IP Alert: Obviousness: The Analytic Framework May Control the Outcome



Obviousness: The Analytic Framework May Control the Outcome

By Sarah A. Kagan

Some aspects of the law of obviousness seem hard to apply, as they are repeatedly challenged on appeals to the Court of Appeals for the Federal Circuit. One such aspect is the role of objective indicia of nonobviousness, which are sometimes also referred to as “secondary considerations.” How do they interact with the prior art considerations? This aspect is at play in the appeal of Merck Sharp & Dohme B.V. v. Warner Chilcott Co., LLC, 212 F.Supp.3d 531 (D. Del. 2016), which was argued at the Federal Circuit on September 8, 2017 (Case No. 16-2583).

The Supreme Court in Graham v. John Deere Co., 383 U.S. 1 (1966) set out three factors by which obviousness or nonobviousness is to be determined: (1) scope and content of the prior art, (2) differences between the prior art and the claimed invention, and (3) level of skill in the art. The

Court additionally indicated that secondary considerations “might be utilized to give light to the circumstances surrounding the origins of the subject matter sought to be patented.” The Court stated that the secondary factors, including commercial success, long felt but unmet need, and failure of others “may have relevancy.”

The Orange Book lists U.S. Patent No. 5,989,581 (the ’581 patent) as protecting Merck’s NuvaRing®, a hormone-releasing vaginal ring. Warner Chilcott filed an Abbreviated New Drug Application (ANDA) seeking to market a generic version before expiry of Merck’s ’581 patent. Warner Chilcott asserted that the ’581 patent was invalid for obviousness, and the District Court for the District of Delaware agreed. Merck appealed the obviousness determination on multiple grounds.

At trial, Merck presented evidence of commercial success, industry recognition, and long-felt need. The district court discounted all evidence of objective indicia of non-obviousness because it found no nexus to the “inventive features.” Merck asserted that the court used an improper legal standard because rather than looking for a nexus between the objective indicia and the invention as a whole, it looked to connect them to individual inventive features. Moreover, Merck asserted in its brief that the district court’s analysis of the objective indicia was improper, because it occurred after the court concluded that the invention was obvious, i.e., that there were no inventive features. Because of the improper timing and improper comparison, Merck argued, the district court could not have found the required nexus between the secondary considerations and the claimed invention.

Merck also urged that NuvaRing® was entitled to a presumption of a nexus because the objective indicia are tied to a product that is disclosed and claimed in the patent. The failure to accord the presumption to NuvaRing® improperly shifted the burden of producing evidence, Merck argued, from Warner Chilcott (to attack the nexus) to Merck (to prove a nexus).

In its brief, Warner Chilcott denied that burden shifting had occurred. It relied on an exceedingly fine distinction: “Accordingly, while the burden of proof never shifted, Merck had the ‘responsibility to set forth evidence in opposition,’ such as evidence of a supposed ‘teaching away.’”

At the oral hearing at the Federal Circuit, the panel of three judges was interested in the issues relating to the objective indicia of non-obviousness. Merck reminded the panel that the district court made two legal errors in its analysis: (1) it failed to presume a nexus even though the evidence related to a commercial product that was disclosed in the patent and co-extensive with the claims; and (2) it looked for a nexus to inventive features rather than to the invention as a whole. Until its rebuttal time, Merck did not discuss the issue of the order of consideration of the objective indicia with respect to other obviousness factors.

Warner Chilcott's counsel was peppered with questions from the panel, including on the issue of the objective indicia. Warner Chilcott defended the district court's analysis by pointing to its proper statements of the law that objective indicia should be considered along with other Graham factors, even though the district court appeared to consider the objective indicia only after finding the claimed subject matter obvious over the prior art. The panel indicated that correctly stating the law did not mean that the district court correctly understood it. The panel pointed to the district court's use of the term "rebut," questioning Warner Chilcott's assertion that the district court correctly understood (and implicitly correctly applied) the legal standard. The term "rebut" seemed to indicate to the panel that the district court improperly shifted the burden to Merck to rebut the conclusion of obviousness with its objective evidence.

When the panel questioned Warner Chilcott on Merck's asserted entitlement to a presumption of a nexus between its objective indicia and the patent claims, Warner Chilcott urged that there was nothing new in the commercial product and that the objective indicia did not demonstrate that there was something new. This position was consistent with the district court's opinion (looking for inventive features), but did not engage the notion of a presumption of a nexus.

Despite the years of case law on the objective indicia of non-obviousness, applying them to the question of obviousness over prior art is difficult. The secondary considerations do not directly relate to the cited prior art but to obviousness in a more general sense of acceptance in the market or field of endeavor, i.e., "to the circumstances surrounding the origins of the subject matter sought to be patented." We look forward to the Federal Circuit's clarification of the proper weighing of the prior art considerations with the objective indicia of obviousness or nonobviousness. Will the panel give deference to the weighing of the district court judge or will it reverse based on an alleged improper analytic process?

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