

FILED

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

2012 DEC 31 P 10:02
U.S. DISTRICT COURT
ALEXANDRIA, VIRGINIA

LIFE TECHNOLOGIES CORPORATION)
5791 Van Allen Way)
Carlsbad, CA 92008)

Civil Action No. 1:12cv1518-CMH/JFA

GENEART AG,)
Josef-Engert-Strasse 11)
93053 Regensburg, Germany,)

APPLIED BIOSYSTEMS, LLC)
5791 Van Allen Way)
Carlsbad, CA 92008)

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, VA 22313)
401 Dulany Street)
Alexandria, VA 22314)

Office of the General Counsel)
United States Patent and Trademark Office)
P.O. Box 15667, Arlington, VA 22215)
Madison Building East, Room 10B20)
600 Dulany Street, Alexandria, VA 22314)

Defendant.)

COMPLAINT

Plaintiffs Life Technologies Corp. ("Life Technologies"), GeneArt AG ("GeneArt") and Applied Biosystems, LLC ("Applied Biosystems") (collectively, "Plaintiffs"), for their complaint against the Honorable David J. Kappos, Under Secretary of Commerce for Intellectual Property

and Director of the United States Patent and Trademark Office, (hereinafter “Kappos” or “Defendant”), states as follows:

NATURE OF THE ACTION

1. This is an action by Life Technologies, GeneArt, and Applied Biosystems, the owners, assignees, or exclusive licensees of United States Patent Nos. 8,211,699 (“the ‘699 patent”), entitled “Methods for Culturing Pluripotent Stem Cells in Suspension Using ERBB3 Ligands”; 8,224,578 (“the ‘578 patent”), entitled “Method and Device for Optimizing a Nucleotide Sequence for the Purpose of Expression of a Protein”; 8,221,607 (“the ‘607 patent”), entitled “High Speed, High Resolution Compositions, Methods and Kits for Capillary Electrophoresis”; 8,232,582 (“the ‘582 patent”), entitled “Ultra-Fast Nucleic Acid Sequencing Device and a Method for Making and Using the Same”; 8,247,219 (“the ‘219 patent”), entitled “Device and Method for Multiple Analyte Detection”; 8,262,900 (“the ‘900 patent”), entitled “Methods and Apparatus for Measuring Analytes Using Large Scale FET Arrays”; 8,268,149 (“the ‘149 patent”), entitled “Electro-Blotting Devices, Systems, and Kits, and Methods for Their Use”; 8,268,249 (“the ‘249 patent”), entitled “Analytical Device with Lightguide Illumination of Capillary and Microgroove Arrays”; 8,246,806 (“the ‘806 patent”), entitled “Multi-Capillary Array Electrophoresis Device”; and 8,287,881 (“the ‘881 patent”), entitled “Synthetic Gagpol Genes and Their Uses” for review of the determination by Defendant, pursuant to, *inter alia*, 35 U.S.C. § 154(b)(3)(B) and 5 U.S.C. §§ 701-706, of the Patent Term Adjustment of the ‘699, ‘578, ‘607, ‘582, ‘219, ‘900, ‘149, ‘249, ‘806, and ‘881 patents. Life Technologies seeks a judgment that the additional patent term for the ‘699 patent be changed from 220 days to 498 days, that the additional patent term for the ‘578 patent be changed from 1168 days to 1560 days, that the additional patent term for the ‘607 patent be changed from 1602 days to 1966 days, that

the additional patent term for the '582 patent be changed from 335 days to 1244 days, that the additional patent term for the '219 patent be changed from 318 days to 611 days, that the additional patent term for the '900 patent be changed from 1168 days to 1226 days, that the additional patent term for the '149 patent be changed from 1078 days to 1549 days, that the additional patent term for the '249 patent be changed from 1053 days to 1586 days, that the additional patent term for the '806 patent be changed from 1163 days to 1393 days, and that the additional patent term for the '881 patent be changed from 1168 days to 1415 days.

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

THE PARTIES

3. Life Technologies is a Delaware corporation with its principal place of business at 5791 Van Allen Way Carlsbad, CA 92008. GeneArt AG is a German corporation that is a wholly owned subsidiary of Life Technologies, with its principal place of business at Josef-Engert-Strasse 11, 93053 Regensburg, Germany. Applied Biosystems LLC is a Delaware corporation that is a wholly owned subsidiary of Life Technologies, with its principal place of business at 5791 Van Allen Way, Carlsbad, CA 92008.

4. Defendant 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; 35 U.S.C. § 154(b); and 5 U.S.C. §§ 701-706.

6. Venue is proper in this district pursuant to at least 35 U.S.C. § 154(b)(4)(A).

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

BACKGROUND AND COMMON ALLEGATIONS

The '699 Patent

8. On information and belief, ViaCyte is the assignee of all right, title, and interest in the '699 patent, as evidenced by records on deposit with the PTO and the face of the '699 patent. Life Technologies is the exclusive licensee of the '699 patent, including the right to control patent prosecution.

9. Allan J. Robins and Thomas C. Schulz are the inventors of patent application number 11/838,054 ("the '054 application"), which was filed on August 13, 2007 (the "Filing Date").

10. On September 28, 2007, the PTO mailed a Notice to File Missing Parts. Applicants responded to the Notice to File Missing Parts on January 28, 2008.

11. On July 31, 2009, the PTO mailed a Requirement for Restriction/Election as to the '054 application (the "Restriction Requirement"). Applicants responded to the Restriction Requirement on November 02, 2009.

12. On November 13, 2009, the PTO mailed a Non-Final Office Action as to the '054 application (the "First Office Action"). Applicants responded to the First Office Action on February 12, 2010.

13. On April 16, 2010, the PTO mailed a Final Office Action as to the '054 application (the "Second Office Action"). Applicants responded to the Second Office Action and filed a Request for Continued Examination (the "RCE") on October 16, 2010.

14. On October 8, 2011, Applicants filed a Supplemental Response for the '054 application.

15. On January 31, 2012, the PTO mailed a Non-Final Office Action as to the '054 application (the "Third Office Action"). Applicants responded to the Third Office Action on February 10, 2012.

16. On February 24, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '054 application (the "Notice of Allowance"). Included in the Notice of Allowance was a Determination of Patent Term Adjustment wherein the PTO indicated that the Patent Term Adjustment to date for the '054 application was 158 days.

17. On May 25, 2012, Applicants paid the issue fee for the '054 application, thereby satisfying all outstanding requirements for issuance of a patent.

18. On June 13, 2012, the PTO mailed an Issue Notification for the '054 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the Patent Term Adjustment for the '054 application was 220 days.

19. On July 3, 2012, the '054 application issued as the '699 patent, reflecting a Patent Term Adjustment of 220 days. A true and correct copy of the '699 patent is attached hereto as Exhibit A.

The '578 Patent

20. GeneArt is the assignee of all right, title, and interest in the '578 patent, as evidenced by records on deposit with the PTO and the face of the '578 patent.

21. David Raab, Marcus Graf, Frank Notka and Ralf Wagner are the inventors of patent application number 10/539,208 (“the ’208 application”), which was filed on June 17, 2005 (the “Filing Date”).

22. On March 13, 2006, the PTO mailed a Notice of DO/EO Missing Requirements as to the ’208 application. Applicants responded to the Notice of DO/EO Missing Requirements on May 24, 2006.

23. On November 12, 2009, the PTO mailed a Requirement for Restriction/Election as to the ’208 application (the “Restriction Requirement”). Applicants responded to the Restriction Requirement on March 30, 2010.

