Pending Patent Legislation: What You Need to Know

11/8/2023

Today's Topics

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- Patent Eligibility Restoration Act
- Prohibiting Adversarial Patents Act
- Affordable Prescriptions for Patients Act
- Coming Attractions

PREVAIL ACT

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PREVAIL Act

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  - Real Party in Interest Definition
  - Duplicate Proceedings and Joinder
  - Estoppel Rules and Interplay with District Court and ITC Final Decisions
  - Presumption of Validity and Evidentiary Standards

PREVAIL Act

- **PGR Changes**
  - Real Party in Interest definition
  - Duplicate Proceedings and Joinder
  - Estoppel Rules and interplay with District Court and ITC final decisions
  - Presumption of Validity and Evidentiary Standards

Patent Eligibility Restoration Act

- Amends Section 100 of the Patent Act to define the term "useful" to require a specific and practical utility to a POSA
- Amends Section 101 of the Patent Act to define certain exclusions from patent eligibility including (1) mathematical formulae; (2) processes that are substantially economic, financial, business, social or artistic; (3) mental processes that occur without or prior to human activity; (4) unmodified genes; (5) unmodified natural materials

Patent Eligibility Restoration Act

- Provides that concepts of 102, 103 and 112 are not considered in the eligibility determination
- Allows the eligibility determination to occur at any point in a litigation with limited discovery

Prohibiting Adversarial Patents Act

- Requires disclosure from applicants regarding funding from foreign adversaries
  - Includes China, Cuba, Iran, Russia, North Korea, Venezuela
- Prohibits entities affiliated with certain "foreign adversaries" from being able to obtain a U.S. Patent.

Affordable Prescriptions for Patients Act

- Amends the FTC Act to create a rebuttable presumption that "product hopping" to a "follow on product" is an unfair methods of competition in violation of Section 5(a) of the FTC Act
- Would also limit the number of patents asserted in BPCIA litigation to 20.

COMING ATTRACTIONS

- RESTORE Patents Act (*eBay*)
- Medication Affordability and Patent Integrity Act (PTO-FDA Disclosure)
- Advancing American Interests Act (ITC enforcement)
- Executive Order Regarding AI

June 20, 2023

Via Electronic Submission
The Honorable Kathi Vidal
U.S. Patent and Trademark Office

600 Dulany Street
Alexandria, VA 22314

RE: PTO-P-2020-0022

Dear Director Vidal,

C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. C4IP welcomes this opportunity to provide feedback on the USPTO's advance notice of proposed rulemaking (ANPRM).[1]

The last decade has seen a dramatic change in the patent enforcement landscape with the arrival of the Patent Trial and Appeal Board (PTAB) after the passage of the Leahy-Smith America Invents Act of 2011 (AIA).[2] The Office has worked diligently to realize that law, acting on Congress's instruction that "the changes made by [the AIA] are not to be used as tools for harassment or a means to prevent market entry through repeated litigation and administrative attacks on the validity of a patent. Doing so would frustrate the purpose of the section as providing quick and cost effective alternatives to litigation."[3]

To achieve these goals, the AIA gives considerable discretion to the Director. Directors have used this authority to achieve uniformity at the PTAB in response to new court decisions or emerging divisions among PTAB panels through interim guidance and precedential decisions, allowing the Agency to react immediately and transparently in real-time.[4] This guidance

1 USPTO, *Changes Under Consideration to Discretionary Institution Practices, Petition Word-Count Limits, and Settlement Practices for America Invents Act Trial Proceedings Before the Patent Trial and Appeal Board*, 88 Fed. Reg. 24503 (April 21, 2023) [hereafter "ANPRM"].
2 Pub. L. 112–29 (2011), https://www.congress.gov/112/plaws/publ29/PLAW-112publ29.pdf.
3 H.R. Rep. No. 112-98, at 48 (2011), https://www.congress.gov/112/crpt/hrpt98/CRPT-112hrpt98.pdf.
4 Cuozzo Speed Technologies, LLC v. Lee, 136 S. Ct. 2131, 2142 (2016); *see also* Ryan David, *PTAB Unveils AIA Review Plans After High Court Shakeup*, Law360 (April 26, 2018) (discussing how the Office issued initial guidance to the PTAB on the Supreme Court's *SAS Institute* ruling within two days), https://www.law360.com/articles/1037720/ptab-unveils-aia-review-plans-after-high-court-shakeup.

benefits the patent system by publicly establishing the operative rules-of-the-road, promoting predictability and certainty.

Notice-and-comment rulemaking, such as the present process, is a logical and appropriate outgrowth of this effort. In key areas of policy, it builds on these initial measures by soliciting additional public input. If the process works properly, practices that have worked well and garnered a sufficient consensus should become part of the Code of Federal Regulations as a permanent part of PTAB practice.

Ideally, this would mean that these issues would be settled, given that a rehashing of the rules again and again will undermine the certainty that is needed for patents to support investment and further innovation. This is what makes the ANPRM and proposed rulemaking to follow so critical.

As the Office itself has acknowledged through its use of the ANPRM rather than an NPRM, the scope of proposals is vast. The many alternative and interrelated changes make it difficult to fully appreciate how implementation of any one proposal would work, opening the door to unintended consequences. Indeed, C4IP is concerned that the broad scope of the ANPRM introduces confusion and instability, as the public is left to wonder what direction the USPTO intends to pursue. The public generally benefits from prompt, clear, and steady direction from the Office.

Overall, C4IP is most supportive of proposed changes that codify existing Office practices, which have a record of how they operate. This appears in line with the AIA's intention of authorizing the Director, where Congress has not acted, to set policies and make improvements without Congressional involvement.[5]

In contrast, other changes are a departure from existing practice and the statutory scheme. While C4IP supports several of these, their nature suggests they would be better pursued through the legislative process.

C4IP applauds the Office for a thorough examination of the many issues that, after over a decade of experience with the AIA, are clearly causing friction. C4IP believes that a subset of the proposals is ready and appropriate for codification.

5 H. Rep. 112-98, at 48 (2011) ("[T]he Committee intends for the USPTO to address potential abuses and current inefficiencies under its expanded procedural authority."); 35 U.S.C. §§ 316; 326.

The Director Should Adopt a Systematic Approach to Discretionary Denials Where There Are Ongoing Parallel Proceedings

Requiring *Sotera* stipulations is a simple, bright-line rule that avoids duplication and promotes efficiency and fairness

The ANPRM proposes many variations of how parallel proceedings between the PTAB, district court, and the ITC could be handled, reflecting that this is an issue where concerns about efficiency, unnecessary duplication, and fairness have been numerous and prominent.[6] C4IP submits that the right balance is to require a *Sotera* stipulation from any petitioner if an IPR or PGR is to be instituted while there is an ongoing parallel proceeding in district court or the ITC involving that petitioner, real-party-in-interest, or privy of the petitioner.[7]

First and foremost, this proposal would promote efficiency and fairness by ensuring that the same issues are not being litigated in two separate tribunals, under different standards. This rule would give petitioners the ability, as the AIA intended, to choose to bring a challenge at the PTAB if they are charged with infringing a patent in district court or the ITC, while it would also ensure the AIA's intent that such an IPR is indeed an *alternative* to district court litigation.[8]

In other words, a mandatory stipulation would give the petitioner the choice of forum for where to bring its validity challenge, but ensure a single forum. This is in keeping with longstanding judicial principle of avoiding duplicative and potentially inconsistent outcomes and the AIA's intention to promote efficiency and reduce costs.[9] It would also prevent petitioners from having

6 *See, e.g.*, *The Patent Trial and Appeal Board After 10 Years: Impact on Innovation and Small Businesses*, hearing before the H. Comm. on the Judiciary, Subcomm. on Courts, Intellectual Property, and the Internet, 117th Cong. (2022) (Earl "Eb" Bright, written testimony), https://www.congress.gov/117/meeting/house/114937/witnesses/HHRG-117-JU03-Wstate-BrightE-20220623.pdf; (Jonathan Rogers, written testimony), https://www.congress.gov/117/meeting/house/114937/witnesses/HHRG-117-JU03-Wstate-RogersJ-20220623.pdf; Steven Carlson & Ryan Schultz, *Tallying Repetitive Inter Partes Review Challenges*, Law360 (2018), https://www.law360.com/articles/1083158; Anne Layne-Farrar, *The Other Thirty Percent: An Economic Assessment of Duplication in PTAB Proceedings and Patent Infringement Litigation*, SSRN (2017), http://dx.doi.org/10.2139/ssrn.2994858; Peter Harter & Gene Quinn, *How IPR Gang Tackling Distorts PTAB Statistics*, IPWatchdog (2017), https://ipwatchdog.com/2017/04/05/ipr-gang-tackling-distorts-ptab-statistics/id=81816/.

