

Kratz, Quintos & Hanson, LLP – IP Newsletter

THERE MUST BE A PROPER REASON IN THE RELEVANT FIELD TO COMBINE THE REFERENCES TO ACHIEVE THE CLAIMED INVENTION TO MAKE AN OBVIOUSNESS REJECTION; OTHERWISE, AN ARGUMENT OF “HINDSIGHT” IS VALID AGAINST THE OBVIOUSNESS REJECTION

by: Daniel A. Geselowitz, Ph.D.

The U.S. Supreme Court case of *KSR Int'l Co. v. Teleflex Inc.* has made it easier for an Examiner to combine references and harder for an applicant to argue against an obviousness rejection. However, it is possible to argue that there is no reason to combine references, as illustrated by the recent U.S. Court of Appeals for the Federal Circuit's decision in *Purdue Pharma L.P. v. Depomed, Inc.*, decided on March 24, 2016, in which Depomed's two patents survived three *inter partes* reviews (IPRs) and appeals to the Federal Circuit.

Depomed owns two related U.S. patents directed to a controlled-release oral dosage form of a soluble drug. Depomed sued Purdue for infringement; and Purdue then filed three petitions at the U.S. PTO requesting the IPRs on the grounds that the claims were obvious, in particular, over a “Baveja” reference and a Shell” reference. A representative claim is as follows:

“Indeed, it remains ‘important to identify a *reason* that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does.*’”

U.S. Court of Appeals for the Federal Circuit

1. A controlled-release oral drug dosage form for releasing a drug whose solubility in water is greater than one part by weight of said drug in ten parts by weight of water,
 - said dosage form comprising a solid polymeric matrix with said drug dispersed therein at a weight ratio of drug to polymer of from about 15:85 to about 80:20,
 - said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode [“the swelling limitation”],
 - that releases said drug into gastric fluid by the dissolution and diffusion of said drug out of said matrix by said gastric fluid,
 - that upon immersion in gastric fluid retains at least about 40% of said drug one hour after such immersion and releases substantially all of said drug within about eight hours after such immersion,
 - and that remains substantially intact until all of said drug is released [“the substantially intact limitation”].

The IPRs were conducted and the U.S. PTO Patent Trial and Appeal Board found that Baveja discloses the limitations of the claim except for the “swelling” and the “substantially intact” limitations, and that Shell discloses these limitations. However, the Board concluded that Purdue had failed to establish by a preponderance of the evidence that the challenged claims would have been obvious over the prior art. Specifically, the Board found that although Baveja and Shell may have interrelated teachings, Purdue had failed to explain “how or why” one of ordinary skill in the art would have combined the “swelling” and “substantially intact” features of the Shell formulation with the Baveja formulation. The Board also found that Purdue had failed to establish that there was a reasonable expectation of success to achieve the claimed invention.

Purdue then appealed to the Federal Circuit, which ruled that the Board did not err, and **affirmed** the Board’s decision. Specifically, the Federal Circuit referred to *KSR*, stating:

[n]evertheless, the Board correctly recognized that “a patent . . . is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR*, 550 U.S. at 418. Indeed, it remains “important to identify a *reason* that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way* the claimed new invention does.” *Id.* (emphases added).

That is, even though one may look to “interrelated teachings” of multiple references, there still must be a specific reason to combine the teachings of the references to achieve the claimed invention. The Federal Circuit decision also noted that Purdue relied on the problem to be solved to supply the reason to combine the prior art, but that Purdue had failed to demonstrate that the problem was known in the art. That is, Purdue improperly relied on hindsight reconstruction of the claimed invention.

Announcement: Kindly be advised that, on July 1, 2016, our Tokyo Liaison Office will move to:
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