24. On June 28, 2010, the PTO mailed a Non-Final Office Action as to the ’208 application (the “First Office Action”). Applicants responded to the First Office Action on December 28, 2010.

25. On March 22, 2011, the PTO mailed a Final Office Action as to the ’208 application (the “Second Office Action”). Applicants responded to the Second Office Action and filed a Request for Continued Examination (the “RCE”) on June 22, 2011.

26. On September 02, 2011, the PTO mailed a Non-Final Office Action as to the ’208 application (the “Third Office Action”).

27. Applicants responded to the Third Office Action on December 29, 2011.

28. On March 15, 2012, the PTO mailed a Notice of Allowance and Fees Due for the ’208 application (the “Notice of Allowance”). Included in the Notice of Allowance was a Determination of Patent Term Adjustment wherein the PTO indicated that the Patent Term Adjustment to date for the ’208 application was 615 days.

29. On June 15, 2012, Applicants filed Drawings for the '208 application and paid the issue fee, thereby satisfying all outstanding requirements for issuance of a patent.

30. On June 27, 2012, the PTO mailed an Issue Notification for the '208 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the Patent Term Adjustment for the '208 application was 1168 days.

31. On July 17, 2012, the '208 application issued as the '578 patent, reflecting a Patent Term Adjustment of 1168 days. A true and correct copy of the '578 patent is attached hereto as Exhibit B.

The '607 Patent

32. Applied Biosystems is the assignee of all right, title, and interest in the '607 patent, as evidenced by records on deposit with the PTO and the face of the '607 patent.

33. Karl O. Voss and Aldrich N. K. Lau are the inventors of patent application number 10/794,486 ("the '486 application"), which was filed on March 05, 2004 (the "Filing Date").

34. On September 19, 2008, the PTO mailed a Non-Final Office Action as to the '486 application (the "First Office Action"). Applicants responded to the First Office Action on December 19, 2008.

On January 21, 2009, Applicants filed an Information Disclosure Statement (IDS) for the '486 application.

35. On March 24, 2009, the PTO mailed a Final Office Action as to the '486 application (the "Second Office Action"). Applicants responded to the Second Office Action and filed a Request for Continued Examination (the "First RCE") on September 24, 2009.

36. On December 3, 2009, the PTO mailed a Final Office Action as to the '486 application (the "Third Office Action"). Applicants responded to the Third Office Action and filed a Request for Continued Examination (the "Second RCE") on June 3, 2010.

37. On May 24, 2011, Applicants filed an IDS for the '486 application.

38. On August 8, 2011, the PTO mailed a Non-Final Office Action as to the '486 application (the "Fourth Office Action"). Applicants responded to the Fourth Office Action on February 8, 2012.

39. On March 20, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '486 application (the "Notice of Allowance"). Included in the Notice of Allowance was a Determination of Patent Term Adjustment wherein the PTO indicated that the Patent Term Adjustment to date for the '486 application was 1233 days.

40. On June 14, 2012, Applicants paid the issue fee for the '486 application, thereby satisfying all outstanding requirements for issuance of a patent.

41. On June 27, 2012, the PTO mailed an Issue Notification for the '486 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the Patent Term Adjustment for the '486 application was 1602 days.

42. On July 17, 2012, the '486 application issued as the '607 patent, reflecting a Patent Term Adjustment of 1602 days. A true and correct copy of the '607 patent is attached hereto as Exhibit C.

The '582 Patent

43. Life Technologies is the assignee of all right, title, and interest in the '582 patent, as evidenced by records on deposit with the PTO and the face of the '582 patent.

44. Jon Sauer and Bart van Zeghbroeck are the inventors of patent application number 11/301,259 (“the ’259 application”), which was filed on December 13, 2005 (the “Filing Date”).

45. On January 17, 2008, the PTO mailed a Non-Final Office Action as to the ’259 application (the “First Office Action”). Applicants responded to the First Office Action on May 19, 2008.

46. On October 06, 2008, Applicants filed an Information Disclosure Statement (IDS) for the ’259 application.

47. On October 15, 2008, the PTO mailed a Non-Final Office Action as to the ’259 application (the “Second Office Action”). Applicants responded to the Second Office Action on April 15, 2009.

48. On August 4, 2009, the PTO mailed a Final Office Action as to the ’259 application (the “Third Office Action”). Applicants responded to the Third Office Action and filed a Request for Continued Examination as to the ’259 application (the “First RCE”) on February 04, 2010.

49. On March 26, 2010, the PTO mailed a Non-Final Office Action as to the ’259 application (the “Fourth Office Action”). Applicants responded to the Fourth Office Action on September 24, 2010.

50. On January 4, 2011, the PTO mailed a Final Office Action as to the ’259 application (the “Fifth Office Action”). Applicants responded to the Fifth Office Action and filed a Request for Continued Examination as to the ’259 application (the “Second RCE”) on April 4, 2011.

51. On May 13, 2011, the PTO mailed a Notice of Allowance and Fees Due for the ’259 application (the “First Notice of Allowance”). Included in the First Notice of Allowance

was a Determination of Patent Term Adjustment wherein the PTO indicated that the Patent Term Adjustment to date for the '259 application was 0 days.

52. On August 15, 2011, Applicants filed a Request for Continued Examination as to the '259 application (the "Third RCE").

53. On September 22, 2011, the PTO mailed a Notice of Allowance and Fees Due for the '259 application (the "Second Notice of Allowance").

54. On December 22, 2011, Applicants filed a Request for Continued Examination as to the '259 application (the "Fourth RCE").

55. On April 02, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '259 application (the "Third Notice of Allowance").

56. On June 29, 2012, Applicants paid the issue fee for the '259 application, thereby satisfying all outstanding requirements for issuance of a patent.

57. On July 11, 2012, the PTO mailed an Issue Notification for the '259 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the Patent Term Adjustment for the '259 application was 335 days.

58. On July 31, 2012, the '259 application issued as the '582 patent, reflecting a Patent Term Adjustment of 335 days. A true and correct copy of the '582 patent is attached hereto as Exhibit D.

The '219 Patent

59. Applied Biosystems is the assignee of all right, title, and interest in the '219 patent, as evidenced by records on deposit with the PTO and the face of the '219 patent.

60. Timothy Woudenberg, Michael Albin, Reid B. Kowallis, Yefim Raysberg, Robert P. Ragusa, and Emily S. Winn-Deen are the inventors of patent application number 11/811,504 (“the ’504 application”), which was filed on June 11, 2007 (the “Filing Date”).

61. On March 2, 2009, the PTO mailed a Non-Final Office Action as to the ’504 application (the “First Office Action”). Applicants responded to the First Office Action on June 2, 2009.

62. On July 27, 2009, Applicants filed an Information Disclosure Statement (IDS) for the ’504 application.

63. On September 3, 2009, the PTO mailed a Final Office Action as to the ’504 application (the “Second Office Action”). Applicants responded to the Second Office Action on March 3, 2010.

64. On April 15, 2010, the PTO mailed a Non-Final Office Action as to the ’504 application (the “Third Office Action”). Applicants responded to the Third Office Action on September 15, 2010.

65. On November 26, 2010, the PTO mailed a Final Office Action as to the ’504 application (the “Fourth Office Action”). Applicants filed a Notice of Appeal on April 26, 2011.

