A rule has implications for federalism under Executive Order 13132, (Federalism), if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, (Consultation and Coordination with Indian Tribal Governments), because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the FOR FURTHER INFORMATION CONTACT section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule will not result in such an expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f). The Coast Guard has determined that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This proposed rule simply promulgates the operating regulations or procedures for drawbridges. Normally such actions are categorically excluded from further review, under paragraph L49, of Chapter 3, Table 3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the FOR FURTHER INFORMATION CONTACT section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at http://www.regulations.gov. If your material cannot be submitted using http://www.regulations.gov, contact the person in the FOR FURTHER INFORMATION CONTACT section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to http://www.regulations.gov and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Documents mentioned in this NPRM as being available in this docket and all public comments, will be in our online docket at http://www.regulations.gov and can be viewed by following that website’s instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 117

Bridges.
seeks public comments on considerations for instituting AIA trials before the Office under the Leahy-Smith America Invents Act (AIA). The USPTO is considering the codification of its current policies and practices, or the modification thereof, through rulemaking and wishes to gather public comments on the Office’s current approach and on various other approaches suggested to the Office by stakeholders. To assist in gathering public input, the USPTO is publishing questions, and seeks focused public comments, on appropriate considerations for instituting AIA trials.

**DATES:** Comment date: Written comments must be received on or before November 19, 2020.

**ADDRESSES:** For reasons of government efficiency, comments must be submitted through the Federal eRulemaking Portal at https://www.regulations.gov. To submit comments via the portal, enter docket number PTO–C–2020–0055 on the home page and click “search.” The site will provide a search results page listing all documents associated with this docket. Find a reference to this Request for Comments and click on the “Comment Now!” icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format or MICROSOFT WORD® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal (https://www.regulations.gov) for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions regarding how to submit comments by mail or by hand delivery, based on the public’s ability to obtain access to USPTO facilities at the time.

**FOR FURTHER INFORMATION CONTACT:**
Scott C. Weidenfeller, Vice Chief Administrative Patent Judge, by telephone at 571–272–9797.

**SUPPLEMENTARY INFORMATION:**

**Background**

Development of This Request for Comments


**Discretion in Deciding Whether To Institute AIA Trials**

**Director’s Discretionary Institution Authority in General**

By way of background, the Patent Trial and Appeal Board (PTAB or Board) instituted a trial on behalf of the Director, 37 CFR 42.4(a); 35 U.S.C. 314. In deciding whether to institute the trial, the Board considers, at a minimum, whether a petitioner has satisfied the relevant statutory institution standard. Even in cases where a petitioner has satisfied the institution standard, the statutes, including 35 U.S.C. 314(a) and 324(a), provide the Director with discretion to deny a petition. See, e.g., 35 U.S.C. 314(a) (“The Director may not authorize an inter partes review to be instituted unless . . .”). The Supreme Court held that “the agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion,” and that there is “no mandate to institute review.” Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2140 (2016).

The Director also is given broad discretion under 35 U.S.C. 315(d) and 325(d) to determine the manner in which “multiple proceedings” before the Office involving the same patent may proceed. Specifically, “the Director may determine the manner in which the . . . other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.” Id.

Under 35 U.S.C. 316(a) and 326(a), the Director shall prescribe regulations for certain enumerated aspects of AIA proceedings, and under 35 U.S.C. 2(b)(2)(A), the Director may establish regulations that “shall govern the conduct of proceedings in the Office.” Further, 35 U.S.C. 316(b) and 326(b) require the Director to “consider the effect of any such regulation [under this section] 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.”


To achieve the appropriate balance envisioned by Congress, the Office has taken into account a variety of factors when determining whether to institute a proceeding. In so doing, the Office has also taken into account the considerations identified in 35 U.S.C. 316(b) and 326(b): 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. The Office has also worked to address the emergence of repeated administrative
attacks on the patentability of the same patent claims and the harassment of patent owners.

