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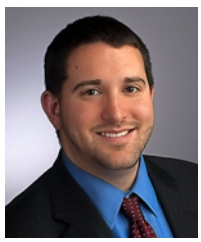
The authors offer advice to both petitioners and patent owners on submitting experimental evidence in a post-grant opposition proceeding.

Considerations for Submission of Experimental Evidence to the Patent Trial and Appeal Board



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Experimental evidence can be a powerful tool in succeeding in an inter partes review proceeding, particularly in the case where inherent properties of prior art are at issue. As indicated by the requirements of 37 C.F.R. § 42.65(b), the Patent Trial and Appeal Board evaluates such experimental evidence and the methodology by which it was obtained. Since the inception of the IPR process, the Board has addressed the submission of experimental evidence only a handful of times.

The authors have reviewed a number of PTAB decisions where at least one party submitted experimental data, identified some general themes, and provide the following observations on the PTAB's evaluation of experimental evidence.

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I. Should Experimental Evidence Be Included In the Petition?

PTAB panel decisions have found that citation to expert testimony in a petition must also discuss the evidence underlying the expert's opinion in the petition itself, rather than relying on disclosure in another document. For example, in *Daicel Corp. v. Celanese International Corp.*, the panel dismissed Petitioner's multiple citations to their expert's declaration as being solely "in support of conclusory statements . . . without discussing the underlying evidence in support thereof."[1] Citing 37 C.F.R. § 42.6(a)(3), the panel stated that "[Petitioner]'s more detailed analysis cannot be incorporated by reference into the petition."[2] This appears consistent with PTAB statements in other contexts that petitioners cannot avoid the 60 page limit for petitions by providing the required analysis in a different document.[3]

In *Purdue Pharma L.P. v. Depomed, Inc.* ("*Depomed I*"), the Petitioner argued in a request for rehearing that

[1] IPR2015-00170, Paper 14 at 20 (P.T.A.B., Decision Denying Institution, Apr. 1, 2015).
[2] *Id.* at 20-21.
[3] *See Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12 at 6-10 (P.T.A.B., Decision Denying Institution, Aug. 29, 2014).

the Board had misapprehended or overlooked Petitioner's expert's opinion that a prior art reference met the ''remain substantially intact'' limitation, citing both to his declaration and evidence elsewhere in the record.[4] The panel rejected this argument, stating: ''It is not the Board's role to play archeologist to uncover any additional support in the record that is not raised and discussed in the Petition and that may bolster [Petitioner's expert's] opinion.''[5]

This serves as a clear warning that petitioners should include all of the evidence underlying their experts' opinions in the petition itself, as failure to do so is not a defect that can be cured.

II. Are Data and Reasoning Supporting Expert's Opinion Adequately Explained?

While PTAB practitioners are likely aware that attorney argument alone is usually insufficient to successfully demonstrate a technical fact in a PTAB proceeding, sometimes even expert testimony may not serve to carry the day where that testimony does not explicitly discuss the underlying supporting evidence.[6] In those cases, the disclosure of experimental evidence upon which the experts are basing their opinions is crucial to success in the IPR setting.

To date, there have been several cases where panels have found that a statement in an expert declaration was insufficient because of a lack of supporting evidence. In *Depomed I* and its related cases, Petitioner challenged Patent Owner's claims to drugs formulated as unit oral dosage forms by incorporating them into polymeric matrices on a number of grounds, including inherent anticipation based on the disclosure of a prior art reference.[7] In support of its inherency position, Petitioner submitted a declaration from an expert who provided his opinion that the dosage forms disclosed by the prior art reference would inherently meet the claimed limitation that the dosage forms remain ''substantially intact.''[8] Although Petitioner argued that its expert's testimony was properly supported by his expertise in the field, the panel, explicitly citing 37 C.F.R. § 42.65(a), found that the expert had failed to provide objective support for his testimony.[9]