7 Sotera Wireless, Inc. v. Masimo Corp., IPR2020–01019, 2020 WL 7049373, at *7 (PTAB Dec. 1, 2020). C4IP agrees with the ANPRM's characterization of *Sotera* that such a stipulation bar challenges in district court that a petitioner raised or reasonably could have raised in its petition, if the petition is instituted. ANPRM, 24515-24516.

8 H. Rep. 112-98, at 48 (2011) (explaining "the purpose of the section as providing quick and cost effective alternatives to litigation").

9 *See, e.g.*, Clements v. Airport Authority of Washoe County, 69 F. 3d 321, 330 (9th Cir. 1995) ("[T]he 'most purely public purpose' served by preclusion rules is that of 'preserving the acceptability of judicial dispute resolution against the corrosive disrespect that would follow if the same matter were twice litigated to inconsistent results.'") (citing 18 Wright, Miller & Cooper, Federal Practice and Procedure: Jurisdiction § 4403 at 12); H. Rep. 112-98 (2011) at 40 (noting efficiency as one of the goals of passing the AIA), https://www.congress.gov/112/crpt/hrpt98/CRPT-112hrpt98.pdf; Anne Layne-Farrar, *The Other Thirty Percent: An Economic Assessment of Duplication in PTAB Proceedings and patent Infringement Litigation* (June 28, 2017) (estimating the number of duplicative parallel proceedings and discussing their costs), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2994858.

multiple opportunities to challenge validity, which is more fair to patent owners in addition to promoting judicial economy.

This approach also has the benefit of providing a clear, bright-line rule for when the Director's discretion will be exercised. The Office has noted the benefits of such bright-line rules in its ANPRM.[10] C4IP agrees that the predictability that such a rule provides is advantageous and in keeping with the mandate of the AIA to promote efficiency. It is also in keeping with recognizing that Administrative Patent Judges are experts in patent law, science, and engineering, and that unnecessarily spending time deciding other issues is a poor use of their time.[11]

In the past, opponents of this approach have suggested that duplication is best avoided by district courts granting stays until the conclusion of a PTAB proceeding.[12] But the AIA granted district courts discretion to stay—or not to stay—cases for IPRs or PGRs, recognizing that there are reasons that such stays are inequitable, for example, the delay and resulting economic harm to the patent owner from continued infringement.[13] This is in notable contrast to the AIA provisions heavily favoring a stay in the now-expired covered business method proceedings.[14]

Moreover, the AIA gave the USPTO Director an explicit directive to "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."[15] While the Director cannot control what a district court does, the Director *can* control whether the PTAB hears a duplicative proceeding. The stipulation will further help to ensure that, even where district court cases have been stayed, the issues within the scope of the IPR or PGR will not be revisited once the post-grant proceeding is over.

The *Sotera* rule should apply equally to IPRs and PGRs and also to district court and ITC proceedings

The Office has proposed that there should not be discretionary denials for PGRs (as opposed to IPRs), or where there is a parallel ITC (instead of district court) case. C4IP respectfully

10 ANPRM, 24516.
11 35 U.S.C. § 6(a) (describing the qualifications of APJs).
12 *See, e.g.*, USPTO, *Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board*, 85 Fed. Reg. 66502 (Oct. 2022) (Comments of R Street Institute), https://www.uspto.gov/sites/default/files/documents/11302020RStreetInstitute.pdf.
13 *See, e.g.*, Zomm, LLC v. Apple Inc., 391 F. Supp. 3d 946, 955-956 (N.D. Cal. 2019) (describing the three-factor test that district court typically assess in deciding whether to grant a stay pending an IPR), https://casetext.com/case/zomm-llc-v-apple-inc; Umber Aggarwal and Kevin Rodkey, *Trending at the PTAB: When to Ask Court for Litigation Stay*, Law360 (Mar. 30, 2023) (discussing recent decisions denying stays and why), https://www.law360.com/articles/1591765.
14 AIA, Pub. L. 112–29 (2011), § 18(b) (providing criteria for a district court to grant a stay and then for an immediate *de novo* interlocutory appeal of a that decision), https://www.congress.gov/112/plaws/publ29/PLAW-112publ29.pdf.
15 35 U.S.C. §§ 316(b); 326(b).

disagrees on both points and believes that PGRs and ITC proceedings should be treated the same as IPRs and district court proceedings, respectively.

The interest in avoiding duplication and promoting fairness to patentees applies equally in both cases, as does avoiding duplication in multiple forums assessing the same issues under different standards. The petitioner will still have its choice of where to bring the invalidity challenge, but it will be limited to a single forum.

In announcing an earlier change in policy that prohibits denials based on parallel ITC proceedings, the Office relied heavily on the argument that ITC proceedings do not "invalidate" a patent, in contrast to district court cases.[16] But this highly formalistic distinction misses the mark. A negative opinion from any forum, the ITC, district courts, or PTAB, creates a cloud over a patent, making any future challenge (if necessary) relatively straightforward and most likely *not* in the patent owner's favor. The *Fintiv* decision made this very point, stating that "it is difficult to maintain a district court proceeding on patent claims determined to be invalid at the ITC."[17] In contrast, the waste and expense of parallel proceedings is clear and predictable, and not in the best interest of the patent system.

Plus, the ITC is part of the Administration, creating the possibility of inconsistent results from two administrative agencies. There is no clear public benefit from having the Administration duplicating efforts in this manner. On balance, there is virtually no upside while there is significant downside to duplicative proceedings between the PTAB and the ITC. And this is the same for IPRs or PGRs.

A Standing Requirement Is Sound Policy but Likely Conflicts with the Statute

The Office has proposed discretionarily denying petitions filed by "non-market competitors." C4IP welcomes the Office's attention to this issue, which has presented vexing problems to the Office from early attempts of hedge-fund managers to sway stock markets to more recent attempts of third parties to gain fast payoffs by challenging patents that underlie district court damages awards.[18] The AIA was intended to make the patent system stronger and more efficient, not to create get-rich-quick schemes that do not advance innovation in any meaningful way. A standing requirement would, and should, prevent these sorts of abuses at the PTAB.

16 USPTO, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation 6-7 (June 22, 2021), https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf.
17 Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 at 9 (PTAB Mar. 20, 2020) (designated precedential May 5, 2020).
18 *See* Dani Kass, *Will the Real Patent Challengers Please Stand Up?* Law360 (April 25, 2023) (discussing these different types of petitions), https://www.law360.com/articles/1599812.

As with standing requirements for virtually all adversarial disputes, such a requirement at the PTAB would also promote fairness and efficiency. For example, the emergence of member organizations that challenge patents at the PTAB while purporting not to act on behalf of their members raises fairness concerns about effectively giving dues-paying members an additional chance to challenge a patent after the member organization has. It would be more appropriate for these members to be estopped from filing separate challenges on their own if the organization files one. For all of these reasons, C4IP strongly supports the rationale behind seeking a standing limitation.

However, C4IP believes that this change should come from Congress rather than the Executive Branch. The Director clearly has considerable discretion when it comes to denying petitions for institution under Sections 314(a) and 324(a).[19] But this discretion is limited where the statute already explicitly speaks to an issue. As the Supreme Court stated in *SAS Institute*, "Where a statute's language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer."[20]

Congress has directly spoken to the issue of standing by specifying only that "a person who is not the owner of a patent" may file a petition to review that patent.[21] In contrast, the statute is silent about how the Director may use his or her discretion to promote efficiency and minimize duplication of proceedings. This provides for the Director's ability to require *Sotera* stipulations, discussed above, or to take other discretionary actions towards that same goal, such as the currently-used *Fintiv* and *General Plastic* tests to prevent multiple, duplicative challenges to a patent.

