

ARE THERE LIMITS ON THE PTAB'S DISCRETIONARY DENIAL OF INTER PARTES REVIEW TRIAL?

By Eric C. Cohen¹

I. INTRODUCTION

Section 6 of the Leahy-Smith America Invents Act (“AIA”), entitled “Post-Grant Review Proceedings”² created “Inter Partes Review” (“IPR”) as a replacement for inter partes reexamination,³ and created a new Post-Grant Review⁴ (“PGR”) proceeding, which permits expanded challenges to newly issued patents within 9 months after the date of the grant of the patent or the issuance of a reissue patent.⁵ The AIA granted the USPTO Director discretion not to institute an IPR or PGR even where the petition has otherwise satisfied the statutory requirements for institution.⁶

The statute provides the Director with the authority to promulgate regulations to conduct IPR and PGR proceedings.⁷ Among other things, the Director may promulgate regulations to set the standards for the showing of “sufficient grounds to institute” a review⁸ and “establishing and governing . . . review under this chapter and the relationship of such review to other proceedings under this title.”⁹ In prescribing regulations, the Director “shall consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the office, and the ability of the Office to timely complete proceedings instituted under this title.”¹⁰

¹ Eric C. Cohen is Special Counsel with Rimon P.C. and is Vice Chair of the IPO Post-Grant Patent Office Practice Committee.

² Leahy-Smith America Invents Act sec. 6, §§ 311–329, 125 Stat. at 299–306.

³ *Id.* § 6(a) (now 35 U.S.C. §§311-319).

⁴ *Id.*, § 6(d) (now 35 U.S.C. §§ 321-329).

⁵ 35 U.S.C. § 321(c).

⁶ 35 U.S.C. §§ 314(a), 324(a) (The Director may not authorize a . . . review to be institute unless the Director determines . . .”).

⁷ 35 U.S.C. §§ 316(a), 326(a).

⁸ 35 U.S.C. §§ 316(a)(2), 326(a)(2).

⁹ 35 U.S.C. §§316(a)(4), 326(a)(4).

¹⁰ 35 U.S.C. §§316(b), 326(b).

The PTAB has increased the number of discretionary denials of institution of IPRs¹¹ in cases in which the petition arguably meets the statutory standard: “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”¹² According to a study undertaken by Unified Patents,¹³ “[i]n 2016, by the most conservative count, just 5 petitions were denied under the Board’s § 314(a) authority; in 2017, it was 15; by 2018, it was 45; and in 2019, it was 75. It is set to be more than double that in 2020.”

This paper questions whether there should be limits on the PTAB’s discretion to deny institution, and if so, what are those limits? The PTAB has issued precedential and informative decisions outlining factors it will consider when determining whether to exercise discretion. But, are those decisions a proper substitute for the issuance of regulations?

II. STATUTORY SCHEME FOR INTER PARTES REVIEW

Under the America Invents Act (“AIA”), “a person who is not the owner of a patent may file with the [USPTO] a petition to institute an [IPR] of the patent[,]” 35 U.S.C. § 311(a). Under section 314, the “Director *may not authorize* an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. §314 (emphasis added). As the phrase “may not authorize” suggests, institution is discretionary. *See Oil States Energy Servs. v. Greene’s Energy Grp., LLC*, 138 S. Ct 1365, 1371 (2018) (“The decision whether to institute [IPR] is committed to the Director’s discretion.”).

¹¹ *See PTAB Procedural Denials and the Rise of § 314*, https://www.unifiedpatents.com/insights/2020/5/13/ptab-procedural-denial-and-the-rise-of-314?gclid=CjwKCAjwjqT5BRAPEiwAJIBuBVOWby0LEbdkKXWRBdMg4_AYfE17T4sSH5o43zcPHUKLit6w83C3_RoC2CgQAvD_BwE

¹² 35 U.S.C. § 314(a).

¹³ See note 11, *supra*.

During the Senate debates on the AIA, Senator Kyl argued that the AIA provisions requiring the USPTO to implement the section 314 threshold via regulations created a “safety valve” that would permit the USPTO to “decline to institute further proceedings if a high volume of pending proceedings threatens the USPTO’s ability to timely complete all proceedings.”¹⁴ Along those same lines, sections 6(c)(2)(B) and 6(f)(2)(B) of the AIA permitted the Director to set a limit on the number of inter partes review and post-grant reviews that were instituted during the first four years that the new proceedings were in effect.¹⁵ None of the discretionary denials, however, cite a high volume of pending proceedings as the reason for exercising discretionary denial.

In a petition for inter partes review, the petitioner may “request to cancel as unpatentable [one] or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.” 35 U.S.C. 311(a). Congress placed time limits on the filing of an IPR petition.¹⁶ Most important for this analysis, a petitioner must file a petition one year or less after the date on which the petitioner has been “served with a complaint alleging infringement of a patent.” 35 U.S.C. §315(b).

The one-year bar under section 315(b) can sometimes be avoided if a late-filed petition is coupled with a motion for joinder with an existing IPR trial under 35 U.S.C. §315(c).¹⁷ This

¹⁴ *Matal*, A Guide to the Legislative History of the America Invents Act, Part II of II, 21 Federal Circuit B. J.539, 610 (2012) (hereinafter, “*Matal*”).

¹⁵ *See*, Leahy-Smith America Invents Act sec. 6(c)(2)(B), (f)(2)(B), 125 Stat. at 304, 311. *See also*, *Matal*, 21 Fed. Cir. B.J. at 605.

¹⁶ 35 U.S.C. § 315.

