IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS AG
Lichtstrasse 35
CH-4056, Basel
Switzerland

NOVARTIS CORPORATION
608 Fifth Avenue
New York, NY 10020

Plaintiffs,

v.

HON. DAVID J. KAPPOS
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313
401 Dulany Street
Alexandria, VA 22314

Office of the General Counsel
United States Patent and Trademark Office
P.O. Box 15667, Arlington, VA 22215
Madison Building East, Room 10B20
600 Dulany Street, Alexandria, VA 22314

Defendant.

Civil Action No. _____

COMPLAINT

Plaintiffs Novartis AG and Novartis Corporation ("Novartis" or "Plaintiffs"), for their complaint against the Honorable David J. Kappos (hereinafter "Kappos" or "Defendant"), state as follows:

NATURE OF THE ACTION

1. This is an action by Novartis, the owner and assignee of U.S. Patent No. 7,081,532; U.S. Patent No. 7,097,827; U.S. Patent No. 7,253,257; U.S. Patent No. 7,323,451; U.S. Patent No. 7,442,388; U.S. Patent No. 7,516,741; U.S. Patent No. 7,687,637; U.S. Patent No. 7,696,216; and U.S. Patent No. 7,776,851 (collectively, the "Novartis Patents") for review of the determination by Defendant, pursuant to, *inter alia*, 35 U.S.C. § 154(b)(3)(B), of the patent term adjustment of each of the Novartis Patents. Novartis seeks a judgment that the patent term for each of the Novartis Patents be increased as reflected in the attached **Exhibit A**. Novartis furthermore seeks a judgment that 37 C.F.R. § 1.703(b)(1) is invalid, unconstitutional and contrary to law.

2. This action arises under 35 U.S.C. § 154, the Fifth Amendment of the Constitution of the United States, and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

THE PARTIES

3. Novartis AG is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

4. Novartis Corporation is a corporation organized and existing under the laws of New York, with its principal place of business at 608 Fifth Avenue, New York, NY 10020. Novartis Corporation is a wholly-owned subsidiary of Novartis AG.

5. Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("PTO"), acting in his official capacity. The Director is the head of the PTO and is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents, and is

designated by statute as the official responsible for determining the period of patent term adjustments under 35 U.S.C. § 154(b)(3)(B).

JURISDICTION AND VENUE

6. This Court has jurisdiction to hear this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), 1361, 2201 & 2202; 35 U.S.C. § 154(b); and 5 U.S.C. §§ 701-706.

7. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

8. This Complaint is being timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

ALLEGATIONS COMMON TO ALL COUNTS

The Novartis Patents

9. Novartis is the assignee of all right, title and interest in the Novartis Patents, as evidenced by records on deposit with the PTO and the face of each of the Novartis Patents attached hereto as **Exhibits B-J**. As such, Novartis is the real party in interest in this case.

10. Calculation of the appropriate patent term for each of the Novartis Patents based upon the relevant prosecution history of each of these patents is summarized in Exhibit A.

Patent Term Guarantee

11. The Patent Term Guarantee Act of 1999, a part of the American Inventors Protection Act ("AIPA"), amended 35 U.S.C. § 154(b) to address concerns that delays by the PTO during the prosecution of patent applications could result in a shortening of the effective life of the resulting patents to less than seventeen years.

12. Amended 35 U.S.C. § 154(b) broadened the universe of cognizable administrative delays by the PTO that could retroactively yield an extension of the patent term to compensate for such prosecution delays ("Patent Term Adjustment" or "PTA").

13. Patent Term Adjustment applies to original utility patent applications (including continuations, divisionals and continuations-in-part) filed on or after May 29, 2000.

14. In calculating PTA, Defendant must take into account PTO delays under 35 U.S.C. § 154(b)(1), any overlapping periods in the PTO delays under 35 U.S.C. § 154(b)(2)(A), and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

15. Under 35 U.S.C. § 154(b)(1)(A), an applicant is entitled to PTA for the PTO's failure to carry out certain acts during processing and examination within defined deadlines ("A Delay").

