

**IN THE UNITED STATES DISTRICT COURT**  
**FOR THE DISTRICT OF COLUMBIA**

Hoffmann-La Roche Inc.  
340 Kingsland Street  
Nutley, New Jersey 07110

and

Morphosys AG  
Lena-Christ-Strasse 48  
82152 Martinsried, Germany

Plaintiffs,

v.

HON. DAVID J. KAPPOS  
Under Secretary of Commerce for Intellectual  
Property and  
Director of the United States Patent and  
Trademark Office  
Office of General Counsel,  
United States Patent and Trademark Office  
P.O. BOX 15667, Arlington, VA 22215  
Madison Building East, Rm. 10B20  
600 Dulany Street, Alexandria, VA 223144

Defendant.

**COMPLAINT**

Plaintiffs, Hoffmann-La Roche Inc. and Morphosys AG (“Roche and Morphosys”), for its complaint against the Honorable David J. Kappos, state as follows:

**NATURE OF THE ACTION**

1. This is an action by the assignees of United States Patent No. 7,794,719 (“the ‘719 patent’”) seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the ‘719 patent be changed from 1016 days to 1412 days.

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

### **JURISDICTION AND VENUE**

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

### **THE PARTIES**

6. Plaintiff Hoffmann-La Roche Inc. is a corporation organized under the laws of New Jersey, having a principal place of business at 340 Kingsland Street, Nutley, New Jersey 07110. Plaintiff Morphosys AG is a corporation organized under the laws of Germany, having a principal place of business at Lena-Christ-Strasse 48, 82152 Martinsried, Germany.

7. Defendant David J. Kappos (“Director”) 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 agency, charged by statute with providing management supervision for the PTO and for the issuance of patents. The Director is the official responsible for determining the period of patent term adjustment under 35 U.S.C. § 154.

### **BACKGROUND**

8. Michael Bardroff, Bernd Bohrmann, Manfred Brockhaus, Walter Huber, Titus Kretschmar, Hansruedi Loetscher, Corinna Lohning, Christer Nordstedt, and Christine Rothe are the inventors of U.S. patent application number 10/505,313 (“the ‘313 application”), which

completed the requirements of 35 U.S.C. 371 on March 7, 2005 and issued as the '719 patent on September 14, 2010. The claims of the '719 patent are directed to anti-amyloid beta antibodies and pharmaceutical compositions. The '719 patent is attached as Exhibit A.

9. Plaintiffs Roche and Morphosys are the assignees of the '719 patent.

10. Under Section 154 of Title 35 of the United States Code, the Director of the PTO must grant a patent term adjustment in accordance with the provisions of section 154(b), which states, in pertinent part, that “[t]he Director shall proceed to grant the patent after completion of the Director’s determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.” 35 U.S.C. § 154(b)(3)(D).

11. In determining patent term adjustment, the Director is required to extend the term of a patent for a period equal to the total number of days attributable to delay by the PTO under 35 U.S.C. §§ 154(b)(1)(A), (B), and (C), as limited by the following: (i) any overlapping periods of PTO delay as specified by 35 U.S.C. § 154(b)(2)(A); (ii) any disclaimer of patent term by the applicant under 35 U.S.C. § 154(b)(2)(B); and (iii) any delay attributable to the applicant under 35 U.S.C. § 154(b)(2)(C).

12. The Director determined that the '719 patent is entitled to 1016 days of patent term adjustment pursuant to 35 U.S.C. § 154(b)(3) and issued the '719 patent reflecting that determination.

13. On November 12, 2010, in accordance with 37 C.F.R. 1.705(d), Plaintiffs filed an Application for Patent Term Adjustment (“Application for PTA”) with the PTO to request correction of the Director’s patent term adjustment determination. The Application for PTA is attached as Exhibit B. Two of the issues raised in the Application for PTA had been raised

previously in Plaintiffs' Petition Under 37 C.F.R. § 1.181(a)(3) to Invoke the Supervisory Authority of the Director ("181 Petition"), filed on August 20, 2010. The 181 Petition is attached as Exhibit C.

14. Section 154(b)(4)(A) of Title 35 provides that "[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 District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such an action." Section 702 of Title 5 further provides, in pertinent part, that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." Having received no reply from the PTO to either its Application for PTA or its 181 Petition, Plaintiffs Roche and Morphosys hereby bring the present action for judicial review of the PTO's calculation of patent term adjustment for the '719 patent.

#### **CLAIM FOR RELIEF**

15. The allegations of paragraphs 1-14 are incorporated into this claim for relief as if fully set forth herein.

16. The patent term adjustment for the '719 patent, as determined by the Director under 35 U.S.C. § 154(b), and as set forth on the face of the patent, is 1016 days. The determination of this 1016 day patent term adjustment is in error because the PTO, and the Director acting in his official capacity, improperly calculated the length of the applicant delay period defined by 35 U.S.C. § 154(b)(2)(C).

17. The correct patent term adjustment for the '719 patent is 1412 days.

18. Under 35 U.S.C. § 154(b)(1)(A), the correct number of days attributable to PTO examination delay (“A Delay”) is 590 days. The Director correctly calculated the A Delay.

19. Under 35 U.S.C. § 154(b)(1)(B), the correct number of days attributable to application pendency in excess of three years (“B Delay”) is 1121 days. The Director correctly calculated the B Delay.