¹⁷ Section 315(c) states, “If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.”

procedure has been most used by parties who are co-defendants in a lawsuit with the original petitioner. As the moving party, Petitioner bears the burden of proving that it is entitled to the requested relief. 37 C.F.R. § 42.20(c). A motion for joinder should: (1) set forth the reasons joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; and (3) explain what impact (if any) joinder would have on the trial schedule for the existing review.¹⁸ The PTAB has determined that section 315(c) permits a petitioner to be joined to a proceeding in which it is not a party or in which it is already a party, and provides discretion to allow joinder of new issues into an existing proceeding.¹⁹ The existence of a time bar under section 315(b) “is one of several factors that may be considered when exercising . . . discretion under §315(c).”²⁰ The PTAB will exercise its discretion “where fairness requires it and to avoid undue prejudice to a party.”²¹

Section 315(d) also permits the Director to exercise discretion to manage multiple proceedings, such as reexamination, reissue and IPRs, pending in the USPTO involving the same patent. The Director “may determine the manner in which the inter partes review or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.”²² Section 316(a) requires the Director to prescribe regulations governing the conduct of inter partes review. 35 U.S.C. §315(a) (“The

¹⁸ *E.g. Electa Inc. v. Best Medical Int’l, Inc.*, IPR2020-00956, Paper 8 at 5 (PTAB, June 24, 2020), citing *Kyocera Corp. v. SoftView, LLC*, IPR2013-00004, Paper 15 at 4 (PTAB Apr. 24, 2013).

¹⁹ *Proppant Express Investments, LLC v. Oren Tech., LLC*, IPR2018-00914, paper 38 at 4 (PTAB, March 13, 2019).

²⁰ *Id.* at 16.

²¹ *Id.* at 19.

²² *Id.*

Director *shall* prescribe relations”) (emphasis supplied). Thus, the Director is required to prescribe regulations

(2) setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a);

* * *

(4) establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title;

* * *

(12) setting a time period for requesting joinder under section 315(c);

Once instituted, “[petitioner] is entitled to a final written decision addressing all of the claims it has challenged.” *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018).

Section 316(b) requires that “the Director shall consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter. Section 316(c) requires that the Patent Trial and Appeal Board “conduct each inter partes review instituted under this chapter.”

III. DISCRETIONARY DENIAL OF INSTITUTION

The PTAB has issued several decisions discussing the factors that may cause the PTAB to exercise discretion to deny institution of a petition that otherwise meets the requirements of section 314. The PTAB has characterized some of those decisions as “precedential” or “informative. A “precedential decision” establishes binding authority concerning major policy or procedural issues, or other issues of exceptional importance, including constitutional questions, important issues regarding statutes, rules, and regulations, important issues regarding case law, or issues of broad applicability to the Board. USPTO Standard Operating Procedure²³ 2, 2-3, 11.

²³ <https://www.uspto.gov/sites/default/files/documents/SOP2%20R10%20FINAL.pdf>.

A. Discretionary Denial of Follow-on Petitions

In *General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha*,²⁴ the PTAB exercised its discretion to deny IPR institution for several follow-on petitions, where institution based on the first petitions filed by the petitioner had been denied. The PTAB denied institution of the follow-on petitions “by exercising our discretion pursuant to 35 U.S.C. §314(a) and 37 C.F.R. § 42.108(a). In exercising its discretion, the PTAB considered the following seven factors:

1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;
3. whether at the time of filing of the second petition the petitioner already received the patent owner’s preliminary response to the first petition or received the Board’s decision on whether to institute review in the first petition;
4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;
6. the finite resources of the Board; and
7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.²⁵

Applying those factors, the PTAB explained,

[W]hen evaluating factor 1, we noted that the same claims of the same patent were at issue. * * * The follow-on petitions were all filed nine months after the filing of the first-filed petitions. At the time Petitioner filed the follow-on petitions, Patent Owner had filed its Preliminary Responses to the first-filed petitions, and the Board had issued Decisions Denying Institution of the first-filed petitions, as well as Decisions Denying Rehearing of those decisions. * * * Petitioner provided no meaningful explanation for the delay in filing the follow-on petitions. Instead, Petitioner stated that it had found new prior art as a result of two

²⁴ IPR2016-01357, Paper No 19 (PTAB, Sept. 6, 2017)(Precedential). In addition to the cited proceeding, this decision was issued in several IPRs that had not been combined. IPR2016-01358, IPR2016-01359, IPR2016-01360, and IPR 2016-1361.

²⁵ *General Plastics*, IPR2016-01357 at 9-10 (citations omitted).

later searches. * * * The new prior art searches did not commence until after the Board issued the Decisions Denying Institution in the proceedings based on the first-filed petitions. * * * Additionally, with respect to factor 6, we found that the Board’s resources would be more fairly expended on initial petitions, rather than follow-on petitions. * * *

With respect to factors 4 and 5, Petitioner provided no explanation in its Petition or in its Reply to Patent Owner’s Preliminary Response of any unexpected circumstances that prompted the new prior art searches, or for the delay. * * * Petitioner demonstrated that it found new prior art but provided no explanation why it could not have found this new prior art earlier—prior to filing the first-filed petitions—through the exercise of reasonable diligence. * * *

We additionally found that Petitioner had modified its challenges in the follow-on petitions in an attempt to cure the deficiencies that the Board identified in its first-filed petitions.

In light of the circumstances of these cases, and our assessment that the factors strongly favored non-institution, we exercised discretion and denied institution under 35 U.S.C. § 314(a) and 37 C.F.R. § 42.108(a).²⁶

The PTAB explained that although there is no *per se* rule precluding the filing of follow-on petitions after the Board’s denial of one or more first-filed petitions, “[o]ur intent in formulating the [seven] factors was to take undue inequities and prejudices to Patent Owner into account.” *Id.* at 15-17. The PTAB also explained that section 314(a) “does not specify any particular circumstance in which review *must* be authorized. That means institution of review is committed to the Director’s discretion, which, in turn, has been delegated to the Board.” *Id.* at 19. The PTAB rejected the Petitioner’s argument that the Board should have granted institution under section 325(d) because the same or substantially the same arguments had not previously been presented to the PTAB in the earlier petitions. The PTAB reasoned that whether the same or substantially the same prior art was previously presented is an issue that may be taken into account in considering institution, but is not, itself dispositive. *Id.* at 19. The Board further noted

