

FILED

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Alexandria Division

2016 JUL -1 P 3:22

CLERK US DISTRICT COURT  
ALEXANDRIA, VIRGINIA

TAKEDA PHARMACEUTICAL COMPANY )  
LIMITED )  
1-1 Doshomachi 4-Chome )  
Chuo-Ku, Osaka-Shi )  
Osaka 541-0045, Japan )  
Plaintiff, )

v. )

Civil Action No. 1:16-cv-852  
(AJT/IDD)

HON. MICHELLE K. LEE )  
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 1450, Alexandria, VA 22313 )  
Madison Building East, Room 10B20 )  
600 Dulany Street, Alexandria, VA 22314 )  
Defendant. )

COMPLAINT

Plaintiff Takeda Pharmaceutical Company Limited (“Plaintiff”), for its Complaint against Defendant, the Honorable Michelle K. Lee, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (“Defendant”), states as follows:

1. This is an action pursuant to 35 U.S.C. § 154(b)(4)(A) by the owner of United States Patent No. 8,900,638 (“the ’638 patent”) (attached as Exhibit A) seeking review of inaccurate and erroneous patent term adjustment calculations made by the United States Patent & Trademark Office (“PTO”) under 35 U.S.C. § 154(b). Specifically, this is an action by Plaintiff seeking a judgment that the patent term adjustment of 312 days calculated by the PTO for the ’638 patent is erroneous and should be corrected as reflected in attached Exhibit B, to 670 days.

2. Plaintiff seeks a judgment that Defendant erred in its interpretation and application of 35 U.S.C. § 154(b)(2)(C)(i)(C).

3. This action arises under 35 U.S.C. § 154, the Administrative Procedure Act (5 U.S.C. §§ 701-706), and the Fifth Amendment to the Constitution of the United States.

## **I. THE PARTIES**

4. Plaintiff is a company organized under the laws of Japan with a place of business at 1-1 Doshomachi 4-Chome, Chuo-Ku, Osaka-Shi, Osaka 541-0045, Japan. Plaintiff is a global leader in the research and development, manufacturing and sales of pharmaceutical drugs.

5. Defendant Michelle K. Lee is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. Defendant is sued in her official capacity. Defendant is the head of the PTO and is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents, and is designated by statute as the official responsible for determining the period for patent term adjustments under 35 U.S.C. § 154(b)(3)(B).

## **II. JURISDICTION AND VENUE**

6. 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), 35 U.S.C. § 154(b), and 5 U.S.C. §§ 701-706.

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

8. This Complaint is timely filed, *inter alia*, in accordance with 35 U.S.C. § 154(b)(4)(A) because it is being filed within 180 days of the date of the PTO's Final Agency Decision on Plaintiff's request for reconsideration, January 7, 2016 ("Decision") (attached as Exhibit C).

### III. THE PATENT TERM GUARANTEE ACT OF 1999

9. The Patent Term Guarantee Act of 1999, a part of the American Inventors Protection Act (“AIPA”), amended 35 U.S.C. § 154(b) to address concerns that delays by the PTO during the prosecution of patent applications could result in a shortening of the effective terms of patents, which now are measured from their respective filing dates. The amendments created patent term adjustment, commonly referred to as “PTA,” in order to compensate patent owners for delays at the PTO. The PTA provisions of 35 U.S.C. § 154(b) apply to original utility patent applications (including continuations, divisionals, and continuations-in-part) filed on or after May 29, 2000.

10. The PTA provisions of 35 U.S.C. § 154(b) guarantee patent term against three types of PTO delay: (A) the failure of the PTO to take action within certain time periods is addressed under 35 U.S.C. § 154(b)(1)(A); (B) the failure of the PTO to issue a patent within 3 years of its actual filing date is addressed under 35 U.S.C. § 154(b)(1)(B); and (C) delays due to interferences, secrecy orders and appeals are addressed under 35 U.S.C. § 154(b)(1)(C).

11. As set forth in 35 U.S.C. § 154(b)(1)(A), delays by the PTO require that “the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.”

12. Any PTA due for PTO delays under 35 U.S.C. § 154(b)(1) is limited by 35 U.S.C. § 154(b)(2), which requires in 35 U.S.C. § 154(b)(2)(A) that the PTO take into account any overlap in the PTO delays, and which also requires in 35 U.S.C. § 154(b)(2)(C)(i) that the PTO take into account any applicant delays, *i.e.*, any “time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” As set forth in 35 U.S.C. § 154(b)(2)(C)(ii), “an applicant shall be deemed to have failed to engage in reasonable efforts to

conclude processing or examination of an application” when the applicant takes “in excess of 3 months . . . to respond to a notice from the Office.” In 35 U.S.C. § 154(b)(2)(C)(iii), the statute delegates the PTO authority to “prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.”

