

FILED

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

2015 OCT -1 P 2: 32

ACTELION PHARMACEUTICALS LTD.
Gewerbstrasse 16
CH - 4123 Allschwil
Switzerland,

Plaintiff,

v.

HON. MICHELLE K. LEE
Under Secretary of Commerce for Intellectual
Property and Director of the United States Patent
and Trademark Office
P.O. Box 1450, Alexandria, VA 22313
401 Dulany Street, Alexandria, VA 22314

Office Of The General Counsel
United States Patent And Trademark Office
P.O. Box 15667, Arlington, VA 22215
Madison Building East, Room 10B20
600 Dulaney Street, Alexandria, VA 22314,

Defendant.

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

Case No. 1:15cv1266-LO/IDD

COMPLAINT

Plaintiff Actelion Pharmaceuticals, Ltd. ("Actelion"), by its undersigned attorneys, for its Complaint against the Honorable Michelle K. Lee ("Defendant"), respectfully states as follows:

NATURE OF ACTION

1. This is an action by the owner and assignee of United States Patent No. 8,518,912 ("the '912 Patent"), pursuant to 35 U.S.C. § 154 (b)(4)(A), 5 U.S.C. §§ 701-706, and the Fifth Amendment of the Constitution of the United States of America, seeking judgment that the patent term adjustment for the '912 Patent be changed from 346 days to 410 days.

2. This action arises under 35 U.S.C. § 154 (b)(4)(A), the Administrative Procedures Act, 5 U.S.C. §§ 701-706, and the Fifth Amendment of the Constitution of the United States of America.

THE PARTIES

3. Plaintiff Actelion Pharmaceuticals Ltd., (hereinafter “Actelion”) is a Limited Liability Company organized under the Laws of Switzerland, having a principal place of business at Gewerbestrasse 16, CH - 4123 Allschwil, Switzerland.

4. Defendant Michelle K. Lee is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (“PTO”), acting in her 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

5. 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); 28 U.S.C. § 2201; 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) and pursuant to 35 U.S.C. § 154(b)(4)(A).

7. This action is timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

ALLEGATIONS COMMON TO ALL COUNTS

8. Eva Caroff, Kurt Hilpert, Francis Hubler, Emmanuel Meyer, and Dorte Renneberg are the inventors of the invention claimed in the U.S. Patent Application Serial No. 12/745,358 (“the’358 Application”) entitled “Phosphonic acid derivates and their use as P2Y₁₂ receptor

antagonists,” filed on May 28, 2010, which issued as the ‘912 Patent on August 27, 2013. A true and correct copy of the ‘912 patent is attached hereto as Exhibit A. A true and correct copy of relevant portions of the file history of the ‘358 application is attached hereto as Exhibit B.

9. Plaintiff Actelion is the owner and assignee of all right, title and interest in the ‘912 Patent, as evidenced by the assignment document recorded with the PTO at Reel/Frame 029942/0935 on March 7, 2013, in which the inventors assigned all rights, title and interest to Actelion, which is the real party in interest in this case.

10. 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)(1) PATENT TERM GUARANTEES, which includes: (A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES and (B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY, and are offset by: (C) REDUCTION OF PERIOD OF ADJUSTMENT.

11. Section 154(b)(1)(A)(i)(II) of Title 35 of the United States Code provides that the term of a patent shall be extended, subject to certain limitations, if issue of the patent is delayed due to failure of the PTO to provide at least one of the notifications under section 132 or a notice of allowance under section 151 of Title 35 no later than 14 months after the date of commencement of the national stage under section 371 in an international application. This is referred to as “A-delay.”

12. The ‘358 application is a national stage entry under 35 U.S.C. § 371 of International Patent Application PCT/IB2008/055002, filed on November 28, 2008, which claims priority to International Patent Application PCT/IB2007/054850, filed on November 29, 2007. The earliest effective priority date for the ‘358 application is November 29, 2007. (Ex. B at 3, 11.)

13. Filed concurrently with the application on May 28, 2010, was a preliminary amendment to the claims, which amendment included four independent claims (claims 1, 13, 14 and 16) and

eleven dependent claims (claims 2-12). A true and correct copy of the preliminary amendment filed on May 28, 2010, is attached hereto as Exhibit C.