²⁶ *Id.* at 10-11.

that the “safety valve” desire to alleviate a backlog “does not limit the discretion under 35 U.S.C. § 314(a) to only circumstances in which there is a high volume of pending proceedings.” *Id.*

Since *General Plastic*, the Board has held that the application of the first *General Plastic* factor is not limited to instances where multiple petitions are filed by the same petitioner.²⁷ When different petitioners challenge the same patent, the Board considers the relationship, if any, between those petitioners when weighing the *General Plastic* factors. *Id.*

According to the PTAB’s Trial Practice Guide, the *General Plastic* factors “are also not exclusive and are not intended to represent all situations where it may be appropriate to deny a petition.”²⁸ For example, the PTAB submits that “one petition should be sufficient to challenge the claims of a patent in most situations.”²⁹

The Trial Practice Guide does not comment on the problem faced by some petitioners, where the patent in suit includes a substantial number of claims, and the patent owner has not limited the claims that it will pursue at trial. The PTAB’s preference for “one petition per patent” provides an incentive for patent owners to delay limiting the number of claims they will pursue at trial until after the petitioner has filed a petition.

“A district court has inherent authority to reasonably limit ... the number of patent claims the parties may assert, ‘to control the dispositions of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.’”³⁰ Limiting the number of patent claims

²⁷ See *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00062 (PTAB Apr. 2, 2019) (Paper 11) (precedential) (denying institution when a party filed follow-on petitions for inter partes review after the denial of an inter partes review request of the same claims filed by the party’s co-defendant).

²⁸ Patent Trial and Appeal Board Consolidated Trial Practice Guide (“TPG”), November 2019 at 58.

²⁹ TPG at 59.

³⁰ *Masimo Corp. v. Philips Elecs. N. Am. Corp.*, 918 F.Supp.2d 277, 282 (D.Del.2013) (internal citations omitted) (quoting *Landis v. N. Am. Co.*, 299 U.S. 248, 254–55, 57 S.Ct. 163, 81 L.Ed.

asserted at the trial is not a denial of due process as long as the court provides the plaintiff with the ability to assert additional claims upon a showing of good cause.³¹

Where an asserted patent includes a large number of claims, it may be necessary for a petitioner to challenge all of the claims in a patent unless the petitioner is certain in advance that certain claims either do not cover the accused instrumentality or because the patent owner has undertaken not to assert certain claims. Because of the word limits on petitions, this may make it impractical to challenge all of the claims in a single petition. Thus, the PTAB should moderate its position regarding multiple petitions regarding the same patent when patents include a large number of claims and the petitioner files multiple petitions in order to effectively make a case under the statute that the claims should be cancelled on the ground that they are unpatentable.

Sometimes, a petitioner may challenge a subset of the claims in a patent based on a good-faith belief that other claims do not cover the accused product. In such cases, follow-on petitions should be permitted if the petitioner becomes aware of a new infringement theory or an intervening claim construction ruling that puts additional patent claims in play in the litigation.

153 (1936)); see also *Thought, Inc. v. Oracle Corp.*, 2013 U.S. Dist. LEXIS 147561, at *4–5, 2013 WL 5587559 (N.D.Cal. Oct. 10, 2013); *Gen-Probe Inc. v. Beckton Dickinson & Co.*, 2012 U.S. Dist. LEXIS 21744, at *6–7, 2012 WL 579490 (S.D.Cal. Feb. 22, 2012); *cf., e.g., Unwired Planet LLC v. Google, Inc.*, 2013 U.S. Dist. LEXIS 146766, at *2,*5, 2013 WL 5592896 (D.Nev. Oct. 10, 2013)(ordering plaintiff to reduce number of claims from 124 to 30); *Classen Immunotherapies, Inc. v. Biogen Idec*, 2013 U.S. Dist. LEXIS 24836, at *9, *11–12, 2013 WL 680379 (D.Md. Feb. 22, 2013) (ordering plaintiff to reduce number of claims from 229 to 30); *Unified Messaging Solutions LLC v. Facebook Inc.*, 2012 WL 11606516, at *1 (E.D.Tex. July 12, 2012) (ordering plaintiff to reduce number of claims from 52 to 15 at the time of its expert report on infringement).

³¹ *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1312 (Fed.Cir.2011); see also *Stamps.com Inc. v. Endicia, Inc.*, 437 F. App'x 897, 900–03 (Fed.Cir.2011) (limiting claims from 629 to 15).

B. Discretionary Denial of Petitions in View of District Court Proceedings

In two recent precedential decisions, the PTAB has explained factors it considers in the exercise of its discretion not to institute an IPR when a district court case involves the same patent. *Apple Inc. v. Fintiv, Inc.*,³²; *NHK Spring Co. v. Intri-Plex Techs., Inc.*³³

In *NHK*, the Board denied institution, relying both on section 325(d) and § 314(a). The Board exercised its discretion to deny institution under section 325(d) because the same prior art had been considered by the examiner during prosecution and the arguments made by the petitioner were no different from the arguments made before the examiner.³⁴ The Board also denied institution under 35 U.S.C. § 314(a) because institution of a trial at the PTAB would be an inefficient use of Board resources in light of the “advanced state” of the parallel district court litigation in which the petitioner had raised the same invalidity challenges.³⁵ The Board also noted that the patent had expired and further considered the fact that the parallel district court proceeding was scheduled to finish six months before the Board reached a final written decision as a factor favoring denial.³⁶ The Board found that the earlier district court trial date presented efficiency considerations that provided an additional basis, separate from the independent concerns under 35 U.S.C. § 325(d), for denying institution. Thus, *NHK* applies to the situation where the district court has set a trial date to occur earlier than the Board’s deadline to issue a final written decision in an instituted proceeding.

³² IPR2020-00019, Paper No. 11 (PTAB, March 20, 2020) (precedential)

³³ IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential).

