

FILED

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA 2013 JAN 17 P 3:35
Alexandria Division**

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

EMOTIONAL BRAIN B.V.,

Civil Action No. 1:13CV76-CMH/JFA

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
Madison Building East, Room 10B20
600 Dulany Street, Alexandria, VA 22314

Defendant.

_____ /

COMPLAINT

Plaintiff, Emotional Brain B.V., (hereinafter "Emotional Brain" 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 Emotional Brain, the owner and assignee of United States Patent No. 8,227,453 ("the '453 patent") for review of the determination by Defendant, pursuant to, inter alia, 35 U.S.C. § 154(b)(4)(A), of the Patent Term Adjustment of the '453 patent. Emotional Brain seeks a judgment that the patent term for the '453 patent be changed from 1023 days to 1404 days. Alternatively, Emotional Brain seeks a judgment that the patent term for the '453 patent be changed from 1023 days to 1128 days. Emotional Brain 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. Emotional Brain is a private company organized and existing under the laws of the Netherlands, with its principal place of business at Louis Armstrongweg 78, 1311 RL Almere, Netherlands. Emotional Brain serves as a center for clinical and scientific research and education in the field of innovation in healthcare, with a specific focus on women's sexual health.

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) and 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 '453 patent

8. Emotional Brain is the assignee of all right, title, and interest in the '453 patent, as evidenced by records on deposit with the PTO and the face of the '453 patent. As such, Emotional Brain is the real party in interest in this case.

9. Jan Johan Adriaan Tuiten is the inventor of patent application number 11/595,778 (“the '778 application”), which was filed on November 10, 2006 (the “Filing Date”).

10. On July 2, 2009, the PTO mailed a Restriction Requirement (the “First Office Action”). Emotional Brain filed a response to the First Office Action on September 4, 2009.

11. On December 18, 2009, the PTO mailed a Non-Final Office Action (the “Second Office Action”). The initial deadline for responding to the Second Office Action was March 18, 2010. Emotional Brain filed a response to the Second Office Action on April 19, 2010.

12. On June 24, 2010, the PTO mailed a Final Office Action (the “Third Office Action”). The initial deadline for responding to the Third Office Action was September 24, 2010. Emotional Brain filed a Request for Continued Examination (the “RCE”) on December 23, 2010.

13. On November 8, 2011, the PTO mailed a Non-Final Office Action (the “Fourth Office Action”). The initial deadline for responding to the Fourth Office Action was February 8, 2012. Emotional Brain filed a response to the Fourth Office Action on February 6, 2012.

14. On April 12, 2012, the PTO mailed a Notice of Allowance and Fees Due (the “Notice of Allowance”). The Notice of Allowance included a Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) wherein the PTO indicated that the Patent Term Adjustment to date for the '778 application was 616 days. Emotional Brain paid the Issue and Publication Fees on June 21, 2012, satisfying all outstanding requirements for issuance of a

patent.

15. On July 4, 2012, the PTO mailed an Issue Notification (the "Issue Notification"). The Issue Notification included a Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) wherein the PTO indicated that the Patent Term Adjustment was 1023 days. The PTO calculated 738 days of "A Delay;" and 407 days of "B Delay," with no overlap between "A and B Delay," and 122 days of Applicant delay, for a total of 1023 days.

16. On July 24, 2012, the '778 application issued as the '453 patent, reflecting that the Patent Term Adjustment was 1023 days. A true and correct copy of the '453 patent is attached hereto as Exhibit A.

Patent Term Guarantee

17. 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.

18. 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").

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

20. 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).

21. 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”).

22. 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”).

23. 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.”

24. 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.

25. 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”).

26. 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

27. 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).

28. 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.

29. 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. Exelixis, Inc. v. Kappos, Case no. 1:12-cv-96 (E.D.Va. Nov. 1, 2012).

30. 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).

31. 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.

32. 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.

33. 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).

34. 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.

35. 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.

36. 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 ‘453 patent

37. Under 35 U.S.C. §§ 154(b)(1)(A)(i) and 154(b)(1)(A)(ii), Emotional Brain is entitled to an adjustment of the term of the ‘453 patent for a period of 738 days. This A Delay is

attributable to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than fourteen (14) months from the actual Filing Date of the application as well as the PTO's failure to respond to a reply under 35 U.S.C. § 132 within four (4) months after the date on which the reply was filed. This consists of the period from January 11, 2008 (the day after 14 months from the Filing Date) through July 2, 2009 (the mailing date of the First Office Action), which is 539 days, and the period from April 24, 2011 (the day after 4 months from the date the RCE was filed) through November 8, 2011 (the date of the Fourth Office Action), which is 199 days, for a total of 738 days.

38. Under 35 U.S.C. § 154(b)(1)(B), Emotional Brain is entitled to an additional adjustment of the term of the '453 patent for a period of 987 days. This B Delay period consists of the period from November 11, 2009 (the day after three years from the Filing Date) through July 24, 2012 (the issue date of the '453 patent), which is 987 days.

