IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PDL BIOPHARMA, INC.	)	
	)	
Plaintiff,	)	C. A. No. _____
	)	
v.	)	**DEMAND FOR JURY TRIAL**
	)	
ALEXION PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR INFRINGEMENT OF
UNITED STATES PATENTS NOS. 5,693,761, 5,693,762 AND 6,180,370

OVERVIEW AND NATURE OF THE ACTION

1. PDL BioPharma, Inc. ("PDL"), is a biopharmaceutical company headquartered in Fremont, California. PDL engages in the discovery, development, and commercialization of therapies for severe or life-threatening illnesses. Since its founding as a start-up company in 1986, PDL has emerged as a leading biotechnology company. PDL's antibody humanization technology, and in particular its licensing of its groundbreaking patents, has enabled the development of some of the most innovative therapeutic advances of the past decade — including therapies for metastatic colorectal cancer, respiratory syncytial virus, and metastatic breast cancer. All of the other nine humanized antibody products currently approved by the FDA for marketing in the United States are covered by patent license agreements with PDL. In addition, numerous other biotechnology companies that are in the process of developing humanized antibodies have obtained licenses or the right to license PDL's antibody humanization patents.

2. Alexion, however, is not one of them. Although Alexion has obtained FDA approval for Alexion's humanized antibody product, Soliris™, for patients with

paroxysmal nocturnal hemoglobinuria ("PNH") and Alexion has launched Soliris, Alexion did so without a license from PDL. Soliris is a humanized antibody that infringes the claims of the patents-in-suit and, on information and belief, is made using methods and polynucleotides practicing the claims of the patents-in-suit.

3. Alexion knows this. In fact, in filings by Alexion with the United States Securities and Exchange Commission, Alexion acknowledged that it was "aware of broad patents owned by third parties relating to the manufacture, use, and sale of recombinant humanized antibodies, recombinant humanized single-chain antibodies, recombinant human antibodies and recombinant human single-chain antibodies." That acknowledgement, on information and belief, referred to the patents-in-suit – the broad patents that leaders in the biotechnology industry have acknowledged and licensed, but that Alexion chose to disregard with respect to Soliris. Soliris is projected to be a blockbuster product, with some projecting annual sales of $800 million per year upon launch.

4. The patent laws give PDL the right to compensation for Alexion's invasion of PDL's patent rights. This is a lawsuit for that compensation. PDL is entitled to at least a reasonable royalty for Alexion's invasion of PDL's patent rights. Because Alexion's infringement was willful, PDL is entitled to treble damages. Because this is an exceptional case, PDL is entitled to its attorneys' fees.

5. Although it would be entitled to injunctive relief, PDL does not seek it. PNH is a serious disease. PDL does not seek to deprive PNH sufferers of this FDA-approved treatment. PDL simply seeks its legal remedies against Alexion because it chose to disregard PDL's patent rights instead of licensing them.

PARTIES

6. PDL BioPharma, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business in Fremont, California. PDL is a technology leader in developing and commercializing acute care treatments for patients suffering from severe or life-threatening diseases. PDL has made groundbreaking contributions to the development of therapeutic antibody treatments for humans. PDL's antibody humanization technology has permitted PDL and licensed companies to create therapeutic antibodies that are highly specific to human disease factors while avoiding or minimizing immune rejection. Licensed companies (and products) include some of the leading companies, and some of the blockbuster products, in the biotechnology industry, including: Genentech (Herceptin®, Xolair®, Raptiva®, Avastin®, Lucentis™); Roche (Zenapax®); MedImmune, Inc. (Synagis®); Wyeth/American Home Products (Mylotarg®); and Biogen Idec/Elan (Tysabri®). Additionally, a substantial number of other companies and research organizations have licensed PDL's portfolio of patents covering antibody humanization technology.

7. Alexion Pharmaceuticals, Inc. ("Alexion") is a corporation organized and existing under the laws of Delaware, with, on information and belief, its principal place of business in Cheshire, CT.

JURISDICTION AND VENUE

8. This action for patent infringement arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq*. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Alexion because Alexion is incorporated in the State of Delaware, conducts business in the State of Delaware and has

infringed, has actively induced and contributed to the infringement of, continues to infringe, and continues to actively induce and contribute to the infringement of the PDL patents as alleged below.

10. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and § 1400(b) because Alexion resides in this district and is subject to personal jurisdiction in this district.

