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Comments of the Biotechnology Innovation Organization to the USPTO Advance Notice of Proposed Rulemaking on modifications to the rules of practice for *inter partes* review (IPR) and post-grant review (PGR) proceedings before the Patent Trial and Appeal Board (PTAB), 88 Fed. Reg. 24503–04

June 20, 2023

Dear Director Vidal,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Office’s consideration of “modifications to the rules of practice for *inter partes* review (IPR) and post-grant review (PGR) proceedings before the Patent Trial and Appeal Board (PTAB),” to “build on and codify existing precedent and guidance on Director’s discretion to determine whether to institute an IPR or PGR” under 35 U.S.C. §§ 314(a), 324(a), 315(d), and 325(d). 88 Fed. Reg. 24503–04.

BIO is the principal trade association representing the biotechnology industry domestically and abroad. BIO’s members depend heavily on robust patent rights and a fair system for adjudicating their validity, and therefore have a significant interest in the procedures and legal standards that govern AIA trial proceedings. BIO’s members not only vigorously defend their patents when their validity is challenged but also, in certain situations, petition for review of patents when such patents were improvidently granted. BIO commends the Office for considering modifications to the rules of practice “to better align the practices with the USPTO’s mission to promote and protect innovation and investment in the same, and with the congressional intent behind the American Invents Act (AIA),” thereby bringing more uniformity, predictability, and fairness to the exercise of its discretion under §§ 314(a) and 324(a), and §§ 315(d) and 325(d). 88 Fed. Reg. 24503.

Consistent with the ANPRM’s expressed goal, BIO believes that “clear, predictable rules where possible, as opposed to balancing tests that decrease certainty,” will further the consistent and fair application of the Office’s discretionary denial as it relates to trial institution, which is significant because the Office’s institution decisions, at least in large part, are not appealable to a federal court. *Id.* at 24506.

However, BIO is cautiously concerned with the immense scope and complexity of proposed rules for discretionary denial in the ANPRM, which itself follows on the heels of other complicated Office requests for comments on robust and reliable patents, Office/FDA interactions, artificial intelligence, amendment practice in the PTAB, and others. Taken together, BIO is concerned that the fast pace and diffuse scope of the Office’s recent requests for



comments is taxing the ability of the patent user community to thoroughly vet proposals and provide the most helpful input.

Congress instituted the AIA to create a more efficient and less costly alternative system for adjudicating validity disputes relative to district court litigation, wherein any party could petition for IPR or PGR of a patent upon a “reasonable likelihood” or “more likely than not” showing, respectively, that the patent was unpatentable based on the prior art or additional grounds in PGRs. In its Request, the Office asks stakeholders to address “changes that would provide for discretionary denials of petitions in the following categories, subject to certain conditions and circumstances” and encompassing “several threshold definitions that apply to one or more” of the following:

1. Petitions filed by certain for-profit entities;
2. Petitions challenging under-resourced patent owner patents where the patentee has or is attempting to bring products to market;
3. Petitions challenging patent claims previously subject to a final adjudication upholding the patent claims against patentability challenges in district court or in post-grant proceedings before the USPTO;
4. Serial petitions;
5. Petitions raising previously addressed prior art or arguments (subject to the 35 U.S.C. 325(d) framework);
6. Parallel petitions; and
7. Petitions challenging patents subject to ongoing parallel litigation in district court.

Id.

Summary of BIO’s Response

BIO commends the USPTO for taking efforts to better ensure that practices at the PTAB align with the USPTO’s mission to promote and protect innovation and investment, and with the congressional intent behind the AIA to provide a less expensive alternative to district court litigation to resolve certain patentability issues while also protecting against patentee harassment. However, as outlined below, many of the proposed threshold definitions and proposed discretionary denial rules require additional clarity on the definitions of the terms as well as the scope of the proposed rules to better determine how each might affect practice at the PTAB.

To this end, BIO (1) requests clarity on the definition and scope of the proposed threshold definition, “substantial relationship”; (2) is concerned that the “compelling merits” test is contradictory to the ANPRM’s express goal of creating clear, predictable rules; (3) supports a broad definition of the terms “field,” “engaged,” and “alleged to engage”; (4) requests clarity on



the definition and scope of the term “commercializing”; (5) supports a narrow definition of the term “prior adjudication”; (6) is concerned about serial petition practice abuse under the proposed rules; (7) identifies additional problem areas concerning serial petition practice that are not addressed by the ANPRM, along with proposed solutions; (8) supports the current bright line rule established under the *Advanced Bionics* framework concerning the application of 35 U.S.C. 325(d); (9) supports the alternative proposed rule requiring a showing of good cause to institute parallel petitions; (10) supports the codification of safe harbor exceptions concerning parallel litigation in the district court; and (11) identifies concerns related to required settlement agreement filings at the pre-institution stage.