16. Under 35 U.S.C. § 154(b)(1)(B), an applicant is entitled to additional PTA attributable to the PTO's "failure . . . to issue a patent within 3 years after the actual filing date of the application in the United States," but not including "any time consumed by continued examination of the application requested by the applicant under section 132(b)" ("B Delay").

17. 35 U.S.C. § 154(b)(2)(A) provides that "to the extent that periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

18. On January 7, 2010, the Court of Appeals for the Federal Circuit in Wyeth v. Kappos, 591 F.3d 1364 (Fed. Cir. 2010) ("Wyeth"), affirmed the District Court ruling in Wyeth v. Dudas, 580 F. Supp. 2d 138 (D.D.C. 2008), that the correct method for calculating overlap of A Delay and B Delay is to aggregate A Delay and B Delay except to the extent that such aggregation would amount to counting the same calendar days twice.

19. 35 U.S.C. § 154(b)(2)(C)(i) also directs that "the period of adjustment of the term of a patent under paragraph [154(b)(1)] shall be reduced by a period equal to the period of time

during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application" ("C Reduction").

20. Under 35 U.S.C. § 154(b)(4)(A), "[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action."

Defendant's Abrogation of the Patent Term Guarantee

21. Defendant has improperly calculated PTA in a manner that deprives patentees of B Delay due to an incorrect interpretation of the effect of the continuing examination procedure under 35 U.S.C. § 132(b) within the context of 35 U.S.C. § 154(b)(1)(B).

22. Defendant has inappropriately promulgated and relied upon 37 C.F.R. § 1.703(b)(1) to support its flawed interpretation of 35 U.S.C. § 154(b)(1)(B) that B Delay permanently ceases to accrue upon the filing of an RCE by an applicant.

23. Instead, 35 U.S.C. § 154(b)(1)(B)(i) merely requires the exclusion of "any time consumed by continued examination of the application requested by the applicant under 35 U.S.C. § 132(b)" when calculating whether the PTO has satisfied the three-year pendency guarantee.

24. When properly construed, if the PTO fails to meet this three-year pendency guarantee, the applicant is entitled to the full remedy afforded by 35 U.S.C. § 154(b)(1)(B): "the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued," subject only to the specific limitations set forth in 35 U.S.C. § 154(b)(2).

25. None of the limitations included within 35 U.S.C. § 154(b)(2) reduce or otherwise affect the PTA remedy in 35 U.S.C. § 154(b)(1)(B) on the basis of time consumed by examination after filing of an RCE.

26. The PTO also promulgated regulations pursuant to 35 U.S.C. § 154(b)(2)(C) specifying applicant actions that will result in a reduction of the additional patent term available under § 154(b)(1)(B). These regulations, set forth at 37 C.F.R. § 1.704, likewise do not include any reduction or limitation based upon time consumed by examination after the filing of an RCE.

27. Accordingly, the plain language of 35 U.S.C. § 154(b)(1)(B) dictates that if an RCE is not filed within three years after the actual filing date of a patent application, the filing of the RCE has no effect upon the accrual of B Delay for that patent. Under such circumstances, the applicant is entitled to B Delay from the day after the three-year pendency period through the date of issuance of the patent, the explicit remedy set forth in 35 U.S.C. § 154(b)(1)(B), subject only to the specific limitations set forth at 35 U.S.C. § 154(b)(2).

28. Furthermore, the plain language of 35 U.S.C. § 154(b)(1)(B) dictates that if an RCE is filed within three years of the actual filing date of a patent application, the filing of the RCE affects the accrual of B Delay for that patent only by tolling the completion of the three-year pendency period. Under such circumstances, the applicant is entitled to B Delay from the day after the three-year pendency as tolled by the filing of the RCE and the completion of the period of continued examination through the date of issuance of the patent, the explicit remedy set forth in 35 U.S.C. § 154(b)(1)(B), subject only to the specific limitations set forth at 35 U.S.C. § 154(b)(2).

