

FILED

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

2012 JUN -1 P 1:09
CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

HUMAN GENOME SCIENCES, INC.)
)
Plaintiff,)
)
v.)
)
DAVID J. KAPPOS, in his official capacity as)
Under Secretary of Commerce for Intellectual)
Property and Director of the United States Patent)
and Trademark Office)
)
)
)
Defendant.)

Case No.: 1:12cv607
GBL/TCB

COMPLAINT

Plaintiff Human Genome Sciences, Inc. ("HGS"), for its complaint against the Honorable David J. Kappos ("Defendant"), states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 8,071,092 ("the '092 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '092 patent be changed from 1,597 days to 2,654 days.

JURISDICTION AND VENUE

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

3. 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), and 1361, 35 U.S.C. § 154(b)(4)(A), and 5 U.S.C. §§ 701-706.

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

5. This Complaint is being timely filed in accordance with 35 U.S.C. § 154(b)(4)(A) and Fed. R. Civ. P. 6(a)(3).

THE PARTIES

6. Plaintiff HGS is a corporation, organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its principal place of business located at 14200 Shady Grove Road, Rockville, MD 20850.

7. Defendant David J. Kappos is sued in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (“PTO”). The Director of the PTO is designated by statute as the official responsible for determining the period of patent term adjustments and, therefore, is the proper defendant in a suit seeking review of such determinations. See 35 U.S.C. §§ 154(b)(3) and 154(b)(4)(A).

BACKGROUND

Patent Term Adjustments

8. Section 154 of title 35 of the United States Code requires that the Director of the PTO grant a patent term adjustment (“PTA”) in accordance with the provisions of section 154(b).

9. In determining PTA, the Director of the PTO must take into account “PTO Delay” under 35 U.S.C. § 154(b)(1), any overlap in “PTO Delay” under 35 U.S.C. § 154(b)(2)(A), and any “Applicant Delay” under 35 U.S.C. § 154(b)(2)(C).

10. “PTO Delay” under 35 U.S.C. § 154(b)(1) breaks down into three categories known as “A Delay,” “B Delay,” and “C Delay.” Only “A Delay” and “B Delay” are at issue in this case.

11. “A Delay” occurs when the PTO fails to act within a particular time period, for example, if the PTO does not “issue a patent within 4 months after the date on which the issue fee was paid . . . and all outstanding requirements were satisfied.” See 35 U.S.C. § 154(b)(1)(A). The statute provides that “the term of the patent shall be extended 1 day for each day after the end of the period specified . . . until the action described . . . is taken.” *Id.*

12. “B Delay” occurs when the PTO fails to issue a patent within three years of the actual filing date of the patent application, excluding certain periods of delay attributable to the applicant. See 35 U.S.C. § 154(b)(1)(B). Similar to “A delays,” the statute provides that “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.” *Id.*

13. 35 U.S.C. § 154(b)(3)(B) states that “the Director shall- (i) make a determination of the period of any patent term adjustment under this subsection, and shall transmit a notice of that determination with the written notice of allowance of the application”

14. The PTO had taken the position that whenever an application is subject to both “A Delay” and “B Delay,” those periods always “overlap” within the meaning of 35 U.S.C. § 154(b)(2)(A) even if they occur on different calendar days. Thus, for the purposes of PTA, the PTO counted the greater of the “A Delay” or the “B Delay,” but never both periods of delay.

15. In *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008), the District Court for the District of Columbia rejected the PTO’s interpretation of 35 U.S.C. § 154(b)(2)(A), and this holding was affirmed by the Federal Circuit in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010). The Court held that “[t]he only way that periods of time can ‘overlap’ is if they occur on the same day” under 35 U.S.C. § 154(b)(2). *Id.* at 141. Thus, “[i]f an ‘A delay’ occurs on one

calendar day and a ‘B delay’ occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day.” *Id* at 141-42.

16. “Applicant Delay” under 35 U.S.C. § 154(b)(2)(C) arises where an applicant “failed to engage in reasonable efforts to conclude prosecution of the application,” and results in a reduction of any accumulated PTA. See 37 C.F.R. § 1.704(a). The Director has prescribed regulations setting out the specific circumstances deemed to be “Applicant Delay.” See 37 C.F.R. § 1.704.

17. 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.”

The ‘092 Patent

18. Guo-Liang Yu, Reinhard Ebner, and Jian Ni are the inventors (also referred to as “Applicants”) of the ‘092 patent, entitled “Methods of Inhibiting B Lymphocytes Using Antibodies to Neutrokin-alpha,” which issued from U.S. Patent Application No. 09/589,288 (“the ‘288 application”) on December 6, 2011. The ‘092 patent is attached hereto as Exhibit A.