Proposed Threshold Definitions

Substantial Relationship of Entities

BIO Requests Clarity on the Definition for the Term and the Standards for Determining When Entities Share a “Substantial Relationship”

Finding the current privity rules inadequate to prevent improper challenges to a patent, the ANPRM proposes to adopt a supplementary “substantial relationship” test that does not appear in the AIA. In doing so, the ANPRM contemplates a definition similar to a concept the Board discussed in *Valve I* and *Valve II*, where the Board expanded the definition of a “related” party to include a co-defendant and a joinder petitioner party. *See Valve v. Electronic Scripting Products*, IPR2019-00062, Paper 11 (PTAB Apr. 2, 2019) (*Valve I*) (precedential); IPR2019-00064, Paper 10 (PTAB May 1, 2019) (*Valve II*) (precedential). Additionally, the proposal would require a patent owner and petitioner to disclose any party with an ownership interest in the patent owner and/or petitioner, any government or third-party litigation funding, and any stake any party has in the outcome of the PTAB proceeding or any parallel proceedings on the challenged claims.

In principle, BIO is supportive of providing the Board additional discretion to take into account relationships between petitioners that may not squarely fit into current privity or real party in interest frameworks. Companies routinely maintain numerous relationships and contracts with each other, their vendors, and their clients, some of which may give rise to an inference of improper coordination and proxy dealings where one party, for example, brings an AIA petition for the conspicuous benefit of another, time-barred party. At the same time, a “substantial relationship” test should not be defined so broadly and applied so rigidly that a company would be barred from seeking review of a patent merely because it is nominally in a business or legal relationship with an earlier petitioner without otherwise being in a position to influence the timing or content of the earlier petition.



Seeking clarity, BIO presents the following questions to the Office:

- Do “substantial relationships” exist in perpetuity?
- Have members of a Joint Defense Group (JDG) established a “substantial relationship”?
- Is a licensor in a “substantial relationship” with their licensee? If so, does that “substantial relationship” exist despite an absence of control and/or influence by either party over the other?
- Would a substantial relationship analysis include disclosure of financial relationships between time-barred parties and the petitioner? If so, how far upstream must one go in naming parties? For example, would a start-up founder have to name every entity that helped fund the business and/or proceeding?

Compelling Merits

BIO is Concerned that the Application of the “Compelling Merits” Test is Contradictory to the ANPRM’s Express Goal of Creating Clear, Predictable Rules

The ANPRM proposes a “compelling merits” test that would eliminate discretionary denials where a petition demonstrates “compelling merits” such that the “evidence at the institution stage leaves the Board with a firm belief or conviction that it is highly likely that the petitioner would prevail with respect to at least one challenged claim[.]” 88 Fed. Reg. 24507. BIO is concerned that under this rule, Administrative Patent Judges (APJs) may effectively come to a decision on the merits before full development of the record is established at trial. As proposed, application of the “compelling merits” test also seems contradictory to the ANPRM’s express goal of “creat[ing] clear, predictable rules where possible, as opposed to balancing tests that decrease certainty[.]” *Id.* at 24506.

Proposed Discretionary Denial Rules

A. Petitions Filed by Certain For-Profit Entities

BIO Supports a Broad Definition of the Terms: “Field”; “Engaged”; and “Alleged to Engage”

The ANPRM contemplates changes to the use of discretionary denials in cases involving petitioners that are not in competition with or accused of infringement by a patent owner. Specifically, the ANPRM proposes to discretionarily deny a petition for IPR or PGR filed by an entity that is a (1) for-profit entity; (2) has not been sued on the challenged patent in a manner sufficient to give rise to declaratory judgment standing; (3) is not otherwise an entity that is



practicing or could be alleged to practice; and (4) does not have a substantial relationship with such an entity. *Id.* at 24508.

A broad construction of the terms may offer relief to patent owners from e.g., subscription-based membership companies acting as petitioner on behalf of its members or from opaque, newly-formed entities with little history of actual commercial operations other than bringing IPR petitions. BIO is, at the same time, mindful of the needs of small company start-ups with a legitimate interest in establishing a presence in a field. For example, as proposed, it is unclear how the Office would distinguish between legitimate product developers and companies that merely purport to be “engaged” in the field. One solution might require a petitioner to show a threshold amount of investment or other substantial commercial activity typical of its field of commerce in order to be deemed “engaged” or “alleged to engage” in a field.

Petitions Challenging Under-Resourced Patent Owner Patents Where the Patentee Has or is Attempting to Bring Products to Market

BIO Requests Clarity on the Definition for the Term and the Standards for Determining Whether an Entity is “Commercializing” a Product

The ANPRM also includes proposed rulemaking aimed to protect under-resourced inventors and companies. Specifically, the ANPRM indicates that, absent compelling merits, the PTAB would deny institution of IPR or PGR when the following requirements are met: (1) where the patent owner had claimed micro entity or small entity status during prosecution; (2) the patent owner has not exceeded eight times the micro entity gross income level; and (3) the patent owner was commercializing the subject matter of a challenged claim at the time the petition was filed. 88 Fed. Reg. 24509.

