

# 37 CFR § 1.132 Practice

Unexpected Results

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# Objectives

- Review basic requirements for Rule 132 Declarations.
- Understand what the declaration should include.
- Understand how the submitted evidence is evaluated.
- Become familiar with what are unexpected results versus expected results.
- Understand how the evidence submitted for one species or limited number of species is evaluated to establish unexpected results for a claimed genus.

## **37 CFR § 1.132**

“When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section.”

- The rule permits applicants to provide evidence to overcome a ground of rejection or an objection.
- Anyone with knowledge of the underlying facts may make a declaration under 37 CFR § 1.132.

## Burden Shifts to Applicant

- Once the examiner has established a *prima facie* case of obviousness, the burden shifts to the applicant to rebut the *prima facie* case.
- Where a *prima facie* case of obviousness is established, the failure to provide rebuttal evidence is dispositive. See MPEP §716.01(a).

# Analysis of Declarations under 37 CFR § 1.132

- To be of probative value, objective evidence must be *factually* supported by an appropriate declaration. See MPEP §716.01(c).
  - Arguments of counsel cannot take the place of evidence in the record. See *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).
  - Attorney statements regarding, e.g., unexpected results, commercial success, long-felt need, inoperability of the prior art, skepticism of experts, and copying are not evidence without a supporting declaration.

## **Analysis of Declarations under 37 CFR § 1.132 (cont.)**

- Declarations may include statements in the form of:
  - Evidence of a fact – comparative test results, sales figures
  - An opinion – statement expressing what the declarant thinks, believes, or infers with regard to certain facts.
  - An allegation – a totally unsupported or uncorroborated statement; e.g., conclusory statements unsupported by factual evidence

## **Analysis of Declarations under 37 CFR § 1.132 (cont.)**

- Weight to be afforded:
  - Evidence of a fact – weight is governed by relevance
  - Opinion – weight is influenced by the underlying basis
    - If facts, weight is given
    - If legal conclusion, weight is not given
  - Allegation – not entitled to any weight

# **Analysis of Declarations under 37 CFR § 1.132 (cont.)**

Examples of evidence supporting secondary considerations:

- Comparative test data used to show unexpected results
- Sales figures used to show commercial success
- Articles, publications, declarations by one of ordinary skill used to show long-felt need
- Comparative test data and declarations by one of ordinary skill to show inoperability of a reference



# Analysis of Declarations under 37 CFR § 1.132 (cont.)

- Factual evidence is preferable to opinion testimony. See MPEP §716.01(c), Section III.
  - Declarant should lay out facts, supported by evidence.
  - Expert opinion supported by documentary evidence may be given weight. See *In re Carroll*, 601 F.2d 1184, 202 USPQ 571 (CCPA 1979).
  - Opinion on the ultimate legal conclusion at issue is not entitled to any weight, although the underlying basis for the opinion may be given some weight. See *In re Chilowsky*, 306 F.2d 908, 134 USPQ 515 (CCPA 1962).
  - Any interest of the expert in the outcome of the case should be taken into consideration.

# Analysis of Declarations under 37 CFR § 1.132 (cont.)

- To be of probative value, evidence of secondary considerations must be related to the claimed invention. See *MPEP* §716.01(b).
- The examiner must determine whether there is a **nexus** between the invention **as claimed** and the evidence of secondary considerations.
  - “Nexus” designates a legally and factually sufficient connection between the **claimed invention** and the objective evidence of nonobviousness such that the evidence should be considered in the determination of nonobviousness. See *Demaco Corp. v. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir. 1988).

## Analysis of Declarations under 37 CFR § 1.132 – The Last Step

- The ultimate determination of patentability must be based on consideration of *the entire record* by a preponderance of the evidence. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). See also MPEP §716.01(d).
  - In other words, an examiner should not reject a claim if, in view of the prior art and any secondary evidence of record, it is “more likely than not” that the claim is patentable.