PTAB panel decisions have similarly given no weight to an expert's testimony where experts failed to show how they arrived at their conclusions. For example, in *Corning Inc. v. DSM IP Assets B.V.*, Petitioner challenged claims of patents related to coated optical fibers.[10] Both parties submitted expert declarations presenting experimental evidence as to whether the Examples of a prior art reference inherently met the critical limitations of a composition having ''a cure dose to attain 95% of the maximum attainable modulus of less than 0.65 J/cm^2'' and a primary coating ''obtained by curing a primary coating composition having a cure dose to attain 95% of the maximum attainable modulus of less than 0.65 J/cm^2.''[11] Both parties presented evidence of the statistical robustness of their data by way of R^2 values (a statistical metric known as ''the coefficient of determination''), but critiqued the way in which the opposing expert calculated these values.[12] The panel noted that while Patent Owner's expert called attention to the data underlying his calculations of R^2, the panel concluded that the Petitioner's expert did not show how she calculated her R^2 values, and accordingly that she had ''point[ed] to no credible underlying data to support her testimony.''[13]

In *Monsanto Co. v. Pioneer Hi-Bred International*, Petitioner submitted a declaration from an expert in support of its challenge to claims directed to a method of enhancing the quality of maize seed by defoliating the plant at between 600 and 850 growing degree days (GDDs) after pollination.[14] Patent Owner argued that Petitioner's expert's attempt to establish that various prior art references taught and/or provided a reason to defoliate maize plants within the claimed 650 to 800 GDD timeframe was entitled to little weight because the expert withheld the data and calculations that supported his opinions.[15] The panel agreed, citing to 37 C.F.R. § 42.65(a) in finding that ''[Petitioner's expert's] declaration fails to provide sufficient underlying data such that one of ordinary skill in the art would have a reasonable basis to believe that his growing degree day calculations and conclusions are correct.''[16] Absent such data, the panel found that Petitioner had failed to identify sufficient credible evidence to establish that the prior art met the GDD limitation of the claims.[17]

Even when experimental data is submitted, Petitioners should be aware that the data—and the experts proffering it—may be closely scrutinized. For example, PTAB decisions indicate the weight given to experimental data submitted will depend on the quality of the data submitted and the credibility of the expert. In *Corning*, the panel, in addressing a conflict between testimony by opposing experts, stated:

> [W]e credit [Patent Owner's expert] over [Petitioner's expert]. [Patent Owner's expert] testimony is detailed and supported by underlying data, while [Petitioner's expert] testimony is general and is not credibly supported by underlying data.[18]

Thus, the panel in the same case suggested that it will evaluate the scientific validity of the evidence based on

[4] IPR2014-00377, Paper 17 at 3, 5 (P.T.A.B., Institution Decision, Aug. 6, 2014).

[5] *Id.* at 5-6.

[6] *See* 37 C.F.R. § 42.65(a) (''Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.'').

[7] *Depomed I*, Paper 9 at 10; *see also Purdue Pharma L.P. v. Depomed, Inc.*, IPR2014-00378, Paper 18 at 2-3 (P.T.A.B., Order Denying Request for Rehearing, Aug. 6, 2014) (''*Depomed II*''); *Endo Pharms. Inc. v. Depomed Inc.*, IPR2014-00653, Paper 12 at 15-16 (P.T.A.B., Decision Denying Institution, Sept. 29, 2014) (''*Depomed III*''); *Endo Pharms. Inc. v. Depomed Inc.*, IPR2014-00655, Paper 12 at 18 (P.T.A.B., Decision Denying Institution, Sept. 29, 2014) (''*Depomed IV*'').

[8] *Depomed I*, Paper 9 at 10.

[9] *Id.* at 12.

[10] IPR2013-00043/IPR2013-00044, Paper 95 at 5-6 (P.T.A.B., Final Written Decision, May 1, 2014).

[11] *Id.* at 8, 10, 12-13.

[12] *See, e.g.*, *id.* at 13, 15-16, 18-19, 21-22.

[13] *Id.* at 21.

[14] IPR2013-00022, Paper 43 at 3 (P.T.A.B., Decision Denying Institution, Apr. 11, 2013).

[15] *Id.* at 6.

[16] *Id.* at 7.

[17] *Id.*

[18] Paper 95 at 23 (citing 37 C.F.R. § 42.65(a) and (b)(5)); *see also id.* at 25.