66. On June 27, 2011, Applicants filed a Request for Continued Examination (the “RCE”).

67. On September 1, 2011, Applicants filed an IDS for the ’504 application.

68. On April 17, 2012, the PTO mailed a Notice of Allowance and Fees Due for the ’504 application (the “Notice of Allowance”). Included in the Notice of Allowance was a Determination of Patent Term Adjustment wherein the PTO indicated that the Patent Term Adjustment to date for the ’504 application was 44 days.

69. On July 17, 2012, Applicants paid the issue fee for the '504 application, thereby satisfying all outstanding requirements for issuance of a patent.

70. On August 01, 2012, the PTO mailed an Issue Notification for the '504 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the Patent Term Adjustment for the '504 application was 318 days.

71. On August 21, 2012, the '504 application issued as the '219 patent, reflecting a Patent Term Adjustment of 318 days. A true and correct copy of the '219 patent is attached hereto as Exhibit E.

The '900 Patent

72. Life Technologies is the assignee of all right, title, and interest in the '900 patent, as evidenced by records on deposit with the PTO and the face of the '900 patent.

73. Jonathan M. Rothberg and Wolfgang Hinz are the inventors of patent application number 12/002,781 ("the '781 application"), which was filed on December 17, 2007 (the "Filing Date").

74. On June 13, 2011, the PTO mailed a Requirement for Restriction/Election as to the '781 application (the "Restriction Requirement"). Applicants responded to the Restriction Requirement on July 12, 2011.

75. On August 19, 2011, the PTO mailed a Non-Final Office Action as to the '781 application (the "First Office Action"). Applicants responded to the First Office Action on November 21, 2011.

76. On February 3, 2012, the PTO mailed a Final Office Action as to the '781 application (the "Second Office Action"). Applicants responded to the Second Office Action on

July 13, 2012 and filed a Request for Continued Examination as to the '781 application (the "RCE").

77. On July 16, 2012, Applicants filed an Information Disclosure Statement (IDS) for the '781 application.

78. On July 24, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '781 application (the "Notice of Allowance"). Included in the Notice of Allowance was a Determination of Patent Term Adjustment wherein the PTO indicated that the Patent Term Adjustment to date for the '781 application was 773 days.

79. On July 27, 2012, Applicants paid the issue fee for the '781 application, thereby satisfying all outstanding requirements for issuance of a patent.

80. On August 22, 2012, the PTO mailed an Issue Notification for the '781 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the Patent Term Adjustment for the '781 application was 1168 days.

81. On September 11, 2012, the '781 application issued as the '900 patent, reflecting a Patent Term Adjustment of 1168 days. A true and correct copy of the '900 patent is attached hereto as Exhibit F.

The '149 Patent

82. Life Technologies is the assignee of all right, title, and interest in the '149 patent, as evidenced by records on deposit with the PTO and the face of the '149 patent.

83. Ilana Margalit, Uri Yogev, Itay Sela, Yuri Katz, and Adam Sartiel are the inventors of patent application number 11/465,850 ("the '850 application"), which was filed on August 21, 2006 (the "Filing Date").

84. On May 27, 2009, the PTO mailed a Non-Final Office Action as to the '850 application (the "First Office Action"). Applicants responded to the First Office Action on November 10, 2009.

85. On March 18, 2010, the PTO mailed a Final Office Action as to the '850 application (the "Second Office Action"). Applicants responded to the Second Office Action on August 10, 2010 and filed a Request for Continued Examination as to the '850 application (the "RCE").

86. On October 6, 2011, the PTO mailed a Non-Final Office Action as to the '850 application (the "Third Office Action"). Applicants responded to the Third Office Action on February 6, 2012.

87. On March 1, 2012, the PTO mailed a Final Office Action as to the '850 application (the "Fourth Office Action"). Applicants responded to the Fourth Office Action on May 1, 2012.

88. On May 21, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '850 application (the "Notice of Allowance"). Included in the Notice of Allowance was a Determination of Patent Term Adjustment wherein the PTO indicated that the Patent Term Adjustment to date for the '850 application was 733 days.

89. On August 21, 2012, Applicants paid the issue fee for the '850 application, thereby satisfying all outstanding requirements for issuance of a patent.

90. On August 29, 2012, the PTO mailed an Issue Notification for the '850 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the Patent Term Adjustment for the '850 application was 1078 days.

91. On September 18, 2012, the '850 application issued as the '149 patent, reflecting a Patent Term Adjustment of 1078 days. A true and correct copy of the '149 patent is attached hereto as Exhibit G.

The '249 Patent

92. Life Technologies is the assignee of all right, title, and interest in the '249 patent, as evidenced by records on deposit with the PTO and the face of the '249 patent.

93. Larry J Carson, Joel R. Dufresne, Patrick R. Fleming, Michael C. Lea, Nicholas A. Lee, and John Shigeura are the inventors of patent application number 11/601,326 ("the '326 application"), which was filed on November 16, 2006 (the "Filing Date").

94. On April 5, 2010, the PTO mailed a Non-Final Office Action as to the '326 application (the "First Office Action"). Applicants responded to the First Office Action on July 6, 2010.

95. On October 6, 2010, the PTO mailed a Final Office Action as to the '326 application (the "Second Office Action"). Applicants responded to the Second Office Action on February 7, 2011 and filed a Request for Continued Examination as to the '326 application (the "RCE").

96. On April 27, 2011, the PTO mailed a Non-Final Office Action as to the '326 application (the "Third Office Action"). Applicants responded to the Third Office Action on July 27, 2011.

97. On October 27, 2011, the PTO mailed a Final Office Action as to the '326 application (the "Fourth Office Action"). Applicants filed a Notice of Appeal on February 27, 2012.

98. On April 24, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '326 application (the "Notice of Allowance"). Included in the Notice of Allowance was a Determination of Patent Term Adjustment wherein the PTO indicated that the Patent Term Adjustment to date for the '326 application was 746 days.

99. On July 23, 2012, Applicants paid the issue fee for the '326 application, thereby satisfying all outstanding requirements for issuance of a patent.

100. On August 29, 2012, the PTO mailed an Issue Notification for the '326 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the Patent Term Adjustment for the '326 application was 1053 days.

101. On September 18, 2012, the '326 application issued as the '249 patent, reflecting a Patent Term Adjustment of 1053 days. A true and correct copy of the '249 patent is attached hereto as Exhibit H.

The '806 Patent

102. Applera Corporation, a predecessor in interest to Applied Biosystems, is the assignee of all right, title, and interest in the '806 patent, as evidenced by records on deposit with the PTO and the face of the '806 patent.

103. Ryoji Inaba, Tomohiro Shoji, Shozo Kasai, Masaya Kojima, Yasushi Shimizu, Seiichi Ugai, and Eric S. Nordman are the inventors of patent application number 11/714,222 ("the '222 application"), which was filed on March 06, 2007 (the "Filing Date").

104. On December 9, 2010, the PTO mailed a Non-Final Office Action as to the '222 application (the "First Office Action"). Applicants responded to the First Office Action on May 9, 2011.

105. On July 5, 2011, the PTO mailed a Final Office Action as to the '222 application (the "Second Office Action"). Applicants responded to the Second Office Action on January 5, 2012 and filed a Request for Continued Examination as to the '222 application (the "RCE").

106. On April 3, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '222 application (the "Notice of Allowance"). Included in the Notice of Allowance was a Determination of Patent Term Adjustment wherein the PTO indicated that the Patent Term Adjustment to date for the '222 application was 794 days.

