

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

IDERA PHARMACEUTICALS, INC.,)
)
Cambridge, MA,)
)
Plaintiff,)

v.)

Civil Action No. _____

HON. DAVID J. KAPPOS,)
)
Under Secretary of Commerce for Intellectual)
Property and Director of the United States Patent)
and Trademark Office)
)
Office of the 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 22314)

Defendant.

COMPLAINT

Plaintiff Idera Pharmaceuticals, Inc., by its undersigned attorneys, states the following for its complaint against the Honorable David J. Kappos (hereinafter, “Kappos,” “Director,” or “Defendant”):

NATURE OF ACTION

1. This is an action by the assignee of United States Patent No. 7,569,554 (“the ‘554 Patent,” attached as Exhibit A), pursuant to 35 U.S.C. § 154(b)(4)(A), seeking judgment that the patent term adjustment for the ‘554 Patent be 606 days, whereby the ‘554 Patent will expire on January 10, 2026.

2. This is an action by the assignee of United States Patent No. 7,517,862 (“the ‘862 Patent,” attached as Exhibit B), pursuant to 35 U.S.C. § 154(b)(4)(A), seeking judgment that the patent term adjustment for the ‘862 Patent be changed from 594 days to 1,174 days.

3. This action arises under 35 U.S.C. § 154(b)(4)(A) and the Administrative Procedures Act, 5 U.S.C. §§ 701-706.

THE PARTIES

4. Plaintiff Idera Pharmaceuticals, Inc. (hereinafter “IPI”), is a corporation organized under the laws of Commonwealth of Massachusetts, having a principal place of business at 167 Sidney Street, Cambridge, Massachusetts.

5. Defendant David J. Kappos is the Under Secretary of Commerce for Intellectual Property and the 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(b)(3).

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over 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.

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

8. With respect to the ‘554 Patent, this Complaint is timely filed in accordance with U.S.C. § 154(b)(4)(A). With respect to the ‘862 Patent, this Complaint is timely filed in connection with 35 U.S.C. § 154(b)(4)(A) by virtue of the doctrine of equitable tolling.

BACKGROUND

9. Ekambar R. Kandimalla, Sudhir Agrawal, Daqing Wang, Lakshmi Bhagat, and Dong Yu are the inventors of the invention claimed in the U.S. Patent Application Serial No. 10/846,167 (the “167 Application”) entitled “Synergistic treatment of cancer using immunomers in conjunction with therapeutic agents,” filing date of May 29, 2000, which issued as the ‘554 Patent on June 9, 2009. A copy of the ‘554 Patent is attached as Exhibit A.

10. Ekambar R. Kandimalla, Sudhir Agrawal, Dong Yu and Lakshmi Bhagat are the inventors of the invention claimed in the U.S. Patent Application Serial No. 10/925,873, entitled “Modulation of Immunostimulatory Properties of Oligonucleotide-based Compounds by Optimal Presentation of 5’ Ends,” filing date of August 25, 2004, which issued as the ‘862 Patent on April 14, 2009. A copy of the ‘862 Patent is attached as Exhibit B.

11. Plaintiff IPI is the owner of the ‘554 Patent, as evidenced by the assignment document recorded with the PTO at Reel 019961/Frame 0144 on October 3, 2007, in which the inventors assigned all rights, title and interest to IPI, which is the real party in interest in this case.

12. Plaintiff IPI is the owner of the ‘862 Patent, as evidenced by the assignment document recorded with the PTO at Reel 017240/Frame 0865 on October 3, 2007, in which the inventors assigned all rights, title and interest to IPI, which is the real party in interest in this case.

13. Section 154 of Title 35 of the United States Code requires that the Director of the PTO grant a patent term adjustment in accordance with the provisions of Section 154(b). Specifically, 35 U.S.C. § 154(b)(3)(D) states that “[t]he Director shall proceed to grant the patent

after completion of the Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination."

14. The '554 Patent is subject to a terminal disclaimer over the '862 patent. 35 U.S.C. § 154(b)(2)(B) provides that "No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer." The permissible patent term adjustment for the '554 patent is, therefore, determined in part with respect to the term of the '862 patent. Accordingly, in order to fully determine the proper term adjustment of the '554 patent, it is necessary and appropriate for this Court to correct the term of the '862 Patent, as prayed for herein.

16. In determining the 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), as limited by any overlapping periods of delay by the PTO as specified under 35 U.S.C. § 154(b)(2)(A), any disclaimer of patent term by applicant under 35 U.S.C. § 154(b)(2)(B), and any delay attributable to the applicant under 35 U.S.C. § 154(b)(2)(C).

