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

and

CENTOCOR, INC.
200 Great Valley Parkway
Malvern, PA 19355,

Defendants.

Civil Case No.

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 complaint, therefore, is timely filed.

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"), Defendant National Institutes of Health ("NIH"), and Defendant Centocor, Inc. 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.

6. On information and belief, Centocor is a Pennsylvania corporation with its principal place of business at 200 Great Valley Parkway, Malvern, PA 19355, and is a wholly owned subsidiary of Johnson & Johnson, a New Jersey corporation.

THE PATENT INTERFERENCE

7. 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.*").

8. On information and belief, DHSS, by and through the NIH, and Centocor are 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.*").

9. 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.

10. 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.

11. 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).

12. 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).

13. 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).

14. 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.

15. 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.

16. 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: November 27, 2007

By: _____

John P. Corrado (D.C. Bar No. 380948)
MORRISON & FOERSTER LLP
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Washington, DC 20006-1888
Phone: (202) 887-1500

Attorneys for Plaintiff
Novartis Vaccines and Diagnostics, Inc.

CIVIL COVER SHEET

JS-44
(Rev.1/05 DC)

I (a) PLAINTIFFS
Novartis Vaccines and Diagnostics, Inc.

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF (EXCEPT IN U.S. PLAINTIFF CASES) 88888

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
John P. Corrado, Esq.
Morrison & Foerster LLP
2000 Pennsylvania Avenue, NW, Suite 5500
Washington, D.C. 20006-1888 202-887-1500

DEFENDANTS
United States Department of Health and Human Services; National Institutes of Health; Centocor, Inc.

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT (IN U.S. PLAINTIFF CASES ONLY) 11001
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) FOR DIVERSITY CASES ONLY!

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT
(Place a X in one category, A-N, that best represents your cause of action and one in a corresponding Nature of Suit)

○ A. *Antitrust*
- ☐ 410 Antitrust

○ B. *Personal Injury/ Malpractice*
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 368 Asbestos Product Liability

○ C. *Administrative Agency Review*
- ☐ 151 Medicare Act

Social Security:
- ☐ 861 HIA ((1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g)
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g)

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ D. *Temporary Restraining Order/Preliminary Injunction*

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

◉ E. *General Civil (Other)* OR **○ F. *Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

Property Rights
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 610 Agriculture
- ☐ 620 Other Food &Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 RR & Truck
- ☐ 650 Airline Regs
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

Other Statutes
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced & Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Satellite TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 900 Appeal of fee determination under equal access to Justice
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act

G. *Habeas Corpus/ 2255*	H. *Employment Discrimination*	I. *FOIA/PRIVACY ACT*	J. *Student Loan*
☐ 530 Habeas Corpus-General ☐ 510 Motion/Vacate Sentence	☐ 442 Civil Rights-Employment (criteria: race, gender/sex, national origin, discrimination, disability age, religion, retaliation) *(If pro se, select this deck)*	☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	☐ 152 Recovery of Defaulted Student Loans (excluding veterans)

K. *Labor/ERISA (non-employment)*	L. *Other Civil Rights (non-employment)*	M. *Contract*	N. *Three-Judge Court*
☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 730 Labor/Mgmt. Reporting & Disclosure Act ☐ 740 Labor Railway Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 444 Welfare ☐ 440 Other Civil Rights ☐ 445 American w/Disabilities-Employment ☐ 446 Americans w/Disabilities-Other	☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	☐ 441 Civil Rights-Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi district Litigation ○ 7 Appeal to District Judge from Mag. Judge

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)

35 USC Section 146

VII. REQUESTED IN COMPLAINT ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 **DEMAND $** _____ Check YES only if demanded in complaint **JURY DEMAND:** YES ☐ NO ☐

VIII. RELATED CASE(S) IF ANY (See instruction) YES ☒ NO ☐ If yes, please complete related case form.

DATE 11/27/2007 **SIGNATURE OF ATTORNEY OF RECORD** _____

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The **JS-44** civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the Cover Sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff is resident of Washington, D.C.; 88888 if plaintiff is resident of the United States but not of Washington, D.C., and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of case.

VI. CAUSE OF ACTION: Cite the US Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASES, IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.