## Analysis of Declarations under 37 CFR § 1.132 – The Last Step (cont.)

- The submission of objective evidence of patentability *does not mandate* a conclusion of patentability. *In re Chupp*, 816 F.2d 643, 2 USPQ2d 1443 (Fed. Cir. 1992). See MPEP §716.01(d).
- A strong case of obviousness may be established such that the objective evidence of nonobviousness is not sufficient to outweigh the evidence of obviousness. See MPEP §716.01(d). See *Media Techs. Licensing LLC v. Upper Deck Co.*, 596 F.3d 1334, 1339 (Fed. Cir. 2010). See also *Cubist Pharm. v. Hospira*, 805 F.3d 1112, 1126 (Fed. Cir. 2015).
- See MPEP §2145 for guidance in determining whether rebuttal evidence is sufficient to overcome a *prima facie* case of obviousness.

# Unexpected Results

- Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is ***really unexpected***. See MPEP §716.02.
- Evidence of unexpected results is frequently in the form of a *direct comparison* of the claimed invention with the ***closest prior art*** which is ***commensurate in scope with the claims***. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

## Unexpected Results (cont.)

- The declaration should include:
  - A description of precisely what was tested. It must include both:
    - The invention as claimed, AND
    - The closest prior art
  - A description of all of the test conditions.
  - Test results. The results must include both:
    - The results of the test performed on the invention as claimed, AND
    - The results of the test performed on the closest prior art
  - An analysis of the test results.

## Unexpected Results (cont.)

- The comparison must be under substantially the same conditions except for the novel features of the invention.
- Precisely what was done should be recited in the declaration, e.g., the actual steps carried out, the materials employed, and the results obtained should be spelled out. Nothing concerning the work relied upon should be left to conjecture.
- Conclusory statements such as “the prior art invention did not perform well” without a showing of the actual results of the test performed on the prior art AND the claimed invention is insufficient.

## Unexpected Results (cont.)

- The claimed invention must be compared with the closest subject matter that *exists* in the prior art. See MPEP §716.02(e).
  - Applicant cannot be required to compare the claimed invention with an invention suggested by a combination of references relied upon by the examiner in a 103 rejection. This would be “requiring comparison of the results of the invention with the results of the invention.”  
See *In re Chapman*, 357 F.2d 418, 422, 148 USPQ 711, 714 (CCPA 1966).
- The claimed invention may be compared with prior art that is closer than that applied by the examiner. See *In re Holladay*, 584 F.2d 384, 199 USPQ 5416 (CCPA 1978).



## Unexpected Results (cont.)

- The showing of unexpected results must be commensurate in scope with the invention *as claimed*. See MPEP §716.02(d).
- The results must be due to the *claimed* features, not to *unclaimed* features.
  - The examiner must also consider whether there are features which are included in the tests reported in the declaration which are not recited in the claims.

## Unexpected Results (cont.)

- The unexpected property or result must actually be unexpected and of statistical and practical significance. See MPEP §716.02(b).
- Synergism is merely a property like any other property – it may be expected or unexpected depending on the particular art.
- The burden is on the applicant to establish that the “results are in fact unexpected and unobvious and of both statistical and practical significance.” *Ex parte Gelles*, 22 USPQ2d 1318 (Bd. Pat. App. & Interf. 1992). See MPEP §716.02(b).

## Unexpected Results (cont.)

- The specification does not need to teach superiority over the prior art, or the advantage of having or using a feature.
- The feature or property in which the superiority or advantage resides must be disclosed, or must inherently flow from the disclosure.
  - The specification need not disclose proportions or values as critical for applicants to present evidence showing the proportions or values to be critical. See *In re Saunders*, 444 F.2d 599, 170 USPQ 213 (CCPA 1971).
- See MPEP §716.02(f).

## Unexpected Results (cont.)

- If unexpected results and/or any other evidence of nonobviousness is found to be present, the evidence of nonobviousness is weighed against the evidence of obviousness.
  - See, e.g., *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372, 82 USPQ2d 1321, 1339 (Fed. Cir. 2007).
  - Also see *Leapfrog Enterprises Inc. v. Fisher-Price Inc.*, 485 F.3d 1157, 1162, 82 USPQ2d 1687, 1692 (Fed. Cir. 2007).

## Unexpected Results (cont.)

- *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372, 82 USPQ2d 1321, 1339 (Fed. Cir. 2007)
- Claims are drawn to amlodipine besylate
- Closest prior art disclosed amlodipine maleate
- “The record establish[ed] such a strong case of obviousness” that allegedly unexpectedly superior results were ultimately insufficient to overcome obviousness conclusion.