17. "An applicant dissatisfied with a determination made by the Director under paragraph (3) shall have a 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 action." 35 U.S.C. § 154(b)(4)(A).

CLAIM FOR RELIEF

COUNT I (THE '554 PATENT)

18. The allegations of paragraphs 1-17 are incorporated in this claim for relief as if fully set forth.

19. The patent term adjustment for the '554 Patent as determined by the Director under 35 U.S.C. § 154(b) and indicated on the face of the '554 Patent is 722 days. (*See Exhibit A* at 1). The patent term adjustment determination of 722 days is in error because the PTO failed to account for two separate PTO delays. In particular, the PTO failed to properly account for the PTO delay that occurred after the date that was three years after the filing date of the '167 Application, pursuant to U.S.C. § 154(b)(1)(B). The correctly calculated patent term adjustment for the '554 Patent is 1,275 days.

20. The '167 Application was filed on May 14, 2004, and issued as the '554 Patent on August 4, 2009.

21. Under 35 U.S.C. § 154(b)(1)(A), the number of days attributable to PTO examination delay ("A Delay") is 668 days. This A Delay period accounts for the following PTO delays: (a) between the date that is fourteen months after the filing date of the '167 Application (*i.e.*, May 14, 2004)), and the date that the notification under 35 U.S.C. § 132 was mailed (*i.e.*, January 8, 2007); and (b) between the date that is four months after applicants' reply under 35 U.S.C. § 132 (*i.e.*, November 30, 2008) and the date that the notification under 35 U.S.C. § 132 was mailed (*i.e.*, April 3, 2009).

22. Under 35 U.S.C. § 154(b)(1)(B), the number of days attributable to PTO delay ("B Delay") is 812 days. This B Delay period accounts for the PTO delay between the date that

was three years after the actual filing date of the '167 Application (*i.e.*, May 14, 2007), and the date that the '554 Patent issued (*i.e.*, August 4, 2009).

23. Under 35 U.S.C. § 154(b)(2)(C), the number of days of applicant delay is 91 days.

24. "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." 35 U.S.C. § 154(b)(2)(A). Here, the overlap between the A Delay period and the B Delay period is 114 days (*i.e.*, the A Delay period that occurred between November 30, 2008 and April 3, 2009).

25. The correct calculated patent term adjustment under 35 U.S.C. §§ 154(b)(1) and 154(b)(2) is the sum of the A Delay period and the B Delay period (*i.e.*, 668 days + 812 days), reduced by the sum of the number of days of overlap between the A Delay Period and the B Delay Period and the period of applicant delay (*i.e.*, 114 days + 91 days). Accordingly, the correct calculated patent term adjustment is 1,275 days.

26. The Director erred in the determination of patent term adjustment by treating the entire period of PTO examination delay under the A Delay period as a period of overlap between the A Delay period and the B Delay period, rather than correctly treating only that part of the A Delay period that occurred after the date that was three years after the actual filing date of the '167 Application. Therefore, the Director erroneously determined that the net patent term adjustment was 722 days without taking into account the effect of a terminal disclaimer, as required by 35 U.S.C. § 154(b)(2)(B).

27. In *Wyeth v. Dudas*, 580 Supp. 2d 138 (D.D.C. 2008), this Court explained the proper construction of the provisions of 35 U.S.C. § 154(b) for determining patent term adjustment. The Court of Appeals For the Federal Circuit affirmed this Court's judgment on

January 7, 2010 in *Wyeth v. Kappos*, Slip op., attached as Exhibit C. In accordance with *Wyeth*, the calculated patent term adjustment for the '554 Patent is properly determined to be 1,275 days as explained above (*i.e.* (657 days + 812 days) minus (114 days + 91 days)).

28. However, the term of the '554 Patent has been disclaimed beyond the full statutory term of the '862 Patent. 35 U.S.C. § 154(b)(2)(b) provides that "No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer." Thus, the permissible patent term adjustment of the '554 is limited by the correct full statutory term of the '862 Patent under 35 U.S.C. § 154(b). As shown in Count II below, the correct full statutory term of the '862 Patent expires on January 10, 2026. Accordingly, the patent term adjustment of the '554 Patent should be 606 days (the time between the unextended patent term expiration of the '554 Patent, which is May 14, 2004, and the correct patent term expiration of the '862 Patent, which is January 10, 2026).

