IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	U.S. Patent No. 9,108,973
Application No.:	14/344,935
Issued:	August 18, 2015
PCT Filing Date:	January 17, 2013
Inventors:	Takeshi Sagara, Satoru Ito, Sachie Otsuki, and Hiroshi Sootome
Assignee:	Taiho Pharmaceutical Co., Ltd.
Title:	3,5-DISUBSTITUTED ALKYNYLBENZENE COMPOUND AND SALT THEREOF
Attorney Docket No.:	2941-212

Mail Stop Hatch-Waxman PTE
U.S. Patent and Trademark Office
Office of Patent Legal Administration
Room MDW 7D55
Dulaney Street (Madison Building)
Alexandria, VA 22314

TRANSMITTAL OF SUPPLEMENT TO APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156

Applicant submits herewith the following:

a. Cover Letter for Supplement to Application for Extension of Patent Term under 35 U.S.C. § 156 for U.S. Patent No. 9,108,973; and

b. Supplement to Application for Extension of Patent Term under 35 U.S.C. § 156 for U.S. Patent No. 9,108,973, with Exhibits A, B and C.

The Commissioner is authorized to charge any additional fees required by this paper or credit any overpayment to Counsel's Deposit Account No. 02-2135.

Date: February 8, 2024 By: /Monica Chin Kitts/

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SUPPLEMENT TO APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156

Commissioner:

On November 29, 2022, Taiho Pharmaceutical Co., Ltd. (hereinafter "Applicant"), acting through its duly authorized attorney, filed an Application for Patent Term Extension (hereinafter "Application") for U.S. Patent No. 9,108,973 (hereinafter "the '973 patent"). The extension was being sought due to delays encountered in the United States Food and Drug Administration (FDA) approval of the drug product Lytgobi® (futibatinib).

Applicant wishes to correct its Application with the following information related to the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred. Applicant has presented replacement paragraphs (3), (5), (10) and (12), which are impacted by this correction. Applicant has provided a comparison of paragraphs (3), (5), (10) and (12) to show the changes

made and an integrated version of the Application (excluding Exhibits 1-8),[1] but including new replacement paragraphs (3), (5), (10) and (12), as **Exhibits A and B**, respectively.

Applicant respectfully requests that the U.S.P.T.O. send a corrected replacement letter to the FDA correcting U.S.P.T.O.'s September 20, 2023 letter to FDA requesting confirmation that the product identified in the Application, LYTGOBI® (futibatinib), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved.

For convenience, Applicant has provided a copy of this Supplement to the FDA, along with a cover letter providing additional information. A copy of this cover letter is attached as **Exhibit C**.

Please replace paragraphs (3), (5), (10) and (12) of the Application with the following:

(3) An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred.

Applicant respectfully submits that Lytgobi received permission for commercial marketing or use by the FDA pursuant to section 505(b) of the FFDCA (21 U.S.C. §355(b)) on October 5, 2022 by virtue of the Corrected Approval Letter that is attached as Exhibit 4 to the Application. As noted in the Corrected Approval Letter from FDA, the September 30, 2022 letter contained errors that required correction by the FDA. By FDA's own admission the September 30, 2022 letter was defective and erroneous; it was not until FDA issued the Corrected Approval Letter on October 5, 2022 at 10:23 AM that Lytgobi received permission for commercial marketing or use by the FDA pursuant to section 505(b) of the FFDCA (21 U.S.C. §355(b)).

[1] Exhibit B reflects that Taiho Oncology, Inc., a subsidiary of Applicant, was the Marketing Applicant for LYTBOBI and references the authorization to rely on regulatory activities filed by Taiho Oncology, Inc. on August 29, 2023.

(5) A statement that the application is being submitted within the sixty-day period permitted for submission pursuant to § 1.720(f) and an identification of the date of the last day on which the application could be submitted.

This application for extension of patent term under 35 U.S.C. § 156 is submitted on November 29, 2022, which is within the permitted 60-day period pursuant to 37 C.F.R. § 1.720(f), which began on October 5, 2022, and the last day of which was December 3, 2022.[2]

[2] By virtue of the calculation of the sixty-day period and the last day on which the application could be submitted as presented herein, Applicant does not waive its right to assert that its prior calculation of the of the sixty-day period and the last day on which the application could be submitted as set forth in the Application dated November 29, 2022 was correct. Applicant also does not waive its right to assert that the manner in which the U.S.P.T.O. calculates the 60-day period is incorrect.

(10) A statement beginning on a new page of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows:

(i) For a patent claiming a human drug, antibiotic, or human biological product:

(A) The effective date of the investigational new drug (IND) application and the IND number;

(B) The date on which a new drug application (NDA) or a Product License Application (PLA) was initially submitted and the NDA or PLA number; and

(C) The date on which the NDA was approved or the Product License issued;

U.S. Patent No. 9,108,973 issued on August 18, 2015.

An original investigational new drug application ("IND") to study futibatinib, 1-[(3S)-3-{4-amino-3-[(3,5-dimethoxyphenyl)ethynyl]1*H*-pyrazolo[3,4-*d*]pyrimidin-1-yl}pyrrolidin-1-yl]prop-2-en-1-one, was submitted by Taiho on December 31, 2013 and was received by the FDA on the same day. The FDA assigned IND No. 121062 to this IND. The IND effective date was March 12, 2014, as it was contingent on the submission of an amended protocol.

A new drug application ("NDA") was initially submitted by Taiho to the FDA on January 31, 2022, and was received by the FDA on the same day. The FDA assigned NDA No. 214801 to the NDA. The NDA was approved on October 5, 2022 as indicated in the corrected approval letter (*see* Exhibit 4 of the Application).

(12) A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined.

