Genentech
A Member of the Roche Group

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The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
600 Dulany Street
P.O. Box 1450
Alexandria, Virginia 22313

Via Electronic Mail to: TrialRFC2018Amendments@uspto.gov

Comments of Genentech, Inc., Roche Diagnostics Operations, Inc., and Roche Diabetes Care, Inc. on the Patent and Trademark Office's Request for Comments on Motion to Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board

Docket No. PTO-P-2018-0062

Dear Director Iancu:

Genentech, Inc., Roche Diagnostics Operations, Inc., and Roche Diabetes Care, Inc. appreciate the opportunity to respond to the U.S. Patent and Trademark Office's ("PTO") request for comments on motions to amend in trial proceedings under the America Invents Act ("AIA") before the Patent Trial and Appeal Board ("Board").[1]

As a leading biotechnology company with over 15,000 employees dedicated to making life-saving medicine a reality, Genentech, a member of the Roche Group, has been a consistent stakeholder in the U.S. patent system for over 40 years.[2] This commitment, combined with the dedication of our scientists and researchers, has generated over 20,000 patents. Today, Genentech has 38 medicines on the market and a promising development pipeline. Continuing our search for solutions to the toughest medical challenges depends on a stable, fair, and predictable patent system that rewards innovation and allows companies like Genentech to focus their resources on research and development.

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[1] 83 Fed. Reg. 54,319 (Oct. 26, 2018).

[2] Genentech, Inc., *Company Information*, http://www.gene.com/media/company-information (last visited Nov. 19, 2018).

As a global leader in healthcare, Roche Diagnostics offers a broad portfolio of tools that help healthcare providers in the prevention, diagnosis and management of diseases like HPV, HIV, hepatitis and diabetes as well as other medical conditions, such as fertility and blood coagulation. These products and services are used by researchers, physicians, patients, hospitals and laboratories worldwide to help improve people's lives. Roche Diagnostics Operations is home to U.S. research and development, laboratory, manufacturing, distribution, IT and administrative operations.

Roche Diabetes Care is dedicated to improving the health and lives of people with diabetes by offering individuals and healthcare professionals innovative products and impactful solutions for convenient, effective, and efficient diabetes management. Our products and services include glucose monitoring devices, insulin delivery systems, and digital health solutions, comprising data management, advice, coaching, and education.

Based on their extensive experience in *inter partes* review ("IPR") proceedings, Genentech, Roche Diagnostics Operations and Roche Diabetes Care (collectively referred to herein as "Genentech") believe that the steps outlined by the PTO in the proposed rulemaking will greatly improve the amendment process and IPRs generally.[3] Congress envisioned that patent owners would have a meaningful opportunity to amend claims at risk of being declared unpatentable and, where possible, emerge from IPR proceedings with intact claims that reflect the inventors' contributions over the prior art. As the PTO's data indicate, that vision has not been realized in practice, with few motions to amend filed and even fewer granted.

The proposal to provide a preliminary, non-binding decision from the Board on the patentability of proposed amendments, followed by the opportunity to submit a second set of claim amendments, will help reinvigorate the amendment process and improve balance in IPRs. It will provide important feedback that allows patent owners to fix correctable problems or address misconceptions about proposed amendments before a final decision is made. It will also help reduce the pressure patent owners face in a one-step amendment process to overcompensate and sacrifice legitimate claim scope in an effort to guarantee that any proposed claim amendments are narrow enough to be accepted. Genentech appreciates the leadership that the PTO has demonstrated and hopes the new amendment system will be implemented quickly. Genentech also agrees that because amendments can only narrow previously granted claims, the burden should continue to be placed on the petitioner to prove the unpatentability of substitute claims.[4]

One aspect of the proposal which Genentech respectfully urges the PTO to reconsider is the statement that "[g]enerally, the Board will render a final written decision only as to the

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[3] Since 2014, there have been 73 petitions for IPR filed against Genentech alone. These petitions involved 27 different patents. Several of the instituted IPRs have involved motions to amend that were not granted.

[4] *Western Digital Corp. v. SPEX Techs., Inc.*, IPR2018–00082 (Paper 13) (P.T.A.B. April 25, 2018)

latest-filed version of the patent owner's motion to amend and substitute claims proposed therein." Genentech suggests that, where requested, the Board should consider both the original motion to amend and the revised motion to amend in the final written decision. Otherwise, the dilemma between requesting the full claim scope to which a patent owner is entitled and seeking to narrow the claims to maximize the chances of the amendments being allowed will continue, as the patent owner decides whether to respond to a preliminary decision by defending its original amendments or abandoning those claims in favor of different amendments.

