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Bayer's Oral Disintegrating Tablet "Levitra" Patent is Obvious

The FDA approved Bayer's drug Levitra for the treatment of erectile disfunction (ED). At that time, Pfizer had a competing drug Viagra and Eli Lilly had Cialis.

Bayer obtained a patent for Levitra which was vardenafil as "an uncoated tablet which disintegrates rapidly in the mouth" - i.e., an oral disintegrating tablet (ODT). Watson sought to market a generic version.

The district court found that the prior art "did not contain an indication that ED drugs would be good candidates for ODT formulations." The Federal Circuit disagreed.

The Federal Circuit explained that the district court failed to consider six prior art references that indicated a "person of ordinary skill in the art would have considered ODT formulations applicable to ED drugs" and "vardenafil in particular."

The court concluded by stating that the "district court cannot, through a credibility determination, ignore the wealth of evidence, especially in this case where the expert did not even address it."

When other factors were also considered, the Federal Circuit found the patent obvious.

COMMENTS:

Seemingly, the Federal Circuit took over the role of opposing expert to determine what prior art should or should not be considered by an expert, rather than leaving the issue as a credibility determination by the trial court or jury.

Merck's Antibiotic Drug "Invanz" Patent is Obvious

Merck sued Hospira when the latter sought to market its generic version of Invanz.

The district court found Merck's patent obvious and invalid, even though "none of the three steps of [the patent claim] was individually taught by the prior art." However, according to the district court, the three steps were "nothing more than conventional manufacturing steps . . . and thus were the product of routine experimentation."

The Federal Circuit acknowledged that the prior art did not disclose the patented "order of the steps", the "specific temperature range", and the "final moisture content."

However, the Federal Circuit concluded that "those are all experimental details that one of ordinary skill would have utilized via routine experimentation".

COMMENTS:

On somewhat of the "flip" side, patent examiners frequently reject a patent application if each element of a patent claim is found in the prior art, but allow the claim if one element cannot be found.

US House of Representatives Holds Hearing on Allergan Patent Transfer to St. Regis Mohawk Tribe

Allergan has sought to shield its patents from inter partes review by the USPTO by transferring its patents to the St. Regis Mohawk Tribe, and then licensing the patents back. Inter partes review could result in the patents being invalidated.

Allergan's position is that the transfer to the Tribe shields the patents from inter partes review because the Tribe has sovereign immunity against those proceedings.

At the same time, Allergan is asserting those patents in district court.

The US House of Representatives conducted a hearing earlier this month to examine the issue. A law professor and IP counsel from industry testified.

The professor pointed out that tribal immunity applies to administrative adjudications. Yet, whether tribal immunity applies to USPTO proceedings is still at issue. The professor apparently stated that tribal infringers, with immunity, "distort the underlying purpose of patent law - to incentivize competition".

The professor supported a Senate bill that removes tribal immunity in inter partes review, and did not believe it to be discriminatory.

COMMENTS:

We can only wait for further developments.

Purdue's "OxyContin" Patent is Obvious

Amneal sought inter partes review in the USPTO to invalidate Purdue's patent for the pain killer OxyContin. The parties were involved in patent litigation over the patent in district court.

OxyContin has been at the center of attention over the national opioid abuse epidemic. Purdue stopped selling the original formulation because it was susceptible to abuse. The present patent sought to make the drug abuse-proof.

The patent claim included an "aversive agent" which sought to prevent injection, inhalation, and/or oral abuse by decreasing the "attractiveness" of the dosage form.

The patent office Board found the patent obvious in view of prior art.

COMMENTS:

The Board's opinion was essentially a discussion of their interpretation of the prior art. No interesting or law was set forth.

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