13. Pursuant to the authority delegated under 35 U.S.C. § 154(b)(2)(C)(iii), the PTO promulgated 37 C.F.R. § 1.704(c), which sets forth specific “[c]ircumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application.” For example, 37 C.F.R. § 1.704(c)(6) identifies “[s]ubmission of a preliminary amendment or other preliminary paper less than one month before the mailing of an Office action . . . or notice of allowance . . . that requires the mailing of a supplemental Office action or notice of allowance.” Also relevant, 37 C.F.R. § 1.704(c)(8) identifies “Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed.”

14. Under 35 U.S.C. § 154(b)(4)(A), “[a]n applicant dissatisfied with the Director’s decision on the applicant’s request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director’s decision on the applicant’s request for reconsideration. Chapter 7 of title 5 shall apply to such action.”

#### **IV. BACKGROUND**

15. Plaintiff is the original applicant and assignee of the ’638 patent, as evidenced by records on deposit with the PTO, including the assignment from the inventors recorded at the

PTO at Reel 23829/Frame 914, and as reflected on the face of the '638 patent, and is the real party in interest in this case.

16. The '638 patent, attached as Exhibit A, was granted from U.S. patent application serial number 12/452,705, which was a U.S. national stage application of PCT Application PCT/JP2008/063228, filed July 16, 1988. The '638 patent commenced U.S. national stage examination on January 19, 2010, and issued to Plaintiff on December 2, 2014.

17. The PTO took 209 days longer than the 14 months allotted in 35 U.S.C. § 154(b)(1)(A)(i) to issue the first Office Action in the application, which it did on October 14, 2011. That period of PTO delay is not in dispute.

18. Plaintiff took 33 days longer than three months to reply to the non-final Office Action mailed December 21, 2011, which it did on April 23, 2012. That period of applicant delay is not in dispute.

19. Plaintiff timely filed a reply to the final Office Action mailed June 27, 2012, by filing a reply on September 27, 2012.

20. The PTO examiner issued an Advisory Action on October 10, 2012, indicating that the reply filed September 27, 2012 did not place the application in condition for allowance.

21. November 27, 2012, Plaintiff filed a reply with a Request for Continued Examination pursuant to 37 C.F.R. § 1.114 ("RCE"). Because the time period for reply continues to run after a final Office Action even after a complete reply has been filed, the PTO assessed 61 days of applicant delay for the reply and RCE filed November 27, 2012. That period of applicant delay is not in dispute.

22. In accordance with PTO practice, after the RCE was filed the application was docketed in the PTO's Patent Application Information Retrieval system as "Docketed New Case – Ready for Examination."

23. On February 26, 2013, October 23, 2013 and November 20, 2013, Plaintiff filed Information Disclosure Statements ("IDSs"), which were timely filed under the PTO's IDS rules. In particular, 37 C.F.R. § 1.97(b)(4) provides that an IDS is timely filed if filed "before the mailing of a first Office action after the filing of a request for continued examination under § 1.114." As explained below, the PTO erred by deducting 358 days of applicant delay for these submissions.

24. On July 11, 2014, nearly sixteen months after the RCE was filed and nearly eight months after the last IDS was filed, the PTO examiner considered the IDSs. Shortly thereafter, on July 18, 2014, nearly sixteen months after the RCE was filed and nearly eight months after the last IDS was filed, the PTO mailed a Notice of Allowance. In the Notice of Allowance, the PTO examiner "acknowledge[d]" the IDSs and their timeliness under 37 C.F.R. § 1.97.

25. The Notice of Allowance was mailed 478 days after the 4 months allotted in 35 U.S.C. § 154(b)(1)(A)(ii) to respond to a reply. This period of PTO delay is not in dispute.

26. On October 17, 2014, Plaintiff filed an amendment under 37 C.F.R. § 312 to correct a typographical error in claims 15 and to cancel claim 26. The 6 day period of applicant delay assessed for this filing is not in dispute.