³⁴ *Id.* at 12-18.

³⁵ *Id.* at 19.

³⁶ *Id.* at 19-20.

*Apple v. Fintiv*³⁷ was a case where the district court had set a trial date a couple of months before the Board’s deadline to issue a final written decision in an instituted proceeding.³⁸ Fintiv had filed its complaint for patent infringement in the Western District of Texas on December 21, 2018.³⁹ In late May 2019, the Court held a case management conference, the court set a *Markman* hearing for November 8, 2020.⁴⁰ After the case management conference but before the *Markman* hearing, Apple filed its petition on October 28, 2019, approximately ten months after it had been served with the complaint.⁴¹ The Court set a trial date for November 16, 2020.⁴² The trial date was re-set due to the covid-19 pandemic for March 8, 2021, approximately two months before a final written decision would be due in the IPR proceeding if it were instituted.⁴³ On March 20, 2020, the PTAB issued a now-precedential decision requiring the parties to provide further briefing on the issue of discretionary denial.⁴⁴

After the parties briefed the issue of discretionary denial, the PTAB issued a decision denying institution.⁴⁵ The PTAB observed that at the time it issued its decision, the parties had exchanged infringement and invalidity contentions, litigated a *Markman* hearing and had received the court’s claim construction order.⁴⁶ The PTAB noted that “some of Petitioner’s challenges contain certain weaknesses [and] the strengths of the merits do not outweigh other

³⁷ IPR2020-00019, Paper No. 11 (PTAB, March 20, 2020) (precedential)

³⁸ IPR2020-00019, Paper 11(PTAB, March 20, 2020) (precedential).

³⁹ Id. at 8.

⁴⁰ Id.

⁴¹ Id.

⁴² Id. at 9, 13.

⁴³ IPR2020-00019, Paper 15 at 10.

⁴⁴ IPR2020-00019, Paper 11(PTAB, March 20, 2020) (precedential).

⁴⁵ IPR2020-00019, Paper 15 (PTAB, May 13, 2020) (informative decision).

⁴⁶ Id at 8-10.

factors in favor of discretionary denial” and that “Petitioner’s case, at least as to two of three independent claims, is a close call.”⁴⁷

Prior to *Apple* and *NHK*, the Board had considered the issue of discretionary denial in connection with early trial dates in civil cases. See, e.g. *Abbott Vascular, Inc. v. FlexStent, LLC*, IPR2019-00882, Paper 11 at 31 (PTAB Oct. 7, 2019) (declining to adopt a bright-line rule that an early trial date alone requires denial in every case); *Magellan Midstream Partners L.P. v. Sunoco Partners Marketing & Terminals L.P.*, IPR2019-01445, Paper 12 at 10 (PTAB Jan. 22, 2020)(citing “unnecessary and counterproductive litigation costs” where district court would most likely have issued a decision before the Board issues a final decision); *Intel Corp. v. VLSI Tech. LLC*, IPR2019-01192, Paper 15 at 11 (PTAB Jan. 9, 2020) (“When considering the impact of parallel litigation in a decision to institute, the Board seeks, among other things, to minimize the duplication of work by two tribunals to resolve the same issue.”); *Illumina, Inc. v. Natera, Inc.*, IPR2019-01201, Paper 19 at 6 (PTAB Dec. 18, 2019) (“We have considered the positions of the parties and find that, on this record, considerations of efficiency, fairness, and the merits of the grounds in the Petition do not weigh in favor of denying the Petition.”).

Under the precedential decisions in *Apple* and *NHK*, the Board will evaluate the following factors for denying institution of an IPR in view of the projected trial date in a district court action involving the same patent:

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;

⁴⁷ Id. at 16, 17.

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.⁴⁸

“[I]n evaluating the factors, the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review.”⁴⁹ As is discussed below, the foregoing factors should not be considered by the Board in exercising discretion not to institute.

1. Factors 1 and 2 – Likelihood of district court stay and proximity to district court trial date

Among other things, the first two factors encourage forum shopping. District courts vary widely in the grant rate of motions to stay lawsuits pending IPRs.⁵⁰ In the 18 months following the Supreme Court’s decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018), the overall percentage of stays pending IPR that were granted rose to 77% over all district courts, but the grant rate varies widely among districts.⁵¹ In the Western District of Texas, Judge Albright has not granted an opposed motion to stay pending IPR.⁵²

⁴⁸ *Apple*, IPR2020-00019, Paper No. 11 at 6.

⁴⁹ *Id.*

⁵⁰ Sayres & Walkstrand, To Stay or Not to Stay Pending IPR? That Should be a Simpler Question, 17 Chicago-Kent Journal of Intellectual Property 52, 55 (2018), noting that motions to stay pending IPR have been denied 30% of the time in the Northern District of California, but over 60% of the time in the Eastern District of Texas).

⁵¹ McClellan, Wilson and Armond, How Increased Stays Pending IPR May Affect Venue Choice, LAW360, Nov. 15, 2019. <https://www.law360.com/articles/1220066/how-increased-stays-pending-ipr-may-affect-venue-choice>.

⁵² Source, Docket Navigator. *See Continental Intermodal Group Trucking LLC v. Sand Revolution LLC et al*, 7:18-cv-00147 (W.D. Tex. Jul. 22, 2020)(denying motion to stay and citing the Seventh Amendment); *Solas OLED Ltd. v. Dell Tech., Inc.*, 6:19-cv-00514 (W.D. Tex. June 23, 2020); *Solas OLED Ltd. v. Google, Inc.*, 6:19-cv-00515 (W.D. Tex. June 23, 2020); *Multimedia Content Management LLC v. DISH Network LLC*, 6:18-cv-00207 (W.D. Tex. May 30, 2019).