(I) Applicant is of the opinion that the '973 patent is eligible for extension under 35 U.S.C. § 156 because it satisfies all of the requirements for such extension as follows:

(a) 35 U.S.C. § 156(a)

The '973 patent claims the Approved Product as defined in 37 C.F.R. § 1.710(a).

(b) 35 U.S.C. § 156(a)(1)

Pursuant to 35 U.S.C. § 154, the term of the '973 patent is currently set to expire on February 13, 2033. This application is, therefore, being submitted prior to the expiration of the term of the '973 patent.

(c) 35 U.S.C. § 156(a)(2)

The term of the '973 patent has never been extended under 35 U.S.C. § 156(e)(1).

(d) 35 U.S.C. § 156(a)(3)

The application for extension is submitted by a registered practitioner on behalf of the owner of record in accordance with the requirement of 35 U.S.C. § 156(d) and the rules of the U.S. Patent and Trademark Office. Proof that Applicant is the owner of record is provided by the following: (1) a copy of the Assignment of the '973 patent to Taiho on January 22, 2014 (by inventors Takeshi Sagara, Satoru Ito, Sachie Otsuki, and Hiroshi Sootome) and a copy of the Recordation of the same with the U.S. Patent and Trademark Office on March 13, 2014 (Exhibit 2). Proof that the registered practitioner is authorized to act on behalf of the patent owner is provided by a copy of the power of attorney filed with the U.S. Patent and Trademark Office in connection with the '973 patent on March 14, 2014 (Exhibit 8).

(e) 35 U.S.C. § 156(a)(4); 37 C.F.R. § 1.720(d)

The Approved Product has been subject to a regulatory review period under section 505(b) of the FFDCA (21 U.S.C. § 355(b)) before its commercial marketing or use.

(f) 35 U.S.C. § 156(a)(5)(A)

The commercial marketing or use of the Approved Product after the regulatory review period is the first permitted commercial marketing and use of the product, as defined in 35 U.S.C. § 156(f), under section 505(b) of the FFDCA (21 U.S.C. § 355(b)).

(g) 35 U.S.C. § 156 (c)(4)

No other patent has been extended for the same regulatory review period for the Approved Product.

(h) 35 U.S.C. § 156(d)(l)

The application is submitted within the permitted 60-day period beginning on the date the Approved Product first received permission for commercial marketing or use, which was October 5, 2022.

(II) Below is a statement as to the length of extension claimed, including how the length of extension was determined.

The term of the '973 patent, currently expiring on February 13, 2033, should be extended for **1330 days** beyond its expiration date under 35 U.S.C. § 154, to **October 5, 2036** in accordance with 35 U.S.C. § 156. The analysis pertaining to these determinations is provided below.

As set forth in 35 U.S.C. § 156(g)(l), the regulatory review period equals the length of time between the effective date of IND No. 121062 of March 12, 2014 and the submission of NDA No. 214801 on January 31, 2022 (*i.e.*, the "testing phase"), a period of 2883 days, plus the length of time between the submission of NDA No. 214801 on January 31, 2022 to the NDA approval on October 5, 2022 (*i.e.*, the "approval phase"), a period of 248 days. These two periods added together equal 3131 days (*i.e.*, the "regulatory review period").

Pursuant to 37 C.F.R. § l.775(d), the term of the patent as extended is determined by subtracting from the 3131-day regulatory review period the following:

(i) 525 days, which is the number of days in the testing phase and the approval phase on or before the issuance of the '973 patent on August 18, 2015;

(ii) 0 day, which is the number of days Applicant did not act with due diligence; and

(iii) 1179 days, which is one-half the number of days remaining in the testing phase after the subtraction of 525 days above (wherein half days are ignored for purposes of this subtraction, as provided by 37 C.F.R. § l.775(d)(l)(iii)).

From the foregoing calculation, an extension of 1427 days results, *i.e.*, the remaining period under 35 U.S.C. § 156(g)(l)(B)(i) (1179 days) plus the remaining period under 35 U.S.C. § 156(g)(l)(B)(ii) (248 days).

Based on the current expiration date of February 13, 2033 under 35 U.S.C. § 154, this length of an extension would provide a new expiration date for the '973 patent of January 10, 2037.

However, the 1427-day extension period is subject to two further potential limitations under 35 U.S.C. § 156.

First, under 35 U.S.C. § 156(g)(6)(A), a maximum extension of five years is permitted. Since the expiration date of the '973 patent is currently February 13, 2033, no patent term extension could extend the term of the '973 patent beyond February 13, 2038. In this case, 35 U.S.C. § 156(g)(6)(A) does not operate to limit the possible extension available to the '973 patent.

Second, under 35 U.S.C. § 156(c)(3), the calculated extension period cannot lead to a patent term that would result in a patent term exceeding 14 years after the date of approval, that is, a patent term expiring after October 5, 2036. Consequently, this provision does operate to limit the possible extension available to the '973 patent.

Accordingly, the '973 patent is eligible for a patent term extension under 35 U.S.C. § 156 of 1330 days to October 5, 2036 given the current expiration date under 35 U.S.C. § 154.

Applicant reserves the right to amend this Application, including to update this patent term extension calculation.

Applicant respectfully requests that the U.S.P.T.O. send a corrected replacement letter to the FDA correcting U.S.P.T.O.'s September 20, 2023 letter to FDA requesting confirmation that the product identified in the Application, LYTGOBI® (futibatinib), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved.

Pursuant to the requirements of 37 C.F.R. § 1.740(b), this Supplement to the application for patent term extension under 35 U.S.C. § 156 are hereby submitted electronically.

Please direct all questions and correspondence regarding this Supplement to the undersigned.

The Director is hereby authorized to charge any additional fees which may be required for this submission or credit any overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

By: ___/Monica Chin Kitts/_____

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