107. On July 3, 2012, Applicants paid the issue fee and filed Drawings for the '222 application, thereby satisfying all outstanding requirements for issuance of a patent.

108. On July 24, 2012, the PTO mailed a Miscellaneous Communication to Applicant for the '222 application.

109. On August 1, 2012, the PTO mailed an Issue Notification for the '222 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the Patent Term Adjustment for the '222 application was 1163 days.

110. On August 21, 2012, the '222 application issued as the '806 patent, reflecting a Patent Term Adjustment of 1163 days. A true and correct copy of the '806 patent is attached hereto as Exhibit I.

The '881 Patent

111. GeneArt is the assignee of all right, title, and interest in the '881 patent, as evidenced by records on deposit with the PTO and the face of the '881 patent.

112. Ralf Wagner, Markus Graf, Ludwig Deml, and Kurt Bieler, are the inventors of patent application number 11/754,755 ("the '755 application"), which was filed on May 29, 2007 (the "Filing Date").

113. On January 26, 2010, the PTO mailed a Requirement for Restriction/Election as to the '755 application (the "Restriction Requirement"). Applicants responded to the Restriction Requirement on February 25, 2010.

114. On June 4, 2010, the PTO mailed a Non-Final Office Action as to the '755 application (the "First Office Action"). Applicants responded to the First Office Action on September 03, 2010.

115. On November 26, 2010, the PTO mailed a Final Office Action as to the '755 application (the "Second Office Action"). Applicants responded to the Second Office Action on February 28, 2011 and filed a Request for Continued Examination as to the '755 application (the "RCE").

116. On June 12, 2012, the PTO mailed a Notice of Allowance and Fees Due for the '755 application (the "First Notice of Allowance"). Included in the Notice of Allowance was a Determination of Patent Term Adjustment wherein the PTO indicated that the Patent Term Adjustment to date for the '755 application was 894 days.

117. On September 12, 2012, Applicants paid the issue fee for the '755 application, thereby satisfying all outstanding requirements for issuance of a patent.

118. On September 26, 2012, the PTO mailed an Issue Notification for the '755 application. Included in the Issue Notification was a Determination of Patent Term Adjustment in which the PTO indicated that the Patent Term Adjustment for the '755 application was 1168 days.

119. On October 16, 2012, the '755 application issued as the '881 patent, reflecting a Patent Term Adjustment of 1168 days. A true and correct copy of the '881 patent is attached hereto as Exhibit J.

Patent Term Guarantee

120. The Patent Term Guarantee Act of 1999, a part of the American Inventors Protection Act (“AIPA”), amended 35 U.S.C. § 154(b), addressed 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.

121. 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”).

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

123. 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).

124. 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”).

125. 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”).

126. 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.”

127. On January 7, 2010, the Court of Appeals for the Federal Circuit in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), 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.

128. 35 U.S.C. § 154(b)(2)(C)(i) 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”).

129. On November 1, 2012, *Exelixis, Inc. v. Kappos*, No. 1:12-cv-00096, 2012 U.S. Dist. LEXIS 157762, at *8 (E.D. Va. Nov. 1, 2012) held that Patent Term Adjustment awards arising from the failure of the PTO to grant a patent within three (3) years of the filing date (known as “B Delays”) are not necessarily reduced by the filing of a Request for Continuation (“RCE”) if the RCE is filed more than three (3) years after the filing date for that patent application. Therefore, the “B Delay” should be calculated from the date three years after filing to the date the patent is issued, whether or not an RCE was filed. *Id.*

130. 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

131. Defendant has improperly calculated the PTA for the '699, '578, '607, '582, '219, '900, '149, '249, '806, and '881 patents 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).

132. 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.

133. 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.

134. 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).

135. 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.

136. 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.

137. 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). *See Exelixis, Inc. v. Kappos*, No. 1:12-cv-00096, 2012 U.S. Dist. LEXIS 157762 (E.D.Va. Nov. 1, 2012).

138. 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.

The Proper Calculation of PTA for the '699 Patent

139. Under 35 U.S.C. § 154(b)(1)(A)(i), Patentee is entitled to an adjustment of the term of the '699 patent for a period of 291 days. This A Delay period is attributable to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the Filing Date of the application. This period consists of the period from October 14, 2008 (the date that is a day after the 14-month period following the Filing Date of the '054 application) through July 31, 2009 (the mailing date of the Restriction Requirement).

140. Under 35 U.S.C. § 154(b)(1)(A)(ii), Patentee is entitled to an additional adjustment of the term of the '699 patent for a period of 349 days. This A Delay period is attributable to the PTO's failure to respond to a reply under 35 U.S.C. § 132 within 4 months after the date a reply was filed. This period consists of the period from February 17, 2011 (the date that is a day after the 4-month period following the filing date of the reply to the Second Office Action) through January 31, 2012 (the mailing date of the Third Office Action), *i.e.*, 349 days.

141. Under 35 U.S.C. § 154(b)(1)(B), Patentee is entitled to an additional adjustment of the term of the '699 patent for a period of 690 days. This B Delay period consists of the period from August 14, 2010 (the date that is a day after the 3-year period following the Filing Date of the '054 application) through July 3, 2012 (the issue date of the '699 patent).

142. There is overlap of A Delay and B Delay of 349 days for the '699 patent pursuant to 35 U.S.C. § 154(b)(2)(A). The overlap period consists of the period from August 14, 2010 (the date that is a day after the 3-year period following the Filing Date of the '054 application) through January 31, 2012 (the mailing date of the Third Office Action), i.e., 349 days.

143. Under 35 U.S.C. § 154(b)(2)(C)(i), 483 days of delay is attributable to Applicants. This Applicant Delay Reduction is the sum total of Applicants' delay in filing the response to the Notice to File Missing Parts on January 28, 2008, a date in excess of three months by 31 days; Applicants' delay in filing the response to the Restriction Requirement on November 2, 2009, a date in excess of three months by 2 days; Applicants' delay in filing the response to the Second Office Action on October 16, 2010, a date in excess of three months by 92 days; Applicants' delay in filing the Supplemental Response on October 08, 2011, a delay of 357 days, and Applicants' delay in payment of the issue fee on May 25, 2012, a date in excess of three months by 1 day.

144. The correct PTA for the '699 patent is 498 days: the sum of the 640 days of A Delay and the 690 days of B Delay, minus the overlap of A Delay and B Delay of 349 days and 483 days of Applicant Delay.

The Proper Calculation of PTA for the '578 Patent

145. Under 35 U.S.C. § 154(b)(1)(A)(i), Patentee is entitled to an adjustment of the term of the '578 patent for a period of 842 days. This A Delay period is attributable to the PTO's

failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the date on which the international application fulfilled the requirements of 35 U.S.C. § 371. This period consists of the period from July 25, 2007 (the date that is a day after the 14-month period following the response to the Notice of DO/EO Missing Requirements) through November 12, 2009 (the mailing date of the Restriction Requirement).

146. Under 35 U.S.C. § 154(b)(1)(B), Patentee is entitled to an additional adjustment of the term of the '578 patent for a period of 1491 days. This B Delay period consists of the period from June 18, 2008 (the date that is a day after the 3-year period following the Filing Date of the '208 application) through July 17, 2012 (the issue date of the '578 patent).

147. There is overlap of A Delay and B Delay of 513 days for the '578 patent pursuant to 35 U.S.C. § 154(b)(2)(A). The overlap period consists of the period from June 18, 2008 (the date that is a day after the 3-year period following the Filing Date of the '208 application) through November 12, 2009 (the mailing date of the Restriction Requirement), *i.e.*, 513 days.

