

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

MOLECULAR INSIGHT )  
PHARMACEUTICALS, INC. )  
160 Second Street )  
Cambridge, MA 02142 )

Plaintiff, )

v. )

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

HON. JON W. DUDAS )  
Under Secretary of Commerce for Intellectual )  
Property and Director of the United States )  
Patent and Trademark Office )  
Madison Building )  
600 Dulany Street )  
Alexandria, VA 22314 )

Defendant. )

**COMPLAINT**

Plaintiff Molecular Insight Pharmaceuticals, Inc., for its complaint against defendant the Honorable Jon W. Dudas, states as follows:

1. This is an action by the owner of United States Patent No. 7,381,399 (“the ‘399 patent”) seeking review of inaccurate and erroneous patent term adjustment calculations made by the United States Patent & Trademark Office (“PTO”). 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 634 days calculated by the PTO for the ‘399 patent should be corrected to 1303 days.
  
2. This action arises under 35 U.S.C. § 154 and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

### **I. THE PARTIES**

3. Plaintiff Molecular Insight Pharmaceuticals, Inc. (“Molecular Insight”) is a company operating under the laws of Massachusetts. Molecular Insight is located at 160 Second Street Cambridge, Massachusetts 02142.
4. Defendant Jon W. Dudas is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. Defendant is sued in his official capacity.

### **II. 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 pursuant to 35 U.S.C. § 154(b)(4)(A).
7. This Complaint is being timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

### **III. BACKGROUND**

8. The ‘399 patent issued to John W. Babich and Kevin P. Maresca on June 3, 2008, based on patent application number 10/386,403, filed March 11, 2003. The ‘399 patent is attached hereto as Exhibit A.
9. Plaintiff Molecular Insight is the assignee of the ‘399 patent, as evidenced by records recorded in the PTO, and is the real party in interest in this case.
10. When the USPTO issued the ‘399 patent on June 3, 2008, it erroneously calculated the entitled patent term adjustment for the ‘399 patent as 634 days. Had the USPTO

calculated the entitled patent term adjustment properly, the '399 patent would be entitled to 1303 days of patent term adjustment.

11. The errors in the USPTO's patent term adjustment calculations are detailed in a recent order from the U.S. District Court for the District of Columbia in an action titled *Wyeth v. Dudas*, Civil Action No. 07-1492 (D.D.C. Sept. 30, 2008) where the 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 Patent Statute. The *Wyeth v. Dudas* opinion is attached as Exhibit B.
12. The correct patent term adjustment methodology identified in the prior *Wyeth v. Dudas* action governs the USPTO's calculation of patent term adjustment for Plaintiff's '399 patent.

#### **IV. COUNT I: U.S. PATENT NO. 7,381,399**

13. Plaintiff incorporates by reference the allegations in paragraphs 1-12 above, as if fully set forth herein.
14. During prosecution of the '399 patent, the patent owner accrued 682 days of patent term adjustment under 35 USC § 154(b)(1)(A), and accrued 815 days of patent term adjustment under 35 USC 154(b)(1)(B).
15. Under the PTO's interpretation of 35 USC § 154, all PTA accrued under 35 U.S.C. § 154(b)(1)(A) and all PTA accrued under 35 USC § 154(b)(1)(B) inherently overlaps and, thus, it has been the PTO position that a patent holder is only eligible for the larger of these two amounts of PTA. For the '399 patent, the PTO erroneously limited the patent

term adjustment for the '399 patent to 815 days (*see* calculation in paragraph 19, below), as shown on the face of the '399 patent.

16. In view of a recent decision from the this Court (*Wyeth v. Dudas*, Civil Action No. 07-1492 (JR)), all days on which 35 USC 154(b)(1)(A) or 35 USC 154(b)(1)(B) apply should accrue patent term adjustment for the '399 patent.
17. Under the interpretation of this Court (*Wyeth v. Dudas*, Civil Action No. 07-1492 (JR)), each day from the day after May 11, 2004 (14 months from the '399 patent application filing date) through to the grant date on June 3, 2008, qualifies for patent term adjustment under 35 U.S.C. § 154(b)(1)(A), 35 U.S.C. § 154(b)(1)(B), or both, a total of **1,484** days. More specifically, each day from the day after May 11, 2004 (14 months from the '399 patent application filing date) through to March 24, 2006 (issuance of a Restriction Requirement) qualifies for patent term adjustment under 35 U.S.C. § 154(b)(1)(A), and each day from the day after March 11, 2006 (three years from the filing date) through to the grant date on June 3, 2008, qualifies for patent term adjustment under 35 U.S.C. § 154(b)(1)(B).
18. The applicant agrees with the PTO's holding of a total applicant prosecution delay of 181 days under 35 USC 154(b)(2)(B) or (C).
19. Under the PTO's interpretation, the PTO had calculated an erroneous patent term adjustment of  $815 - 181 = 634$  days.

20. It is accordingly believed that the overall PTA accrued by the patent holder is 1,484 - 181 = **1,303 days**, and the patent holder accordingly requests 1,303 - 634 = **669 ADDITIONAL days** of Patent Term Adjustment.

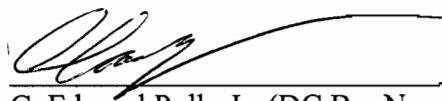
WHEREFORE, Plaintiff respectfully prays that this Court:

A. Issue an Order changing the period of patent term adjustment for the '399 patent term from 634 days to 1303 days and requiring Defendant to alter the terms of the '399 patent to reflect the 1303 days of actual patent term adjustment due the '399 patent.

B. 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 1, 2008

Respectfully submitted,



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