

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

NOVARTIS AG  
Lichtstrasse 35  
CH-4056, Basel  
Switzerland

Plaintiff,

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**

Plaintiff Novartis AG (“Novartis” or “Plaintiff”), for its complaint against the Honorable David J. Kappos (hereinafter “Kappos” or “Defendant”), states as follows:

**NATURE OF THE ACTION**

1. This is an action by Novartis, the owner and assignee of United States Patent No. 7,807,155 (the “155 patent”) 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 the '155 patent. Novartis seeks a judgment that the patent term for the '155 patent be changed from 637 days to 772 days. In the alternative, Novartis seeks a judgment that the patent term for the '155 patent be changed from 637 days to 721 days. 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. 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**

5. 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.

6. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).
7. This Complaint is being timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

### **ALLEGATIONS COMMON TO ALL COUNTS**

#### **The '155 Patent**

8. Novartis is the assignee of all right, title and interest in the '155 patent, as evidenced by records on deposit with the PTO and the face of the '155 patent. As such, Novartis is the real party in interest in this case.

9. Franco E. Di Padova, Hermann Gram, Hans Hofstetter, Margit Jeschke, Jean-Michel Rondeau and Wim Van Den Berg are the inventors of patent application number 11/658,344 ("the '344 application") which was filed (*i.e.*, met all 371(c) requirements) on March 2, 2007 (the "Filing Date"). The '344 application is a national stage application of international Patent Cooperation Treaty ("PCT") application number PCT/EP05/08470 which claims priority to August 5, 2004 (the "PCT Priority Date").

10. On October 15, 2009, the PTO mailed a Non-Final Rejection as to the '344 application (the "First Office Action").

11. On February 23, 2010, the PTO mailed a Notice of Allowance and Fees Due for the '344 application (the "First Notice of Allowance"). Included in the First Notice of Allowance was a Determination of Patent Term Adjustment in which the PTO indicated that the patent term adjustment to date for the '344 application was 531 days.

12. On May 24, 2010, Novartis filed with the PTO a Request for Continued Examination ("RCE") as to the '344 application.

13. On July 14, 2010, the PTO mailed a Notice of Allowance and Fees Due for the

'344 application (the "Second Notice of Allowance"). Included in the Second Notice of Allowance was a Determination of Patent Term Adjustment in which the PTO indicated that the patent term adjustment to date for the '344 application was 530 days.

14. On August 31, 2010, Novartis paid the issue fee for the '344 application, thereby satisfying all outstanding requirements for issuance of a patent therefrom.

15. On September 15, 2010, the PTO mailed an Issue Notification for the '344 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the patent term adjustment for the '344 application was 637 days.

16. On October 5, 2010, the '344 application issued as the '155 patent, reflecting a patent term adjustment of 637 days. A true and correct copy of the '155 patent is attached hereto as Exhibit A.

17. On March 28, 2011, Novartis filed with the PTO a Patent Term Adjustment Petition requesting that the PTO change its patent term adjustment for the '155 patent (the "PTA Petition").

18. The PTA Petition is still pending before the PTO.

#### **Patent Term Guarantee**

19. 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.

20. 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”).

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

22. 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).

23. 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”).

24. 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”).

25. 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.”

26. 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.

27. 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”).

28. 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**

29. 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).

30. 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.

31. 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.

32. 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).

33. 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.

34. 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.

35. 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).

36. 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.

37. 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.

38. 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.

**The Proper Calculation of PTA for the '155 Patent**

39. Under 35 U.S.C. § 154(b)(1)(A)(i), Novartis is entitled to an adjustment of the term of the '155 patent for a period of 531 days. This A Delay period is attributable to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the actual filing date of the application. This period consists of the period from May 2, 2008 (14 months after the Filing Date) through October 15, 2009 (the mailing date of the First Office Action).

40. Under 35 U.S.C. § 154(b)(1)(B), Novartis is entitled to an additional adjustment of the term of the '155 patent for a period of 242 days. This B Delay period consists of the period from February 5, 2010 (three years and thirty months after the PCT Priority Date) through October 5, 2010 (the issue date of the '155 patent).

