Biotechnology Innovation Organization

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 22314

Attn: Scott C. Weidenfeller, Vice Chief Administrative Patent Judge
Re: Request for Comments on Discretion to Institute Trials
Before the Patent Trial and Appeal Board

Via Electronic Mail to https://regulations.gov (Docket No. PTO-C-2020-0055)

Dear Director Iancu:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Office's consideration of "the codification of its current policies and practices, or the modification thereof," relating to the exercise of its discretion under 35 U.S.C. §§ 314(a), 324(a), 315(d), and 325(d).

BIO is the principal trade association representing the biotechnology industry domestically and abroad. BIO's members depend heavily on robust patent rights and a fair system for adjudicating their validity, and therefore have a significant interest in the procedures and legal standards that govern AIA trial proceedings. BIO's members not only vigorously defend their patents when their validity is challenged but also, in certain situations, petition for review of patents when such patents were improvidently granted. BIO commends the Office for bringing more uniformity, predictability, and fairness to the exercise of its discretion under §§ 314(a) and 324(a), and §§ 315(d) and 325(d), through the issuance of precedential and informative opinions (hereafter "Discretionary Opinions") and its recently updated Consolidated Trial Practice Guide (November 2019) ("CTPG").

BIO applauds the Office for now considering the consolidation of these practices and procedures in the form of properly promulgated rules, as part of its "ongoing effort to achieve consistency and fairness … as it relates to considerations for instituting AIA trials." 85 Fed. Reg. 66503. BIO believes that the promulgation of such rules will further the consistent and fair application of the Office's discretion as it relates to trial institution, which is particularly important because the Office's institution decisions, at least in large part, are not appealable to a federal court.

In its Request for Comments ("Request"), the Office expresses its concerns regarding (1) serial or parallel petitions challenging the same patent and (2) petitions involving advanced parallel

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proceedings in other tribunals (particularly those in district courts and the ITC). With respect to serial or parallel petitions, the Office's concerns include "timely completion of proceedings and efficient administration of the Office" (particularly following the Supreme Court decision in *SAS Institute Inc. v. Iancu*, 138 S.Ct. 1348 (2018)) and "fairness" when multiple petitions (more than one or two) are filed against the same patent. With respect to advanced parallel proceedings in other tribunals, the Office's concerns include "the[ir] potential to undermine Congress's intent that AIA proceedings be quick and cost-effective alternatives and instead may add costs, lengthen the proceedings, and risk coordinated branches of the Government having different outcomes on similar facts." 85 Fed. Reg. 66505. BIO shares these concerns.

In its Request, the Office asks stakeholders to address the following seven questions:

Serial Petitions

1. Should the Office promulgate 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?

2. Alternatively, in deciding whether to institute a petition, should the Office (a) altogether disregard whether the claims have previously been challenged in another petition, or (b) altogether decline to institute if the claims have previously been challenged in another petition?

Parallel Petitions

3. Should the Office promulgate 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?

4. Alternatively, in deciding whether to institute more than one petition filed at or about the same time on the same patent, should the Office (a) altogether disregard the number of petitions filed, or (b) altogether decline to institute on more than one petition?

Proceedings in Other Tribunals

5. Should the Office promulgate a rule with a case-specific analysis, such as generally outlined in *Fintiv* and its progeny, for deciding whether to institute a

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petition on a patent that is or has been subject to other proceedings in a U.S. district court or the ITC?

6. Alternatively, in deciding whether to institute a petition on a patent that is or has been subject to other proceedings in district court or the ITC, should the Office (a) altogether disregard such other proceedings, or (b) altogether decline to institute if the patent that is or has been subject to such other proceedings, unless the district court or the ITC has indicated that it will stay the action?

Other Considerations

7. Whether or not the Office promulgates rules on these issues, are there any other modifications the Office should make in its approach to serial and parallel AIA petitions, proceedings in other tribunals, or other use of discretion in deciding whether to institute an AIA trial?

