Prosecuting Patent Applications: Establishing Unexpected Results

The purpose of this article is to provide suggestions on how to effectively make a showing of unexpected results during prosecution before the U.S. Patent and Trademark Office in order to overcome a rejection based on obviousness under 35 U.S.C. §103(a).

I. General Comments

“One way for a patent applicant to rebut a prima facie case of obviousness is to make a showing of ‘unexpected results,’ i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected. The basic principle behind this rule is straightforward – that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious.” In re Soni, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995).

In the chemical arts, which are unpredictable relative to the mechanical and electrical arts, making a showing of unexpected results is a commonly used tool for overcoming a prima facie case of obviousness. As a chemical practitioner, I am routinely asserting that there is evidence of unexpected results. This led to an interest in learning more about how the Board treats a showing of unexpected results. As such, I reviewed about 100 cases decided by the Board. It became readily apparent from the decisions that the Board was looking to see if certain requirements were met, and if the requirements were not met, the Examiner’s obviousness rejection was affirmed.

I was surprised to find that the Board reversed the obviousness rejections in only about 10% of the cases where the Board agreed with the Examiner that a prima facie case of obviousness existed and that unexpected results had been asserted by Appellants.1

1 In coming up with this reversal rate of “about 10%”, a keyword search was performed on November 25-26, 2010 at the Board’s website (http://des.uspto.gov/foia/BPAIReadingRoom.jsp) for the term “unexpected.” The results list was ordered by decision date and reviewed starting with the most recent decision. Cases were retained that met certain criteria. The criteria was based on actions of the Board. Cases met the criteria if the Board: a) took the position that Appellants were arguing that there was timely filed evidence of unexpected results in response to a rejection under 35 U.S.C. §103(a); b) agreed with the Examiner that a prima facie case of obviousness existed over the cited art; and c) weighted the asserted
It was surprising to find such a low reversal rate. Admittedly, this rate may be deflated somewhat by cases where Appellants have merely argued that there are advantages associated with the invention (i.e., there was no intention to argue unexpected results), and the Board, for completeness of the record, indicated that the evidence is insufficient to show unexpected results. Nevertheless, it is believed that the effect these cases have on the magnitude of the reversal rate is minimal.

This finding brings to mind some questions. Is the Patent and Trademark Office very good at teaching Examiners how to analyze for unexpected results (or lack thereof)? Is the Board actually giving substantial weight to the Examiner’s determination that the results are not unexpected in view of the Examiner’s expertise in the art?

Answering these particular questions goes beyond the scope of this article; however, this article can serve a purpose by explaining the requirements for a proper showing of unexpected results, and how best to satisfy these requirements.

First, it needs to be clear who holds the burden of production and when the burden shifts. The Examiner bears the initial burden of presenting a *prima facie* case of obviousness, and if that burden is met, the burden shifts to the Applicant to come forward with evidence or argument in rebuttal. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Once a *prima facie* case of obviousness exists, Applicant bears the burden of rebutting the *prima facie* case by the presentation of evidence of secondary considerations (such as unexpected results). When such evidence is submitted, all of the evidence must be considered anew. *In re Piasecki*, 745 F2d 1468, 1472-1473, 223 USPQ 785, 787-788 (Fed. Cir. 1984).

It is true that a showing of unexpected results can be made using the examples in the specification. *In re Soni*, F.3d at 750, USPQ2d at 1687, (“Consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention

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All other cases were excluded. Upon reaching 109 cases meeting the criteria, the review of cases was discontinued. Of the 109 cases retained, 12 cases were found where the Examiner’s rejections were reversed. This gives a reversal rate of 11.0%, which I refer to herein as being “about 10%.”
provides unexpected results.”). However, based on the requirements for a proper showing of unexpected results, it is far better to make a showing in the form of a Declaration under 37 C.F.R. §1.132 executed by an inventor or one skilled in the art. Even in situations where Applicant is relying on the experiments which have already been reported in the specification, it is best to reiterate the specification’s experiments in the Declaration, so that the “story” of patentability is presented in a nice package for the Examiner. Also, it is very unlikely that the specification was drafted with sufficient foresight to know the exact combination of references which are now being cited by the Examiner. As such, the Declaration provides a vehicle for the Declarant to make comments on the exact combination of cited references. Examiners will naturally give more weight to opinions of a Declarant who is better trained than the attorney to make inferences from the cited references.

I – A. Compare with the Closest Prior Art

One of the more common criticisms made by the Board in the cases that were reviewed, was that the claimed subject matter was not compared to the closest prior art. In re Baxter Travenol Labs., 952 F.2d 388, 392, 21 USPQ2d 1281, 1285 (Fed. Cir. 1991) (“When unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art.”).

