

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

FILED

**(Alexandria Division)**

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U.S. DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA, VIRGINIA

DSM I.P. ASSETS B.V.

Plaintiff,

v.

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

Defendant.

Civil Action No. 1:12cv1490  
GBL/TRJ

**COMPLAINT**

Plaintiff DSM I.P. Assets B.V. ("DSM"), through its attorneys, brings this action against the Honorable David J. Kappos, and states as follows:

**NATURE OF THE ACTION**

1. This is an action by DSM, the assignee of United States Patent No. 8,206,981 B2 ("the '981 patent"), seeking judgment that the patent term adjustment ("PTA") for the '981 patent be changed from 975 days to 1157 days. Such an action is expressly contemplated and permitted by 35 U.S.C. § 154(b)(4)(A).

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 DSM is a company organized under the laws of the Netherlands, having its principal place of business in Heerlen, Netherlands.

4. Defendant David J. Kappos is the Under Secretary of Commerce for Intellectual Property and the Director of the United States Patent and Trademark Office (“USPTO”), acting in his official capacity. The Director is the head of the USPTO and is responsible for providing policy direction and management supervision for the USPTO and for the issuance of patents, and is designated by statute as the official responsible for determining the period of patent term adjustments under 35 U.S.C. § 154.

### **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) 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 the Leahy-Smith America Invents Act. Pub. L. No. 112-29, § 9, 125 Stat. 316 (2011).

7. This Complaint is timely filed, within the deadline of 180 days after the grant of the patent in accordance with 35 U.S.C. § 154(b)(4)(A).

### **BACKGROUND**

#### **Patent Term Adjustments**

8. The American Inventors Protection Act of 1999 (“AIPA”) included changes to the patent laws – codified in 35 U.S.C. § 154 – granting inventors additional patent term if certain conditions are met.

9. Under 35 U.S.C. § 154(a)(2), when a patent issues, it is granted a twenty year term from the date on which the underlying application was filed in the United States, or from certain earlier dates referenced in the application. The twenty year period begins to run before a patent is issued. Accordingly, any delay in the USPTO's processing of an application reduces the duration of the patent term.

10. To prevent USPTO delays from decreasing patent term, Congress directed the USPTO to grant successful applicants adjustments of their patent terms to compensate for three categories of processing delay by the USPTO. The three guaranteed adjustments are codified in § 154(b) under sub-sections 35 U.S.C. §§ 154-(b)(1)(A), (B), and (C), and are commonly known as "A Delay," "B Delay," and "C Delay," respectively.

11. At issue in this case is "B Delay," which is based on a statutory "guarantee of no more than 3-Year application pendency." Under this guarantee, applicants are granted additional patent term "if the issue of an original patent is delayed due to the failure of the [USPTO] to issue a patent within three years after the actual filing date of the application in the United States." *See* 35 U.S.C. § 154(b)(1)(B). In calculating whether the USPTO has met its three-year pendency guarantee or if, instead, the applicant's right to patent term adjustment is triggered, the statute excludes three categories of time: 1) time consumed by continued examination of the application requested by the applicant under 35 U.S.C. § 132(b); 2) time consumed by interferences, appeals, or secrecy orders; and 3) time consumed by processing delays requested by the applicant. *See* 35 U.S.C. § 154(b)(1)(B)(i)-(iii).

12. This Court in *Exelixis, Inc. v. Hon. David J. Kappos*, No. 1:12cv96, 2012 WL 5398876 (E.D. Va. Nov. 1, 2012), has held that the USPTO's current interpretation of 35 U.S.C. § 154(b)(1)(B) is incorrect. Specifically, this Court has held that filing a request for

continued examination (“RCE”) has “no impact on the PTA after the three-year deadline has passed and [that 35 U.S.C. § 154(b)(1)(B)] clearly provides no basis for any RCEs to reduce PTA; instead, RCEs operate [ ] to toll the three-year guarantee deadline, if, and only if, they are filed within three years of the application filing date.” *Exelixis*, 2012 WL 5398876, at \*7. Accordingly, 35 U.S.C. § 154(b)(1)(B) guarantees issuance of a patent from a pending patent application within three years after the actual filing date, not including time consumed *during that three-year period* by continued examination after the filing of a request for continued examination. *See* 35 U.S.C. § 154(b)(1)(B)(i).

13. The remedy to the applicant for the USPTO’s failure to meet this guarantee, requires that “the term of the patent shall be extended 1 day for each day after the end of the 3-year period until the patent is issued,” subject to specific limits set forth at 35 U.S.C. § 154(b)(2). The scope of the remedy is limited only by 35 U.S.C. § 154(b)(2)(A-C), which set forth certain conditions under which the period of additional patent term granted to an applicant may be limited or reduced. Notably, these conditions do not purport to reduce or limit patent term adjustments on the basis of time consumed by examination after filing of an RCE.