85 Fed. Reg. 66506.

1. Summary of BIO's Response

In response to the Office's Questions 1 though 6, BIO recommends that the Office exercise its rule-making authority and, for each area of inquiry, "promulgate a rule with a case-specific analysis, such as generally outlined" in the Office's Discretionary Opinions and CTPG. BIO does not recommend the adoption of bright-line rules, i.e., either to (a) "altogether disregard" the timing or number of petitions filed or whether the patent is or has been subject to ITC or district court proceedings, or (b) "altogether decline to institute" if claims have been previously challenged in another petition or more than one petition has been filed or if the patent is or has been subject to ITC or district court proceedings.

With respect to Office question 7, BIO urges the Office to consider expanding the "related matters" notice requirement under 37 C.F.R. § 42.8. and section D.2. of the CTPG. If there is ongoing parallel litigation in another tribunal, especially in instances where the petitioner or its privy or real-party in interest is a party to that parallel litigation, the petitioner should include a statement (i) that the issues do not overlap and/or (ii) if one or more issues do overlap, whether the parallel litigation in the other tribunal is or is not expected to be completed before the PTAB would render its final written decision. When issues regarding parallel proceedings in another tribunal are raised, BIO applauds the PTAB's requests in appropriate cases for additional briefing on whether it should exercise its discretion to deny institution. BIO recommends that the Office codify through notice and comment rulemaking situations in which such briefing will be required, for example, when the petitioner's statement indicates that overlapping issues may be first decided in a parallel litigation.

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BIO offers the following more detailed comments to Questions 5 and 6 and codification of the *Fintiv* factors, i.e., factors to consider in discretionary denial of IPR (and PGR) petitions if the patent is in parallel district court or ITC litigation which implicates the Office's most recent line of Discretionary Opinions. BIO also supports the promulgation of rules to capture the Office's case-by-case analyses in serial and parallel petition cases (Questions 1 through 4) for substantially the same or similar reasons given in its response to Questions 5 and 6 and for the reasons the Office has given in its Request.

2. BIO's Rationale for Supporting Notice and Comment Rulemaking to Codify The Office's Case-Specific Analysis, Including Its *Fintiv* Factors

Again, BIO applauds the Office's issuance of its Discretionary Opinions. However, BIO believes that promulgating rules through notice and comment rulemaking to codify the Office's case-specific analysis, including its *Fintiv* factors, would represent good policy and implement Congress's stated intent, including its intent that AIA proceedings be quick and cost-effective alternatives to federal court litigation. There are many good reasons to do so, as explained below.

Like the Office's discretionary authority, its rulemaking authority in the areas implicated by the Request cannot be reasonably challenged. *See* 35 U.S.C. § 2(b)(2)(A) ("The Office … (2) may establish regulations, not inconsistent with law, which—(A) shall govern the conduct of proceedings in the Office …."). *See also id*. § 316(a)(4) (granting the Office the authority to issue "regulations … establishing and governing inter partes review" under 35 U.S.C.) (quoted in *Cuozzo Speed Technologies, LLC v. Lee*, 136 S.Ct. 2131, 2136 (2016)). And rules promulgated pursuant to § 316(a)(4) through notice and comment rulemaking may be entitled to *Chevron* deference. *See Cuozzo*, at 2135 (applying the deferential review standard established in *Chevron* and holding that the Office's regulation questioned in *Cuozzo* was "a reasonable exercise of the Patent Office's rulemaking authority"). *See also Aqua Products, Inc. v. Matal*, 872 F.3d 1290 *passim* (Fed. Cir. 2017) (in a divided opinion, discussing the Office's rulemaking in a different context and indicating a number of views as to when *Chevron* deference should be accorded to Office rulemaking).