20. Under 35 U.S.C. § 154(b)(2)(C), the correct number of days of applicant delay is 103 days, corresponding to six periods of delay occurring: (i) from July 28, 2007, to August 6, 2007, for a period of 10 days; (ii) from October 26, 2007, to November 13, 2007, for a period of 19 days; (iii) from April 29, 2008 to July 2, 2008, for a period of 65 days; (iv) from January 17, 2009, to January 21, 2009, for a period of 5 days; (v) from July 30, 2009, to July 31, 2009, for a period of 2 days; and (vi) from January 15, 2009, to January 16, 2009, for a period of 2 days.

21. The Director incorrectly calculated a total applicant delay of 499 days.

22. The Director correctly calculated periods of applicant delay as occurring: (i) from July 28, 2007, to August 6, 2007; (ii) from October 26, 2007, to November 13, 2007; (iii) from April 29, 2008 to July 2, 2008; (iv) from January 17, 2009, to January 21, 2009; and (v) from July 30, 2009, to July 31, 2009.

23. The Director incorrectly calculated periods of applicant delay in three separate instances, as explained in each of the following three paragraphs.

24. Plaintiffs filed a response to a Restriction Requirement on July 27, 2007. The PTO mailed a Notice of Non-Compliant Amendment on October 18, 2007, and Plaintiffs filed a response thereto on October 25, 2007. The PTO has charged applicant delay under 37 C.F.R. 1.704(c)(7) for a period of 80 days (90 days reduced by 10 days of overlapping applicant delay),

beginning on July 28, 2007, and ending on October 25, 2007. Assessment of applicant delay would be appropriate only if the response filed on July 27, 2007 was non-compliant. However, the response filed on July 27, 2007 was fully compliant and the Notice of Non-Compliant Amendment mailed on October 18, 2007 was improper. See Exhibit C. In view of the fact that the response filed on July 27, 2007 was compliant, Plaintiffs should not have been assessed applicant delay under 37 C.F.R. 1.704(c)(7) for the period beginning on July 28, 2007, and ending on October 25, 2007.

25. Plaintiffs filed a response to Office Action on July 2, 2008. Subsequently, Plaintiffs filed a supplemental response requested by the Examiner on July 28, 2008. The PTO mailed a Notice of Non-Responsive Amendment on October 14, 2008, and Plaintiffs filed a response thereto on January 16, 2009. The PTO has charged applicant delay for a period of 198 days, beginning on July 3, 2008 and ending on January 16, 2009. Assessment of the applicant delay would be appropriate only if the responses filed on July 2, 2008 and July 28, 2008 were non-responsive. However, the responses filed on July 2, 2008 and July 28, 2008 were fully compliant and the Notice of Non-Responsive Amendment mailed on October 14, 2008 was improper. See Exhibit C. In view of the fact that the responses filed on July 2, 2008 and July 28, 2008 were responsive, Plaintiffs should not have been assessed applicant delay under 37 C.F.R. 1.704(c)(7) for the 198 day period beginning on July 3, 2008, and ending on January 16, 2009. The correct calculation of applicant delay associated with this filing is 2 days, from January 15, 2009 (the day after the date that is three months from the date on which the Notice of Non-Responsive Amendment was mailed) to January 16, 2009 (the date on which the response was filed).

26. The PTO mailed a Notice of Allowance and Fees Due including a Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) on August 21, 2009. On October 16, 2009, Plaintiffs timely filed an application for patent term adjustment under 37 C.F.R. § 1.705(b). No other filing was made on that date. On line 95 of the Patent Term Adjustments tab of the PAIR/PALM system, an “Amendment after Notice of Allowance (Rule 312)” is entered as having been filed on October 16, 2009, and an applicant delay of 120 days was accorded in connection with this entry. 37 C.F.R. 1.704(e) states that “[s]ubmission of an application for patent term adjustment under [37 C.F.R.] § 1.705(b) (with or without request under § 1.705(c) for reinstatement of reduced patent term adjustment) will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraph (c)(10) of this section.” Because no filing other than an application for patent term adjustment (and its associated supporting documentation) was filed on October 16, 2009, the calculation of 120 days of applicant delay is incorrect. The correct calculation of applicant delay associated with this filing is 0 days.

27. Section 154(b)(2)(A) of Title 35 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.” The overlap between the A Delay period and the B Delay period in the prosecution of the ‘719 patent is 196 days. The Director correctly calculated the overlap between the A Delay period and the B Delay period.

28. The ‘719 patent is not subject to a disclaimer of term. Thus the period of patent term adjustment is not limited under 35 U.S.C. § 154(b)(2)(B).

29. 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 (590 days + 1121 days = 1711 days) minus the number of days of overlap of A Delay and B Delay (196 days) and applicant delay (103 days), for a net correct patent term adjustment of 1412 days for the '719 patent.

30. Accordingly, the Director's determination that the '719 patent is entitled to only 1016 days of patent term adjustment, as evidenced by the PTO Decision, 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**

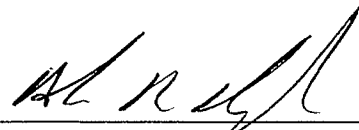
Wherefore, Plaintiffs demand judgment against Defendant and respectfully request that this Court enter Orders:

A. Changing the period of patent term adjustment for the '719 patent term from 1016 days to 1412 days, and requiring the Director to extend the term of the '719 patent by 396 days to reflect the correct 1412 day patent term adjustment.

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

Dated: March 10, 2011

Respectfully Submitted,



Andrew R. Kopsidas, Bar No. 476237  
kopsidas@fr.com

FISH & RICHARDSON P.C.  
1425 K Street, N.W.  
Washington, D.C. 20005  
Telephone: 202-783-5070  
Facsimile: 202-783-2331



Attorney for Plaintiffs  
Hoffmann-La Roche Inc. and  
Morphosys AG