The case-specific analysis the Office has developed attempt to balance Congress’s intent for AIA proceedings to be “quick and cost effective alternatives to litigation,” on the one hand, with “the importance of quiet title to patent owners to ensure continued investment resources,” on the other hand. H.R. Rep. No. 112–98, pt. 1, at 48 (2011). For example, the Office has set forth, in various precedential PTAB decisions, various factors used in its case-specific analysis. See, e.g., General Plastic Co., Ltd. v. Canon Kabushiki Kaisha, IPR2016–01357, 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. v. Elec. Scripting Prods., Inc., IPR2019–00062, –00063, –00064, 2019 WL 1490575 (PTAB Apr. 2, 2019) (precedential) (Valve I) (explaining that the Board considers any relationship between petitioners when weighing the General Plastic factor); 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); 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).

These same considerations are also represented in various informative decisions. See, e.g., Sand Revolution II, LLC v. Continental Intermodal Group-Trucking LLC, 2020 WL 3273334 (PTAB June 16, 2020) (informative) (applying the factors set forth in the precluded Fintiv decision to grant institution); Apple Inc. v. Fintiv, Inc., IPR2020–00019, 2020 WL 2486683 (PTAB May 13, 2020) (informative) (applying the factors set forth in the precluded Fintiv decision to deny institution); Adaptics Ltd. v. Perfect Co., IPR2018–01596, 2019 WL 1084284 (PTAB Mar. 6, 2019) (informative) (applying discretion to deny a petition where the petitioner lacks particularity in identifying the asserted challenges that resulted in voluminous and excessive grounds); Deeper, UAB v. Vexilar, Inc., IPR2018–01310, 2019 WL 328753 (PTAB Jan. 24, 2019) (informative) (applying discretion to deny a petition where the petitioner demonstrates a reasonable likelihood of prevailing only as to 2 claims out of 23 claims challenged and only as to 1 of 4 asserted grounds of unpatentability); Chevron Oronite Co. v. Infinium USA L.P., IPR2018–00923, 2018 WL 5862245 (PTAB Nov. 7, 2018) (informative) (applying discretion to deny a petition where the petitioner demonstrates a reasonable likelihood of prevailing only as to 2 claims out of 20 claims challenged).

As the Office explained in the Consolidated Trial Practice Guide, consideration of this case-specific analysis is “part of a balanced assessment of all relevant circumstances in the case, including the merits.” CTPG at 58 (discussing consideration of the merits as part of a balanced assessment of the General Plastic factors); see also Fintiv, 2020 WL 2126495, at *2–3, 6–7 (discussing consideration of the merits in the context of discretionary denial).

Informed by similar considerations, the Office has also provided guidance on the number of petitions typically required by a petitioner to challenge the same patent at or about the same time. See CTPG 59–61 (first introduced in Trial Practice Guide Update (July 2019) at 26–28, available at https://www.uspto.gov/TrialPracticeGuide3 requiring petitioners to rank multiple petitions filed at the same time that seek to challenge the same patent). The Board explained that, based on its prior experience, “one petition should be sufficient to challenge the claims of a patent in most situations.” Id. at 59. In some cases, depending on circumstances, “two petitions by a petitioner may be needed, although this should be rare.” Id. The Board, however, concluded that it is “unlikely that circumstances will arise where three or more petitions by a petitioner with respect to a particular patent will be appropriate.” Id.

The Office is now considering promulgating rules based on the framework of the guidance provided in these decisions and in the Consolidated Trial Practice Guide, or a modified framework as appropriate, based on public input and further analysis. These considerations form the impetus for this request for comments and the questions presented below.

