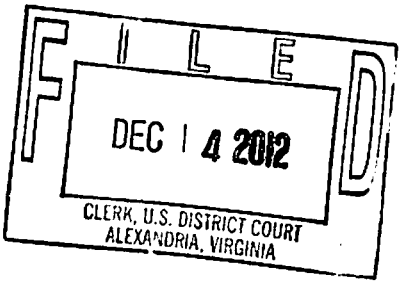
IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION



University of Iowa Research Foundation
Iowa Centers for Enterprise
2660 University Capitol Centre,
Iowa City, IA 52242-5500

Coley Pharmaceutical GmbH
Merowingerplatz 1a
D-40225 Düsseldorf, Germany

Ottawa Hospital Research Institute
725 Parkdale Avenue
Ottawa, Ontario K1Y 4E9, Canada

Pfizer Inc.
235 East 42nd Street
New York, N.Y. 10017-5755

Plaintiffs,

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, Virginia 22313-1450
401 Dulany Street
Alexandria, Virginia 22314

Office of General Counsel
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
Madison Building East, Rm 10B20
600 Dulany Street
Alexandria, VA 22314

Defendant.

Civil Action No. 1:12-cv-1444 TSE/TCB

COMPLAINT

Plaintiffs, the University of Iowa Research Foundation, Coley Pharmaceutical GmbH, the Ottawa Hospital Research Institute and Pfizer Inc., for their complaint against the Honorable David J. Kappos ("Kappos"), state as follows:

NATURE OF THE ACTION

1. This is an action by Plaintiffs, the assignees, owners and licensee of United States Patent No. 8,202,688 (the "'688 Patent") seeking review of the denial of the correct patent term adjustment for that patent by the Defendant Director of the United States Patent and Trademark Office ("USPTO"). Plaintiffs seek a judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '688 Patent be changed from 739 days to 2418 days.

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. The University of Iowa Research Foundation is a corporation organized under the laws of Iowa and having a principal place of business at Iowa Centers for Enterprise, 2660 University Capital Centre, Iowa City, Iowa.

4. Coley Pharmaceutical GmbH is a corporation organized under the laws of Germany, having a principal place of business at Merowingerplatz 1a, Düsseldorf, Germany.

5. Ottawa Hospital Research Institute is a corporation organized under the laws of Canada, having a principal place of business at 725 Parkdale Avenue, Ottawa, Ontario, Canada. On or about March 19, 2009, the Ottawa Health Research Institute changed its name to Ottawa Hospital Research Institute.

6. Pfizer Inc. is a Delaware corporation having a principal place of business at 235 East 42nd Street, New York, NY. The '688 Patent is exclusively licensed to Pfizer Inc.

7. Defendant David J. Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the USPTO, acting in his official capacity. Kappos, as the head of the USPTO, 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.

JURISDICTION AND VENUE

8. 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 and 2202, 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. §§ 701-706.

9. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

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

FACTS

11. Heather L. Davis, Joachim Schorr and Arthur M. Krieg are the inventors of patent application number 10/300,247 ("'247 application"), which issued as the '688 Patent. The '688 Patent is attached hereto as Exhibit A.

12. University of Iowa Research Foundation, Coley Pharmaceutical GmbH and Ottawa Hospital Research Institute are the assignees of the '688 Patent.

13. The '247 application is a continuation application of 10/023,909, which is a division of application 09/325,193. The chain of assignments from the inventors to University of Iowa Research Foundation, Coley Pharmaceutical GmbH and Ottawa Hospital Research Institute were previously recorded in the USPTO for application 09/325,193.

14. Inventor Davis assigned her rights to the Loeb Health Research Institute at the Ottawa Hospital. The Loeb Health Research Institute at the Ottawa Hospital transferred all its assets and liabilities to The Ottawa Health Research Institute on April 1, 2001.

15. Inventor Schorr assigned his rights to CpG ImmunoPharmaceuticals GmbH. CpG ImmunoPharmaceuticals GmbH changed its name to Coley Pharmaceutical GmbH on July 13, 2000.

16. Inventor Krieg assigned his rights to the University of Iowa Research Foundation.

17. The University of Iowa Research Foundation, Coley Pharmaceutical GmbH, Ottawa Hospital Research Institute and Pfizer, Inc. are the real parties of interest in this case.

18. Section 154 of 35 U.S.C. requires that the Director of the USPTO grant a patent term adjustment in accordance with the provisions of section 154(b). Specifically, 35 U.S.C. § 154(b)(3)(D) states that "[t]he Director shall proceed to grant the patent after completion of the Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination."

19. In calculating the patent term adjustment, the Director must account *inter alia* for USPTO delays under 35 U.S.C. § 154(b)(1) and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

20. Under 35 U.S.C. § 154(b)(1)(A), an applicant is entitled to a patent term adjustment for the USPTO's failure to carry out certain acts during processing and examination within defined deadlines ("A Delay").

21. Under 35 U.S.C. § 154(b)(1)(B), an applicant is entitled to additional patent term adjustment attributable to the USPTO'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").