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the perceived credibility of the witness introducing the same.[19]

III. Do Experiments Faithfully Reproduce the Prior Art?

When a petition includes arguments on inherent anticipation, parties should be aware that PTAB panels are particularly critical of experimental evidence used to show that a claimed property is inherent in a prior art composition or as a result of a prior art process. Therefore, the party proffering such evidence must do more than have an expert simply state that the experiments were the same as (or conducted on the same materials as) those disclosed in the prior art reference.

For example, in *Depomed I*, Petitioner submitted a declaration from an expert who testified that he had reproduced one of the dosage forms disclosed in a prior art reference.[20] In response, Patent Owner argued that Petitioner's expert did not establish that the dosage form he prepared was actually the same as the dosage form disclosed in the prior art.[21] The panel agreed with the Patent Owner, dismissing Petitioner's argument that the law does not require a positive control to establish inherent anticipation.[22] Instead, the panel reasoned:

> The question, however, is whether Petitioner comes forward with sufficient evidence from which we can reasonably find that [Petitioner's expert] prepared a dosage form that was the same as [the prior art] dosage form. Based on the particular facts presented in this case, we are persuaded that the lack of basic control evidence—which is a fundamental tenet of the scientific method—precludes such a finding.[23]

The decision even appeared to provide guidance to future experts, indicating that Petitioner's expert could have made this showing, for example, by ''subject[ing] the tablets that he prepared to the same dissolution study disclosed in Baveja to demonstrate that his tablets achieved the same results as those disclosed'' in the prior art reference.[24]

PTAB panel decisions have also refused to admit or consider experimental evidence presented in a post-filing publication that compared a prior art composition to a commercial embodiment of the challenged claims. In *Merial Ltd. v. Virbac*, Petitioner submitted a post-filing publication in an effort to show that Petitioner's prior art veterinary anti-flea composition was practically equivalent to Patent Owner's claimed commercial product.[25] As an evidentiary matter, the panel refused to admit the post-filing publication into evidence on hearsay grounds.[26] In response to Petitioner's attempt to admit the post-filing publication into evidence as an admission by party opponent, the panel declined to give any weight to the reference because it failed to provide a disclosure sufficient for the panel to determine the precise differences between the tested products.[27] Though not expressly stated, it might be expected that the Board would similarly have had difficulty confirming that Petitioner's tested composition was the same as the prior art disclosure based on the failure of the reference to indicate the precise ingredient make-up of the tested compositions.

Despite the stringency with which PTAB panel decisions have required the prior art to be replicated in experimental testing, decisions have also suggested that the proponent of experimental evidence may have some wiggle room in varying from the disclosure of the prior art.[28] However, parties should be prepared to submit adequate reasons for why those changes were made and why they do not affect the outcome in such situations.

In *Daicel*, Petitioner challenged claims to a process for removing permanganate reducing compounds and alkyl iodides from intermediate streams during production of acetic acid by the carbonylation of methanol in the presence of a Group VIII metal carbonylation catalyst.[29] Petitioner relied on a prior art patent which allegedly described the challenged process with the exception of failing to explicitly state that dimethyl ether (DME) was present in the second overhead stream.[30] In attempting to show inherent anticipation of the challenged claims by the prior art patent, Petitioner submitted a declaration from its expert which included experimental evidence (produced in 2011, three years before the petition was filed) based on the prior art patent, asserting that the process set forth in the prior art patent necessarily resulted in the critical limitation of DME being present in the second overhead.[31] While Petitioner's expert declaration acknowledged differences in the extraction and distillation conditions, as well as the amounts of various reactants in the reaction liquid used in the 2011 experiments as compared to the relevant example of the prior art patent, it stated that ''it was not feasible to run the equipment in exactly the same way as was used in the [prior art] patent example,'' and characterized the differences as ''slight'' and a ''few minor deviations'' which would not have affected the outcome with respect to the critical presence of DME in the overhead.[32] Petitioner's expert further testified that the prior art patent listed numerous components and ranges that could be used in the reaction liquid, and that the conditions chosen were within the scope of those ranges.[33] In response, Patent Owner pointed to disclosure in both the prior art patent itself, as well as an additional prior art patent which showed that these differences were in fact material and affected the impurity content of the reaction product.[34]

