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Patent Litigation Advisory

Federal Circuit Issues Opinion on "Inherent Obviousness" in Patent Claim, Invalidating Orange Book Listed Pharma Patent

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KEY POINTS

- Federal Circuit issued precedential opinion in *Hospira Inc. v. Fresenius Kabi USA, LLC* that affirmed obviousness of a liquid drug patent claim, encouraging future patent challengers to raise the issue of "inherent obviousness."
- Hospira made two arguments on appeal that the district court's inherency finding was improper, and the Federal Circuit rejected both arguments.
- The Federal Circuit's decision shows why patent owners and alleged infringers should assess whether inherency can be used as part of an obviousness defense.

On January 9, the US Circuit Court for the Federal Circuit issued a precedential opinion affirming the obviousness of a patent claim directed to a ready-to-use liquid drug formulation with allegedly better stability than previous formulations. See *Hospira Inc. v. Fresenius Kabi USA, LLC* ___ F.3d ___ (Fed. Cir. Jan. 9, 2020). The opinion also clarifies some of the nuances of inherency in an obviousness analysis, potentially providing patent challengers with more motivation to raise "inherent obviousness" arguments in future cases.

The Federal Circuit upheld Northern District of Illinois Judge Rebecca Pallmeyer's order, holding claim 6 of U.S. Patent No. 8,648,106 ("the '106 patent"), covering Hospira's Precedex Premix® (dexmedetomidine hydrochloride) 4 µg/mL product as a ready-to-use intravenous (IV) sedative, invalid as obvious. The court relied on two prior art products to make this determination — (1) Precedex Concentrate®, a 100 µg/mL product of the same drug that needed to be diluted to 4 µg/mL before being injected, and (2) Dexdomitor®, a ready-to-use veterinary sedative containing 500 µg/mL of the same drug. In addition to requiring 4 µg/mL of dexmedetomidine or its salt(s), Claim 6 also required that the drug concentration of the formulation not decrease more than about 2 percent for at least five months upon storage in a sealed glass container (the "stability limitation"). This stability limitation was found to be inherent in the prior art's express teachings of a 4 µg/mL ready-to-use product coupled with non-prior art stability data from more than 20 tested samples of that product, all of which showed the claimed less than 2 percent degradation after at least five months.

In affirming the district court's decision, the Federal Circuit reiterated that "inherency may supply a missing claim limitation in an obviousness analysis," but to do so, "the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art." On appeal, Hospira argued that the district court's inherency finding was improper because the lower court (1) relied on testing of the 20 samples that was not itself prior art and (2) applied a lower "reasonable expectation of success" standard rather than the proper "necessarily or natural result" standard for inherency. The Federal Circuit rejected both of these arguments.

Using Non-Prior Art to Prove Inherent Properties of Prior Art

In rejecting Hospira's first argument, the Federal Circuit held that "[e]xtrinsic evidence can be used to demonstrate what is 'necessarily present' in a prior art embodiment even if the extrinsic evidence is not itself prior art." The panel also stated that "the work of the inventor or the patentee can be used as the evidence of inherency." However, it cautioned that "[t]he later evidence is not itself prior art; it only helps to elucidate what the prior art consisted of."

The Federal Circuit also rejected Hospira's critiques of the specific inherency evidence presented in this case. For example, the panel rejected Hospira's argument that all the tested samples were made by a single method and held that "the unclaimed manufacturing variables in [the patent specification] do not, as a matter of law, preclude a finding of inherency in this case." They reasoned that "Claim 6 is not a method claim, it is not a product-by-process claim, and there are no limitations in claim 6 regarding the manufacturing process by which the recited … composition must be prepared. Importing such limitations from [the patent Example] into the claim, as Hospira seeks to do, would be improper." Further, the panel noted, "Hospira did not present evidence of even a single sample of the 4 µg/mL preferred embodiment that failed to meet the [stability] limitation" or "that samples prepared by a different process might not meet that limitation."

Finally, the Federal Circuit relied on expert testimony and statistical evidence in the trial record that showed the drug was very stable at any concentration and that 25-fold dilution of the prior art stable formulations "does not affect its inherent stability" to support its overarching holding that Judge Pallmeyer's decision was not clearly erroneous.

No Additional "Reasonable Expectation" Required if Property is Proven to Be Inherent

Turning to Hospira's second argument, the Federal Circuit found no reversible error in the district court's finding of inherency but did find that Judge Pallmeyer made a harmless error by "engag[ing] in unnecessary analysis in evaluating whether [evidence presented] would enable a person of ordinary skill to have had a reasonable expectation of successfully achieving the [stability] limitation." More specifically, the panel held that "[t]he [lower] court thus conflated the standards for inherency and reasonable expectation of success" but "that was harmless error that did not infect its inherency analysis and findings." Summarizing the correct analysis, the Federal Circuit stated "[i]f a property of a composition is in fact inherent, there is no question of a reasonable expectation of success in achieving it." In light of this decision, both patent owners and alleged infringers should assess whether inherency can or will be used as part of an obviousness defense.

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