

## 1.132 Declarations for Traversing Rejections

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Long before the AIA, declarations were a tool that was available during patent prosecution to put evidence, *e.g.*, post-filing data and expert opinions, in front of an Examiner to rebut obviousness or lack of enablement rejections. However, unless essential to obtain allowance, such declarations were often used only as a last resort. Indeed, some practitioners avoided declarations unless absolutely necessary out of concern for seeding the prosecution record with expert or inventor testimonial statements that could potentially be used against the patent owner during a future litigation.

Even still, since arguments of counsel cannot take the place of evidence in the record, certain evidence submitted to the U.S. Patent and Trademark Office (USPTO) must be supported by a declaration. Such evidence can include, for example, expert statements supporting unexpected results, commercial success, solution to a long-felt need, inoperability of the prior art, or evidence supporting attribution of a reference to the Applicant or prior public disclosure of subject matter derived from an inventor. Furthermore, a response to an obviousness rejection including a well-written 37 C.F.R. § 1.132 Declaration can be more persuasive to an Examiner than well-written legal and/or technical arguments by the patent attorney alone.

Decisions from the Patent Trial and Appeal Board (PTAB) suggest that 1.132 Declarations can also be persuasive to the Board when considering whether to institute or not institute an *Inter Partes* Review (IPR) or Post-Grant Review (PGR). The overall number of cases before the PTAB where objective evidence has been found to be persuasive is fairly low. However, lessons from Board decisions seem to be driving a trend to submit objective evidence during prosecution in an effort to strengthen the record. And failure to address objective evidence of record can be fatal to IPR or PGR institution. *See, e.g., Coalition for Affordable Drugs V LLC v. Hoffman-LaRoche, Inc.*, IPR2015-01792 (PTAB Mar. 11, 2016) (Paper 14) and *Merial Ltd. v. Virbac*, IPR2014-01279, Paper 13 (PTAB Jan. 22, 2015) (denying institution for failure to address objective evidence considered by examiner during original prosecution); *Omron Oilfield & Marine Inc. v. MD/TOTCO*, IPR2013-00265, Paper 11 (PTAB Oct. 31, 2013) (denying institution for failure to address objective evidence successfully argued during reexamination). Furthermore, recent Board decisions have found objective evidence sufficient to overcome a *prima facie* case of obviousness. *See, e.g., Xactware Solutions, Inc. v. Eagle View Techs., Inc.*, IPR2016-00592 (Paper 50) (PTAB August 25, 2017); *InnoPharma, Inc. et al. v. Bausch & Lomb Incorporated et al.*, IPR2015-00903, Paper 82 (PTAB July 28, 2016); *Leapfrog Product Development, LLC v. Lifefactory, Inc.*, IPR2015-00614, Paper 31 (PTAB Aug. 17, 2016).

As practitioners look for ways to help protect patents from institution of IPR or PGR, prosecution practices are evolving. Thought should still be put into statements made in declarations during prosecution that might be used against the patent owner in a future litigation, but the benefit of strengthening the prosecution record to help avoid IPR or PGR institution and having objective evidence in the record to support a non-obviousness position, provides an incentive to consider submitting 1.132 Declarations during prosecution. Such declarations are no longer considered a last resort.

### 1. Types of Declarations Post-AIA

Pre-AIA and Post AIA Declarations		
Purpose of Declaration	37 CFR Rule	
	Pre-AIA (First-to-Invent) Applications	AIA (First-to-File) Applications
Traversal of rejection or objection ( <i>e.g.</i> , unexpected results, commercial success, etc.)	1.132	1.132
Other Declarations		
Show earlier date of invention	1.131(a)	No longer available
Attribution (Katz-type Declaration)	1.132	1.130(a)

Prior public disclosure	Not available	1.130(b)
Common ownership declaration filed with terminal disclaimer	1.131(c) (formerly pre-AIA 1.130(a))  (more frequently used common ownership statement under pre-AIA 103(c))	No longer available  (frequently used common ownership statement under AIA 102(b)(2)(c))

Table is adapted from USPTO's "Effective Use of AIA (FITF) Evidentiary Declarations under Rule 130," Slide 54 (Sept. 18, 2015).

## 2. When can you file a 1.132 Declaration?

- Prior to a final rejection;
- Before appeal in an application not having a final rejection;
- After final rejection, but before or on the same date of filing an appeal, upon a showing of good and sufficient reasons why it was not earlier presented; or
- After prosecution is closed if filed with a Request for Continued Examination (RCE).