On the other hand, the Office's proposed standing requirement runs headlong into the clear statutory language allowing anyone besides the patent owner to bring a challenge. It therefore seems that the Director cannot categorically prohibit certain classes of persons from bringing PTAB challenges, even if he or she can deny petitions on many other grounds.

At the very least, the implementation of this kind of rule would likely lead to litigation. Such litigation would prolong uncertainty, cost the public and the Office, and not be guaranteed to have a positive outcome. C4IP submits that a better course would be for the Office to support a statutory change, and to that end, could substantially help by collecting data to show how the PTAB system would be improved by having a standing requirement for petitioners.

19 *See* Cuozzo Speed Technologies, LLC v. Lee, 136 S. Ct. 2131, 2140 (2016) ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion").
20 SAS Institute Inc. v. Iancu, 138 S. Ct. 1348, 1355 (2018) (overturning the Director's partial institution practice as being in conflict with the plain language of 35 U.S.C. § 318(a)).
21 35 U.S.C. §§ 311(a), 321(a).

If the Office does proceed with a standing requirement, C4IP suggests that the Office consider removing the carve-out for non-profit groups. Many of the abuses described in the ANPRM could easily come from an organization that has formed itself as a non-profit.

The Proposed "Compelling Merits" Test Is in Tension with the AIA and Should Not Be Adopted

The Office has proposed that, if a petition presents a challenge having "compelling merits," that would override any discretionary denial. C4IP has several concerns with this approach.

A key concern is that this proposal seems at odds with the statutory standards for institution, thereby exceeding the scope of the Director's rulemaking authority. The Office acknowledges that this standard is intended to be higher than the statutory institution standards for IPRs and PGRs and even higher than the statutory standard for final written decisions for both. While the Office characterizes this proposal as an exception to discretionary denials, the sheer number of cases where there is likely to be some basis for a discretionary denial means, in practice, the "compelling merits" test will be the *de facto* standard for institution.

This is not only contrary to the AIA, it also appears to effectively give patents the presumption of validity that they have in district court.[22] Overcoming that presumption requires clear and convincing evidence,[23] in direct contrast to the preponderance-of-evidence standard the statute requires for IPRs and PGRs.

As a policy matter, C4IP believes this "clear and convincing evidence" standard should be the standard to invalidate patents under IPRs and PGRs. This standard better reflects the deference that should be given to the agency's initial decision to issue the patent, aligns the Office's standard to that of the district courts, helps account for hindsight bias when assessing obviousness, and has the effect of making patents a more reliable basis for investment.[24] But this is a policy choice for Congress, not the Office.

There are also practical concerns with the "compelling merits" test. It asks APJs to decide, at institution, if the merits case appears even stronger than what is needed at the final written decision. While the Office's proposal suggests that this will not pre-judge the final written decision because more evidence might come to light during the trial phase, this is likely cold comfort to patent holders when the same 3-judge panel presides over the whole proceeding. It

22 35 U.S.C. § 282(a) (presumption of validity for issued patents).
23 Microsoft Corp. v. i4i Ltd. Partnership, 564 U.S. 91, 95-98 (2011) (discussing the presumption of validity and clear and convincing evidence standard).
24 *See* In re Cyclobenzaprine Hydrochloride, 676 F. 3d 1063, 1070-71 (Fed. Cir. 2012) (discussing hindsight bias).

seems designed to deprive patent holders of a meaningful opportunity to contest patentability after institution.

In addition, it is odd for the Office to be acting as a *de facto* appellate body for district court decisions when the Office believes the court made a "compelling" error—any such error is properly addressed by an appeal to the Federal Circuit.

Finally, this proposal leaves an undue amount of discretion in the hands of APJs to rely on the "compelling merits" basis anytime there are no other valid reasons for discretionary denial. Discretionary denial is designed in part to promote finality, such as where the Office has already considered art or arguments. Allowing this finality to become constantly undone is counterproductive and harmful to the innovation that stable patent rights are intended to promote.

The Director Should Always Deny Petitions Where Another Forum Has Affirmed the Validity of a Patent

The Office has proposed denying a petition challenging a patent where the petition, real-party-in-interest, or privy has lost an invalidity challenge in district court unless "compelling merits" dictate otherwise. C4IP submits that it would be more appropriate and efficient to simply deny such petitions. It is in the best interest of the patent system to avoid duplication of reviews and promote finality of adjudicated issues.

As discussed above, the usage of the "compelling merits" test at institution raises questions about the limits of the Director's rulemaking authority. Moreover, the exception seems to ignore the ability of the party who lost invalidity arguments in district court or the ITC to appeal the decision to the Federal Circuit.

The Proposed Patent Owner Disclosure Requirements Are Ill-Conceived and Legally Questionable

The Office is considering requiring a patent owner to disclose patent ownership information, any applicable government funding of the research leading to the patent, sources of funding in parallel litigation, and anyone who might have a stake in that litigation as either (a) a new mandatory disclosure, or (b) as a precondition to the patent owner requesting a discretionary denial. C4IP has serious concerns with these proposals.

First, the Office has not provided a clear explanation for why this information is needed or relevant, as would be required to comply with the requirement that agency action not be

"arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law."[25] In two places where the Office suggests collecting this broad scope of information, no explanation at all is given for why it is needed.[26]

Worse, however, is earlier in the ANPRM, where the Office implies that this information would be used to ascertain whether certain patent owners have business models that the Office—somehow—determines do not promote innovation. [27] The implication is that these disfavored business models would be punished. But if the Office has duly examined and issued a patent to named inventors, it is difficult to see how the identity of the patent's owner should affect the "second look" of these post-grant proceedings. The Office has not explained which business models might be disfavored and why, opening the door to arbitrary decision-making. The Office has offered no substantial explanation of why this information is appropriate or necessary for PTAB proceedings.

In addition, the Office provides no analysis of the burden and expense of compliance. For example, the ANPRM refers to ownership interests "similar" to the beneficial ownership interest reporting requirement of the Securities and Exchange Commission.[28] But the complex rules circumscribing determination of beneficial ownership require specialized expertise, which would necessarily create new cost burdens for patent owners already having to face the average $500,000 expense of defending a post-grant proceeding.[29]

Moreover, this proposal does not acknowledge the ongoing work of other federal agencies to collect this information, pursuant to Congressional command.[30] For the patent system to require a different version of ownership data from all patent holders would be a considerable change in policy that—as work from other agencies shows—should come from Congress and not the Office. There should also be far more coordination with the other information being collecting to eliminate redundancy and reduce costs, especially for small businesses.

25 5 U.S.C. 706(2)(A).
26 *See* ANPRM, 24507 (proposing, *inter alia*, collecting disclosure of "beneficial ownership interests similar to what the Securities and Exchange Commission requires."); 24517 (proposing disclosure as a precondition to getting a discretionary denial).
27 *See* ANPRM, 24505 ("The Office is seeking input on how it can protect those working to bring their ideas to market either directly or indirectly, while not emboldening or supporting economic business models that do not advance innovation. For example, the Office seeks input on to whether to require identification of anyone having an ownership interest in the patent owner or petitioner.").
28 ANPRM, 24507.
29 *Navigating the PTAB: A Primer on The Patent Trial and Appeal Board*, The Michelson Institute for Intellectual Property (Dec. 8, 2021), https://michelsonip.com/navigating-the-ptab-patent-trial-and-appeal-board/.
30 Department of the Treasury, Financial Crimes Enforcement Network, *Beneficial Ownership Information Reporting Requirements*, 87 Fed. Reg. 59498 (Sept. 30, 2022), https://www.govinfo.gov/content/pkg/FR-2022-09-30/pdf/2022-21020.pdf; William Quick, *It's Time To Prep For Corporate Transparency Act Compliance*, Law360 (May 23, 2023), https://www.law360.com/articles/1680487 (calling this law "furthest and widest-reaching federal business entity law ever enacted" that is estimated to affect 32 million businesses).