148. Under 35 U.S.C. § 154(b)(2)(C)(i), 260 days of delay is attributable to Applicants. This Applicant Delay Reduction is the sum total of Applicants' delay in filing the response to Restriction Requirement on March 30, 2010, a delay of 109 days; Applicants' delay in filing a response to the First Office Action on December 28, 2010, a date in excess of three months by 91 days; Applicants' delay in filing a response to the Third Office Action on December 29, 2011, a date in excess of three months by 27 days; and Applicants' delay in filing the Drawings on June 15, 2012, a delay 33 days;

149. The correct PTA for the '578 patent is 1560 days: the sum of the 842 days of A Delay and the 1491 days of B Delay, minus the overlap of A Delay and B Delay of 513 days and 260 days of Applicant Delay.

The Proper Calculation of PTA for the '607 Patent

150. Under 35 U.S.C. § 154(b)(1)(A)(i), Patentee is entitled to an adjustment of the term of the '607 patent for a period of 1233 days. This A Delay period is attributable to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the Filing Date of the application. This period consists of the period from May 06, 2005 (the date that is a day after the 14-month period following the Filing Date of the '486 application) through September 19, 2008 (the mailing date of the First Office Action).

151. Under 35 U.S.C. § 154(b)(1)(A)(ii), Patentee is entitled to an additional adjustment of the term of the '607 patent for a period of 309 days. This A Delay period is attributable to the PTO's failure to respond to a reply under 35 U.S.C. § 132 within 4 months after the date a reply was filed. This period consists of the period from October 4, 2010 (the date that is a day after the 4-month period following the filing date of the reply to the Third Office Action) through August 8, 2011 (the mailing date of the Fourth Office Action), *i.e.*, 309 days.

152. Under 35 U.S.C. § 154(b)(1)(B), Patentee is entitled to an additional adjustment of the term of the '607 patent for a period of 1961 days. This B Delay period consists of the period from March 6, 2007 (the date that is a day after the 3-year period following the Filing Date of the '486 application) through July 17, 2012 (the issue date of the '607 patent).

153. There is overlap of A Delay and B Delay of 873 days for the '607 patent pursuant to 35 U.S.C. § 154(b)(2)(A). The overlap period consists of the period from March 06, 2007 (the date that is a day after the 3-year period following the Filing Date of the '486 application) through September 19, 2008 (the mailing date of the First Office Action), *i.e.*, 564 days, and the period from October 4, 2010 (the date that is a day after the 4-month period following the filing

date of the reply to the Third Office Action) through August 8, 2011 (the mailing date of the Fourth Office Action), *i.e.*, 309 days.

154. Under 35 U.S.C. § 154(b)(2)(C)(i), 664 days of delay is attributable to Applicants. This Applicant Delay Reduction is the sum total of Applicants' delay in filing the IDS on January 21, 2009, a delay of 33 days; Applicants' delay in filing the response to the Second Office Action on September 24, 2009, a date in excess of three months by 92 days; Applicants' delay in filing the response to the Third Office Action on June 3, 2008, a date in excess of three months by 92 days; Applicants' delay in filing the IDS on May 24, 2011, a delay of 355 days, and Applicants' delay in filing the response to the Fourth Office Action on February 8, 2012, a date in excess of three months by 92 days.

155. The correct PTA for the '607 patent is 1966 days: the sum of the 1542 days of A Delay and the 1961 days of B Delay, minus the overlap of A Delay and B Delay of 873 days and 664 days of Applicant Delay.

The Proper Calculation of PTA for the '582 Patent

156. Under 35 U.S.C. § 154(b)(1)(A)(i), Patentee is entitled to an adjustment of the term of the '582 patent for a period of 338 days. This A Delay period is attributable to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the Filing Date of the application. This period consists of the period from February 14, 2007 (the date that is a day after the 14-month period following the Filing Date of the '259 application) through January 17, 2008 (the mailing date of the First Office Action).

157. Under 35 U.S.C. § 154(b)(1)(A)(ii), Patentee is entitled to an additional adjustment of the term of the '582 patent for a period of 26 days. This A Delay period is attributable to the PTO's failure to respond to a reply under 35 U.S.C. § 132 within 4 months

after the date a reply was filed. This period consists of the period from September 20, 2008 (the date that is a day after the 4-month period following the filing date of the reply to the First Office Action) through October 15, 2008 (the mailing date of the Second Office Action), *i.e.*, 26 days.

158. Under 35 U.S.C. § 154(b)(1)(B), Patentee is entitled to an additional adjustment of the term of the '582 patent for a period of 1326 days. This B Delay period consists of the period from December 14, 2008 (the date that is a day after the 3-year period following the Filing Date of the '259 application) through July 31, 2012 (the issue date of the '582 patent).

159. Under 35 U.S.C. § 154(b)(2)(C)(i), 446 days of delay is attributable to Applicants. This Applicant Delay Reduction is the sum total of Applicants' delay in filing the response to the First Office Action on May 19, 2008, a date in excess of three months by 32 days; Applicants' delay in filing the IDS on October 6, 2008, a delay of 140 days; Applicants' delay in filing the reply to the Second Office Action on April 15, 2009, a date in excess of three months by 90 days; Applicants' delay in filing the response to the Third Office Action on February 4, 2010, a date in excess of three months by 92 days; Applicants' delay in filing the reply to the Fourth Office Action on September 24, 2010, a date in excess of three months by 90 days; Applicants' delay in filing the reply to the Fifth Office Action on August 15, 2011, a date in excess of three months by 2 days

160. The correct PTA for the '582 patent is 1244 days: the sum of the 364 days of A Delay and the 1326 days of B Delay, minus the overlap of A Delay and B Delay of 0 days and 446 days of Applicant Delay.

The Proper Calculation of PTA for the '219 Patent

161. Under 35 U.S.C. § 154(b)(1)(A)(i), Patentee is entitled to an adjustment of the term of the '219 patent for a period of 203 days. This A Delay period is attributable to the PTO's

failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the Filing Date of the application. This period consists of the period from August 12, 2008 (the date that is a day after the 14-month period following the Filing Date of the '054 application) through March 2, 2009 (the mailing date of the First Office Action).

162. Under 35 U.S.C. § 154(b)(1)(A)(ii), Patentee is entitled to an additional adjustment of the term of the '219 patent for a period of 173 days. This A Delay period is attributable to the PTO's failure to respond to a reply under 35 U.S.C. § 132 within 4 months after the date a reply was filed. This period consists of the period from October 28, 2011 (the date that is a day after the 4-month period following the filing date of the RCE) through April 17, 2012 (the mailing date of the Notice of Allowance), *i.e.*, 173 days.

163. Under 35 U.S.C. § 154(b)(1)(B), Patentee is entitled to an additional adjustment of the term of the '219 patent for a period of 740 days. This B Delay period consists of the periods from June 11, 2010 (the date that is a day after the 3-year period following the Filing Date of the '504 application) through April 26, 2011 (the filing date of the Notice of Appeal) and June 27, 2011 (the filing date of the RCE) through August 21, 2012 (the issue date of the '219 patent).

164. There is overlap of A Delay and B Delay of 173 days for the '219 patent pursuant to 35 U.S.C. § 154(b)(2)(A). The overlap period consists of the period from October 28, 2011 (the date that is a day after the 4-month period following the filing date of the RCE) through April 17, 2012 (the mailing date of the Notice of Allowance), *i.e.*, 173 days.

