

FILED

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF VIRGINIA 2012 MAY 25 P 3:34

CLERK US DISTRICT COURT  
ALEXANDRIA, VIRGINIA

EXELIXIS, INC., a Delaware corporation,  
210 East Grand Avenue  
South San Francisco, CA 94080

Civil Action No. 1:12cv574

LMB/TRJ

Plaintiff,

v.

HON. DAVID J. KAPPOS  
Under Secretary of Commerce for Intellectual  
Property and Director of the United States  
Patent and Trademark Office,  
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.

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**COMPLAINT**

Plaintiff Exelixis, Inc. ("Exelixis" 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 Exelixis, the owner and assignee of United States Patent No. 8,067,436 (the "436 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 '436 patent. Exelixis seeks a judgment that the patent term for the '436 patent be changed from 949 days to 1109 days. In the alternative,

Exelixis seeks a judgment that the patent term for the '436 patent be changed from 949 days to 1101 days. Exelixis 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. Exelixis, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 210 East Grand Avenue, South San Francisco, CA 94080.

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. 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, 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 the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 9, 125 Stat. 316 (2011).

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

**ALLEGATIONS COMMON TO ALL COUNTS**

**The '436 Patent**

8. Exelixis is the assignee of all right, title, and interest in the '436 patent, as evidenced by records on deposit with the PTO and the face of the '436 patent. As such, Exelixis is the real party in interest in this case.

9. Lynne Canne Bannen, Diva Sze-Ming Chan, Jeff Chen, Lisa Esther Dalrymple, Timothy Patrick Forsyth, Tai Phat Huynh, Vasu Jammalamadaka, Richard George Khoury, James William Leahy, Morrison B. Mac, Grace Mann, Larry W. Mann, John M. Nuss, Jason Jevious Parks, Craig Stacy Takeuchi, Yong Wang, Wei Xu are the inventors of patent application number 11/753,514 ("the '514 application"), which was filed on May 24, 2007 (the "Filing Date").

10. The '514 application is a continuation of 11/586,751, filed October 26, 2006, which is a continuation of 10/573,336, filed September 18, 2006, which is a national stage application of international Patent Cooperation Treaty ("PCT") application number PCT/US2004/031523, filed September 24, 2004, and which claims priority to 60/577,384, filed June 4, 2004, 60/535,337, filed January 9, 2004, and 60/506,181, filed September 26, 2003 (the "PCT Priority Date").

11. On July 20, 2010, the PTO mailed a Non-Final Action as to the '514 application (the "First Office Action"). Exelixis responded to the First Office Action on November 11, 2010.

12. On December 23, 2010, the PTO mailed a Final Rejection as to the '514 application (the "Second Office Action"). Exelixis filed an Amendment After Final Rejection on March 23, 2011.

13. On June 16, 2011, the Examiner issued an Advisory Action as to the '514 application (the "Advisory Action").

14. On June 23, 2011, Exelixis filed an Amendment After Final Rejection and a Request for Continued Examination as to the '514 application (the "RCE").

15. On July 1, 2011, the PTO mailed a Notice of Allowance and Fees Due for the '514 application (the "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 '514 application was 612 days.

16. On September 30, 2011, Exelixis paid the issue fee for the '514 application, satisfying all outstanding requirements for issuance of a patent.

17. On November 9, 2011, the PTO mailed an Issue Notification for the '514 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 '514 application was 949 days. The PTO calculated 726 days of "A Delay," 394 days of "B Delay," 57 days of overlap between "A and B Delay" and 114 days of Applicant Delay.

18. On November 29, 2011, the '514 application issued as the '436 patent, reflecting a Patent Term Adjustment of 949 days. A true and correct copy of the '436 patent is attached hereto as Exhibit A.

19. On January 27, 2012, Exelixis filed with the PTO a Patent Term Adjustment Petition requesting that the PTO change its Patent Term Adjustment for the '436 patent (the "PTA Petition").

20. On February 6, 2012, the PTO dismissed Exelixis's Patent Term Adjustment Petition.

### **Patent Term Guarantee**

21. 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.

22. 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").

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

24. 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).

25. 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").

26. 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").

27. 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."

28. 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.

29. Section 154(b)(2)(C)(i) of 35 U.S.C. 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").

30. 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**

31. Defendant has improperly calculated PTA 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).

32. 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.

33. 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.

34. 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).

35. 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.

36. 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.

37. 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).

38. 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.

39. 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.

40. 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. The period encompassed by mailing a Notice of Allowance to issuance of a patent occurs in all cases where a patent issues and is not unique to situations where an RCE was filed and thus should not properly be included in the limitation on time "consumed by 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 '436 Patent**

41. Under 35 U.S.C. § 154(b)(1)(A)(i), Exelixis is entitled to an adjustment of the term of the '436 patent for a period of 726 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 July 24, 2008 (14 months after the Filing Date) through July 20, 2010 (the mailing date of the non-final Office Action).