14. Pursuant to 37 C.F.R. § 1.703(a)(1), as amended by the AIA Technical Corrections Act, Pub. L. No. 112-274, 126 Stat. 2456 (2013) (codified in scattered sections of 35 U.S.C.), the 14-month period calculated pursuant to 35 U.S.C. § 154(b)(1)(A)(i)(II) begins on the date of commencement of the national stage of an international application. This is the date that is 30 months from the earliest priority date of the international application. For the '358 application, the date of commencement of the national stage is June 1, 2010. (The original Patent Term Adjustment calculation assumed a National Stage Commencement date of Saturday, May 29, 2010. The PTO subsequently revised this commencement date to Tuesday, June 1, 2010, on the ground that when the 30-month date falls on a weekend or Federal Holiday, the Commencement date becomes the next business day, which in this case is Tuesday, June 1, 2010, because Monday, May 31, 2010, was a Federal Holiday). Pursuant to 35 U.S.C. § 154(b)(1)(A)(i), the 14-month deadline for the PTO to issue at least one of the notifications under section 132 or a notice of allowance under section 151 was thus August 1, 2011. (Ex. B at 100.)

15. The PTO issued a first Requirement for Restriction in the '358 application on March 14, 2012. (Ex. B at 15-21.) This paper, however, failed to include all scopes presented in the claims. (Ex. B at 17-18.)

16. Because the restriction requirement presented by the examiner did not restrict all the different scopes in the claims but instead omitted certain claim scopes of interest entirely, it was not a proper restriction requirement, and it was not possible for the Plaintiff to respond with a provisional election as required by 37 C.F.R. § 1.143, which provides in relevant part, "In requesting reconsideration *the applicant must indicate a provisional election of one invention for prosecution*, which invention shall be the one elected in the event the requirement becomes final." (Emphasis added).

17. Following the issuance of the first Restriction Requirement, a telephonic interview was conducted between the examiner and Plaintiff's representative. The Plaintiff's representative

pointed out that the restriction requirement did not address all the claimed scopes. The examiner agreed and indicated that a new restriction requirement would be issued to supersede the first restriction requirement. No election was made during the interview. (Ex. B at 89.)

18. The PTO then issued a second Requirement for Restriction in the '358 application on April 18, 2012. (Ex. B at 23-30.) The second Restriction Requirement stated that "[t]his office action supersedes and replaces the previous office action mailed on 03/14/12 in its entirety." (Ex. B at 25.) This second Requirement for Restriction, however, did not cure the defects of the first Requirement for Restriction. Again, it was not possible to make a compliant response with a provisional election because the restriction requirement excluded certain subject matter from the claims.

19. Following issuance of the second Restriction Requirement, a second telephonic interview was conducted between the examiner and Plaintiff's representative. At this second interview, the examiner agreed there had been an error and indicated that the present restriction requirement was to be vacated and superseded by a third restriction requirement. When the Examiner did not promptly provide the corrected restriction requirement, Plaintiff's representative submitted a paper to the PTO on May 18, 2012 (the due date for response to the second restriction requirement) memorializing the substance of the interview and reminding the examiner that the Applicants were still awaiting the corrected restriction requirement. This paper neither discussed the merits of the case nor made any express or implied election of claims or species. Instead, this paper indicated that by agreement between the examiner and Plaintiff's representative, no election was required in response to the second Restriction Requirement, and said second Restriction Requirement was to be rendered moot by issuance of a third restriction requirement. (Ex. B at 34-35; 89.)

20. The PTO issued a third Requirement for Restriction in the '358 application on June 21, 2012. The third Restriction Requirement stated that "[t]his action supersedes the previous restriction requirement mailed on 04/18/12." (Ex. B at 37-44.)

21. Neither the first nor the second restriction requirements addressed all scopes of the claims of the '358 application, and Plaintiff's representative did not make, and could not make, a

substantive response to either action with a provisional election as required by the rules. (Ex. B at 17-18; 25-26; 34-35; 89.)

22. In response to the third restriction requirement, Plaintiff's representative filed a timely complete response with an election on July 23, 2012. (Ex. B at 46-73.)

23. Plaintiff's election of the invention of Group I in response to the third restriction requirement encompassed a scope of invention that had been omitted and would not have been possible to elect from the first or second restriction requirements due to the failure of those first two restriction requirements to include and address the Plaintiff's entire claim scope (in particular, the elected scope). (Ex. B at 70-71.) Had the Plaintiff made a formal election in response to either the first or second restriction requirements, Plaintiff would have been preempted and foreclosed from claiming a portion of the original subject matter to which Plaintiff had an absolute right to elect for prosecution. Alternatively, had the Plaintiff responded by claiming the ultimately elected subject matter, Plaintiff's response would have been non-compliant under 37 C.F.R. § 1.143, due to the Plaintiff's failure to make a provisional election of any of the scopes identified in the first and second restriction requirements, as this elected subject matter was not addressed or included in the scopes identified by the examiner.