The following table⁵³ shows that the average time to trial for all civil cases in Delaware and New Jersey, where over 90% of Hatch-Waxman ANDA cases are filed, was 29.3 months in Delaware and 40.8 months in New Jersey.⁵⁴ In contrast, the average time to trial in jurisdictions favored by patent assertion entities was 17.7 for the Eastern District of Texas and 24.3 months in the Western District of Texas. Moreover, according to statistics published by the federal judiciary, only 2.1 percent of federal cases were tried in 2019.⁵⁵

District	Patent Cases filed in 2020	Percent of all Patent Cases	Non-ANDA Patent Cases in 2020	ANDA Patent Cases in 2020	Percent of all ANDA Cases	Average Time to Trial⁵⁶
Western Dist. Texas	559	21.4%	559	0	0	24.3
District of Delaware	484	18.48%	390	94	50.538%	29.3
Eastern Dist. Texas	256	9.77%	256	0	0	17.7
Central Dist. Cal.	213	8.13%	213	0	0	32.2
Northern Dist. Cal.	150	5.73%	150	0	0	22.0
Northern Dist. Ill.	141	5.38%	139	2	0.11%	39.0
District of New Jersey	112	4.28%	35	77	41.398%	40.8
Total cases filed	2434	79%		186	93%	

In some fast-track jurisdictions, judges will set a presumptive trial date in the original case management order. Because the average time to trial in the Eastern District of Texas is 17.7 months for the small percentage of cases that actually are tried, the trial date set in an initial case management order would by definition be before or very close to the date for a final written

⁵³ Source, https://www.uscourts.gov/sites/default/files/data_tables/fcms_na_distcomparison0331.2020.pdf; See <https://search.docketnavigator.com/patent/binder/298255/2>. The average time to trial is based on a federal report for the 12 month period ending March 31, 2020, which is representative of time to trial before the current pandemic.

⁵⁴ Id.

⁵⁵ <https://www.uscourts.gov/statistics/table/c-4/statistical-tables-federal-judiciary/2019/12/31>.

⁵⁶ This is for all civil cases for the 12 month period ending March 31, 2020. See note 53, supra for source of data.

decision in an IPR. That would not be true in Delaware or New Jersey, however where over 90% of ANDA cases are filed.

It has been reported that Judge Albright in the Western District of Texas is “the busiest patent judge in America.”⁵⁷ Judge Albright’s standard Order governing patent proceedings sets a presumptive claim constructive hearing date for 24 weeks after the case management conference, and a trial within one year after the claim construction hearing.⁵⁸ Assuming that the case management conference is held 90 days after the complaint is served, this means that the trial will take place a little over a year and a half after the complaint is filed. The Order also requires parties to “discuss significantly narrowing the number of claims asserted and prior art references at issue” 26 weeks after the claim construction hearing.⁵⁹ This means that the defendant will not know which claims will be asserted in the trial until over a year has passed.

Consider that the statute provides a one-year time limit from the date a party is served with a complaint for patent infringement to file a petition for IPR on the asserted patent. The legislative history arguably demonstrates that Congress intended the timing of a district court trial should not impact the Director’s discretion in determining whether or not to institute an IPR. The bill passed by the Senate had imposed a six-month deadline, but the deadline was extended to one year because “technology companies, in particular, have noted that they are often sued by defendants asserting multiple patents with large numbers of vague claims, making it difficult to determine in the first few months of the litigation which claims will be relevant and how those

⁵⁷ https://www.law360.com/articles/1294310/4-things-to-know-about-new-wdtx-patent-procedures?nl_pk=8d1d493e-312c-4694-85dd-7611d46594fb&utm_source=newsletter&utm_medium=email&utm_campaign=special

⁵⁸ <https://www.txwd.uscourts.gov/wp-content/uploads/Standing%20Orders/Waco/Albright/Sample%20Order%20Governing%20Proceedings%20-%20Patent%20Cases%20071720.pdf>, at 8.

⁵⁹ *Id.* at 9

claims are alleged to read on the defendant's products. * * * [I]n light of the present bill's enhanced estoppels, it is important that the section 315(b) deadline afford defendants a reasonable opportunity to identify and understand the patent claims that are relevant to the litigation."⁶⁰ In addition, pre-AIA section 317(b) for inter partes reexaminations required that an inter partes reexamination be terminated if a civil action involving the inter partes requester resulted in a final judgment that the patent was not invalid.⁶¹ That provision was not included in the AIA for inter partes review or post-grant review.⁶²

In another context, the Supreme Court has held that the equitable defense of laches cannot be asserted when a complaint is filed within the limitations period of a statute.⁶³ The same logic should apply to IPRs. If a petitioner files within the one-year time frame, it should not matter whether the district court decision will occur before or after the PTAB's final written decision.

As noted above, the precedential *Apple* decision by the PTAB arose from a lawsuit filed by Fintiv in the Western District of Texas, which was assigned to Judge Albright.⁶⁴ Venue in the Western District of Texas was based in part on the allegation that Apple "operates brick-and-mortar Apple Stores" in that district.⁶⁵ Fintiv appears to be a non-practicing entity, located in Austin, Texas.⁶⁶ The patent allegedly covers a "mobile wallet that enables the provisioning of

⁶⁰ *Matal*, 21 Fed. Cir. B.J. at 612, quoting 157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011).

⁶¹ 35 U.S.C. § 317(b)(2006).

⁶² *Matal*, 21 Fed. Cir. B.J. at 612,

⁶³ *SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 137 S.Ct. 954 (2017) (laches cannot be asserted as a defense to alleged infringement that occurred within Patent Act's six-year limitations period); *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 572 U.S. —, 134 S.Ct. 1962, 188 L.Ed.2d 979 (2014) (same holding applied with respect to the Copyright Act's statute of limitations).

⁶⁴ *Fintiv, Inc. v. Apple, Inc.* 6:18-cv-372 (W.D. Tex.).

⁶⁵ *Id.*, Amended Complaint, ¶ 7, Dkt. 28.

