UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS VACCINES AND DIAGNOSTICS, INC.
4560 Horton Street
Emeryville, California 94605,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
as represented by Secretary Michael O. Leavitt,
200 Independence Ave., S.W.
Washington, D.C. 20201

and

NATIONAL INSTITUTES OF HEALTH
9000 Rockville Pike
Bethesda, MD 20892,

Defendants.

Civil Case No. 07-CV-02138 (RWR)

DEFENDANTS' ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT

Defendants United States Department of Health and Human Services ("DHHS") and National Institutes of Health (“NIH”) (collectively, "Defendants") answer the allegations of the "First Amended Complaint For Review Of Interference Determination Pursuant To 35 U.S.C. Section 146" of Plaintiff Novartis Vaccines and Diagnostics, Inc. ("Plaintiff") as follows:

1. Defendants admit that this purports to be an action under 35 U.S.C. § 146 to review certain decisions of the Board of Patent Appeals and Interferences (the “Board”) of the United States Patent and Trademark Office (“PTO”) in Patent Interference No. 105,291 ("the '291 interference"). The averments contained in the remaining sentences of paragraph 1 are conclusions of law to which no response is required. To the extent that they are deemed to be averments of fact, Defendants deny them.

2. Defendants admit that 35 U.S.C. § 146 allows for review of interference decisions by this Court and that venue is proper in this district under 28 U.S.C. § 1391 and 35 U.S.C. § 146. Defendants deny that this Court has personal jurisdiction over DHHS and NIH under 35 U.S.C. § 146. Under that statute, the United States, as represented by the Secretary of DHHS, was a real party in interest to the '291 interference as shown by PTO records at the time of the decisions complained of.

3. Defendants lack information sufficient to form a belief concerning the nature of Plaintiff's business and, therefore, deny the allegations of paragraph 3.

4. Admitted.

5. Admitted.

6. Defendants admit only that U.S. Patent No. 6,531,276 ("Luciw '276 patent") issued March 11, 2003, is entitled "Methods for Detecting Human Immunodeficiency Virus Nucleic Acid," issued from U.S. Patent Application No. 08/403,588 filed March 14, 1995, and lists Paul A. Luciw and Dino Dina ("Luciw, *et al.*") as the named inventors. Defendants lack information sufficient to form a belief concerning Plaintiff's alleged ownership rights in the Luciw '276 patent and, therefore, deny the remaining allegations of paragraph 6.

7. Admitted.

8. Admitted.

9. Defendants admit that the United States, as represented by the Secretary of DHHS, is now the owner of the entire right, title, and interest in and to the inventions disclosed in U.S. Patent Application No. 06/693,866 ("Chang '866 Application"). To the extent that there are any other factual averments in paragraph 9, they are denied.

10. Admitted.

11. Admitted.

12. Defendants admit that the Board issued a Decision on Preliminary Motions (Paper 98) on September 1, 2006, and that the Board denied Luciw, *et al.*'s four preliminary motions.

Defendants deny that the rulings on Luciw, *et al.*'s motions were erroneous. To the extent that there are any other factual averments in paragraph 12, they are denied.

13. Defendants admit that the Board issued a Decision on Luciw's Request for Rehearing (Paper 109) on December 26, 2006, and that the Board denied Luciw, *et al.*'s request for reconsideration of Luciw Motion 2. Defendants deny that the ruling on Luciw, *et al.*'s request was erroneous.

14. Defendants admit that the Board issued a Decision (Paper 143) on priority of the parties inventions on September 28, 2007. Defendants deny that the priority decision was erroneous in granting Chang, *et al.*'s priority motion and dismissing Luciw, *et al.*'s priority motion. To the extent that there are any other factual averments in paragraph 14, they are denied.

15. Defendants admit that the Board issued and entered a Judgment (Paper 144) in the '291 interference (Paper 144) on September 28, 2007, adverse to Luciw, *et al.* and favorable to Chang, *et al*. Defendants further admit that the Judgment ordered that priority as to Count 1 be entered against Luciw, *et al.* and that Luciw, *et al.* are not entitled to claims 1-45 of the Luciw '276 patent. Defendants deny that the Judgment was erroneous and contrary to fact and law.

16. Defendants admit that Plaintiff purports to be dissatisfied with the determination of the Board in the ‘291 interference. Defendants deny that the rulings and judgment of the Board adverse to Luciw, *et al.* in (i) the Board's Decision on Preliminary Motions (Paper 98), dated September 1, 2006, (ii) the Board's Decision on Luciw's Request for Rehearing (Paper 104), dated December 26, 2006, (iii) the Board's Decision (Paper 143) on priority, dated September 28, 2007, and (iv) the Board's Judgment (Paper 144), dated September 28, 2007, were erroneous and that Plaintiff is entitled to any judgment modifying or overturning the disputed rulings or judgment of the Board.

17. Defendants deny that Plaintiff (a) is entitled to priority of invention and (b) was the first to invent the subject matter of Count 1 in the '291 interference.

18. Paragraphs A-I set forth Plaintiff's demands for judgment and are not averments of facts requiring a response. To the extent that they are considered averments of fact, Defendants deny them. Plaintiff is not entitled to the relief sought in paragraphs A-I.

AFFIRMATIVE DEFENSES

First Affirmative Defense

19. The '291 interference was initiated by the Board on February 28, 2005, between the Luciw '276 patent and the Chang '866 application. The Board rendered (i) a Decision on Preliminary Motions (Paper 98) on September 1, 2006, (ii) a Decision on Luciw's Request for Rehearing (Paper 109) on December 26, 2006, (iii) a Priority Decision (Paper 143), dated September 28, 2007, and (iv) a Judgment (Paper 144) on priority on September 28, 2007, limited portions of which have been appealed by Plaintiff in the instant action pursuant to 35 U.S.C. § 146.