22. Defendant has calculated the patent term adjustment 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).

23. Defendant has inappropriately promulgated and relied upon 37 C.F.R. § 1.703(b)(1) to support its incorrect interpretation of 35 U.S.C. § 154(b)(1)(B) that B Delay permanently ceases to accrue upon the filing of a Request for Continued Examination ("RCE") by an applicant.

24. 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 USPTO has satisfied the three-year pendency guarantee.

25. As properly construed, if the USPTO 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).

26. None of the limitations specified in 35 U.S.C. § 154(b)(2) reduce or otherwise affect the patent term adjustment remedy in 35 U.S.C. § 154(b)(1)(B) on the basis of time consumed by examination after filing of an RCE.

27. The USPTO 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 adjustment specified 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.

28. 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 date of filing of a patent application, the filing of an 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).

29. To the extent that 37 C.F.R. § 1.703(b)(1) conflicts with the plain and unambiguous language of 35 U.S.C. § 154(b)(I)(B), this subsection of the regulation is invalid.

30. In the alternative, even if the remedy afforded under 35 U.S.C. § 154(b)(1)(B) is not determined to be limited by "any time consumed by continued examination of the application requested by the applicant under section 132(b)," the USPTO still has improperly calculated the patent term adjustment in a manner that deprives patentees of B Delay due to its incorrect interpretation of the effect of the filing an RCE.

31. On November 1, 2012, the United States District Court for the Eastern District of Virginia in *Exelixis, Inc. v. Kappos,* No. 1:12cv96, 2012 U.S. Dist. LEXIS 157762 (E.D. Va. Nov. 1, 2012) declared and ordered that an RCE filed in a patent application more than three years after the filing date for that patent application has no effect on patent term adjustment, and that "RCE's operate only to toll the three year guarantee deadline, if, and only if, they are filed within three years of the application filing date. Thus, the PTO erred in construing subparagraph (B) to the contrary." *Id.* at *6.

32. On November 15, 2012, the United States District Court for the District of Columbia in *Novartis AG v. Kappos,* No. 10-cv-1138 (D.D.C. Nov. 15, 2012) adopted the rationale of the court in *Exelixis* to determine that the USPTO's determination of patent term adjustment is contrary to the plain and unambiguous language of § 154(b)(1)(B) and that it contravenes the structure and purpose of the statute.

33. 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 Eastern District of Virginia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action."

CLAIM FOR RELIEF

COUNT ONE

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

34. The allegations of paragraphs 1-33 are incorporated in this claim for relief as if fully set forth.

35. The patent term adjustment for the '688 Patent, as determined by the Defendant under 35 U.S.C. § 154(b), and listed on the face of the '688 Patent, is 739 days. (See Ex. A at p.1). The determination of the 739 day patent term adjustment is in error in that, pursuant to 35 U.S.C. § 154(b)(1)(B), the USPTO failed to extend the term of the patent by one day for each day after the end of a three-year period commencing with the actual filing date of the '247 application until the issue date of the '688 Patent. The correct patent term adjustment for the '688 Patent is 2418 days.

36. The '247 application was filed on November 20, 2002 and issued as the '688 Patent on June 19, 2012. (See Ex. A at p.1)

37. Five RCEs were filed in the '247 application. All five RCEs were filed more than 3 years from the filing date of the '247 application.

38. A first RCE was filed in the '247 application on July 5, 2007, more than 3 years from the filing date of the '247 application. A second RCE was filed in the '247 application on October 31, 2007, more than 3 years from the filing date of the '247 application. A third RCE was filed in the '247 application on September 29, 2009, more than 3 years from the filing date of the '247 application. A fourth RCE was filed in the '247 application on October 12, 2010, more than 3 years from the filing date of the '247 application. A fifth RCE was filed in the '247 application on January 19, 2012, more than 3 years from the filing date of the '247 application. The five RCEs including certificates of electronic filing or certificates of mailing are attached hereto as Exhibit B.

39. Under 35 U.S.C. § 154(b)(1)(A), a period of 838 days is attributable to USPTO examination delay (A Delay). The total period of A Delay is the aggregate of four separate periods.

40. Under 35 U.S.C. § 154(b)(1)(A), a period of 709 days from January 20, 2004 to December 29, 2005 under 35 U.S.C. § 154(b)(1)(A)(i) is attributable to USPTO examination delay due to failure by the USPTO to mail an action under 35 U.S.C. § 132 not later than 14 months after the actual filing date of the application (A Delay).

41. Under 35 U.S.C. § 154(b)(1)(A), a period of 93 days from June 14, 2008 to September 15, 2008 under 35 U.S.C. § 154(b)(1)(A)(ii) is attributable to USPTO examination delay due to failure by the USPTO to reply under section 35 U.S.C. § 132 within 4 months after the date on which a reply was filed by Applicant (A Delay).