⁶⁶ *Id.*, ¶ 5.

contactless cards.”⁶⁷ Fintiv does not allege that it manufactures or sells any products.⁶⁸ Indeed, the Western District of Texas has become a haven for lawsuits filed against brick-and-mortar retailers by NPEs.⁶⁹

2. Factor 3 - Investment in the parallel proceeding

This factor should not be considered for the same reason that the timing of the district court’s trial should not be considered: It encourages forum shopping. Further, it is directly related to the trial date set by the court.

Fast-track district court case management all but ensures that the parties will have had a significant investment in the civil case before the defendant has had a reasonable opportunity to identify and understand the patent claims that are relevant to the litigation.⁷⁰ For example, assuming that the case management conference occurs within 90 days of the filing of a complaint, a claim construction hearing would take place about 38 weeks after a complaint is served in the Western District of Texas,⁷¹ ensuring that the parties and court will have had a significant investment in the case before the PTAB decides whether to institute. Penalizing a petitioner because the petitioner has taken time to make this determination is inconsistent with the one-year time bar that Congress instituted.

⁶⁷ *Id.*, ¶ 28.

⁶⁸ *Id.*

⁶⁹ Based on the results of a search of docketnavigator.com of patent cases filed since August 1, 2020 until August 1, 2020, 675 patent infringement cases were filed in the Western District of Texas, a very significant number of them by non-practicing entities. The defendants include Huawei, Office Depot, Facebook, Acer, BlackBerry, Intel, Xerox, Juniper Networks, Bose, Hilton, Hyatt, Starwood, Uber Technologies, Google, Apple, Fujitsu, Hewlett Packard, Samsung, Micron, ZTE, Microsoft, and others.

⁷⁰ *Matal*, 21 Fed. Cir. B.J. at 612, quoting 157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011).

⁷¹ <https://www.txwd.uscourts.gov/wp-content/uploads/Standing%20Orders/Waco/Albright/Sample%20Order%20Governing%20Proceedings%20-%20Patent%20Cases%20071720.pdf>, at 8.

Moreover, the cost of filing a petition for inter partes review is significant: \$15,500 per petition for up to 20 claims of a single patent. In contrast, the filing fee for a complaint in district court is \$400.⁷² Thus, filing an IPR petition is a significant decision, especially where it is possible that the infringement claim may be defeated by the Court’s claim construction or by a motion to dismiss because the claim arguably covers patent-ineligible subject matter. The weighing of the relative effort that the parties have put into the district court case versus an IPR petition fails to take into consideration the factors discussed above that arguably convinced Congress to extend the time for filing IPRs from six months to one year after service of a complaint.⁷³

3. Factor 4 – Overlap of Issues

The fourth factor—whether issues raised in the IPR and in the district court case are similar, should also be disregarded. To begin with, the issues raised in the two forums are not quite the same. In an IPR, the petitioner “may request to cancel as *unpatentable* 1 or more claims of a patent,”⁷⁴ and the Board issues a “final written decision with respect to the *patentability* of any patent claim challenged by the petitioner”⁷⁵ The petitioner has “the burden of proving a proposition of unpatentability by a preponderance of the evidence.”⁷⁶ In contrast, patents are presumed valid in patent infringement litigation,⁷⁷ and the defendant has the burden of proving *invalidity* by clear and convincing evidence.⁷⁸

⁷² 28 U.S.C. §1914(a) (\$350 filing fee); administrative fee of \$50

(<https://www.uscourts.gov/services-forms/fees/district-court-miscellaneous-fee-schedule>)

⁷³ *Matal*, 21 Fed. Cir. B.J. at 612, quoting 157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011).

⁷⁴ 35 U.S.C. §311(b) (emphasis added).

⁷⁵ 35 U.S.C. §318(a) (emphasis added).

⁷⁶ 35 U.S.C. §316(e).

⁷⁷ 35 U.S.C. §282

⁷⁸ *Microsoft Corp. v. i4i Limited Partnership*, 131 S.Ct. 2238, 2242 (2011).

The PTO in reexamination and IPR proceedings and the court system in patent infringement actions “take different approaches in determining validity and on the same evidence could quite correctly come to different conclusions.”⁷⁹ Should a challenger in a civil case fail to prove that a patent is invalid by clear and convincing evidence, the court will not find the patent “valid,” only that “the patent challenger did not carry the ‘burden of establishing invalidity in the particular case before the court.’”⁸⁰ In contrast, in PTO reexaminations and in IPR proceedings, “the standard of proof—a preponderance of the evidence—is substantially lower than in a civil case” and there is no presumption of validity in reexamination proceedings.⁸¹

4. Factor 5 – Whether the petitioner and the defendant in the parallel proceeding are the same party

The USPTO has recognized that “86.8% of patents at issue in AIA proceedings also have been the subject of litigation in the federal courts.”⁸² This was part of the USPTO’s justification for changing the claim construction standard in IPRs from broadest reasonable interpretation to the standard applied by district courts under *Phillips* and its progeny.⁸³ Thus, according to the USPTO’s own statistics, it is likely that the parties in both proceedings will be the same. But what if they are not? The PTAB has exercised discretion to refuse to institute a later-filed IPR by a co-defendant, where the first IPR had been denied on substantive grounds.⁸⁴ This puts defendants in a catch-22 position that we believe was not intended by Congress. One reason for

⁷⁹ *In re Swanson*, 540 F.3d 1368, 1377 (Fed.Cir.2008).

⁸⁰ *Id.*

⁸¹ *Id.* at 1378.

⁸² “Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board,” Federal Register 83, No. 197 (October 11, 2018): 51340, 51342.

⁸³ *Id.* at 51341, referring to *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed Cir. 2005)(en banc).

⁸⁴ See *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00062 (PTAB Apr. 2, 2019) (Paper 11) (precedential).

the one-year deadline for filing IPRs is that “High-technology companies, in particular, have noted that they are often sued by defendants asserting multiple patents with large numbers of vague claims, making it difficult to determine in the first few months of the litigation which claims will be relevant and how those claims are alleged to read on the defendant’s products.”⁸⁵ Yet that is precisely the situation that exists today.

