IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ABRAXIS BIOSCIENCE, LLC,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civil Action No. 1:23-CV-33 (Kleeh)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Abraxis BioScience, LLC ("Abraxis" or "Plaintiff"), by its undersigned attorneys, for its Complaint against defendant Mylan Pharmaceuticals Inc. ("Mylan" or "Defendant"), alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq*., arising from Mylan's filing of Abbreviated New Drug Application ("ANDA") No. 217877 ("Mylan's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Plaintiff's Abraxane® (paclitaxel protein-bound particles for injectable suspension) drug product ("Mylan's ANDA Product") prior to the expiration of United States Patent No. 7,820,788 (the "'788 Patent" or "the Patent-in-Suit"), which is owned by Plaintiff.

The Parties

2. Plaintiff Abraxis is a wholly owned subsidiary of Celgene Corporation, which is in turn a wholly owned subsidiary of the Bristol-Myers Squibb Company. Abraxis is a

corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. On information and belief, Mylan is a corporation organized and existing under the laws of West Virginia and has a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505.

The Patent-in-Suit

4. On October 26, 2010, the USPTO duly and lawfully issued the '788 Patent, titled, "Compositions and Methods of Delivery of Pharmacological Agents." The '788 Patent is assigned to Abraxis. A copy of the '788 Patent is attached hereto as Exhibit A.

The Abraxane® Drug Product

5. Abraxis holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for paclitaxel protein-bound particles for injectable suspension (NDA No. 21-660), which it sells under the trade name Abraxane®. Abraxane® is an FDA-approved prescription medicine used for the treatment of certain hard-to-treat forms of cancer, including: (1) metastatic breast cancer (after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy); (2) locally advanced or metastatic non-small cell lung cancer, as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy; and (3) metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine. The claims of the Patent-in-Suit cover, *inter alia*, pharmaceutical compositions and methods of use and administration of paclitaxel protein-bound particles for injection, including Abraxane®.

6. Pursuant to 21 U.S.C. § 355(b)(1)(A)(viii) and attendant FDA regulations, the Patent-in-Suit is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Abraxane®.

7. The labeling for Abraxane® instructs and encourages physicians and other healthcare workers to administer Abraxane® according to one or more of the methods claimed in the Patent-in-Suit.

Jurisdiction and Venue

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over Mylan by virtue of, *inter alia*, its systematic and continuous contacts with this Judicial District. For instance and on information and belief, Mylan is incorporated in this Judicial District and maintains its principal place of business in this Judicial District. *See, e.g.*, Viatris Inc. 2022 Form 10-K at 163 (identifying West Virginia as the "state or country of organization" for Mylan); Answer to Complaint for Patent Infringement, *Bausch Health Ireland Ltd., et al. v. Mylan Pharm. Inc.*, No. 22-85, ECF No. 5 (N.D.W. Va. Sept. 13, 2022) ("MPI is a corporation organized and existing under the laws of West Virginia and admits that its principal place of business is at 3711 Collins Ferry Road, Morgantown, WV 26505."). On further information and belief, Mylan is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On further information and belief, Mylan has purposefully conducted and continues to conduct business in this Judicial District, including the purposeful

sale and distribution of drug products. On further information and belief, this Judicial District will be a destination for the generic drug products described in Mylan's ANDA.

10. For at least the reasons set forth in Paragraph 9 above, venue is proper in this Judicial District pursuant to 28 U.S.C. § 1400(b).

Acts Giving Rise To This Suit

11. Pursuant to Section 505 of the FFDCA, Mylan filed Mylan's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of Mylan's ANDA Product before the Patent-in-Suit expires.

12. On information and belief, following FDA approval of Mylan's ANDA, Mylan will make, use, offer for sale, or sell Mylan's ANDA Product throughout the United States, or import such generic products into the United States.

13. On information and belief, in connection with the filing of its ANDA as described above, Mylan provided a written certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Mylan's Paragraph IV Certification"), alleging that the claims of the Patent-in-Suit are invalid and/or will not be infringed by the activities described in Mylan's ANDA.

