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United States District Court  
for the  
Eastern District of Virginia

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CLERK US DISTRICT COURT  
ALEXANDRIA, VIRGINIA

**Yeda Research and Development Co., Ltd.,** )  
Plaintiff )  
 )  
v. )  
 )  
**Hon. David J. Kappos,** )  
Under Secretary of Commerce for )  
Intellectual Property and Director of the )  
United States Patent and Trademark Office, )  
Defendant )

Civil Action No. 1:11cv1272

LO/TCB

**COMPLAINT**

Plaintiff Yeda Research and Development Co., Ltd. ("Yeda") alleges as follows:

**Introduction**

1. This is an action under 35 U.S.C. § 154(b)(4)(A) seeking a change in the patent term adjustment ("PTA") conferred by the United States Patent and Trademark Office ("USPTO") on U.S. Patent 7,947,672 (the "'672 patent," attached as Exhibit A). In determining one portion of the PTA for the '672 patent (the so-called "B Delay"), the USPTO applied the calculation described in 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1) and conferred 1303 days of PTA. However, the calculation described in those regulations is contrary to the plain language of 35 U.S.C. § 154(b)(1)(B)(i). Applying the calculation described in the statute, instead of the calculation in the regulations, changes the PTA for the '672 patent from 1303 days to 1526 days.

**Parties**

2. Plaintiff Yeda Research and Development Co., Ltd. ("Yeda") is a corporation organized under the laws of Israel with its primary place of business at the Weizmann Institute of

Science, P.O. Box 95, Rehovot 76100, Israel. Yeda is the owner of all right, title, and interest in and to the '672 patent by assignment from the inventors recorded in the USPTO on June 28, 2006 at reel 017855, frame 0591.

3. Defendant David J. Kappos (the "Director") is named in his official capacity as the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. The Director's addresses are P.O. Box 15667, Arlington, VA 22215 and Mason Building East, Room 10B20, 600 Dulany Street, Alexandria, VA 22314. Under 35 U.S.C. § 3(a)(1), the powers and duties of the USPTO are vested in the Director.

#### **Jurisdiction and Venue**

4. This Court has subject matter jurisdiction under 5 U.S.C. §§ 701-06, 28 U.S.C. §§ 1331, 1338(a), and 1361, and 35 U.S.C. § 154(b)(4)(A).

5. Venue is proper in this District under 35 U.S.C. § 154(b)(4)(A) (as recently amended by Section 9 of Pub. L. 112-29, the Leahy-Smith America Invents Act), and 5 U.S.C. § 703.

6. This Complaint is timely under 35 U.S.C. § 154(b)(4)(A).

#### **Prosecution History of the '672 patent**

7. On November 17, 2002, Yeda filed Israeli patent application no. 152900 listing inventors Avigdor Scherz, Alexander Brandis, Ohad Mazor, Yoram Salomon, and Hugo Scheer.

8. On November 17, 2003, Yeda timely filed Patent Cooperation Treaty application no. PCT/IL03/00973 (the "PCT application"), claiming priority to Israeli patent application no. 152900. The PCT application designated the United States.

9. On May 13, 2005, Yeda, acting for the inventor-assignors (the “Applicant”), timely filed a request to commence United States national stage processing of the PCT application under 35 U.S.C. § 371(f).

10. The USPTO assigned the United States national stage of the PCT application serial number 10/534,692 (the “ ’692 application”).

11. On May 17, 2005, the United States national stage processing of the PCT application commenced. *See* 35 U.S.C. § 371(b).

12. On November 9, 2005, the Applicant satisfied the requirements of 35 U.S.C. § 371(c).

13. On November 9, 2005, the Applicant also filed a preliminary amendment and a first information disclosure statement.

14. On August 6, 2008, the USPTO first responded to the ’692 application under 35 U.S.C. § 132 by mailing a first restriction and election requirement under 35 U.S.C. § 121.

15. On October 6, 2008, the Applicant responded to the first restriction and election requirement by filing a first election.

16. On December 17, 2008, the USPTO responded to the first election by mailing a second restriction and election requirement.

17. On January 15, 2009, the Applicant responded to the second restriction and election requirement by filing a second election.

18. On March 19, 2009, the USPTO responded to the second election by mailing a third restriction and election requirement.

19. On June 18, 2009, the Applicant responded to the third restriction and election requirement by filing a third election.