19. HGS is the assignee of the ‘092 patent, as evidenced by the assignment document recorded at the PTO for the parent application, U.S. Patent Application No. 09/507,968.

20. The ‘288 application that issued as the ‘092 patent was filed on June 8, 2000, and, therefore, the ‘092 patent is eligible for patent term adjustment under 35 U.S.C. § 154.

21. The ‘092 patent is subject to a terminal disclaimer based on the expiration date of the full statutory term of U.S. Patent No. 7,879,328. The 20-year patent term for U.S. Patent No. 7,879,328 expires on June 15, 2021. The face of U.S. Patent No. 7,879,328 indicates that it is entitled to 762 days of patent term adjustment.

PTO PTA Calculation Errors

22. Both the PTO's calculation of "PTO Delay" arising under 35 U.S.C. § 154(b)(1)(A)(iv) (also referred to as "A Delay") and the PTO's calculation of "PTO Delay" arising under 35 U.S.C. § 154(b)(1)(B) (also referred to as "B Delay") are in error.

23. An "Application for Patent Term Adjustment Pursuant to 37 C.F.R. § 1.705(b)" (hereinafter "First Petition to Correct PTA") was filed by Applicants with the PTO on October 25, 2011, in an effort to have the PTO correct PTA calculation errors identified herein. The PTO "dismissed as premature" the First Petition to Correct PTA by way of a "Decision on Request for Reconsideration of Patent Term Adjustment" dated November 4, 2011.

24. An "Application for Patent Term Adjustment (37 C.F.R. § 1.705(d)) and Statement of the Correct Patent Term Adjustment and Basis Therefor Under 37 C.F.R. § 1.702" (hereinafter "Second Petition to Correct PTA") was filed by Applicants with the PTO on February 6, 2012, in an effort to have the PTO correct PTA calculation errors identified herein. The PTO "dismissed" (i.e., denied) the Second Petition to Correct PTA by way of a "Decision on Request for Reconsideration of Patent Term Adjustment" dated February 28, 2012.

Improper Calculation of "A Delay"

25. Under 35 U.S.C. § 154(b)(1)(A)(iv), the failure of the PTO to "issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied" results in an extension of the patent term by "1 day for each day after the end of the period." Such a delay by the PTO is one of several types of delay by the PTO referred to as "A Delay."

26. Under 37 C.F.R. § 1.703(a)(6), "[t]he period of adjustment . . . is . . . [t]he number of days, if any, in the period beginning on the day after the date that is four months after the date

the issue fee was paid and all outstanding requirements were satisfied and ending on the date a patent was issued.”

27. A Notice of Allowance was mailed by the PTO with respect to the ‘288 application on July 27, 2009.

28. An issue fee transmittal, together with the payment of the appropriate issue fee, was timely filed by Applicants with respect to the ‘288 application on October 22, 2009, which is within the required three months of the July 27, 2009, mailing date of the Notice of Allowance, thereby satisfying the requirements under 37 C.F.R. § 1.703(a)(6) on October 22, 2009.

29. The day after the date that is four months after the date the issue fee was paid and all outstanding requirements were satisfied is February 23, 2010.

30. An Issue Notification was mailed by the PTO with respect to the ‘288 application on September 15, 2010, indicating a projected patent issue date of October 5, 2010.

31. A petition to withdraw the ‘288 application from issue, together with a Request for Continued Examination (“RCE”), was filed by Applicants on September 23, 2010. As such, Applicants ended the period of adjustment under 37 C.F.R. § 1.703(a)(6) on September 23, 2010, prior to issuance of the ‘092 patent.

32. The PTO failed to issue the ‘092 patent within 4 months after the date the issue fee was paid by Applicants and all outstanding requirements were satisfied.

33. The PTO’s PTA calculation indicates that the total “A Delay” is 1,677 days. The PTO’s PTA calculation does not reflect any delay by the PTO to issue the ‘092 patent within 4 months after the issue fee was paid by Applicants and all outstanding requirements were satisfied.

34. The “A Delay” properly includes the time period from the day after the date four months after the issue fee was paid by Applicants and all outstanding requirements were satisfied (i.e., February 23, 2010) to the date Applicants filed a petition to withdraw the patent from issue (i.e., September 23, 2010), which is a time period of 213 days. See 35 U.S.C. § 154(b)(1)(A) and 37 C.F.R. § 1.703(a)(6).