41. In the alternative, under 35 U.S.C. § 154(b)(1)(B), Novartis is entitled to an additional adjustment of the term of the '155 patent for a period of 191 days. This B Delay period consists of the period from February 5, 2010 (three years and thirty months after the PCT Priority Date) through May 24, 2010 (filing of the RCE) and the period from July 14, 2010 (mailing of the Second Notice of Allowance) through October 5, 2010 (the issue date of the '155 patent).

42. There is no overlap of A Delay and B Delay for the '155 patent pursuant to 35 U.S.C. § 154(b)(2)(A).

43. Under 35 U.S.C. § 154(b)(2)(C)(i), one day of delay is attributable to Novartis. This C Reduction resulted from Novartis' delay in filing its RCE in response to the First Notice of Allowance on May 24, 2010, a date in excess of three months by one day.



44. The correct PTA for the '155 patent is 772 days: the sum of the 531 days of A Delay and the 242 days of B Delay, minus the 1 day of C Reduction.

45. In the alternative, the correct PTA for the '155 patent is 721 days: the sum of the 531 days of A Delay and the 191 days of B Delay, minus the 1 day of C Reduction.

### **CLAIMS FOR RELIEF**

#### **COUNT ONE (Patent Term Adjustment Under 35 U.S.C. § 154)**

46. The allegations of paragraphs 1-45 are incorporated in this claim for relief as if fully set forth herein.

47. The PTO's calculation of B Delay for the '155 patent 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 the RCE.

48. Novartis filed an RCE during prosecution of the '344 application more than three years after the actual filing date of that application.

49. Novartis' filing of the RCE during prosecution of the '344 application has no effect upon the accrual of B Delay for the '155 patent.

50. In the alternative, the PTO's calculation of B Delay for the '155 patent 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."

51. Continued examination of the '344 application by the PTO concluded on the date the PTO mailed to Novartis the Second Notice of Allowance.

52. The '155 patent accrued B Delay for the period from the date the PTO mailed to Novartis the Second Notice of Allowance through the date of issuance of that patent.

53. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '155 patent that deprived Novartis of the appropriate PTA for this patent.

54. Novartis is entitled to additional patent term for the '155 patent such that the 637 days of PTA granted by the PTO should be changed to 772 days or, in the alternative, to at least 721 days.

**COUNT TWO**  
**(Violation of the Fifth Amendment of the**  
**Constitution of the United States)**

55. The allegations of paragraphs 1-54 are incorporated in this claim for relief as if fully set forth herein.

56. 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."

57. Novartis enjoys a substantial and cognizable private property right in the full and complete term of the '155 patent.

58. Novartis has not failed to pay any necessary maintenance fees to the PTO required to maintain its rights in the '155 patent.

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 reliance upon this regulatory subsection in improperly calculating B Delay when determining PTA for the '155 patent permanently deprived Novartis of patent term to which it was entitled under 35 U.S.C. § 154(b).

60. Defendant's purposeful and deliberate diminution of the patent term of the '155 patent constitutes a taking of Novartis' property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

61. Novartis is entitled to additional patent term for the '155 patent such that the 637 days of PTA granted by the PTO should be changed to 772 days or, in the alternative, to at least 721 days.

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

62. The allegations of paragraphs 1-61 are incorporated in this claim for relief as if fully set forth herein.

63. 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 the '155 patent were contrary to law.

64. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '155 patent 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).

65. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '155 patent were final agency actions that are reviewable by a district court in accordance with 5 U.S.C. § 704.

66. 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.

67. 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 the '155 patent.

68. 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 the '155 patent.

69. An order invalidating 37 C.F.R. § 1.703(b)(1) and directing Defendant to recalculate PTA for the '155 patent 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.

70. Novartis is entitled to additional patent term for the '155 patent such that the 637 days of PTA granted by the PTO should be changed to 772 days or, in the alternative, to at least 721 days.

**WHEREFORE**, Novartis respectfully prays that this Court:

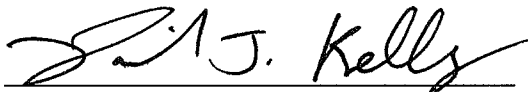
A. Issue an Order changing the period of PTA for the '155 patent from 637 days to 772 days or, in the alternative, to at least 721 days, and requiring Defendant to alter the term of the '155 patent to reflect such additional PTA;

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: April 1, 2011

Handwritten signature of Daniel J. Kelly in black ink, written over a horizontal line.

Daniel J. Kelly (DC Bar No. 397795)

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