CAFC Invalidates Patents for Lacking Written Description of Chemical Genus Covering “Analogs”

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On June 7, 2011, the Court of Appeals for the Federal Circuit (CAFC) upheld a summary judgment in the matter of *Boston Scientific v. Johnson & Johnson.* The court held that certain claims of three U.S. patents covering a combination of drug-eluting stents and "rapamycin, or a macrocyclic lactone analog thereof" were invalid for lack of written description under 35 U.S.C. § 112. The court also held that certain claims of a U.S. patent covering a drug-eluting stent comprising "rapamycin or a macrocyclic triene analog thereof" were similarly invalid for lack of written description.

The patents at issue in this case are directed toward stents that were designed to be placed in arteries and release an immunosuppressive agent, like rapamycin (sirolimus), to prevent restenosis, the repeat narrowing of the artery. Three of the patents ("the 1997 patents") claim a drug-eluting stent using rapamycin, or a "macrocyclic lactone analog thereof," which the district court construed to mean "sirolimus or a macrocyclic lactone molecule with a structure similar to sirolimus." Relying in part on *Ariad v. Eli Lilly* (CAFC 2010), the court held that the common specification of these patents lacked a "representative number of species falling within the scope of the genus [of rapamycin analogs] or structural features common to the members of the genus." In particular, the court found that the specification provided no examples of such analogs, little guidance on how to determine the structure of a rapamycin analog (besides providing the structure of rapamycin), and no correlation between the structure and function of rapamycin or its analogs to provide adequate written description of the claimed genus.

Appellants argued that information on structure and mode of action for rapamycin analogs was available in the prior art at the time of filing the 1997 patents, so it was therefore not necessary to specify these characteristics to support the claimed genus. The court disagreed and determined that little was known in the art regarding the prevention of restenosis using drug-eluding stents at the time of filing. The court also noted that appellants disclosed the uncertainty of such compounds in the specification of these patents and characterized their activity as unpredictable in response to an allegation of obviousness in a summary judgment motion.

The court disagreed with further argument by the appellants that a patentee's requirement to provide support for a genus was somewhat lessened when a claim is directed toward a combination of known

elements rather than a novel compound. The court emphasized that the "test for written description is the same whether the claim is to a novel compound or a novel combination of known elements."

The court also invalidated a similar fourth patent because no specific examples or other structural information existed with respect to the claimed *sub-genus* of a "macrocyclic triene analog." In view of the "insufficient support for the highly specific functional requirements" of this sub-genus, the court ruled that this patent did not demonstrate that the inventors were in possession of the claimed invention, and therefore did not fulfill written description requirements.

While the *Boston Scientific* case is directed toward claims covering drug-eluting stents, it provides important guidance regarding support for a chemical genus. Although it may not be necessary to provide an extensive number of species to support a genus that is well-known in the art (*e.g.*, "pharmaceutically acceptable salts thereof" or "prodrugs thereof"), this case highlights the need to provide a sufficient number of species and, if necessary, additional structural information in a patent application to provide adequate written description for a novel generic structure. Supporting species and examples are also necessary when only a limited number of examples of a genus are known, or the generic structure is being claimed in combination with other previously known elements. This case also emphasizes the importance of defining sub-generic positions when covering new classes of chemical compositions.

If you have any questions about this case, or any other aspect of chemical / pharmaceutical patent law, please contact Brian C. Trinque, Ph.D. or Giulio A. DeConti.