COUNT II (THE '862 PATENT)

29. The allegations of paragraphs 1-28 are incorporated in this claim for relief as if fully set forth.

30. As hereinbefore alleged, the '554 Patent is subject to a terminal disclaimer and its permissible patent term adjustment is determined, in part with respect to the '862 Patent. The '862 Patent issued from U.S. Application No. 10/925,873 ("the '873 Application"). The patent term adjustment for the '862 Patent as determined by the Director under 35 U.S.C. § 154(b) and indicated on the face of the '862 Patent is 594 days. (*See Exhibit B* at 1). The patent term adjustment determination of 594 days is in error because the PTO failed to account for two separate PTO delays. In particular, the PTO failed to properly account for the PTO delay that

occurred after the date that was three years after the filing date of the '873 Application, pursuant to U.S.C. § 154(b)(1)(B). The correct patent term adjustment for the '862 Patent is 1,174 days.

31. The '873 Application was filed on August 25, 2004, and issued as the '862 Patent on April 14, 2009.

32. Under 35 U.S.C. § 154(b)(1)(A), the number of days attributable to PTO examination delay ("A Delay") is 687 days. This A Delay period accounts for the PTO delay between the date that is fourteen months after the filing date of the '873 Application (*i.e.*, August 25, 2004)), and the date that the notification under 35 U.S.C. § 132 was mailed (*i.e.*, September 12, 2007).

33. Under 35 U.S.C. § 154(b)(1)(B), the number of days attributable to PTO delay ("B Delay") is 598 days. This B Delay period accounts for the PTO delay between the date that was three years after the actual filing date of the '873 Application (*i.e.*, August 25, 2007), and the date that the '862 Patent issued (*i.e.*, April 14, 2009).

34. Under 35 U.S.C. § 154(b)(2)(C), the number of days of applicant delay is 93 days.

35. "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." 35 U.S.C. § 154(b)(2)(A). Here, the overlap between the A Delay period and the B Delay period is 18 days (*i.e.*, the beginning of the B Delay period on August 25, 2007 and the end of the A Delay period on September 12, 2007).

36. The correct patent term adjustment under 35 U.S.C. §§ 154(b)(1) and 154(b)(2) is the sum of the A Delay period and the B Delay period (*i.e.*, 687 days + 598 days), reduced by the sum of the number of days of overlap between the A Delay Period and the B Delay Period and

the period of applicant delay (*i.e.*, 18 days + 93 days). Accordingly, the correct patent term adjustment is 1,174 days.

37. The Director erred in the determination of patent term adjustment by treating the entire period of PTO examination delay under the A Delay period as a period of overlap between the A Delay period and the B Delay period, rather than correctly treating only that part of the A Delay period that occurred after the date that was three years after the actual filing date of the '873 Application. The Director further erred in the determination of patent term adjustment by dismissing the Request for Reconsideration of Patent Term Adjustment, filed May 11, 2009, attached as Exhibit D. Therefore, the Director erroneously determined that the net patent term adjustment was 594 days.

38. In *Wyeth v. Dudas*, 580 Supp. 2d 138 (D.D.C. 2008), this Court explained the proper construction of the provisions of 35 U.S.C. § 154(b) for determining patent term adjustment. The Court of Appeals For the Federal Circuit affirmed this Court's judgment on January 7, 2010. In accordance with *Wyeth*, the patent term adjustment for the '862 Patent is properly determined to be 1,174 days as explained above (*i.e.* (687 days + 598 days) minus (18 days + 93 days). Accordingly, the correctly determined adjusted patent term of the '862 Patent expires on January 10, 2026 (the unextended patent term expiration of the '862 Patent, which is August 25, 2024 + 1,174 days).

39. The '862 Patent is not subject to a terminal disclaimer.

40. This Court's decision in *Wyeth v. Dudas*, as affirmed by The Court of Appeals For The Federal Circuit constitutes a change in law sufficient to invoke the doctrine of equitable tolling to allow for the filing of Count II of this complaint at this time.

41. The Director's determination that the '862 patent is entitled to 594 days of patent term adjustment is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Idera Pharmaceuticals, Inc. prays that this Court issues an Order:

(A) Changing the period of patent term adjustment for the '554 Patent term to 606 days, whereby the '554 Patent expires on January 10, 2026 and requiring the Director to extend the term of the '554 Patent to reflect the 606 day patent term adjustment;

(B) Changing the period of patent term adjustment for the '862 Patent term from 594 days to 1,174 days and requiring the Director to extend the term of the '862 Patent to reflect the 1,174 day patent term adjustment; and

(C) Granting other and further relief as the nature of this case may admit or require and as may be just and equitable.

This 28th day of January, 2010.

Respectfully submitted,

/s/ Michael A. Murphy
Michael A. Murphy (D.C. Bar No. 450122)
PRETI FLAHERTY BELIVEAU
& PACHIOS LLP
Exchange Place
53 State Street, 30th Floor
Boston, Massachusetts 02109
(617) 226-3800
(617) 226-3801 (fax)
Email: mmurphy@preti.com