

July 9, 2018

Submitted Via email: PTABNPR2018@uspto.gov

Mail Stop Patent Board
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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

**Re: Amgen’s Comments on Changes to the Claim Construction Standard for Interpreting Claims in
Trial Proceedings Before the Patent Trial and Appeal Board; Fed. Reg. Vol. 83, No. 90 (May 9,
2018), Docket Number PTO-P-2018-0036**

Dear Judge Tierney and Judge Bonilla:

Amgen Inc. provides the following comments in response to the notice identified above and thanks the United States Patent and Trademark Office (“the USPTO” or “the Office”) in advance for its thoughtful consideration of these comments.

Our country has just reached the historic milestone of the 10 millionth issued U.S. patent, a celebration of one of the greatest drivers of innovation in history—the U.S. patent system. Amgen applauds the efforts of the Office to propose and enact rules and policies that increase the incentives for innovation and the value of patents.

Amgen supports patent rules that provide certainty, uniformity, and predictability to the public, and for these reasons, Amgen supports the proposed changes to the claim construction standard in proceedings before the USPTO’s Patent Trial and Appeal Board (“PTAB”). The current standard used by the PTAB, the broadest reasonable interpretation (“BRI”) standard, encourages multiple challenges and dual track strategies that increase the costs, uncertainty and inefficiencies of contesting a patent. The proposed rule change will have the PTAB apply the same standard as used by the courts in patent litigation and will promote greater certainty, consistency and efficiency in challenging patents, and will provide a more fair outcome for the patentee, the challengers and the public.

About Amgen

Established in 1980 as a biotech start-up, Amgen became a pioneer in the biotechnology industry and has grown to be one of the world's leading biotechnology companies. Amgen has developed many first-in-class, breakthrough therapies used to treat millions of patients around the world. Amgen continues its commitment to serve patients by researching human biology to invent and develop new therapeutic products for the benefit of patients suffering from serious illness in areas of high unmet medical need. As one example, Amgen recently launched a new, first-in-class product to treat migraines that acts on a different biological pathway than prior treatments, bringing new hope to those patients suffering the debilitating effects of migraines.

Amgen holds over a thousand U.S. patents directed to a wide array of inventions in many different areas of scientific research. Similar to other companies in our industry, Amgen's business model depends on securing patents to protect the large investment of time and resources to discover, develop and bring to market new breakthrough therapies. Amgen's success would not have been possible without a strong, reliable patent system to protect its inventions.

The Proposed Change from the BRI to the *Phillips* Claim Construction Standard

The Leahy-Smith America Invents Act ("AIA") was signed into law in 2011 and, among other things, provides for post-grant proceedings before the USPTO's PTAB. These proceedings allow challenges to issued patents outside of patent litigation in the courts and were intended to improve efficiency in our patent system and reduce overall costs in patent challenges. Due in large part to parallel proceedings that now occur with potentially different outcomes, the cost to challenge patents has increased, unpredictability has been introduced into the U.S. patent system, and overall efficiency has decreased – just the opposite of what Congress intended.

The main reason for this increased uncertainty and inefficiency is the different claim construction standard applied by the PTAB as compared to the standard used in patent litigation in the courts. A patent can be upheld by the courts only to be invalidated by the PTAB applying a broader construction of the patent claims. This gives patent infringers multiple attempts to invalidate a patent by pursuing challenges both in the courts and before the PTAB. Not only does this increase the cost and inefficiencies of the patent system but it weakens the system and the overall value of patents. The proposed rule would change the claim construction standard in PTAB proceedings to adopt the same standard used by the courts—*i.e.*, the *Phillips* standard.¹

Amgen agrees that standardizing PTAB proceedings by using the *Phillips* standard for claim construction is the proper course of action. This change will reduce the number of duplicate challenges in the courts and the PTO as patent challengers will be more likely to select a single forum instead of pursuing a multi-track approach. In cases involving both PTAB and court proceedings, the change will also promote efficiency, as the judges in one forum can rely on prior claim construction

¹ *Phillips v. AWH Corporation*, 415 F.3d 1303 (Fed. Cir. 2005)

decisions of the other because they are applying the same standard. Thus, this change will improve consistency and predictability of the patent grant as well as increasing judicial efficiency.

Implementation of the New Standard

The Notice provides the following summary of how the *Phillips* standard and progeny decisions would be followed:

“ . . . including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. This proposed change would replace the BRI standard for construing unexpired patent claims and proposed claims in IPR, PGR, and CBM proceedings with an approach that follows the framework set forth in *Phillips*.”²

In *Phillips*, the court set forth a standard with several factors to consider when interpreting the scope and meaning of a claim. “The Office would apply the principles that the Federal Circuit articulated in *Phillips* and its progeny.”³ It is Amgen’s understanding that, as stated, the complete *Phillips* framework will be followed, as will later Federal Circuit decisions stemming from *Phillips*. The focus of the courts’ approach to claim construction is how a person of skill in the relevant technical field would understand and apply the claim term using the patent specification and prosecution history of the patent as the primary guide. Absent an effort by the patentee to define a term differently, a claim term is given its ordinary and customary meaning as used in the field. Relevant scientific publications and appropriate expert input can assist in illuminating this meaning. Amgen agrees that this is the correct manner to implement this new rule.

Additionally, as articulated in The Notice, applying the *Phillips* standard to proposed claim amendments during a post-grant proceeding is the most reasonable approach to take. This approach should result in greater consistency in claim interpretation throughout the proceedings, which in turn facilitates fairness, predictability, and efficiency in the patent system.

The Notice proposes that the *Phillips* standard will apply “to all pending IPR, PGR, and CBM proceedings before PTAB.”⁴ Amgen agrees that the PTAB should apply this new standard to all proceedings still pending before the PTAB. If a different claim construction would make a difference in the outcome before the PTAB, the PTAB should apply the new standard and make the decision right.

Predictably, there might be some inconveniences initially after the new rules go into effect. Cases that are still pending, but that have progressed far into the proceeding may require a new round of briefing and quite possibly new hearings. Other cases may, at the very least, require allowances for additional pages in submissions. However, these cases would be cleared in due course over the short term and all new cases would start off under the new standard. Accordingly, Amgen agrees that the proposal to apply the new rules to all pending proceedings before the PTAB is the appropriate course of action.

² Fed. Reg. Vol. 83, No. 90 (May 9, 2018), p.21223, 2nd col., 2nd par.

³ Fed. Reg. Vol. 83, No. 90 (May 9, 2018), p.21223, 2nd col., 3rd par.].

⁴ Fed. Reg. Vol. 83, No. 90 (May 9, 2018), p.21224, 1st col., 3rd par.].

Conclusion

At a time in our country's history where we are well into another technological revolution in every technology area imaginable, particularly a biological revolution, bolstering our existing patent system and striving to improve it is critical to support and nurture future innovation. Amgen commends the USPTO for the proposed claim construction rule change, and thanks the Office and the Director for the opportunity to provide comment. Amgen supports this proposed change from the BRI standard to the *Phillips* standard for all cases currently pending with the PTAB. Amgen looks forward to working with the Office in the future to continue to help in improving and optimizing our patent system.

Respectfully Submitted,



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