BIO is not opposed to this proposal and welcomes the Office’s interest in providing relief to genuinely small, resource-limited, patent-holding businesses. At the same time, BIO believes that care must be taken to ensure that this safe harbor carve-out for small businesses cannot be abused by patent-assertion entities that engage in only token commercialization activities. The ANPRM proposes to deny review if a patent is owned by an “under-resourced” patent owner “attempting to bring products to market.” However, it is not unusual for abusive patent-assertion entities to attempt a similar approach to portray themselves. Moreover, the PTAB likely lacks the resources to adequately investigate or evaluate such a claim. For greater clarity, BIO recommends to clarify that “commercialize” include clinical trials, pre-clinical research, and/or other bona fide development work typical in the field. Additionally, BIO members had questions around the standards for determining when a patent-holding business is so small and “under-resourced” so as to benefit from this proposed rule. BIO assumes that the proposed rule envisions patentees to whom the cost of defending a patent in an AIA proceeding would be so great that it genuinely interferes with their ability to maintain normal business operations and



commercialization activities. On the other hand, a small entity patentee that has sufficient resources to engage in significant patent enforcement might be presumed to also have sufficient resources to defend the patent(s) in question in an AIA proceeding, especially when safeguards against serial or parallel petitioning are otherwise in place.

Petitions Challenging Patent Claims Previously Subject to a Final Adjudication Upholding the Patent Claims Against Patentability Challenges in District Court or in Post-grant Proceedings before the USPTO

BIO Supports a Narrow Definition of the Term “Prior Adjudication”

As a threshold matter, BIO is unsure whether the PTAB has authority to determine an entity’s Article III standing. Regardless, if the PTAB gives effect to the proposed rule to deny institution on previously adjudicated claims, BIO does not currently see a strong need to include prior reexamination proceedings.

Serial Petitions

BIO is Concerned About Undisclosed Parties and Abuse of the Serial Petition Practice

The ANPRM proposes replacing the seven non-exclusive *General Plastic (General Plastic Industrial v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017) (precedential)) factors with a bright line rule: With two exceptions, the PTAB would exercise its discretion to deny any serial IPR or PGR petition (having at least one overlapping challenged claim) filed by the prior petitioner, real party in interest or privy to that petitioner, a party with a “significant relationship” to that petitioner, or a party that previously joined that petitioner in an instituted IPR or PGR. The two exceptions are (1) where the art was not evaluated on the merits, or (2) exceptional circumstances are shown.

Alternatively, a stricter proposal would exercise discretion to deny *any* serial petition, regardless of the petitioner’s relationship to the prior petition or petitioner, unless “compelling merits” are shown. BIO believes that this stricter proposal is not yet ready for vetting and may require additional statutory authority, given that it is likely to apply to a potentially broad range of petitioners and uses an institution standard that is nowhere to be found in the statute (“compelling merits”).

Overall, BIO believes that at least the former proposal could simplify the current factor test while underscoring the need for petitioners to anticipate and proactively address future issues, effectively raising the stakes for first-filed petitions. However, BIO is concerned about the



potential for undisclosed parties establishing a “significant relationship” with the petitioner *following* institution. Thus, BIO suggests and supports inclusion of a mechanism to entertain an otherwise untimely motion to dismiss based on newly revealed facts indicating the formation of a “substantial relationship” between parties.

Relatedly, BIO also identifies specific fact patterns raising issues that it believes are insufficiently addressed in the USPTO’s current application of *General Plastic*. Problems arise when a petitioner files an initial IPR or PGR, and then the same or *another* petitioner significantly delays in filing an IPR or PGR on the same patent (or a patent that is related to or has substantially similar claims). A particular example of this issue arises when a petitioner files an initial IPR or PGR, and then that same petitioner delays (until after the Patent Owner Preliminary Response (POPR), institution decision, or even later) the filing of additional petitions on patents that are related to or have substantially similar claims.¹ These practices encourage one-sided gamesmanship, allow unfair road-mapping, and create unnecessary and inappropriate inefficiencies in the post-grant review process for the Board and for patentees.

Problem A

Problem A is specific to when one petitioner files an initial IPR or PGR, and then another (or the same) petitioner significantly delays in filing another IPR or PGR challenging the same patent, or challenging a patent including substantially similar claims, which encourages one-sided gamesmanship, allows unfair road-mapping, and creates unnecessary and inappropriate inefficiencies in the post-grant review process for the Board and the patentee.