Notably, at least a majority of the Federal Circuit judges in *Aqua Products* would not give *Chevron* deference to Office adjudications (sometimes referred to as adjudicative rulemaking). *See id.* at 1328-1334 (Moore, J., concurring) (explaining why notice and comment rulemaking is required and rejecting the argument that the Office is entitled to *Chevron* deference for its adjudicative rulemaking):

> The promulgation of substantive regulations, consistent with the APA, requires notice of proposed rulemaking published in the Federal Register and an

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> opportunity for comment before the rules may take effect. 5 U.S.C. § 553(b)–(c). It requires an agency to "notify the public of the proposal, invite them to comment on its shortcomings, consider and respond to their arguments, and explain its final decision in a statement of the rule's basis and purpose."

Id. at 1331.

Application of *Fintiv* factors 1 through 6 takes into account the efficiency of the Office, and at least factors 4 and 6 take into account the integrity of the patent system. *See* 35 U.S.C. §§ 316(a)(4), (b). Thus, based on the Office's consideration of these factors, the Office is well-positioned to propose regulations through notice and comment rulemaking that would be entitled to judicial deference, if adopted. Such notice and comment rulemaking would give stakeholders an opportunity to express their views and, if such rules were adopted, would provide greater clarity and certainty to stakeholders regarding the Office's approach particularly if such rules are given judicial deference.

BIO is not aware of any valid reason not to codify the Office's case-specific analyses for discretionary institution denials under §§ 314(b) and 324(a), and §§ 315(d) and 325(d), including the *Fintiv* factors, through notice and comment rulemaking. In fact, even ardent critics of the Office's use of discretionary institution denials seem to encourage the promulgation of rules to guide that discretion.[1]

3. BIO Supports The Office's Position That It Has Discretionary Authority to Deny Institution When There is Ongoing Federal Tribunal Litigation

As a substantive matter, the Office clearly has the discretion to deny institution when there is ongoing Federal tribunal litigation, such as in district court or the ITC. BIO agrees with the Office that "the agency's decision to deny a petition is a matter committed to the Patent Office's discretion," and "there is no mandate to institute review." *Cuozzo*, 136 S.Ct. at 2140 (quoted in Request, at 66503). The Supreme Court further reaffirmed its position with respect to the Office's discretionary authority when it distinguished that authority from the statutory requirement that the Office consider all the claims, once it instituted an IPR. *SAS Institute Inc. v. Iancu*, 138 S.Ct. 1348, 1356 (2018) ("§ 314(a) invests the Director with discretion on the question whether to institute review"); *id.* at 1361 ("Even if there is one potentially meritorious challenge, we have said that the statute contains 'no mandate to institute review,' so the Director

[1] *See, e.g.*, Apple et al's Motion for Summary Judgment in *Apple Inc. v. Iancu*, Case 5:20-cv-06128, at 23 (N.D. Cal. Nov. 23, 2020) (hereafter "Apple SJ Motion") ("Even if the Director had authority to adopt the *NHK-Fintiv* rule, he could do so only by following the procedures for notice-and-comment rulemaking."); Dietrick & Stroud, *Rules to Bind You: Problems with the USPTO's Rulemaking Procedures*, at 2-3, SSRN -id3737709 (to be published in New Mexico L. Rev. (winter 2020-2021) (recognizing the Office's substantive rulemaking authority).

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still has discretion to deny a petition."). Congress has not spoken (and thus has not provided guidance) on situations in which the Office should exercise its discretion not to institute a trial, even when the petition is sufficient to institute on the merits. Thus, that determination is up to the Office. *See, e.g.*, *Cuozzo*, 136 S.Ct. at 2140 (confirming that the AIA contains "no mandate to institute review" and thus the institution decision is "committed … to the Patent Office's discretion").