24. The PTO agreed that the first two Requirements for Restriction were in error and that no compliant response would be possible. That is why the PTO decided to withdraw and replace both of these Requirements for Restriction without requiring a substantive response. The first proper action on the part of the PTO was the third Requirement for Restriction, and delay between the filing of the application and the issuance of the third Requirement for Restriction should be attributable to the PTO.

25. The '358 application issued as the '912 patent on August 27, 2013. The Patent Term Adjustment indicated in the Issue Notification mailed on August 7, 2013, was 314 days. (Ex. B at 82.)

26. This Patent Term Adjustment determination included a period of A-delay of 229 days, which was calculated from the end of the 14-month period calculated pursuant to 35 U.S.C. §

154(b)(1)(A)(i)(II), July 29, 2011, until the mailing of the First Restriction Requirement, March 14, 2012. Under the PTO's interpretation of the rules at that time, the mailing of the first Restriction Requirement stopped the running of the "A-delay" clock. (This PTA determination was made based on a national stage commencement date of May 29, 2010). (Ex. B at 88-90.)

27. Plaintiff's representatives subsequently filed an application for Patent Term Adjustment under 37 C.F.R. § 1.705(b) on October 28, 2013, subsequent to which Plaintiff's representatives filed a Request for Reconsideration of Patent Term Adjustment in view of the AIA Technical Corrections Act on July 31, 2014. (Ex. B at 86-90; 94.)

28. The PTO issued a recalculation of PTA in view of the AIA Technical Corrections Act on September 29, 2014, which recalculated the total PTA as 311 days. This calculation reduced the amount of "A-delay" from 229 days to 226 days, based on the revision of the National Stage Commencement date from May 29, 2010, to June 1, 2010. (Ex. B at 97.)

29. In response to the application for Patent Term Adjustment filed on October 28, 2013, the PTO issued a Decision on November 10, 2014, which changed the PTA from 311 days to 346 days. (Ex. B at 99-101.)

30. This change was based on the conclusion that the "A-delay" clock was not stopped by the mailing of the first Restriction Requirement, but rather, was stopped by the mailing of the second Restriction Requirement. The PTO claimed in the Decision that the PTO issued the Second Restriction Requirement *sua sponte* (even though the PTO was well aware that the issuance of the Second Restriction Requirement was the result of the telephone conversation with the applicant's representative, pointing out the error). The "A-delay" was therefore changed from 226 days to 261 days. (Ex. B at 99-100.)

31. Plaintiff's representatives filed a Request for Reconsideration of PTA on December 3, 2014, asking that, *inter alia*, the PTO should recognize that the second Restriction Requirement was rendered moot by the Examiner's express indication that a third restriction requirement would be issued. As such, Plaintiffs requested that the "A-delay" be calculated to run from the 14-month date, August 1, 2011, until the mailing of the third Restriction Requirement, June 21, 2012. This calculation results in an "A-delay" of 325 days. (Ex. B at 108-114.)

32. On April 7, 2015, the PTO issued a Final Decision on PTA, which decision upheld the previous ruling of 346 days of PTA, including 261 days of A-delay. A true copy of the April 7, 2015 Final Decision on PTA is attached hereto as Exhibit D.

33. While conceding that the PTO had vacated the second Restriction Requirement, the PTO concluded that vacatur of an office action does not signify that the office action is void *ab initio*. (Ex. D at 4-5.)

34. In the Final Decision, the PTO further concluded that the record indisputably shows that the PTO mailed a notification under 35 U.S.C. § 132, as required by 35 U.S.C. § 154(b)(1)(A)(i), which notification was the second Restriction Requirement, mailed April 18, 2012. (Ex. D. at 5.)

35. In the Final Decision, the PTO concluded that the first Restriction Requirement did not stop the “A-delay” clock, and therefore that it did not consider the first Restriction Requirement to be a notification under 35 U.S.C. § 132. (Ex. D at 4-5.)

36. The PTO thus treated the first and second Restriction Requirements with respect to the running of the “A-delay” clock differently based solely on the applicant’s decision to provide a written record of the interview with the examiner. The PTO’s own rules require the submission of a writing documenting the substance of the interview. *See, e.g.*, 37 C.F.R. § 1.2 requiring that PTO business is to be transacted in writing and 37 C.F.R. § 1.133 requiring that interviews be memorialized. But by making a distinction such as the PTO has made in this case, the PTO sends a clear message to applicants that (regardless of what the rules say) if applicants point out obvious PTO errors in writing, they will be penalized. By penalizing the applicant for making a written record of the interview with respect to the second restriction requirement, the PTO exercised its regulatory power in an arbitrary and capricious manner.

