

**Keywords: Lack of Enablement, 1.132 Declaration, Examples, Undue Experimentation**

**General: There is no *per se* requirement for examples to meet the enablement requirement. However, the need for examples to prevent undue experimentation will be assessed by weighing a variety of factors.**

*Ex parte Wheeler*

65 U.S.P.Q.2d 1664 (Bd. Pat. App. 2003)

*Non-Precedential*

Decided July 26, 2002

**I. Facts**

Appellant Wheeler filed the patent application under appeal to cover various methods of isolating and utilizing ungulate (hooved animal, i.e., livestock) embryonic stem (ES) cells. The Examiner rejected all of the pending claims for obviousness-type double patenting and for lack of enablement. In regard to the double patenting rejections, the Appellant agreed to file a terminal disclaimer. In regard to the rejection for lack of enablement, the Examiner asserted that the specification was enabled for swine but not for the entire class of ungulates. In support of this position, the Examiner relied upon several references to show that mammalian species differ in their embryonic development.

In response to this rejection, the Appellant provided a declaration under 37 C.F.R. § 1.132 that allegedly showed that the claimed methods were used to produce sheep ES cells. The Examiner concluded that the declaration did not overcome the rejection because the alleged sheep ES cells were not sufficiently proven to be ES cells.

The Appellant appealed from this rejection, electing for the pending claims to stand or fall in two separate groups. The first group of claims, represented by claim 1, was directed to a method for making a chimeric ungulate, i.e., a hooved animal having a mixture of genetically different cells. The second group of claims, represented by claim 15, was directed to a method of isolating and purifying an ES cell culture.

**II. Issues**

- A. Was claim 1 enabled by the specification for ungulates in general?
- B. Was claim 15 enabled by the specification for ungulates in general?

**III. Discussion**

- A. Yes. The Board noted that claim 1 did not require that the ES cells used to make the chimeric ungulate be prepared in any particular way, such as by the disclosed method. In addition, the Board noted that the Examiner was mistaken to insist that an ES cell used for making a chimeric ungulate be totipotent, i.e., capable of differentiating to any cell type. The specification stated that suitable ES cells for forming chimeric ungulates could be pluripotent, i.e., capable of differentiating to some, but not all, cell types, though totipotent cells were preferred.

In addition, the Board disagreed with the Examiner's position that more than one working example was required to enable a broad genus in an unpredictable art. The Board emphasized that examples are merely one factor in determining whether undue experimentation would be required to practice the claims. No *per se* requirement for even a single working example exists. Instead, all relevant factors must be considered. In regard to claim 1, the unpredictability of the art relied upon by the Examiner largely demonstrated the difficulty in isolating *totipotent* ES cells. However, such totipotent ES cells were not required by claim 1, per the specification. Therefore, the Examiner failed to show that undue experimentation would be required to make pluripotent ES cells to produce chimeric ungulates, as recited in claim 1.

- B. No. With regard to claim 15, the Examiner met his burden of establishing lack of enablement. In particular, the Examiner set forth a reasonable explanation as to why he believed the scope of the claim was not enabled by the specification, shifting the burden to the Appellant to prove the specification is indeed enabling.

The Examiner noted that the claim encompassed many divergent animal groups and that others had incorrectly asserted that they had done what the Appellant now claimed, i.e., isolating ES cells. As a result, a skilled artisan now set a high standard of proof before accepting that a cell line comprises ES cells. The Examiner argued that the Appellant had only met this high standard of proof with regard to swine and that undue experimentation would be required to practice the claimed method with other ungulates.

The Board agreed with the Examiner that, with regard to claim 15, the factors considered in assessing whether undue experimentation would be required weighed against enablement. The specification provided detailed guidance only with respect to swine cells, not those of other ungulates. In addition, the §1.132 declaration filed by the Appellant demonstrated a technique contrary to the claimed technique and therefore did not demonstrate enablement of claim 15 with regard to other ungulates. Therefore, the Appellant failed to rebut the Examiner's argument for lack of enablement.

#### **IV. Conclusion**

While there is no *per se* requirement for working examples in the specification to establish enablement, examples may be desirable in circumstances where the claims are broad, the art is unpredictable, the relative skill of those in the art is low, or where the state of the prior art is such that the claimed subject matter may be met with a high degree of skepticism.

Furthermore, an Examiner has a very low initial burden to meet to support a rejection for lack of enablement: a reasonable explanation for the belief that the scope of the claim is not adequately enabled. If this burden is met, the burden shifts to the Applicant to establish enablement.