



A Member of the Roche Group

December 23, 2019

The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property
and Director of the U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
Via MTABurden2019@uspto.gov

RE: Comments of Genentech, Inc. (“Genentech”) in Response to the USPTO’s Proposed Rules of Practice To Allocate the Burden of Persuasion on Motions To Amend in Trial Proceedings Before the Patent Trial and Appeal Board (Docket No.: PTO-P-2019-0011)

Dear Director Iancu:

Genentech appreciates the United States Patent and Trademark Office’s (“USPTO” or “Office”) continuous efforts toward fostering innovation and strengthening the U.S. patent system as a whole. We also applaud the USPTO’s dedication to ensuring that post-grant trial proceedings adequately protect the incentives to innovate. We are grateful for the opportunity to work with the Office to develop balanced and fair post-grant trial proceedings that accomplish such goals and we thank the Office for the opportunity to submit the following comments in connection with the USPTO’s Notice of Proposed Rulemaking on Rules of Practice To Allocate the Burden of Persuasion on Motions To Amend in Trial Proceedings Before the Patent Trial and Appeal Board (“Board”) (the “Notice”). 84 Fed. Reg. 56,401 (Oct. 22, 2019).

With 15,000 employees dedicated to making life-saving medicine a reality, Genentech has been a consistent stakeholder in the U.S. patent system for over 40 years. This commitment combined with the dedication of our scientists and researchers has generated over 20,000 U.S. patents. Today, Genentech has over 40 medicines on the market and a promising development pipeline. Continuation of this search for solutions to the toughest medical challenges depends on a stable and predictable patent system that rewards innovation and allows companies like Genentech to focus their resources on research and development.

A predictable patent system also requires stability in post-grant trial proceedings, which is why our comments below specifically address “instances where a party does not meet its burden, [and] the Board may, in the interests of justice, justify a determination regarding the patentability of amended claims based on the record as a whole.” 84 Fed. Reg. 56,401. In particular, we urge the USPTO to exercise caution as to when the Board exercises its discretion to step in “in the interests of justice.”

Sua Sponte Board Action “in the Interest of Justice” Should Be Rare

First, as “anticipated by the Office” in the proposed rule, we agree that in the instance where a party does not meet its burden and where the Board may step in “in the interest of justice” to justify a determination regarding the patentability of amended claims based on the record as a whole, the Board should step in to evaluate a motion to amend that is unopposed or considered to be insufficiently opposed by a petitioner *only in rare circumstances*. See 84 Fed. Reg. at 56,404 (emphasis added) (“The Office anticipates that the Board will exercise such discretion only in rare circumstances.”).

Post-grant proceedings were deliberately established by Congress to be adjudicatory in nature where the petitioner dictates the bounds of the proceeding. See H. Rep. 112-98, at 42 (2011) (“The Act converts inter partes reexamination from an examinational to an adjudicative proceeding...”); see also *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018) (“Congress chose to structure a process in which it’s the petitioner, not the Director, who gets to define the contours of the proceeding.”) Accordingly, so long as a petitioner does not oppose a motion to amend, there is little if any basis for the Board to do so on the petitioner’s behalf.

If the Board Steps In, the Patent Owner Must Be Allowed a Substantive Response

Second, if the Board does step in “in the interest of justice,” and to the extent that any new or previously unaddressed issues are raised, the patent owner must be provided with a meaningful opportunity to respond to such issues.

We believe that the Board, asserting its authority “in the interest of justice,” should not be allowed to raise any new issues of patentability or additional evidence relating to a motion to amend. However, if the Board *is* permitted to raise new issues or evidence at all, such issues and evidence should be presented in writing and the patent owner then afforded an opportunity to respond to such evidence in writing and at oral hearing before any final written decision is promulgated. Allowing the patent owner a meaningful opportunity to respond is consistent with Administrative Procedure Act protections, due process, and the interests of justice to the patent owner.

Lastly, we believe that any decision by the Board to intervene *sua sponte* should provide a “good cause” basis for extending the 12-month statutory deadline. See 37 C.F.R. § 42.100(c) (providing that the 12-month deadline “can be extended by up to six months for good cause by the Chief Administrative Patent Judge”). Allowing such Board intervention to be considered “good cause” for extending the statutory deadline necessarily reciprocates the “interest of justice” for the patent owner to adequately respond to the Board.

Conclusion

Again, we thank the USPTO for its dedication to ensuring that the post-grant trial proceedings adequately protect the incentives to innovate. We appreciate the opportunity to comment on

this proposed rule and look forward to continuing the discussion on how to develop balanced and fair post-grant trial proceedings that accomplish these goals.

We would be glad to provide any additional information, and welcome any questions or comments that you may have.

Best regards,

/Laurie L. Hill/

Laurie L. Hill
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