The proposals to require disclosure of third-party litigation funding and who has stakes in parallel district court proceedings are particularly troubling considering the lack of nexus to the merits of a post-grant proceeding. It seems clear that some district courts believe they have the ability to require this information if they deem it relevant.[31] In contrast, it is unclear how this information would or should impact the Office's reassessment of a patent and what jurisdiction the Office has to collect this information about proceedings in another forum.

The proposed requirements are also in tension with the AIA, which provides no indication that it intended a patent owner requirement to disclose anything about its identity (beyond possessing title to the patent) or sources of funds. The statute repeatedly refers to the "patent owner," in contrast to the statute's clear directive that other relationships to the petitioner are relevant, namely the "real-party-in-interest" (RPI) and any "privy."[32] Further arguing against the use of the Director's rulemaking authority to require these disclosures, there are express statutory provisions covering the recording of patent ownership and identification of sources of government funding.[33]

The Director's Current Approach to Section 325(d) Already Appropriately Balances the Equities

The ANPRM proposes new ways for the PTAB to consider whether, under the language of 35 U.S.C. § 325(d), denial of an IPR or PGR is appropriate because the Office has already considered a particular prior art reference or argument. C4IP believes that the current 2-part test under the precedential *Advanced Bionics* and *Becton, Dickinson* decisions should be what the Office codifies (if anything). The Office has had several years of experience with this approach. It works well. The *Becton/Advanced Bionics* test is balanced, aligned with the statute, and familiar to parties appearing before the Board. [34]

The principal difference from current practice in the Office's proposal seems to be that "mere citation" of references in an IDS is automatically insufficient and that only art that was the basis of a rejection in an application (or related applications under certain circumstances) will bar future challenges. But the Office subsequently acknowledges—in line with the text of § 325(d)—that if "substantially" the same prior art was in an IDS, it would still count.

31 *See, e.g.*, Lamplight Licensing LLC v. ABB, Inc., Civ. No. 22-418-CFC (D. Del. May 22, 2023), https://scholar.google.com/scholar_case?case=8256711126382299076&hl=en&as_sdt=20006.
32 35 U.S.C. §§ 312(a)(2), 322(a)(2) (requiring petitions to identify all real-parties-in-interest); §§ 315(b), 315(e), 325(e) (providing for certain estoppels applying to the privy of a petitioner).
33 35 U.S.C. § 202(c)(6) (requiring identification of U.S. government support in the specification); § 251 (providing for recordation of ownership to void fraudulent transfers).
34 Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH, IPR2019–01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential); Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017–01586, Paper 8 at 17-18 (PTAB Dec. 15, 2017) (precedential as to section III.C.5, first paragraph).

This concession suggests that the Office's proposed bright line rule is not that clear-cut, since frequently, other prior art cited in an IDS will provide the same teachings as art the examiner relied upon. It seems doubtful that this rule would therefore provide for the efficiency the Office claims to seek.

The proposed rule also seems to unfairly heighten the burdens on patent owners to maintain quiet title to their patents. For example, if an IDS-cited reference has the same teachings as art discussed in a rejection, it would seem that patent owners would have to overcome a presumption *against* denial based on that reference under this rule. If the references are truly cumulative, it is unclear why it should be even harder for a patent owner to prove it, and contrary to the purpose of § 325(d) to guard against repetitive attacks on a patent.[35]

In contrast, the existing framework under *Becton, Dickinson* directs the PTAB to consider the following factors relevant to whether a petitioner's art or arguments are substantially the same: "(a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; . . . (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art."[36] These factors more carefully account for the cumulative nature of prior art references and arguments, and thereby better protect a patent holder from redundant and repetitive challenges in line with § 325(d).

Importantly, parties and litigants have experience with the *Becton/Advanced Bionics* framework.[37] Changing the test will introduce a period of uncertainty, which is not warranted when there are no obvious shortcomings of the current test and the benefits of the change are unclear.

The Office Properly Seeks to Codify Certain Existing PTAB Practices

C4IP believes the proposals to address serial and parallel petitions are good candidates for codification of existing practice. Some of the Office's proposals for both appear generally in line with these established practices.

C4IP also supports proposals to require separate briefings when issues ancillary to the merits of a case are presented. It makes sense to ensure that the merits are addressed

35 *See* H. Rept. 112z-98, at 48 (2011).
36 Becton, Dickinson, IPR2017–01586, Paper 8 at 17-18.
37 See, e.g., Eugene Goryunov & Clint Wilkins, *Discretionary Denial Under Section 325(d): Nuances of Advanced Bionics Framework for Prior Art Cited in an IDS During Prosecution*, IPWatchdog (Oct. 31, 2022), https://ipwatchdog.com/2022/10/31/discretionary-denial-section-325d-nuances-advanced-bionics-framework-prior-art-cited-ids-prosecution/id=152394/.

thoroughly while allowing for appropriate briefing of other issues. This is an existing practice for parallel petitions.[38] The proposal to also have this practice for other discretionary denials is a logical extension.

* * *

In sum, C4IP believes the Office should proceed with (1) *Sotera* stipulations being required in IPRs and PGRs when parallel district court or ITC proceedings are pending; (2) denial of IPR or PGR institution where a petitioner, RPI, or privy has lost an invalidity challenge in court; (3) the current practice for serial and parallel petitions; (4) separate briefing for discretionary issues; and (5) current § 325(d) practice.

C4IP also believes there should be no "compelling merits" exception to any basis for discretionary denials and is strongly opposed to the proposals to require additional ownership and funding disclosures for patent holders as irrelevant to the merits of PTAB review and harmful to small businesses.

C4IP hopes the Office will pursue and support legislative change for a standing requirement and a clear-and-convincing evidence standard for IPRs and PGRs. This approach, instead of rulemaking, would seem to be a more sustainable basis on which to seek these types of changes, given their tension with existing statutory provisions.

C4IP again thanks the Office for providing this opportunity to comment and looks forward to further engagement with the Office on these important issues.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

38 USPTO, *Patent Trial and Appeal Board Consolidated Trial Practice Guide* 59-60 (Nov. 2019), https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf?MURL=.

March 10, 2023

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the U.S. Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Submitted via www.regulations.gov
[Docket No. PTO-P-2022-0037]

Director Vidal,

The Council for Innovation Promotion (C4IP) appreciates the opportunity to respond to your November 7, 2022, Request for Comments (RFC) on Joint USPTO-FDA Collaboration Initiatives. *See* 87 Fed. Reg. 67,019 (Nov. 7, 2022). The RFC seeks public comments on areas for USPTO-FDA Collaboration in response to President Biden's Executive Order in July 2021 on Promoting Competition in the American Economy, 86 Fed. Reg. 36,987 (July 14, 2021), including efforts to provide greater access to medicines for American Families and increase marketplace competition.

Led by former USPTO Directors and federal judges, C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property (IP) rights that drive our nation's innovation, boost economic competitiveness, and improve lives around the world. C4IP serves as a trusted partner to Congress and the Biden administration, as officials seek to develop policies and make operational decisions to ensure a well-functioning IP system that bolsters U.S. innovative competitiveness and investment in new technologies.

C4IP believes in our shared goals of providing greater access to innovative, life-saving, life-improving medicines and socially beneficial innovation. With that in mind, we write to highlight two aspects of the proposed USPTO-FDA collaboration that we believe will impede the achievement of these goals. First, the proposed USPTO-FDA collaboration is advancing in the

absence of any reliable evidence of a problem that needs solving. The IP and innovation communities, therefore, need an evidence-based study and analysis before any additional collaboration commences along the lines suggested by the RFC. Second, the collaboration, as currently proposed, does not sufficiently address the distinct roles and expertise—both technical and legal—of the two agencies. The current proposal will lead to an interagency entanglement that will likely exceed the bounds of permissible agency action and will undermine the patent system by interjecting the voices of numerous federal agencies—none of which have patent-law expertise—into the patent examination and review process.