General Plastic has been regularly applied in the context of the same petitioner filing a later petition on the same patent as the original petition. Further, as the Board has acknowledged, the application of the *General Plastic* factors is not limited to situations where the same petitioner files serial petitions on the same challenged claims. *See, e.g.*, Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019) (“TPG”) at 57 (citing *Valve Corp. v. Elec. Scripting Prods., Inc.*, Case IPR2019-00062, -00063, -00084, Paper 11 (PTAB Apr. 2, 2019)). This is appropriate because the same concerns of fairness and efficiency are present when the same petitioner delays in filing a petition on substantially similar claims of a different patent, or when a new petitioner delays in filing a petition on the same patent or substantially similar claims to those challenged in the original petition.

¹ For purposes of this discussion, BIO suggests that patents should be considered “related” if they are within a patent family or are associated by virtue of a terminal disclaimer. Similarly, for this discussion BIO suggests that claims can be identified as “substantially similar” based on a rule of reason analysis, including consideration of, *e.g.*, overlapping limitations and (as with the USPTO’s § 325(d) analysis) overlap in the art or arguments asserted to challenge the claims.



The practice of delayed petitions allows a petitioner to await responsive disclosures of the patent owner’s substantive positions, counter-arguments, and other reactions (in the form of, *e.g.*, a POPR, Patent Owner Response (POR), expert testimony, proposed amendments, oral arguments, and the like) or substantive guidance from the Board (in the form of, *e.g.*, an institution decision, preliminary guidance on proposed amendments, questions at an oral hearing, or even a final written decision) before filing petitions on related or substantially similar claims. This allows the petitioner a one-sided opportunity to gather and analyze this feedback on first-round arguments before recalibrating, adjusting, and firing against new claims (with overlapping or identical limitations) in a later IPR or PGR—harassing and gaining unfair advantage against the patent owner while side-stepping the USPTO’s existing mechanisms aimed at limiting improper serial challenges.

The Board has previously addressed this sort of situation, and found that it presented a basis for § 314(a) discretionary denial. For example, in *Samsung Electronics Co., Ltd. v. Elm 3DS Innovations, LLC*, IPR2017-01305, Paper 11 (PTAB Oct. 17, 2017) (“*Samsung*”), the Board considered § 314(a) discretionary denial when the petitioner was challenging a patent that had previously been the subject of two denied IPRs brought by a different petitioner (with institution decisions issued “over seven months” before the petition was filed), and where the same petitioner had itself participated in 14 other completed IPRs challenging “related” patents. *Id.* at 3–4, 20. In deciding to deny institution, the Board noted, *inter alia*, the significant information advantage enjoyed by this petitioner, which applied three of the same prior art references in its new petition, but swapped out a fourth to address weaknesses identified in the prior IPRs (*id.* at 8, 10–13 (citing “remarkable” similarity)):

[A]t the time of filing the instant Petition, [petitioner] had available information from (i) the *prior petitions* [challenging the same patent], (ii) Patent Owner’s *Preliminary Responses* in [those IPRs], (iii) our *decisions denying institution* in [those IPRs] that explained, among other things, the shortcomings of those petitions relative to [a reference the present petitioner swapped for another in the petition at issue], (iv) the *Patent Owner’s Responses* in the fourteen related *inter partes* reviews that have significant overlap in claim construction issues and motivation to combine, among other issues, and (v) *deposition testimony of Petitioner’s [expert]* declarant [(who was the same in the two prior IPRs challenging the same patent)] *and Patent Owner’s [expert]* declarant. Furthermore, Petitioner...had the [*prior*] *opportunity to develop and present its arguments* in the fourteen *inter partes* reviews.

Finally, we recognize that, should we institute an *inter partes* review in the instant proceeding, Petitioner also would have available to it *our final written decisions* in those fourteen *inter partes* reviews [which involved, *e.g.*] the Hsu and Leedy ‘695 combination [present in the current petition].



Id. at 15–16, 20–21 (emphasis added) (applying these facts in evaluating, *inter alia*, “[t]he third *General Plastic* factor”). BIO respectfully submits that the *Samsung* decision helpfully illustrates the sorts of opportunities for improper road-mapping that petitioners enjoy when they significantly delay IPRs or PGRs despite their knowledge of prior proceedings, and the burdens and inefficiencies that such repetitive petitions impose on the Board and patentees. *See also Shenzhen Silver Star Intelligent Tech. v. iRobot Corp.*, IPR2018-00761, Paper 9 at 13 (PTAB Oct. 1, 2018); *United Fire Protection Corp. v. Engineered Corrosion Solutions, LLC*, IPR2018-00991, Paper 10 at 17–18 (PTAB Nov. 15, 2018). And while *Samsung* itself was an example in which the Board noted and relied on these factors in denying institution of a later third-party petitioner’s petition in 2017, it is our practical observation that the USPTO’s current application of *General Plastic* has *not* tended toward similar rigorous application of these considerations to later petitioners (or related patents or patents with substantially similar claims), at least in recent years.