27. The PTO awarded 312 days PTA to the '638 patent. Plaintiff timely filed a Request for Reconsideration in accordance with 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(b), seeking a PTA award of 670 days. In a decision dated January 7, 2016, the PTO denied Plaintiff's request for reconsideration, based on its erroneous interpretation and application of

35 U.S.C. § 154(b)(2)(C)(i), and its erroneous application of 37 C.F.R. § 1.704(c)(8) to the instant case, which led to the deduction of 358 days for applicant delay for the IDSs that were timely filed while the application was awaiting examination after the RCE filed November 27, 2012.

#### **V. THE PROPER CALCULATION OF PTA**

28. Under 35 U.S.C. § 154(b)(2)(C)(i), “[t]he period of adjustment of the term of a patent under [§ 154(b)(1)] shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” Here, however, contrary to the statute, the PTO erroneously reduced the PTA due on the ’638 patent. In particular, the PTO erroneously reduced the PTA award by charging 358 days for alleged applicant delay for the IDSs that were, in fact, timely and properly filed while the application was awaiting examination after the RCE filed November 27, 2012. That the PTA deduction at issue is contrary to the governing principle set forth in the statute is further demonstrated in the Notice of Allowance, where the PTO examiner acknowledged consideration of the items submitted with the IDSs, demonstrating that the timing of the filing of the IDSs did not interfere with the examination process, but rather, were submitted in ample time for the PTO examiner to consider the cited references before issuing the Notice of Allowance nearly 8 months later.

29. Timely filing an IDS while an application is awaiting examination after an RCE has been filed does not constitute any “fail[ure] to engage in reasonable efforts to conclude prosecution of the application.” Thus, the PTA deduction at issue is contrary to law.

30. In its Decision, the PTO cited 37 C.F.R. § 1.704(c)(8), but the PTO’s reliance on that rule is misplaced, because the IDSs at issue were not part of “a supplemental reply or other

paper . . . after a reply has been filed.” Rather, the IDSs were independent submissions filed while the application was awaiting examination after the filing of the RCE, to ensure compliance with the duty of candor to the USPTO, and were timely filed in accordance with the PTO’s rule governing the submission of IDSs after an RCE.

31. Contrary to the PTO’s position, 37 CFR § 1.704(c)(8) does not apply to post-RCE submissions. The rule itself does not refer to post-RCE submissions, and no commentary in the Federal Register Notice in which the final rule was promulgated indicates that 37 CFR § 1.704(c)(8) applies to post-RCE submissions. *See* 65 Fed. Reg. 181, at 56366-94 (Sep. 18, 2000) (Exhibit C). Thus, the PTA rules do not support the PTA deduction at issue, which invoked 37 C.F.R. § 1.704(c)(8) in the context of a post-RCE submission.

32. Although the PTO noted in the Decision that the IDSs did not comply with 37 C.F.R. § 1.704(d), that does not impact the PTA determination. While 37 C.F.R. § 1.704(d) provides limited exceptions to circumstances that can lead to deductions for Applicant Delay under 37 C.F.R. § 1.704(c)(6), (c)(8), (c)(9), and (c)(10), none of these exceptions are relevant here. As shown above, no exception to 37 C.F.R. § 1.704(c)(6) was needed, and 37 C.F.R. § 1.704(c)(9)-(10) are not relevant to the facts at hand. As also shown above, contrary to the PTO’s position, 37 C.F.R. § 1.704(c)(8) does not apply to post-RCE submissions. Thus, even without a certification under 37 C.F.R. § 1.704(d), the IDSs do not support the PTA deduction at issue.

33. Given that the PTO docketed an application awaiting examination after the filing of an RCE as a “Docketed New Case – Ready for Examination,” if any PTO rule governs post-RCE submissions it should be 37 C.F.R. § 1.704(c)(6). That rule identifies as applicant delay the “[s]ubmission of a preliminary amendment or other preliminary paper less than one month

before the mailing of an Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151.” The applicability of this rule to post-RCE IDS submissions would be consistent with the IDS rules, which treat post-RCE IDSs similar to IDSs filed in a brand new application that has not yet received a first Office Action on the merits:

(b) An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:

- (1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
- (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
- (3) **Before the mailing of a first Office action on the merits; or**
- (4) **Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.**

37 C.F.R. § 1.97(b) (emphasis added).

34. Because the PTO treats a post-RCE application as a new application for docketing, examination and IDS purposes (as reflected in the parallel language of 37 C.F.R. § 1.97(b)(3) and (4)), if any PTA rule applies to post-RCE submissions, it should be 37 C.F.R. § 1.704(c)(6), not 37 C.F.R. § 1.704(c)(8). However, that rule would not support a deduction here, because none of the IDS submissions were made “less than one month before the mailing of an Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151,” and none “require[d] the mailing of a supplemental Office action or notice of allowance.”