14. No earlier than February 22, 2023, Mylan sent written notice of its Paragraph IV Certification to Abraxis ("Mylan's Notice Letter"). Mylan's Notice Letter alleged that the claims of the Patent-in-Suit are invalid and/or will not be infringed by the activities described in Mylan's ANDA. Mylan's Notice Letter also informed Abraxis that Mylan seeks approval to market Mylan's ANDA Product before the Patent-in-Suit expires.

Count I: Infringement of the '788 Patent

15. Abraxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

16. Mylan, by the submission of Mylan's Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of Mylan's ANDA Product, prior to the expiration of the '788 Patent.

17. Mylan's ANDA has been pending before the FDA since at least February 22, 2023, the date that Mylan sent Mylan's Notice Letter to Abraxis.

18. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of Mylan's ANDA Product, prior to the expiration of the '788 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

19. There is a justiciable controversy between the parties hereto as to the infringement of the '788 Patent.

20. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '788 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan's ANDA Product in or into the United States.

21. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will induce infringement of one or more claims of the '788 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan's ANDA Product in or into the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will

intentionally encourage acts of direct infringement with knowledge of the '788 Patent and knowledge that its acts are encouraging infringement.

22. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '788 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's ANDA Product in or into the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's ANDA Product is especially adapted for a use that infringes one or more claims of the '788 Patent and that there is no substantial non-infringing use for Mylan's ANDA Product.

23. Abraxis will be substantially and irreparably damaged and harmed if Mylan's infringement of the '788 Patent is not enjoined.

24. Abraxis does not have an adequate remedy at law.

25. This case is an exceptional one, and Abraxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Abraxis respectfully requests the following relief:

(A) A Judgment that Mylan has infringed the Patent-in-Suit by submitting ANDA No. 217877;

(B) A Judgment that Mylan has infringed, and that Mylan's making, using, offering to sell, selling, or importing Mylan's ANDA Product will infringe one or more claims of the Patent-in-Suit;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 217877 be a date which is not earlier than the later of the expiration of the Patent-in-Suit, or any later expiration of exclusivity to which Abraxis is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Mylan and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Mylan's ANDA Product until after the expiration of the Patent-in-Suit, or any later expiration of exclusivity to which Abraxis is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Mylan, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any paclitaxel protein-bound particles of injectable suspension compositions or methods claimed in the Patent-in-Suit, or from actively inducing or contributing to the infringement of any claim of the Patent-in-Suit, until after the expiration of the Patent-in-Suit, or any later expiration of exclusivity to which Mylan is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Mylan's ANDA Product will directly infringe, induce, and/or contribute to infringement of the Patent-in-Suit;

(G) To the extent that Mylan has committed any acts with respect to the paclitaxel protein-bound particles of injectable suspension compositions or methods claimed in the Patent-in-Suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Abraxis damages for such acts;

(H) If Mylan engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Mylan's ANDA Product prior to the expiration of the Patent-in-Suit, a Judgment awarding damages to Abraxis resulting from such infringement, together with interest;

(I) A Judgment declaring that the Patent-in-Suit remains valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Abraxis its attorneys' fees, costs, and expenses incurred in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: April 6, 2023

By: */s/Chad L. Taylor*

Frank E. Simmerman, Jr. (WV Bar # 3403)
Chad L. Taylor (WV Bar #10564)
Frank E. Simmerman, III (WV Bar #11589)
254 E. Main St.
Clarksburg, WV 26301
(304) 623-4900
clt@simmermanlaw.com
fes@simmermanlaw.com
trey@simmermanlaw.com

SIMMERMAN LAW OFFICE PLLC

Attorneys for Plaintiff
Abraxis BioScience, LLC

Of Counsel:

F. Dominic Cerrito
Andrew S. Chalson
Daniel C. Wiesner
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

Matthew J. Hertko
JONES DAY
110 North Wacker Drive, Suite 4800
Chicago, IL 60606
(312) 782-3939