165. Under 35 U.S.C. § 154(b)(2)(C)(i), 332 days of delay is attributable to Applicants. This Applicant Delay Reduction is the sum total of Applicants' delay in filing the IDS on July 27, 2009, a delay of 55 days; Applicants' delay in filing the response to the Second Office

Action on March 3, 2010, a date in excess of three months by 90 days; Applicants' delay in filing the response to the Third Office Action on September 15, 2010, a date in excess of three months by 62 days; Applicants' delay in filing the Notice of Appeal on April 26, 2011, a date in excess of three months by 59 days, and Applicants' delay in filing the IDS on September 1, 2011, a delay of 66 days.

166. The correct PTA for the '219 patent is 611 days: the sum of the 376 days of A Delay and the 740 days of B Delay, minus the overlap of A Delay and B Delay of 173 days and 332 days of Applicant Delay.

The Proper Calculation of PTA for the '900 Patent

167. Under 35 U.S.C. § 154(b)(1)(A)(i), Patentee is entitled to an adjustment of the term of the '900 patent for a period of 846 days. This A Delay period is attributable to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the Filing Date of the application. This period consists of the period from February 18, 2009 (the date that is a day after the 14-month period following the Filing Date of the '781 application) through June 13, 2011 (the mailing date of the Restriction Requirement).

168. Under 35 U.S.C. § 154(b)(1)(B), Patentee is entitled to an additional adjustment of the term of the '900 patent for a period of 634 days. This B Delay period consists of the period from December 18, 2010 (the date that is a day after the 3-year period following the Filing Date of the '781 application) through September 11, 2012 (the issue date of the '900 patent).

169. There is overlap of A Delay and B Delay of 178 days for the '900 patent pursuant to 35 U.S.C. § 154(b)(2)(A). The overlap period consists of the period from December 18, 2010 (the date that is a day after the 3-year period following the Filing Date of the '781 application) through June 13, 2011 (the mailing date of the Restriction Requirement), *i.e.*, 178 days.

170. Under 35 U.S.C. § 154(b)(2)(C)(i), 76 days of delay is attributable to Applicants. This Applicant Delay Reduction is the sum total of Applicants' delay in filing the response to the First Office Action on November 21, 2011, a date in excess of three months by 2 days; Applicants' delay in filing the response to the Second Office Action on July 13, 2012, a date in excess of three months by 71 days, and Applicants' delay in filing the IDS on July 16, 2012, a delay of 3 days.

171. The correct PTA for the '900 patent is 1226 days: the sum of the 846 days of A Delay and the 634 days of B Delay, minus the overlap of A Delay and B Delay of 178 days and 76 days of Applicant Delay.

The Proper Calculation of PTA for the '149 Patent

172. Under 35 U.S.C. § 154(b)(1)(A)(i), Patentee is entitled to an adjustment of the term of the '149 patent for a period of 584 days. This A Delay period is attributable to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the Filing Date of the application. This period consists of the period from October 22, 2007 (the date that is a day after the 14-month period following the Filing Date of the '850 application) through May 27, 2009 (the mailing date of the First Office Action).

173. Under 35 U.S.C. § 154(b)(1)(A)(ii), Patentee is entitled to an additional adjustment of the term of the '149 patent for a period of 308 days. This A Delay period is attributable to the PTO's failure to respond to a reply under 35 U.S.C. § 132 within 4 months after the date a reply was filed. This period consists of the period from March 11, 2010 (the date that is a day after the 4-month period following the filing date of the reply to the First Office Action) through March 18, 2010 (the mailing date of the Second Office Action), *i.e.*, 8 days, and the period from December 11, 2010 (the date that is a day after the 4-month period following the

filing date of the reply to the Second Office Action) through October 6, 2011 (the mailing date of the Third Office Action), *i.e.*, 300 days.

174. Under 35 U.S.C. § 154(b)(1)(B), Patentee is entitled to an additional adjustment of the term of the '149 patent for a period of 1124 days. This B Delay period consists of the period from August 22, 2009 (the date that is a day after the 3-year period following the Filing Date of the '850 application) through September 18, 2012 (the issue date of the '149 patent).

175. There is overlap of A Delay and B Delay of 308 days for the '149 patent pursuant to 35 U.S.C. § 154(b)(2)(A). The overlap period consists of the period from March 11, 2010 (the date that is a day after the 4-month period following the filing date of the reply to the First Office Action) through March 18, 2010 (the mailing date of the Second Office Action), *i.e.*, 8 days, and the period from December 11, 2010 (the date that is a day after the 4-month period following the filing date of the reply to the Second Office Action) through October 6, 2011 (the mailing date of the Third Office Action), *i.e.*, 300 days.

176. Under 35 U.S.C. § 154(b)(2)(C)(i), 159 days of delay is attributable to Applicants. This Applicant Delay Reduction is the sum total of Applicants' delay in filing the response to the First Office Action on November 10, 2009, a date in excess of three months by 75 days; Applicants' delay in filing the response to the Second Office Action on August 10, 2010, a date in excess of three months by 53 days; and Applicants' delay in filing the response to the Third Office Action on February 6, 2012, a date in excess of three months by 31 days.

177. The correct PTA for the '149 patent is 1549 days: the sum of the 892 days of A Delay and the 1124 days of B Delay, minus the overlap of A Delay and B Delay of 308 days and 159 days of Applicant Delay.

The Proper Calculation of PTA for the '249 Patent

178. Under 35 U.S.C. § 154(b)(1)(A)(i), Patentee is entitled to an adjustment of the term of the '249 patent for a period of 810 days. This A Delay period is attributable to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the Filing Date of the application. This period consists of the period from January 17, 2008 (the date that is a day after the 14-month period following the Filing Date of the '326 application) through April 5, 2010 (the mailing date of the First Office Action).

179. Under 35 U.S.C. § 154(b)(1)(B), Patentee is entitled to an additional adjustment of the term of the '249 patent for a period of 980 days. This B Delay period consists of the period from November 17, 2009 (the date that is a day after the 3-year period following the Filing Date of the '326 application) through February 27, 2012 (the filing date of the Notice of Appeal) and April 24, 2012 (the mailing date of the Notice of Allowance) through September 18, 2012 (the issue date of the '249 patent).

180. There is overlap of A Delay and B Delay of 140 days for the '249 patent pursuant to 35 U.S.C. § 154(b)(2)(A). The overlap period consists of the period from November 17, 2009 (the date that is a day after the 3-year period following the Filing Date of the '326 application) through April 05, 2010 (the mailing date of the First Office Action), *i.e.*, 140 days.

181. Under 35 U.S.C. § 154(b)(2)(C)(i), 64 days of delay is attributable to Applicants. This Applicant Delay Reduction is the sum total of Applicants' delay in filing a response to the First Office Action on July 06, 2010, a date in excess of three months by 1 day; Applicants' delay in filing the response to the Second Office Action on February 07, 2011, a date in excess of three months by 32 days; Applicants' delay in filing the Notice of Appeal on February 27, 2012, a date in excess of three months by 31 days.

182. The correct PTA for the '249 patent is 1586 days: the sum of the 810 days of A Delay and the 980 days of B Delay, minus the overlap of A Delay and B Delay of 140 days and 64 days of Applicant Delay.