39. Pursuant to 35 U.S.C. § 154(b)(2)(A), there is an overlap of 199 days of A Delay and B Delay. This overlap consists of the period from April 24, 2011 (the day after 4 months from the date the RCE was filed) through November 8, 2011 (the date of the Fourth Office Action), which is 199 days.

40. Under 37 C.F.R. § 1.704, 122 days of delay are attributable to Emotional Brain. This delay consists of the period from March 19, 2010 (the initial deadline for responding to the Second Office Action) through April 19, 2010 (the date Emotional Brain responded to the Second Office Action), which is 32 days, and the period from September 25, 2010 (the initial deadline for responding to the Third Office Action) through December 23, 2012 (the date Emotional Brain filed the RCE), which is 90 days, for a total of 122 days.

41. In the alternative, under 35 U.S.C. § 154(b)(1)(B), Emotional Brain is entitled to

an additional adjustment of the term of the '453 patent for a period of 512 days. This B Delay period consists of the period from November 11, 2009 (the day after three years from the Filing Date) through December 23, 2010 (the day of the filing of the RCE), which is 408 days, and the period from April 12, 2012 (the day of the mailing of the Notice of Allowance) to July 24, 2012 (the issue date of the '453 patent), which is 104 days, for a total of 512 days.

42. Pursuant to 35 U.S.C. § 154(b)(2)(A), there is no overlap of A Delay and B Delay in the alternative B Delay calculation.

43. Under 35 U.S.C. § 154(b)(2)(C)(i), 122 days of delay are attributable to Emotional Brain. This delay consists of the period from March 19, 2010 (the initial deadline for responding to the Second Office Action) through April 19, 2010 (the date Emotional Brain responded to the Second Office Action), which is 32 days, and the period from September 25, 2010 (the initial deadline for responding to the Third Office Action) through December 23, 2012 (the date Emotional Brain filed the RCE), which is 90 days, for a total of 122 days.

44. The correct PTA for the '453 patent is 1404 days: the sum of the 738 days of A Delay and the 987 days of B Delay, subtracting the 199 days of overlapping days between the A Delay and the B Delay, and subtracting the 122 days of delay attributable to Emotional Brain.

45. In the alternative, the correct PTA for the '453 patent is 1128 days: the sum of the 738 days of A Delay and the 512 days of B Delay and subtracting the 122 days of delay attributable to Emotional Brain.

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 '453 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 Emotional Brain filed the RCE.

48. Emotional Brain filed an RCE during prosecution of the '778 application more than three years after the actual Filing Date of that application.

49. Emotional Brain's filing of the RCE during prosecution of the '778 application has no effect upon the accrual of B Delay for the '453 patent.

50. In the alternative, the PTO's calculation of B Delay for the '453 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 '778 application by the PTO concluded on the date the PTO mailed to Emotional Brain the Notice of Allowance.

52. The '453 patent accrued B Delay for the period from the date the PTO mailed to Emotional Brain the 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 '453 patent that deprived Emotional Brain of the appropriate PTA for this patent.

54. Emotional Brain is entitled to additional patent term for the '453 patent such that the 1023 days of PTA granted by the PTO should be changed to 1404 days or, in the alternative, to at least 1128 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. Emotional Brain enjoys a substantial and cognizable private property right in the full and complete term of the ‘453 patent.

58. Emotional Brain has not failed to pay any necessary maintenance fees to the PTO required to maintain its rights in the ‘453 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 ‘453 patent permanently deprived Emotional Brain 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 ‘453 patent constitutes a taking of Emotional Brain's property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

61. Emotional Brain is entitled to additional patent term for the ‘453 patent such that the 1023 days of PTA granted by the PTO should be changed to 1404 days or, in the alternative, to at least 1128 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 '453 patent were contrary to law.

64. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '453 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 Emotional Brain's 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 '453 patent were final agency actions that are reviewable by a district court in accordance with 5 U.S.C. § 704.

66. Emotional Brain 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. Emotional Brain 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 '453 patent Emotional Brain 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 '453 patent.

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

69. An order invalidating 37 C.F.R. § 1.703(b)(1) and directing Defendant to recalculate PTA for the '453 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. Emotional Brain is entitled to additional patent term for the '453 patent such that the 1023 days of PTA granted by the PTO should be changed to 1404 days or, in the alternative, to at least 1128 days.

WHEREFORE, Emotional Brain respectfully prays that this Court:

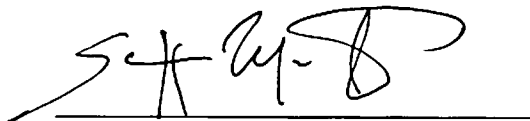
A. Issue an Order changing the period of PTA for the '453 patent from 1023 days to 1404 days or, in the alternative, to at least 1128 days, and requiring Defendant to alter the term of the '453 patent to reflect such additional PTA;

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: January 16, 2012

Respectfully submitted,



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