

FILED

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Alexandria Division

2014 AUG 13 P 4: 48  
COURT  
ALEXANDRIA, VIRGINIA

UCB, INC., )  
)  
Plaintiff, )  
)  
v. )  
)  
YEDA RESEARCH AND )  
DEVELOPMENT CO. LTD., )  
)  
Defendant. )

Civil Action No. 1:14 CV 1038-LMB-TCB

Plaintiff UCB, Inc. ("UCB"), for its Complaint against Yeda Research and Development Co. Ltd. ("Yeda"), hereby alleges as follows:

**NATURE OF THE CASE**

1. UCB seeks a declaration that U.S. Patent No. 6,090,923 entitled "Murine Monoclonal Antibody Binding TNF $\alpha$ " (the "Wallach" patent, attached as Exhibit A) is invalid, unenforceable and not infringed by UCB's Cimzia® product, a humanized PEGylated Fab' fragment ("Cimzia®").

**THE PARTIES**

2. Plaintiff UCB is a corporation organized and existing under the laws of Delaware, having a place of business at 1950 Lake Park Dr., Smyrna, GA 30080.

3. On information and belief, Defendant Yeda is an entity having its principal place of business in Rehovot, Israel. On information and belief, Yeda is in the business of securing, licensing and enforcing patents based upon research work performed at the Weizmann Institute of Science.

### **JURISDICTION AND VENUE**

4. This action arises under the Declaratory Judgment Act, Title 28 of United States Code, Chapter 151, for the purpose of determining an actual and justiciable controversy between the parties hereto. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Yeda pursuant to 35 U.S.C. § 293, and by virtue of, inter alia, having previously availed itself of the rights and benefits of this forum.

6. Venue is proper in this district pursuant to 28 U.S.C. § 1391.

### **THE WALLACH PATENT**

7. The United States Patent and Trademark Office issued the Wallach patent on July 18, 2000. The Wallach patent lists David Wallach, Talia Han and Zelig Eshhar as its inventors.

8. On information and belief, Yeda is the sole assignee of the Wallach patent.

9. The patent application that became the Wallach Patent, U.S. Pat. Appl. No. 07/794,365, was filed on November 13, 1991. U.S. Pat. Appl. No. 07/794,365 was a continuation of U.S. Pat. Appl. No. 07/351,290, which was filed on May 8, 1989, and subsequently was abandoned. U.S. Pat. Appl. No. 07/351,290 was a continuation of U.S. Pat. Appl. No. 06/808,262, which was filed on December 12, 1985, and subsequently was abandoned.

10. The Wallach patent claims priority to an Israeli patent application, No. 73883, which was filed on December 20, 1984.

11. The Wallach patent describes a purified form of a cytotoxic protein, termed "CT," that originates in human mononuclear cells. The Wallach patent provides a process for preparing such purified CT in essentially homogenous form. The Wallach patent also describes a monoclonal antibody, termed "CT-1," that is specific for CT.

12. The Wallach patent claims a “monoclonal antibody which specifically binds a human cytotoxin” that is characterized by features of that cytotoxin. During prosecution of the Wallach patent, the patent applicants asserted that the claimed “human cytotoxin” is the cytotoxin commonly known as tumor necrosis factor alpha (“TNF- $\alpha$ ”). The Wallach patent specification does not disclose or otherwise characterize the cytotoxin as TNF- $\alpha$ .

#### **CERTOLIZUMAB PEGOL (CIMZIA®)**

13. Certolizumab pegol, marketed in the United States and elsewhere under the brand name Cimzia®, is a recombinant, humanized PEGylated Fab’ fragment marketed and sold by UCB. The administration of Cimzia® reduces levels of TNF- $\alpha$ , which diminishes the symptoms of various auto-immune diseases.

14. Cimzia® was originally approved for sale in the United States by the Food & Drug Administration on April 22, 2008. Cimzia® is currently approved in the United States for the treatment of Crohn’s Disease, Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis.

15. Cimzia® was first sold in the United States in April 2008. Cimzia® has been on sale in the United States continuously since that time.