20. On September 24, 2009, the USPTO responded to the third election by mailing a non-final office action.

21. On January 25, 2010, the Applicant responded to the non-final office action by filing a second amendment.

22. On March 1, 2010, the Applicant filed a second information disclosure statement.

23. On March 4, 2010, the Applicant filed a third information disclosure statement.

24. On April 26, 2010, the USPTO responded to the second amendment by mailing a final office action.

25. On July 23, 2010, the Applicant responded to the final office action by filing a request for continued examination under 35 U.S.C. § 132(b) and 37 C.F.R. §1.114 (an "RCE") with a third amendment.

26. On July 23, 2010, the Applicant also filed a fourth information disclosure statement.

27. On September 22, 2010, the USPTO responded to the third amendment by mailing a notice of allowance.

28. On September 22, 2010, the USPTO also mailed a "Determination of Patent Term Adjustment under 35 U.S.C. § 154(b)" calculating a PTA of 505 days.

29. On November 2, 2010, the Applicant responded to the notice of allowance by paying the issue fee.

30. On November 2, 2010, the Applicant also timely filed an application under 37 C.F.R. § 1.705(b) (denominated a "Petition" by the USPTO) seeking a PTA of "1477 days, which may be extended or reduced based upon the actual date of issuance of a patent." The November 2, 2010, application sought the same correction that is sought in this Complaint.

31. On January 12, 2011, the USPTO dismissed the November 2, 2010, application.

32. On May 24, 2011, the '692 application issued as the '672 patent. The first page of the patent states that "the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1303 days."

33. On July 22, 2011, the Applicant timely filed an application under 37 C.F.R. § 1.705(d) (denominated a "Petition" by the USPTO) seeking a PTA of 1526 days. The July 22, 2011 application sought the same correction that is sought in this Complaint.

34. On August 4, 2011, the USPTO responded by dismissing the July 22, 2011 application.

35. On August 31, 2011, the Applicant filed a request for reconsideration of the dismissal of the 37 C.F.R. § 1.705(d) application seeking that it be either granted or denied on the merits, instead of being dismissed.

36. On October 18, 2011, the USPTO dismissed the request for reconsideration.

37. No terminal disclaimer was filed during the prosecution of the '692 application.

**The USPTO's Determination of PTA for the '672 patent**

38. 35 U.S.C. § 154(b)(3)(B) requires the Director to determine PTA for the '672 patent.

39. The correct amount of PTA due the '672 patent is described at 35 U.S.C. § 154(b) and is properly determined by the following steps, numbered in conformity with the relevant subsections of § 154(b):

(1)(A) adding 1 day for each day that the USPTO fails to meet certain deadlines during examination of the application ("A Delay"), including:

(i)(II) providing a initial response to the application within 14 months after an international application enters the United States national stage; and

- (iv) issuing the patent within 4 months after payment of the issue fee; and
- (1)(B) adding 1 day for each day after 3 years that the patent has not yet issued, subject to certain conditions (“B Delay”); and
- (2)(A) subtracting any overlap of the A Delay and the B Delay above, as interpreted by *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010) (“Overlap”);
- (2)(C) subtracting any time during which the Applicant fails to take reasonable efforts to conclude prosecution of the application (“Applicant Delay”).

40. Exhibit B is a printout of the USPTO’s determination of PTA for the ’672 patent, as shown on the PAIR section of the USPTO’s website.

41. The USPTO correctly determined the amount of PTA under 35 U.S.C. § 154(b)(1)(A)(i)(II) (“14-Month A Delay”) as 575 days. *See* Ex. B. Because the USPTO failed to provide a notification under 35 U.S.C. § 132 not later than 14 months after the date on which the PCT application fulfilled the requirements of 35 U.S.C. § 371 (*i.e.*, not later than January 9, 2007), the ’672 patent was due one day of PTA for each day after January 9, 2007, until such a notification was provided. That notification was provided on August 6, 2008, which was 575 days after the 14-month date. Hence, the USPTO correctly determined that the ’672 patent was due 575 days of PTA caused by 14-Month A Delay. *See* Ex. B.