## Unexpected Results (cont.)

- *Leapfrog Enterprises Inc. v. Fisher-Price Inc.*, 485 F.3d 1157, 1162, 82 USPQ2d 1687, 1692 (Fed. Cir. 2007)
- Claims are drawn to an interactive learning device.
- “Given the strength of the *prima facie* obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion” of obviousness.

## Example 1 – PTO Bears the Initial Burden of Proof

- Claims are drawn to a combination of zeolites with other laundry detergent builders.
- Evidence submitted for the claimed composition showed a more than additive result for some combinations, but also showed lack of a superior result for other combinations.
- Board determined that the claims were not limited to those specific combinations for which data showed synergy.
- The Federal Circuit reversed, citing the absence of prior art rendering the composition obvious.
- See *In re Corkill*, 771 F. 2d 1496, 226 USPQ 1005 (Fed. Cir. 1985).

## Example 2 – Results Not Unexpected

- Claims are drawn to a composition comprising saccharin and L-aspartyl-L-phenylalanine methyl ester.
- Evidence was submitted that showed greater than additive results for the claimed mixture.
- Prior art taught the general expectation of greater than additive results when using the claimed mixture.
- With this record the total evidence would indicate that the results were not unexpected.
- See *Ex parte The NutraSweet Co.*, 19 USPQ2d 1586 (Bd. Pat. App. & Interf. 1991).

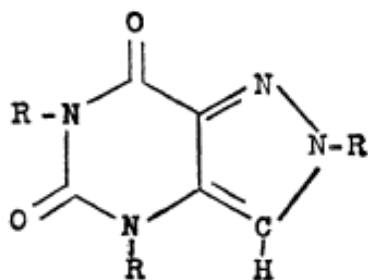


## Example 3 – Evidence of a Superior Property

- Claims are drawn to a single compound: N-(ethoxymethyl)-2'-trifluoromethyl-6'-methyl-2-chloroacetanilide
- Closest prior art compound: N-(ethoxyethyl)-2'-trifluoromethyl-6'-methyl-2-chloroacetanilide
- Evidence of superiority of a property shared with the prior art.
- See *In re Chupp*, 816 F.2d. 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987).

## Example 4 – Unknown Property

- Claim 1 recites: A compound of the structural formula



where R is a lower alkyl radical containing more than one and less than five carbon atoms.

- Evidence of unexpected property not found in the prior art.
- See *In re Papesch*, 315 F. 2d 381, 137 USPQ 43 (CCPA 1963).

## Example 5 – Expected Beneficial Result

- Claim 1 recites: Process for the sterilization of a polyolefinic composition by irradiation, characterized in that a polyolefinic composition containing an antioxidant chosen from phenolic polyesters is subjected to a sterilizing dose of high-energy radiation.
- Prior art taught that the claimed antioxidant is very efficient and provides better results compared with the prior art antioxidants.
- See *Ex parte Blanc*, 13 USPQ2d 1383 (Bd. Pat. App. & Interf. 1989).

## Example 6 – Unexpected Results Must Be Commensurate in Scope

- Claims were drawn to a method at “an elevated temperature range”
- Claimed scope allowed temperatures as low as 60 °C.
- Evidence was submitted that showed unexpected results at 110 °C and 130 °C.
- Dependent claim 8 limited the recited temperature range to being “in excess of 100 °C”
- Prior art taught improved results at 60 °C.
- See *In re Clemens*, 622 F. 2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980).

## Reminder

- The weight given to a declaration depends on whether it presents allegations, opinions or facts.
- The weight to be given to a declaration is a *judgment call* based on the particular facts of the case.

## Review of Examiner's Decision

- Applicant has the right to petition a denial of entry of a Rule 132 declaration.
- The examiner's decision that a declaration under Rule 132 does not overcome a rejection is reviewed by appeal to the Board.



## Summary

- A declaration should provide evidence directed to the issue at hand (e.g., unexpected results)
- Any declaration of unexpected results must establish that the result is unexpected, unobvious, and of statistical and practical significance.
- Patentability is based on a preponderance of the evidence.



# Questions?

***Thank you!***

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