35. Because 37 C.F.R. § 1.704(c)(8) does not govern post-RCE submissions, and because 37 C.F.R. § 1.704(c)(6) does not provide for a deduction here, no Applicant Delay should be charged for any of the IDSs filed February 26, 2013, October 23, 2013 or November 20, 2013. Therefore, PTA should be recalculated without the improper deduction of 358 days of PTA.

36. In its Decision, the PTO cited its obligation to award PTA if it fails to respond to an RCE submission within four months, but there is no indication that the filing of the post-RCE IDSs at issue had any impact on the time the PTO took to respond to the RCE submission. To the contrary, the PTO took nearly sixteen months after the RCE was filed and nearly eight months after the last IDS was filed before issuing the Notice of Allowance. There is no evidence that the IDSs had any impact on the time it took for the PTO to reply to the RCE. Rather, it was the PTO's own docketing policies and the low priority given to RCEs that were responsible for the delay. The underlying facts show that it was the PTO, not Plaintiff, who was responsible for the lengthy delay in examination between the November 27, 2012 RCE and the July 18, 2014 Notice of Allowance.

37. In its Decision, the PTO cited the Federal Circuit decision in *Gilead Sciences, Inc. v. Lee*, 778 F.3d 1341 (Fed. Cir. 2015). That case did not address the post-RCE time period at issue here, and so does not directly govern the instant case. Moreover, while the court stated that the PTA statute permits the PTO to charge applicant delay for conduct "having the potential to result in delay irrespective of whether such delay actually occurred," the PTO already has determined that an IDS (or other submission) filed in an application awaiting examination does not warrant a charge for Applicant Delay unless the submission is made "less than one month before the mailing of an Office action ... or notice of allowance" and "requires the mailing of a supplemental Office action or notice of allowance," as set forth in 37 CFR § 1.704(c)(6). Because neither requirement is met here, the 358 day deduction for alleged Applicant Delay for the post-RCE IDSs is improper, and not supported by *Gilead* or the PTA statute itself.

## **VI. DEFENDANT'S VIOLATION OF THE PATENT TERM GUARANTEE**

38. Defendant violated the patent term guarantee statute by improperly calculating PTA for the '638 patent in a manner that deprives Plaintiff of the full amount of PTA owed under the statute, by erroneously reducing the PTA award in a manner that is not authorized by 35 U.S.C. § 154(b)(2)(C).

39. Defendant improperly relied on 37 C.F.R. § 1.704(c)(8) to support its flawed calculation of PTA. Nothing in that rule or the commentary in the Federal Register Notice in which the final rule was promulgated indicates that it applies to an IDS filed after an RCE and before the first Office action following an RCE. Defendant's improper application of that rule led to a patent term reduction that is plainly contrary to the clear and unambiguous language of 35 U.S.C. § 154(b)(2)(C)(i).

40. Defendant improperly relies on *Gilead Sciences, Inc. v. Lee*, 778 F.3d 1341 (Fed. Cir. 2015), which did not address the post-RCE time period at issue here, and so does not govern the instant case.

41. Because Defendant's application of 37 C.F.R. § 1.704(c)(8) and *Gilead* conflicts with the clear and unambiguous language of 35 U.S.C. § 154(b)(2)(C)(i) and judicial interpretations thereof, Plaintiff seeks correction of PTA to reflect 670 days of PTA.

## **VII. COUNT ONE – PATENT TERM ADJUSTMENT UNDER 35 U.S.C. § 154**

42. The allegations of paragraphs 1-41 are hereby incorporated by reference in this claim as if fully set forth herein.

43. The PTO did not comply with 35 U.S.C. § 154(b)(2)(C)(i) in determining the reduction of Plaintiff's patent term adjustment, and thus unfairly deprived Plaintiff of the full amount of PTA Plaintiff is entitled to pursuant to 35 U.S.C. § 154(b)(1)(A).

44. On February 26, 2013, October 23, 2013 and November 20, 2013, Plaintiff timely filed IDSs after an RCE.

45. The PTO inappropriately applied 37 C.F.R. § 1.704(c)(8) to the IDSs filed after the RCE, when calculating the PTA for the '638 patent, resulting in an incorrect calculation of PTA that deprived Plaintiff of the full and appropriate term of the '638 patent, and in a manner contrary to 35 U.S.C. § 154(b)(2)(C)(i).