42. The USPTO correctly determined the amount of PTA under 35 U.S.C. § 154(b)(1)(A)(iv) (“4-Month A Delay”) as 83 days. *See* Ex. B. Because the USPTO failed to issue the ’672 patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirement were satisfied (*i.e.*, not later than March 2, 2011), the ’672 patent was due one day of PTA for each day after March 2, 2011, until issuance. The ’672 patent issued on May 24, 2011, which was 83 days after the 4-month date. Hence, the USPTO correctly determined that the ’672 patent was due 83 days of PTA cause by 4-Month A Delay. *See* Ex. B.

43. The USPTO determined that the '672 patent was due 796 days of PTA under 35 U.S.C. § 154(b)(1)(B) ("B Delay"). *See* Ex. B. Upon information and belief, the USPTO performed that determination as follows, using the method described in 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1). Because the USPTO failed to issue the '672 patent within 3 years of the actual filing date in the U.S. (*i.e.*, within 3 years after the commencement of the United States national stage of processing for the PCT application on May 17, 2005, that is, by May 17, 2008), the USPTO determined that the '672 patent was due one day of PTA for each day after May 17, 2008 until the earlier of either the day the '672 patent issued or the day before the Applicant filed an RCE. The Applicant filed an RCE on July 23, 2010, while the '672 patent issued on May 24, 2011. Thus, upon information and belief, the USPTO determined the amount of B Delay to be the number of days from May 18, 2008 through July 22, 2010, which is 796 days.

44. The USPTO determined the amount of PTA excluded under 35 U.S.C. § 154(b)(2)(A), as interpreted by *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010) ("Overlap") as 81 days. *See* Ex. B. Because the period of 14-Month A Delay began on January 10, 2007, and ended on November 7, 2008, and because the period of B Delay began on May 17, 2008 and ended at some time after November 7, 2008, the period from May 17, 2008 through November 7, 2008 (*i.e.*, 81 days) was both 14-Month A Delay and B delay. Hence, the USPTO determined that the '672 patent should have 81 days of Overlap excluded. *See* Ex. B.

45. The USPTO correctly determined the amount of PTA excluded under 35 U.S.C. § 154(b)(2)(C) ("Applicant Delay") as 70 days, in two parts. *See* Ex. B.

46. First, under 35 U.S.C. § 154(b)(2)(C)(ii), because the Applicant took longer than 3 months to file an amendment in reply to the non-final office action mailed on September 24,

2009, the Applicant Delay included the number of days beginning on the day after the date that is three months after the date of mailing or transmission of the September 24, 2009, non-final office action (*i.e.*, December 25, 2009) and ending on the date the amendment was filed (*i.e.*, January 25, 2010), or 32 days. *See Ex. B; see also 37 C.F.R. § 1.704(b).*

47. Second, under 37 C.F. R. § 1.704(c)(8), because the Applicant thereafter filed second and third information disclosure statements on March 1 and 4, 2010, respectively, constituting supplemental replies or other papers after a reply had been filed, the Applicant Delay included the number of days beginning on the day after the date that the amendment was filed (*i.e.*, January 26, 2010) and ending on the date that the third information disclosure statement was filed (*i.e.*, March 4, 2010), or 38 days. *See Ex. B.*

48. Thus, the USPTO correctly determined that the total amount of PTA excluded for Applicant Delay was 32 days plus 38 days, for 70 days in total.

49. Thus, the amount of PTA determined by the USPTO for the '672 patent was as follows (numbered in conformity with the relevant subsections of § 154(b)):

- (1)(A) taking the sum of all A Delay, *namely*,
  - (i)(II) 575 days of 14-Month A Delay and
  - (iv) 83 days of 4-Month A Delay;
- (1)(B) adding 796 days of B Delay,
- (2)(A) subtracting 81 days of Overlap
- (2)(C) subtracting 70 days of Applicant Delay;

for a net total of 1303 days. *See Ex. B.*

**COUNT I**  
**Award of an Additional 223 Days of Patent Term Adjustment**  
**per 35 U.S.C. § 154(b)(1)(B)(i)**

50. All previous paragraphs are incorporated into this claim for relief.



51. The USPTO erred by failing to correctly apply 35 U.S.C. § 154(b)(1)(B)(i) after the applicant filed an RCE. Pursuant to and in accordance with its rules, the USPTO determined that the amount of B Delay for the '672 patent was 796 days. *See* 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1). However, the governing statute dictates that the B Delay is instead 1102 days.

52. 35 U.S.C. § 154(b)(1)(B) states, in relevant part:

(B) Guarantee of no more than 3-year application pendency.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including—

- (i) any time consumed by continued examination of the application requested by the applicant under section 132(b);
- (ii) . . . ; or
- (iii) . . . ,

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.