#### **Patent Term Adjustments Of The ‘981 Patent**

14. The ‘981 Patent issued on June 26, 2012, and is attached as Exhibit A.

15. John Crowley, Maik Wubben, and Jose Manuel Coco Martin are the inventors of patent application number 10/591,118 (“the ‘118 application”), entitled “Process for Cell Culturing by Continuous Perfusion and Alternating Tangential Flow,” which issued as the ‘981 patent.

16. The Proceedings in the USPTO with respect to the ‘981 patent are reflected in the administrative record. That record includes patent term adjustment history, which explains the

USPTO's calculation of the adjustment. The USPTO's worksheet for the '981 patent is attached as Exhibit B.

17. The USPTO admits that during prosecution of the '981 patent, there were 602 days of "A Delay." (*See Ex. B*).

18. The USPTO further admits that during prosecution of the '981 patent, there were 0 days of "C Delay." (*See Ex. B*).

19. The USPTO has credited the '981 patent with 786 days of "B Delay." (*See Ex. B*).

20. The USPTO, however, failed to credit the '981 patent with the entire amount of "B Delay" guaranteed to it.

21. The application that led to the '981 patent was filed as a national phase application which commenced under 35 U.S.C. § 371(b) on September 5, 2006. Thus, one day of "B Delay" should have been credited for every additional day of prosecution (subject to statutory exceptions) beginning on September 6, 2009. *See* 35 U.S.C. § 154(b)(1)(B).

22. An RCE was filed during prosecution of the '981 patent on November 1, 2011, but does not impact the calculation of "B Delay" because it was filed after September 6, 2009. *See* 35 U.S.C. § 154(b)(1)(B).

23. The properly calculated "B Delay" for the '981 patent is 1025 days, *i.e.*, one day for every day between September 6, 2009 and June 26, 2012.

24. The properly calculated "B Delay" overlaps with 321 days of "A Delay" (264 days plus 57 days). (*See Ex. B*).

25. The USPTO has stated that there were 149 days of applicant delay. (*See Ex. B*).

26. The properly calculated patent term adjustment for the '981 patent is 1157 days – *i.e.*, 602 days (“A Delay”) plus 1025 days (“B Delay”) plus 0 days (“C delay”) less 321 days (overlapped delays) less 149 days (applicant delay).

27. The properly calculated patent term adjustment for the '981 patent is 182 days greater than the currently granted patent term adjustment.

28. The USPTO’s exclusion of the additional 182 days is contrary to 35 U.S.C. § 154(b)(1). Specifically, as discussed above, the patent term adjustment statute, 35 U.S.C. § 154(b)(1) provides that, once “B Delay” is triggered, “the term of the patent shall be extended 1 day for each day after the end of the that three-year period until the patent is issued,” subject only to specific limits set forth at 35 U.S.C. § 154(b)(2). Once the three-year period has ended and the “B Delay” provision is triggered, the statute does not allow the USPTO to ignore days occurring after the filing of an RCE for purposes of calculating “B Delay.”

**CLAIM FOR RELIEF**

**COUNT ONE**

('981 Patent - Patent Term Adjustment Under 35 U.S.C. § 154)

29. DSM incorporates the allegations of paragraphs 1 - 28 as if fully set forth herein.

30. The currently challenged patent term adjustment for the '981 patent, as determined by the USPTO under 35 U.S.C. § 154(b), and listed on the face of the '981 patent, is 975 days. (*See* Ex. A at p.1). This determination was based on an improper interpretation of 35 U.S.C. § 154(b)(1)(B) that improperly excluded time consumed by continued examination of the application requested by the applicant under section 132(b).

31. The properly calculated patent term adjustment for the '981 patent is 1157 days.

32. The PTO's incorrect calculation of the "B delay" adjustment for the '981 patent led to an incorrect calculation of the total patent term adjustment for the '981 patent. The PTO's calculation of the total term adjustment for the '981 patent was based on an improper interpretation of 35 U.S.C. § 154(b)(1)(B).

33. The PTO's patent term adjustment calculation of 975 days for the '981 patent is contrary to its statutory jurisdiction and authority, and arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

**WHEREFORE**, Plaintiff respectfully prays that this Court:

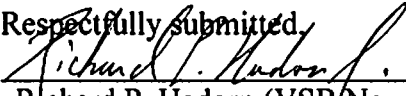
A. Issue an Order changing the period of patent term adjustment for the '981 patent from 975 days to 1157 days, and requiring Defendant to alter the term of the '981 patent to reflect the 1157 day patent term adjustment.

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

Dated: December 21, 2012

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