

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CELGENE CORPORATION,)	
)	
Plaintiff,)	Civil Action No. 10-348-GMS
)	
v.)	JURY TRIAL DEMANDED
)	
CYCLACEL PHARMACEUTICALS, INC.,)	
)	
Defendant.)	

FIRST AMENDED COMPLAINT

Plaintiff Celgene Corporation (“Celgene”), by its attorneys, for its Complaint against Cyclacel Pharmaceuticals, Inc. (“Cyclacel”), alleges as follows:

NATURE OF ACTION

1. This is an action for a declaration of non-infringement and invalidity of a series of patents owned by Cyclacel, known as the “Skov Patents.” The President and Chief Executive Officer of Cyclacel has recently and with specificity threatened litigation against Celgene for purportedly infringing the Skov Patents by means of Celgene’s ISTODAX® brand drug. Celgene disputes that it infringes a valid claim of any of the Skov Patents. An actual controversy has arisen and now exists between Celgene and Cyclacel regarding the Skov Patents of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

THE PARTIES

2. Plaintiff Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. Defendant Cyclacel is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 200 Connell Drive, Suite 1500, Berkeley Heights, New Jersey 07922.

JURISDICTION AND VENUE

4. This is an action under the Federal Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, for a declaration pursuant to the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 (federal question) and 1338(a) (action arising under an Act of Congress relating to patents).

6. This Court has personal jurisdiction over Cyclacel because it is incorporated under the laws of the State of Delaware and is therefore a resident of the State, and, on information and belief, by virtue of its continuous and systematic contacts with Delaware in the normal course of its business.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b) for at least the reasons that Cyclacel resides in Delaware, and, on information and belief, does business in this district.

GENERAL ALLEGATIONS

8. Cyclacel was formed following a definitive agreement in December 2005 between Cyclacel Group plc and Xcyte Therapies, Inc. (“Xcyte”) to combine the two companies. As part of this merger, Cyclacel acquired Xcyte’s patent portfolio, including the Skov Patents. Xcyte’s assignment of the Skov Patents to Cyclacel was recorded in the United States Patent and Trademark Office in early 2006.

9. The Skov Patents that Cyclacel acquired as part of the Xcyte transaction include: (a) United States Patent No. 6,403,555, entitled “Depsipeptide And Congeners Thereof For Use As Immunosuppressants” (the “555 patent”); (b) United States Patent No. 6,548,479, entitled

“Therapeutic Uses Of Depsipeptide And Congeners Thereof” (the “479 patent”); (c) United States Patent No. 6,828,302, entitled “Therapeutic Uses Of Depsipeptide And Congeners Thereof” (the “302 patent”); and (d) United States Patent No. 7,041,639, entitled “Depsipeptide And Congeners Thereof For Use As Immunosuppressants” (the “639 patent”). Attached as Exhibit A through D, respectively, are true and correct copies of the '555 patent, '479 patent, '302 patent, and '639 patent.

10. In March 2005, several months before the merger agreement leading to the creation of Cyclacel, Gloucester Pharmaceuticals, Inc. (“Gloucester”) initiated an opposition proceeding before the European Patent Office (the “EPO”) against Xcyte regarding a European counterpart to the Skov Patents. By the Decision dated October 22, 2009, the EPO held the European counterpart of the Skov Patents to be invalid and unenforceable. Cyclacel filed an appeal of that decision on March 1, 2010. Cyclacel’s appeal in Europe remains pending.

11. In early 2010, Celgene acquired Gloucester, including its romidepsin product known as the ISTODAX® brand drug. The ISTODAX® brand drug is a histone deacetylase inhibitor, which was approved by the United States Food and Drug Administration in November 2009 to treat cutaneous T-cell lymphoma in patients who have received at least one prior systemic therapy. Celgene currently markets and sells the ISTODAX® brand drug throughout the country, including in this judicial district.

12. Following the acquisition of Gloucester, Celgene took over the prosecution of the opposition to the Skov Patents in Europe and will file a response to Cyclacel’s appeal of the EPO Decision. Cyclacel and Celgene are thus presently, and directly, adverse regarding the Skov Patents in Europe.

