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August 18, 2014

VIA EMAIL: AC96.comments@uspto.gov

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Re: Docket No. PTO-P-2014-0023: Changes to Patent Term Adjustment in View of the Federal Circuit Decision in *Novartis v. Lee*:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the enclosed views of PhRMA's members on the Notice of Proposed Rulemaking on Changes to Patent Term Adjustment in View of the Federal Circuit Decision in *Novartis v. Lee*, 79 Fed. Reg. 34,681 (June 18, 2014). PhRMA's members appreciate the PTO seeking comments on the proposed changes, and would welcome further dialogue with the PTO with respect to the proposed changes.

Please feel free to contact me if you have any questions.

Sincerely,

David E. Korn

Enclosure

Comments of the Pharmaceutical Research and Manufacturers of America
Docket No.: PTO–P–2014–0023
August 18, 2014

Comments of the Pharmaceutical Research and Manufacturers of America on the PTO's Proposed Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis v. Lee

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to submit comments in connection with the Patent and Trademark Office ("PTO" or "Office") Notice of Proposed Rulemaking on Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis v. Lee.[1]

PhRMA's member companies are leading research-based pharmaceutical innovators devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA's membership ranges in size from small emerging companies to multi-national corporations that employ tens of thousands of Americans, and encompass both research-based pharmaceutical and biotechnology companies. The U.S. biopharmaceutical sector supported a total of 3.4 million jobs throughout the economy, and directly employed more than 810,000 Americans in 2011.[2] The industry's overall economic impact is substantial – in 2011, the industry accounted for nearly $800 billion in economic output.[3]

The U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business research and development ("R&D"), representing about one in five dollars spent on domestic R&D by U.S. businesses.[4] PhRMA member investment in discovering and developing new medicines reached over $51 billion in 2013.[5] Medicines developed by the sector have produced large improvements in health across a broad range of diseases, with the rapid growth of biological knowledge creating growing opportunities for continued profound advances against our most complex and costly diseases. Developing a new medicine takes between 10 and 15 years of work and costs an average of over $1 billion of investment in R&D.[6] Like innovators across the spectrum of American industries, biopharmaceutical companies make the substantial R&D investments that yield new medicines in reliance on a legal regime that provides protection for any resulting intellectual property. Our companies rely on patents to protect their inventions and provide an opportunity to recover their research investments. But patents are particularly

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1 79 Fed. Reg. 34,681-34,685 (June 18, 2014).

2 Pharmaceutical Research and Manufacturers of America, *PhRMA Profile*, 2014 at ii (citing Battelle Technology Partnership Practice, *The Economic Impact of the U.S. Biopharmaceutical Industry*, Battelle Memorial Institute (Columbus, OH), July 2013.).

3 *Id*. at v.

4 Battelle Technology Partnership Practice, *The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It*, April 2014.

5 Pharmaceutical Research and Manufacturers of America, *PhRMA Profile*, 2014 at ii (citing Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 1981–2013.).

6 *Id*. (citing J.A. DiMasi and H.G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different*? Managerial and Decision Economics 2007; 28(4–5): 469–479; J. Mestre-Ferrandiz, J. Sussex, and A. Towse, *The R&D Cost of a New Medicine*, London, UK: Office of Health Economics, 2012; S.M. Paul, *et al.*, *How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Challenge*, Nature Reviews Drug Discovery 2010; 9: 203–214.).

important to biopharmaceutical innovation given the research-intensive nature of this sector and the substantial investment needed to discover and develop products that meet FDA approval requirements.[7]

Bringing new life-saving and life-improving products to people is the central role of our member companies. Because intellectual property is critical to carrying out this mission, PhRMA members appreciate the efforts of the PTO to implement the Federal Circuit's decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014), regarding the calculation of Patent Term Adjustment ("PTA"). However, in PhRMA's view, the PTO's proposed rulemaking departs from the Federal Circuit's holding in *Novartis* and should not be adopted in full.

I. The PTO's Proposed Patent Term Adjustment Rules Should Be Modified To Account For PTO Delay And To Prevent Distinguishing Prosecutions In Which There Is A Request For Continued Examination.

In response to the Federal Circuit's holding in *Novartis* that the PTO's original rules were not consistent with 35 U.S.C. § 154(b), the PTO is proposing amendments to its PTA calculation rules for applications in which a Request for Continued Examination ("RCE") has been filed. The PTO's proposed amendments go well beyond the court's holding and should not be adopted in full.

The Federal Circuit held in *Novartis* that, with respect to PTA calculations, "allowance-to-issuance time is not to be distinguished according to whether there is a continued examination in a prosecution. Either way such time is plainly attributable to the PTO"[8] and, therefore, should be included as PTO delay under 35 U.S.C. § 154(b)(1)(B) ("B delay") in a PTA calculation. The Federal Circuit also noted that "the PTO has explained that [35 U.S.C.] § 154(b)(1)(B) is best understood as making distinctions based on whether certain delays are attributable to the PTO."[9]

The PTO proposes amending 37 C.F.R. § 1.703(b)(1) to demarcate time that is considered "continued examination" and, therefore, not eligible for B delay. The first part of the PTO's proposed change to 37 C.F.R. § 1.703(b)(1) is to replace "ending on the date the patent was issued" with "ending on the date of mailing of a notice of allowance under 35 U.S.C. 151…".[10] This amendment would exclude the date of allowance from the calculation of B delay, which appears to be inconsistent with the *Novartis* case. ("The common-sense understanding of 'time consumed by continued examination'…is time up to allowance, but not later…")[11]

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7 *See* Claude Barfield & John E. Calfee. *Biotechnology and the Patent System: Balancing Innovation and Property Rights*, at 1-2 (AEI PRESS 2007). ("Without patent protection, investors would see little prospect of profits sufficient to recoup their investments and offset the accompanying financial risk."); *see generally* Battelle Technology Partnership Practice, *The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It*, April 2014; Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. OF INT'L ECONOMIC L. 849 (2002).

