IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS VACCINES AND DIAGNOSTICS, INC., AND NOVARTIS PHARMA AG, *Plaintiffs*, v. MEDIMMUNE, LLC, BIOGEN IDEC, INC., AND ALEXION PHARMACEUTICALS, INC., *Defendants*.	Civil Action No. 11-cv-00084-SLR-MPT JURY TRIAL DEMANDED [redacted] **REDACTED PUBLIC VERSION**

NOVARTIS VACCINES AND DIAGNOSTICS, INC. AND NOVARTIS PHARMA AG'S MOTION FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

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I. Introduction

Pursuant to Federal Rules of Civil Procedure 15(a) and 16(b), and Local Rule 15.1, Plaintiff Novartis Vaccines and Diagnostics, Inc. ("NVD") and Plaintiff Novartis Pharma AG ("Pharma") (collectively "Plaintiffs") respectfully request the Court's leave to file a Second Amended Complaint for Patent Infringement to address three issues. First, it clarifies that Plaintiff Pharma is *not* asserting patent infringement against Defendant Alexion Pharmaceuticals, Inc. ("Alexion"). Second, it recognizes that former Defendant MedImmune, LLC ("MedImmune") has settled and is no longer a party to this case. Third, it addresses Defendant Biogen Idec, Inc.'s ("Biogen's") stated reason for opposing the amendment—that Plaintiffs' willfulness allegations do not specifically allege pre-filing knowledge of the patent-in-suit, which knowledge has now been shown through discovery.

For these reasons, and those described in Plaintiffs' Opening Brief in Support of its Motion, Plaintiffs respectfully ask that the court grant its Motion for Leave to File a Second Amended Complaint for Patent Infringement. Pursuant to Local Rule 15.1, a proposed amended pleading is attached to the Opening Brief as Exhibit A and a form of the amended pleading underlining the materials to be added is attached as Exhibit B.

The undersigned hereby certifies that, pursuant to Local Rule 7.1.1, on April 22, 2013, counsel for Plaintiffs met and conferred with counsel for Defendants to inquire whether they would consent to Plaintiffs' proposed amendments. During that meeting, counsel for Biogen indicated that it would not consent and counsel for Alexion indicated that it would respond promptly. However, on April 23, 2013, Alexion sent a letter indicating that it was unclear on the proposed amendments. NVD again explained the changes shortly after receiving Alexion's letter. On April 23, 2013, Alexion requested that Plaintiffs delay filing their motion to amend.

Plaintiffs delayed filing their motion to amend for one day and advised Alexion that if no response was received by the close of business on April 24, 2013, then Plaintiffs would proceed to file the motion to amend as an opposed motion. Alexion has advised that it does not oppose Plaintiffs' motion to amend.

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NOVARTIS VACCINES AND DIAGNOSTICS, INC., AND NOVARTIS PHARMA AG, *Plaintiffs*, v. MEDIMMUNE, LLC, BIOGEN IDEC, INC., AND ALEXION PHARMACEUTICALS, INC., *Defendants*.	Civil Action No. 11-cv-00084-SLR-MPT

[PROPOSED] ORDER GRANTING MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT FOR PATENT INFRINGMENT

Plaintiffs' Motion for Leave to File a Second Amended Complaint for Patent Infringement addressing a potential ambiguity to clarify that Novartis Pharma AG is not asserting patent infringement against Alexion Pharmaceuticals, Inc., recognizing that former Defendant MedImmune, LLC, has settled and is no longer a party to this case, and addressing Defendant Biogen Idec, Inc.'s, stated reason for opposing the amendment—that Plaintiffs' willfulness allegations do not specifically allege pre-filing knowledge of the patent-in-suit—is hereby GRANTED.