In the “Ideal Declaration,” a direct comparison is made between the closest prior art and the claimed invention. A representative number of examples of the closest prior art (usually the primary reference in the rejection) are exactly repeated. These become the comparative examples for purposes of the Declaration. Then inventive examples are prepared by modifying a single variable of the prior art examples so the new examples fall within the scope of the currently claimed invention. In this Ideal Declaration, the inventive examples are shown to have at least one greatly improved property over that displayed by the comparative examples, and the magnitude of the improvement is clearly unexpected.

However, more often than not, an Ideal Declaration is not practical. Running new experiments may be too costly/time consuming. There may be multiple variables which have to be modified for the comparative example to fall within the scope of the current set of claims. Also, even more perplexing is dealing with cited references having examples which are so vaguely
described that repeating the examples would involve a significant amount of
guess work. In these situations, declarative evidence can still be used to
overcome the *prima facie* case.

**I – B. Indirect Comparison with Prior Art**

Even an indirect comparison with respect to unexpected results is
permissible. *See e.g In re Boesch and Slaney*, 617 F.2d at 276-77, 205 USPQ
245, 256, (CCPA 1979), and cases cited therein) (“proof of unexpected
properties may be in the form of direct or indirect comparative testing of the
claimed compounds (here, alloys) and the closest prior art”); *In re Blondel*,
499 F.2d 1311, 1317, 182 USPQ 294, 298 (CCPA 1974). However, in such a
case, Applicant must establish that the asserted indirect evidence
demonstrates unexpected results for the claimed alloys. *See, e.g., Blondel*,
499 F.2d at 1317, 182 USPQ at 298 (“Appellants’ brief goes through a
detailed, step-by-step analysis of the evidence in support of the conclusion to
be drawn from the indirect comparison,” establishing that the indirect
evidence provided a reliable indication of the performance of the closest
claimed and prior art compounds).

**I – C. Interview Examiner Before Conducting Tests**

Ascertaining the degree to which the evidence compares results of the
claimed subject matter against those of the closest prior art is largely
subjective. As such, unless the Ideal Declaration (discussed above) can be
prepared, it is best to conduct an Interview with the Examiner to discuss the
experimental design prior to conducting any experiments. It is far better to
receive criticism of the experimental design prior to expending time/capital
in conducting the experiments.

**I – D. How Many Tests Need to be Conducted?**

Another of the more common criticisms made by the Board in the cases that
were reviewed, was that the showing of unexpected results was not
commensurate in scope with the claimed invention. “In order to establish
unexpected results for a claimed invention, objective evidence of non-
obviousness must be commensurate in scope with the claims which the
Evidence is offered to support.” *In re Clemens*, 622 F.2d 1029, 1035, 206 USPQ 289, 296 (CCPA 1980).

**I – E. What is “Unexpected?”**

Lastly, there were cases where the Board would simply find that the evidence did not rise to the level of being “unexpected.”

**I – F. Conclusion**

In summary, three common criticisms made by the Board were: i) the results were not “unexpected;” ii) the comparison was not made with the closest prior art; and iii) the showing of unexpected results was not commensurate in scope with the claimed invention.

In order to address these criticisms, a Rule 132 Declaration should include the following sections.

**II. Sections of a Rule 132 Declaration**

**Section 1: Background of the Declarant**

The first section establishes that the Declarant is at least one of ordinary skill, if not an expert in the art. In the alternative, it is possible to attach the Declarant’s *curriculum vitae* to the Declaration.

**Section 2: Current Form of the Rejected Independent Claims**

The reader should have as much information as possible within (or attached to the Declaration) to reduce the burden of the Examiner’s review. This includes the current form of the rejected independent claims.

**Section 3: Experimental Section and Data**
Even when relying on the experiments in the specification, these experiments should be repeated in the Rule 132 Declaration (again, to reduce the burden of the Examiner’s review).

There should also be a statement that the experiments described in the Declaration were performed by the Declarant or by someone under his/her direct supervision.

Section 4: Expectations of One Skilled in the Art

This is the section where the Declarant makes it clear that the experiments are valid for comparison with the closest prior art regardless of whether a direct or indirect comparison has been made to the closest prior art.

The Declarant should provide a discussion of the teachings of the cited art with emphasis on the experimental evidence disclosed in the cited art. The discussion focuses on what the cited art teaches the skilled artisan about the type of properties asserted by the inventors as being unexpectedly superior to the properties of the product/process of the cited prior art.