35. In calculating only 1,677 days for the period of “A Delay,” the PTO failed to correctly calculate the period of “A Delay” by failing to include the period of 213 days of PTO delay from the day after the date four months after the issue fee was paid by Applicants and all outstanding requirements were satisfied (i.e., February 23, 2010) to the date Applicants filed a petition to withdraw the patent from issue (i.e., September 23, 2010), as required by 35 U.S.C. § 154(b)(1)(A) and 37 C.F.R. §§ 1.702(a) and 1.703(a). Therefore, the correct period of A delay is 1,890 days (i.e., 1,677 days + 213 days).

Improper Calculation of “B Delay”

36. Under 35 U.S.C. § 154(b)(1)(B), the failure of the PTO to “issue a patent within 3 years after the actual filing date of the application” results in an extension of the patent term by “1 day for each day after the end of that 3-year period until the patent is issued.” Such a delay by the PTO is referred to as “B Delay.”

37. Under 37 C.F.R. § 1.703(b), “[t]he period of adjustment . . . is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed . . . and ending on the date a patent was issued, but not including the sum of [recited] periods.”

38. The day after the date that is three years after the date on which the ‘288 application was filed is June 9, 2003.

39. The ‘092 patent issued on December 6, 2011.

40. The number of days in the period beginning on the day after the date that is three years after the date on which the '288 application was filed (i.e., June 9, 2003) and ending on the date the '092 a patent was issued (i.e., December 6, 2011) is 3,103 days.

41. 35 U.S.C. § 154(b)(1)(B) also states that the period of delay due to the failure of the PTO to issue a patent within 3 years after the actual filing date does not include, *inter alia*, (a) "any time consumed by continued examination of the application requested by the applicant under section 132(b)," (b) "any time consumed by a proceeding under section 135(a)," i.e., an interference proceeding, and (c) "any time consumed by appellate review by the Board of Patent Appeals and Interferences [("BPAI")."

42. A Notice of Appeal was filed by Applicants with respect to the '288 application on February 12, 2003.

43. In response to the Notice of Appeal, an Office Action under 35 U.S.C. § 132 was mailed by the PTO on June 3, 2003.

44. Jurisdiction over the '288 application did not pass to the BPAI between the time of the filing of the Notice of Appeal by Applicants on February 12, 2003, and the mailing of an Office Action by the PTO on June 3, 2003.

45. The number of days beginning on the date on which the Notice of Appeal was filed by Applicants on February 12, 2003, and ending on the date of mailing of an action by the PTO under 35 U.S.C. § 132 on June 3, 2003, is 112 days (hereinafter referred to as "Time Period 1").

46. A first RCE was filed by Applicants with respect to the '288 application on December 2, 2004.

47. The PTO declared an interference involving the '288 application on August 15, 2006.

48. The PTO has treated the interference involving the '288 application as terminated on September 15, 2008.

49. The number of days beginning on the date the interference involving the '288 application was declared by the PTO on August 15, 2006, and ending on the date on which the interference involving the '288 application has been treated as terminated by the PTO on September 15, 2008, is 763 days (hereinafter referred to as "Time Period 2").

50. The PTO mailed a first Notice of Allowance to Applicants on July 27, 2009.

51. The number of days beginning on the date of the filing of the first RCE by Applicants on December 2, 2004, until the date on which the PTO mailed the first Notice of Allowance to Applicants on July 27, 2009, is 1,698 days (hereinafter referred to as "Time Period 3").

52. Time Period 3 wholly encompasses Time Period 2, and Time Period 3 exclusive of Time Period 2 consists of 935 days.

53. A second RCE was filed by Applicants with respect to the '288 application on September 23, 2010.

54. The number of days beginning on the date on which the PTO mailed the first Notice of Allowance to Applicants on July 27, 2009, until the date of the filing of the second RCE by Applicants on September 23, 2010, is 423 days (hereinafter referred to as "Time Period 4").

55. The PTO mailed a second Notice of Allowance to Applicants on July 25, 2011.

56. The number of days beginning on the date of the filing of the second RCE by Applicants on September 23, 2010, until the date on which the PTO mailed the second Notice of Allowance to Applicants on July 25, 2011, is 305 days (hereinafter referred to as "Time Period 5").

57. The number of days beginning on the date on which the PTO mailed the second Notice of Allowance to Applicants on July 25, 2011, and ending on the date on which the PTO issued the '092 patent on December 6, 2011, is 135 days (hereinafter referred to as "Time Period 6").

58. The period of "B Delay" calculated by the PTO is 430 days.

Time Period 1 – "B Delay" Calculation Relating to Notice of Appeal

59. 35 U.S.C. § 154(b)(1)(B) states that the period of delay due to the failure of the PTO to issue a patent within 3 years after the actual filing date does not include "any time consumed by appellate review by the Board of Patent Appeals and Interferences."