20. The evidence presented by Plaintiff before the Board does not support the relief now sought before this Court. On information and belief, Plaintiff knew or should have known of those deficiencies. For example, from the earliest stage of the interference, Plaintiff knew or should have known that it had the burden to make a *prima facie* case in support of its motions. Similarly, in the priority phase, Plaintiff knew or should have known that it had the burden to prove a priority date earlier than Chang's reduction to practice.

21. On information and belief, Plaintiff deliberately and knowingly submitted motions and priority proofs to the Board that were not supported by the requisite evidence.

22. Plaintiff should be estopped by virtue of their conduct before the Board from seeking to discover or introduce in this Court any additional evidence not introduced before the Board.

Second Affirmative Defense

23. Before the Board, Defendants timely moved for judgment in their favor on the ground that Plaintiff's claims were unpatentable both in view of the prior art (Chang Motion 2)

and for failure to comply with the written description/enablement requirements of 35 U.S.C. § 112 (Chang Motion 4). These motions were denied by the Board.

24. Should this Court reverse the Board's priority ruling, the Court should also reverse the Board's rulings on Chang Motion 2 and Chang Motion 4, such that claims 1-45 of the Luciw '276 patent are found unpatentable in view of the prior art and/or under 35 U.S.C. § 112, first paragraph, for lack of written description and/or enablement.

Third Affirmative Defense

25. Before the Board, Defendants timely moved to deny Luciw, *et al.*, benefit of its priority applications for failure to comply with the written description and enablement requirements of 35 U.S.C. § 112 (Chang Motion 3). This motion was denied by the Board.

26. Should the Court reverse the Board's priority ruling, the Court should also reverse the Board's ruling that Luciw is entitled to benefit of its priority applications.

27. The Chang '866 Application, filed January 23, 1985, was not challenged by Luciw, *et al.* and predates all of Luciw's priority applications except Luciw's earliest priority application, U.S. Patent Application No. 06/667,501 ("Luciw '501 Application"), filed October 31, 1984. Accordingly, Chang, *et al.* would be entitled to judgment in its favor if Luciw, *et al.* were denied benefit of at least the Luciw '501 Application.

Fourth Affirmative Defense

28. Before the Board, Chang, *et al.* timely moved to be accorded benefit of U.S. Patent Application No. 06/643,306 ("Chang '306 Application"), filed August 22, 1984, for the interference count (Chang Motion 5). This motion was denied by the Board.

29. Should the Court reverse the Board's priority ruling, the Court should also reverse the Board's ruling that Chang, *et al.* are not entitled to be accorded benefit of the Chang '306 Application.

30. Since the Chang '306 Application was filed before any of Luciw, *et al.*'s priority applications, Chang, *et al.* would be entitled to an award of priority if Chang, *et al.* were

accorded benefit of either its '306 Application or its later filed priority application, U.S. Patent Application No. 06/659,399 ("Chang '399 Application"), and priority was decided solely on the basis of the parties' respective priority applications.

Fifth Affirmative Defense

31. Plaintiff fails to state a claim upon which relief can be granted against Defendants.

Sixth Affirmative Defense

32. An interference-in-fact, pursuant to 35 U.S.C. § 135, existed at all times in the '291 interference, until the Board's Judgment on September 28, 2007.

Seventh Affirmative Defense

33. The United States, as represented by the Secretary of DHHS, was at all times a real party in interest to the '291 interference.

Eighth Affirmative Defense

34. Chang, *et al.* were properly awarded priority of the subject matter of Count 1 in the '291 interference.

REQUESTS FOR RELIEF

Defendants deny that Plaintiff is entitled to any of the relief demanded in its Complaint. Further, Defendants respectfully request that this Court:

A. Dismiss the Complaint with prejudice;

B. Affirm the Board's appealed Priority Decision (Paper 143), dated September 28, 2007, and Judgment (Paper 144), dated September 28, 2007, in the '291 interference;

C. Affirm the Board's denial of Luciw Motion 1 in holding that the claims of the Luciw '276 patent interfere-in-fact with the claims of the Chang '866 Application;

D. Affirm the Board's denial of Luciw Motion 2 in holding that claims 2-4 and 7-45 of the Luciw '276 patent correspond to Count 1;

E. Affirm the Board's denial of Luciw Motion 3 in holding that Chang, *et al.* are entitled to benefit of the Chang '339 Application, filed October 10, 1984;

F. Affirm the Board's denial of Luciw Motion 4 in holding that the claims of the Chang '866 Application are not anticipated under 35 U.S.C. § 102(e);

G. Affirm the decision of the Board awarding priority to Chang, *et al.*;

H. Hold that Plaintiff is estopped from seeking discovery and introducing additional evidence relating to the parties' motions and the determination of priority;

I. If the Court reverses the Board's priority ruling, hold that claims 1-45 of the Luciw '276 patent are unpatentable over the prior art (Chang Motion 2) and/or under 35 U.S.C. § 112, ¶ 1 for lack of written description and/or enablement (Chang Motion 4);

J. If the Court reverses the Board's priority ruling, hold that Luciw, *et al.* be denied benefit of its priority applications (Chang Motion 3);

K. If the Court reverses the Board's priority ruling, hold that Chang, *et al.* are entitled to the priority benefit of the Chang '306 Application, filed August 22, 1984 (Chang Motion 5);

L. Award Defendants its costs and reasonable attorney fees incurred in these proceedings; and

M. Enter such other and further relief as the Court deems just and proper.

February 1, 2008

Respectfully submitted,

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