

December 21, 2018

Submitted Via email: TrialRFC2018Amendments@uspto.gov

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

Attention: Acting Deputy Chief Administrative Patent Judge Jacqueline Wright Bonilla or Vice Chief Administrative Patent Judges Michael Tierney, PTAB Request for Comments 2018

Re: Amgen's Comments on Proposed Motion to Amend Practice and Procedures in Trial Proceedings Before the Patent Trial and Appeal Board; Fed. Reg. Vol. 83, No. 209 (October 29, 2018), Docket Number PTO-P-2018-0062

Dear Judge Bonilla and Judge Tierney:

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.

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 amendment procedure in proceedings before the USPTO's Patent Trial and Appeal Board ("PTAB"). The proposed changes will continue to promote greater 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 biopharmaceutical 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.

AMGEN'S RESPONSES IN REPLY TO QUESTIONS REGARDING THE PROPOSED AMENDMENT PROCESS AND PILOT PROGRAM FROM USPTO REQUEST FOR COMMENTS

1. Should the Office modify its current practice to implement the proposal summarized above and presented in part in Appendix A1? Why or why not?

Yes, Amgen supports the Office's modification of current practice to implement the proposed changes. These changes to the claim amendment practice at the PTAB are a welcome improvement to the process, and should continue the Director's efforts to improve AIA trial proceedings. Amgen does, however, have concerns and suggested improvements that are discussed further below in the various responses.

2. Please provide comments on any aspect of the proposed amendment process, including, but not limited to, the content of the papers provided by the parties and the Office and the timing of those papers during an AIA trial.

Receiving a Preliminary Decision on the Motion to Amend prior to the Patent Owner reply being due is a welcome proposal. This should make the process fairer for all parties and allows the proposed timeline to function as intended, as the Parties have a chance to prepare arguments related to the claims sooner, rather than later in the process.

Additionally, we submit that the substitute claims could, at the election of the Patent Owner, be treated in a contingent manner, i.e., the amendments are only entered and reviewed if the original claims are held invalid. We support the Office's proposal that the Patent Owner should be allowed further changes to the proposed amendments if required. This approach will result in the most efficient use of the Office's time and resources but facilitate a fair outcome in the proceedings.

The Motion to Amend could be supported by declaratory evidence as necessary to support the patentability of the amended claims.

3. How does the timeline in Appendix A1 impact the parties' abilities to present their respective cases? If changes to the timeline are warranted, what specific changes are needed and why?

We believe that the proposed timeline—*although tight*—should allow adequate time for the Parties to respond to the issues raised by any proposed amendments. Additionally, the Director has discretion under the statute to extend the timeline of an AIA trial by up to six months, and this should be freely utilized if the proposed amendments require more fulsome consideration.

4. If the Office implements this proposal, should the Board prepare a preliminary decision in every proceeding where a patent owner files a motion to amend that proposes substitute claims?

Yes, a written preliminary decision should be prepared by the Board in every proceeding where a patent owner files a motion to amend that proposes amended claims including those submitted on a contingent basis.

5. What information should a preliminary decision include to provide the most assistance to the parties in presenting their case? For example, is there certain information that may be particularly useful as the parties consider arguments and evidence to present in their papers, how issues may be narrowed for presentation to the Board, and/or whether to discuss a settlement?

The Board's preliminary decision should set forth a preliminary opinion on patentability of the amended claims. This decision should discuss any prior art that is applied and how the prior art does or does not renders the claims unpatentable. In content, the preliminary opinion might be similar to the decision on institution of the proceedings in analyzing the Petitioner's arguments of unpatentability based on the prior art of the proposed amended claims.

6. If the Office implements this proposal, should there be any limits on the substance of the claims that may be proposed in the revised motion to amend? For example, should patent owners be permitted only to add limitations to, or otherwise narrow the scope of, the claims proposed in the originally-filed motion to amend?

Any revisions requested in a revised motion to amend the claims should be limited to address issues or objections raised by the Petitioner or in the Board's preliminary decision. While generally these may be narrowing revisions to the originally proposed amendments, some revisions might include a change to a word or phrase that provides greater clarity, or has better support in the specification, and such revisions should not be strictly scrutinized as whether it is a narrowing revision or not. The point is to arrive at a valid patent claim in light of the art cited in the proceeding and not to create some procedural hurdles that end up as traps for the Patent Owner.

7. What is the most effective way for parties and the Office to use declaration testimony during the procedure discussed above? For example, how and when should parties rely on declaration

testimony? When should cross-examination of declaration witnesses take place, if at all, in the process? At what stage of briefing should a party be able to rely on cross-examination (deposition transcripts) testimony of a witness?