The purpose of this section is to be able to quantify the change in properties that one of ordinary skill would expect (based on the teachings of all the cited art) by doing what Applicant has done to the closest prior art example to bring the example within the current claims. This becomes tricky when multiple variables are involved, but an honest attempt at a best guess is needed.

Here is a simple example. The present inventors are asserting that the increased hardness shown in the claimed composition (component A and component B) is unexpectedly superior to the hardness of the composition of the cited prior art. The Examiner has made a *prima facie* case of obviousness using two references. The primary reference teaches a composition of component A and component B’. A secondary reference is used to teach that component B is used in similar compositions for the same purpose as the composition of the primary reference. The Examiner correctly asserts that it would be obvious to replace component B’ of the primary reference with component B of the secondary reference to make a composition of component A and component B with a reasonable expectation of success. For purposes of this simple example, this section of the Declaration should
discuss what the primary reference teaches about the hardness of the composition which includes component A. Is there some suggestion in the primary reference or the secondary reference that component B adds to the hardness? What value of hardness would be expected for the composition of component A and component B based on both the teachings of the primary reference and the secondary reference?

This section should also address any differences between the comparative examples in the Declaration and the examples of the closest prior art. For instance, if the comparative examples in the Declaration use a different solvent than is described in the example of the closest prior art, then the Declarant should mention why a different solvent was used and that the use of the different solvent would not be expected to have a significant effect on the property relied upon for patentability.

Also, if the cited reference is missing a description of aspects of the experiment which is now being repeated by the Declarant, then an explanation should be included of the missing aspects and what the Declarant did to remedy the deficiency.

*Section 5: Comparison Between Expected Results and Actual Results*

This is the section where the Declarant makes it clear that the results are “unexpected.”

“A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness” of the claimed subject matter. *In re Corkill*, 771 F.2d 1496, 1501, 226 USPQ 1005, 1009 (Fed. Cir. 1985) (*citing United States v. Adams*, 383 U.S. 39, 51-52 (1966)).

In this section, the expected results of Section 4 are compared with the actual results of Section 3. The case law does not require that the “unexpected results” are the stuff of ground-breaking science. Rather, all that is required is a greater than expected result.

Finally, it is often useful to explain the practical significance of the improved results. For instance, regarding the Example discussed in Section 4 above, the Declarant might state, “Because the hardness is increased by
___% in accordance with the present invention, the product life is longer than the most commonly used product ____ while achieving a cost savings of ___%...”.

Section 6: Scope of Proffered Evidence and Scope of Current Claims

This is the section where the Declarant makes it clear that the showing of unexpected results is commensurate with the scope of the claims.

This becomes an issue in any situation where the current claims encompass even a single embodiment which has not been tested. For example, Applicant has asserted that a certain portion of the claimed compound is the active part for binding to a receptor and this active part effects the unexpected results. Applicant also asserts that the other part of the compound is inactive (with respect to the receptor binding property) and can have a variety of structures. The total number of compounds tested was 15, but the claim includes 100 compounds, each varying in structure in the inactive part. All 100 compounds have a single identical structural feature as the active part.

If the Declarant feels comfortable doing so, he can include technical arguments in this section to convince the Examiner that one skilled in the art would reasonably conclude that, based on the evidence of record, all of the 100 compounds would be expected to bind to the receptor and have results similar to the 15 tested compounds.

Section 7: Legal Liability

This section includes a description of the possible penalties for knowingly including false statements.

III. Additional Comments and Conclusion

If the Declaration is to be prepared by someone with a vested interest in the outcome of prosecution, the practitioner should consider whether it is possible to have sections 4 and 6 signed off by an uninterested person of ordinary skill in the art, since sections 4 and 6 include assertions of opinion.
If the Declarant has a financial interest in the outcome of the case or is being paid to prepare the Declaration, the Declarant should reveal the interest to the Examiner. It has been held that where the Declarant was held out to be “independent” or “unbiased,” when in fact this was not true, the submission of the Declaration was constituted “inequitable conduct” rendering the resulting patent unenforceable. See *Paragon Podiatry Laboratory Inc. v. KLM Laboratories Inc.*, 984 F2d 1182, 25 USPQ2d 1561 (Fed. Cir. 1993) and *Ferring B.V. v. Barr Laboratories Inc.*, 437 F3d 1181, 78 USPQ2d 1161 (Fed. Cir. 2006)

As a side note, it is a good idea to have backup claims limited to the tested examples.

In conclusion, a good Declaration fulfils the burden placed on Applicant when a *prima facie* case of obviousness exists. By separately addressing all of the requirements for establishing unexpected results, the Declaration can be an effective tool to convince the Examiner, and if necessary the Board, that the invention is patentable.