The Proper Calculation of PTA for the '806 Patent

183. Under 35 U.S.C. § 154(b)(1)(A)(i), Patentee is entitled to an adjustment of the term of the '806 patent for a period of 947 days. This A Delay period is attributable to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the Filing Date of the application. This period consists of the period from May 7, 2008 (the date that is a day after the 14-month period following the Filing Date of the '222 application) through December 9, 2010 (the mailing date of the First Office Action).

184. Under 35 U.S.C. § 154(b)(1)(B), Patentee is entitled to an additional adjustment of the term of the '806 patent for a period of 899 days. This B Delay period consists of the period from March 7, 2010 (the date that is a day after the 3-year period following the Filing Date of the '222 application) through August 21, 2012 (the issue date of the '806 patent).

185. There is overlap of A Delay and B Delay of 278 days for the '806 patent pursuant to 35 U.S.C. § 154(b)(2)(A). The overlap period consists of the period from March 7, 2010 (the date that is a day after the 3-year period following the Filing Date of the '222 application) through December 9, 2010 (the mailing date of the First Office Action), *i.e.*, 278 days.

186. Under 35 U.S.C. § 154(b)(2)(C)(i), 175 days of delay is attributable to Applicants. This Applicant Delay Reduction is the sum total of Applicants' delay in filing the response to the First Office Action on May 9, 2011, a date in excess of three months by 61 days; Applicants' delay in filing the response to the Second Office Action on January 05, 2012, a date in excess of

three months by 92 days; and Applicants' delay in filing the Drawings on July 03, 2012, a delay of 22 days.

187. The correct PTA for the '806 patent is 1393 days: the sum of the 947 days of A Delay and the 899 days of B Delay, minus the overlap of A Delay and B Delay of 278 days and 175 days of Applicant Delay.

The Proper Calculation of PTA for the '881 Patent

188. Under 35 U.S.C. § 154(b)(1)(A)(i), Patentee is entitled to an adjustment of the term of the '881 patent for a period of 546 days. This A Delay period is attributable to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the Filing Date of the application. This period consists of the period from July 30, 2008 (the date that is a day after the 14-month period following the Filing Date of the '755 application) through January 26, 2010 (the mailing date of the Restriction Requirement).

189. Under 35 U.S.C. § 154(b)(1)(A)(ii), Patentee is entitled to an additional adjustment of the term of the '881 patent for a period of 350 days. This A Delay period is attributable to the PTO's failure to respond to a reply under 35 U.S.C. § 132 within 4 months after the date a reply was filed. This period consists of the period from June 29, 2011 (the date that is a day after the 4-month period following the filing date of the reply to the Second Office Action) through June 12, 2012 (the mailing date of the Third Office Action), *i.e.*, 350 days.

190. Under 35 U.S.C. § 154(b)(1)(B), Patentee is entitled to an additional adjustment of the term of the '881 patent for a period of 871 days. This B Delay period consists of the period from May 30, 2010 (the date that is a day after the 3-year period following the Filing Date of the '755 application) through October 16, 2012 (the issue date of the '881 patent).

191. There is overlap of A Delay and B Delay of 350 days for the '881 patent pursuant to 35 U.S.C. § 154(b)(2)(A). The overlap period consists of the period from June 29, 2011 (the date that is a day after the 4-month period following the filing date of the reply to the Second Office Action) through June 12, 2012 (the mailing date of the Third Office Action), *i.e.*, 350 days.

192. Under 35 U.S.C. § 154(b)(2)(C)(i), 2 days of delay is attributable to Applicants. This Applicant Delay Reduction is Applicants' delay in filing the First RCE as a response to Second Office Action on February 28, 2011, a date in excess of three months by 2 days.

193. The correct PTA for the '881 patent is 1415 days: the sum of the 896 days of A Delay and the 871 days of B Delay, minus the overlap of A Delay and B Delay of 350 days and 2 days of Applicant Delay.

CLAIMS

COUNT 1: The '699 Patent

194. The allegations of paragraphs 1-193 are incorporated in this claim for relief as if fully set forth herein.

195. The PTO's calculation of B Delay for the '699 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 Applicants filed the RCE.

196. Applicants filed an RCE during prosecution of the '054 application, which was filed more than three years after the actual Filing Date of that application.

197. Applicants' filing of the RCE during prosecution of the '054 application has no effect upon the accrual of B Delay for the '699 patent.

198. The '699 patent accrued B Delay for the period from August 14, 2010 (the date that is a day after the 3-year period following the Filing Date of the '054 application) through July 3, 2012 (the issue date of the '699 patent) for a total of 690 days of B delay.

199. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '699 patent that deprived Patentee of the appropriate PTA for this patent.

200. Patentee is entitled to additional patent term for the '699 patent such that the 220 days of PTA granted by the PTO should be changed to 498 days.

COUNT 2: The '578 Patent

201. The allegations of paragraphs 1-193 are incorporated in this claim for relief as if fully set forth herein.

202. The PTO's calculation of B Delay for the '578 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 Applicants filed the RCE.

203. Applicants filed an RCE during prosecution of the '208 application, which was filed more than three years after the actual Filing Date of that application.

204. Applicants' filing of the RCEs during prosecution of the '208 application has no effect upon the accrual of B Delay for the '578 patent.

205. The '578 patent accrued B Delay for the period from June 18, 2008 (the date that is a day after the 3-year period following the Filing Date of the '208 application) through July 17, 2012 (the issue date of the '578 patent) for a total of 1491 days of B delay.

206. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '578 patent that deprived Patentee of the appropriate PTA for this patent.

207. Patentee is entitled to additional patent term for the '578 patent such that the 1168 days of PTA granted by the PTO should be changed to 1560 days.

COUNT 3: The '607 Patent

208. The allegations of paragraphs 1-193 are incorporated in this claim for relief as if fully set forth herein.

209. The PTO's calculation of B Delay for the '607 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 Applicants filed the RCE.

210. Applicants filed two RCEs during prosecution of the '486 application, both of which were filed more than three years after the actual Filing Date of that application.

211. Applicants' filing of the RCEs during prosecution of the '486 application has no effect upon the accrual of B Delay for the '607 patent.

212. The '607 patent accrued B Delay for the period from March 6, 2007 (the date that is a day after the 3-year period following the Filing Date of the '486 application) through July 17, 2012 (the issue date of the '607 patent) for a total of 1961 days of B delay.

213. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '607 patent that deprived Patentee of the appropriate PTA for this patent.

214. Patentee is entitled to additional patent term for the '607 patent such that the 1602 days of PTA granted by the PTO should be changed to 1966 days.

COUNT 4: The '582 Patent

215. The allegations of paragraphs 1-193 are incorporated in this claim for relief as if fully set forth herein.

216. The PTO's calculation of B Delay for the '582 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 Applicants filed the RCE.

217. Applicants filed four RCEs during prosecution of the '259 application, all of which were filed more than three years after the actual Filing Date of that application.

218. Applicants' filing of the RCEs during prosecution of the '259 application has no effect upon the accrual of B Delay for the '582 patent.

219. The '582 patent accrued B Delay for the period from December 14, 2008 (the date that is a day after the 3-year period following the Filing Date of the '259 application) through July 31, 2012 (the issue date of the '582 patent) for a total of 1326 days of B delay.

220. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '582 patent that deprived Patentee of the appropriate PTA for this patent.

221. Patentee is entitled to additional patent term for the '582 patent such that the 335 days of PTA granted by the PTO should be changed to 1244 days.