46. Reduction of the PTA by 358 days as Applicant Delay is inconsistent with 35 U.S.C. § 154(b)(2)(C)(i).

47. The PTO's reduction of PTA by 358 days as Applicant Delay is also arbitrary and capricious in view of the clear and unambiguous language under 35 U.S.C. § 154(b)(2)(C)(i).

48. Plaintiff is entitled to an additional 358 days of patent term for the '638 patent such that the 312 days of PTA granted by the PTO should be changed to 670 days.

#### **VIII. COUNT TWO – DECLARATORY JUDGMENT UNDER THE ADMINISTRATIVE PROCEDURES ACT**

49. The allegations of paragraphs 1-48 are hereby incorporated by reference in this claim as if fully set forth herein.

50. The PTO's application of 37 C.F.R. § 1.704(c)(8), to the facts of this case is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A) because it produces the unfair and irrational result of reducing PTA for a time period during which Plaintiff did not fail to engage in reasonable efforts to conclude prosecution of the application. This is contrary to the intent of 35 U.S.C. § 154(b)(2)(C)(i) to limit a reduction of period of adjustment "to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application."

51. Furthermore, the PTO's actions are arbitrary and capricious because the PTO has not always charged deductions for post-RCE submissions.

52. Erroneous application of 37 C.F.R. § 1.704(c)(8) by the PTO resulted in an incorrect calculation of PTA that deprived Plaintiff of the full and appropriate term of the '638 patent. The PTO's reduction of PTA by 358 days for alleged applicant delay is arbitrary and capricious, and unlawful pursuant to 5 U.S.C. § 706(2)(A).

53. Plaintiff has adequately exhausted all of the available administrative remedies under 35 U.S.C. § 154(b)(3)(A)-(B) or, in the alternative, pursuit of any further administrative remedies is futile.

54. Defendant's determination of PTA for the '638 patent on January 7, 2016, under 35 U.S.C. § 154(b)(3)(B)(ii), is the final agency action and is reviewable by a district court in accordance with 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. § 704.

55. The PTO's action caused Plaintiff to suffer legal wrong and adversely affected the rights of Plaintiff under the '638 patent. Plaintiff will suffer irreparable injury if Defendant is not directed to recalculate PTA for the '638 patent.

56. An order directing Defendant to recalculate PTA for the '638 patent would not substantially injure any other interested parties, and the public interest will be furthered by correcting a procedural action that is contrary to law.

57. Plaintiff is entitled to additional patent term for the '638 patent such that the 312 days of PTA granted by the PTO should be changed to 670 days.

**IX. COUNT III – VIOLATION OF THE FIFTH AMENDMENT**

58. The allegations of paragraphs 1-57 are incorporated in this claim for relief as if fully set forth herein.

59. The Fifth Amendment of the Constitution of the United States provides in relevant part, “nor shall private property be taken for public use, without just compensation.”

60. Plaintiff enjoys a substantial and cognizable private property right in the full and complete term of the '638 patent.

61. Plaintiff was deprived of due process, *inter alia*, because the PTO relied upon a rule, 37 C.F.R. § 1.704(c)(8), that does not apply to submissions made after a RCE and by citing case law that did not address such submissions.

62. Plaintiff has not failed to pay any necessary maintenance fees to the PTO required to maintain their rights in the '638 patent.

63. Defendant's reliance upon 37 C.F.R. § 1.704(c)(8) in improperly calculating the PTA for the '638 patent would permanently deprive Plaintiff of the patent term to which it is entitled under 35 U.S.C. § 154(b) if not corrected by this Court.

64. Defendant's purposeful and deliberate diminution of the patent term of the '638 patent constitutes a taking of Plaintiff's property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

65. Plaintiff is entitled to additional patent term for the '638 patent such that the 312 days of PTA granted by the PTO should be changed to 670 days.

WHEREFORE, Plaintiff respectfully prays that this Court:

A. Issue an Order changing the PTA for the '638 patent from 312 days to 670 days, in accordance with 35 U.S.C. § 154(b)(4)(A) and requiring Defendant to correct the term of the '638 patent to reflect such additional PTA;

B. Declare pursuant to 35 U.S.C. § 154(b)(4)(A) that 37 C.F.R. § 1.704(c)(8), as applied, is invalid and contrary to law; and

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

Dated: July 1, 2016

Respectfully submitted,



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