

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

MORPHOSYS AG,

Plaintiff,

v.

**JANSSEN BIOTECH, INC., GENMAB
US, INC. and
GENMAB A/S**

Defendants.

C.A. No.

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff MorphoSys AG (“MorphoSys”), for its Complaint against Defendants Janssen Biotech, Inc. (“Janssen”), Genmab A/S (“Genmab”) and Genmab US, Inc. (collectively “Defendants”) hereby alleges as follows:

PARTIES

1. Plaintiff MorphoSys is a German biotechnology company with its principal place of business at Lena-Christ-Str. 48, 82152 Martinsried/Planegg, Germany.

2. MorphoSys is a leading pharmaceutical company in the field of therapeutic antibodies and well-known for its innovative antibody technologies. Founded in Martinsried /Planegg near Munich in 1992, MorphoSys is committed to developing exceptional new treatments for patients suffering from serious diseases. MorphoSys is the recipient of several awards, including the 2009 Technology Pioneer award, and the 2013 Mediscience Award. MorphoSys has also succeeded in building a therapeutic pipeline of more than 100 human antibody drug candidates for the treatment of diseases such as inflammatory disease, cancer, and Alzheimer’s disease.

3. Upon information and belief, Defendant Janssen is a Pennsylvania corporation with its principal place of business at 800 Ridgeview Road, Horsham, Pennsylvania 19044.

4. Upon information and belief, Defendant Genmab is a Danish biotechnology company with its principal place of business at Bredgade 34E, 1260 Copenhagen K, Denmark.

5. Upon information and belief, Defendant Genmab US, Inc. is a wholly owned subsidiary of Genmab A/S, and is a corporation organized and existing under the laws of the state of Delaware.

NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patent No. 8,263,746 (the “746 Patent”), under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* This action arises out of Defendants’ current manufacture, use, sale, offer to sell within the United States directly and/or indirectly of Defendants’ anti-CD38 antibody known as Darzalex (daratumumab) for the treatment of patients with multiple myeloma.

JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over Janssen because, among other things, Janssen has committed, aided, abetted, contributed to, and/or participated in the commission of patent infringement in this judicial district and elsewhere that led to a foreseeable harm and injury to MorphoSys through its manufacture, use, sale, offer to sell within the United States of its Darzalex (daratumumab) products.

9. This Court also has personal jurisdiction over Janssen because, among other reasons, Janssen has established minimum contacts within the forum such that the exercise of jurisdiction over Janssen will not offend traditional notions of fair play and substantial justice.

For instance, Janssen has placed products that practice the claimed invention of the '746 Patent into the stream of commerce with the reasonable expectations and/or knowledge that purchasers and users of such products were located within the District of Delaware. Janssen has sold, advertised, marketed and distributed products in this District that practice the claimed invention of the '746 Patent.

10. This court has personal jurisdiction over Genmab, under Fed. R. Civ. P. 4(k)(2), because on information and belief Genmab A/S is not subject to jurisdiction in any particular state's courts of general jurisdiction, and because Genmab A/S has extensive contacts with the United States, and exercising jurisdiction over Genmab is consistent with the laws of the United States and the Constitution. Among other things, Genmab has a commercial relationship and business dealings with Janssen in the United States, through and with its wholly owned subsidiary and United States corporation, Genmab US, Inc. (formerly Genmab, Inc.). Upon information and belief, Genmab also markets its infringing product, Darzalex, in the United States. Genmab has also availed itself of the United States patent system, and has been granted U.S. Patent No. 7,829,673.

11. Upon information and belief, Genmab, Inc., a corporation formed and existing under the laws of the state of Delaware, is a wholly owned subsidiary of Genmab. Genmab, Inc. became Genmab US, Inc. in 2013.

12. Upon information and belief, Genmab, Inc., under the control of Genmab, led the business development effort in constructing the August 2012 agreement between Janssen and Genmab for the manufacture, development, and advertisement of Darzalex.

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

FACTUAL BACKGROUND

14. United States Patent No. 8,263,746 (the “746 Patent”), entitled “Anti-CD38 Human Antibodies and Uses Thereof,” was duly and legally issued by the United States Patent and Trademark Office on September 11, 2012. A true and correct copy of the ‘746 Patent is attached hereto as **Exhibit A**.

15. MorphoSys is the assignee of the ‘746 Patent and has the right to sue and recover damages for any current or past infringement of the ‘746 Patent. The ‘746 Patent covers certain anti-CD38 antibodies.