Dated: _____, 2013

_____
Hon. Sue L. Robinson
UNITED STATES DISTRICT JUDGE

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FOR THE DISTRICT OF DELAWARE

NOVARTIS VACCINES AND DIAGNOSTICS, INC., AND NOVARTIS PHARMA AG, *Plaintiffs*, v. BIOGEN IDEC, INC., AND ALEXION PHARMACEUTICALS, INC. *Defendants*.	Civil Action No. 11-cv-00084 (SLR) JURY TRIAL DEMANDED

Second Amended Complaint For Patent Infringement

Plaintiffs Novartis Vaccines and Diagnostics, Inc. ("V&D"), and Novartis Pharma AG ("Pharma") (collectively "Plaintiffs"), by and through their undersigned counsel, file this Complaint. V&D is filing against Biogen Idec, Inc. ("Biogen"), and Alexion Pharmaceuticals, Inc. ("Alexion"), and Pharma is filing against Biogen only. This Complaint alleges upon knowledge as to matters relating to each of the Plaintiffs and upon information and belief as to all other matters as follows:

Nature of the Action

1. This is an action for patent infringement.

Parties

2. Plaintiff V&D is a corporation organized and existing under the laws of Delaware, having places of business in Emeryville, California and Cambridge, Massachusetts. V&D is engaged in the research, development, manufacture and sale of pharmaceutical products, including vaccines and diagnostic products.

3, Plaintiff Pharma is a corporation organized and existing under the laws of Switzerland, having a place of business in Basel, Switzerland. Pharma is engaged in development, manufacture, and sale of pharmaceutical products.

4. Defendant Biogen is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 14 Cambridge Center, Cambridge, Massachusetts, 02142. Biogen is engaged in the research, development, manufacture and sale of, among other things, pharmaceutical products.

5. Defendant Alexion is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 352 Knotter Drive, Cheshire, CT 06410. Alexion is engaged in the research, development, manufacture and sale of, among other things, pharmaceutical products.

Jurisdiction And Venue

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, 35 U.S.C. § 101 et seq.

7. The Defendants are subject to personal jurisdiction in this district because each is a corporation organized and existing under the laws of the state of Delaware and/or has established minimum contacts with the forum such that the exercise of jurisdiction over the Defendants will not offend traditional notions of fair play and substantial justice.

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

9. On November 18, 1997, United States Patent No. 5,688,688 (the "'688 Patent"), entitled "Vector for Expression of a Polypeptide in a Mammalian Cell," was duly and legally issued to inventors Paul Luciw, Dino Dina, Steven Rosenberg, Barbara S. Chapman, Richard M.

Thayer and Nancy Haigwood. A true and correct copy of the '688 Patent is attached hereto as Exhibit 1.

10. Upon issuance, the '688 Patent was assigned to Chiron Corporation ("Chiron"), a biotechnology firm that was formerly based in Emeryville, California.

11. On April 20, 2006, Chiron was acquired by merger and became an indirect, wholly owned subsidiary of Novartis AG. After the acquisition, Chiron's vaccines and blood-testing units were combined to form what is now known as V&D.

12. As successor to Chiron, V&D holds all right, title and interest in the '688 Patent.

13. V&D and Pharma entered into an exclusive license agreement effective July 1, 2012, whereby Pharma became an exclusive licensee of the '688 Patent [redacted].

14. The '688 Patent discloses and claims, among other things, gene expression constructs for the expression of polypeptides in mammalian cells.

15. Non-party Lonza Group AG, through one or more of its affiliates, manufactures and sells a commercial gene expression system—the Lonza GS Expression System™—that uses the same technology claimed in the '688 Patent. A typical expression vector used in the Lonza GS Expression System™ includes each of the four primary elements of the claimed inventions: (a) an upstream SV40 origin of replication; (b) a downstream SV40 polyadenylation region; (c) a transcriptional regulatory region from the human cytomegalovirus ("hCMV") immediate early region IE1, inclusive of the promoter, enhancer and Intron A; and (d) a polypeptide coding sequence encoding a heterologous polypeptide. Accordingly, use of the expression vectors associated with the Lonza GS Expression System™, or use of an expression system into which such vectors are incorporated, infringes one or more claims of the '688 Patent.

