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July 9, 2018

VIA EMAIL: PTABNPR2018@uspto.gov

The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
600 Dulaney Street
PO Box 1450
Alexandria, VA 22313

Attention: Vice Chief Administrative Patent Judges Michael Tierney and Jacqueline Wright Bonilla, PTAB Notice of Proposed Rulemaking 2018

Re: Docket No. PTO-P-2018-0036

Dear Director Iancu:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the enclosed views of PhRMA's members in response to the proposal on "Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board." PhRMA's members appreciate the USPTO seeking comments on the proposed changes.

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

Respectfully submitted,

David E. Korn

Enclosure

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Comments of the Pharmaceutical Research and Manufacturers of America on the USPTO's Request for Comments on Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board (Docket No.: PTO-P-2018-0036)

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents leading biotechnology and pharmaceutical companies that are dedicated to researching and developing new and improved medicines. PhRMA appreciates the work of the United States Patent and Trademark Office ("USPTO" or "Office") in providing incentives for innovation in biopharmaceuticals and other sectors, and the ongoing work to consider potential reforms to Patent Trial and Appeal Board (PTAB) procedures.

Intellectual property protections are essential for biopharmaceuticals given the costly, lengthy and risky process for discovering, developing, and obtaining FDA approval for medicines. The U.S. biopharmaceutical industry supports more than 4.74 million jobs across the economy and is the single largest funder of domestic business research and development (R&D). While medicines developed by the industry have produced large improvements in health across a broad range of diseases, they come with significant costs and risks for these developers. Indeed, developing one new medicine takes over a decade and costs an average of $2.6 billion. Our members spent $65.5 billion in 2016 alone researching and developing medicines.

It is important that the USPTO maintain the intellectual property protections afforded by the Patent Act in order to foster research and development of innovations that benefit patients. Reducing intellectual property protections would lead to reduced incentives for innovation throughout the biopharmaceutical ecosystem.

PhRMA submits that improvements to PTAB proceedings are necessary to make them more fair and balanced, provide due process protections for patent owners, and give greater certainty for investment in new technologies. Inter partes review ("IPR") proceedings and post-grant review ("PGR") proceedings were created by the America Invents Act ("AIA") in 2011. However, the implementation of the proceedings has raised uncertainty concerning patent protections, reduced the reliability of patents, increased costs through duplicative proceedings, and limited the ability to protect important innovations. The proceedings should be improved to avoid reducing incentives for innovation in biopharmaceuticals and other important technologies.

As such, we appreciate the USPTO's proposing changes to the claim construction standard used in IPR, PGR, and CBM proceedings.[1] We believe the changes, if implemented,

[1] 83 Fed. Reg. 21221 (May 9, 2018).

would be a significant step toward making the proceedings more predictable[2] and more like the alternative to court proceedings intended by Congress.[3]

I. PhRMA Supports the Proposal to Modify the Claim Construction Standard Applied in IPR and PGR Proceedings for Non-Expired Patents

PhRMA supports the USPTO's proposal to revise its regulations to mandate that the PTAB apply the same claim construction standard in IPR and PGR proceedings as that applied by district courts.[4] The USPTO has the authority to modify the claim construction used in IPR and PGR proceedings[5] from the broadest reasonable interpretation standard ("BRI") to the *Phillips*-type claim construction standard applied by district courts.[6] The *Phillips* claim construction standard is more appropriate for IPR and PGR proceedings than the BRI standard because, in contrast to prosecution of patent applications, IPR and PGR proceedings are after patent issuance and more adjudicative like a court proceeding.[7] Thus, the claim construction standard used in IPR and PGR proceedings should be the same as that used in federal courts.

The BRI standard currently applied by the PTAB is broader than the *Phillips* claim construction standard applied by a district court. This difference in claim construction standards can lead to multiple challenges and inconsistent results between IPR and PGR proceedings and federal court proceedings, and subject patent owners to unpredictable results. Having the same claim construction standard in IPR and PGR proceedings as in district court reduces the risk of these inconsistent results.

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[2] Director Iancu recognized the need for predictability in the patent system when addressing the Committee on the Judiciary of the U.S. House of Representatives on May 22, 2018, in stating, "we are focused on enhancing the country's innovation ecosystem and providing strong, reliable and predictable intellectual property rights. In order for the intellectual property system to function as intended, rights owners and the public alike must have confidence in the system. When patent owners and the public have confidence in the patents we grant, inventors are encouraged to invent, investments are made, companies grow, jobs are created, science and technology advance." *See* https://judiciary.house.gov/wp-content/uploads/2018/05/Director-Iancu-Testimony.pdf.