16. The ‘746 patent is directed to antibodies that are specific for CD38, a surface protein that is expressed by multiple myeloma cells. The inventors of the ‘746 patent were able to identify an anti-CD38 antibody that binds CD38 and has particular kinds of efficacy in killing CD38 expressing cells.

17. This therapy is especially important given the gravity of the disease. Multiple myeloma is a common blood cancer in the U.S., that afflicts tens of thousands of new patients yearly, with over ten thousand people dying from the disease in the U.S. last year alone.

18. Upon information and belief, Genmab developed daratumumab (later known as Darzalex).

19. Upon information and belief, Darzalex is an anti-CD38 antibody indicated for treatment of patients with multiple myeloma.

20. Upon information and belief, in August 2012 Genmab granted Janssen a license to develop, manufacture, and commercialize Darzalex.

21. Upon information and belief, this August 2012 license includes several milestone payments to be remitted by Janssen to Genmab, some upon information and belief has already been paid, and includes a \$55 million upfront payment and a \$45 million payment for the first

sale in the United States, made by Janssen. This license agreement included a provision in which Johnson & Johnson Corporation, Janssen's parent, would invest \$80 million in Genmab shares.

22. Upon information and belief, the Food and Drug Administration granted approval to Genmab for Darzalex (daratumumab) on November 16, 2015 for the treatment of certain types of patients with multiple myeloma.

23. Upon information and belief, Genmab participated in clinical trials in the United States related to the development of Darzalex. Both Janssen and Genmab pursued the clinical development of Darzalex for sale in the United States.

24. Upon information and belief, Janssen has been advertising, manufacturing and selling Darzalex in the United States since at least November 2015. Genmab has also frequently issued press releases promoting Darzalex, and detailing the milestones achieved in developing the Darzalex product in the United States.

25. Upon information and belief, Genmab A/S markets Darzalex and promotes the sale of Darzalex in the United States.

26. Upon information and belief, Janssen sells, markets and promotes the sale of Darzalex in the United States.

27. Upon information and belief, Genmab is the assignee for United States Patent No. 7,829,673 (the "'673 Patent"), filed March 23, 2006.

28. Upon information and belief, Genmab relied on the MOR3079 antibody in the benchmarking analysis of the '673 Patent. The MOR3079 antibody is described in PCT publication WO/2005/103083; this application is cited in the body and on the face of the '673 Patent and was cited by Genmab on an Information Disclosure Statement during prosecution of the '673 patent. The '746 Patent is the National Phase patent, which derived from PCT

publication WO/2005/103083. Darzalex has been reported to have the efficacy in killing CD38 expressing cells in the manner described in the '746 patent, such that, upon information and belief, it mediates killing of a CD38+ target cell in the manner recited by one or more claims of the '746 patent. *See, e.g.*, Claim 1, 8. Darzalex also contains an antibody-binding region which specifically binds to CD38.

29. MorphoSys issued a press release concerning the issuance of the '746 patent on June 12, 2012 and its subject matter related to anti-CD38 antibodies. <http://www.euroinvestor.dk/nyheder/2012/12/06/morphosys-strengthens-patent-position-on-anti-cd38-cancer-program-mor202/12157906>. Upon information and belief, Genmab knew of the '746 patent as part of its efforts to develop anti-CD38 antibodies and seek partners for Darzalex.

30. Janssen filed a European Opposition to EP2511297 on January 7, 2016; Genmab filed a European Opposition brief to the same patent on January 8, 2016. The '746 Patent is the National Stage Entry of PCT/IB05/02746, WIPO application No. WO 2005/103083, which was also published as EP2511297. Both EP2511297 and the '746 Patent claim priority to the same five United States Provisional Applications, 60/614,471; 60/599,014; 60/553,948; 60/547,584; and 60/541,911.

31. Upon information and belief, Janssen was aware of the '746 Patent as of at least January 7, 2016.

32. Upon information and belief, Genmab and Genmab, US, Inc. were aware of the '746 Patent as of at least January 8, 2016.

33. Upon information and belief, Genmab and Genmab US, Inc. acted in concert with Janssen in the development, manufacture, FDA approval, and marketing of Darzalex. Upon

information and belief, Genmab has provided technical support in the making, using and selling of Darzalex.

34. Upon information and belief, Janssen, Genmab and Genmab US, Inc. were aware of Darzalex's infringement of one or more claims of the '746 patent and/or understood the high probability of Darzalex's infringement and took deliberate actions to avoid learning of that infringement, including in the manner by which they examined and tested the qualities of Darzaelx.