The comments below elaborate on these points and, in the process, respond to questions 1-4, 8-11, 13, and 15-17 regarding the proposed amendment process, pilot program, and allocation of the burden of persuasion.

I. The Current Amendment Process Is Not Working As Intended

Congress envisioned that amendments would be an integral part of IPRs and gave patent owners the opportunity to file at least one motion to amend as a matter of right.[5] As the PTO's General Counsel explained in a 2004 hearing, "[b]y providing for the possibility of amendment of challenged claims, the proposed system would preserve the merited benefits of patent claims better than the win-all or lose-all validity contests in district court."[6] Used properly, amendments can "strengthen and clarify" patents while ensuring the patent owners still receive a benefit proportionate to their contributions to the art.[7]

Yet "the current amendment process in AIA proceedings is not working as intended."[8] Instead of being an iterative process focused on getting to the correct claim scope, the amendment process has become an all-or-nothing contest, which heavily favors petitioners challenging patent validity. "Despite repeated recognition of the importance of the patent owner's right to amend during IPR proceedings—by Congress, courts, and the PTO alike—patent owners largely have been prevented from amending claims in the context of IPRs."[9]

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[5] 35 U.S.C. § 316(d)(1); *see also Aqua Prod., Inc. v. Matal*, 872 F.3d 1290, 1299 (Fed. Cir. 2017) (O'Malley, J., plurality op.) ("Congress deemed the patent owner's right to amend so important that, in § 316(d), it mandated that the patent owner be permitted to amend the patent *as of right* at least once during the course of an IPR, provided certain specified statutory conditions were met.").

[6] *Patent Quality Improvement: Post-Grant Opposition: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 108th Cong. 10 (2004) (statement of PTO General Counsel James A. Toupin).

[7] *Aqua Prod.*, 872 F.3d at 1312 (O'Malley, J., plurality op.).

[8] Andrei Iancu, Director of the U.S. Patent and Trademark Office, *Remarks at the American Intellectual Property Law Association Annual Meeting* (Oct. 25, 2018) (transcript available at https://www.uspto.gov/about-us/news-updates/remarks-director-iancu-american-intellectual-property-law-association-annual) ("Iancu AIPLA Remarks")

[9] *Aqua Prod.*, 872 F.3d at 1312 (O'Malley, J., plurality op.).

The numbers are stark, and Genentech appreciates the PTO's collection of data on the amendment process and transparency in sharing that data. As noted in the Notice of Proposed Rulemaking, two PTO studies found that the vast majority of amendments are rejected.[10] Since the passage of the AIA, of the 189 motions to amend requesting substitute claims that the Board decided, the Board denied the motion in 171 trials, and granted-in-part and denied-in-part in another 11 trials, leaving only 4 percent of motions to amend granted outright. While motions to amend are filed in only about 10 percent of all AIA trials, this is likely in part because "parties have simply stopped even trying to amend the claims because they see the effort as largely futile."[11]

The PTO's findings, which comport with Genentech's own experience and understanding, make clear that reform is needed. As Director Iancu recently said, "to fully implement the intent of the AIA," the amendment process must be "feasible and meaningful . . . It is not in the interest of the patent system as a whole to invalidate a patent entirely if it actually describes patentable subject matter, and appropriately-scoped claims can be drafted."[12]

II. The Proposed Amendment Process And Pilot Program Will Cure Many Current Deficiencies

Genentech strongly supports the PTO's proposal to ensure that the amendment process is more viable and even-handed. Instituting the two-step amendment process described in the proposed rule will generate a number of important benefits for patent owners and petitioners alike, including:

- Ensuring that patent owners who have made a contribution to the art emerge from IPR with the appropriate claim scope, rather than nothing, if there is any problem with the original claims.

- Providing patent owners and petitioners with detailed analysis and guidance before a final decision is reached, thereby increasing transparency and avoiding any undue surprises.

- Allowing patent owners and petitioners a chance to clarify their arguments prior to a final decision.

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[10] 83 Fed. Reg. at 54,320-21. The two studies are: Patent & Trademark Office, *Patent Trial and Appeal Board Motion to Amend Study* (2016), https://www.uspto.gov/sites/default/files/documents/2016-04-30%20PTAB%20MTA%20study.pdf; and Patent & Trademark Office, *Patent Trial and Appeal Board Motion to Amend Study*, https://www.uspto.gov/sites/default/files/documents/PTAB%20MTA%20Study%20%28Installment%204%20-%20update%20through%2003-31-2018%29.pdf (last visited Nov. 19, 2018).

[11] Iancu AIPLA Remarks.