37. Since both the first and second Restriction Requirements were each subsequently superseded by new restriction requirements, and since neither the first nor the second Restriction Requirement was, or reasonably could be, substantively replied to by Plaintiff’s representatives, it was improper for the PTO nevertheless to treat the second Restriction Requirement as a notification under 35 U.S.C. § 132 that stopped the “A delay” clock.

38. The intent of the provisions of Section 154(b) of Title 35 of United States Code is to provide for the adjustment of Patent Term for patents whose issue was delayed due to actions taken by the PTO. Section 154(b)(1)(A) provides for a Guarantee of prompt action by the PTO, and Section 154(b)(1)(B) provides for a Guarantee of no more than 3-year application pendency, both Guarantees limited by the provisions of Section 154(b)(2)(C) that the period of patent term adjustment shall be reduced by the period of time during which the applicant for patent failed to engage in reasonable efforts to conclude prosecution.

39. These statutory provisions have been implemented by Section 1.701, *et. seq.*, of Title 37 of the Code of Federal Regulations. Section 1.705(c)(7) thereof specifically provides that the submission by an applicant of a reply having an omission (i.e., a defective reply) qualifies as applicant delay from the day after the date that the defective reply is submitted until the day that a subsequent corrective reply is submitted. The rationale behind this is that by filing a first defective reply, the applicant is delaying prosecution because the PTO has to wait for a corrected reply to be filed in order to continue prosecution of the application.

40. It is inconsistent with the purpose behind 35 U.S.C. § 154(b), the rationale behind 37 C.F.R. § 1.705(c)(7), public policy and due process of law, for the PTO to consider a defective reply by an applicant to cause a delay of prosecution, whereas a defective office action issued by the PTO does not delay prosecution.¹ Therefore, where the PTO has failed to issue a notification under Section 132 within the 14-month time-frame set by 35 U.S.C. § 154(b)(1)(A)(i), and subsequently issues a notification under Section 132 which is defective on its face, it would be an unequitable, arbitrary and capricious exercise of the PTO's authority to deem such a defective notification sufficient to stop the running of the "A-delay" clock. An applicant can no more respond to a defective office action than the PTO can respond to a defective reply.

¹ The issue of whether a notification under Section 132, whether it is defective or not, stops the running of the "A-delay" clock is currently the subject of an appeal to the Court of Appeals for the Federal Circuit, see *Pfizer v. Lee*, No. 15-1265, filed March 24, 2015. *Pfizer* does not present the issue of what happens when, as in this case, the response is so defective that no response in compliance with the rules is possible, nor the PTO's practice (as seen in this case) of penalizing applicants for memorializing interviews with examiners in writing by characterizing such interview summaries as applicant responses that affect PTA.

41. Both the first and second Restriction Requirements issued during prosecution of the '358 application were defective on their face because they failed to address all aspects of the pending claims. Both the first and second Restriction requirements were subsequently withdrawn and superseded in view of these defects. Therefore, only the third Restriction Requirement, mailed on June 21, 2012, should have qualified to stop the running of the "A-delay" clock, and therefore, to stop the accumulation of Patent Term delay attributable to the PTO. "A delay" should have been calculated to run from August 1, 2011 until June 21, 2012, resulting in an "A-delay" of 325 days.

42. The PTO's calculation that the '912 patent is entitled to 346 days is incorrect, because it counts 261 days of "A-delay," rather than the correct value of 325 days of "A-delay." Therefore, the PTO should have found that the '912 patent is entitled to 410 days of PTA.

COUNT 1 - Action for Adjustment of Patent Term under 35 U.S.C. § 154(b)

43. The allegations of paragraphs 1-42 are incorporated in this claim for relief as if fully set forth herein.

44. United States Patent No. 8,518,912, assigned to Plaintiff, issued on August 27, 2013, and the Defendant, by the Petition Decision dated April 7, 2015, granted a Patent Term Adjustment of 346 days.

45. Defendant's Petition Decision dated April 7, 2015, is a final agency decision within the meaning of 5 U.S.C. § 704 for the purposes of seeking judicial review.

46. The Defendant's granted patent term adjustment of 346 days includes a period of "A Delay" of 261 days, a period of "B delay" of 87 days, and a period of "Applicant's delay" of 2 days, with zero overlapping days and zero days of "C delay."

47. The correct patent term adjustment for the '912 patent is properly determined to be 410 days ((("A Delay": 325 + "B Delay": 87 + "C delay": 0) – (Overlapping days: 0) – ("Applicant's delay": 2) = 410 days).