An Evidence-Based Study is Necessary Before Undertaking Any Collaboration

Our first concern with the proposed USPTO-FDA collaboration is that it is being advanced without competent, reliable evidence demonstrating the need for the contemplated far-reaching actions. Without complete information, the USPTO may be led down a path resting on incomplete and erroneous assumptions.

Evidence is key to making an informed decision. Evidence forms the foundation of any meaningful technical decision, and evidence is necessary for rational agency decision-making, especially so for decisions that need to pass muster under the Administrative Procedure Act. *See, e.g.,* 5 U.S.C. § 556(b). The need for evidence-based agency decision-making is so important that Congress enacted the Foundations for Evidence-Based Policymaking Act of 2018, which created a framework for federal agencies to use comprehensive and integrated approaches to gathering evidence and enhancing the government's ability to perform those evidence-building activities. Pub. L. No. 115-435, 132 Stat. 5529 (Jan. 14, 2019).[1]

In our view, the current dialogue lacks the necessary evidentiary record to support all aspects of the agencies' proposed collaboration. Various parties, such as I-MAK, have made various claims about how patents are supposedly impeding access to medicines. The accuracy and reliability of I-MAK's drug patent numbers, as presented in their attention-grabbing pamphlets

[1] The Foundations for Evidence-Based Policymaking Act requires, for example, that agencies develop evidence-building plans that identify policy questions and the evidence that the agency expects to develop to address them. See generally GAO, Evidence-Based Policymaking, Survey Data Identify Opportunities to Strengthen Capacity Across Federal Agencies, GAO-21-536 (July 2021), https://www.gao.gov/products/gao-21-536.

like "Overpatented, Overpriced" (2018) and "America's Bestselling Drugs of 2019," have been called into question.[2][3] I-MAK, for its part, remains unmoved and continues to repeat its tenuous claims.

We need not rehash all the arguments here, as the comments submitted to date underscore our more salient point: We need reliable evidence and concrete data to understand whether there exist valid bases for taking the extraordinary measures proposed by the RFC. The only way to fill the current evidentiary gap is to conduct proper information gathering and studies.

As it currently stands, many of the RFC's proposed actions seem to be solutions searching for a problem. For instance, the USPTO states that it is seeking to "[e]ngage in greater FDA collaboration in AIA proceedings." 87 Fed. Reg. at 67,021. But is there any evidence that the particular type of patents in AIA proceedings that would be subject to this "greater FDA collaboration" are so different from other patents to require another agency's involvement while other patents do not? In other words, what is the evidence that would justify singling out such patents? Indeed, the USPTO historically has resisted singling out patents or technologies for disparate treatment, and has insisted that the patent system applies equally to all. Plus, is there any evidence that the FDA's participation in AIA patent adjudicatory proceedings would, in fact, be beneficial to AIA proceedings?

Further, precisely what types of patents would the contemplated FDA participation be for? Would it be limited solely to "pharmaceutical" patents, however that is defined, or would it include all patents that are in any FDA-regulated products and services? In other words, as currently written, the USPTO may well be opening the door to the FDA's participation in the patent process for any patents directed to pharmaceuticals, biologicals, medical devices, dietary supplements, food products, and cosmetic products—an extraordinary breadth of technology. And how about other types of patents and other agencies? Will the USPTO next seek "greater collaboration" in AIA proceedings from the Department of Agriculture for agriculture-related patents?[4] Or from the Department of Energy for energy-related patents?

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[2] Ltr. of Adam Mossoff at 2 (Feb. 1, 2023), https://www.regulations.gov/comment/PTO-P-2022-0025-0107; *see id.* at 7 ("These unverified, unexplained, and vast discrepancies between the Orange Book listings and I-MAK's drug patent numbers raise serious questions about the unreliability and veracity of I-MAK claims.").
[3] Ltr. from Sen. Thom Tillis to I-MAK (Jan. 31, 2022), https://ipwatchdog.com/wp-content/uploads/2022/02/1.31.2022-LTR-from-Senator-Tillis-to-IMAK-re-Patent-Data-Sources.pdf.
[4] *See* Ltr. from Vidal to Vilsak & Moffitt (Mar. 7, 2023), https://www.uspto.gov/sites/default/files/documents/uspto-usda-letters03072023.pdf; USPTO, Director's Blog, Increasing Transparency, Boosting Competition, and Supporting Innovation Can Deliver Better Choices for Farmers in the Seed Marketplace (Mar. 7, 2023), https://www.uspto.gov/blog/director/entry/increasing-transparency-boosting-competition-and.

The proposal may lead to numerous other federal agencies—all with no expertise in patent law—becoming involved in the patent examination and adjudication process. We are unaware of any evidence-based reasoning to support such a sweeping approach.

The lack of evidence traces back to the FDA's letter to the USPTO in September 2021. There, FDA expressed concerns about so-called "patent thickets," "product hopping," and "evergreening."[5] But the FDA's letter lacked any specific quantitative data about the extent of those supposed deleterious practices.

In C4IP's view, some forms of agency collaboration can be net-positive, and the USPTO already collaborates with the FDA and other agencies to their mutual benefit. But the type and extent of collaboration must be carefully considered and guided by evidence-based decision-making. Before proceeding with any of the proposed additional collaboration initiatives, therefore, we urge the USPTO to undertake a detailed study to gather the data and rationally assess what, if any, further collaboration initiatives are necessary and appropriate to advance our shared goal of providing greater access to innovative life-saving and life-improving medicines and socially beneficial innovation. The data collected needs to identify the specific problems that have allegedly taken place, and the quantities of such problems. In addition, evidence should be provided that the proposed solutions will in fact solve those problems.

Respecting and Balancing the Different Statutory Roles of USPTO and FDA

Our second concern relates to the problematic entanglement of the distinct roles of the USPTO and the FDA. The RFC seemingly contemplates action and decision-making by FDA that extends far beyond what Congress authorized. The USPTO-FDA coordination—as proposed—will likely lead to improper FDA participation in substantive patent legal decisions. This entanglement is problematic because USPTO and FDA focus on entirely different technical and legal issues and are charged with administering entirely different statutes.

[5] *See* Ltr. from Janet Woodcock, M.D., U.S. Food & Drug Administration, to Andrew Hirshfield, USPTO (Sept. 10, 2021), https://www.fda.gov/media/152086/download; https://www.uspto.gov/sites/default/files/documents/EO14036-FDALettertoPTO.pdf.

As an initial point, targeted collaboration between or among federal agencies can, if appropriately implemented, lead to better decision-making in the Executive Branch. For that reason, Congress can and has authorized various inter-agency collaborations. When Congress authorizes agencies to collaborate, the federal agencies are duly empowered to undertake the shared actions and decision-making that ordinarily are not within the prescribed scope of authority of the individual agencies. They can undertake the necessary training and rulemaking to ensure that agency actions comply with the law.

As of now, however, Congress has not authorized the FDA to participate in any decision-making relating to patent laws. The USPTO alone is charged with reviewing and granting patents. *See, e.g.,* 35 U.S.C. § 2(a) (establishing the USPTO as "responsible for the granting and issuing of patents"); id. § 3 (authorizing the Director to be "responsible for providing policy direction and management supervision for the Office and for the issuance of patents"). The FDA's authorization, in contrast, concerns safety and efficacy issues for food, drugs, dietary supplements, medical devices, cosmetics, and certain other consumer and health products. *See, e.g.,* 21 U.S.C. § 301 et seq. C4IP thus sees no current authorized basis for the FDA to be involved in substantive Patent Office actions, such as AIA proceedings. Moving forward with the contemplated collaboration could invite legal challenges that will distract each agency from its respective mission.

Furthermore, the fundamentally distinct missions of the USPTO and FDA should give pause to the proposed collaboration, especially with respect to including the FDA in the patent review process, whether examination or post-grant proceedings on particular patents. For instance, and as mentioned above, the RFC proposes to "[e]ngage in greater FDA collaboration in AIA proceedings." 87 Fed. Reg. at 67,021. That proposal is an extraordinary, unprecedented, and troubling step that would allow a separate federal agency to inject itself into the PTO's administrative adjudication of patent rights in a particular area of technology.