Whether or not paired with such improper gamesmanship and road-mapping, the practice of serial petition filing imposes needless inefficiencies on the Board and patent owners. For example, when the petitioner spreads out its challenges to patents that are related to or have substantially similar claims, it deprives the Board and patent owner of opportunities to streamline the process—such as by combining or coordinating in time the activities in these related matters (from depositions and briefing to Board calls and oral arguments)—and further results in multiple, potentially inconsistent determinations. This, in turn, means engaging in (and paying for) unnecessarily duplicative activities over and over again.

Proposed Solution to Problem A

BIO proposes the following procedure to address the efficiency concerns in this scenario: BIO proposes that the USPTO affirmatively require substantive analysis of the *General Plastic* factors consistent with *Samsung* when (1) a later petitioner is aware or should be aware of a previous IPR or PGR by another petitioner but significantly delays in filing its own petition and takes advantage of substantive information made available by its delay (such as, *e.g.*, another petitioner’s prior substantive petition arguments and cited art; the patentee’s POPR, POR, proposed amendments, expert testimony oral arguments, etc.; or guidance from the Board, such as an institution decision, guidance on a motion to amend, questioning at an oral hearing, or final written decision) or (2) a petitioner who filed an earlier petition on a related patent or a patent with substantially similar claims waits to file its subsequent petition.

In addition to this fundamental proposal for re-invigorated application of *General Plastic*, with meaningful attention to road-mapping and gamesmanship concerns in the context of later third-party petitioners, BIO provides provide the following refining suggestions.



First, to the extent the Board may find it useful, in this *General Plastic* analysis, to have specific, clear information about the nature of a later petitioner’s knowledge or use of a prior IPR or PGR and its substance (including of specific cited prior art references), BIO respectfully submits that the USPTO may wish to require *verified petitioner responses to questions posed by the Board*. These questions could be standardized by the USPTO to promote fairness and uniformity, and to avoid ambiguities petitioners might otherwise introduce through strategic wording in their petitions or other submissions. **Second**, the USPTO may more expansively apply its statutory § 325(d) discretion to deny institution of a later filer’s petition in situations where the same or substantially the same prior art or arguments are already before the Board but are pending consideration and have not yet been the subject of a substantive Office determination (*see section E, infra*). Recognizing that changes to IPR and PGR practice may in some instances encourage the shifting of abusive practices to other USPTO post-grant challenge mechanisms, BIO notes that § 325(d) applies not only to IPRs and PGRs, but also to *ex parte* reexaminations. *See, e.g., In re Vivint*, 14 F.4th 1342 (Fed. Cir. 2021). **Third**, the Board may condition its institution of a petition that has a significant overlap of art or arguments with a previously-filed IPR or PGR on the petitioner’s agreement to be bound by the Board’s determinations regarding the overlapping art or arguments in a final written decision in the earlier-filed IPR or PGR. **Fourth**, to the extent the USPTO may have concerns about limiting challenges by a petitioner that had not been sued or charged with infringement of the challenged patent by the time of the Original Proceeding but is later sued or charged with infringement, BIO respectfully submits that the USPTO can confirm that this is among the factors to be considered by the Board in conducting a *General Plastic* analysis in connection with post-suit or post-charge petitions. **Fifth**, and finally, if the USPTO decides to implement its proposed “substantial relationship” analysis, further guidance on the foregoing issues could be provided in context of that analysis.

Problem B

Problem B is specific to petitioners who themselves significantly delay filing of additional IPRs (or PGRs) on related patents or patents with substantially similar claims.

The practice of the same petitioner filing a later IPR or PGR on a related patent or with substantially similar claims presents particular gamesmanship concerns as it encourages petitioners to file an initial IPR or PGR on a patent with less commercial significance or infringement risk first to obtain the benefit of road-mapping before filing later petition(s) on more important or significant patents.

Proposed Solution to Problem B

If a petitioner chooses to delay in filing such subsequent petitions, it should have the burden to justify that choice. BIO proposes the USPTO should consider a procedure that is fair to both petitioners and patent owners and provides reasonable notice to both parties



about filing such IPRs or PGRs close in time—thereby encouraging efficiencies in the USPTO’s post-grant review mechanisms.

BIO proposes, for example, that the USPTO consider the following optional notice procedure to assign presumptions for the *General Plastic* analysis:

- (1) A petitioner may choose to serve a patent owner with an “Opening Notice” advising the patent owner of the petitioner’s intention to file an IPR or PGR (an Original Proceeding) challenging some or all of a patent owned by the patent owner within a certain number of months (*e.g.*, 3 months) before that filing, and ask that within a prescribed period of time (*e.g.*, 1 month) the patent owner provide a Responsive Notice identifying any other patents of patent owner that (1) are related or include substantially similar claims, and (2) the patent owner asserts should, for the sake of efficiency, be challenged by an IPR or PGR (if at all) at the same time as the contemplated Original Proceeding (Identified Patents).
- (2) If petitioner chooses to provide the requested Opening Notice, and
 - a. if the patent owner chooses to provide a “Responsive Notice” including Identified Patents, Petitioner shall be entitled to a presumption against discretionary denial under *General Plastic* for any IPR or PGR it files challenging one of the Identified Patents within a certain time period (*e.g.*, 3 months) of the Responsive Notice;
 - b. if the patent owner chooses *not* to provide a Responsive Notice, or does not include a challenged patent among the Identified Patents in a Responsive Notice, there shall be a presumption against discretionary denial under *General Plastic* for any later IPR or PGR challenges by Petitioner to any patent that the patent owner could have included in a Responsive Notice as an Identified Patent, but did not, absent good cause (see (3)).
- (3) If a petitioner chooses not to provide an Opening Notice (or if patent owner establishes good cause for not having provided a Responsive Notice), and petitioner files an IPR or PGR, then, at the same time it provides its initial mandatory notice, patent owner may file and serve an “Optional Notice of Related or Substantially Similar Patent(s)” identifying related patents or patents with substantially similar claims that PO asserts should, for the sake of efficiency, be challenged by an IPR or PGR (if at all) at the same time as the contemplated Original Proceeding (“Identified Patents”). Any Optional Notice of Related or Substantially Similar Patent(s) shall also include a demand that petitioner file and serve notice of its intent to file any such IPR or PGR (“Notice of Intent to Challenge”) within a certain time period from the Optional Notice (*e.g.*, 1 month),



and that the petitioner actually file any such IPR or PGR within a specified number of months from the Optional Notice (*e.g.*, 3 months (“Filing Window”)).

- (4) If the Petitioner files a timely Notice of Intent to Challenge, the Office shall extend the POPR due date in the Original Proceeding to a date one month after the end of the Filing Window.
- (5) If Petitioner chooses to provide a timely Notice of Intent to Challenge and files any IPR or PGR identified in that Notice of Intent to Challenge within the Filing Window, (a) there shall be a presumption against discretionary denial under General Plastic for such IPR or PGR (“Later Proceeding”), and (b) the Office shall further extend the POPR due date in the Original Proceeding to more closely match the POPR date in any Later Proceedings.
- (6) If the Petitioner does not provide a timely Notice of Intent to Challenge, or does not file a corresponding IPR or PGR within the Filing Window for one of the Identified Patents, or does not file an Original Proceeding within 6 months of an Original Notice, there shall be a presumption in favor of discretionary denial under General Plastic for any IPR or PGR it files challenging any such Identified Patent.

At a minimum, even if no new procedures are added to address this concern, we respectfully submit that the USPTO should clarify that the *General Plastic* analysis must be affirmatively addressed by the Board when a later IPR or PGR is filed by the same petitioner, including when the later IPR (or PGR) is directed to a different patent that is related or challenges substantially similar claims. This application of *General Plastic* to a different patent with the same petitioner would be consistent with Congress’s intent to establish IPRs and PGRs as an efficient, lower-cost challenge procedure (H.R. Rep. No. 112–98, pt. 1, at 40 (2011); 2011 U.S.C.C.A.N. 67, 69; S. Rep. No. 110-259, at 20 (2008)); with the Board’s expressed concerns about promoting efficiency and discouraging unfair behavior (*e.g.*, gamesmanship and road-mapping); and with existing Board decisions relating to *General Plastic* involving a different petitioner and the same patent, and the same petitioner and different (but related) patents, including, *e.g.*, *Samsung v. Elm 3DS Innovations, LLC*, IPR2017-01305, Paper 11 at 3–4 (PTAB Oct. 17, 2017) (denying institution following § 314(a) *General Plastic* analysis where petitioner had previously challenged 14 “related” patents but *not* the patent at issue in this IPR; challenged patent had also been the subject of IPRs by different petitioner). Doing so would assure that *General Plastic* is consistently applied in this circumstance, which is otherwise ripe for petitioner abuse.



Petitions Raising Previously Addressed Prior Art or Arguments (Subject to the 35 U.S.C. 325(d) Framework)

BIO Supports the Current Bright Line Rule Established Under the Advanced Bionics Framework

The ANPRM proposes limiting the application of 35 U.S.C. 325(d) to situations in which the Office previously addressed the prior art or arguments and articulated its consideration of the same in the record. In other words, the citation, without more, of a reference on an Information Disclosure Statement (IDS), in a Notice of References Cited, or in search results would not be considered sufficient to be deemed “previously addressed.”

BIO’s concerns arise out of the fact that applicants do not have control over what an examiner chooses to cite in the record. Compared to the current bright line test under *Advanced Bionics* that incentivizes disclosure and fulsome examination, BIO believes this proposed rule muddies the water and may deter compliance with the duty of disclosure. BIO also has questions related to how the PTAB would handle new combinations of prior art under the proposed rule.