Count II

(Biogen's Infringement of U.S. Patent No. 5,688,688)

16. Plaintiffs V&D and Pharma incorporate by reference and re-allege paragraphs 1-15 above as though fully stated herein.

17. Plaintiffs V&D and Pharma allege that Defendant Biogen has been and currently is directly infringing, contributorily infringing, and/or inducing infringement of the '688 Patent by, among other things, making or causing to be made Tysabri® without authority or license from Plaintiffs V&D and Pharma. Tysabri is manufactured in the United States using the Lonza GS Expression System™.

18. Defendant Biogen is liable for infringement of the '688 Patent pursuant to 35 U.S.C. § 271.

19. Defendant Biogen's acts of infringement have caused damage to Plaintiffs V&D and Pharma, and Plaintiffs V&D and Pharma are entitled to recover from Biogen the damages sustained by Plaintiffs V&D and Pharma as a result of the Biogen's wrongful acts in an amount subject to proof at trial.

20. Defendant Biogen has known of the '688 Patent and of its infringement by the manufacture of Tysabri at least as early as November 2010, and Biogen's infringement of the '688 Patent has been and continues to be deliberate and willful, justifying the assessment of treble damages pursuant to 35 U.S.C. § 284, and this is an exceptional case, justifying the award of attorneys' fees and costs pursuant to 35 U.S.C. § 285.

Count III

(Alexion's Infringement of U.S. Patent No. 5,688,688)

21. Plaintiff V&D incorporates by reference and re-alleges paragraphs 1-20 above as though fully stated herein.

22. Plaintiff V&D alleges that Defendant Alexion has been and currently is directly infringing, contributorily infringing, and/or inducing infringement of the '688 Patent by, among other things, making or causing to be made Soliris® without authority or license from V&D. Soliris is manufactured in the United States using the Lonza GS Expression System™.

23. Defendant Alexion is liable for infringement of the '688 Patent pursuant to 35 U.S.C. § 271.

24. Defendant Alexion's acts of infringement have caused damage to Plaintiff V&D, and V&D is entitled to recover from Alexion the damages sustained by V&D as a result of the Alexion's wrongful acts in an amount subject to proof at trial.

25. Defendant Alexion has known of the '688 Patent and of its infringement by the manufacture of Soliris at least as early as May 2006, and Alexion's infringement of the '688 Patent has been and continues to be deliberate and willful, justifying the assessment of treble damages pursuant to 35 U.S.C. § 284, and this is an exceptional case, justifying the award of attorneys' fees and costs pursuant to 35 U.S.C. § 285.

26. **Prayer for Relief**

WHEREFORE:

A. Plaintiffs V&D and Pharma demand judgment declaring that Biogen has infringed and continues to infringe the '688 Patent and finding such infringement willful;

B. Plaintiff V&D demands judgment declaring that Alexion has infringed and continues to infringe the '688 Patent and finding such infringement willful;

C. Plaintiff V&D demands judgment awarding Plaintiff V&D compensatory damages for Biogen and Alexion's infringement, together with interest and costs pursuant to 35 U.S.C. § 284;

D. Plaintiff Pharma demands judgment awarding Pharma compensatory damages for Biogen's infringement, together with interest and costs pursuant to 35 U.S.C. § 284;

E. Plaintiffs V&D and Pharma demand judgment trebling any and all damages awarded to each of them for willful acts of infringement complained of herein;

F. Plaintiffs V&D and Pharma demand judgment awarding each of them reasonable attorneys' fees pursuant to 35 U.S.C 285; and

G. Plaintiffs V&D and Pharma demand judgment granting each of them such other and further relief as this Court deems just and proper.

Jury Demand

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs V&D and Pharma demand a trial by jury.

Dated: _____, 2013

/s/ Richard K. Herrmann

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