C4IP sees many reasons to be concerned. Unlike the USPTO's patent examiners or administrative patent judges, FDA employees are not trained on issues of patentable subject matter, claim construction, non-obviousness, enablement, and other patentability criteria. Any FDA participation could inject issues outside the patent statutes.

Issues outside the patent statutes have no place in the patentability analysis. For instance, Senator Warren recently asserted that "[s]ubcutaneous injection for delivery of treatments and medications" is "an obvious use" since "Insulin was discovered in 1921."[6] But that contention is a vast and incorrect oversimplification of drug development, pharmacology, and science in general. Under patent law, a snap judgment of an invention being "obvious" is not the proper standard upon which to assess patentability. *See, e.g., Graham v. John Deere Co.,* 383 U.S. 1, 17 (1966) (establishing the proper legal test for assessing the non-obviousness of an invention). Whether a technical advance—pioneering or otherwise—warrants patent protection depends, in part, on objective evidence of non-obviousness. The proposal articulated in the RFC, to allow for "greater FDA collaboration in AIA proceedings," risks erroneous patentability decisions based on improper legal standards and irrelevant evidence.

FDA standards are not just "different" from USPTO standards; they can be entirely incompatible with patent law. Indeed, as the U.S. Court of Appeals for the Federal Circuit has explained: "Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings." *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994). In other words, an invention—such as a new medical device, drug formulation or new dietary supplement—may meet all the requirements for patentability, but nevertheless, it may not satisfy stricter FDA requirements that would not permit the product to be marketed in the United States. There could be any number of reasons why the FDA would reject an application to market a particular product, yet the product itself is covered by a valid patent claim.

There are more reasons to be concerned about the proposal to engage FDA in AIA and other Patent Office proceedings. First, Congress established AIA proceedings to "provid[e] quick and cost effective alternatives to litigation." H.R. Rep. No. 112-98, pt. 1, at 48 (2011), 2011 U.S.C.C.A.N. 67, 78. With the RFC's proposed actions, however, adding the FDA to AIA proceedings will only complicate those proceedings, make them more expensive for patent owners, and further decrease the reliability of the U.S. patent system.

[6] https://www.warren.senate.gov/imo/media/doc/2023.02.22%20Letter%20to%20USPTO%20re%20Keytruda%20patent1.pdf.

Second, because of the adversarial nature of AIA proceedings, we see little reason for the FDA or any other federal agency to be involved. Congress intended that post-grant AIA proceedings to be alternatives to district court litigation, and they are fundamentally adversary proceedings between a patent owner and a patent challenger. *See Return Mail, Inc. v. U.S. Postal Serv.*, 139 S. Ct. 1853, 1858 (2019) ("[T]he AIA post-issuance review proceedings are adversarial, adjudicatory proceedings between the 'person' who petitioned for review and the patent owner."). In an adversarial system, the parties are entrusted with bringing forth the evidence and arguments they need, and the government should not put its thumb on the scale. We thus fail to see how the FDA's participation—or the participation of USDA, EPA, FTC, or other agencies—would be a net benefit to the patent system. We note that pharmaceutical patents have been litigated in Article III courts for decades, and yet the FDA never collaborates with the district court judge or the accused infringer in those cases.

Third, the same problems and concerns would apply equally in the context of the examination of patent applications and the reexamination or reissue of issued patents. If the FDA imposes its own views on the examination and reexamination process, patent examiners will receive conflicting messages. With over 8,000 examiners, the Patent Office works diligently to educate and train its examining corps to apply the patent laws in a consistent manner. Involvement by another agency in these proceedings would add unacceptable confusion, uncertainty, and delay.

All this is not to say that the USPTO and the FDA (or other agencies) cannot and should not share any information or not collaborate at all. On the contrary, there are numerous reasonable opportunities for the USPTO and the FDA to work together, and they already do. The FDA could, for example, provide training on how to search and identify certain publicly available information relating to drug applications. Conversely, USPTO public resources may offer education on key elements of the patent examination process that can benefit the FDA and the public.

But if any proposed collaboration extends into the decision-making analyses of the USPTO, then that extends too far and unnecessarily invites the problems noted above. Among other things, the FDA and other agencies should not be permitted to provide any input into or analysis about patentability and whether any pending patent applications or issued patents

satisfy the patent law requirements. And certainly, no FDA input should be in reference to any specific pending patent application or any specific patent office proceeding concerning an issued patent.

We further note that any member of the public may submit potentially relevant information to a patent examiner. *See* 35 U.S.C. § 122(e). The USPTO and the FDA could therefore establish procedures for the FDA to submit public information to the patent examiner, in accordance with the current statute. Importantly, though, such submissions are not invitations for third parties (including other federal agencies) to advance arguments about the merits of the patent application:

> The statutory requirement for a concise description of relevance should not be interpreted as permitting a third party to participate in the prosecution of an application, as 35 U.S.C. 122(c) prohibits the initiation of a protest or other form of pre-issuance opposition for published applications without the consent of the applicant. Therefore, while a concise description of relevance may include claim charts (i.e., mapping various portions of a submitted document to different claim elements), the concise description of relevance is not an invitation to a third party to propose rejections of the claims or set forth arguments relating to an Office action in the application or to an applicant's reply to an Office action in the application.

MPEP § 1134; *see also* 37 C.F.R. § 1.290 ("A third-party submission may not be entered or considered by the Office if any part of the submission is not in compliance with 35 U.S.C. 122(e) and this section.").

* * *

Overall, we submit that it is premature to implement significant new policies and substantial changes to current patent procedures without a thorough study based on reliable data. At a minimum, the contemplated USPTO-FDA collaboration proposals raise significant concerns with their likely impact on the reliability and robustness of the patent system.

Just as problematic is the realistic possibility of USPTO and FDA actions and decision-making that are not authorized by Congress. Without the proper statutory authority, the FDA has no proper role deciding whether patent applications should issue into U.S. patents or whether duly issued U.S. patents should be cancelled.

We at the Council for Innovation Promotion have dedicated our careers to the patent system and understand its far-reaching impacts. We applaud the agency for actively soliciting public input on proposed initiatives. We urge you to remain committed to evidence-based policymaking that supports American innovation.

Thank you again for the opportunity to comment.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

January 31, 2023

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the U.S. Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Director Vidal,

The Council for Innovation Promotion (C4IP) appreciates the opportunity to respond to your October 4, 2022 Request for Comments (RFC) on Initiatives to Ensure the Robustness and Reliability of Patent Rights (87 Fed. Reg. 60130).

The RFC sought "initial public comments on proposed initiatives directed at bolstering the robustness and reliability of patents to incentivize and protect new and nonobvious inventions while facilitating the broader dissemination of public knowledge to promote innovation and competition."

Founded and chaired by former directors of the USPTO, C4IP is a bipartisan coalition dedicated to supporting a strong, effective patent system that bolsters U.S. innovation, strengthens our nation's economic competitiveness, and improves lives everywhere.

During the last few months, our coalition has engaged policymakers on a number of fronts and sought to facilitate productive and informed conversations relevant to the intellectual property system. From a discussion of the proposed TRIPS waiver with former U.S. Secretary of Commerce Gary Locke to letters addressing the Patent Eligibility Restoration Act of 2022 (S.4734), the Interagency Patent Coordination and Improvement Act of 2022 (S.4430), and misuse of the Bayh-Dole Act, C4IP has distinguished itself as a non-partisan partner to those considering policies impacting America's intellectual property system.

In this spirit, we hope the candid nature of our response is helpful.

In general, we are concerned with the direction of the questions posted by the RFC, as they imply that our patent system needs an extensive overhaul. It does not.

By their very nature, patents are forward-looking instruments in that they last a number of years. That is why the patent system is so dependent on stability and predictability. Importantly, patent policy and administration should be approached with a steady hand, and changes need to be measured and thoroughly vetted both for their need as well as for their

consequences. Many in the public may read this RFC as signaling that the entire system could soon change in unpredictable ways — negatively affecting both the value of patent rights as well as the interest of new entrants to seek and rely on patent rights.

