

**Keywords:** anticipation; inherency; obviousness; routine experimentation and expectation of success motivations; teaching away

**General:** Inherency-type Section 102 rejections may require evidence when applied and routine experimentation and expectation of success Section 103 rejections may require supporting evidence under the TSM test when the references teach away from the claims.

*Ex parte Whalen*

89 U.S.P.Q.2d 1078 (B.P.A.I. 2008)

Application No. 10/281,142

**I. Facts**

Appellants filed a patent application (the '142 application) directed to a composition for embolizing an aneurysm. The composition was described, and claimed in independent claims 1 and 2, as including a biocompatible polymer, a biocompatible contrast agent, and a biocompatible solvent. Furthermore, the biocompatible polymer was claimed to be of a molecular weight sufficient to impart to the composition a viscosity of at least about 150 CentiStokes (cSt) at 40° Celsius (C). The specification of the '142 application noted that the high viscosity of the compound rendered it difficult to employ conventional delivery means when using the compound, but cited threaded syringes (detailed in two provisional patent applications) that rendered the use of a highly viscous compound practical.

During prosecution, the Examiner rejected claims 1-17 under obviousness-type double patenting, and claims 1-6, 9, 10, and 14-17 under 35 U.S.C. § 102(b) or 35 U.S.C. § 103(a) as anticipated by or obvious in view of Taki et al., "A new liquid material for embolization of arteriovenous malformations" (hereinafter "Taki"). The Examiner also rejected claims 1-13 and 15-17 under 35 U.S.C. § 103(a) as obvious in view of Evans et al., U.S. Patent No. 5,695,480 (hereinafter "Evans"), and claims 1-17 under 35 U.S.C. § 103(a) as obvious in view of Greff et al., U.S. Patent No. 5,667,767 (hereinafter "Greff").

Appellants successfully argued that claims 1-17 did not describe obvious variants of the compositions of the prior art cited in the obviousness-type double patenting rejection because the Examiner failed to show that any of the prior art described a composition with a viscosity of at least about 150 cSt at 40° C. Accordingly the Board overturned the obviousness-type double patenting rejection of claims 1-17.

In support of the Section 102 rejection, the Examiner argued that the compositions of Evans and Taki inherently possess the same viscosity as the claimed composition because they comprise similar components used in overlapping ranges of concentrations as those claimed. To support the Section 103 rejections, the Examiner argued that the claimed compositions would have been obvious in view of each of Evans, Taki, and Greff under the reasoning that it would have been obvious to optimize the viscosity range of the known compositions of Evans, Taki, and Greff by routine experimentation.

Appellants countered that Evans, Taki, and Greff only generally referred to the viscosity of their compounds and, when referenced, disclosed that the compositions should have a viscosity of well under 150 cSt (Evans and Greff) or are of a "low viscosity" (Taki). Thus, Appellants argued, it was unclear as to the motivation for one skilled in the art to make and use a high viscosity embolic composition.

**II. Issues**

- 1) Did the Examiner err in rejecting claims 1-6, 9, 10, and 14-17 of the '142 application under 35 U.S.C. § 102(b)?

- 2) Did the Examiner err in rejecting claims 1-17 of the '142 application under 35 U.S.C. § 103(a)?

### III. Discussion

1) Yes. The Board found that none of the references cited by the Examiner expressly described an embolizing composition having a viscosity of at least 150 cSt at 40° C. The Board continued by finding that even if some of the compositions in the broad disclosure of Evans might have a viscosity of at least 150 cSt at 40° C, that possibility alone is not adequate to support a finding of inherent anticipation.

To support this conclusion, the Board cited *In re Oelrich* for the proposition that “Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981). The Board also cited *Ex parte Skinner*, stating “[T]he examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner’s belief that the functional limitation is an inherent characteristic of the prior art” before the burden is shifted to the applicant to disprove the inherency.” *Ex parte Skinner*, 2 U.S.P.Q.2d 1788, 1789 (B.P.A.I. 1986).

Thus, the Board reasoned, since the Examiner had failed to show any evidence or scientific reasoning that a *specific* composition disclosed by Evans is within the scope of the rejected claims, the Examiner had failed to make out a case of anticipation by Evans. The Board also concluded that Taki also failed to expressly or inherently meet all limitations of the instant claims. Accordingly, the Board reversed the Section 102 rejection by the Examiner.

2) Yes. The Board found that the Examiner based the Section 103 rejection on the supposition that a person of ordinary skill would have been motivated to optimize the viscosities of the Evans, Taki, and Greff compositions because of a reasonable expectation of success in achieving the safest clinical outcome and avoiding transvenous passage of the embolizing composition. While acknowledging that “the discovery of an optimum value of a variable in a known process is normally obvious,” *In re Antonie*, 559 F.2d 618, 620 (C.C.P.A. 1977), the Board noted that this was not always the case. Specifically, the Board cited an exception to the aforementioned rule where the parameter optimized was not recognized in the prior art as one that would affect the results.

The Board found that the Examiner failed to point to any teaching in the cited references, or provide any explanation based on scientific reasoning, that would support the conclusion that those skilled in the art would have considered it obvious to “optimize” the prior art compositions by increasing their viscosity to the level recited in the claims. Indeed, the Board found that Evans taught that the preferred composition had a viscosity of less than 75 cSt at 40° C, Greff taught a compound with a viscosity of 145 cSt at 20° C, and that Taki merely taught a compound with a low viscosity for easy injection through a micro-balloon catheter, that is, the references all suggested that low viscosity was a desired property in embolic compositions.

The Board went on to state that the Supreme Court held that a rigid and mandatory application of the “teaching-suggestion-motivation,” or TSM test is incompatible with its precedents. *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). However, the Board reasoned, the Court did not discard the TSM test completely, noting that its precedents showed that an invention “composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art” and that the TSM test must be applied flexibly because “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements in the way the claimed new invention does.” *Id.* at 1740-41.

Based on the reference applied by the Examiner, the Board concluded that the prior art taught away from the claimed solution, and that as such, obviousness cannot be proven merely by showing that a

known composition could have been modified by routine experimentation or solely on the expectation of success. Instead, the Board reasoned, for obviousness it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that would result in the claimed composition via, for example, additional evidence under the TSM test. Because the Examiner had failed to provide any evidence as to why one of ordinary skill in the art would modify the compositions of Evans, Taki, or Greff, the Board found that the Examiner had not made out a prima facie case of obviousness under Section 103. Accordingly, the Board overturned the Section 103 rejection of claims 1-17.

#### **IV. Conclusion**

To maintain a Section 102 rejection using inherency, the Examiner must provide some evidence or scientific reasoning to establish the reasonableness of the Examiner's belief that the functional limitation is an inherent characteristic of the prior art. Furthermore, an obviousness rejection based on "routine experimentation" and "expectation of success" are not sufficient to prove obviousness when the prior art teaches away from the claimed invention. Instead, additional evidence may be required under the TSM test to show a teaching, suggestion, or motivation that renders the rejected claim obvious.