

**Keywords:** inherency; instructions

**General:** Prior art indicating instructions and use that would inherently obtain claimed benefits (pharmacological effect) invalidate claims despite recitation of the benefits (and instructions and information for use to obtain improved pharmacological benefits, absent some new function or result, do not make the claims patentable).

*King Pharmaceuticals, Inc. v. Eon Labs, Inc.*  
No. 2009-1437, -1438 (Fed. Cir., decided Aug. 2, 2010)

## I. Facts

King Pharmaceuticals owns two patents (USP 6,407,128 and USP 6,683,102) relating to metaxalone, a muscle relaxant used to treat discomforts associated with acute, painful musculoskeletal conditions; and sells a brand version of the drug, Skelaxin. Metaxalone was discovered in the 1960's, and King obtained rights through a series of acquisitions. The claims of the patents relate to the administration of metaxalone with food to improve its bioavailability. For example, claim 1 of the '128 patent reads:

1. A method of increasing the oral bioavailability of metaxalone to a patient receiving metaxalone therapy comprising administering to the patient a therapeutically effective amount of metaxalone in a pharmaceutical composition with food.

Certain of the claims also require providing information relating to the use of metaxalone with food, such as claim 1 of the '102 patent:

2. A method of using metaxalone in the treatment of musculoskeletal conditions comprising: providing the patient with a therapeutically effective amount of metaxalone; and informing the patient that the administration of metaxalone with food results in an increase in at least one of C(max) and AUC(last) of metaxalone compared to administration without food.

Eon Labs, intending to begin testing and marketing a competing product, filed an ANDA, indicating that the claims of both patents either would not be infringed or were invalid. The present suit ensued (actually between Eon and a predecessor of King, Elan Pharmaceuticals, although King replaced Elan in the suit).

Eon presented a number of references indicating that health care professionals had, for years, been advised to administer metaxalone with food to avoid gastrointestinal distress. King argued that the preamble of the claims, relating to the recognition of increased bioavailability, or the provision of information with the drug saved the claims from invalidity in view of the prior art. The district court ruled, on summary judgment, that all claims of both patents were invalid under one of 35 U.S.C. 101, 102 or 103. King appealed.

## II. Issues

- A. Did the recitation of increased bioavailability in the preamble of the claims render patentable claims that otherwise recite a known method?
- B. Did the recitation of "informing" sufficiently patentably distinguish the claims over the prior art?

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### III. Discussion

- A. No. The district court, and the Federal Circuit agreed that the prior art clearly taught the administration of metaxalone with food. Moreover, because the claimed increases bioavailability would inherently flow from such administration, the court ruled that the claims with such recitations were inherently anticipated. Interestingly, the court did not address the fact that King's argument essentially concentrated on the preamble (likely because the actual mechanism for increasing the bioavailability was recited in the body of the claims).

King also argued that, although the prior art may have taught the administration of metaxalone with food, the increased bioavailability claimed did not *necessarily* inure, as required for an inherent anticipation finding. In support of the position, King provided expert reports regarding particular foods and timing tested to enhance the bioavailability. In the court's view, however, this argument failed for several reasons. First, the claims did not recite any particular regimen or food types or quantities. As for timing, the King patents themselves indicated a wide range of times for food consumption, both before and after administration of the drug. Certain disclosures simply indicated "breakfast, lunch and dinner." Finally, the court cited well-established precedent for the holding that prior art that sometimes anticipates does anticipate (which is seemingly inconsistent with the "necessary" requirement required for inherency).

- B. No. The district court had ruled against certain of the "informing" claims on the basis of 35 U.S.C. 101, indicating that providing information does not meet the subject matter requirement. King argued that the district court had failed to consider the claim as a whole, and that the holding was therefore reversible error. The Federal Circuit agreed on this point, but because the court also had the issues of anticipation and obviousness before it, considered whether the same claims would have been anticipated or obvious.

The Federal Circuit emphasized the "claim as a whole" rule, and proceeded to analyze the "informing" language in this light. The analysis appears much the same, however, with the court observing first that the metaxalone-with-food limitation was not patentable, such that the "informing" recitation could only save the claim from anticipation if it added novelty when considered in connection with other recitations ("any new and unobvious functional relationship between the printed matter and the substrate", to quote *In re Gulack*, a 1983 Federal Circuit case). The court recognized that some publication or presentation of information could offer interaction with other claim elements so as to rise to patentability. However, that was not the case here.

Although extending its "printed matter" line of precedent, the court was clearly concerned, probably rightfully, that King's proposed approach could lead to "the indefinite patenting of known products by the simple inclusion of novel, yet functionally unrelated limitations." The concern had been addressed in the court's earlier case of *In re Nagi*, and was somewhat extended here.