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DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2019-0007]

Patent Term Adjustment Procedures in View of the Federal Circuit Decision in *Supernus Pharm., Inc.* v. *Iancu*

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) is modifying its patent term adjustment procedures in view of the decision by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) in *Supernus Pharm., Inc.* v. *Iancu* (*Supernus*). The USPTO makes the patent term adjustment determinations indicated in patents by a computer program that uses information recorded in its Patent Application Locating and Monitoring (PALM) system. The event from which the Federal Circuit measured the beginning of the patent term adjustment reduction period in *Supernus* — a notice to the applicant from a foreign patent authority— is not an event that is recorded in the

USPTO's PALM system. Thus, the USPTO will continue to make the patent term adjustment determinations indicated in patents under the existing regulations using information recorded in its PALM system. A patentee who believes that the period of patent term adjustment reduction exceeds the period of time during which the patentee failed to engage in reasonable efforts to conclude prosecution of the application may raise the issue in a timely request for reconsideration of the patent term adjustment, providing any relevant information that is not recorded in the USPTO's PALM system. The USPTO's decision on any timely filed patentee request for reconsideration will apply the Federal Circuit's decision in *Supernus* in view of the information presented by the patentee.

DATES: The procedure set forth in this notice is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Kery A. Fries, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, at 571-272-7757.

SUPPLEMENTARY INFORMATION: Under 35 U.S.C. 154(b)(1), an applicant is entitled (subject to certain conditions and limitations) to patent term adjustment for the following reasons: (1) if the USPTO fails to take certain actions during the examination and issue process within specified time frames (35 U.S.C. 154(b)(1)(A)) ("A" delays);

(2) if the USPTO fails to issue a patent within three years of the actual filing date of the application (35 U.S.C. 154(b)(1)(B)) ("B" delays); and (3) for delays due to a proceeding under 35 U.S.C. 135(a) (*e.g.*, derivation, interference, secrecy order, or successful appellate review (35 U.S.C. 154(b)(1)(C)) ("C" delays). 35 U.S.C. 154(b)(2) places limitations on the period of patent term adjustment granted under 35 U.S.C. 154(b)(1), one of which is that the period of patent term adjustment under 35 U.S.C. 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 (or processing or examination) of the application (35 U.S.C. 154(b)(2)(C)(i)). 35 U.S.C. 154(b)(2) directs the USPTO 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." (35 U.S.C. 154(b)(2)(C)(iii)). The USPTO has prescribed such regulations in 37 CFR 1.704. Further, 35 U.S.C. 154(b)(3)(A) directs the USPTO to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments." The USPTO has prescribed such regulations in 37 CFR 1.705.

On January 23, 2019, the Federal Circuit issued a decision in *Supernus* pertaining to the patent term adjustment provisions of 35 U.S.C. 154(b), and specifically to a reduction of patent term adjustment under 37 CFR 1.704(c)(8) resulting from the submission of an information disclosure statement after the filing of a request for continued examination under 37 CFR 1.114. *See Supernus Pharm., Inc.* v. *Iancu*, 913 F.3d 1351 (Fed. Cir. 2019). Specifically, the applicant in *Supernus* filed a supplemental information

disclosure statement on November 29, 2012, after the filing of a request for continued examination on February 22, 2011. *Id*. at 1354-55. The supplemental information disclosure statement of November 29, 2012 in *Supernus* contained documents cited by the European Patent Office (EPO) in the counterpart EPO patent (from an opposition filed in the EPO patent) in a notice issued by the EPO on August 21, 2012. *Id*. The supplemental information disclosure statement of November 29, 2012 also included the opposition filed in the EPO patent and the EPO's notice of the opposition. *Id*.

37 CFR 1.704(c)(8), the regulatory provision at issue in *Supernus*, provides as a circumstance that constitutes a failure of the applicant to engage in reasonable efforts to conclude prosecution (processing or examination) of an application: "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, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed." *Id*. The Federal Circuit in *Supernus* noted that it previously held 37 CFR 1.704(c)(8) to be "'a reasonable interpretation of the [patent term adjustment] statute' insofar as it includes 'not only applicant conduct or behavior that results in actual delay, but also those having the potential to result in delay irrespective of whether such delay actually occurred.'" 913 F.3d at 1356 (quoting *Gilead Scis., Inc.* v. *Lee*, 778 F.3d 1341, 1349-50 (Fed. Cir. 2015)). And also that 37 CFR 1.704(c)(8) "encompasses the filing of a supplemental [information

disclosure statement] in the calculated delay period." *Id*. The Federal Circuit, however, held that the period of reduction provided for in 37 CFR 1.704(c)(8) as applied in *Supernus* exceeded the period of time during which Supernus failed to engage in reasonable efforts to conclude prosecution of the application because there were no identifiable efforts that Supernus could have undertaken to conclude prosecution of its application during the period between the filing of the request for continued examination (on February 22, 2011) and the EPO's notice of the opposition (on August 21, 2012). *Id*. at 1360. Specifically, the Federal Circuit held that as 35 U.S.C. 154(b)(2)(C)(i) provides that patent term adjustment "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," the USPTO cannot count as applicant delay under 35 U.S.C. 154(b)(2)(C) "a period of time during which there is no identifiable effort in which the applicant could have engaged to conclude prosecution." *Supernus*, 913 F.3d at 1359.[1] Thus, the Federal Circuit restricted the patent term adjustment reduction under 37 CFR 1.704(c)(8) due to the filing of the supplemental information disclosure statement on November 29, 2012 to 100 days, corresponding to the period between the notice issued

[1] The patent term adjustment reduction at issue in *Supernus* can be avoided by the prompt submission of the information disclosure statement. Specifically, 37 CFR 1.704(d) provides a "safe harbor" in that a paper containing only an information disclosure statement in compliance with 37 CFR 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under 37 CFR 1.704(c)(6), (c)(8), (c)(9), or (c)(10) if the information disclosure statement is accompanied by one of the statements set forth in 37 CFR 1.704(d)(1)(i) or (d)(1)(ii). *See Interim Procedure for Requesting Recalculation of the Patent Term Adjustment With Respect to Information Disclosure Statements Accompanied by a Safe Harbor Statement*, 83 FR 55102 (Nov. 2, 2018).

by the EPO on August 21, 2012 and the filing of the supplemental information disclosure statement on November 29, 2012. *Id*. at 1360.