The parties should be permitted to submit declaration testimony, including cross-examination of declaration witnesses, to support their respective positions on a Motion to Amend. Normally, such declaratory witnesses should be made available for deposition after filing such declarations and before the responsive pleading is filed. In some instances, these depositions could take place after the preliminary opinion and before the Patent Owner's response in the proceeding.

8. If a petitioner ceases to participate in an AIA trial and the Board solicits patent examiner assistance regarding a motion to amend, how should the Board weigh an examiner advisory report relative to arguments and evidence provided by a patent owner? What type of assistance or information should a patent examiner provide? Should prior art searches by examiners be limited to those relevant to new limitations added to proposed substitute claims and reasons to combine related to such limitations?

The Board should give careful consideration to an Examiner's report, but should not provide it with any more or less weight as compared to arguments and evidence provided by the Patent Owner. The Examiner's report should be limited to only references relevant to the new limitations in the amended claims.

9. Should the Board solicit patent examiner assistance in other circumstances, and if so, what circumstances? For example, should the Board solicit patent examiner assistance when the petitioner remains in the AIA trial but chooses not to oppose the motion to amend?

Yes, if the Board feels this additional assistance is needed.

10. Should a motion to amend filed under the proposed new process be contingent or non-contingent? For purposes of this question, "contingent" means that the Board will provide a final decision on the patentability of a proposed substitute claim only if it determines that a corresponding original claim is unpatentable (as in the current proposal); and "non-contingent" means that the Board will provide a final decision on the patentability of substitute claims in place of determining the patentability of corresponding original claims.

We submit that it is an important aspect of the process that, at the Patent Owner's election, a motion to amend may be made contingent on a decision finding the original corresponding claim to be unpatentable. In some instances, however, the Patent Owner may elect to substitute the claims by amendment, i.e., a non-contingent motion, and not seek a decision on the original claims. Providing this option to the Patent Owner will focus and streamline the amendment process.

11. If the Office implements the proposal in which the Board issues a preliminary decision on a motion to amend, as discussed above, should any additional changes be made to the current default trial schedule to accommodate the new practice?

See above answers to Questions 2 and 3.

12. What impact would implementing the proposals above have on small or micro entities who participate as parties in AIA trial proceedings?

It is quite possible, if not expected, that there will be cost increases associated with implementing the proposals during an AIA trial proceeding. However, these increases may ultimately result in a less expensive process for all parties.

13. Should the Office consider additional options for changing the timing and/or the Board's procedures for handling motions to amend that are not covered by the proposals above? If so, please provide additional options or proposals for the Office to consider, and discuss the advantages or disadvantages of implementation.

See the answers provided in Questions 2, 3 and 11.

14. Should the Office consider not proceeding with the pilot program in AIA trials where both parties agree to opt-out of the program?

If both parties agree to opt-out, this pilot program should not be used.

AMGEN'S RESPONSES IN REPLY TO QUESTIONS REGARDING POTENTIAL RULEMAKING TO ALLOCATE BURDEN OF PERSUASION AS SET FORTH IN THE WESTERN DIGITAL ORDER

15. Should the Office engage in rulemaking to allocate the burden of persuasion regarding the patentability of proposed substitute claims in a motion to amend as set forth in the Western Digital order? What are the advantages or disadvantages of doing so?

No rulemaking should be necessary to implement the direction provided by the court in Western Digital. The Board can provide its understanding of the impact of Western Digital in its decisions on motions to amend.

16. If the Office continues to allocate the burden as set forth in the Western Digital order, under what circumstances should the Board itself be able to justify findings of unpatentability? Only if the petitioner withdraws from the proceeding? Or are there situations where the Board itself should be

able to justify findings of unpatentability when the petitioner remains in the proceeding? What are the advantages or disadvantages?

The Board should use any evidence in the record to determine unpatentability, regardless of whether a Petitioner continues to participate or not.

17. If the Office adopts the current proposal including a preliminary decision by the Board on a motion to amend, do the answers to questions 15 and 16 change?

No.

Conclusion

Amgen commends the Office for its continued efforts to improve our patent system, most recently with the proposed revisions to PTAB trials motion to amend practice. The goal of the amendment process is to allow the Patent Owner to secure protection for patentable subject matter. Amgen believes that these proposals make great strides in accomplishing that goal. We thank the Office and the Director for the opportunity to provide comment, and we look forward to working with the Office in the future to continue to help in improving and optimizing our patent system.

Respectfully Submitted,



Stuart L. Watt
Vice President, Law & Intellectual Property Officer
Amgen Inc.



Michael G. Penn
Principal Counsel
Amgen Inc.