Genentech
A Member of the Roche Group

December 3, 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 https://www.regulations.gov

RE: Docket No. PTO–C–2020–0055, Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board

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. 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.

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 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

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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, however, depends on a stable and predictable intellectual property system that protects innovation.

To that end, Genentech and Roche Diabetes Care (collectively referred to as "Genentech") 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.

The AIA grants the Director broad authority in setting the standards for when to institute an Inter Partes Review ("IPR") and the Supreme Court has affirmed the Director's discretion.[1] Section 314(a) sets a minimum threshold below which the Director "may not authorize" an IPR,[2] and the statute provides the Director with discretion to deny a petition in cases where this institution standard has been met. Sections 315(d) and 325(d) provide the Director with broad discretion to decide the manner in which multiple proceedings before the Office that involve the same patent may proceed.[3] This discretion includes granting the Director the authority to deny petitions based on proceedings in other forums as was done in the precedential opinion *Apple Inc. v. Fintiv, Inc.*[4]

We are grateful that the Director has utilized his authority to promulgate guidance to help ensure that the AIA post-grant proceedings strike the right balance of maintaining meritorious challenges by petitioners while not creating excessive costs and uncertainty for the patent owner as well as burden and expense for the Office. The case-by-case approach that the Director has taken by making precedential the *General Plastic, Valve I, Valve II, Becton Dickinson,* and *Fintiv* decisions has been critical to preventing gamesmanship while still providing flexibility to the Office.[5]

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[1] "[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion." *Cuozzo Speed Techs., LLC v. Lee,* 136 S. Ct. 2131, 2140 (2016); *see also SAS Institute Inc. v. Iancu,* 2018 WL 1914661 ("§314(a) invests the Director with discretion on the question *whether* to institute review").

[2] 35 U.S.C. §315(a).

[3] "...the Director may determine the manner in which the [inter partes review or post-grant review] or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding." 35 U.S.C. §§315(d), 325(d).

[4] *Apple Inc. v. Fintiv, Inc.,* IPR2020– 00019, 2020 WL 2126495 (PTAB Mar. 20, 2020) (precedential) (summarizing the factors the Office has considered when a patent owner argues for discretionary denial under *NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc.,* IPR2018–00752, 2018 WL 4373643 (PTAB Sept. 12, 2018) (precedential) due to an earlier trial date).

[5] *See, e.g., General Plastic Co., Ltd. v. Canon Kabushiki Kaisha, I*PR2016–01357, 2017 WL 3917706, at *7 (PTAB Sept. 6, 2017) (precedential) (providing a nonexclusive list of factors that the Board considers when evaluating discretionary denial of follow-on petitions, also known as ''serial'' petitions, under 35 U.S.C. 314(a)); *Valve Corp.*

We further appreciate that the Office is now considering promulgating rules governing the institution of AIA post-grant proceedings based on the framework of the guidance provided in the aforementioned decisions and in the Consolidated Trial Practice Guide. Such promulgation of rules by the Office under the Administrative Procedure Act is appropriate because of the discretion given to the USPTO by Congress. And while designating opinions via the Precedential Opinion Panel is also appropriate, we appreciate that further memorializing such guidance through the rulemaking process provides increased predictability, certainty, and notice to stakeholders and to the public.

Serial Petitions

Genentech supports the promulgation of a rule with a case-specific analysis such as generally outlined in *General Plastic, Valve I, Valve II* and their progeny, for deciding whether to institute a petition on claims that have previously been challenged in another petition.

Serial petitions create a constant barrage of filings as well as unnecessary uncertainty regarding the scope of patent rights. They also divert resources that could be used for new innovation towards fighting already-fought battles in IPRs.

The burden from serial petitions falls not only on patent owners, but also on the Office. Repetitive petitions on the same patent disproportionately consume time and resources that could be devoted to ensuring the quality of other patents. This remains true even if the PTAB ultimately declines to institute the petition, since pre-institution proceedings also take their toll. The goal should therefore be not just to ensure that abusive and repetitive petitions are denied, but to deter their filing in the first place.

Genentech appreciates the USPTO's acknowledgement that these serial petition problems exist and is grateful for the efforts that the Office has already made toward remedying these serial petitions concerns. We particularly appreciate the additional guidance that came from making the *General Plastic, Valve I, Valve II,* and their progeny precedential. We also appreciate that the list of factors the PTAB will consider are non-exclusive, as the precedential cases invite parties to identify on a case-by-case basis any new factors that the parties deem important to an institution decision. Moreover, and consistent with the factors promulgated in *Becton Dickinson*, the Board should be skeptical in all circumstances of petitions that do not present materially

v. Elec. Scripting Prods., Inc., IPR2019–00062, –00063, –00084, 2019 WL 1490575 (PTAB Apr. 2, 2019) (precedential) (Valve I) (explaining that the Board considers any relationship between petitioners when weighing the General Plastic factors); *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019–00064, –00065, –00085, 2019 WL 1965688 (PTAB May 1, 2019) (Valve II) (applying the first General Plastic factor to a petitioner that joined a previously instituted IPR proceeding and, therefore, is considered to have previously filed a petition directed to the same claims of the same patent); *Becton Dickinson & Co. v. B. Braun Melsungen AG*, Case IPR2017-01586, slip op. at 17-18 (PTAB Dec. 15, 2017)(precedential) (summarizing factors relating to denying institution under § 325(d) based on similarities, differences, and the nature of the asserted art and the prior art evaluated during examination); *Apple Inc. v. Fintiv, Inc.*, IPR2020– 00019, 2020 WL 2126495 (PTAB Mar. 20, 2020) (precedential) (summarizing the factors the Office has considered when a patent owner argues for discretionary denial under *NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc.*, IPR2018–00752, 2018 WL 4373643 (PTAB Sept. 12, 2018) (precedential) due to an earlier trial date).

