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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

MEDIMMUNE, LLC,

Plaintiff,

v.

PDL BIOPHARMA, INC.,

Defendant.

No. CV 08 5590

FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT NON-INFRINGEMENT AND INVALIDITY AND CONTRACTUAL RIGHTS

## FIRST AMENDED COMPLAINT

Plaintiff MedImmune, LLC (f/k/a MedImmune, Inc.) ("MedImmune"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for declaratory relief pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §2201. MedImmune seeks a declaration that U.S. Patent Nos. 5,585,089, 5,693,761, 5,693,762, 6,180,370, and 7,022,500 are invalid and/or not infringed by MedImmune's antibody products palivizumab and motavizumab, and that MedImmune owes no payments under a patent license agreement with PDL BioPharma, Inc. (f/k/a Protein Design Labs, Inc.) ("PDL"), assignee of the patents.

## PARTIES, JURISDICTION, AND VENUE

2. Plaintiff MedImmune is a biotechnology company with its principal place of business in Gaithersburg, Maryland. MedImmune uses biotechnology to develop and produce antibody therapies, including for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus ("RSV") in vulnerable infants.

3. PDL is a biopharmaceutical company with its headquarters at 1400 Seaport Blvd., Redwood City, CA. On information and belief, PDL is the assignee of United States Patent Nos. 5,585,089, 5,693,761, 5,693,762, 6,180,370, and 7,022,500 (collectively, "the PDL patents"), entitled Humanized Immunoglobulins, directed to, *inter alia*, certain humanized antibodies and methods of preparing such antibodies. PDL is the successor-in-interest of Protein Design Labs, Inc.

4. On information and belief, PDL's headquarters in Redwood City are its only place of business in the United States.

5. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§1331, 1337, 1338(a), and 2201. This Court has jurisdiction over any state law claims asserted hereunder pursuant to 28 U.S.C. §1367.

6. This Court has personal jurisdiction over Defendant PDL because the company has its principal place of business in this district and, on information and belief, regularly

transacts business within this District in a substantial, continuous and systematic way.

7. Venue is proper in this district pursuant to 28 U.S.C. §§1391 and 1400(b), because PDL has its principal place of business in this district, resides in this district and is subject to personal jurisdiction in this district.

## BACKGROUND

8. In 1997, Protein Design Labs, Inc., the predecessor-in-interest of PDL granted the predecessor-in-interest of MedImmune a license to develop, manufacture, and sell anti-RSV antibodies that would otherwise infringe a valid claim of certain patents of PDL, including the PDL patents, in exchange for a royalty on sales of such products (hereinafter, "License Agreement").

9. In the 1990s MedImmune developed the humanized antibody palivizumab for the treatment of RSV. Palivizumab received FDA approval in 1998 and has been sold since then under the trade name Synagis®. Since then MedImmune has made regular royalty payments to PDL under the License Agreement on sales of Synagis®.

10. MedImmune has developed a next-generation anti-RSV antibody, motavizumab. A Biologic License Application to market motavizumab for the prevention of lower respiratory tract disease caused by RSV was filed by MedImmune in January 2008 and accepted for filing as a standard application in March 2008. MedImmune has prepared commercial quantities of motavizumab and expects to initiate marketing of this product upon FDA approval.

11. Prior to the initiation of this lawsuit, MedImmune informed PDL in writing that MedImmune was contesting whether Synagis® or motavizumab infringed any valid claim of the PDL patents. PDL has taken the position that both Synagis® and motavizumab infringe the PDL patents.

**COUNT I—DECLARATORY JUDGMENT OF NON-INFRINGEMENT**

12. MedImmune incorporates each of the preceding paragraphs as if fully set forth herein.

13. An actual controversy and exists between the parties concerning whether, absent the License Agreement, Synagis® and motavizumab infringe the PDL patents.

14. The unlicensed commercial manufacture, use, offer for sale, sale and/or importation into the United States of Synagis®, do not infringe United States Patent No. 5,585,089, or contribute to or induce infringement by others.

15. The unlicensed commercial manufacture, use, offer for sale, sale and/or importation into the United States of Synagis® do not infringe United States Patent No. 5,693,761, or contribute to or induce infringement by others.

16. The unlicensed commercial manufacture, use, offer for sale, sale and/or importation into the United States of Synagis® do not infringe United States Patent No. 5,693,762, or contribute to or induce infringement by others.

17. The unlicensed commercial manufacture, use, offer for sale, sale and/or importation into the United States of Synagis® do not infringe United States Patent No. 6,180,370, or contribute to or induce infringement by others.

18. The unlicensed commercial manufacture, use, offer for sale, sale and/or importation into the United States of Synagis® do not infringe United States Patent No. 7,022,500, or contribute to or induce infringement by others.