Agreeing with Patent Owner, the panel decision found that Petitioner's expert had provided no support for his characterization of the differences between the 2011 experiments and the prior art patent example as ''slight'' and ''minor,'' nor had he provided any reason why it was not feasible to run the experiments in the

[19] *Id.*, Paper 104, at 4 (''In this respect, we found that the results were not scientifically valid based essentially on the credible testimony of [Patent Owner's expert].'').
[20] Paper 17 at 3.
[21] *Id.* at 11.
[22] *Id.* at 4.
[23] *Id.*
[24] *Id.*
[25] IPR2014-01279, Paper 13 at 6 (P.T.A.B., Decision Denying Institution, Jan. 22, 2015).
[26] *Id.*
[27] *Id.*
[28] *See Daicel*, Paper 14 at 19-20.
[29] Paper 14 at 3.
[30] *Id.* at 16.
[31] *Id.* at 15.
[32] *Id.* at 15-16, 19.
[33] *Id.* at 19.
[34] *Id.* at 18-19.

same way as disclosed in the relevant example of the prior art patent.[35] The decision also stated that ''Petitioner has not explained sufficiently why one of ordinary skill in the art, upon considering the [prior art] patent, would have chosen the combination of reaction components and specific concentrations used in [Petitioner's expert's] Experiment . . . .''[36] Further, based on the disclosure pointed to by the Patent Owner in both the prior art patents which indicated that differences in concentrations of reactants would affect the reaction products, the panel was ''not persuaded by [Petitioner's expert's] unsupported statements that at least some DME would be present in the reaction product of the [prior art] patent Example'' based on the 2011 experiments.[37]

While Petitioner in *Daicel* failed to carry the burden necessary to prove inherent anticipation, the panel's decision suggests that variations from the disclosure of a prior art reference in this context might be permissible, provided that they are accompanied by an explanation of why one of ordinary skill in the art would have made those changes.

IV. Does the Tested Property Correlate with the Claimed Property?

Proponents of experimental evidence to show an inherent property should be careful to either measure exactly the claimed property or show sufficient correlation between the measured property and the claimed property.

In *Plant Science, Inc. v. The Andersons, Inc.*, Petitioner challenged claims of Patent Owner's patent directed to water-dispersible methylene urea particles for the delivery of biomolecules, where the claims recited that ''the nitrogen containing ingredient, the fertilizer, and the binder component present in a form such that contact with water causes particle dispersion into more than 100 pieces in a time period of up to 1 hour.''[38] Petitioner relied on a declaration submitted during the prosecution of the challenged patent for the proposition that a prior art reference inherently disclosed that its compositions dispersed into more than 100 pieces when contacted with water.[39] The declaration reported that a sample made according to Example A in the challenged patent had an ''index of dispersibility'' of 100 percent, while the prior art reference's examples reported dispersion index values of 95, 99 and 95 percent.[40] Petitioner argued that the prior art reference accordingly ''describe[d] essentially the same dispersibility obtained by the [challenged] patent'' and therefore met the limitation ''contact with water causes particle dispersion into more than 100 pieces.''[41]

The panel disagreed, finding that the experimental evidence disclosed in the prior art reference and the declaration submitted during prosecution both tested for a property different than the claimed property, and failed to properly show a correlation between the tested and claimed properties, stating:

> Petitioners do not provide any evidence or explanation that a dispersibility index value of about 100% using the [prior art reference] test necessarily means that the particles disperse into more than 100 pieces. As Patent Owner points out, [the prior art reference] does not disclose any correlation between its dispersion index and the number of pieces into which a particle disperses, and Petitioners do not provide any evidence establishing such a correlation. The information presented, therefore, does not show sufficiently that [the prior art reference] inherently describes pellets or granules that disperse into more than 100 pieces in a time period of up to 1 hour upon contact with water.[42]

Similarly, in *Depomed I*, Petitioner attempted to invalidate claims to a drug dosage form that exhibits certain characteristics upon immersion in gastric fluid using a prior art reference, which disclosed diltiazem drug dosage form swelling and release tests in deionized water.[43] Petitioner's expert, addressing the difference, stated that ''[a]lthough the experiments were conducted in water, in my opinion, [the prior art reference's] matrices would perform in significantly the same manner if immersed in [simulated gastric fluid],'' quoting a prior art paper that stated ''[r]elease rates of drugs will not be affected by pH unless drug solubility varies greatly over the normal pH range.''[44]