different art, but it should be especially skeptical of serial petitions that do not identify materially stronger references.

As the USPTO contemplates future rulemaking, we encourage the Office to memorialize such non-exclusive factors in its rulemaking. In doing so, we believe it is important for the rules to be clear that the factors are not limited to instances where multiple petitions are filed by the same petitioner, but that they also apply to situations in which multiple parties file petitions against the same patent. Such petitions by multiple parties on the same patent can create all of the concerns described above, particularly when they use identical or nearly identical art to that art previously presented. We appreciate that the Office already evaluates petitions from separate filers, as noted in the Request for Comments, and support the USPTO's continued efforts to that end.[6] Lastly, any further rulemaking should also ensure that the PTAB considers the total number of petitions filed against the challenged patent when deciding whether to institute review to prevent potential duplication and to safeguard against potential harassment against patent owners.

Parallel Petitions

Genentech supports the promulgation of a rule with a case-specific analysis, such as generally outlined in the Consolidated Trial Practice Guide, for deciding whether to institute more than one petition filed at or about the same time on the same patent.

As noted in the Consolidated Trial Practice Guide, parallel petitions "may place a substantial and unnecessary burden on the [PTAB] and the patent owner and could raise fairness, timing, and efficiency concerns."[7] Like serial petitions, parallel petitions can create unnecessary uncertainty regarding the scope of patent rights and divert resources that could be used for new innovation towards fighting already-fought or ongoing battles in IPRs.

Although there may be circumstances where filing a parallel petition is necessary, we believe these situations are and will be rare, which is why we support a case-by-case evaluation. We agree with the Office's assessment that "multiple petitions by a petitioner are not necessary in the vast majority of cases" and that "a substantial majority of patents have been challenged with a single petition."[8]

We appreciate the Office's attention and guidance on parallel petitions already and believe that further memorializing such guidance in a rulemaking would foster greater clarity and certainty for patent owners, in addition to guarding against potential gamesmanship in the process.

Proceedings in Other Tribunals

[6] "Since *General Plastic*, the Office has explained that the application of the first *General Plastic* factor is not limited to instances where multiple petitions are filed by the same petitioner." Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board Docket No. PTO–C–2020–0055 (Oct. 20, 2020).
[7] PTAB Consolidated Trial Practice Guide, at 59 (Nov. 2019).
[8] PTAB Consolidated Trial Practice Guide, at 59 (Nov. 2019)(noting that it should be rare that two petitions by a petitioner may be needed, and "unlikely that circumstances will arise where three or more petitions by a petitioner with respect to a particular patent will be appropriate").

Genentech supports the promulgation of a rule with a case-specific analysis, such as generally outlined in *Fintiv* and its progeny, for deciding whether to institute a petition on a patent that is or has been subject to other proceedings in a U.S. district court or the ITC.

As noted above, the AIA gives the Director broad discretion to consider whether it is appropriate to institute an AIA post-grant proceeding to challenge a patent already under review by a federal tribunal. This allows the Office to focus its limited resources on the disputes that will have the most immediate real-world impact. The *Fintiv* factors provide precisely this guidance. The consistency in their application across several different 3-judge panels at the PTAB over time will increase predictability for litigants and businesses alike. Yet, because no one *Fintiv* factor is dispositive, the factors also provide important flexibility to analyze the facts unique to each petition on a case-by-case basis.

For example, we routinely navigate specialized statutory proceedings such as the Hatch-Waxman Act or the Biologics Price Competition and Innovation Act ("BPCIA"): statutes which provide comprehensive, streamlined procedures for resolving patent disputes relating to biosimilars and generic drugs. And while these statutes are not directly named in the *Fintiv* factors, we believe that the existing *Fintiv* framework provides the flexibility to address both statutory schemes. Several of the factors are directly on-point to evaluate such proceedings and the "catch-all" factor, factor six, provides additional leeway to the address circumstances that are specific to the Hatch-Waxman and BPCIA context.

Accordingly, Genentech supports promulgating rules to codify the *Fintiv* factors because they are broad enough to be flexible in a variety of situations, yet set enough to provide consistency as applied both now and in the future.

Conclusion

We applaud all that the USPTO has done and is doing to reduce the burden from serial and parallel petitions and to provide guidance and predictability at the PTAB. Thank you again for your leadership in supporting strong intellectual property protections. We appreciate this opportunity to provide our perspectives and suggestions and look forward to continuing the dialogue on these important issues.

Sincerely,

/Laurie L. Hill/

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