60. 37 C.F.R. § 1.703(b)(4) states that the period of adjustment under § 1.702(b) does not include "[t]he number of days, if any, in the period beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences was filed under 35 U.S.C. 134 and § 41.31 of this title and ending on the date of the last decision by the Board of Patent Appeals and Interferences or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145, or on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first, if the appeal did not result in a decision by the Board of Patent Appeals and Interferences."

61. In calculating the period of "B Delay," the PTO erroneously included a reduction in the period of "B Delay" of 112 days for Time Period 1, i.e., the time period beginning on February 12, 2003, the date on which a Notice of Appeal was filed by Applicants, and ending on June 3, 2003, the date of mailing of an action by the PTO under 35 U.S.C. § 132.

62. The PTO issued a Notice of Proposed Rule Making on December 28, 2011, in which the PTO proposes to clarify the rules of practice to indicate that the period of appellate

review under the PTA provisions of 35 U.S.C. § 154(b)(1)(B) begins when jurisdiction over the application passes to the BPAI, rather than the date on which a Notice of Appeal to the BPAI is filed by the applicants. Proposed Rules, 76 Fed. Reg. 81432, 81437 (Dec. 28, 2011).

63. The Notice of Proposed Rule Making states, *inter alia*, that the PTO is proposing to amend 37 C.F.R. § 1.703(b)(4) to define the period of delay “as the sum of the number of days, if any, in the period beginning on the date on which jurisdiction over the application passes to the BPAI under § 41.35 of this title and ending on the date of a final decision in favor of the applicant by the BPAI or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145.” Proposed Rules, 76 Fed. Reg. at 81435.

64. The period of delay calculated under 37 C.F.R. § 1.703(b)(4) for the ‘092 patent should be 0 days, i.e., Time Period 1 should not be excluded from the period of “B Delay,” because the filing of the Notice of Appeal did not result in jurisdiction over the ‘288 application passing to the BPAI.

65. Accordingly, the PTA calculation for the ‘092 patent should *not* include a reduction in the period of “B Delay” of 112 days, i.e., the period of “B Delay” should include Time Period 1, such that the period of “B Delay” as calculated by the PTO should be increased by 112 days.

Time Period 2 – “B Delay” Calculation Relating to Interference

66. 35 U.S.C. § 154(b)(1)(B) states that the period of delay due to the failure of the PTO to issue a patent within 3 years after the actual filing date does not include “any time consumed by a proceeding under section 135(a).” An interference is a proceeding under 35 U.S.C. § 135(a).

67. 37 C.F.R. § 1.703(b)(2) states that the period of adjustment under § 1.702(b) does not include “[t]he number of days, if any, in the period beginning on the date an interference was

declared or redeclared to involve the application in the interference and ending on the date that the interference was terminated with respect to the application.”

68. Accordingly, if the period of “B Delay” includes Time Period 2, i.e., the period beginning on August 15, 2006, the date on which an interference involving ‘288 application was declared by the PTO, and ending on September 15, 2008, the date the PTO has determined to be the termination date of the interference involving the ‘288 application, then the PTA calculation for the ‘092 patent should include a reduction in the period of “B Delay” of 763 days for Time Period 2.

Time Periods 3-6 – “B Delay” Calculation Relating to Filing of RCE

69. 35 U.S.C. § 154(b)(1)(B) states that the period of delay due to the failure of the PTO to issue a patent within 3 years after the actual filing date does not include “any time consumed by continued examination of the application requested by the applicant under section 132(b).”

70. In contrast to 35 U.S.C. § 154(b)(1)(B), 37 C.F.R. § 1.703(b) states that the period of time after the filing of an RCE is not to be considered in calculating the patent term adjustment under 37 C.F.R. § 1.702(b). Specifically, 37 C.F.R. § 1.703(b)(1) states that the period of adjustment does not include “the sum of . . . [t]he number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued.”

71. In calculating the period of “B Delay,” the PTO erroneously subtracted Time Period 3, Time Period 4, Time Period 5, and Time Period 6. In effect, the PTO excluded from the period of “B Delay” all of the time after the filing of the first RCE by Applicants until the issuance of the ‘092 patent.

72. However, 37 C.F.R. § 1.703(b) is in conflict with 35 U.S.C. § 154(b)(1)(B). In particular, unlike 35 U.S.C. § 154(b)(1)(B), 37 C.F.R. § 1.703(b) indicates that the period of time after the filing of a RCE is not to be considered in calculating the patent term adjustment under 37 C.F.R. § 1.702(b). Thus, while the determination of patent term adjustment is controlled by 35 U.S.C. § 154, which contains no such exclusion of the time period from the filing of an RCE until the issue of the patent for purposes of calculating the PTA, 37 C.F.R. § 1.703(b) cuts off the PTA period under 35 U.S.C. § 154(b)(1)(B) with the filing of an RCE.