If the PTAB gives effect to the rule, BIO *first* suggests the USPTO should, at minimum, *also* expressly include art that is part of the file history *and is cumulative of art cited by the examiner in a rejection*. To do otherwise would improperly ignore both the statute and the process by which the USPTO actually conducts examinations: examiners are instructed that “[m]erely cumulative rejections, *i.e.*, those which would clearly fall if the primary rejection were not sustained, should be avoided” (MPEP § 2120), and § 325(d) explicitly rejects limiting its scope to identical art, embracing “the same *or substantially the same* prior art”—as well as “the same or substantially the same *arguments*,” without regard to which art is involved. *Second*, the Board should expressly confirm, as is its practice, that in considering whether the same or substantially the same prior art or arguments “previously were presented to the Office” (in accordance with the language of (§ 325(d)), the Board includes analysis of the prosecution history for *related* patents in the family. *Becton, Dickinson and Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 22–23 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph); *Motorola Mobility LLC v. Maxell, Ltd.*, IPR2022-01287, Paper11 at 16 n.8 (PTAB Feb. 2, 2023); *see also Blue Gentian, LLC v. Tristar Products, Inc.*, ___ F.4th ___ (Fed. Cir. June 9, 2023), slip op. n.3 at 14 (“Statements made by the patentee during prosecution of [one] patent can be relevant to the other patents in the family—particularly where...added limitations are carried forward”). *Third*, the language of § 325(d) is not limited to *concluded proceedings*. Therefore, the USPTO should also confirm in any rulemaking relating to § 325(d) that the analysis also considers any earlier IPRs or PGRs, as well as earlier reexaminations,² *even if they remain pending (including if the institution decision has not yet issued)*. The contrary view unfairly burdens the patent owner, and

² As noted above, recognizing that changes to IPR and PGR practice may in some instances encourage the shifting of abusive practices to other USPTO post-grant challenge mechanisms, BIO observes again that § 325(d) applies not only to IPRs and PGRs, but also to *ex parte* reexaminations. *See In re Vivint*, 14 F.4th 1342 (Fed. Cir. 2021).



improperly limits the Board’s § 325(d) discretion to curb “piling on” by would-be petitioners simply because they file while another proceeding is underway. (BIO notes that any concerns that the already-pending IPR or PGR might be denied institution or otherwise terminated before reaching a final written decision can be addressed in a motion for rehearing, which the Board can permit even if the normal time for rehearing has expired. *See, e.g.*, 37 C.F.R. § 42.5(c)(3).)

Parallel Petitions

BIO is Concerned the Proposed Rule for Parallel Petitions Favors Petitioners with Deep Pockets; thus, BIO Supports the Alternative Proposed Rule Requiring a Showing of Good Cause to Institute Parallel Petitions

BIO supports codifying existing practices concerning parallel petition practice at the PTAB. In general, parallel petitions streamline litigation, and thereby outcomes, benefiting both the patent owner and petitioner. In this respect, there is relative harmony between both parties concerning the shared interests of increasing efficiency and lowering costs in an AIA trial. However, the proposals promoted under the ANPRM threaten to disrupt this balance by “considering changes to provide that, instead of filing multiple petitions, a petitioner may pay additional fees for a higher word-count limit.” 88 Fed. Reg. 24513.

BIO is concerned that this proposal disproportionately favors petitioners with deep pockets and contradicts “the congressional intent behind the American Invents Act (AIA) to provide a less-expensive alternative to district court litigation to resolve certain patentability issues while also protecting against patentee harassment.” *Id.* at 24503. As proposed, “instead of filing multiple petitions, a petitioner may pay additional fees for a higher word-count limit” effectively allowing a petitioner to file “two petitions as one long petition equal in length to two current petitions.” *Id.* at 24513. Thus, even though the ANPRM states that “[f]iling more than one petition with a higher word-count limit (*i.e.*, two or more long parallel petitions) challenging the same patent by the same petitioner...would not be permitted” (*id.*), because an AIA trial must be instituted under the all-or-nothing approach promulgated by *SAS Institute v. Iancu*, 138 S.Ct. 1348, 1354 (2018), the effect is an increase in defense costs for patent owners who must address every challenged claim, meritorious or not. In contrast, the current system of ranking parallel petitions as well as the alternative proposal, may result in trial being instituted on a subset of the parallel petitions such that the patent owner proceeds through trial on fewer grounds than under the proposed rule.

Moreover, BIO does not believe that the increased burden on the patent owner is effectively mitigated by the fact that the proposed rule also states that “[i]f a petitioner pays the fees for filing a petition with a higher word-count limit” the patent owner’s responsive filings “may be filed with proportionally higher word-count limits at no additional charge to either party.” 88 Fed. Reg. 24513. For this reason, BIO favors the alternative proposal in the ANPRM providing that “when determining whether to institute an IPR or PGR, the Board will not institute parallel



petitions unless the petitioner has made a showing of good cause as to why parallel petitions are necessary” by identifying “in a separate five-page paper” the “ranking of the petitions in the order in which it wishes the Board to consider the merits” and “a succinct explanation of the differences between the petitions, why the issues addressed by the differences in the petitions are material, and why the Board should exercise its discretion to institute additional petitions.” *Id.* The ANPRM proposes that “[t]he patent owner may [then] file a response to the ranking” in kind.