The final rule to implement the patent term adjustment provisions of the Leahy-Smith America Invents Act Technical Corrections Act contains a comprehensive discussion of the USPTO's procedures for patent term adjustment determinations and requests for reconsideration of the patent term adjustment determinations. *See Revisions to Implement the Patent Term Adjustment Provisions of the Leahy-Smith America Invents Act Technical Corrections Act*, 79 FR 27755, 27757-58 (May 15, 2014). The USPTO makes the patent term adjustment determinations indicated in patents by a computer program that uses information recorded in its PALM system relating to the communications exchanged between applicants and the Office during the patent application process. *Id*. at 27757. The patent term adjustment determination to be indicated in a patent is calculated at the time of the mailing of the Issue Notification and is provided with the Issue Notification and printed on the front page of the patent. The event from which the Federal Circuit measured the beginning of the patent term adjustment reduction in *Supernus* (the EPO's notice to Supernus of the opposition on August 21, 2012) is an event external to the USPTO and is thus not an event that is recorded in the USPTO's PALM system. In addition, the USPTO expects that the situation in *Supernus* should arise infrequently. An extended delay between the filing of a request for continued examination and the subsequent Office action (932 days in *Supernus*) should be a rare occurrence now, as the average time between the filing of a

request for continued examination and the subsequent Office action is currently only 79 days. Thus, the USPTO's patent term adjustment determinations indicated in patents as provided for in 37 CFR 1.705(a) will continue to be based upon the beginning and ending dates of events recorded in the USPTO's PALM system as specified in 37 CFR 1.703 and 1.704 (including 37 CFR 1.704(c)(8)).

A patentee dissatisfied with the patent term adjustment indicated on the patent may file a request for reconsideration under 37 CFR 1.705(b). A patentee who believes that the period of reduction provided for in 37 CFR 1.704(c)(8) (or any of 37 CFR 1.704(c)) exceeds the period of time during which the patentee failed to engage in reasonable efforts to conclude prosecution of the application because there is **no identifiable effort** the patentee could have undertaken to conclude prosecution of the underlying application[2] may raise the issue in a timely request for reconsideration of the patent term adjustment under 37 CFR 1.705(b). The request for reconsideration must provide any relevant information, including factual support, which is not recorded in the USPTO's PALM system to show that there was no identifiable effort the patentee could have

[2] An argument presenting a justification for a failure to engage in reasonable efforts to conclude prosecution is distinct from an argument that there is no identifiable effort a patentee could have undertaken to conclude prosecution. 35 U.S.C. 154(b)(3)(C) provides for reinstatement of "all or part of the cumulative period of time of an adjustment under [35 U.S.C. 154(b)(2)(C)(ii)] if the applicant, prior to the issuance of the patent, makes a showing that, in spite of all due care, the applicant was unable to respond within the 3-month period" and is distinct from an argument that there is no identifiable effort a patentee could have undertaken to conclude prosecution. Any request for reinstatement of "all or part of the cumulative period of time of an adjustment under [35 U.S.C. 154(b)(2)(C)(ii)]" on the basis of "a showing that, in spite of all due care, the applicant was unable to respond within the 3-month period" must comply with the requirements of 35 U.S.C. 154(b)(3)(C) and 37 CFR 1.705(c).

undertaken to conclude prosecution of the underlying application during a portion of the period provided for in 37 CFR 1.704(c)(8) (or any of the periods set forth in 37 CFR 1.704(c)). For example, in a situation analogous to *Supernus*, the request for reconsideration must include the facts concerning how and when each of the documents contained in the information disclosure statement at issue were first cited by the USPTO or a foreign patent authority in a related or counterpart application. *See* 37 CFR 1.705(b)(2)((iv) (stating that a request for reconsideration must be accompanied by a statement of the facts involved, specifying "[a]ny circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in [37 CFR] 1.704"). The USPTO's decision on any timely filed patentee request for reconsideration will apply the Federal Circuit's decision in *Supernus* in view of the information presented by the patentee.

While the USPTO has adopted *ad hoc* procedures for seeking reconsideration of the patent term adjustment determination in the past when there have been changes to the interpretation of the provisions of 35 U.S.C. 154(b) as a result of court decisions, these *ad hoc* procedures were adopted because former 35 U.S.C. 154(b)(4) provided a time period for seeking judicial review that was not related to the filing of a request for reconsideration of the USPTO's patent term adjustment determination or the date of the USPTO's decision on any request for reconsideration of the USPTO's patent term adjustment determination. *See* 79 FR at 27759. As 37 CFR 1.705 now provides that its

two-month time period may be extended under the provisions of 37 CFR 1.136(a) (permitting an applicant to request reconsideration of the patent term adjustment indicated on the patent as late as seven months after the date the patent was granted), the USPTO is not adopting an *ad hoc* procedure for requesting a patent term adjustment recalculation specifically directed to the Federal Circuit decision in *Supernus*. *Id*.

Paperwork Reduction Act: This notice involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*.). The collection of information involved in this notice is covered by OMB control number 0651-0020.

Dated: May 3, 2019.

Andrei Iancu,
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.
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