Discretion Under 35 U.S.C. 314(a) and 324(a)

Addressing Serial Petitions

In General Plastic, the Board recognized the goals of the AIA and also “recognize[d] the potential for abuse of the review process by repeated attacks on patents.” 2017 WL 3917706, at *7 (citing H.R. Rep. No. 112–98, pt. 1, at 48 (2011)). To aid the Board’s assessment of “the potential impacts on both the efficiency of the IPR process and the fundamental fairness of the process for all parties,” General Plastic enumerated a number of nonexclusive factors that the Board will consider in a case-specific analysis for exercising discretion on instituting an IPR, especially as to “follow-on” or “serial” petitions challenging the same patent as challenged previously in an IPR, PGR, or CBM proceeding. Id. at *8. The General Plastic nonexclusive factors include: (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 had already received a 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 an 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 one year after the date on which the Director notices institution of review. Id. at *7.

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. For instance, in Valve I, the Board denied institution when a party filed follow-on petitions for IPR after the denial of an earlier IPR request of the same claims filed by the party’s co-defendant. Valve I, 2019 WL 1490575, at *4–5. The Board held that when different petitioners challenge the same patent, the Board considers the relationship, if any, between those petitioners when weighing the General Plastic factor. Id. The Office also explained, in Valve II, that the first General Plastic factor
applies to a later petitioner when this petitioner previously joined an
instituted IPR proceeding and, therefore, was considered to have previously filed a petition directed to the same claims of the same patent. Valve II, 2019 WL 1965688, at *4–5. The relationships between petitioners in follow-on
petition scenarios depend on the circumstances of the follow-on petition scenario.

Addressing Timely Completion of Proceeding and Efficient
Administration of the Office

General Plastic also includes additional factors that are not limited to the follow-on petitions but are more generally directed toward the timely completion of proceedings and efficient administration of the Office. Under SAS, if the Board decides to institute based on one claim, it must institute on all claims and grounds set forth in the petition. SAS, 138 S. Ct. at 1359–60; Adidas AG v. Nike, Inc., 894 F.3d 1256, 1258 (Fed. Cir. 2018) (“[e]qual treatment of claims and grounds for institution purposes has pervasive support in SAS”). As explained in the Consolidated Trial Practice Guide, however, the Board may decide not to institute the petition if it determines that the petition meets the standards for institution in relation to fewer than all the challenges presented, even when the petition includes at least one claim subject to a challenge that otherwise meets the criteria for institution. CTPG at 64 (discussing Deeper and Chevron). Likewise, the Board may decide not to institute where deficiencies in the petition, such as a lack of particularity in identifying the asserted challenges, result in voluminous and excessive grounds. See Adaptics, 2019 WL 1084284, at *7–10.

Addressing Parallel Petitions

As explained in the Consolidated Trial Practice Guide in relation to parallel petitions challenging the same patent at or about the same time, in the Board’s experience, one petition should be sufficient for a petitioner to challenge the claims of a patent in most situations. CTPG at 59. The Office has explained that “[t]wo or more petitions filed against the same patent at or about the same time (e.g., before the first preliminary response by a patent owner) may place a substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns.” Id. The Office has also explained that “multiple petitions by a petitioner are not necessary in the vast majority of cases.” Id. (“To date, a substantial majority of patents have been challenged with a single petition.”).

Nonetheless, the Office explained that circumstances may exist in which more than one petition may be necessary, including, for example, when a patent owner has asserted a large number of claims in litigation or when there is a dispute about priority date, thereby requiring unpatentability challenges under multiple prior art references. Id. “In such cases two petitions by a petitioner may be needed, although this should be rare.” Id. The Office also explained that “based on prior experience, the Board finds it unlikely that circumstances will arise where three or more petitions by a petitioner with respect to a particular patent will be appropriate.” Id. To aid the Board in this case-specific analysis for determining whether more than one petition is necessary, the Office directed the parties to address the issue in their pre-institution filings. Id. at 59–60.

Addressing Proceedings in Other Tribunals

The Consolidated Trial Practice Guide explains that events in other proceedings related to the same patent, either at the Office, in U.S. district courts or at the U.S. International Trade Commission (ITC), may also impact the institution decision. CTPG at 58. In a prior precedent, for example, the Board found that the advanced state of a district court proceeding was a factor weighing in favor of not instituting under 35 U.S.C. 314(a), in addition to arguments under 35 U.S.C. 325(d). NHK, 2018 WL 4373643, at *7. Such advanced proceedings in other tribunals have the potential to undermine the intent that AIA proceedings be quick and cost-effective alternatives, and instead may add costs, lengthen the proceedings, and risk coordinate branches of the Government having different outcomes on similar facts.