13. On March 17, 2010, approximately two weeks after Cyclacel filed its appeal of the EPO Decision, Cyclacel's President and Chief Executive Officer, Spiro Rombotis, contacted a Celgene executive regarding the Skov Patents. Mr. Rombotis telephoned Gertjan Bartlema, a Director of Business Development at Celgene, and said that Cyclacel has "a problem with Celgene." Mr. Rombotis told Mr. Bartlema that Cyclacel had been advised by its outside counsel that Celgene infringes one or more of the Skov Patents through the ISTODAX® brand drug Celgene acquired from Gloucester. Mr. Rombotis also warned that Cyclacel has the obligation to defend Xcyte's patent estate, and that it would. Perceiving Cyclacel's statements as a clear accusation of patent infringement, Mr. Bartlema referred Mr. Rombotis to Celgene's in-house patent counsel, Richard T. Girards, Jr.

14. On April 19, 2010, Mr. Rombotis telephoned Mr. Girards, and continued to make clear Cyclacel's claim of infringement and intent imminently to sue Celgene for patent infringement. Mr. Rombotis told Mr. Girards that both Cyclacel and its patent counsel have determined that Celgene infringes the patents Cyclacel acquired from Xcyte. Further, Mr. Rombotis emphasized that the prospect of filing suit against Celgene posed little impact to Cyclacel's bottom line because its patent attorneys work on a contingent fee basis. Mr. Rombotis indicated that Cyclacel also was seriously considering, upon advice of its attorneys, waiting for sales of the ISTODAX® brand drug to "build up" to file suit against Celgene.

15. Celgene has considered the Skov Patents and their relevance to the ISTODAX® brand drug. Celgene does not agree that it infringes any valid claim of the Skov Patents. Celgene claims the right to continue sales of the ISTODAX® brand drug without taking a license to the patents Cyclacel acquired from Xcyte.

FIRST CAUSE OF ACTION
(Declaratory Judgment of Non-infringement as to the '555 Patent)

16. Celgene incorporates by reference paragraphs 1 through 15 above as though fully set forth herein.

17. Celgene has not infringed and is not infringing, directly, indirectly, contributorily, by active inducement, or otherwise, any valid claim of the '555 Patent.

SECOND CAUSE OF ACTION
(Declaratory Judgment of Non-infringement as to the '479 Patent)

18. Celgene incorporates by reference paragraphs 1 through 15 above as though fully set forth herein.

19. Celgene has not infringed and is not infringing, directly, indirectly, contributorily, by active inducement, or otherwise, any valid claim of the '479 Patent.

THIRD CAUSE OF ACTION
(Declaratory Judgment of Non-infringement as to the '302 Patent)

20. Celgene incorporates by reference paragraphs 1 through 15 above as though fully set forth herein.

21. Celgene has not infringed and is not infringing, directly, indirectly, contributorily, by active inducement, or otherwise, any valid claim of the '302 Patent.

FOURTH CAUSE OF ACTION
(Declaratory Judgment of Non-infringement as to the '639 Patent)

22. Celgene incorporates by reference paragraphs 1 through 15 above as though fully set forth herein.

23. Celgene has not infringed and is not infringing, directly, indirectly, contributorily, by active inducement, or otherwise, any valid claim of the '639 Patent.

**FIFTH CAUSE OF ACTION
(Declaratory Judgment of Invalidity as to the '555, '479, '302 and '639 Patents)**

24. Celgene incorporates by reference paragraphs 1 through 15 above as though fully set forth herein.

25. The claims of the '555 Patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code, including, without limitation, Sections 101, 102, 103 and/or 112.

26. The claims of the '479 Patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code, including, without limitation, Sections 101, 102, 103 and/or 112.

27. The claims of the '302 Patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code, including, without limitation, Sections 101, 102, 103 and/or 112.

28. The claims of the '639 Patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code, including, without limitation, Sections 101, 102, 103 and/or 112.

Demand for Jury Trial

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

Prayer For Relief

WHEREFORE, Plaintiff respectfully requests the following relief:

(A) Enter judgment declaring that Celgene does not infringe a valid claim of the '555 Patent;

(B) Enter judgment declaring that Celgene does not infringe a valid claim of the '479 Patent;

(C) Enter judgment declaring that Celgene does not infringe a valid claim of the '302 Patent;

(D) Enter judgment declaring that Celgene does not infringe a valid claim of the '639 Patent;

(E) Enter judgment declaring that the claims of the '555, '479, '302, and '639 patents are invalid; and

(F) For such other and further relief as this Court may deem just and proper.

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