

FILED

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION

2012 DEC 21 12 13 22

CLERK OF DISTRICT COURT  
ALEXANDRIA, VIRGINIA

CONARIS RESEARCH INSTITUTE AG,  
Schauenburgerstrasse 116  
Kiel, Germany 24118

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. 1:12cv 1482

LMB/JFA

**COMPLAINT**

Plaintiff Conaris Research Institute AG (“Conaris” or “Plaintiff”), for its complaint against the Honorable David J. Kappos, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, (hereinafter “Kappos” or “Defendant”), states as follows:

**NATURE OF THE ACTION**

1. This is an action by Conaris, the owner and assignee of United States Patent No. 8,206,948 (“the ‘948 patent”), entitled “Optimized Nucleotide Sequences Encoding SGP130” for review of the determination by Defendant, pursuant to, *inter alia*, 35 U.S.C. § 154(b)(3)(B) and 5 U.S.C. §§ 701-706, of the Patent Term Adjustment of the ‘948 patent. Conaris seeks a

judgment that the additional patent term for the '948 patent be changed from 450 days to 865 days.

2. This action arises under 35 U.S.C. § 154, and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

### **THE PARTIES**

3. Conaris is a limited corporation under German law with its principal place of business at Schauenburgerstrasse 116 in Kiel, Germany.

4. Defendant 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. As such, Kappos 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; 35 U.S.C. § 154(b); and 5 U.S.C. §§ 701-706.

6. Venue is proper in this district pursuant to at least 35 U.S.C. § 154(b)(4)(A).

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

### **BACKGROUND AND COMMON ALLEGATIONS**

#### **The '948 Patent**

8. Conaris is the assignee of all right, title, and interest in the '948 patent, as evidenced by records on deposit with the PTO and the face of the '948 patent.

9. Dirk Seegert, Georg Wätzig, Nikolaus Rahaus, Jessica Daecke, and Stefan Rose-John are the inventors of patent application serial number 11/660,461 ("the '461 application") for which the national stage commenced under 35 U.S.C. § 371(b) or (f) on February 27, 2007

(the “Commencement Date”). The ‘461 application claims priority to August 27, 2004 (the “Priority Date”).

10. On July 26, 2007, the PTO mailed a Notification of Missing Parts Under 35 U.S.C. § 371 in the United States Designated/Elected Offices. Conaris responded to the Notification of Missing Parts on November 16, 2007, paying fees and submitting oath and declarations from the inventor (*i.e.*, met all 35 U.S.C. § 371(c) requirements) (the “Filing or 371(c) Date”).

11. On February 7, 2008, the PTO mailed a Notification of Defective Response with regards to completion of the sequence listing in the case. Conaris responded to the Notification of Defective Response on March 5, 2008.

12. On June 11, 2009, the PTO mailed a Restriction/Election Requirement as to the ‘461 application (the “Restriction Requirement”). Conaris responded to the Restriction Requirement on August 5, 2009.

13. On November 16, 2009, the PTO mailed a Non-Final Office Action as to the ‘461 application (the “First Office Action”). Conaris responded to the First Office Action on February 16, 2010.

14. On April 30, 2010, the PTO mailed a Final Office Action as to the ‘461 application (the “Second Office Action”). Conaris filed a Request for Continued Examination (“First RCE”) and responded to the Second Office Action on July 30, 2010.

15. On September 15, 2010, the PTO mailed a Non-Final Office Action as to the ‘461 application (the “Third Office Action”). Conaris responded to the Third Office Action on December 15, 2010.

16. On March 1, 2011, the PTO mailed a Final Office Action as to the ‘461 application (the “Fourth Office Action”). Conaris filed a Request for Continued Examination (“Second RCE”) and a response to the Fourth Office Action on June 1, 2011.

17. On February 23, 2012, Conaris filed a Supplemental Response to the Fourth Office Action at the express request of the Examiner regarding minor revisions to figure descriptors in the specification.

18. On March 1, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '461 application (the "First Notice of Allowance"). Included in the Notice of Allowance was a Determination of Patent Term Adjustment wherein the PTO indicated that the Patent Term Adjustment to date for the '461 application was 298 days.

19. On May 29, 2012, Conaris paid the issue fee for the '461 application, thereby satisfying all outstanding requirements for issuance of a patent.

20. On June 6, 2012, the PTO mailed an Issue Notification for the '461 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 '461 application was 450 days.

21. On June 26, 2012, the '461 application issued as the '948 patent, reflecting a Patent Term Adjustment of 450 days. A true and correct copy of the '948 patent is attached hereto as Exhibit A.

### **Patent Term Guarantee**

22. The Patent Term Guarantee Act of 1999, a part of the American Inventors Protection Act ("AIPA"), amended 35 U.S.C. § 154(b), addressed 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.

23. 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").

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

25. 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).

26. 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").

27. 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").

28. 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."

29. On January 7, 2010, the Court of Appeals for the Federal Circuit in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), 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.

30. 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").