29. To the extent that 37 C.F.R. § 1.703(b)(1) conflicts with the straightforward and unambiguous language of 35 U.S.C. § 154(b)(1)(B), this subsection of the regulation is invalid.

30. In the alternative, even if the remedy afforded under 35 U.S.C. § 154(b)(1)(B) somehow can be construed to be limited by "any time consumed by continued examination of the application requested by the applicant under section 132(b)," the PTO still has improperly calculated PTA in a manner that deprives patentees of B Delay due to its incorrect interpretation of the effect of filing an RCE.

31. The only time properly "consumed by continued examination" is the period from the date the applicant files an RCE through the date the PTO thereafter mails a Notice of Allowance, an event that concludes the continued examination. Accordingly, an applicant is entitled to accrue B Delay for the period from the date of the mailing of a Notice of Allowance through the date of issuance of the patent.

CLAIMS FOR RELIEF

COUNT ONE
(Patent Term Adjustment Under 35 U.S.C. § 154 as to Timeliness)

32. The allegations of paragraphs 1-31 are incorporated in this claim for relief as if fully set forth herein.

33. The 180 day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) only applies to a re-determination of PTA by Defendant under "paragraph (3)," i.e., 35 U.S.C. § 154(b)(3).

34. 35 U.S.C. § 154(b)(3), by its plain terms, therefore governs a PTA determination by Defendant only in conjunction with a notice of allowance of a patent application.

35. 35 U.S.C. § 154(b)(3) does not cover a PTA determination by Defendant in conjunction with the issuance of a patent.

36. Due to the narrow scope of 35 U.S.C. § 154(b)(3), the limitation period in 35 U.S.C. § 154(b)(4)(A) does not restrict the time within which a patentee, through a civil action in

this District, may appeal a PTA determination by Defendant made contemporaneous with the grant of a patent.

37. In this action, Novartis is seeking a recalculation of PTA for each of the Novartis Patents determined by Defendant upon issuance of each of these patents.

38. As a result, The 180 day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) is inapplicable to Novartis' claim herein.

39. Novartis therefore is not time barred by 35 U.S.C. § 154(b)(4)(A) in appealing the PTA determination by Defendant as to each of the Novartis Patents.

40. Novartis therefore is entitled to additional patent term for each of the Novartis Patents as reflected in Exhibit A.

COUNT TWO
(Patent Term Adjustment Under 35 U.S.C. § 154 Concerning Filing of an RCE)

41. The allegations of paragraphs 1-40 are incorporated in this claim for relief as if fully set forth herein.

42. The PTO's calculation of B Delay for each of the Novartis Patents was based upon a flawed interpretation of 35 U.S.C. § 154(b)(1)(B) that wrongly excluded all otherwise compensable PTO delay that accrued after Novartis filed an RCE during the prosecution of those patents.

43. Novartis filed an RCE during prosecution of each of the applications corresponding to each of the Novartis Patents.

44. Where Novartis filed an RCE more than three years after the actual filing date of a patent application corresponding to one of the Novartis Patents, Novartis' filing of the RCE during prosecution of each such application has no effect upon the accrual of B Delay for each of these Novartis Patents.

45. Where Novartis filed an RCE within three years of the actual filing date of a patent application corresponding to one of the Novartis Patents, Novartis' filing of the RCE during prosecution of each such application affects the accrual of B Delay for each of these Novartis Patents only by delaying the beginning of accrual of B Delay past the three year anniversary of the filing date by an amount of time equal to the entire period "consumed by continuing examination."

46. In the alternative, regardless of whether Novartis filed an RCE within or after three years of the actual filing date of a patent application corresponding to one of the Novartis Patents, the PTO's calculation of B Delay for each of the Novartis Patents was based upon an interpretation of 35 U.S.C. § 154(b)(1)(B) that improperly excluded PTO delay that was not "consumed by continuing examination."

