IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS VACCINES AND DIAGNOSTICS, INC.
4560 Horton Street
Emeryville, California 94608,

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)

FIRST AMENDED COMPLAINT FOR REVIEW OF INTERFERENCE DETERMINATION PURSUANT TO 35 U.S.C. SECTION 146

Plaintiff Novartis Vaccines and Diagnostics, Inc. (formerly, Chiron Corporation) through its undersigned attorneys, as and for its Complaint against Defendants, alleges as follows:

NATURE OF ACTION

1. This is an action under 35 U.S.C. § 146 to review a decision of the Board of Patent Appeals and Interferences (the "Board") of the United States Patent and Trademark Office ("PTO") in a patent interference. Specifically, this action seeks review of the Decision on Preliminary Motions (Paper 98), dated September 1, 2006, Decision on Luciw Request for

Rehearing (Paper 109), dated December 26, 2006, Decision – Priority (Paper 143), dated September 28, 2007, and Judgment (Paper 144), dated September 28, 2007, entered by the Board in Patent Interference No. 105,291 ("the '291 Interference"). Pursuant to 35 U.S.C. § 146 and 37 C.F.R. § 1.304(a)(1), the time period for filing a civil action for remedy regarding these determinations ends on November 28, 2007. This suit was timely filed on November 27, 2007.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction of this action under 28 U.S.C. §§ 1331 and 1338 and 35 U.S.C. § 146. This Court has personal jurisdiction over Defendant United States Department of Health and Human Services ("DHSS") and Defendant National Institutes of Health ("NIH") pursuant to 35 U.S.C. § 146. Venue is proper in this district under 28 U.S.C. § 1391 and 35 U.S.C. § 146.

PARTIES

3. Plaintiff Novartis Vaccines and Diagnostics, Inc. ("Novartis") is a Delaware corporation with a principal place of business at 4560 Horton Street, Emeryville, California 94608.

4. On information and belief, the DHSS is an agency of the United States Government and has its principal place of business at 200 Independence Ave., S.W., Washington, D.C. 20201. On information and belief, the DHSS's interest in the subject matter of this litigation is represented by Secretary Michael O. Leavitt, who is being sued in his official capacity as Secretary of the DHSS.

5. On information and belief, the NIH is an agency of the DHSS and has its principal place of business at 9000 Rockville Pike, Bethesda, Maryland 20892.

THE PATENT INTERFERENCE

6. Novartis is the owner of the entire right, title, and interest in and to U.S. Patent No. 6,531,276 (issued March 11, 2003) ("the Luciw '276 patent"), entitled "Methods for Detecting Human Immunodeficiency Virus Nucleic Acid." The patent was issued from an

application 08/403,588 filed on March 14, 1995. The named inventors are Paul A. Luciw and Dino Dina (collectively referred to as "Luciw, *et al.*").

7. At the time this suit was initiated, on information and belief, DHSS, by and through the NIH, and Centocor Inc., a Pennsylvania corporation with its principle place of business at 200 Great Valley Parkway, Malvern, PA 19355, were the owners of the entire right, title, and interest in and to the inventions disclosed in U.S. Patent Application No. 06/693,866 (filed January 23, 1985) ("the Chang '866 application"), entitled "Cloning and Expression of HTLV-III DNA." The named inventors of the Chang '866 application are Nancy T. Chang, Robert C. Gallo, and Flossie Wong-Staal (collectively referred to as "Chang, *et al.*").

8. On December 13, 2007, after being served with the original complaint in the instant action, counsel for the NIH and DHSS represented to Novartis's counsel that Centocor has assigned its entire right, title, and interest to the Chang '866 application to the NIH.

9. Based on the representations of counsel for the NIH and DHSS, Novartis is informed, and thereon believes, that DHSS, by and through the NIH, is the owner of the entire right, title, and interest in and to the inventions disclosed in the Chang '866 application.

10. On February 28, 2005, the Board declared and instituted the '291 Interference between the Luciw '276 patent and the Chang '866 application, based on subject matter defined by a single count, Count 1.

11. The Board held that the claims of the parties corresponding to Count 1 of the '291 Interference are Claims 1-45 of the Luciw '276 patent and Claims 75-81 of the Chang '866 application.