Since designating NHK as precedent, the Board has applied nonexclusive factors that it considers in a case-specific analysis when a patent owner raises an argument for discretionary denial based on a parallel proceeding in another tribunal, such as a U.S. district court. The Board recently summarized these factors in Fintiv: (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 the 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. Fintiv, 2020 WL 2126495, at *2–3. The Board explained that “[t]hese 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.

Public Input

The Office has received input from stakeholders on the Office policies discussed above and on use of the Office’s discretion in institution of an AIA trial. The most prevalent input that the Office has received from stakeholders is that the case-specific analysis outlined above helps to ensure that (a) AIA proceedings do not create excessive costs and uncertainty for the patent owner and the system, while (b) meritorious challenges by petitioners can be maintained.

However, some stakeholders have proposed that the Office adopt a bright-line rule that it should use its discretion to preclude claims from being subject to more than one AIA proceeding, regardless of the circumstances. In other words, once a trial is instituted against certain claims, this proposal would preclude the Office from instituting further AIA trials that include challenges by any party to any of the same claims if the patent owner opposes institution.

Other stakeholders have proposed that the Office should only permit more than one AIA proceeding if the follow-on petition is unrelated to the prior petitioner. A petitioner, a petitioner’s real parties in interest, and privies of a petitioner would be limited to filing a single petition for a challenged claim, regardless of the circumstances.

By contrast, the Office has received input from some stakeholders proposing that the Office adopt a bright-line approach that there should be no limits on the number of petitions that can be filed or the number of AIA trials that can be instituted against the claims of a patent, so long as the petition complies with statutory timing requirements, e.g., the one-year bar under 35 U.S.C. 315(b), and meets the particular institution
threshold of showing that at least one claim of the patent is unpatentable.

The Office has also received input from stakeholders proposing that the Office adopt a bright-line rule that precludes institution of an AIA trial against challenged claims if the patent owner opposes institution and any of the challenged claims are or have been asserted against the petitioner, the petitioner’s real party in interest, or a privy of the petitioner in a district court or ITC action that is unlikely to be stayed.

By contrast, the Office also has received input from other stakeholders proposing that the Office adopt a bright-line rule to eliminate any consideration of the state of any district court or ITC actions involving the challenged patent, so long as the petition complies with statutory timing requirements and meets the particular institution threshold of showing that at least one claim of the patent is unpatentable.

In light of the various contrasting views from some stakeholders, the Office solicits further public input on what should be considered as part of a balanced assessment of the relevant circumstances when exercising its discretion to institute an AIA trial.

Issues for Comment

The USPTO seeks comments on considerations for instituting AIA trials as it relates to serial and parallel AIA petitions, as well as proceedings in other tribunals. The questions enumerated below are a preliminary guide to aid the USPTO in collecting relevant information to assist in modifications, if any, to its current practices, and in the development of any possible rulemaking on this subject. The questions should not be taken as an indication that the USPTO has taken a position or is predisposed to any particular views. The USPTO welcomes comments from the public on any issues believed to be relevant to these topics, and is particularly interested in answers to the following 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 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?

Andrei Iancu,
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2020–22946 Filed 10–19–20; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721


RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances (20–10.B)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances which are the subject of premanufacture notices (PMNs). This action would require persons to notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of any of these chemical substances for an activity that is designated as a significant new use by this proposed rule. This action would further require that persons not commence manufacture or processing for the significant new use until they have submitted a Significant New Use Notice (SNUN), and EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken any risk management actions as are required as a result of that determination.

DATES: Comments must be received on or before November 19, 2020.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0497, using the Federal eRulemaking Portal at http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit https://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: William Wysong, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001;