53. The plain language of 35 U.S.C. § 154(b)(1)(B) sets up a “trigger” condition which denotes when B Delay applies, and a “remedy” of how much B Delay PTA will be granted if and when the “trigger” condition is satisfied.

54. The “trigger” condition consists of the first phrase of 35 U.S.C. § 154(b)(1)(B) (up to the second dash) plus the three exclusions denoted (i), (ii), and (iii). Only exclusion (i) is applicable in this case. This exclusion states that when determining if the “trigger” condition is met, *i.e.*, whether USPTO issued a patent within 3 years, one does not count any time consumed by an RCE.

55. In the case of the '672 patent, the “trigger” condition is satisfied. Even excluding the entire period after the applicants filed an RCE on July 23, 2010, the USPTO still took more

than 3 years to issue the '672 patent. In fact, that 3-year period ended on May 17, 2008, which was even before the USPTO first responded to the application under 35 U.S.C. §§ 121 and 132.

56. Having satisfied the “trigger” condition, the “remedy” portion of the statute governs the amount of B Delay PTA to be awarded. The “remedy” portion is the flush language which follows 35 U.S.C. § 154(b)(1)(B)(iii) (*i.e.*, “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”).

57. The amount of B Delay PTA to be awarded to the '672 patent is 1 day for each day after the end of that 3-year period (*i.e.*, after May 17, 2008) until the patent was issued (*i.e.*, May 24, 2011), or 1102 days.

58. Because the amount of B Delay PTA includes the 83-day period for which 4-Month A Delay PTA was awarded (*i.e.*, from March 3, 2011 to May 24, 2011), the A Delay and the B Delay overlap during that 83-day period. Thus, when the B Delay is corrected from 796 days to 1102 days, the amount of Overlap must also be increased by 83 days, changing it from 81 days to 164 days.

59. The USPTO’s interpretation of 35 U.S.C. § 154(b)(1)(B)(i) is manifested at 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1). In accordance with 37 C.F.R. 1.703(b)(1), the USPTO declined to attribute any B Delay to the '672 patent for the period beginning on the date on which the applicants filed an RCE and ending on the date the '672 patent issued. In effect, under the USPTO’s rules, the filing of an RCE immediately cuts off accrual of any future B Delay.

60. The USPTO’s interpretation of 35 U.S.C. § 154(b)(1)(B)(i), as articulated in 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1), is contrary to the plain language of that statute. Instead of applying the exception of 35 U.S.C. § 154(b)(1)(B)(i) (concerning RCEs) to the “trigger” portion of the statute, as required by the plain language of that statute, these regulations

erroneously apply the exception of 35 U.S.C. § 154(b)(1)(B)(i) to the “remedy” portion.

Correctly interpreted, the plain language of 35 U.S.C. § 154(b)(1)(B) makes the filing of an RCE relevant only to whether or not B Delay is triggered, but not to how long the term of the patent is adjusted if and when B Delay is triggered.

61. The amount of PTA that would be due the '672 patent had the USPTO correctly applied 35 U.S.C. § 154(b)(1)(B)(i) after the applicant filed an RCE is (numbering conforms to the subsections of § 154(b)):

- (1)(A) taking the sum of all A Delay, namely,
  - (i)(II) 575 days of 14-Month A Delay and
  - (iv) 83 days of 4-Month A Delay;
- (1)(B) adding 1102 days of B Delay;
- (2)(A) subtracting 164 days of Overlap;
- (2)(C) subtracting 70 days of Applicant Delay;

for a net total of 1526 days.

62. The USPTO's use of 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1) in determining the for '672 patent, and the failure to determine at least 1526 days of PTA for the '672 patent, was arbitrary, capricious, an abuse of discretion, not according to law, and in excess of the Director's statutory authority.

#### **Relief Sought**

63. Wherefore, Yeda seeks:
- (a) judgment that the correct period of patent term adjustment for the '672 patent is 1526 days;
  - (b) an order compelling the Director to change the amount of patent term adjustment for the '672 patent from 1303 to 1526 days and to issue an appropriate Certificate of Correction for the '672 patent; and

(c) such other relief as is just and proper.

Dated: November 18, 2011

Respectfully submitted,



Craig G. Falls (Va. Bar No.72926)

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