Genentech
A Member of the Roche Group

June 26, 2020

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 PTABNPRM2020@uspto.gov

RE: Docket No. PTO-P-2019-0024, Request for Comments for Changes to the PTAB Rules of Practice for Instituting on All Challenged Patent Claims and All Grounds and Eliminating the Presumption at Institution Favoring Petitioner as to Testimonial Evidence

Dear Director Iancu:

Genentech, Inc., a member of the Roche Group, is a U.S. company that has been investing in American innovation and delivering on the promise of biotechnology for over 40 years. We are dedicated to following the science, and in doing so, creating medicines and treatments for people living with serious and life-threatening diseases. We are transforming the treatment of serious medical conditions, including cancer, autoimmune conditions, and infectious diseases. Last year alone, 127 million patients worldwide benefited from our medicines.

Today, Genentech has over 40 medicines on the market and a promising development pipeline. These medicines represent just the beginning of our journey in finding breakthrough therapies—and indeed, cures—through innovations that build on what we know to push the boundaries of scientific advancement and treatment. Every day, our teams work to solve some of the hardest biomedical problems, always with the goal of putting patients first.

Roche Molecular Solutions is a U.S. company that develops, manufactures and supplies a wide array of innovative medical diagnostic products with a broad portfolio including oncology, virology, microbiology, and blood screening tests. Roche Molecular Solutions offers comprehensive in vitro diagnostic solutions, covering molecular diagnostics, based on Nobel Prize-winning Polymerase Chain Reaction; Roche Sequencing Solutions, Roche Tissue Diagnostics and IT and Decision support solutions that include NAVIFY Tumor Board. From liquid biopsy to innovative technologies that enable quicker, more effective identification of multidrug-resistant organisms, Roche Molecular Solutions is committed to developing diagnostic solutions that allow clinicians to determine the best possible course of care for individual patients.

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Roche Diabetes Care is a U.S. company that 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. Roche Diabetes Care has been pioneering innovative diabetes technologies and services for more than 40 years. More than 5,500 employees in over 100 markets worldwide work every day to support people with diabetes and those at risk to achieve more time in their target ranges and experience true relief from the daily therapy routines. Being a global leader in integrated Personalized Diabetes Management (iPDM), Roche Diabetes Care collaborates with thought leaders around the globe, including people with diabetes, caregivers, healthcare providers and payers. Roche Diabetes Care aims to transform and advance care provision and foster sustainable care structures. Under the brands RocheDiabetes, Accu-Chek and mySugr, comprising glucose monitoring, insulin delivery systems and digital solutions, Roche Diabetes Care unites with its partners to create patient-centered value. By building and collaborating in an open ecosystem, connecting devices and digital solutions as well as contextualizing relevant data points, Roche Diabetes Care enables deeper insights and a better understanding of the disease, leading to personalized and effective therapy adjustments. For better outcomes and true relief.

The life-changing work of our scientists depends on a stable and predictable intellectual property system that protects innovation. To that end, we appreciate the U.S. Patent and Trademark Office's ("USPTO" or "Office") continued dedication to improving and clarifying the rules of practice regarding trial proceedings under the America Invents Act ("AIA") before the Patent Trial and Appeals Board ("PTAB") and we are grateful for the opportunity to provide our thoughts on these important issues.

Genentech, Roche Molecular Solutions, and Roche Diabetes Care (collectively referred to as "Genentech") support these proposed changes, and believe they will create greater fairness and increased predictability at the PTAB.

Proposed Rule Change to Require that the Board Institute on All Challenged Claims and All Grounds Raised, or Deny a Petition in its Entirety

Genentech supports the USPTO's proposal to change its rules of practice to either institute PTAB proceedings on all grounds of unpatentability for all claims that are challenged in the petition or deny the petition. This change is consistent with the Supreme Court in *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

Proposed Rule Change Regarding Sur-Replies

Genentech supports the USPTO's proposal to further solidify the current standard of practice of providing sur-replies to principal briefs. This allows a patent owner to respond to new exhibits or other new information in the petitioner's reply, creating critical balance and due process during PTAB proceedings. In other words, this change affords patent owners a fair opportunity to be heard at an important stage of the proceeding.

Genentech also supports the USPTO's proposal to change its rules to conform to the current practice of allowing a patent owner to respond to a decision on institution in its response and sur-reply. Again, memorializing such an existing practice is important to maintaining equity and

parity by allowing the patent owner to be heard on the content of an institution decision and the petitioner's reply.

Proposal to Eliminate the Presumption that a Genuine Issue of Material Fact Created by Patent Owner's Testimonial Evidence Filed with a Preliminary Response be Viewed in Light Most Favorable to Petitioner

Genentech supports the USPTO's proposal to eliminate the presumption that a genuine issue of material fact created by patent owner's testimonial evidence filed with a preliminary response be viewed in the light most favorable to the petitioner for the purposes of deciding whether to institute a PTAB proceeding.

We believe that weighing disputed issues of fact material to institution in favor of the petitioner is at odds with Congress's placement of the burden of proof on a petitioner, and that the proposed change would correctly recalibrate that burden in a manner consistent with Congress's intention in the AIA. *See* 35 U.S.C. §§ 314(a), 316(e), 324(a).

The USPTO also acknowledges in its Federal Register notice that a presumption in favor of the petitioner for genuine issues of material fact may be viewed as discouraging patent owners from filing testimonial evidence with its preliminary response because some patent owners may believe that such testimony will not be given any weight at the time of institution. Genentech agrees with this concern, and supports the proposed change as a way to ensure important balances in the PTAB proceedings.

Conclusion

We applaud the USPTO for requesting stakeholder input on such important proposals to improve and clarify the rules of practice regarding trial proceedings under the AIA that are before the PTAB. Genentech is supportive of such changes and believes they are necessary to create and maintain fair and equitable proceedings. Thank you again for your leadership in supporting strong intellectual property protections and in setting forth such important proposals.

Sincerely,

/Laurie L. Hill/

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