

Intellectual Property Alert: Is Functional Similarity Between Compounds Sufficient to Create a *Prima Facie* Case of Obviousness?

By Sarah A. Kagan

May 2, 2018 — Anacor Pharmaceuticals, the dissatisfied patent owner in an *inter partes* review (IPR), and the U.S. Patent and Trademark Office (USPTO) as intervenor participated in an oral argument at the U.S. Court of Appeals for the Federal Circuit on April 6, 2018. *Anacor Pharmaceuticals, Inc. v. Iancu, Intervenor,* 2017-1947. The Patent Trial and Appeal Board (PTAB) found claim 6 of Anacor's U.S. Patent 7,582,621 obvious in an IPR brought by the Coalition for Affordable Drugs X LLC, in IPR2015-01776, decided February 23, 2017. The Coalition did not participate in the appeal.¹

Claim 6 is directed to treating onchomycosis (nail bed infection) caused by *Tinea unguium* in an animal with a particular compound (1,3-dihydro-5'-fluoro-1-hydroxy-2,1-benzoxaborole). The infectious agent, also called ringworm, is a fungus of the group dermatophytes. The compound is also known as tavaborole.

Anacor contends that the PTAB wrongly combined references based on similar functions of compounds disclosed in the references, rather than on the compounds' structures. Anacor asserts that the PTAB's approach lacks both scientific and legal underpinnings because similarity of structure is required to reasonably predict function of a compound.

Anacor further contends that the compounds of the combined references were too structurally dissimilar to support a *prima facie* case of obviousness. While both were boron-containing heterocycles, the compounds themselves were not close homologs of each other.

Judge Reyna, sitting along with Judges Bryson and Stoll, seemed concerned that structural similarity is required for obviousness but is not found in these references. Judge Reyna pushed the USPTO to identify legal support for its theory that structural similarity is the required basis for obviousness only when new compounds are claimed. The USPTO pointed to *In re Merck & Co. Inc.*, 800 F.2d 1091 (Fed. Cir. 1986) as the best case for this point. But the USPTO admits in its brief that *Merck* involved structural similarity as well as functional similarity, and the structural similarity was much closer

¹ The Coalition was formed by hedge fund manager J. Kyle Bass to challenge potentially weak drug patents and profit by short-selling the stock of owners of challenged patents.

(only one atom differed) than for the compounds in the combined references. *Merck* does not seem to limit the use of structural similarity to new compounds rather than methods of using compounds.

On the other hand, Anacor did not point to any legal support for its position that obviousness of a method using a chemical compound can *only* be based on structural similarity. Close structural similarity and similar utilities may be used to form a *prima facie* case, but Anacor did not point to any precedent that indicated that this must be the rational underpinning for a *prima facie* case.

Anacor also argued that the IPR trial procedure was improper because the theory of obviousness in the petition to institute the IPR was different from the theory in the final written decision, denying Anacor adequate notice to respond. It also argued that burdens of proof were improperly shifted to Anacor to disprove obviousness when a *prima facie* case had not been properly made.

The panel seemed to be more engaged by the requirements of a *prima facie* case, rather than with mandating the choreography of PTAB trials. The Federal Circuit's decision in this case should shed light on how rigid the court wants to make its rules on *prima facie* obviousness for claims to use of chemical compounds. Requiring structural similarity to provide a rational underpinning may be too rigid a rule for the Federal Circuit, whose penchant for rigid rules has been repeatedly criticized by the U.S. Supreme Court.

Click here to listen to the oral arguments in Anacor Pharmaceuticals, Inc. v. Iancu.

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