Consequently, while it is appropriate for the agency to lead public discussions and engage in a productive dialogue on improvements to the system, the current RFC directs the public to question fundamental functions of the patent system. The framing of the questions suggests that the USPTO is pursuing an imbalanced inquiry into our patent system, one that wrongly assumes that major problems exist. Even as the USPTO is pursuing an ambitious goal of quadrupling the number of U.S. inventors, the RFC gives little consideration to the needs of individual innovators, small companies, and startups and may discourage those new entrants from putting in the effort needed to obtain rights.

Our response to the RFC is guided by four themes: Reliance on Accurate Data in Policymaking, Maintaining a Balanced Perspective, A Grounded View of Patent Quality, and The Weight of Unintended Consequences.

Reliance on Accurate Data in Policymaking

We are concerned that inaccurate and misleading data and reports are disproportionately driving public policy discussions related to the patent system.

For example, there is no evidence that drug innovators routinely submit misleading or contradictory statements to the FDA and USPTO — and certainly not for the purpose of obtaining unwarranted patents. This narrative is fueled by faulty and unsubstantiated drug patent numbers released by activist organizations like the Initiative for Medicines, Access & Knowledge (I-MAK). And, in fact, based on such claims from I-MAK, Members of Congress have introduced legislation attempting to address this alleged activity (see, e.g., S.4430, Interagency Patent Coordination and Improvement Act of 2022).

The underlying premise of these activist groups is faulty. There is no evidence that innovators make such submissions in order to improperly obtain multiple patents on the same invention, as opposed to protecting their multiple inventions as appropriate under the laws. Nor is there evidence that the patent system is improperly impeding the launch of less-expensive generics. On the contrary, generic penetration in the United States is among the highest of all OECD countries. Today, about nine in 10 U.S. prescriptions are filled with generic drugs. On average, generics only fill about half of all prescriptions written in OECD countries.

All this while the United States remains the world's most prolific innovator of life-saving pharmaceuticals. Indeed, two-thirds of all new drugs approved over the past decade

originated in U.S. labs, among them numerous medical breakthroughs. The government should be very careful before disturbing this precious balance that has been achieved over the last several decades through carefully-crafted and well-balanced major legislation, including the Hatch-Waxman Act, the Bayh-Dole Act, and the Biologics Price Competition and Innovation Act (BPCIA).

The USPTO should look more closely at I-MAK's claims so that it may engage, inform, and redirect, if possible, legislative and administrative efforts aimed at destabilizing the patent system to the detriment of American innovation. I-MAK's "statistics" have at times been directly contradicted by objective data from official databases, namely the FDA's Orange Book — a public list of approved drugs and their patent information. In a 2019 report, for example, I-MAK asserted that the drugs Eliquis and Xarelto — used to treat blood clots — were covered by 31 and 32 patents, respectively. However, the FDA's Orange Book has listed at most three patents for Eliquis and six patents for Xarelto. I-MAK also claims that the exclusivity periods for drugs covered by so-called "patent thickets" will block competition for decades – yet, generics have already entered the market in frequent cases. Similar data discrepancies abound.

Senator Thom Tillis, in his January 2022 letter to the USPTO, has also requested that the agency itself apply its expertise to review I-MAK's data before citing it or relying on it. Matters of patent law and policy are complex, and misguided policy can lead to dire consequences for innovative industries in a delicately balanced system. There is certainly room to debate the contours of reform, but false information should play no role in the discussions. Policymaking should be guided by thoughtful action and based on accurate data and replicable methodology. And, the USPTO has a critical role to play to proactively lead and inform these complex policy discussions.

At a minimum, patent policy should be guided by balanced data, and relying exclusively on I-MAK presents a one-sided perspective.

Maintaining a Balanced Perspective

Contemporary public dialogue regarding the patent system has been recently motivated by a suspicion of drug patents and a presumption that drug companies are gaming the system. This is then used against the entire patent system and innovators in all industries. We are concerned, in particular, about allegations that pharmaceutical manufacturers file for large numbers of undeserved patents on drugs to inappropriately thwart competition from generics companies. This narrative significantly misunderstands how drug development and the patent system work.

In reality, for the enormous amount of capital spent on research and development, the pharmaceutical industry seeks a modest number of patents in comparison with other

industries — including the high-tech and automotive sectors. When the USPTO does issue a drug patent, as with all other patents, it is because the pharmaceutical innovation is useful, novel, and nonobvious — the congressionally-mandated criteria an invention must meet in order to warrant patent protection.

Those patents can represent real and inventive improvements to a medication that result from years spent researching and navigating the FDA approval process. These improvements often offer substantial benefits for patients, such as greater dosing flexibility and easier adherence to their treatment regimen.

Such improvements to existing technology are a fundamental part of the process of innovation in all sectors of the economy. Virtually every step taken to improve science, manufacturing, or technology is incremental — and follow-on — as inventors build on their own advances and the advances of others. Indeed, the very basis of a patent — requiring public disclosure as a quid pro quo in exchange for protection — is to enable this progression.

Companies in all industries routinely improve existing products and obtain new patents for these improvements. It would be absurd to assert that companies making smartphones are cheating the system by seeking patent protection for improvements in new models of their phones, or that automobile manufacturers are abusing patent laws by patenting improvements to their vehicles.

Put another way, the pharmaceutical industry interacts with the patent system just like every other industry. It ought not to face additional obstacles to obtain patent protection or be singled out for discriminatory policymaking. If this industry is singled out now, which industry will be next?

The USPTO should foster a regulatory environment that rewards innovative improvements that meet the requirements for patent protection as set forth by Congress, without regard for the industry in which those improvements are made. Without this environment, it is likely that major discoveries will not be pursued to the same level. Curtailing follow-on innovation essentially curtails all innovation. By attempting to change the patent system to address perceived issues in just one industry, the USPTO would impact all industries and the American economy at large.

A Grounded View of Patent Quality

Patent quality must always be a major focus for the USPTO — as it has been going back to its founding. In truth, the USPTO has performed and adapted well on patent quality, especially given the constantly evolving nature of technology, court decisions, and laws.

We believe the USPTO has the most robust quality measurement system of any major patent office globally. The USPTO's Office of Patent Quality Assurance employs robust processes to identify statutory compliance errors. The USPTO has also made a dedicated commitment to build, manage, and train its examination corps to avert, identify, and correct errors in the patent application review process.

Of course, patent quality will never be perfect. Each patent application is a complex document that attempts to describe and distinguish a new innovation in the physical world. Those descriptions will never be exactly precise. So, patent examination itself cannot reasonably be expected to work flawlessly or weed out every error — even though the USPTO does a laudable job overall. As a result, it is impractical to expect levels of quality such as those seen in manufactured goods.

Moreover, quality goes both ways — the agency should be as concerned about failing to issue deserving patents, as it is with preventing invalid patents from issuance. Each deserving patent not issued correlates to capital not flowing into the economy, jobs not created, services not launched, and discoveries not reaching consumers and the public.

Of course, patent quality must always remain a priority for the USPTO. But it should not be its only priority. Solely concentrating on quality has the effect of stalling activities aimed at strengthening patent rights overall until the quality of patents is "good enough" — which will never be the case for those who prefer a weak patent system. The perfect should not be the enemy of the good.

The USPTO's focus should span all aspects of the patent system — including but not limited to quality. The agency must not forsake the important work of strengthening the rights of patentees and the enforceability of patents while it works continuously, as it should, to improve patent quality.

The Weight of Unintended Consequences

The value of intellectual property relies, in large measure, on the certainty and predictability of the system itself. This is the challenge the USPTO faces moving forward: From enabling consistent and timely examiner decisions across approximately 9,000 examiners — in light of an ever-growing body of the prior art — to building a reliable body of law that the courts and the public can depend on.