47. Any continued examination by the PTO during the prosecution of an application corresponding to each of the Novartis Patents concluded on the dates the PTO mailed to Novartis a notice of allowance linked to each such continued examination.

48. Each of the Novartis Patents accrued B Delay for the period from the dates the PTO mailed to Novartis the respective notices of allowance corresponding to each continued examination initiated during the prosecution of each corresponding application through the dates of issuance of each of these patents.

49. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for each of the Novartis Patents that deprived Novartis of the appropriate PTA for each of these patents.

50. Novartis therefore is entitled to additional patent term for each of the Novartis Patents as reflected in Exhibit A.

COUNT THREE
(Violation of the Fifth Amendment of the Constitution of the United States)

51. The allegations of paragraphs 1-50 are incorporated in this claim for relief as if fully set forth herein.

52. The Fifth Amendment of the Constitution of the United States provides in relevant part, "[N]or shall private property be taken for public use, without just compensation."

53. Novartis enjoys a substantial and cognizable private property right in the full and complete term of each of the Novartis Patents.

54. Novartis has not failed to pay any necessary maintenance fees to the PTO required to maintain its rights in any of the Novartis Patents.

55. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1), the regulatory subsection interpreting 35 U.S.C. § 154(b)(1)(B)(i), and reliance upon this regulatory subsection in improperly calculating B Delay when determining PTA for each of the Novartis Patents permanently deprived Novartis of patent term to which it was entitled under 35 U.S.C. § 154(b).

56. Defendant's purposeful and deliberate diminution of the patent term of each of the Novartis Patents constitutes a taking of Novartis' property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

57. Novartis therefore is entitled to additional patent term for each of the Novartis Patents as reflected in Exhibit A.

COUNT FOUR
(Declaratory Judgment Under The Administrative Procedures Act, 5 U.S.C. § 702 et seq.)

58. The allegations of paragraphs 1-57 are incorporated in this claim for relief as if fully set forth herein.

59. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1), the regulatory subsection interpreting 35 U.S.C. § 154(b)(1)(B)(i), and its improper calculation of B Delay when determining PTA for each of the Novartis Patents were contrary to law.

60. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for each of the Novartis Patents are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A); contrary to Novartis' constitutional rights within the meaning of 5 U.S.C. § 706(2)(B); and in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C).

61. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for each of the Novartis Patents were final agency actions that are reviewable by a district court in accordance with 5 U.S.C. § 704.

62. Novartis has adequately exhausted all of its available administrative remedies under 35 U.S.C. § 154 or, in the alternative, pursuit of any further administrative remedies is futile.

63. Novartis has been afforded no adequate remedy at law for Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for each of the Novartis Patents.

64. Novartis will suffer irreparable injury if 37 C.F.R. § 1.703(b)(1) is not invalidated and Defendant is not directed to recalculate PTA for each of the Novartis Patents.

65. An order invalidating 37 C.F.R. § 1.703(b)(1) and directing Defendant to recalculate PTA for each of the Novartis Patents would not substantially injure any other interested parties, and the public interest will be furthered by invalidation of a regulatory subsection and recalculation of PTA that is contrary to law.

66. Novartis therefore is entitled to additional patent term for each of the Novartis Patents as reflected in Exhibit A.

WHEREFORE, Novartis respectfully prays that this Court:

A. Issue an Order changing the period of PTA for each of the Novartis Patents as set forth in Exhibit A, and requiring Defendant to revise the patent term of each of the Novartis Patents to reflect such additional PTA;

B. Declare pursuant to 28 U.S.C. § 2201 that 37 C.F.R. § 1.703(b)(1) is invalid, unconstitutional and contrary to law; and

C. Grant such other and further relief as the nature of the case may admit or require and as may be just and equitable.

Respectfully submitted,

Dated: May 3, 2011

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