[3] *See e.g.*, 157 Cong. Rec. S1348, S1350 (daily ed. Mar. 8, 2011) (statement of Sen. Patrick Leahy) (noting that the purpose of the AIA was to "streamline the current 'inter partes' system so that it will be a more efficient alternative to litigation."); Senate Debate, 157 Cong. Rec. S5347, S5354, (daily ed. Sept. 7, 2011) (Statement of Administration Policy on H.R. 1249) (discussing how the AIA created new trial proceedings ―to increase the quality and certainty of patent rights and offer cost-effective, timely alternatives to district court litigation.").

[4] 83 Fed. Reg. 21221, 21225-26, proposed 37 C.F.R. §§ 42.100(b) (for IPR proceedings); 42.200(b) (for PGR proceedings).

[5] *See, e.g., Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016) (finding that the AIA allows the USPTO to issue rules regarding claim construction in *inter partes* review proceedings).

[6] Federal courts apply the claim construction standard outlined in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) (claim terms should be given "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention").

[7] *See, e.g., Idle Free Systs. v. Bergstrom, Inc.*, IPR2012-00027, Paper 26, at 7 (PTAB June 11, 2013) ("An *inter partes* review is neither a patent examination nor a patent reexamination."); *see also Abbott Labs v. Cordis Corp.*, 710 F.3d 1318, 1326 (Fed. Cir. 2013) (The AIA "convert[ed] inter partes reexamination from an examinational to an adjudicative proceeding.") (internal quotation omitted).

By modifying the claim construction standard to be the same in IPR and PGR proceedings as in district court proceedings, the USPTO would promote greater efficiency by reducing the dual-track challenges to patent validity. Creating one uniform standard for claim construction in IPR, PGR, and district court proceedings also would reduce the potential for inconsistent outcomes between IPR and PGR proceedings and district court proceedings, reduce uncertainty for patent owners, decrease costs associated with litigating different standards based upon the tribunal, and promote fairness of the patent system.[8] It also would provide greater predictability for the general public, better serving the public notice function of patents, by providing a more consistent framework after patent issuance.

Under the *Phillips* claim construction standard, unless the patent applicant has specifically defined the claim terms, the PTAB should give the words of a claim their "ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application."[9] Importantly, "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification."[10] In other words, the PTAB should "focus at the outset on how the patentee used the claim term in the claims, specification, and prosecution history, rather than starting with a broad definition and whittling it down." In doing so, "the risk of systematic overbreadth is greatly reduced."[11] The PTAB should take into account how the applicant and the Office used the claim terms during examination and all other relevant proceedings before the Office.

PhRMA also supports the proposal that the same standard should apply to claims subject to a motion to amend. It is possible that amended patent claims could be substituted into pending litigation, so the same considerations about comity with courts should apply as for original claims in a patent. In addition, it would be more efficient to have PTAB judges apply the same standard for claim construction for all claims in all PTAB trials and avoid confusion among different claims or different proceedings.

II. The USPTO Should Consider Prior Claim Constructions by Courts

PhRMA believes that the USPTO should not be considering claim construction *de novo* when a court has previously construed the claims. Courts undertake a full analysis of the construction of claims, based on a more complete record than would be available to the PTAB. The construction by a court can thus be more robust, and the PTAB should at a minimum

[8] As Senator Leahy explained, the purposes of the AIA were to "establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs, while making sure no party's access to court is denied." 157 Cong. Rec. S5322, S5327 (daily ed. Sept. 6, 2011). As Senator Kyl further explained, "[t]he overarching purpose and effect of the [AIA] is to create a patent system that is clearer, fairer, more transparent, and more objective." 157 Cong. Rec. S5319 (daily ed. Sept. 6, 2011).

[9] *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*).

[10] *Id.*

[11] *Id.* at 1321.

consider and give deference to it.[12] As such, if the PTAB considers a prior court construction but decides to apply a different construction than the one adopted by a district court, then the PTAB should provide an explanation for this different construction. This would help avoid a situation where a district court construes a claim in such a way that it is found valid and infringed, but later found invalid by the PTAB due to the failure to adopt the court's claim construction.

III. Conclusion

PhRMA appreciates the USPTO's proposal and supports prompt finalization and implementation of the proposed regulations. PhRMA believes that the proposed new claim construction standard should apply to all claim constructions by the PTAB in IPR, PGR, and CBM proceedings after the effective date. PhRMA and its member companies are committed to helping the USPTO find solutions to the many challenges it faces now and in the future.

[12] Since *Markman*, it is well established that claim construction is a matter of law. ("The first is a question of law, to be determined by the court, construing the letters-patent, and the description of the invention and specification of claim annexed to them." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384 (1996)). Given that claim construction is ultimately a question of law, the PTAB should defer to a prior court construction when construing claims.