The panel concluded this testimony was insufficient to establish that the prior art reference's dosage forms would necessarily and inherently perform in the same manner upon immersion in gastric fluid as they would in deionized water.[45] First, it found that the prior art paper indicated that release rates were not affected by pH, provided that drug solubility does not vary greatly over the normal pH range—a property which Petitioner's expert did not address with respect to the drug diltiazem disclosed in the prior art reference.[46] Moreover, the decision finely dissected Petitioner's expert's statement that the prior art reference's matrices would perform in ''*significantly* the same manner'' in deionized water and simulated gastric fluid, noting that he did not explain what exactly that meant, leaving open the possibility that their behavior may in fact differ between the two media.[47]

V. If Evidence Is Deemed Insufficient, Who Loses?

As discussed above, PTAB panel decisions suggest that PTAB panels may scrutinize experimental evidence submitted by either party, as well as the testimony of the expert proffering the evidence. Panel decisions have also addressed instances where both parties submit experimental evidence relevant to the same limitation—Petitioner in an attempt to prove the inherency of a particular limitation; Patent Owner in an attempt to disprove the inherency of the limitation. Though no formal burden-shifting analysis is applied in these situations, decisions suggest that panels will not lose sight of the overall scheme—the Petitioner bears the ultimate burden of proof of invalidity, and thus, inherency.

For example, in *Corning*, as discussed above, the panel decision addressed a conflict between opposing experts, concluding that the results of a test by Petitioner to show inherency were not scientifically valid

[35] *Id.* at 19.
[36] *Id.* at 19-20.
[37] *Id.* at 20.
[38] IPR2014-00940, Paper 8 at 2-3 (P.T.A.B., Decision Denying Institution, Dec. 17, 2014).
[39] *Id.* at 6-7.
[40] *Id.* at 7.
[41] *Id.* at 7-8.
[42] *Id.* at 8 (internal citations omitted).
[43] Paper 9 at 13.
[44] *Id.* at 13-14.
[45] *Id.* at 14-15.
[46] *Id.* at 14.
[47] *Id.* at 14 (emphasis in original).

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based on the credible testimony of Patent Owner's expert.[48] However, this was not the end of the inquiry. The panel decision concluded that because of the scientific invalidity of its tests, Petitioner had failed to sustain its burden of proof by establishing inherency of the limitation at issue by a preponderance of the evidence.[49] It noted: ''While [Patent Owner] does not have any burden to *disprove* inherency, it failed to establish that the relevant limitation is *not* inherent.''[50] Because both parties had failed to establish either inherency or lack thereof, the panel found that ''the party with the burden of proof necessarily loses.''[51]

Corning provides an instructive example where Patent Owner failed to prove a lack of inherency based on its own experimental testing, but nonetheless prevailed in the proceeding because of a similar failure by Petitioner.

VI. To What Extent Does an Inherent Limitation Need to be Shown?

PTAB panel decisions have also explicitly cited U.S. Court of Appeals for the Federal Circuit case law for the proposition that in order to inherently anticipate a claim, a prior art reference need only meet the limitation to the extent the patented claim does.

For example, in *Ariosa Diagnostics v. ISIS Innovation Ltd.*, Petitioner challenged claims directed to prenatal detection methods, in particular a method of detecting paternally inherited nucleic acids from a mother's blood sample by amplification of the nucleic acid and subsequently detecting the nucleic acid.[52] The Petitioner asserted that a prior art reference which disclosed amplification of nucleic acids in maternal blood samples followed by detection of DNA using gel electrophoresis inherently anticipated the claimed method because that blood would inherently contain paternally inherited fetal nucleic acid.[53] Patent Owner argued lack of anticipation because the amplification technique used by the prior art reference did not always work and that the data included in the reference were of poor quality.[54] The panel disagreed, citing to Federal Circuit cases to show that the doctrine of inherency is not so strict.[55] In particular, the panel noted that ''[t]o anticipate, the prior art need only meet the inherently disclosed limitation to the extent the patented method does.''[56]