73. 37 C.F.R. § 1.703(b) should not control the determination of the PTA under 35 U.S.C. § 154(b)(1)(B) to the extent that the provisions of 37 C.F.R. § 1.703(b) conflict with the provisions of 35 U.S.C. § 154(b)(1)(B).

74. The period of “B Delay” should include Time Period 3, i.e., the period of time from the filing of the first RCE (i.e., December 2, 2004) until the mailing of the first Notice of Allowance (i.e., July 27, 2009), excluding the overlap with Time Period 2, i.e., the period of time for the interference.

75. The period of “B Delay” should include Time Period 4, i.e., the period of time from the mailing of the first Notice of Allowance (i.e., July 27, 2009) until the filing of the second RCE (i.e., September 23, 2010).

76. The period of “B Delay” should include Time Period 5, i.e., the period of time from the filing of the second RCE (i.e., September 23, 2010) until the mailing of the second Notice of Allowance (i.e., July 25, 2011).

77. The period of “B Delay” should include Time Period 6, i.e., the period of time from the mailing of the second Notice of Allowance (i.e., July 25, 2011) until the date of issuance of the ‘092 patent (i.e., December 6, 2011).

78. 37 C.F.R. § 1.702(b) indicates that “[a]ny delay in the processing of the application by the Office that was requested by the applicant” is not to be included in the consideration of the 3-year pendency guarantee.

79. Even assuming that the filing of an RCE is a delay in the processing of the application requested by the applicant, the subsequent indication by the PTO that the application is allowable ends such a delay and causes the application to be “back on track” with respect to typical prosecution in the absence of an RCE.

80. Under such an interpretation, the time period from an indication of allowability by the PTO and ending on the date the patent issued does not constitute “[a]ny delay in the processing of the application by the Office that was requested by the applicant,” such that the time period from an indication of allowability by the PTO and ending on date the patent issued should not be excluded from calculation of the period of “B Delay.”

81. Under such an interpretation, the filing of an RCE would cause the period of “B Delay” to include the period of time from one day after the 3-year pendency anniversary and ending on the date the patent issued minus the period of time from the filing of the RCE until the indication of allowability by the PTO (as opposed to ending on the patent issuance date). In other words, under such an interpretation, the period of “B Delay” would stop with the filing of an RCE by an applicant but would start again with the indication of allowability by the PTO because the application is “back on track.”

Correct Calculation of “B Delay”

82. The correct “B Delay” calculation should be 2,340 days when the period of B delay currently calculated by the PTO (i.e., 430 days) is adjusted to include (a) Time Period 1, i.e., the 112 days for the period beginning on February 12, 2003, the date on which a Notice of Appeal was filed, and ending on June 3, 2003, the date of mailing of an action under 35 U.S.C. § 132,

(b) Time Period 3, i.e., the 1,698 days for the period beginning on December 2, 2004, the date on which a first RCE was filed, until July 27, 2009, the date of mailing of a first Notice of Allowance, excluding overlapping Time Period 2, i.e., the 763 days for the period beginning on August 15, 2006, the date on which an interference involving '288 application was declared by the PTO, and ending on September 15, 2008, the date the PTO has determined to be the termination date of the interference involving the '288 application, (c) Time Period 4, i.e., the 423 days for the period beginning on July 27, 2009, the date of mailing of a first Notice of Allowance, until September 23, 2010, the date on which a second RCE was filed, (d) Time Period 5, i.e., the 305 days for the period beginning on September 23, 2010, the date on which a second RCE was filed, until July 25, 2011, the date of mailing of a second Notice of Allowance, and (e) Time Period 6, i.e., the 135 days for the period beginning on July 25, 2011, the date of mailing of a second Notice of Allowance, and ending on December 6, 2011, the date the '092 patent issued (i.e., 430 days + 112 days + 1698 days – 763 days + 423 days + 305 days + 135 days = 2,340 days).

Calculation of Overlap in PTO Delay

83. The PTO's patent term adjustment calculation indicates that the total "C Delay" is 763 days.

84. When the period of "B Delay" is corrected to include the period from the day after the date that is three years after the date on which the '288 application was filed (i.e., June 9, 2003) through the date the '092 patent issued (i.e., December 6, 2011), the entire period of "A Delay" (i.e., 1,890 days) overlaps with either "B Delay" or "C Delay," such that the total number of overlapping days between the "A Delay" and "B Delay" and between the "A Delay" and "C Delay" is 1,890 days.