8 *Novartis AG v. Lee*, 740 F.3d 593, 602 (Fed. Cir. 2014).

9 *Id.*

10 79 Fed. Reg. 34685 (June 18, 2014).

11 740 F.3d. at 602 (underlined emphasis added). The court in *Novartis* also stated:

In addition, the rest of the amendment, which distinguishes applications that do not proceed directly to grant, also goes beyond the *Novartis* holding. Specifically, the PTO's proposed addition to 37 C.F.R. § 1.703(b)(1) shown in the underlined portion below is not consistent with the Federal Circuit's holding in *Novartis*.

> 37 C.F.R. 1.703 Period of adjustment of patent term due to examination delay.
> . . .
> (b) The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the sum of the following periods:
> (1) The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of a notice of allowance under 35 U.S.C. 151, unless prosecution in the application is reopened, in which case the period of adjustment under § 1.702(b) also does not include the number of days, if any, in the period or periods beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed or the date of mailing of an action under 35 U.S.C. 132, whichever occurs first, and ending on the date of mailing of a subsequent notice of allowance under 35 U.S.C. 151;[12]

This amendment would exclude (in cases in which an RCE has been filed) *all* post-allowance examination time from PTA calculation as "time consumed by continued examination." While the Federal Register Notice cites *Novartis* as holding that "the time consumed by continued examination does not include the time after a notice of allowance, unless the Office actually resumes examination of the application after allowance,"[13] the *Novartis* case did not involve prosecution reopening after allowance and this issue was not specifically addressed by the court.[14]

> [W]e agree with Novartis on its second § 154(b)(1)(B) issue. Novartis argues that the "time consumed by continued examination" should be limited to the time before allowance…. 740 F.3d. at 601-02 (underlined emphasis added).

12 79 Fed. Reg. 34685 (June 18, 2014) (underlined emphasis added).

13 79 Fed. Reg. 34682 (June 18, 2014).

14 In fact, the court stated:

> The possible existence of these exceptional cases [of prosecution being reopened after allowance] does not support a general rule excluding time between allowance and issuance. In the present case, time after allowance was not time caused by continued examination. 740 F.3d. at 602.

The Federal Circuit held in *Novartis* that when calculating patent term adjustment, "[t]here is no basis for distinguishing a continued-examination case."[15] In PhRMA's view, the PTO's proposed addition to 37 C.F.R. § 1.703(b)(1) improperly distinguishes the treatment of post-allowance examination based on whether an RCE has been filed. Under the proposed amendment, if an RCE is filed, any post-allowance examination time does not earn B delay whereas, if an RCE had not been filed, this post-allowance examination time would earn such delay (if it occurs more than three years after the application was filed). Neither 35 U.S.C. § 154(b)(1)(B) nor the *Novartis* holding supports this distinction.

The PTO's proposed rule is particularly troubling because it would prevent PTA from accruing if prosecution is reopened after allowance, regardless of whether such prosecution was reopened by the applicant (e.g., through the filing of a request for continued examination) or reopened by the PTO. Under the proposed rule, the PTO could reopen prosecution (e.g., to consider a reference that was cited after allowance *or of its own initiative*) and the applicant would not receive B delay for this additional time. This result is inconsistent with the Federal Circuit's emphasis in *Novartis* on providing B delay for time "plainly attributable to the PTO,"[16] and with the PTO's position in that case that B delay is based on "whether certain delays are attributable to the PTO."[17] The PTO's proposed rules should be amended at least to provide that any post-allowance examination time due to reopening of prosecution by the PTO should be included in the calculation of B delay.

II. The PTO's Proposed Amendment To 37 C.F.R. § 1.704(c) Is Unnecessary And Should Not Be Adopted.

The PTO's proposed addition to 37 C.F.R. § 1.704(c) should also not be adopted. The proposal appears to indicate that the filing of an RCE after allowance will result in a deduction from the total PTA award corresponding to the number of days between the first notice of allowance and the subsequent RCE, an issue that was also not addressed by *Novartis*. Such a rule is unnecessary and also penalizes applicants when filing RCE's such as in order to cite material references after allowance. Furthermore, it is unclear whether this amendment applies regardless of whether there is any B delay. If the amendment applies to all applications, regardless of whether any B delay is awarded, then it is overly broad.

III. Conclusion

PhRMA appreciates the PTO's efforts to implement the Federal Circuit's decision in *Novartis v. Lee* and the opportunity to offer its perspective on the PTO's proposals. PhRMA and its member companies are committed to helping the PTO find solutions to the many challenges it faces today and in the years to come.

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15 *Id.*
16 *Id.*
17 *Id.*