

IN THE UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF COLUMBIA

THE GENERAL HOSPITAL CORPORATION  
55 Fruit Street  
Boston, MA 02114

Plaintiff,

v.

HON. JON W. DUDAS  
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  
600 Dulaney Street  
Arlington, VA 22314

Defendant.

Civil Action No. \_\_\_\_\_

**COMPLAINT**

Plaintiff The General Hospital Corporation, for its Complaint against the Honorable Jon W. Dudas, states as follows:

1. This is an action by the owner of U.S. Patent No. 7,367,341 (“the ‘341 patent”) seeking review of inaccurate and erroneous patent term adjustment calculations made by the United States Patent and Trademark Office (“USPTO”). Specifically, this is an action by Plaintiff under 35 U.S.C. § 154(b)(4)(A) seeking a judgment that the patent term adjustment of 214 days calculated by the USPTO for the ‘341 patent should be corrected to 515 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. Plaintiff The General Hospital Corporation is a corporation organized under the laws of the Commonwealth of Massachusetts and having a principal place of business at 55 Fruit Street, Boston, MA 02114.

4. Defendant Jon W. Dudas is the Under Secretary of Commerce for Intellectual Property and Director of the USPTO, acting in his official capacity. The Director of the USPTO (“Director”) is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents, and is designated by 35 U.S.C. § 154(b)(3)(B) as the official responsible for determining the period of patent term adjustment.

**JURISDICTION AND VENUE**

5. This Court has jurisdiction over this action and is authorized to issue the requested relief to Plaintiff 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.

6. Venue is proper in this district by virtue of 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) in view of the doctrine of equitable tolling.

**FACTS**

8. On May 6, 2008 the USPTO issued to Richard Rox Anderson and Dieter Manstein the ‘341 patent based on U.S. Patent Application Serial No. 10/391,221 filed on March 17, 2003, entitled “Methods and Devices for Selective Disruption of Fatty Tissue by Controlled Cooling,” a true copy of which is attached hereto as Exhibit 1.

9. Plaintiff The General Hospital Corporation is the assignee and owner of the ‘341 patent as evidenced by an assignment executed by Richard Rox Anderson and Dieter Manstein and

recorded with the USPTO at Reel 015378, Frame 0692 of the USPTO assignment records. Plaintiff The General Hospital Corporation is the real party in interest in this case.

10. Pursuant to 35 U.S.C. § 154, the Director is required to grant a patent term adjustment in accordance with the provisions of 35 U.S.C. § 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.”

11. In calculating the patent term adjustment, the Director is required to consider USPTO delays under 35 U.S.C. § 154(b)(1)(A) and (B), any overlapping periods in the USPTO delays under 35 U.S.C. § 154(b)(2)(A), and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

12. The patent term adjustment for the ‘341 patent, as determined by the Defendant under 35 U.S.C. § 154(b) and listed on the face of the ‘341 patent, is 214 days. *See* Exhibit 1 at 1.

13. Had the USPTO calculated the entitled patent term adjustment properly, the ‘341 patent would be entitled to 515 days of patent term adjustment.

14. The errors in the USPTO’s patent term adjustment calculation are detailed in a recent decision from this Court in *Wyeth v. Dudas*, ---- F. Supp. 2d ----, 88 U.S.P.Q.2d 1538 (BNA) (D.D.C. 2008), *appeal docketed*, No. 08-5502 (Fed. Cir. Dec. 24, 2008), where this Court granted summary judgment against the USPTO holding that the USPTO’s patent term adjustment calculation methodology was erroneous as a matter of law and inconsistent with the 35 U.S.C. § 154. A true copy of the *Wyeth v. Dudas* opinion is attached hereto as Exhibit 2.

15. The correct patent term adjustment methodology identified in the *Wyeth v. Dudas* decision governs the USPTO’s calculation of patent term adjustment for the Plaintiff’s ‘341 patent.

**CLAIM FOR RELIEF**

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

17. During prosecution of the '341 patent, Plaintiff accrued 362 days of patent term adjustment under 35 U.S.C. § 154(b)(1)(A), and accrued 315 days of patent term adjustment under 35 U.S.C. § 154(b)(1)(B).