85. When the period of "B Delay" includes a reduction for the period of time from the filing of the first RCE (i.e., from December 2, 2004) until the mailing of the first Notice of Allowance (i.e., until July 27, 2009), and the period of time from the filing of the second RCE (i.e., from September 23, 2010) until the mailing of the second Notice of Allowance (i.e., until July 25, 2011), 62 days of "A Delay" overlap with "B Delay," and 763 days of "A Delay" overlap with "C Delay," such that the total number of overlapping days between the "A Delay" and "B Delay" and between the "A Delay" and "C Delay" is 825 days.

86. When the period of "B Delay" includes a reduction for the period of time from the filing of the first RCE (i.e., from December 2, 2004) until the mailing of the second Notice of Allowance (i.e., until July 25, 2011), 62 days of "A Delay" overlap with "B Delay," and 763 days of "A Delay" overlap with "C Delay," such that the total number of overlapping days between the "A Delay" and "B Delay" and between the "A Delay" and "C Delay" is 825 days.

87. When the period of "B Delay" includes a reduction for the period from December 2, 2004, the date on which a first RCE was filed, through December 6, 2011, the date the '092 patent issued, 62 days of "A Delay" overlap with "B Delay," and 763 days of "A Delay" overlap with "C Delay," such that the total number of overlapping days between the "A Delay" and "B Delay" and between the "A Delay" and "C Delay" is 825 days.

Calculation of "Applicant Delay"

88. The PTO's PTA calculation indicates that the total "Applicant Delay" under 37 C.F.R. § 1.704 is 449 days.

89. The PTO's PTA calculation indicates an "Applicant Delay" of 92 days from May 21, 2001, the day after the date that is three months after the date of mailing of a Restriction Requirement, through August 20, 2001, on which date a Reply to Restriction Requirement was filed by Applicants.

90. The PTO's PTA calculation indicates an "Applicant Delay" of 86 days from February 7, 2002, the day after the date that is three months after the date of mailing of an Office Action, through May 3, 2002, on which date a Reply to Office Action was filed by Applicants.

91. The PTO's PTA calculation indicates an "Applicant Delay" of 91 days from November 14, 2002, the day after the date that is three months after the date of mailing of an Office Action, through February 12, 2003, on which date a Notice of Appeal was filed by Applicants.

92. The PTO's PTA calculation indicates an "Applicant Delay" of 90 days from September 4, 2003, the day after the date that is three months after the date of mailing of an Office Action, through December 2, 2003, on which date a Reply to Office Action was filed by Applicants.

93. The PTO's PTA calculation indicates an "Applicant Delay" of 90 days from September 4, 2004, the day after the date that is three months after the date of mailing of an Office Action, through December 2, 2004, on which date a Request for Continued Examination was filed by Applicants.

94. Other than the circumstances described above, there have been no circumstances that could reasonably be construed as a failure of Applicants to engage in reasonable efforts to conclude processing or examination of this application.

Correct PTA Calculation

95. When the period of "B Delay" is corrected to include the period from the day after the date that is three years after the date on which the '288 application was filed (i.e., June 9, 2003) until the date the '092 patent issued (i.e., December 6, 2011), the correct PTA is 2,654 days. The correct PTA represents the combination of (1) the examination delay of 1,890 days by the PTO under 37 C.F.R. §§ 1.702(a) and 1.703(a), (2) the examination delay of 2,340 days by

the PTO under 37 C.F.R. §§ 1.702(b) and 1.703(b), and (3) the examination delay of 763 days by the PTO under 37 C.F.R. §§ 1.702(c)-(e) and 1.703(c)-(e), *minus* 1890 overlapping days between the “A Delay” and “B Delay,” and the “A Delay” and “C Delay,” *minus* 449 days of “Applicant Delay” under 37 C.F.R. § 1.704 (i.e., $(1,890 + 2,340 + 763) - 1890 - 449 = 2,654$).

96. If the period of “B Delay” is corrected to include the period from the day after the date that is three years after the date on which the ‘288 application was filed (i.e., June 9, 2003) through the date the ‘092 patent issued (i.e., December 6, 2011), minus the period of time from the filing of the first RCE (i.e., from December 2, 2004) until the mailing of the first Notice of Allowance (i.e., until July 27, 2009), and minus the period of time from the filing of the second RCE (i.e., from September 23, 2010) until the mailing of the second Notice of Allowance (i.e., until July 25, 2011), then the PTA would be 2,479 days. This PTA represents the combination of (1) the examination delay of 1,890 days by the PTO under 37 C.F.R. §§ 1.702(a) and 1.703(a), (2) the examination delay of 1,100 days by the PTO under 37 C.F.R. §§ 1.702(b) and 1.703(b), and (3) the examination delay of 763 days by the PTO under 37 C.F.R. §§ 1.702(c)-(e) and 1.703(c)-(e), *minus* 825 overlapping days between the “A Delay” and “B Delay,” and the “A Delay” and “C Delay,” *minus* 449 days of “Applicant Delay” under 37 C.F.R. § 1.704 (i.e., $(1,890 + 1,100 + 763) - 825 - 449 = 2,479$).