5. Factor 6 – Other Considerations

The PTAB attempts to justify discretionary denial on the ground that “it may impose unfair costs to a patent owner if the petitioner, faced with the prospect of a looming trial date, waits until the district court trial has progressed significantly before filing a petition at the Office.”⁸⁶ But the patent statute itself permits multiple proceedings; and it permits a defendant in a lawsuit to file an IPR petition for up to a year after it has been served.

In addition to providing the one-year limitation for filing an IPR petition after being sued, Section 315,⁸⁷ entitled “Relation to other proceedings or actions,” specifies the relationships between civil actions and IPRs. Section 314(d) entitled “Multiple Proceedings”⁸⁸ permits the Director to manage multiple proceedings “in the Office” but not in courts: “during the pendency of an inter partes review, if another proceeding or matter involving the patent is *before the Office*, the Director may determine the manner in which the inter partes review or other proceeding or matter may proceed.”⁸⁹ Significantly, this section of the statute does not provide the Director with any authority to consider the status of district court litigation in determining whether to institute an IPR.

⁸⁵ *Matal*, 21 Fed. Cir. B.J. at 612, quoting 157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011).

⁸⁶ *Apple, Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper No. 11 at ___ (PTAB, March 20, 2020).

⁸⁷ 35 U.S.C. §315.

⁸⁸ 35 U.S.C. §315(d).

⁸⁹ *Id.*

On the other hand, Section 316(a)(4) requires the Director to enact *regulations* to govern the relationship between IPRs and district court cases.⁹⁰ The process of issuing regulations includes a period for public comment by stakeholders. The issuance of proposed regulations would provide greatly needed input on factors that the Director could consider with respect to the management of IPRs in the face of parallel district court proceedings.

Take for example, Hatch Waxman patent infringement cases.⁹¹ The owner of a new drug application (“NDA”) for a brand name drug must submit to the U.S. Food and Drug Administration (“FDA”) a list of patents that claim the drug active ingredient, formulation, and methods of use.⁹² FDA publishes the list in its so-called “Orange Book.”⁹³ A company that wants to market a generic version of the brand-name drug must file an abbreviated new drug application (“ANDA”) and make one of four certifications concerning any patents listed in the Orange Book.⁹⁴ The Hatch-Waxman act provides a period of six months’ exclusivity for the first ANDA filer who makes a paragraph IV certification.⁹⁵ This regulatory scheme provides no incentive for a first-filer to file an IPR for a listed patent. However, an ANDA filer who is not the first filer may have an incentive to file an IPR, since the second filer does not get the first-to-file exclusivity. In short, in Hatch-Waxman patent cases, ANDA filers know the patents that

⁹⁰ 35 U.S.C. §316(d).

⁹¹ Cases filed under 35 U.S.C. §271(e)(2).

⁹² 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(b)(1).

⁹³ 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(e).

⁹⁴ An ANDA can be filed if the generic drug manufacturer's active ingredient is the "bioequivalent" of the listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv). When submitting an ANDA, a manufacturer must certify one of four statements concerning the applicable listed drug: (i) the listed drug is not patented (a "Paragraph I certification"); (ii) the listed drug's patent has expired (a "Paragraph II certification"); (iii) the expiration date of the listed drug's patent (a "Paragraph III certification"); or (iv) the listed drug's patent "is invalid or ... it will not be infringed by the manufacture, use, or sale of the new drug" covered by the ANDA (a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

⁹⁵ 21 U.S.C. 505(j)(2)(B)(i); 21CFR 314.95.

allegedly cover the brand-name products and are required to notify FDA with respect to the listed patents when they file their ANDAs.

In sharp contrast, tech companies often have little, if any notice of patents asserted against them.⁹⁶ Tech companies are often sued by so-called non-practicing entities (“NPE”s) who assert poor-quality patents against hundreds of defendants and attempt to get cost-of-litigation settlements.⁹⁷ Moreover, tech companies are more susceptible to forum shopping than, for example, drug companies.

The contrast between the two types of patent litigation discussed above provides a reason for consideration of factors different from those outlined in the *Apple* decision. Perhaps the most important factor should be the relationship between the parties: is this a lawsuit between competitors; is the patent subject to a statutory scheme; or is it an attempted patent hold-up? This is not to say that a lawsuit filed by a non-practicing entity is per se done for an improper purpose. The non-practicing entity could be a university, or it could be an individual inventor who has been ignored by a manufacturer who refuses to review or recognize her patent. But the overall context in which the lawsuit was filed, and whether the lawsuit was filed by an entity that is engaging in predatory behavior should certainly be considered. IPR proceedings were designed to combat bad actors asserting poor-quality patents, but not necessarily in place of the statutory scheme for litigating patents covering drugs.

⁹⁶ Patent Assertion Entity Activity; An FTC Study, at 47; <https://www.ftc.gov/reports/patent-assertion-entity-activity-ftc-study>

⁹⁷ https://www.unifiedpatents.com/insights/2016/7/27/unified-challenges-the-three-most-prolific-patent-trolls-of-2016?gclid=Cj0KCCQjw6575BRCQARIsAMp-ksNmT7sn7EsHiZ9P2WHwN0LWWlnI-JNEPsV7U_EL8dVG0ul4JmuHmnYaAglfEALw_wcB

The PTAB has referred to section 325(d)⁹⁸ as authority for considering whether to exercise discretion not to institute an otherwise proper IPR petition, when “the same or substantially the same prior art or arguments were presented to the Office.”⁹⁹ This provision of Section 325(d), is explicitly applicable to IPRs and reexaminations because it encompasses Chapter 30 (ex parte reexaminations) and Chapter 31 (IPRs).¹⁰⁰ There is no parallel provision in the statute, however, that would permit the Director to exercise discretion not to institute an IPR because the same or substantially the same prior art or arguments are or have been presented to a U.S. District Court.