BIO is aware that some stakeholders and advocacy groups are challenging whether the Board has authority to even consider the status of parallel district court proceedings as part of its decision under § 314(a) in deciding whether to deny institution.[2] Implicit in such criticism is an apparent belief that a petitioner who files a legally sufficient petition within one year after being sued in district court has an absolute right to institution if the petition meets the statutory requirements under §§ 311 and 312 and the evidentiary threshold of § 314(a). In other words, their position is that Congress spoke on this issue by creating the one-year deadline for filing a petition found in § 315(b).[3] That argument misses the mark.[4] It is true that the AIA sets forth conditions under which the Office may not consider or institute a petition unless certain necessary requirements are met, but nowhere does the statute provide conditions under which the Office *must* institute. Thus, the prohibition of § 315(b) against instituting petitions that are filed more than 1 year after service of process does not limit the Office's discretion with respect to petitions that are filed within that one year. And it certainly does not prohibit the Office from considering parallel litigation under § 314(b) during that one-year period, and its impact on the Office and the parties, including patent owner. That deadline also does not foreclose determining whether institution would result in a cheaper, quicker, more efficient way to decide the issues. If it had been Congress's intent that all meritorious petitions filed within one year of the start of litigation must be instituted, Congress could have written that affirmatively in many different ways. But it has not.

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[2] *See, e.g.*, Complaint in *Apple Inc. v. Iancu*, Case No. 5:20-cv-06128 (8/31/20 N.D. Cal.): https://patentlyo.com/media/2020/09/20cv06128.pdf;
Letter to Congress from various technology and e-commerce companies (dated January 8, 2020): https://static1.squarespace.com/static/571681753c44d835a440c8b5/t/5f80a2ae87588022730eb3cb/1602265775602/DD+Letter+%28House+version%29+%28final%29+-+Copy.pdf (hereafter "January 8 Letter").
Letter to Congress by various industry advocacy groups (dated October 26, 2020): https://Office.patentspostgrant.com/wp-content/uploads/sites/34/2020/06/ipr-discretionary-denial-letters538428483.pdf.

[3] *See, e.g.*, Apple SJ Motion, at 10.

[4] The Federal Circuit has rejected such an argument. *See In re Cisco Sys*., 2020 WL 6373016, at *2 (addressing the Board's "authority to consider the status of parallel district court proceedings as part of its decision under § 314(a) in deciding whether to deny institution" and finding that "[s]uch challenges, both procedural and substantive, rank as questions closely tied to the application and interpretation of statutes relating to the Patent Office's decision whether to initiate review").

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4. BIO's Rationale for Supporting The Office's Exercise of Its Discretion through Its Application of The *Fintiv* Factors

As part of its case-specific analysis in *Apple Inc. v. Fintiv, Inc.*, the Office considered the non-exclusive factors relevant to the *Fintiv* case (known as the *Fintiv* factors): 1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted; 2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision; 3. investment in the parallel proceeding by the court and the parties; 4. overlap between issues raised in the petition and in the parallel proceeding; 5. whether the petitioner and the defendant in the parallel proceeding are the same party; and 6. other circumstances that impact the Board's exercise of discretion, including the merits. 2020 WL 2126495, at *2-3.

In *Fintiv*, the Board found: "These factors relate to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding.'' *Id.* at *3 (quoted in Request, at 66505). BIO agrees with that assessment, as the *Fintiv* factors are consistent with Congress's stated intent to create a cheaper, quicker, more efficient alternative to litigation and to take into account the "economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete instituted proceedings." 85 Fed. Reg. 66503.

BIO believes that consideration and proper weighing of all relevant *Fintiv* factors – including those that the Board has emphasized in denying institution[5] – will tend to lead to fair and equitable results. There is nothing inherently unfair about denying institution in cases in which (1) the issues raised in the petition are likely to be decided in the parallel federal court litigation before a PTAB final written decision (cases in which the federal court litigation is advanced, the issues have been developed, and significant costs have already been incurred), especially if (2) the petition would likely be denied on the merits anyway. *See, e.g., Apple Inc. v. Fintiv, Inc.*, 2020 WL 2486683 *passim* (applying all the *Fintiv* factors to support deny institution). In addition, judicious application of the *Fintiv* factors systematically advances Congress's efficiency goals by tending to filter out the very cases where the benefits of the IPR – a cheaper, quicker, more efficient alternative to litigation -- are very unlikely to be realized.