97. If the period of “B Delay” is corrected to include the period from the day after the date that is three years after the date on which the ‘288 application was filed (i.e., June 9, 2003) through the date the ‘092 patent issued (i.e., December 6, 2011), minus the period of time from the filing of the first RCE (i.e., from December 2, 2004) until the mailing of the second Notice of Allowance (i.e., until July 25, 2011), then the PTA would be 2,056 days. This PTA represents the combination of (1) the examination delay of 1,890 days by the PTO under 37 C.F.R. §§

1.702(a) and 1.703(a), (2) the examination delay of 677 days by the PTO under 37 C.F.R. §§ 1.702(b) and 1.703(b), and (3) the examination delay of 763 days by the PTO under 37 C.F.R. §§ 1.702(c)-(e) and 1.703(c)-(e), *minus* 825 overlapping days between the “A Delay” and “B Delay,” and the “A Delay” and “C Delay,” *minus* 449 days of “Applicant Delay” under 37 C.F.R. § 1.704 (i.e., $(1,890 + 677 + 763) - 825 - 449 = 2,056$).

98. If the period of “B Delay” includes a reduction for the period from the date on which a first RCE was filed (i.e., December 2, 2004) through the date the ‘092 patent issued (i.e., December 6, 2011), then the PTA would be 1,921 days. This PTA represents the combination of (1) the examination delay of 1,890 days by the PTO under 37 C.F.R. §§ 1.702(a) and 1.703(a), (2) the examination delay of 542 days by the PTO under 37 C.F.R. §§ 1.702(b) and 1.703(b), (3) the examination delay of 763 days by the PTO under 37 C.F.R. §§ 1.702(c)-(e) and 1.703(c)-(e), *minus* 825 overlapping days between the “A Delay” and “B Delay,” and the “A Delay” and “C Delay,” *minus* 449 days of “Applicant Delay” under 37 C.F.R. § 1.704 (i.e., $(1,890 + 542 + 763) - 825 - 449 = 1,921$).

99. The PTO’s determination of the PTA for the ‘092 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

CLAIM FOR RELIEF

100. The allegations of paragraphs 1-99 are incorporated in this claim for relief as if fully set forth herein.

101. The PTA for the ‘092 patent, as determined by the Defendant under 35 U.S.C. § 154(b) and listed on the face of the ‘092 patent, is 1,597 days. See Exhibit A at 1.

102. Under 35 U.S.C. § 154(b)(1)(A), Plaintiff is entitled to an adjustment of the term of the '092 patent of 1,890 days, the number of days attributable to PTO examination delay ("A Delay").

103. Under 35 U.S.C. § 154(b)(1)(B), Plaintiff is entitled to an adjustment of the term of the '092 patent of 112 days, which is the number of days for the period beginning on February 12, 2003, the date on which a Notice of Appeal was filed, and ending on June 3, 2003, the date of mailing of an action under 35 U.S.C. § 132 ("B Delay").

104. Under 35 U.S.C. § 154(b)(1)(B), Plaintiff is entitled to an adjustment of the term of the '092 patent of 1,698 days, which is the number of days for the period beginning on December 2, 2004, the date on which a first RCE was filed, until July 27, 2009, the date of mailing of a first Notice of Allowance, excluding 763 days for the period beginning on August 15, 2006, the date on which an interference involving '288 application was declared by the PTO, and ending on September 15, 2008, the date the PTO has determined to be the termination date of the interference involving the '288 application ("B Delay").

105. Under 35 U.S.C. § 154(b)(1)(B), Plaintiff is entitled to an adjustment of the term of the '092 patent of 423 days, which is the number of days for the period beginning on July 27, 2009, the date of mailing of a first Notice of Allowance, until September 23, 2010, the date on which a second RCE was filed ("B Delay").

106. Under 35 U.S.C. § 154(b)(1)(B), Plaintiff is entitled to an adjustment of the term of the '092 patent of 305 days, which is the number of days for the period beginning on September 23, 2010, the date on which a second RCE was filed, until July 25, 2011, the date of mailing of a second Notice of Allowance ("B Delay").