Thus, the panel construed the claim to require the amplification and detection of paternally inherited nucleic acids from a mother's blood sample utilizing amplification and detection.[57] The panel found that the prior art method (which amplified nucleic acid in the serum of blood obtained from a pregnant woman) performed the steps recited in the method, and the natural result of those steps was the amplification of fetal nucleic acid, which was inherently present in the serum.[58] Whether a person skilled in the art following the teachings of the prior art would appreciate that such paternally inherited nucleic acid was actually amplified and detected was ''irrelevant to the analysis'' because the claim did not require a step of identifying the source of the nucleic acid.[59] Furthermore, because the challenged patent did not specify any particular conditions under which the amplification or detection steps were to be carried out, the panel ''decline[d] to read such limitations into the claim.''[60]

Similarly, in *Biodelivery Sciences Int'l v. Monosol*, Petitioner challenged claims related to methods for making rapid dissolve thin film drug delivery compositions for the oral administration of active components.[61] The challenged claims all required the critical limitation of ''polymer matrix during film casting is a shear-thinning pseudoplastic fluid when exposed to shear rates of 10-10^5 sec^{-1}.''[62] The panel construed this term to require that ''the polymer matrix is a shear-thinning pseudoplastic fluid when exposed to shear rates *throughout the entire range of 10-105 sec-1*, and not just a portion of the range.''[63]

Petitioner's expert ''observed that a polymer matrix formed according to [the prior art example] was a shear-thinning pseudoplastic fluid when exposed to shear rates of 10 to 10^3 sec^{-1},'' but Petitioner did not address whether the same polymer matrix exhibited the same property when exposed to shear rates above 10^3 sec^{-1} and up to 10^5 sec^{-1}.[64] Another of Petitioner's experts testified that a person of ordinary skill in the art would have expected that this behavior to continue at shear rates above 10^3 sec^{-1}.[65] However, the panel was not persuaded because: (1) the Petitioner failed to make this argument or refer to the expert's statement in the petition; (2) the expert did not cite to credible evidence or provide persuasive explanation to support this opinion and (3) anticipation by inherency requires that ''the missing descriptive matter is necessarily present in the thing described in the reference.'' The panel noted that Petitioner's expert's ''unexplained, conclusory testimony that a skilled artisan 'would have expected' a certain result constitutes probabilities or possibilities, which is insufficient to establish inherency.''[66] As a result, the inherent anticipation ground was denied.

VII. Conclusion

Despite the numerous pitfalls that await the unwary submitted or experimental evidence, properly conducted testing which is carefully presented can be a powerful tool for making the case for or against patentability of a challenged claim. In view of the scrutiny with which PTAB panel decisions treat experimental evidence, Petitioners should carefully consider whether

[48] Paper 104 at 4.
[49] Paper 95 at 27.
[50] *Id.* (emphasis added).
[51] *Id.*
[52] IPR2012-000222, Paper 166 at 3-4, 7 (P.T.A.B., Final Written Decision, Sept. 2, 2014).
[53] *Id.* at 29-31.
[54] *Id.* at 32-33.
[55] *See id.* at 33-35 (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 74 U.S.P.Q.2d 1398 (Fed. Cir 2005) (69 PTCJ 613, 4/15/05), and *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 95 U.S.P.Q.2d 1833 (Fed. Cir. 2010) (80 PTCJ 470, 8/6/10)).
[56] *Id.* at 34 (citing *King Pharms.* at 1276).
[57] *Id.* at 35.
[58] *Id.*
[59] *Id.* at 36.
[60] *Id.* at 35.
[61] IPR2014-00794, Paper 7 at 3 (P.T.A.B., Decision Denying Institution, Nov. 5, 2014).
[62] *Id.* at 5.
[63] *Id.* at 6.
[64] *Id.* at 8-9.
[65] *Id.* at 9.
[66] *Id.* at 10.

experimental evidence is necessary to invalidate the challenged claims. Patent Owners should similarly scrutinize experimental evidence submitted by Petitioners to identify any flaws in the methodology or quality of the data relied on by the Petitioners.

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