



## American Intellectual Property Law Association

December 3, 2019

The Honorable Andrei Iancu  
Under Secretary of Commerce for Intellectual Property  
and Director of the United States Patent and Trademark Office  
600 Dulany Street  
Alexandria, VA 22314  
*Attention: Kery Fries*

Via email: [AD38.comments@uspto.gov](mailto:AD38.comments@uspto.gov)

**RE:                   Comments on Notice of Proposed Rulemaking Regarding Patent Term Adjustment Reductions in View of the Federal Circuit Decision in *Supernus Pharm., Inc. v. Iancu* [Docket No. PTO-P-2019-0019]**

Dear Director Iancu:

AIPLA appreciates the efforts by the U.S. Patent and Trademark Office in preparing this Notice of Proposed Rulemaking (NPRM) for Patent Term Adjustment Reductions in View of the Federal Circuit Decision in *Supernus Pharm., Inc. v. Iancu*, 913 F.3d 1351 (Fed. Cir. 2019) (*Supernus*).

AIPLA is a national bar association of approximately 12,000 members engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

We agree that many of the Office's proposed revisions to 37 CFR §§ 1.704(c)(1) through (c)(14) are consistent with the requirement set forth in the *Supernus* decision that a reduction in patent term adjustment correspond to "the period from the beginning to the end of the applicant's failure to engage in reasonable efforts to conclude prosecution."<sup>1</sup>

However, we have concerns with the Office's proposed revision to Section 1.704(c)(6). Under the current rule, the period of reduction of patent term in this section is "the lesser of: (i) The number of days, if any, beginning on the day after the mailing date of the original Office action or notice of allowance and ending on the date of mailing of the supplemental Office action or notice of allowance ; or (ii) Four months[.]" The Office's proposed revision removes the four-month limit on the reduction, and calculates the amount of reduction from a date eight months

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<sup>1</sup> *Supernus*, 913 F.3d at 1359.

from the filing or national entry date of the application, specifically: “the number of days, if any, beginning on the day after the date that is eight months from either the date on which the application was filed under 35 U.S.C. § 111(a) or the date of commencement of the national stage under 35 U.S.C. § 371(b) or (f) in an international application and ending on the date the preliminary amendment or other preliminary paper was filed.” We believe there are situations where an applicant would be harshly penalized under the revised rule for filing a preliminary paper outside of the eight-month window, even though the applicant’s actions did not constitute a failure to engage in reasonable efforts to conclude prosecution of the application.

For example, an applicant may wish to use the Patent Prosecution Highway (PPH) Program after receiving a notice of an allowable claim from a foreign patent office. Such an applicant may need to file a preliminary amendment in order meet the PPH requirement that the claims sufficiently correspond to the allowed claims in the foreign counterpart application. The applicant’s actions in such a case are not dilatory; rather, the applicant is making an effort to speed up the conclusion of prosecution of the U.S. application. But under the proposed revision to Section 1.704(c)(6), the applicant that files such a preliminary amendment for the PPH program could have its patent term adjustment reduced if the decision from the foreign patent office was received more than eight months after the U.S. filing or national stage commencement date.

Even outside of the PPH program, an applicant may need to file a preliminary amendment more than eight months after the filing date or national stage commencement date after learning of prior art that necessitates a narrowing of the claim scope. Such a preliminary amendment is not the result of a failure to engage in an effort to conclude prosecution of the application. Quite the opposite, the applicant is fulfilling its duty to seek only claims that it believes are patentable. Yet, the applicant could be harshly penalized under the proposed revision to Section 1.704(c)(6).

We note that the eight-month timeframe for filing a preliminary paper in the proposed revision is generally inconsistent with the average pendency to a first Office action on the merits at the Office. Per October 2019 statistics provided at the USPTO’s data visualization center,<sup>2</sup> the office-wide average pendency to a first action on the merits is 14.8 months, and the forward-looking first action pendency is 15.5 months. The Office’s average pendency is therefore much longer than the eight-month window afforded by the proposed revision to Section 1.704(c)(6). Thus, the proposed revision to the rule may penalize an applicant for filing a preliminary amendment during a timeframe when the applicant will not be expecting the Office to be preparing an Office action. Moreover, the average pendency to Office actions from Technology Centers 1700, 2100, 3600, and 3700 appear to be significantly greater than the office-wide average.<sup>3</sup> Thus, applicants in certain technologies would be more adversely affected than others under the proposed rule.

We also believe that the revisions to Section 1.704(c)(6) could result in an unfair penalty to an applicant who should be awarded significant adjustments under 37 CFR § 1.704(a)(1), which provides additional term to an applicant when the USPTO does not issue a first Office action or

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<sup>2</sup> See <https://www.uspto.gov/dashboards/patents/main.dashxml> (last accessed December 2, 2019).

<sup>3</sup> See Technology Center Level Data, *Ibid.*

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a notice of allowance within 14 months of the filing date or national stage commencement date. With the proposed revision to the rule, there could be situations where the Office's delay in taking action on an application is far greater than the prosecution delay resulting from the applicant's filing of a preliminary paper, yet the applicant would lose almost all of the patent term adjustment.

In view of our concerns, we suggest that Section 1.704(c)(6) not be revised as set forth in the NPRM, but rather be revised in a manner that will not result in such unfair penalties on applicants. As one possibility, the four-month limit on the reduction in patent term adjustment could be maintained in the rule. As another possibility, we propose that the amount of reduction in patent term adjustment in Section 1.704(c)(6) could be calculated based on when an Office action or notice of allowance is mailed, for example, "the number of days, if any, beginning one month before the original Office action or notice of allowance is mailed and ending on the date that the preliminary amendment or other preliminary paper was filed." Such a rule would be more consistent with expectations of applicants based on the average pendency to a first Office action on the merits at the USPTO.

We also propose that the Office develop a petition process that allows applicants to negate the loss of patent term adjustment under 37 CFR § 1.704. As outlined above, there may be instances where an applicant's actions are a reasonable effort to conclude prosecution of the application, yet the applicant is nevertheless penalized under the rule. The Office should provide a redress for such situations.

Thank you again for the opportunity to make these comments. AIPLA supports the USPTO's efforts on improving the patent system, welcomes the opportunity to answer any questions these comments may raise, and looks forward to a continuing dialogue on this very important subject.

Sincerely,

A handwritten signature in blue ink that reads "Barbara A. Fiocco". The signature is written in a cursive, flowing style.

Barbara A. Fiocco

President

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