107. Under 35 U.S.C. § 154(b)(1)(B), Plaintiff is entitled to an adjustment of the term of the '092 patent of 135 days, which is the number of days for the period beginning on July 25, 2011, the date of mailing of a second Notice of Allowance, and ending on December 6, 2011, the date the '092 patent issued ("B Delay").

108. 35 U.S.C. § 154(b)(2)(A) provides that "to the extent that periods of delay attributable to grounds specified in paragraph [b](1) overlap, the period of any adjustment . . . shall not exceed the actual number of days the issuance of the patent was delayed." In *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008), the Court explained that for purposes of identifying "overlap" between "A Delay" and "B Delay" under 35 U.S.C. § 154(b)(2)(A), the "period of delay" for "B Delay" begins when the PTO has failed to issue a patent within three years, not before.

109. In accordance with *Wyeth*, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is the sum of the "A Delay" and "B Delay" and "C Delay" (1,890 + 2,340 + 763 = 4,993 days) reduced by the number of days of "A Delay" that overlaps with "B Delay," and the number of days of "A Delay" that overlaps with "C Delay," (1,890 days) and reduced by the number of days of applicant delay (449 days) for a net adjustment of 2,654 days.

110. If the period of "B Delay" is corrected to include the period from the day after the date that is three years after the date on which the '288 application was filed (i.e., June 9, 2003) through the date the '092 patent issued (i.e., December 6, 2011), minus the period of time from the filing of the first RCE (i.e., from December 2, 2004) until the mailing of the first Notice of Allowance (i.e., until July 27, 2009), and minus the period of time from the filing of the second RCE (i.e., from September 23, 2010) until the mailing of the second Notice of Allowance (i.e., until July 25, 2011), then the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2),

in accordance with *Wyeth*, is the sum of the “A Delay” and “B Delay” and “C Delay” (1,890 + 1,100 + 763 = 3,753 days) reduced by the number of days of “A Delay” that overlaps with “B Delay,” and the number of days of “A Delay” that overlaps with “C Delay,” (825 days) and reduced by the number of days of applicant delay (449 days) for a net adjustment of 2,479 days.

111. If the period of “B Delay” is corrected to include the period from the day after the date that is three years after the date on which the ‘288 application was filed (i.e., June 9, 2003) through the date the ‘092 patent issued (i.e., December 6, 2011), minus the period of time from the filing of the first RCE (i.e., from December 2, 2004) until the mailing of the second Notice of Allowance (i.e., until July 25, 2011), then the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2), in accordance with *Wyeth*, is the sum of the “A Delay” and “B Delay” and “C Delay” (1,890 + 677 + 763 = 3,330 days) reduced by the number of days of “A Delay” that overlaps with “B Delay,” and the number of days of “A Delay” that overlaps with “C Delay,” (825 days) and reduced by the number of days of applicant delay (449 days) for a net adjustment of 2,056 days.

112. If the period of “B Delay” includes a reduction for the period from the date on which a first RCE was filed (i.e., December 2, 2004) through the date the ‘092 patent issued (i.e., December 6, 2011), then the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2), in accordance with *Wyeth*, is the sum of the “A Delay” and “B Delay” and “C Delay” (1,890 + 542 + 763 = 3,195 days) reduced by the number of days of “A Delay” that overlaps with “B Delay,” and the number of days of “A Delay” that overlaps with “C Delay,” (825 days) and reduced by the number of days of applicant delay (449 days) for a net adjustment of 1,921 days.

113. The Director's determination that the '092 patent is entitled to only 1,597 days of patent term adjustment is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation.

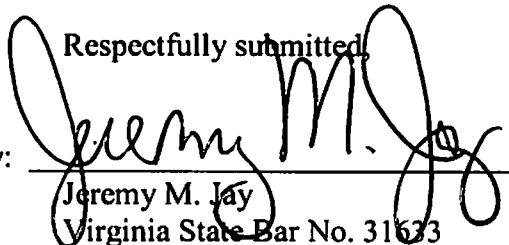
PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant and respectfully requests that this Court enter Orders:

A. Changing the period of PTA for the '092 patent from 1,597 days to 2,654 days, and requiring Defendant to extend the term of the '092 patent to reflect the 2,654-day PTA;

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

Dated: June 1, 2012

Respectfully submitted,
By: 
Jeremy M. Jay
Virginia State Bar No. 31633
LEYDIG, VOIT & MAYER, PC
700 Thirteenth Street N.W., Suite 300
Washington, D.C. 20005-3960
Tel: (202) 737-6770
Fax: (202) 737-6776
E-mail: jjay@leydig.com

*Attorney for Plaintiff
Human Genome Sciences, Inc.*