COUNT 5: The '219 Patent

222. The allegations of paragraphs 1-193 are incorporated in this claim for relief as if fully set forth herein.

223. The PTO's calculation of B Delay for the '219 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 Applicants filed the RCE.

224. Applicants filed an RCE during prosecution of the '504 application, which was filed more than three years after the actual Filing Date of that application.

225. Applicants' filing of the RCEs during prosecution of the '504 application has no effect upon the accrual of B Delay for the '219 patent.

226. The '219 patent accrued B Delay for the period from June 12, 2010 (the date that is a day after the 3-year period following the Filing Date of the '504 application) through August 21, 2012 (the issue date of the '219 patent) for a total of 740 days of B delay.

227. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '219 patent that deprived Patentee of the appropriate PTA for this patent.

228. Patentee is entitled to additional patent term for the '219 patent such that the 318 days of PTA granted by the PTO should be changed to 611 days.

COUNT 6: The '900 Patent

229. The allegations of paragraphs 1-193 are incorporated in this claim for relief as if fully set forth herein.

230. The PTO's calculation of B Delay for the '900 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 Applicants filed the RCE.

231. Applicants filed an RCE during prosecution of the '781 application, which was filed more than three years after the actual Filing Date of that application.

232. Applicants' filing of the RCEs during prosecution of the '781 application has no effect upon the accrual of B Delay for the '900 patent.

233. The '900 patent accrued B Delay for the period from December 18, 2010 (the date that is a day after the 3-year period following the Filing Date of the '781 application) through September 11, 2012 (the issue date of the '900 patent) for a total of 634 days of B delay.

234. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '900 patent that deprived Patentee of the appropriate PTA for this patent.

235. Patentee is entitled to additional patent term for the '900 patent such that the 1168 days of PTA granted by the PTO should be changed to 1226 days.

COUNT 7: The '149 Patent

236. The allegations of paragraphs 1-193 are incorporated in this claim for relief as if fully set forth herein.

237. The PTO's calculation of B Delay for the '149 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 Applicants filed the RCE.

238. Applicants filed an RCE during prosecution of the '850 application, which was filed more than three years after the actual Filing Date of that application.

239. Applicants' filing of the RCEs during prosecution of the '850 application has no effect upon the accrual of B Delay for the '149 patent.

240. The '149 patent accrued B Delay for the period from August 22, 2009 (the date that is a day after the 3-year period following the Filing Date of the '850 application) through September 18, 2012 (the issue date of the '149 patent) for a total of 1124 days of B delay.

241. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '149 patent that deprived Patentee of the appropriate PTA for this patent.

242. Patentee is entitled to additional patent term for the '149 patent such that the 1078 days of PTA granted by the PTO should be changed to 1549 days.

COUNT 8: The '249 Patent

243. The allegations of paragraphs 1-193 are incorporated in this claim for relief as if fully set forth herein.

244. The PTO's calculation of B Delay for the '249 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 Applicants filed the RCE.

245. Applicants filed an RCE during prosecution of the '326 application, which was filed more than three years after the actual Filing Date of that application.

246. Applicants' filing of the RCEs during prosecution of the '326 application has no effect upon the accrual of B Delay for the '249 patent.

247. The '249 patent accrued B Delay for the period from November 17, 2009 (the date that is a day after the 3-year period following the Filing Date of the '326 application) through September 18, 2012 (the issue date of the '249 patent) for a total of 980 days of B delay.

248. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '249 patent that deprived Patentee of the appropriate PTA for this patent.

249. Patentee is entitled to additional patent term for the '249 patent such that the 1053 days of PTA granted by the PTO should be changed to 1586 days.

COUNT 9: The '806 Patent

250. The allegations of paragraphs 1-193 are incorporated in this claim for relief as if fully set forth herein.

251. The PTO's calculation of B Delay for the '806 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 Applicants filed the RCE.

252. Applicants filed an RCE during prosecution of the '222 application, which was filed more than three years after the actual Filing Date of that application.

253. Applicants' filing of the RCEs during prosecution of the '222 application has no effect upon the accrual of B Delay for the '806 patent.

254. The '806 patent accrued B Delay for the period from March 7, 2010 (the date that is a day after the 3-year period following the Filing Date of the '222 application) through August 21, 2012 (the issue date of the '806 patent) for a total of 899 days of B delay.

255. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '806 patent that deprived Patentee of the appropriate PTA for this patent.

256. Patentee is entitled to additional patent term for the '806 patent such that the 1163 days of PTA granted by the PTO should be changed to 1393 days.

COUNT 10: The '881 Patent

257. The allegations of paragraphs 1-193 are incorporated in this claim for relief as if fully set forth herein.

258. The PTO's calculation of B Delay for the '881 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 Applicants filed the RCE.

259. Applicants filed an RCE during prosecution of the '755 application, which was filed more than three years after the actual Filing Date of that application.

260. Applicants' filing of the RCEs during prosecution of the '755 application has no effect upon the accrual of B Delay for the '881 patent.

261. The '881 patent accrued B Delay for the period from May 29, 2010 (the date that is a day after the 3-year period following the Filing Date of the '755 application) through October 16, 2012 (the issue date of the '881 patent) for a total of 871 days of B delay.

262. The PTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation B Delay for the '881 patent that deprived Patentee of the appropriate PTA for this patent.

263. Patentee is entitled to additional patent term for the '881 patent such that the 1168 days of PTA granted by the PTO should be changed to 1415 days.

REQUEST FOR RELIEF

WHEREFORE, Life Technologies respectfully prays that this Court:

A. Issue an Order changing the period of PTA for the '699 patent from 220 days to 498 days and requiring Defendant to alter the term of the '699 patent to reflect such additional PTA;

B. Issue an Order changing the period of PTA for the '578 patent from 1168 days to 1560 days and requiring Defendant to alter the term of the '578 patent to reflect such additional PTA;

C. Issue an Order changing the period of PTA for the '607 patent from 1602 days to 1966 days and requiring Defendant to alter the term of the '607 patent to reflect such additional PTA;

D. Issue an Order changing the period of PTA for the '582 patent from 335 days to 1244 days and requiring Defendant to alter the term of the '582 patent to reflect such additional PTA;

E. Issue an Order changing the period of PTA for the '219 patent from 318 days to 611 days and requiring Defendant to alter the term of the '219 patent to reflect such additional PTA;

F. Issue an Order changing the period of PTA for the '900 patent from 1168 days to 1226 days and requiring Defendant to alter the term of the '900 patent to reflect such additional PTA;

G. Issue an Order changing the period of PTA for the '149 patent from 1078 days to 1549 days and requiring Defendant to alter the term of the '149 patent to reflect such additional PTA;

H. Issue an Order changing the period of PTA for the '249 patent from 1053 days to 1586 days and requiring Defendant to alter the term of the '249 patent to reflect such additional PTA;

I. Issue an Order changing the period of PTA for the '806 patent from 1163 days to 1393 days and requiring Defendant to alter the term of the '806 patent to reflect such additional PTA;

J. Issue an Order changing the period of PTA for the '881 patent from 1168 days to 1415 days and requiring Defendant to alter the term of the '881 patent to reflect such additional

PTA; and

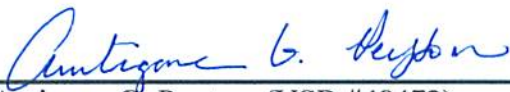
K. Grant such other and further relief as the nature of the case may admit or require and as may be just and equitable.

Dated: December 31, 2012

Respectfully submitted,

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