19. The unlicensed commercial manufacture, use, offer for sale, sale and/or importation into the United States of motavizumab will not infringe United States Patent No. 5,585,089, or contribute to or induce infringement by others.

20. The unlicensed commercial manufacture, use, offer for sale, sale and/or importation into the United States of motavizumab will not infringe United States Patent No. 5,693,761, or contribute to or induce infringement by others.

21. The unlicensed commercial manufacture, use, offer for sale, sale and/or

importation into the United States of motavizumab will not infringe United States Patent No. 5,693,762, or contribute to or induce infringement by others.

22. The unlicensed commercial manufacture, use, offer for sale, sale and/or importation into the United States of motavizumab will not infringe United States Patent No. 6,180,370 or contribute to or induce infringement by others.

23. The unlicensed commercial manufacture, use, offer for sale, sale and/or importation into the United States of motavizumab will not infringe United States Patent No. 7,022,500 or contribute to or induce infringement by others.

24. MedImmune hereby seeks a declaratory judgment that neither Synagis® nor motavizumab infringe any claim of any of the PDL patents.

**COUNT II—DECLARATORY JUDGMENT OF INVALIDITY**

25. MedImmune incorporates each of the preceding paragraphs as if fully set forth herein.

26. United States Patent No. 5,585,089 is invalid under 35 U.S.C. §§101, 102, 103, 112, *et seq*. and/or under the judicially created doctrine of obviousness type double patenting.

27. United States Patent No. 5,693,761 is invalid under 35 U.S.C. §§101, 102, 103, 112, *et seq*. and/or under the judicially created doctrine of obviousness type double patenting.

28. United States Patent No. 5,693,762 is invalid under 35 U.S.C. §§101, 102, 103, 112, *et seq*. and/or under the judicially created doctrine of obviousness type double patenting.

29. United States Patent No. 6,180,370 is invalid under 35 U.S.C. §§101, 102, 103, 112, *et seq*. and/or under the judicially created doctrine of obviousness type double patenting.

30. United States Patent No. 7,022,500 is invalid under 35 U.S.C. §§101, 102, 103, 112, *et seq*. and/or under the judicially created doctrine of obviousness type double

patenting.

31. MedImmune hereby seeks a declaratory judgment that each of the PDL patents is invalid under 35 U.S.C. §§101, 102, 103, 112, *et seq*. and/or under the judicially created doctrine of obviousness type double patenting.

## COUNT III—DECLARATORY JUDGMENT OF CONTRACTUAL RIGHTS

32. MedImmune incorporates each of the preceding paragraphs as if fully set forth herein.

33. Royalties are owed under the License Agreement for Synagis® and motavizumab manufactured and sold in the U.S. only if the development, importation, manufacture, use, or sale of Synagis® and/or motavizumab would, but for the License Agreement, infringe a valid claim of the PDL patents.



34. Because the parties dispute whether Synagis® and motavizumab infringe the PDL patents and whether the PDL patents are valid, an actual controversy exists between the parties concerning the rights and obligations of MedImmune under the terms of the License Agreement.

35. MedImmune has no obligation to make payments to PDL under the License Agreement pertaining to Synagis® or motavizumab that is manufactured and sold, because Synagis® and motavizumab do not infringe any valid claim of the PDL patents. The basis for invalidity of the PDL Patents arises under the patent laws of the United States, 35 U.S.C. §§101, 102, 103, 112, *et seq*. and/or the judicially created doctrine of obviousness type double patenting.

36. MedImmune hereby seeks a declaratory judgment that it owes no payments under the License Agreement pertaining to Synagis® or motavizumab that is manufactured and sold in the United States, and that any payments made to PDL under the License Agreement, post-dating this Complaint, based on sales of Synagis® or motavizumab that is manufactured, sold and used in the United States, are subject to the equitable powers of the

Court.

**PRAYER FOR RELIEF**

WHEREFORE, plaintiff MedImmune requests that judgment be entered in favor of MedImmune and against PDL and requests the following relief:

(a) A declaration that MedImmune's development, manufacture, use, offer for sale, sale and/or importation into the United States of its Synagis® and motavizumab products do not infringe any valid and enforceable claim of the PDL patents, or contribute to or induce infringement by others or;

(b) A declaration that the PDL patents are invalid under 35 U.S.C. §§101, 102, 103, 112, *et seq*. and/or the judicially created doctrine of obviousness type double patenting;

(c) A declaration that PDL is not entitled to any royalties on sales of Synagis® and motavizumab that is manufactured and sold in the United States because the PDL patents are invalid and/or because MedImmune's development, manufacture, use, offer for sale, sale and/or importation into the United States of either product does not infringe any valid claim of the PDL patents;

(d) A declaration that this in an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. §285;

(e) Costs and expenses in this action; and

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

DATED: December 18, 2008.

Respectfully,

GERSON A. ZWEIFACH
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