judicial District.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 5,399,363

- 12. Élan realleges and incorporates by reference the allegations set forth in paragraphs 1-11 above.
- On information and belief, defendant Abraxis has been, and currently is, directly and/or indirectly infringing the '363 patent by making, using, selling, and/or offering for sale Abraxane®; contributing to the use of Abraxane® by others; and/or inducing others to use Abraxane®.
- 14. On information and belief, defendant Abraxis's infringement of the '363 patent has been and continues to be willful and deliberate.
- On information and belief, defendant Abraxis's infringement of the '363 patent will continue unless enjoined by this Court. As a result of the infringing conduct of Abraxis, Élan has suffered and will continue to suffer irreparable harm for which there is no adequate remedy at law. Accordingly, Élan is entitled to temporary, preliminary and/or permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

16. As a direct and proximate consequence of defendant Abraxis's infringement of the '363 patent, Élan has been damaged, and will be further damaged, and is entitled to be compensated for such damages pursuant to 35 U.S.C. § 284 in an amount not yet determinable, but which will be determined at trial.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 5,834,025

- 17. Élan realleges and incorporates by reference the allegations set forth in paragraphs 1-16 above.
- 18. On information and belief, defendant Abraxis has been, and currently is, directly and/or indirectly infringing the '025 patent by making, using, selling, and/or offering for sale Abraxane®; contributing to the use of Abraxane® by others; and/or inducing others to use Abraxane® in a manner that infringes the '025 patent.
- 19. On information and belief, defendant Abraxis's infringement of the '025 patent has been and continues to be willful and deliberate.
- 20. On information and belief, defendant Abraxis's infringement of the '025 patent will continue unless enjoined by this Court. As a result of the infringing conduct of Abraxis, Élan has suffered and will continue to suffer irreparable harm for which there is no adequate remedy at law. Accordingly, Élan is entitled to temporary, preliminary and/or permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.
- As a direct and proximate consequence of defendant Abraxis's infringement of the '025 patent, Élan has been damaged, and will be further damaged, and is entitled to be compensated for such damages pursuant to 35 U.S.C. § 284 in an amount not yet determinable, but which will be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Élan prays for entry of judgment against defendant Abraxis as follows:

That Abraxis has infringed the '363 and '025 patents under 35 U.S.C. §§ 271 et seq.;

That injunctions, preliminary and permanent, be issued by this Court restraining Abraxis, its respective officers, agents, servants, directors, and employees, and all persons in active concert or participation with each, from directly or indirectly infringing, or inducing or contributing to the infringement by others of the '363 and '025 patents;

That Abraxis be required to provide to Élan an accounting of all gains, profits, and advantages derived by Abraxis's infringement of the '363 and '025 patents, and that Élan be awarded damages adequate to compensate Élan for the wrongful infringing acts by Abraxis, in accordance with 35 U.S.C. § 284;

That the damages awarded to Élan be increased up to three times, in view of Abraxis's willful infringement, in accordance with 35 U.S.C. § 284;

That this case be declared to be exceptional in favor of Élan under 35 U.S.C. § 285, and that Élan be awarded its reasonable attorneys' fees and other expenses incurred in connection with this action;

That Élan be awarded its interest and costs of suit incurred in this action; and

That Élan be awarded such other and further relief as this Court may deem just
and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b) and Local Rule 38.1, Élan hereby demands a jury trial for all issues in this case that are properly subject to a jury trial.

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