COUNT I

Infringement of the '746 Patent by Janssen

35. Paragraphs 1 through 34 are incorporated by reference as if fully stated herein.

36. Janssen, either alone or in conjunction with others, has infringed and will continue to infringe, one or more claims of the '746 Patent under 35 U.S.C. § 271, either literally and/or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing into the United States certain anti-CD38 antibodies, for example and without limitation, Darzalex.

37. MorphoSys has been and continues to be damaged by Janssen's infringement of the '746 Patent.

38. On information and belief, Janssen acted with knowledge of the '746 Patent and the high likelihood that its daratumumab products infringe the '746 Patent without a reasonable basis for a good faith belief that it would not be liable for infringement of the '746 patent, and thus Janssen's ongoing and past infringement is willful and deliberate.

39. This case is exceptional, and MorphoSys is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II

Infringement of the '746 Patent by Genmab

40. Paragraphs 1 through 39 are incorporated by reference as if fully stated herein.

41. On information and belief, Genmab, alone or in conjunction with others including Janssen, has directly and/or indirectly infringed and will continue to infringe, either literally or by the doctrine of equivalents, one or more claims of the '746 Patent under 35 U.S.C. § 271 by directly and/or indirectly making, using, offering to sell, selling and/or importing into the United States certain anti-CD38 antibodies, for example and without limitation, Darzalex.

42. MorphoSys has been and continues to be damaged by Genmab's infringement of the '746 Patent.

43. On information and belief, Genmab has acted with knowledge of the '746 Patent and the high likelihood that its daratumumab products infringed the '746 Patent, and thus its ongoing and past infringement is willful and deliberate.

COUNT III

Infringement of the '746 Patent by Genmab US, Inc.

44. Paragraphs 1 through 43 are incorporated by reference as if fully stated herein.

45. On information and belief, Genmab US Inc., alone or in conjunction with others including Janssen, has directly and/or indirectly infringed and will continue to infringe, either literally or by the doctrine of equivalents, one or more claims of the '746 Patent under 35 U.S.C. § 271 by directly and/or indirectly making, using, offering to sell, selling and/or importing into the United States certain anti-CD38 antibodies, for example and without limitation, Darzalex.

46. MorphoSys has been and continues to be damaged by Genmab US, Inc.'s infringement of the '746 Patent.

47. On information and belief, Genmab US, Inc. has acted with knowledge of the '746 Patent and the high likelihood that its daratumumab products infringed the '746 Patent, and thus its ongoing and past infringement is willful and deliberate.

COUNT IV

Infringement of the '746 patent by Janssen/Genmab/Genmab US, Inc.

48. Paragraphs 1 through 47 are incorporated by reference as if fully stated herein.

49. Janssen/Genmab/Genmab US, Inc., either alone or in conjunction with each other, have infringed and will continue to infringe directly or indirectly, one or more claims of the '746 Patent under 35 U.S.C. § 271, either literally and/or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing into the United States certain anti-CD38 antibodies, for example and without limitation, Darzalex.

50. MorphoSys has been and continues to be damaged by Janssen/Genmab/Genmab US, Inc.'s infringement of the '746 Patent.

51. On information and belief, Janssen/Genmab/Genmab US, Inc. acted with knowledge of the '746 Patent and the high likelihood that its daratumumab products infringe the '746 Patent, and thus Janssen's ongoing and past infringement is willful and deliberate.

52. This case is exceptional, and MorphoSys is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, MorphoSys respectfully request that the Court enter judgment against Defendants, and for the following relief:

- A. A judgment that Defendants have infringed at least one claim of the '746 Patent;
- B. A judgment that Defendants infringement of the '746 Patent was willful and deliberate;

C. An award to MorphoSys of damages adequate to compensate it for Defendants' past infringement and any continuing or future infringement including interest, costs, and disbursements as justified under 35 U.S.C. § 284.

D. Trebling any and all damages awarded to MorphoSys based on Defendants' willful and deliberate infringement, pursuant to 35 U.S.C. § 285;

E. A judgment that this case is exceptional within the meaning of 35 U.S.C. § 285 and a judgment awarding MorphoSys its reasonable attorneys' fees, costs and expenses accrued in this action pursuant to 35 U.S.C. § 285;

F. Such other and further relief in law or equity as the Court deems just and appropriate.

DEMAND FOR JURY TRIAL

MorphoSys hereby demands a trial by jury on all issues so triable.

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