12. On September 1, 2006, the Board issued a Decision on Preliminary Motions (Paper 98) that erroneously denied Luciw, *et al.*'s preliminary motions. First, the Board erroneously denied Luciw, *et al.*'s motion that the parties' claims did not interfere-in-fact because the Chang '866 application's claims did not include a fundamental limitation required by the Luciw '276 patent's claims (Luciw Motion 1). Second, the Board erroneously denied

Luciw, *et al.*'s motion to designate claims 2-4 and 7-45 of the Luciw '276 patent as not corresponding to Count 1 (Luciw Motion 2). Third, the Board erroneously denied Luciw, *et al.*'s motion that for purposes of establishing priority, Chang, *et al.* should not be afforded benefit of an earlier filed patent application, Application No. 06/659,339, filed in the United States on October 10, 1984, because the application fails to describe and enable a constructive reduction to practice of an embodiment within the scope of Count 1 (Luciw Motion 3). Finally, the Board erroneously denied Luciw, *et al.*'s motion that the Chang '866 application's Claims 75-81 were anticipated, and hence unpatentable, under 35 U.S.C. § 102(e) (Luciw Motion 4).

13. On December 26, 2006, the Board issued a Decision on Luciw Request for Rehearing (Paper 109) that erroneously denied Luciw, *et al.*'s request for reconsideration of the Board's denial of Luciw, *et al.*'s Motion 2 in the Board's Decision on Preliminary Motions (Paper 98).

14. On September 28, 2007, the Board issued its Decision on priority of the parties' inventions (Paper 143). The Board's Decision erroneously dismissed Luciw, *et al.*'s motion for judgment based on the priority of their invention over that of Chang, *et al.* because Luciw, *et al.* had conceived of their invention prior to the effective filing date of the Chang, *et al.* invention and then diligently worked toward a constructive reduction to practice (Luciw Motion 6).

15. On September 28, 2007, the Board issued and entered Judgment in the '291 Interference (Paper 144) adverse to Luciw, *et al.*, and favorable to Chang, *et al.*, which erroneously ordered, contrary to fact and law, that:

a. Priority as to Count 1 be entered against Luciw, *et al.*; and

b. Luciw, *et al.* are not entitled to Claims 1-45 of the Luciw '276 patent.

16. Novartis, as a real party in interest, is dissatisfied with the determinations of the Board in the '291 Interference. The rulings and judgment of the Board in its Decision on Preliminary Motions, dated September 1, 2006, its Decision on Luciw Request for Rehearing, dated December 26, 2006, its Priority Decision, dated September 28, 2007, and its Judgment,

dated September 28, 2007, in the '291 Interference were erroneous. Novartis is entitled to a judgment correcting the erroneous judgment and rulings of the Board based on the record before the Board and any additional evidence that Novartis may introduce in this action.

17. Novartis is furthermore entitled to priority of invention, as it was the first to invent the subject matter of Count 1 in the '291 Interference.

WHEREFORE, Novartis demands judgment that:

A. The Board's Decision on Preliminary Motions, dated September 1, 2006, Decision on Luciw Request for Rehearing, dated December 26, 2006, Priority Decision, dated September 28, 2007, and Judgment, dated September 28, 2007, in the '291 Interference be reversed and vacated;

B. The Luciw '276 patent's claims do not interfere-in-fact with the Chang '866 application's claims;

C. Claims 2-4 and 7-45 of the Luciw '276 patent are designated as not corresponding to Count 1;

D. Chang, *et al.* are not entitled to the benefit of U.S. Application No. 06/659,339, filed October 10, 1984, because the application fails to describe and enable a constructive reduction to practice of an embodiment within the scope of Count 1;

E. Chang's Claims 75-81 are anticipated, and hence unpatentable, under 35 U.S.C. § 102(e);

F. Luciw, *et al.* are awarded priority as to Count 1 and are entitled to a patent containing claims embodying Count 1 and all claims in the interference corresponding to the Count;

G. Chang, *et al.* are not entitled to a patent on Claims 75-81 of the Chang '866 application.

H. Costs and attorney fees be awarded in favor of Novartis against Defendants; and

I. Novartis is granted such other and further relief as may be appropriate.

Dated: December 19, 2007

By: _____

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