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In This Issue

Federal Circuit Affirms Invalidity For Obviousness of Pharmaceutical Formulation Claims

The Federal Circuit recently affirmed a district court's finding of invalidity due to obviousness of a pharmaceutical formulation patent. In *Tyco Healthcare Group v. Mutual Pharmaceutical Co. et al.*, plaintiff Tyco sued Mutual for infringement of a patent that covered specific formulations for the insomnia drug temazepam-sold under the brand name Restoril®. The patent contained two claims directed to certain dosages of the crystalline form of temazepam. Mutual moved for summary judgment of invalidity, and the district court granted Mutual's motion holding that the claims of the patent were invalid for obviousness. The claims were held obvious in light of Tyco's prior patents claiming a range of dosages that included the claims at issue along with a 1983 edition of the British National Formulary.

On appeal, Tyco argued that the district court erred because all "the properties of a composition of matter relevant to patentability must be considered in evaluating whether that composition would have been obvious in light of the prior art, and that the unclaimed property of effectiveness in treating insomnia renders the claims at issue nonobvious." The Federal Circuit disagreed with Tyco's argument, reasoning that under Federal Circuit precedent, the discovery of a new use of a previously known composition, even when that use or property is not obvious, cannot "impart patentability to the known composition." The Federal Circuit did not agree with any of Tyco's other ancillary arguments that the prior art taught away from the claimed invention, or that unexpected results or commercial success of Restoril® showed nonobviousness.

Federal Circuits Holds That Letters to Industry Did Not Confer Subject Matter Jurisdiction for Declaratory Judgment Claim of Invalidity

In a case where the patents-in-suit relate to dietary supplements in food products, the Federal Circuit reversed the district court's finding that it had subject matter jurisdiction over Plaintiff's declaratory judgment claim on invalidity. In *Creative Compounds v. Starmark Labs*, Starmark sued for declaratory judgment of invalidity and non-infringement of the '373 patent. In response, Creative Compounds counterclaimed for invalidity of the unrelated '273 patent. At the district court, the judge granted summary judgment of invalidity as to the '273 patent and decided that it had subject matter jurisdiction to hear the claim by denying Creative's motion to dismiss pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. Among other issues raised by both parties, Creative appealed to the Federal Circuit on the issue of subject matter jurisdiction.

The Federal Circuit reviewed various letters sent by Creative to the dietary supplement industry claiming that various products infringed the '273 patent.

However, each of these letters were sent to other companies in the industry and were never sent to Starmark. Starmark could not even claim that these letters were sent to customers because the letters were sent three months before Starmark was even formed. In the absence of an indemnity agreement, the Federal Circuit noted, Starmark has "at most, only an economic interest in clarifying its customers' rights under Creative's patents." Such economic interest alone the Court explained, was not enough to satisfy the "actual controversy' requirement of the Declaratory Judgment Act. The Federal Circuit accordingly vacated the district court's order that the '273 patent was invalid because it did not have the jurisdiction to make that determination in the first place.

Drug Eluting Stent Patents are Held Invalid for Lack of Written Description

In *Boston Scientific v. Johnson & Johnson*, the Federal Circuit affirmed a district court finding that two patents directed to drug-eluting coronary stents were invalid due to lack of written description. Each of the patents contained limitations in the claims directed to an "analog of rapamycin"- limitations that were added years after the priority date for both patents. The district court found that the claims were broader than the disclosure in the patent.

On appeal, Boston Scientific argued that the specification was sufficient, but the Federal Circuit did not accept these arguments. Instead, the panel, lead by Judge Moore (formerly a district judge in Ohio) relied on the holding in *Ariad* and stated that a "sufficient description of a genus requires the disclosure of either a representative number of species falling within the scope of the genus [so that] one of skill in the art can visualize or recognize the members of the genus." In the patents-in-suit, the Federal Circuit reasoned, were no descriptions or examples of the "analogs" and failed to disclose any sub genus of the types specifically claimed. Judge Moore seemed particularly concerned with the lack of examples, and stated that although examples are not always required to satisfy the written description requirement under Section 112, the lack of any examples should be considered when determining whether the claimed invention is adequately described.

Judge Gajarsa concurred with the majority, but explained in a separate opinion that he believed the better analysis for invalidity of claims that are broader than the patent disclosure is under Section 112, paragraph 1 for enablement. The enablement requirement was more straightforward according to Judge Gajarsa, rather than parties and courts trying to determine "how the written description requirement applies to novel compounds as opposed to novel combinations of known elements."

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