Regardless of the proposed rule the USPTO ultimately chooses to effect, if any, BIO requests clarity on the following questions:

- Will the option to purchase an increased word-count limit be capped at 100%?
- Presuming this rule will incentivize institution on significantly more grounds, how does this rule affect estoppel?

Parallel Litigation

BIO Supports the Codification of Safe Harbors but Questions Whether the PTAB Has Authority to Effectively Modify the Statutory Period for Filing a Petition

The ANPRM introduces several safe harbor exceptions concerning discretionary denial for parallel litigation in the district court. Under one of the proposed rules, unless a safe harbor exception is met, the Board will apply “a clear, predictable rule” and deny institution in view of pending parallel district court litigation involving at least one of the challenged claims if the Board determines a trial in the district court action is likely to occur before the projected statutory deadline for a final written decision. *Id.* at 24514. Some safe harbors under consideration include that if (1) the petitioner files a *Sotera* stipulation, (2) the district court litigation is stayed, or (3) the petition presents compelling merits, the Board will not employ discretionary denial. *Id.* at 24515–516. While BIO has some reservations concerning the definition and scope of “compelling merits,” in principle BIO is not disagreeable to codifying these safe harbors.

However, BIO is concerned that the PTAB lacks authority to promulgate a separate safe harbor under consideration by modifying the statutory period of 1-year and instead, considering the filing date of the parallel district court proceeding, such that the Board would not deny institution if a petition is filed within six months after the date on which the petitioner, a real party in interest, or a privy thereof is served with a complaint alleging infringement of the patent. *Id.* at 24515.



Settlement Agreements

The ANPRM also proposes changes to the rules to clarify that parties must file with the Office true copies of all settlement agreements, including pre-institution settlement agreements similar to post-institution settlement agreements. Additionally, the ANPRM proposes to clarify that parties are required to file a true copy of any subsequent settlement agreements between the parties in connection with, or in contemplation of, the termination. *Id.* at 24517–518.

BIO is concerned about required filings at the pre-institution stage. **First**, as a matter of statutory authority, 35 U.S.C. §§ 317 and 327, which address the filing of settlement agreements in connection with motions to terminate in an IPR or PGR, respectively, are *limited only to terminations of already-instituted proceedings*. See, e.g., *id.* at § 317(a) (“Any *inter partes* review *instituted under this chapter* shall be terminated...”), § 317(b) (“Any agreement...in connection with...termination of an *inter partes* review *under this section*”). Indeed, the ANPRM acknowledges that §§ 317 and 327 do not support the proposed extension to pre-institution motions. See ANPRM, 88 Fed. Reg. 24503 (Apr. 21, 2023) at 24517 (“Although 35 U.S.C. 135(e), 317(b), and 327(b) require filing of settlement agreements made in connection with, or in contemplation of, the termination of a proceeding that has been instituted, *these statutory provisions do not expressly govern AIA pre-institution settlement.*”); Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, 77 FR 48612, 48625 (Aug. 14, 2012) (final rule)), and this appears to be beyond the USPTO’s authority. **Second**, limiting the filing requirement to instituted proceedings (as the statute provides) makes sense as a practical and policy matter. As a practical matter, the months immediately following the filing of an IPR or PGR may present the first real opportunity for a discussion between a petitioner and patent owner, and there is far less time to formalize settlement agreements at the pre-institution stage (with the statutory requirement of an institution decision within three months of the POPR, 37 C.F.R. § 42.107(b)) than in the post-institution stage. Settlement is favored as by the USPTO as a matter of policy,³ and settlement in this period—which significantly conserves the Board’s limited resources—may be complicated or thwarted altogether by a requirement to rapidly memorialize and file any understandings relating to settlement formed in this extremely limited time. Further, during this period no formal review has actually commenced (see, e.g., 35 U.S.C. § 314(c)) and typically no significant engagement of the machinery of government (such as the rendering of an institution decision) has yet taken place. Thus, just as no filing with the PTAB of settlement agreements reached immediately *prior to* the filing of an IPR or PGR is required, it makes little sense to treat a settlement reached immediately *after* a filing differently—and this is reflected in Congress’s statutory decision, in §§ 317 and 327, to require such filings only of post-institution settlements.

³ See, e.g., Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019), 86 (“There are strong public policy reasons to favor settlement between the parties to a proceeding. The Board will be available to facilitate settlement discussions, and where appropriate, may require a settlement discussion”).



BIO commends the Office for its outreach to the patent user community and for its untiring efforts to improve and fine-tune the operations of the PTAB to the fair and balanced benefit of inventors, innovators, and technology implementers alike. We look forward to further engagement with the Office on the important questions raised in this ANPRM.

Respectfully submitted,

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