48. The '912 Patent is not subject to a terminal disclaimer, so the provisions of 35 U.S.C. § 154(b)(2)(B) do not apply and the full 410 days of patent term adjustment should be granted.

49. The Defendant's determination that the '912 Patent is entitled to 346 days of patent term adjustment is arbitrary, capricious, an abuse of discretion, clear error or otherwise not in accordance with law and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

50. Plaintiffs are thus entitled to additional patent term for the '912 patent, such that the 346 days of PTA granted by the PTO should be changed to 410 days.

COUNT 2 – Administrative Procedures Act

51. The allegations of paragraphs 1 – 50 are incorporated in this claim for relief as if fully set forth herein.

52. The United States Patent and Trademark Office ("PTO") is an agency of the United States government. Judicial review of PTO action is not precluded and is expressly permitted by statute. The calculation of patent term is determined by statute and is not committed to the PTO's discretion.

53. Defendant's interpretation of 35 U.S.C. § 154(b)(1)(A)(i) that a defective and subsequently superseded restriction requirement qualifies as a valid notification under 35 U.S.C. § 132, if the applicant makes a written record of a telephone call pointing out the error, but not if the applicant does not make such a record, is arbitrary and capricious, inconsistent with the PTO's own rules that PTO business should be conducted in writing and that interview summaries in particular should be memorialized in writing, and has resulted in the improper calculation "A-delay" for the '912 patent.

54. Defendant's conclusion that the second Restriction Requirement, although admitted by the PTO to be in error and not susceptible to a compliant response, and although subsequently voided, was nevertheless a valid notification within the meaning of 35 U.S.C. § 154((b)(1)(A)(i),

is arbitrary and capricious and is an abuse of discretion, or is otherwise not in accordance with the law within the meaning of 5 U.S.C. § 706(2)(A).

55. Plaintiff, as assignee of the '912 patent, has suffered legal wrong because of the PTO's actions in miscalculating the term of the '912 patent and failing to provide an adequate remedy for correction of such miscalculation. Plaintiff is and has been adversely affected and aggrieved by such actions. There is no adequate remedy available to Plaintiff, either administratively through the PTO or in any other forum, other than this Court.

56. The conduct of the PTO in miscalculating the term of the '912 patent and then failing and refusing to provide an adequate remedy for correction of such miscalculation is

- (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
- (B) contrary to constitutional right, power, privilege, or immunity;
- (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
- (D) without observance of procedure required by law;
- (E) unsupported by substantial evidence; and
- (F) unwarranted by the facts.

57. Plaintiffs are entitled to additional patent term for the '912 patent, such that the 346 days of PTA granted by the PTO should be changed to 410 days.

COUNT 3 – United States Constitution

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

59. The Fifth Amendment to the Constitution of the United States provides in relevant part that no person shall be "deprived of . . . property, without due process of law; 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 '912 patent.

61. Defendant's improper determination of the Patent Term Adjustment accorded to the '912 patent constitutes a permanent deprivation of Plaintiff's patent term and rights to which Plaintiff is entitled under 35 U.S.C. § 154(b).

62. The Defendant's failure to accord the statutorily mandated term to the '912 patent, effectively dedicating a portion of the term of that patent to the public, constitutes an arbitrary and unjustified deprivation and taking of a property right established by Article I, Section 8, of the United States Constitution and secured by the Fifth Amendment of the United States Constitution, without just compensation.

63. Plaintiffs are entitled to additional patent term for the '912 patent, such that the 346 days of PTA granted by the PTO should be changed to 410 days.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Actelion Pharmaceuticals Ltd., respectfully prays that this Court:

(A) Issue an Order declaring that the correct period of the patent term adjustment for the '912 Patent is 410 days, and setting aside the prior determination of the PTO;

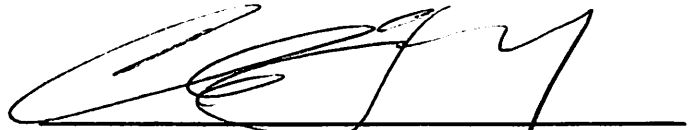
(B) Issue an Order compelling the Defendant forthwith to change the period of the patent term adjustment for the '912 Patent to 410 days, and compelling the Director to extend the term of the '912 Patent to reflect the 410 days of patent term adjustment;

(C) Issue an award of the Plaintiff's reasonable attorneys' fees, expenses and costs of suit, in accordance with 28 U.S.C. § 2412, 35 U.S.C. § 285, and other applicable law; and

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

Dated: October 1, 2015

Respectfully submitted,



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