[12] *Id.*

- Promoting earlier and more efficient resolution of IPRs, as parties are better able to judge if claims can and should be narrowed.

- Making patent owners more comfortable with the amendment process, leading to greater use than in the past, when patent owners worried that offering an amendment would be futile or be misconstrued as an admission that their claims were weak.

- Promoting a level playing field, in which IPR is used to strengthen patents, not just invalidate them.

Because the preliminary decision will be so beneficial, the Board should provide one in every proceeding where a patent owner files a motion to amend proposing substitute claims, as the pilot program plans to do.

Genentech further encourages the PTO to transition quickly from a pilot program to a final rule, which will foster long-term stability and certainty. That transition should be accompanied by an opportunity for formal stakeholder review and comment.

III. The Amendment Process Should Be Iterative And Not Force Artificial Decision Points

As supportive as Genentech is of the PTO's proposed rule, it respectfully suggests one improvement. Genentech is concerned that the pathway described in Alternative 1 may unfairly force patent owners to decide between pointing out correctable flaws in the Board's preliminary reasoning and presenting an entirely new revised amendment.[13] Instead of aiding the Board in determining the proper claim scope, this binary choice could instead perpetuate the current frustrations patent owners have with IPR amendments.

Under Alternative 1, if the Board's preliminary decision indicates that the motion to amend fails to meet any statutory or regulatory requirements, or that the petitioner demonstrates a reasonable likelihood of establishing the unpatentability of any proposed substitute claims, the patent owner may either: (1) reply to the petitioner's opposition and argue that the Board made a mistake in its initial review of the proposed amendment (thus sticking with the proposed amendment); or (2) submit a revised motion to amend, modifying the proposed new substitute claims and presenting new arguments for why the revised amendment meets statutory and regulatory requirements and is patentable. The PTO has indicated that generally the final written decision will address only "the latest-filed version of the patent owner's motion to amend and substitute claims proposed therein."[14]

Instead of facing this binary choice, a patent owner should have the option to ask that the Board consider both sets of amendments contingently in the final written decision. That

[13] 83 Fed. Reg. at 54,322-23.

[14] *Id.* at 54,323.

is, both the original amendment with an argument as to why the Board's initial reasoning is mistaken, as well as a new revised amendment, should be considered. While not nearly at the scale of the amendment opportunities in the European Patent Office, this more iterative process would mitigate the problem of forcing the patent owner to drop what could be a meritorious amendment and increase the Board's likelihood of determining the correct claim scope.

Proceeding with two contingent amendments aligns with the AIA. Section 316(d)(2) states that *at least* one motion to amend may be filed as of right and contemplates that "[a]dditional motions to amend may be … permitted by regulations prescribed by the Director."[15] The statute thus provides that the PTO may consider more than one motion to amend, rather than limiting itself to consideration of a single motion. Further, § 316(d)(1) contemplates that a patent owner may, "[f]or *each* challenged claim, propose a *reasonable number* of substitute *claims*."[16] This statutory language—and, in particular, the plural "claims"—contemplates a system in which patent owners offer more than one substitute claim for each original claim from the outset, presenting the Board with a menu of increasingly narrow substitutes that help preserve legitimate claim scope. The PTO, however, has constrained the ability of patent owners to present multiple substitute claims by presuming that "only one substitute claim would be needed to replace each challenged claim" absent "a demonstration of need."[17] Considering up to two amendments in the final written decision would be more consistent with the statutory language allowing a "reasonable number of substitute claims" "for each challenged claim."[18] At the same time, because there would be an opportunity for feedback between each amendment, the process would be more focused and contained than the even greater number of substitute claims arguably contemplated by Congress.

Considering more than one amendment in the final written decision would not impose a significant additional burden on the Board. Many patent owners are likely not to offer a second motion to amend at all, or after being confronted with the Board's preliminary views on the first motion to amend, will realize that the preferable course is to offer a second motion to amend in lieu of the first. Where the patent owner does request that the Board consider two sets of amendments, the Board would have already provided its preliminary views on the first amendment in the preliminary decision, and would only need to consider any responsive arguments to determine whether to adhere to those views or to correct any error identified in its analysis.

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[15] 35 U.S.C. § 316(d)(2).

[16] 35 U.S.C. § 316(d)(1)(B) (emphasis added).

[17] 37 C.F.R. § 42.121.

[18] 35 U.S.C. § 316(d)(1)(B).