[5] *See* Womble Bond Dickinson, "*An Initial Statistical Analysis of the PTAB's Recent 'NHK-Fintiv Factor' Institution Decisions*," https://www.womblebonddickinson.com/us/insights/articles-and-briefings/initial-statistical-analysis-ptab-recent-nhk-fintiv-factor-institution-decisions ("WBD Analysis"). The WBD Analysis was based on 24 cases applying "the *NHK-Fintiv* rule." Notably, it concluded that "the PTAB rarely issues a decision that is inconsistent with its findings" on Factors 4 and 6, i.e., "overlap between issues raised in the petition and in the parallel proceeding" and "the merits." WBD Analysis, at "Tier 1 Factors." The WBD Analysis also concluded that Factors 2 and 3 often "reflect the outcome of the PTAB institution decision" but "tend to rely on more mutual support from the other factors." WBD Analysis, at "Tier 2 Factors."

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Conversely, abolishing the *Fintiv* factors would mean advocating for a framework that systematically embraces duplicative, redundant litigation and increased expenditure of time, money, and judicial resources, thus perpetuating disputes instead of resolving them sooner. By all accounts Congress could not have intended such an outcome, and special justification would be needed if the system were to be used in this way, particularly in view of Congress's intent to create an *alternative* to litigation.

Defendants in federal court infringement cases derive a significant benefit from having access to dual systems, as it offers them the opportunity to challenge a patent twice, i.e., in federal court and in the Office. This benefit was conferred by the AIA and it will continue to be available, for better or worse, in the majority of cases. However, for reasons of fairness, integrity and efficiency of the system, Congress limited that opportunity in a number of ways, including granting the Office discretion to exercise its institution authority in ways that further the underlying goals of post-grant practice, i.e., to provide a cheaper, quicker, more efficient alternative to litigation that also is fair to both parties, i.e., the petitioner and the patent owner.

5. BIO's Observations on Certain Criticisms Leveled Against The *Fintiv* Factors

Controversy over the Office's exercise of its discretion, including through the *Fintiv* factors, seems driven by a belief that petitioners in AIA proceedings fare better than defendants in district court litigation, at least in some district courts. Thus, in essence, opponents have raised arguments that the Office is more likely to reach the "right" result than district courts when "bad" or "low-quality" patents are at stake. In this context, critics have pointed to case management practices in district courts that arguably reduce the likelihood of an AIA review if the *Fintiv* factors are applied. In fact, opponents are most critical of district courts that have moved cases along efficiently and quickly – just as Congress sought moving them along by enacting the AIA.[6]

While it is of course true that events in parallel district court litigation can influence the outcome of a *Fintiv* analysis, complaints about aspects of district court case management practices cannot and should not be relevant to how the Office should exercise its § 314 discretion. It cannot be the role of the PTAB to "even the scales of justice," and take corrective action for the benefit of litigants that feel unfairly treated by the way a district court manages its cases. Stakeholders that object to the operation of federal courts, including forum management, can and should raise their

[6] An oft-repeated criticism is that the PTAB considers when a trial would take place even though trial dates often move. BIO believes that critics have over-emphasized this factor (*see, e.g.*, Apple SJ Motion, at 7-9), which is only one of six factors, none of which alone has been dispositive to date. With respect to the timing factor, the PTAB considers how far in advance of its own final written decision trial is scheduled to take place. The projected trial date is considered along with other equally important or even more important factors, such as whether the art, arguments, and/or parties are the same, and whether the litigation has advanced to a stage where the supposed efficiency gains of using the PTAB can no longer be realized.

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objections in court and through the appellate process. Throughout, it should not be forgotten that application of the *Fintiv* factors at the PTAB is likely to create desirable behavioral incentives. District court defendants who want AIA review of an asserted patent are in a better position if they petition as early as feasible rather than as late as possible. Plaintiffs who might otherwise operate on shifting legal theories or other dilatory practices would find it in their interest to move the district court case along efficiently.