31. On November 1, 2012, *Exelixis, Inc. v. Kappos*, No. 1:12-cv-00096, 2012 U.S. Dist. LEXIS 157762, at \*8 (E.D. Va. Nov. 1, 2012) held that Patent Term Adjustment awards arising from the failure of the PTO to grant a patent within three (3) years of the filing date (known as "B delays") are not necessarily reduced by the filing of a Request for Continued

Examination (“RCE”) if the RCE is filed more than three (3) years after the filing date for that patent application. Therefore, the “B delay” should be calculated from the date three years after filing to the date the patent is issued, whether or not an RCE was filed. *Id.*

32. Under 35 U.S.C. § 154(b)(4)(A), “an 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 Eastern District of Virginia 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 for the ‘948 patent**

33. Defendant has improperly calculated the PTA for the ‘948 patent in a manner that deprives patentees of B Delay due to an incorrect interpretation of the effect of the Continued Examination procedure under 35 U.S.C. § 132(b) within the context of 35 U.S.C. § 154(b)(1)(B).

34. 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.

35. 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.

36. 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).

37. 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.

38. 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.

39. 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). *See Exelixis, Inc. v. Kappos*, No. 1:12-cv-00096, 2012 U.S. Dist. LEXIS 157762 (E.D. Va. Nov. 1, 2012).

40. 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.

**The Proper Calculation of PTA for the '948 patent**

41. Under 35 U.S.C. § 154(b)(1)(A)(i), Conaris is entitled to an adjustment of the term of the '948 patent for a period of 146 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 January 16, 2009 (14 months after the Filing Date) through June 11, 2009 (the mailing date of the Restriction Requirement).

42. Under 35 U.S.C. § 154(b)(1)(A)(ii), Conaris is entitled to an adjustment of the term of the '948 patent for a period of 152 days. This A Delay period is attributable to the PTO's failure to respond to a reply under 35 U.S.C. § 132 within 4 months after the date a reply was filed. This period consists of the period from October 1, 2011 (4 months after the mailing

date of the reply to the Fourth Office Action) through March 1, 2012 (the mailing date of the Notice of Allowance).

43. Under 35 U.S.C. § 154(b)(1)(B), Conaris is entitled to an additional adjustment of the term of the '948 patent of 552 days, for a total period of delay of 850 days. This B Delay period consists of the period from February 27, 2010 (three years after the Commencement Date) through June 26, 2012 (the issue date of the '948 patent).

44. There is overlap of A Delay and B Delay of 152 days for the '948 patent pursuant to 35 U.S.C. § 154(b)(2)(A). The overlap period consists of the period from October 1, 2011 (4 months after the mailing date of the reply to the Fourth Office Action) through March 1, 2012 (the mailing date of the Notice of Allowance).

45. Under 35 U.S.C. § 154(b)(2)(C)(i), the total period of USPTO delay is reduced by the period of applicant delay. In its original calculation, the PTO found no applicant delay. In a review of the record, Applicants calculated 131 days of delay attributable to Conaris' delay in responding to the PTO's Notification of Missing Parts, from October 26, 2007 (three months after the PTO's Notification of Missing Parts) to March 5, 2008 (Applicants' Response to the PTO's Notification of Defective Response). Conaris provides notice of this error pursuant to its duty under MPEP § 2733.

46. The correct PTA for the '948 patent is 865 days: the sum of the 298 days of A Delay and the 850 days of B Delay minus the overlap of A Delay and B Delay of 152 days and 131 days of Applicant Delay.

### **CLAIMS FOR RELIEF**

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

47. The allegations of paragraphs 1-49 are incorporated in this claim for relief as if fully set forth herein.

48. The PTO's calculation of B Delay for the '948 patent was based upon an incorrect commencement date and a flawed interpretation of 35 U.S.C. § 154(b)(1)(B) that



wrongly excluded all otherwise compensable PTO delay that accrued after Conaris filed the RCE.

49. Conaris filed two RCEs during prosecution of the '461 application, all of which were filed more than three years after the actual Filing Date of that application.

50. Conaris's filing of the RCEs during prosecution of the '461 application has no effect upon the accrual of B Delay for the '948 patent.

51. Continued examination of the '461 application by the PTO concluded on the date the PTO mailed to Conaris the Notice of Allowance.

52. The '948 patent accrued B Delay for the period from February 16, 2010 (three (3) years after the Commencement Date) through June 26, 2012 (the issue date of the '948 patent) for a total of 850 days of B delay.

53. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '948 patent that deprived Conaris of the appropriate PTA for this patent.

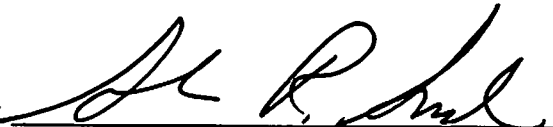
54. Conaris is entitled to additional patent term for the '948 patent such that the 450 days of PTA granted by the PTO should be changed to 865 days.

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

A. Issue an Order changing the period of PTA for the '948 patent from 450 days to 865 days and requiring Defendant to alter the term of the '948 patent to reflect such additional PTA; and

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

Dated: December 20, 2012

By:   
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