#### **THE PRESENCE OF AN ACTUAL CONTROVERSY**

16. On February 23, 2014, Yeda sent a letter to UCB S.A. alleging that Cimzia® is covered by the Wallach Patent and offering a non-exclusive license to the Wallach patent. UCB S.A. is an affiliate of UCB, and UCB is the entity responsible for marketing and selling Cimzia® in the United States.

17. In response, UCB sent a letter to Yeda, on April 24, 2014, stating UCB’s belief that Cimzia® does not infringe any claim of the Wallach patent.

18. On June 20, 2014, Yeda sent UCB a second letter, reiterating and further detailing Yeda's assertion that Cimzia® infringes the claims of the Wallach patent.

19. Since February 2014, Yeda has alleged and maintained that UCB infringes the Wallach patent. Yeda's conduct demonstrates a real and immediate threat to UCB's sale of Cimzia® within the United States. There is an actual and justiciable controversy between UCB and Yeda with respect to whether UCB's making, using, offering to sell and selling of Cimzia® will infringe any valid and enforceable claim of the Wallach patent. This dispute is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

### **FIRST CAUSE OF ACTION**

#### **PATENT INVALIDITY**

20. UCB incorporates the allegations of paragraphs 1 through 19 as if fully set forth herein.

21. An actual controversy has arisen and now exists between the parties concerning the validity of the Wallach patent.

22. The Wallach patent is invalid under 35 U.S.C. § 101, *et seq.*

23. UCB hereby seeks a declaratory judgment that the Wallach patent is invalid under 35 U.S.C. § 101, *et seq.*

### **SECOND CAUSE OF ACTION**

#### **NON-INFRINGEMENT**

24. UCB incorporates the allegations of paragraphs 1 through 23 as if fully set forth herein.

25. An actual controversy has arisen and now exists between the parties concerning whether Cimzia® infringes any valid and enforceable claim of the Wallach patent.

26. UCB seeks a declaratory judgment that by its making, using, offering to sell, selling, and/or importing Cimzia® in/into the United States, UCB does not and will not infringe any valid and enforceable claim of the Wallach patent.

### **THIRD CAUSE OF ACTION**

#### **PROSECUTION LACHES**

27. UCB incorporates the allegations of paragraphs 1 through 26 as if fully set forth herein.

28. An actual controversy has arisen and now exists between the parties concerning the enforceability of the Wallach patent.

29. The Wallach patent is unenforceable under the doctrine of prosecution laches. The Wallach patent issued after an unreasonable and unexplained delay over nearly fifteen years of prosecution.

30. UCB hereby seeks a declaratory judgment that the Wallach patent is unenforceable due to prosecution laches.

### **FOURTH CAUSE OF ACTION**

#### **LACHES**

31. UCB incorporates the allegations of paragraphs 1 through 30 as if fully set forth herein.

32. An actual controversy has arisen and now exists between the parties concerning whether Yeda unreasonably delayed raising UCB's alleged infringement and whether Yeda's delay was unjustified.

33. UCB hereby seeks a declaratory judgment that any claim for infringement by UCB of the Wallach patent is barred, in whole or in part, by the doctrine of laches.

**PRAYER FOR RELIEF**

**WHEREFORE, Plaintiff requests that judgment be entered in favor of UCB and against**

**Defendant Yeda:**

- 1. Declaring that the Wallach patent is invalid;**
- 2. Declaring that the Wallach patent is not enforceable;**
- 3. Declaring that Cimzia® does not infringe any valid and enforceable claim of the Wallach patent;**
- 4. Declaration that the Wallach Patent is unenforceable due to prosecution laches;**
- 5. Declaration that any claim for infringement by UCB of the Wallach patent is barred, in whole or in part, by the doctrine of laches;**
- 6. Enjoining Yeda from enforcing the Wallach patent;**
- 7. Awarding UCB its costs and attorneys' fees; and**
- 8. Awarding UCB such other relief as the Court may deem just and proper under the circumstances.**

Respectfully submitted,

By 

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