Similarly, the notion that that there are many meritorious petitions for review of invalid patents that would have been instituted "but for" the *Fintiv* factors[7] should be taken with a grain of salt. While common in public debate, it is of course unhelpful to presuppose *ex ante* that challenged patents are invalid, or that petitions challenging them have merit, when neither has been determined by any competent body. In particular, it is not at all clear that most (or even many) of the AIA petitions that have been denied under *NHK/Fintiv* would have been granted on the merits.[8] To the contrary, initial indications are that the substantive strength or weakness of a petition plays a significant role in a *Fintiv* analysis, and that the Board rarely issues discretionary denials unless it discerns substantive weaknesses of a petition that buttress other factors.[9]

Finally, while opponents now criticize the Office's exercise of its discretion when that exercise has resulted in denials of institution, they have defended the Office's discretionary authority

[7] *See e.g.*, January 8 Letter, *supra* note 2. The Letter relies on a Unified Patents (UP) October 21, 2020 report "PTAB/District Court Trial Date Denials Spiraling Upward," available at https://www.unifiedpatents.com/insights/2020/10/21/ptabdistrict-court-trial-date-denials-spiraling-upward-ptab-discretionary-denials-third-quarter-report. The report indicates that about 4.9% of all institution decisions in Q1-3 of 2020 were denials of institution under NHK/Fintiv. While in itself helpful for the ongoing debate over discretionary institution denials, the report's contribution can be more fully appreciated by perusing the underlying cases which were helpfully provided with the report (available at: https://portal.unifiedpatents.com/ptab/caselist?discretionary_denial_refs=Nhk+Spring+%2F+Fintiv&sort=-filing_date). For example, with respect to the first 4 institution denials referenced in the report, a trial based on a fifth IPR petition by the same party attacking the same claims of the same patent was instituted (IPR2020-00798). The next 2 IPR denials involved a similar situation in that a trial based on a third IPR petition was instituted (IPR2020-00806). It is thus important to understand that denial of petitions under *Fintiv* has not always insulated the challenged patents from PTAB review. A closer examination of the next two IPRs on UP's list exposes another important aspect: In each, the Board analyzed all the *Fintiv* factors, including the merits, and determined that consideration of the merits weighed against institution. This further illustrates that the notion of PTAB panels woodenly denying petitions without regard to their merits is not generally true.

[8] Other recent UP statistics show that institution rates have remained fairly consistent in recent years, despite *Fintiv* and its progeny. *See PTAB/District Court Trial Date Denials Spiraling Upward: PTAB Discretionary Denials Third-Quarter Report* (Oct. 21, 2020), at Table 1, available at https://www.unifiedpatents.com/insights/2020/10/21/ptabdistrict-court-trial-date-denials-spiraling-upward-ptab-discretionary-denials-third-quarter-report (showing institution rates around 60% for years 2017-2019 and 59% for 2020).

[9] *See* WBD Analysis, *supra* note 5.

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when exercised in ways that resulted in institutions of AIA trials. Such less-than-consistent positions can only stem from a desire to gain a tactical advantage in patent litigation, including "two bites at the apple," to attack patents that have been asserted in district court. The position of other stakeholders has been exactly the reverse. Yet, what's sauce for the goose is sauce for the gander, and for better or worse the Office's broad discretionary authority under § 314(b) appears to be fairly well-established. To be sure, BIO does not believe that the Office's institution discretion is limitless, but we are persuaded that the use of the factors enumerated in its Discretionary Opinions and CTPG to guide that discretion, and their promulgation in rules, clearly is within the Office's authority. BIO is hopeful that the Office will continue to take seriously the heightened responsibility that comes with its so-far largely unreviewable institution discretion, and that it will exercise that authority judiciously and consistently, with restraint and accountability to all stakeholders. The promulgation of rules is an excellent step in this direction, and BIO looks forward to further engagement with the Office on this important task.

Respectfully submitted,

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