42. Under 35 U.S.C. § 154(b)(1)(B), Exelixis is entitled to an additional adjustment of the term of the '436 patent for a period of 554 days. This B Delay period consists of the period from May 25, 2010 (three years after the Filing Date) through November 29, 2011 (the issue date of the '436 patent).

43. In the alternative, under 35 U.S.C. § 154(b)(1)(B), Exelixis is entitled to an additional adjustment of the term of the '436 patent for a period of 546 days. This B Delay period consists of the period from May 25, 2010 (three years after the Filing Date) through June 23, 2011 (filing of the RCE) and the period from July 1, 2011 (mailing of the Notice of Allowance) through November 29, 2011 (the issue date of the '436 patent).

44. Pursuant to 35 U.S.C. § 154(b)(2)(A), there is an overlap of A Delay and B Delay of 57 days. The First Office Action was issued after May 25, 2010 (three years after the Filing Date). Therefore, the overlap of A Delay and B Delay occurred between May 25, 2010 (three years after the Filing Date) and July 20, 2010 (the date of the first Office Action), for a total of 57 days.

45. Under 35 U.S.C. § 154(b)(2)(C)(i), 114 days of delay is attributable to Exelixis. Twenty-two days of Applicant Delay Reduction resulted from Exelixis' delay in filing a response to the non-final Office Action on November 11, 2010, a date in excess of three months by 22 days.



46. An additional 92 days of Applicant Delay Reduction resulted from Exelixis filing a response to the Final Office Action, an Amendment After Final Rejection and a Request for Continued Examination, on June 23, 2011, a date in excess of three months by 92 days.

47. The correct PTA for the '436 patent is 1109 days: the sum of the 726 days of A Delay and the 554 days of B Delay, minus the 114 days of Applicant Delay and the 57 days of overlap between A Delay and B Delay.

48. In the alternative, the correct PTA for the '436 patent is 1101 days: the sum of the 726 days of A Delay and the 546 days of B Delay, minus the 114 days of Applicant Delay and the 57 days of overlap between A Delay and B Delay.

### **CLAIMS FOR RELIEF**

#### **COUNT ONE**

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

49. The allegations of paragraphs 1-48 are incorporated in this claim for relief as if fully set forth herein.

50. The PTO's calculation of B Delay for the '436 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 Exelixis filed the RCE.

51. Exelixis filed an RCE during prosecution of the '514 application more than three years after the actual Filing Date of that application.

52. Exelixis' filing of the RCE during prosecution of the '514 application has no effect upon the accrual of B Delay for the '436 patent.

53. In the alternative, the PTO's calculation of B Delay for the '436 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."

54. Continued examination of the '514 application by the PTO concluded on the date the PTO mailed to Exelixis the Notice of Allowance.

55. The '436 patent accrued B Delay for the period from the date the PTO mailed to Exelixis the Notice of Allowance through the date of issuance of that patent.

56. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '436 patent that deprived Exelixis of the appropriate PTA for this patent.

57. Exelixis is entitled to additional patent term for the '436 patent such that the 949 days of PTA granted by the PTO should be changed to 1109 days or, in the alternative, to at least 1101 days.

## **COUNT TWO**

### **(Violation of the Fifth Amendment of the Constitution of the United States)**

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

59. 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."

60. Exelixis enjoys a substantial and cognizable private property right in the full and complete term of the '436 patent.

61. Exelixis has not failed to pay any necessary maintenance fees to the PTO required to maintain its rights in the '436 patent.

62. 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 '436 patent permanently deprived Exelixis of patent term to which it was entitled under 35 U.S.C. § 154(b).

63. Defendant's purposeful and deliberate diminution of the patent term of the '436 patent constitutes a taking of Exelixis' property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

64. Exelixis is entitled to additional patent term for the '436 patent such that the 949 days of PTA granted by the PTO should be changed to 1109 days or, in the alternative, to at least 1101 days.

**COUNT THREE**

**(Declaratory Judgment Under The Administrative Procedures Act,**

**5 U.S.C. § 702 et seq.)**

65. The allegations of paragraphs 1-64 are incorporated in this claim for relief as if fully set forth herein.

66. 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 '436 patent were contrary to law.

67. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '436 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 Exelixis' 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).

68. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '436 patent were final agency actions that are reviewable by a district court in accordance with 5 U.S.C. § 704.

69. Exelixis 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.

70. Exelixis 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 '436 patent.

71. Exelixis 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 '436 patent.

72. There is an actual controversy between the parties within this Court's jurisdiction.

73. An order invalidating 37 C.F.R. § 1.703(b)(1) and directing Defendant to recalculate PTA for the '436 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.

74. Exelixis is entitled to additional patent term for the '436 patent such that the 949 days of PTA granted by the PTO should be changed to 1109 days or, in the alternative, to at least 1101 days.

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

A. Issue an Order changing the period of PTA for the '436 patent from 949 days to 1109 days or, in the alternative, to at least 1101 days, and requiring Defendant to alter the term of the '436 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.

Dated: May 25, 2012

Respectfully submitted,

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