IV. Maintaining Good Cause Extensions Follows The AIA's Statutory Scheme

Genentech appreciates the PTO's concern with keeping the proposed pilot process within the normal one-year time limit for an IPR, but understands that the PTO is not precluding the Board from using its discretion to extend individual proceedings where there is good cause to do so. The good cause exception is squarely grounded in the AIA's text. As § 316(a)(11) states, "[t]he Director shall prescribe regulations . . . requiring that the final determination in an inter partes review be issued not later than 1 year after the date on which the Director notices the institution of a review under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months."[19] Although the PTO has proposed a default schedule that makes it possible to complete an IPR within a year, there are likely to be proceedings that warrant additional time. Genentech trusts that the PTO's diligence in crafting a speedy default schedule will not be misconstrued as a signal to individual panels to elevate speed over substance where the circumstances establish good cause for taking additional time to get the outcome right.

V. The Proposed Rule Correctly Limits Patent Examiner Involvement

The PTO's proposal contemplates soliciting patent examiner assistance, at the request of the Board, only when the petitioner ceases to participate altogether and the patent owner files a motion to amend. Genentech agrees that patent examiner involvement is unnecessary in other circumstances. IPR is an adversarial process, and the petitioner has every incentive to identify the most relevant prior art and challenge proposed amendments.

The absence of examiner involvement should not give rise to any concern that a patent emerging from IPR which is challenged in district court will lose its presumption of validity. The Board is more than qualified to conduct a thorough analysis of amended claims in light of the prior art of record. Further, because any amendment must be narrower than the original claim, the Board examines amendments within the footprint of prior approved patentable claims, which were subject to a full examination process and examiner search.[20] In any event, the presumption of validity is statutory and does not depend on whether an

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[19] *See also* 37 C.F.R. § 42.100(c) ("An inter partes review proceeding shall be administered such that pendency before the Board after institution is normally no more than one year. The time can be extended by up to six months for good cause by the Chief Administrative Patent Judge, or adjusted by the Board in the case of joinder.").

[20] *See* 35 U.S.C. § 316(d)(3) ("An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.").

examiner has directly considered a particular piece of prior art.[21] The clear and convincing evidence standard is likewise tied to the statutory presumption of validity.[22]

VI. The Burden Should Be On The Petitioner To Prove Nonpatentability

Genentech supports the PTO's suggestion to promulgate a regulation placing the burden on petitioners to prove the unpatentability of proposed amendments. The fractured decisions in *Aqua Products* left some uncertainty regarding the long-term stability of the rule announced in Judge O'Malley's plurality opinion. Subsequent panel decisions have continued to place the burden on petitioners.[23] But it is important for the patent community to have certainty going forward that the rule will not change.

For all the reasons explained in Judge O'Malley's opinion, it is appropriate—if not required—to place the burden on the petitioner. The statute provides that "the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence." 35 U.S.C. § 316(e). It does not refer narrowly to the burden of challenging the original claims, but rather relates broadly to any "proposition of unpatentability." That includes any argument that amended claims are unpatentable.

It is also important to remember that "[a]n amendment . . . may not enlarge the scope of the claims of the patent or introduce new matter."[24] The question of whether an amendment proposed in IPR is patentable therefore does not arise in a vacuum. An amendment takes claims that were already deemed patentable by the PTO after full examination and narrows them. A challenge to the patentability of an amendment is thus an extension of the petitioner's original challenge, and the burden properly remains on the petitioner to prove unpatentability.

VII. Conclusion

Genentech appreciates the Office's efforts to revisit its rules and increase the fairness and efficiency of the IPR amendment process. Genentech also appreciates the opportunity to offer its perspective on this important issue. We look forward to continuing this helpful

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[21] 35 U.S.C. § 282(a); *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 100 (2011) ("by its express terms, § 282 establishes a presumption of patent validity, and it provides that a challenger must overcome that presumption to prevail on an invalidity defense").

[22] *See Microsoft*, 564 U.S. at 101 ("Our decision in *RCA*, 293 U.S. 1, 55 S.Ct. 928, 79 L.Ed. 163, is authoritative. There, tracing nearly a century of case law from this Court and others, Justice Cardozo wrote for a unanimous Court that 'there is a presumption of validity, a presumption not to be overthrown except by clear and cogent evidence.'").

[23] *Bosch Auto. Serv. Sols., LLC v. Matal*, 878 F.3d 1027, 1040 (Fed. Cir. 2017), *as amended on reh'g in part* (Mar. 15, 2018).

[24] 35 U.S.C. § 316(d)(3).

dialogue with the Office and supporting the steps it is taking to provide greater clarity in AIA proceedings to patentees, challengers, and the public.Sincerely,

/s/ Laurie L. Hill
Laurie L. Hill
Vice President, Intellectual Property
Genentech, Inc., A Member of the Roche Group