Each major policy change must be led by thorough studies that demonstrate it is needed and that it will have the intended consequences. And each change must be carefully weighed to avoid unintended, disruptive consequences. To that point, the June 8 letter from six

U.S. senators to the USPTO — included in the background of the RFC — caused reasonable apprehension. The letter, without material substantiation, attributed much of the alleged "patent thicket" issue to continuation filing practices.

There is worry within the intellectual property community that biopharma concerns will be used as a wedge issue for returning to some previously proposed and ill-conceived general limitations on continuation practices. Those 2006 proposed rules — on broadly limiting the number of claims that would be examined and continuations that would be allowed — caused significant unrest within the innovative ecosystem and resulted in the USPTO being sued with success.

The USPTO should take extra care when considering changes to continuation filing practices not to repeat the mistakes of recent history. Such changes — even if well-intentioned — could disrupt innovators who rely on continuation filings to claim the rightful scope of their inventions. For example, variations of proposals such as requiring a "second look" have been tried and found unsuccessful in the past.

Again, the framing of the questions in the RFC, in some places, suggests that the Office believes an extensive overhaul is needed to continuation practice or to divisionals or restrictions. We see no evidence that an extensive overhaul is needed. The practice of continuation is not an abuse of the system; rather, it is often necessary to enable fulsome examination and dialogue between examiner and applicant when dealing with a new, complex technology that incorporates multiple inventions.

The RFC also asks about increasing initial patent application filing fees to match the cost of USPTO examination. This is a major potential policy change. It is one that could upend a fundamental aspect of America's patent system, which was designed to be accessible and to democratize invention.

Unlike major patent offices in some other jurisdictions, U.S. policymakers have long ago made a purposeful decision to keep up-front filing fees low in order to encourage more inventors. This is a feature — not a bug — of our patent system, one that allows inventors to obtain protection and attempt success in the marketplace in order to fund their further efforts. And this approach has worked remarkably well, with the United States leading the world over the past two centuries in innovation and technology development. We question the need and the basis for disrupting this long tradition. And the USPTO should ensure that any fundamental changes to the existing fee structure will not undermine current and continuing efforts to expand participation in the innovation ecosystem by those who benefit the most from lower entry fees, including startups, underserved communities, and people of lower incomes.

We at the Council for Innovation Promotion have dedicated our careers to the patent system and understand its far-reaching impacts. We applaud the agency for actively soliciting public input on proposed initiatives. And we urge you to remain committed to evidence-based policymaking that supports American innovation. No major change — along the lines suggested by much of the RFC — should be made without thorough studies and detailed input from all stakeholder groups.

Thank you again for the opportunity to comment. We invite you to consider us a resource as the USPTO weighs these important issues.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

[117H5184]

.....

(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend section 337 of the Tariff Act of 1930 with respect to requirements for domestic industries, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. SCHWEIKERT introduced the following bill; which was referred to the Committee on _____

A BILL

To amend section 337 of the Tariff Act of 1930 with respect to requirements for domestic industries, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Advancing America's Interests Act''.

SEC. 2. PURPOSE.

The purpose of this Act is to ensure that the resources of the United States International Trade Commis-

sion are focused on protecting genuine domestic industries and to safeguard the public health and welfare and the United States economy (including competitive conditions).

SEC. 3. UNFAIR PRACTICES IN IMPORT TRADE.

(a) IN GENERAL.—Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) is amended as follows:

(1) Subsection (a) is amended—

(A) in paragraph (3)—

(i) by striking ''or'' at the end of subparagraph (B);

(ii) in subparagraph (C), by striking ''engineering, research and development, or licensing.'' and inserting ''engineering and research and development; or''; and

(iii) by adding after subparagraph (C) the following:

''(D) substantial investment in licensing activities that leads to the adoption and development of articles that incorporate the patent, copyright, trademark, mask work, or design.'';

(B) by redesignating paragraph (4) as paragraph (5); and

(C) by inserting after paragraph (3) the following:

''(4) For purposes of paragraph (3), the complainant may not rely upon activities by its licensees unless the license leads to the adoption and development of articles that incorporate the claimed patent, copyright, trademark, mask work, or design for sale in the United States.''.

(2) Subsection (b) is amended—

(A) in paragraph (1), by inserting after the first sentence the following: ''For a complaint under oath, a person may be relied upon to qualify as an industry under subsection (a)(2) only if the person joins the complaint under oath, except that nothing in this sentence shall be construed to compel such a person to join the complaint.''; and

(B) by adding at the end the following:

''(4)(A) The Commission shall identify, at the beginning of an investigation, whether the investigation presents a dispositive issue appropriate for an expedited fact finding and an abbreviated hearing limited to that issue, and shall direct the assigned administrative law judge to issue an initial determination on such issue not later than 100 days after the investigation is instituted.

''(B) Any initial determination by the assigned administrative law judge under subparagraph (A) shall stay the investigation pending Commission action.''.

(3) Subsection (c) is amended—

(A) by striking the first sentence and inserting the following: ''(1) The Commission shall determine, with respect to each investigation conducted by it under this section, whether or not there is a violation of this section, except that the Commission—

''(A) may, by issuing a consent order or on the basis of an agreement between the private parties to the investigation, including an agreement to present the matter for arbitration, terminate any such investigation, in whole or in part, without making such a determination; or

''(B) may determine during the course of the investigation that the exclusion of articles under investigation would not be in the interest of the public, after considering the nature of the articles concerned and the effect of such exclusion upon the public health and welfare, the United States economy (including competitive conditions), the production of like or directly competitive articles by the complainant and its licensees, and United States consumers, and terminate any such investigation, in whole or in part, without making any further determination.'';

(B) in the second sentence, by striking ''Each determination'' and inserting the following:

''(2) Each determination'';

(C) by striking ''its findings on the public health and welfare, competitive conditions in the United States economy,'' and inserting ''its findings on the public health and welfare, the United States economy (including competitive conditions),''; and

(D) by inserting ''by the complainant and its licensees'' after ''the production of like or directly competitive articles in the United States''.

(4) Subsection (d)(1) is amended by striking the first sentence and inserting the following: ''(1) If the Commission determines, as a result of an investigation under this section, that there is both (A) a violation of this section and (B) exclusion of the articles concerned is in the interest of the public, after considering the nature of the articles concerned and the effect of such exclusion upon the public health and welfare, the United States economy (including competitive conditions), the production of like or directly competitive articles in the United

States by complainant and its licensees, and United States consumers, then the Commission shall direct that the articles concerned that are imported by any person violating the provisions of this section be excluded from entry into the United States.''.

(5) Subsection (e)(1) is amended by striking the first sentence and inserting the following: ''If, during the course of an investigation under this section, the Commission determines that there is reason to believe that there is a violation of this section and that exclusion of the articles concerned would be in the interest of the public, the Commission may direct that the articles concerned that are imported by any person with respect to whom there is reason to believe that such person is violating this section be excluded from entry into the United States, after considering the nature of the articles concerned and the effect of such exclusion upon the public health and welfare, the United States economy (including competitive conditions), the production of like or directly competitive articles in the United States by the complainant and its licensees, and United States consumers.''.

(6) Subsection (f)(1) is amended by striking the first sentence and inserting the following: ''In addi-

tion to, or in lieu of, taking action under subsection (d) or (e), the Commission may issue and cause to be served on any person violating this section, or believed to be violating this section, as the case may be, an order directing such person to cease and desist from engaging in the unfair methods or acts involved, after considering the nature of the articles concerned and the effect of such order upon the public health and welfare, the United States economy (including competitive conditions), the production of like or directly competitive articles in the United States by complainant and its licensees and United States consumers.''.

(7) Subsection (g)(1) is amended by amending the matter following subparagraph (E) to read as follows:

''the Commission shall presume the facts alleged in the complaint to be true and shall, upon request, issue an exclusion from entry or a cease and desist order, or both, limited to that person, after considering the nature of the articles concerned and the effect of such exclusion or order upon the public health and welfare, the United States economy (including competitive conditions), the production of like or directly competitive articles in the United

States by the complainant and its licensees and United States consumers.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to complaints filed under section 337 of the Tariff Act of 1930 on or after the date of the enactment of this Act.