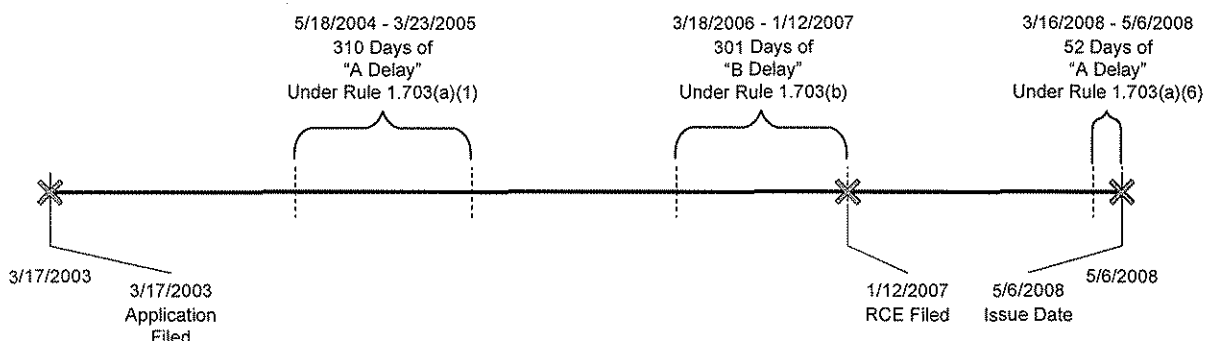
18. Under the USPTO's interpretation of 35 U.S.C. § 154, all patent term adjustment accrued under 35 U.S.C. § 154(b)(1)(A) and 35 U.S.C. § 154(b)(1)(B) inherently overlaps and, thus, it has been the USPTO's position that a patent holder is only eligible for the larger of these two amounts of patent term adjustment, that is, 362 days for the '341 patent.

19. In view of the recent decision from this Court in *Wyeth v. Dudas*, the USPTO is obligated to award patent term adjustment under both 35 U.S.C. § 154(b)(1)(A) and 35 U.S.C. § 154(b)(1)(B) except where both delays occur on the same day, in which case the applicant is awarded a single day of patent term adjustment.

20. Plaintiff agrees with the USPTO's calculation of 362 days of "A Delay" under 35 U.S.C. § 154(b)(1)(A).

21. Plaintiff respectfully asserts that USPTO erred in not awarding any "B Delay" under 35 U.S.C. § 154(b)(1)(B) for the failure of the USPTO to issue the '341 patent on or before March 17, 2006 (three years after the filing date). Specifically, Plaintiff is entitled to 301 days of patent term adjustment for the period between March 18, 2006 (three years and one day after the application filing date) and January 12, 2007 (the date on which a Request for Continued Examination ("RCE") was filed).

22. The 362 days of “A Delay” and the 301 days of “B Delay” do not overlap as depicted below:



23. Under the proper analysis set forth in *Wyeth v. Dudas*, Plaintiff is entitled to 515 days of patent term adjustment (362 days of “A Delay”, plus 301 days of “B Delay”, less 0 days of overlap between the periods of “A Delay” and “B Delay”, less 148 days of applicant delay).

24. This Court’s decision in *Wyeth v. Dudas* constituted a change in the law sufficient to invoke the doctrine of equitable tolling to allow for the filing of this complaint at this time.

**PRAYERS FOR RELIEF**

WHEREFORE, Plaintiffs request that this Court:

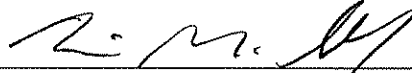
(a) Issue an Order changing the period of patent term adjustment for the ‘341 patent from 214 days to 515 days and requiring Defendant to issue a Certificate of Correction to alter the terms of ‘314 patent to reflect the corrected 515 days of patent term adjustment; and

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

Date: January 16, 2009

Respectfully submitted,

**EDWARDS ANGELL PALMER & DODGE LLP**



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