IV. RULEMAKING VERSUS PRECEDENTIAL DECISION

In *Aqua Products v. Matal*,¹⁰¹ in a concurring opinion, Judge Moore noted, “Where Congress has chosen to delegate rulemaking authority by regulation, including in the grant of delegated authority before us today, the exercise of that delegated authority must be through the promulgation of regulations in order to be entitled to Chevron deference.”¹⁰² “The promulgation of substantive regulations, consistent with the APA, requires notice of proposed rulemaking published in the Federal Register and an opportunity for comment before the rules may take effect. 5 U.S.C. § 553(b)–(c).⁴ 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.’”¹⁰³

⁹⁸ 35 U.S.C. §325(d).

⁹⁹ E.g., *Hengdian Group DMEGC Magnetics Co., Ltd. v. Hitachi Metals, Ltd.*, IPR2017-01313, Paper 9 at 2 (PTAB 2017).

¹⁰⁰ 35 U.S.C. §325(d) (“In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because the same or substantially the same prior art or arguments were presented to the Office.”)

¹⁰¹ 872 F.3d 1290, 1319-20 (Fed. Cir. 2017) (en banc).

¹⁰² *Id.* at 1331.

¹⁰³ *Id.*

Judge Moore questioned whether precedential decisions should be entitled to *Chevron*¹⁰⁴

deference:

[P]recedential Board decisions are not subject to notice and comment. Precedential Board decisions are posted on the Board's website and are not published in the Federal Register, and there is no opportunity for public comment prior to the designation as precedential. Finally, neither the authority to designate opinions as precedential nor the process for doing so is to be found in the statute; rather this agency grant of power to itself is articulated only in the agency's own Standard Operating Procedures. Regardless of whether precedential Board decisions constitute formal agency adjudication, they are not subject to the same requirements as notice and comment rulemaking through regulation. Rulemaking through regulation is different from rulemaking through adjudication.¹⁰⁵

Section 316(a)(4) requires the Director to “prescribe regulations . . . (4) establishing and governing inter partes review under this chapter *and the relationship of such review to other proceedings under this title.*” Thus, Congress specifically required the Director to prescribe

¹⁰⁴ *Chevron, U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). *Chevron* requires a court reviewing an agency's construction of a statute it administers to determine first “whether Congress has directly spoken to the precise question at issue.” 467 U.S. at 842, 104 S.Ct. 2778. If the answer is yes, the inquiry ends, and the court must give effect to Congress's unambiguous intent. *Id.* at 842–43, 104 S.Ct. 2778. If the answer is no, the court must consider “whether the agency's answer [to the precise question at issue] is based on a permissible construction of the statute.” *Id.* at 843, 104 S.Ct. 2778. The agency's “interpretation governs in the absence of unambiguous statutory language to the contrary or unreasonable resolution of language that is ambiguous.” *United States v. Eurodif S.A.*, 555 U.S. 305, 316, 129 S.Ct. 878, 172 L.Ed.2d 679 (2009) (citing *United States v. Mead*, 533 U.S. 218, 229–30, 121 S.Ct. 2164, 150 L.Ed.2d 292 (2001)). When a statute expressly grants an agency rulemaking authority and does not “unambiguously direct[]” the agency to adopt a particular rule, the agency may “enact rules that are reasonable in light of the text, nature, and purpose of the statute.” *Cuozzo Speed Tech. LLC v. Lee*, 136 S.Ct. 2131, 2142 (2016) (citing *Mead*, 533 U.S. at 229, 121 S.Ct. 2164, and *Chevron*, 467 U.S. at 843, 104 S.Ct. 2778). When the PTO does adopt rules, moreover, “[w]e accept the [Director's] interpretation of Patent and Trademark Office regulations unless that interpretation is plainly erroneous or inconsistent with the regulation.” *In re Sullivan*, 362 F.3d 1324, 1326 (Fed. Cir. 2004) (citing *Auer v. Robbins*, 519 U.S. 452, 461–62 (1997), and *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414, 65 S.Ct. 1215, 89 L.Ed. 1700 (1945) (internal quotations omitted)).

¹⁰⁵ *Id.* at 1331-32.

regulations governing the relationship of inter partes review to district court cases. Per Judge Moore, this should not and probably cannot be done through precedential decisions.

V. CAN THE DIRECTOR'S DISCRETIONARY DENIAL BE CHALLENGED?

The Supreme Court has held that the prohibition against appealing institution decisions is fairly absolute.¹⁰⁶ It left open the question of whether an institution decision could be appealed on due process grounds. Could a decision not to institute based on discretionary denial be challenged on constitutional grounds? Or would the Federal Circuit entertain a petition for a writ of mandamus?

VI. SHOULD CONGRESS ELIMINATE THE DIRECTOR'S DISCRETION TO DENY INSTITUTION?

In the absence of the right to appeal institution decisions, it would be extremely difficult to challenge the Director's exercise of discretionary denial of otherwise meritorious IPR petitions. We submit that Congress should eliminate the Director's discretion to refuse to institute IPRs where the petition and other papers of record establish a likelihood that at least one claim of the challenged patent is unpatentable. Otherwise, Congress' intent to provide a timely route to challenge weak patents may be thwarted. This is a particularly acute problem for the tech industry. At the same time, Congress may wish to consider whether ANDA filers should be required to choose between filing a petition for IPR or from filing an ANDA with a Paragraph IV certification to challenge patents listed in the Orange Book under the procedures established by the Hatch-Waxman Act. In short, the problems presented by the Director's exercise of discretionary denial call for Congress to reassess that discretion in future legislation.

¹⁰⁶ *Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2131, 2141-42 (2016), the Court held that under section 314(d), the Director's decision whether to institute was not appealable, but reserved judgment whether the prohibition extended to constitutional questions. *Thryv, Inc. v. Click to Call Tech. LP*, 140 S. Ct. 1367, 1373 (2020), the Court also left this issue open.

