

Keywords: obviousness; unexpected results; inequitable conduct; claim interpretation; conjunction

General: Based on intrinsic evidence, the Federal Circuit affirms a district court claim construction decision in which the conjunction “and” is used to express mutually exclusive alternatives. Additionally, in view of evidence of unpredictability among alternative formulations, unexpected results, and objective indicia of nonobviousness, the Federal Circuit affirms the lower court finding of nonobviousness of a claimed compound.

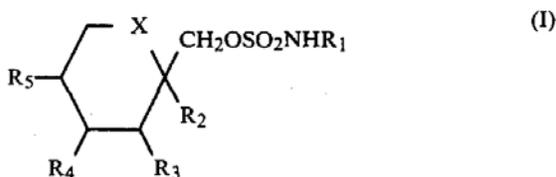
Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.
 No. 2007-1223 (Fed. Cir. 2008)
 Decided March 31, 2008

I. Facts

Ortho-McNeil Pharmaceutical, Inc., is the owner of U.S. Patent No. 4,513,006 (“the ‘006 patent”), which claims the drug topiramate. Notably, the inventor of the ‘006 patent discovered anticonvulsive properties of topiramate, an intermediate compound created during a search for new antidiabetic drugs. During the term of the ‘006 patent, Mylan Laboratories filed an abbreviated new drug application (ANDA) with the FDA and certified that the ‘006 patent was invalid or not infringed by Mylan’s pharmaceutical composition. Ortho-McNeil promptly filed an infringement suit against Mylan.

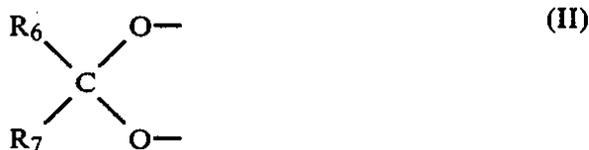
Claim 1 of the ‘006 patent reads:

1. A sulfamate of the following formula (I):



wherein

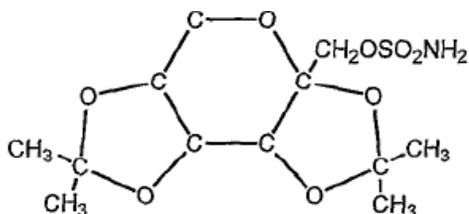
- X is oxygen;
- R1 is hydrogen or alkyl; and
- R2, R3, R4 and R5 are independently hydrogen or lower alkyl and R2 and R3 and/or R4 and R5 together may be a group of the following formula (II):



wherein

- R6 and R7 are the same or different and are hydrogen, lower alkyl or are alkyl and are joined to form a cyclopentyl or cyclohexyl ring.

Further, it is noted that topiramate has the following structure:



During a Markman proceeding, Mylan focused on the claim recitation “R2, R3, R4 and R5 are independently hydrogen or lower alkyl *and* R2 and R3 and/or R4 and R5 together may be a group of the following formula (II)” (emphasis added). Particularly, Mylan argued that this recitation included two required limitations: (1) that “R2, R3, R4 and R5 are independently hydrogen or lower alkyl” and (2) that “R2 and R3 and/or R4 and R5 together may be a group of the following formula (II).” As the drug topiramate only exhibits the second of these features, Mylan argued that its generic version of the drug does not infringe the ‘006 patent.

The district court, however, rejected this argument, and construed the term “and” as linking two *alternative* features—essentially construing the term “and” to mean “or.” Mylan stipulated to infringement of the ‘006 patent based on the district court’s claim construction. Accordingly, the district court granted summary judgment of infringement to Ortho-McNeil. The district court also rejected Mylan’s affirmative defenses of inequitable conduct and invalidity based on obviousness, and permanently enjoined Mylan from future infringing activities.

II. Issues

- A. Did the district court err in construing the term “and” to mean “or”?
- B. Did the district court err in ruling against Mylan’s affirmative defense of invalidity based on obviousness?

III. Discussion

- A. No. The Federal Circuit panel agreed with the district court that the recitations “R2, R3, R4 and R5 are independently hydrogen or lower alkyl” and “R2 and R3 and/or R4 and R5 together may be a group of the following formula (II)” were alternative subsets of compounds, and that topiramate is an example of the second subset. Particularly, the panel noted that “and” was used in the claim in conjunction with the adverbs “independently” and “together” and, given this context, that the subunits R2, R3, R4, and R5 are not always required to be a hydrogen or lower alkyl.

Additionally, the panel explored a laundry list of other evidence in support of this claim construction. First, the panel suggested that several dependent claims would be rendered meaningless if the “and” at issue were construed as conjunctive. Further, the court noted that the specification of the ‘006 patent uses “and” to link alternative chemical structures in stating:

R2, R3, R4 and R5 are independently hydrogen or lower alkyl *and*,
when X is CH₂, R4 and R5 may be alkene groups joined to form a

benzene ring *and* when X is oxygen, R2 and R3 and/or R4 and R5 together may be a methylenedioxy group of the following formula
II

(Emphasis added.) Still further, the court relied on a dictionary definition of “and” that indicated the term could be used to link alternatives. Again, based on this collection of evidence, the panel affirmed the district court’s construction of “and” as linking alternative features of the claim.

- B. No. On appeal, Mylan cited *KSR* for the proposition that “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp,” and argued that one skilled in the art would have designed an FBPase inhibitor, of which topiramate is an example, in searching for a diabetes drug. The Federal Circuit, however, noted that the invention does not present a small number of solutions that are easily explored to show obviousness. Rather, the court noted that the ordinarily skilled artisan would have had no reason to select among a number of unpredictable alternatives to even produce topiramate as an intermediate, and would have had to stop at the intermediate compound and test it for properties far removed from the original purpose of the development (as an antidiabetic drug). The court also noted evidence of objective criteria showing nonobviousness, including unexpected results, skepticism of experts, copying, and commercial success. Consequently, the Federal Circuit affirmed the district court finding that the ‘006 patent is not obvious.