Nixon Peabody LLP

Federal Circuit Patent Watch

SEPTEMBER 6, 2006

Alza Corp. v. Mylan Labs., Inc.

No. 06-1019, Federal Circuit (*Gajarsa*, Clevenger, Prost)

[O]ur anti-hindsight jurisprudence is a test that rests on the unremarkable premise that legal determinations of obviousness, as with such determinations generally, should be based on evidence rather than on mere speculation or conjecture.

On September 6, 2006, the Federal Circuit affirmed the district court's judgment that Mylan did not infringe U.S. Patent No. 6,124,355, which related to a once-a-day extended release formulation of the anti-incontinence drug oxybutynin, by filing an Abbreviated New Drug Application for generic Ditropan XL®, and that the '355 patent was invalid as obvious under 35 U.S.C. § 103. The Federal Circuit stated:

> In *Graham*, the Court held that that the obviousness analysis begins with several basic factual inquiries: "[(1)] the scope and content of the prior art are to be determined; [(2)] differences between the prior art and the claims at issue are to be ascertained; and [(3)] the level of ordinary skill in the pertinent art resolved." After ascertaining these facts, the Court held that the obviousness vel non of the invention is then determined "against th[e] background" of the *Graham* factors. Clearly, the Court recognized the importance of guarding against hindsight, as is evident in its discussion of the role of secondary considerations as "serv[ing] to guard against slipping into use of hindsight and to resist the temptation to read into the prior art the teachings of the invention in issue."
>
> The Court of Appeals for the Federal Circuit's and its predecessor's "motivation to combine" requirement likewise prevents statutorily proscribed hindsight reasoning when determining the obviousness of an invention. According to the "motivation-suggesting-teaching" test, a court must ask "whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims."

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This requirement has been developed consistent with the Supreme Court's obviousness jurisprudence, as expressed in *Graham,* and the text of the obviousness statute that directs us to conduct the obviousness inquiry "at the time the invention was made. [T]he "motivation to combine" requirement "[e]ntails consideration of both the 'scope and content of the prior art' and 'level of ordinary skill in the pertinent art' aspects of the *Graham* test."

At its core, our anti-hindsight jurisprudence is a test that rests on the unremarkable premise that legal determinations of obviousness, as with such determinations generally, should be based on evidence rather than on mere speculation or conjecture ... A suggestion, teaching, or motivation to combine the relevant prior art teachings does not have to be found explicitly in the prior art, as "the teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references ... The test for an implicit showing is what the combined teachings, knowledge of one or ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." However, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning, with some rational underpinning, to support the legal conclusion of obviousness ...

There is flexibility in our obviousness jurisprudence because a motivation may be found implicitly in the prior art. [O]ur approach has permitted us to continue to address an issue of law not readily amenable to bright-line rules, as we recall and are guided by the wisdom of the Supreme Court in striving for a "practical test of patentability."

For more information on these issues or other intellectual property law matters, please contact **Lawrence M. Sung, Ph.D.** at lsung@nixonpeabody.com or (202) 585-8221.

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