42. Under 35 U.S.C. § 154(b)(1)(A), a period of 14 days from May 15, 2009 to May 29, 2009 under 35 U.S.C. § 154(b)(1)(A)(ii) is attributable to USPTO examination delay due to failure by the USPTO to reply under section 35 U.S.C. § 132 within 4 months after the date on which a reply was filed by Applicant (A Delay).

43. Under 35 U.S.C. § 154(b)(1)(A), a period of 22 days from August 28, 2011 to September 19, 2011 under 35 U.S.C. § 154(b)(1)(A)(ii) is attributable to USPTO examination delay due to failure by the USPTO to reply under section 35 U.S.C. § 132 within 4 months after the date on which a reply was filed by Applicant (A Delay).

44. Thus, the total period of A Delay is 838 days (709 days + 93 days + 14 days + 22 days).

45. Under 35 U.S.C. § 154(b)(1)(B), the Plaintiffs are entitled to an additional adjustment of the term of the '688 Patent of a period of 2403 days from November 20, 2005 to June 19, 2012, which is the number of days the issue date of the '688 Patent exceeds a three-year period running from the actual filing date of the '247 application (B Delay).

46. The USPTO's determination of the B Delay only included the number of days exceeding a three-year period running from the actual filing date of the '247 application to the day before the RCE was filed (i.e., 595 days from November 20, 2005 to July 8, 2007).

47. Thus, the total period of A Delay + B Delay is 3241 days (838 days + 2403 days).

48. Under 35 U.S.C. § 154(b)(2)(A), the total period of USPTO delay is reduced by the overlapping days between A Delay and B Delay. The total period of overlapping days between A Delay and B Delay is 168 days.

49. The total period of overlapping days between A Delay and B Delay is the aggregate of four separate periods. The first period of overlapping days between A Delay and B

Delay is a period of 39 days of November 20, 2005 to December 29, 2005. The second period of overlapping days between A Delay and B Delay is a period of 93 days from June 14, 2008 to September 15, 2008. The third period of overlapping days between A Delay and B Delay is a period of 14 days from May 15, 2009 to May 29, 2009. The fourth period of overlapping days between A Delay and B Delay is a period of 22 days from August 28, 2011 to September 19, 2011.

50. Thus, the total period of USPTO delay is 3073 days, which is the sum of the period of A Delay (838 days) and the period of the B Delay (2403 days) minus the period of overlapping days between A Delay and B Delay (168 days).

51. Under 35 U.S.C. § 154(b)(2)(C), the total period of USPTO delay is reduced by the period of applicant delay, which is 655 days as determined by the USPTO.

52. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is 2418 days which is the difference between the total period of USPTO delay (3073 days) and the period of applicant delay (655 days).

53. The '688 Patent is not subject to a terminal disclaimer.

54. The USPTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation of the B Delay for the '688 Patent and deprived patentee of the appropriate PTA for this patent.

55. Plaintiffs are entitled to additional patent term for the '688 Patent such that the 739 days of patent term adjustment granted by the USPTO should be changed to 2418 days.

COUNT TWO

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

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

57. 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."

58. Plaintiffs enjoy a substantial and cognizable private property right in the full and complete term of the '688 Patent.

59. Plaintiffs have not failed to pay any necessary maintenance fees to the USPTO required to maintain its rights in the '688 Patent.

60. 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 the B Delay for the '688 Patent permanently deprived Plaintiffs of the appropriate PTA for this patent to which it was entitled under 35 U.S.C. § 154(b).

61. Defendant's purposeful and deliberate diminution of the patent term of the '688 Patent constitutes a taking of Plaintiffs' property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

62. Plaintiffs are entitled to additional patent term for the '688 Patent such that the 739 days of patent term adjustment granted by the USPTO should be changed to 2418 days.

COUNT THREE

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

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

64. 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 the B Delay when determining the patent term adjustment for the '688 Patent were contrary to law.

65. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of patent term adjustment for the '688 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 Plaintiffs' 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).

66. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '688 Patent were final agency actions that are reviewable by a district court in accordance with 5 U.S.C. § 704.

67. Plaintiffs have 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.

68. Plaintiffs have been afforded no adequate remedy at law for the Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of patent term adjustment for the '688 Patent.

69. Plaintiffs will suffer irreparable injury if 37 C.F.R. § 1.703(b)(1) is not invalidated and the Defendant is not directed to recalculate patent term adjustment for the '688 Patent.

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

71. An order invalidating 37 C.F.R. § 1.703(b)(1) and directing the Defendant to recalculate patent term adjustment for the '688 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 patent term adjustment that is contrary to law.

72. Plaintiffs are entitled to additional patent term for the '688 Patent such that the 739 days of patent term adjustment granted by the USPTO should be changed to 2418 days.

WHEREFORE, Plaintiffs respectfully pray that this Court:

1. Issue an Order changing the period of patent term adjustment for the '688 Patent term from 739 days to 2418 days and requiring the Defendant to alter the terms of the '688 Patent to reflect the 2418 day patent term adjustment.

2. 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

3. 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 13, 2012

Respectfully submitted,

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