FIRST CLAIM FOR RELIEF
(PATENT INFRINGEMENT – U.S. PATENT NO. 5,693,761)

11. PDL here incorporates ¶¶ 1 – 10, above.

12. At all relevant times, PDL has been and is the owner of all right, title, and interest in U.S. Pat. No. 5,693,761 ("the '761 Patent"), entitled "Polynucleotides Encoding Improved Humanized Immunoglobulins," which the United States Patent and Trademark Office ("PTO") duly and legally issued on December 2, 1997. Pursuant to D. Del. LR 3.2, a true and correct copy of the '761 Patent is attached as Exhibit A.

13. Alexion, without license or authorization and in violation of 35 U.S.C. § 271, has infringed and is currently infringing the '761 Patent in violation of 35 U.S.C. § 271 directly, contributorily, and by inducement by, without limitation, making, using, selling, offering for sale, and/or importing Soliris in the United States.

14. Alexion has had actual and constructive knowledge of the '761 Patent. Pursuant to 35 U.S.C. § 284, PDL is entitled to damages adequate to compensate for the infringement but in no event less that a reasonable royalty.

15. Alexion's infringement of the '761 Patent has been and is willful, and pursuant to 35 U.S.C. § 284, PDL is entitled to treble damages.

16. This case is exceptional and therefore PDL is entitled to its attorneys' fees

pursuant to 35 U.S.C. § 285.

SECOND CLAIM FOR RELIEF
(PATENT INFRINGEMENT – U.S. PATENT NO. 5,693,762)

17. PDL here incorporates ¶¶ 1 – 10, above.

18. At all relevant times, PDL has been and is the owner of all right, title, and interest in U.S. Pat. No. 5,693,762 ("the '762 Patent"), entitled "Humanized Immunoglobulins," which the PTO duly and legally issued on December 2, 1997. Pursuant to D. Del. LR 3.2, a true and correct copy of the '762 Patent is attached as Exhibit B.

19. Alexion, without license or authorization and in violation of 35 U.S.C. § 271, has infringed and is currently infringing the '762 Patent in violation of 35 U.S.C. § 271 directly, contributorily, and by inducement by, without limitation, making, using, selling, offering for sale, and/or importing Soliris in the United States.

20. Alexion has had actual and constructive knowledge of the '762 Patent. Pursuant to 35 U.S.C. § 284, PDL is entitled to damages adequate to compensate for the infringement but in no event less that a reasonable royalty.

21. Alexion's infringement of the '762 Patent has been and is willful, and pursuant to 35 U.S.C. § 284, PDL is entitled to treble damages.

22. This case is exceptional and therefore PDL is entitled to its attorneys' fees pursuant to 35 U.S.C. § 285.

THIRD CLAIM FOR RELIEF
(PATENT INFRINGEMENT – U.S. PATENT NO. 6,180,370 B1)

23. PDL here incorporates ¶¶ 1 – 10, above.

24. At all relevant times, PDL has been and is the owner of all right, title, and interest in U.S. Pat. No. 6,180,370 B1 ("the '370 Patent"), entitled "Humanized

Immunoglobulins and Methods of Making the Same," which the PTO duly and legally issued on January 30, 2001. Pursuant to D. Del. LR 3.2, a true and correct copy of the '370 Patent is attached as Exhibit C.

25. Alexion, without license or authorization and in violation of 35 U.S.C. § 271, has infringed and is currently infringing the '370 Patent in violation of 35 U.S.C. § 271 directly, contributorily, and by inducement by, without limitation, making, using, selling, offering for sale, and/or importing Soliris in the United States.

26. Alexion has had actual and constructive knowledge of the '370 Patent. Pursuant to 35 U.S.C. § 284, PDL is entitled to damages adequate to compensate for the infringement but in no event less that a reasonable royalty.

27. Alexion's infringement of the '370 Patent has been and is willful, and pursuant to 35 U.S.C. § 284, PDL is entitled to treble damages.

28. This case is exceptional and therefore PDL is entitled to its attorneys' fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, PDL asks this Court to enter judgment in its favor against Alexion and grant the following relief:

A. An adjudication that Alexion has infringed the '761 Patent, the '762 Patent, and the '370 Patent directly, contributorily, and by inducement in violation of 35 U.S.C. § 271.

B. An award of damages of at least a reasonable royalty pursuant to 35 U.S.C. § 284 for the infringement of the '761 Patent, '762 Patent, and '370 Patent.

C. An award of treble damages against Alexion pursuant to 35 U.S.C. § 284 because the infringement was willful.

D. An award of PDL's cost of suit and attorneys' fees pursuant to 35 U.S.C. § 285 due to the exceptional nature of this case, or as otherwise permitted by law.

E. Any further relief that this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), PDL hereby demands a jury trial for all issues so triable in this action.

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