## 3. What kind of evidence can you submit in a 1.132 Declaration?

- Any evidence submitted to traverse a claim rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under section 37 CFR 1.132. See MPEP §716.
- Evidence can include post-filing data accompanied by factual statements from a declarant with first-hand knowledge of the data, *e.g.*, to show enablement or differences in the claims compared to the prior art. Factual evidence is preferable to opinion testimony. See MPEP 716.01(c), Section III.
- Evidence can also include expert opinions based on facts in view of the expert's knowledge, *e.g.*, in support of no reasonable expectation of success. While an expert opinion as to a legal conclusion is not entitled to any weight, the underlying basis for the opinion may be persuasive. *In re Chilowsky*, 306 F.2d 908, 134 USPQ 515 (CCPA 1962).
- Declarations are commonly used to submit objective evidence of inoperability of the cited references or of non-obviousness, *e.g.*, evidence of criticality or unexpected results, commercial success, long-felt but unmet need, failure of others, copying, skepticism of experts, etc.

## 4. Standards for objective evidence of non-obviousness:

- The objective evidence must be reasonably commensurate in scope with the claims.
- To be of probative value, any objective evidence must have a causal relationship to merits of the claimed invention (nexus requirement). For example, commercial success or industry praise must be related to the merits of the claimed invention, not the prior art. Determining nexus is fact dependent, and the Federal Circuit has indicated that a patentee can demonstrate nexus for a claimed combination "as a whole" in the sense that proof of nexus is not limited to so-called "novel elements." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1330 (Fed. Cir. 2016).
- 1.132 Declarations to rebut a *prima facie* case of obviousness, *e.g.*, showing unexpected properties over the art, must compare the claimed subject matter with the closest prior art to be effective. See MPEP 716.02(e) citing *In re Burckel*, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979).

## 5. Post-AIA Considerations:

- Relevant and compelling evidence in the file wrapper or relevant public documents from related proceedings (*e.g.*, litigation or reexamination) can be used in arguments in a party's briefs, *e.g.*, a Patent Owner's Preliminary Response in an IPR or PGR petition.
- Well-drafted declarations addressing objective evidence in the prosecution record can tip the balance to non-institution by the PTAB. In particular, when the *prima facie* case is weak, objective evidence can be particularly persuasive. See, *e.g.*, *Hologic, Inc. v. Biomerieux, Inc.*, IPR2018-00567, Paper 9 (PTAB August 4, 2018); *Coalition for Affordable Drugs II LLC v. Cosmo Technologies Ltd.*, IPR2015-00988, Paper 55 (PTAB Oct. 5, 2016).
- But, objective evidence must be reasonably commensurate with the scope of the claims, and it needs a nexus to be persuasive. Final written decisions are made on a claim-by-claim basis; thus, objective evidence that is not

commensurate in scope with one or more claims will not help any non-commensurate claims. *See, e.g., Acrux DDS Pty Ltd. et al. v. Kaken Pharmaceutical Co., Ltd. et al.*, IPR2017-00190, Paper 80 at 42-52 (PTAB June 6, 2018); *Praxair Technology, Inc. v. Entegris, Inc.*, IPR2016-01845, Paper 20 at 34-38 (PTAB March 29, 2018).

- Parties and individuals involved in USPTO proceedings have “a duty of candor and good faith.” But inequitable conduct cannot be the basis for challenging a patent in an IPR or PGR; so there would likely be no estoppel precluding a losing IPR or PGR petitioner from raising inequitable conduct in any subsequent litigation.
- Establishing a legally and factually strong record of patentability—including non-obviousness—during prosecution can increase the likelihood of avoiding IPR or PGR institution.

## **6. Other considerations:**

- Identify the declarant and any relationship to the applicant(s), assignee(s) or application in the declaration (*see, e.g., Ferring B.V. v. Barr Laboratories, Inc.* 437 F.3d 1181 (Fed. Cir. 2006), finding inequitable conduct because Applicants failed to disclose that individuals who submitted declarations in support of patentability had affiliations with the assignee).
- Have an agreement with the declarant in place to protect against disclosure of confidential information, discussions and/or draft documents.
- Continue to select experts and fact witnesses with the possibility of future litigation and possible deposition in mind.
- Do not prepare 1.132 Declarations in haste. Prepare concise and persuasive declarations that avoid statements that are unnecessary or could be considered inconsistent.