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Janssen v. Teva: Federal Circuit Upholds Claims to Pharmaceutical Dosing Regimen, Clarifies Presumption of Obviousness for Overlapping Prior Art Ranges

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On July 8, the US Court of Appeals for the Federal Circuit issued a precedential opinion in *Janssen Pharmaceuticals, Inc. et al. v. Teva Pharmaceuticals USA, Inc.*[1] affirming the district court's finding that patent claims to a dosing regimen for the Janssen drug Invega Sustenna were not obvious in view of prior art reciting dosing ranges that overlapped with the claimed ranges. Rejecting arguments that such an overlap in ranges necessarily triggered a prima facie presumption of obviousness, the court reiterated that the presumption is only applicable after a fact-specific inquiry.[2] In this case, the court refused to apply the presumption, even though the prior art disclosed administering the claimed amounts of drug, because the claimed amounts were intertwined with other elements that made the presumption more than just picking a value from an overlapping prior art range.

Background

Janssen sued Teva in the US District Court for the District of New Jersey under the Hatch-Waxman Act after Teva filed an abbreviated new drug application (ANDA) on a generic version of Invega Sustenna (paliperidone palmitate). Janssen's US Patent No. 9,439,906 (the '906 patent) concerns dosing regimens for paliperidone palmitate extended-release injection products for the treatment of schizophrenia. The '906 patent claims a dosing regimen in which a patient is administered two different "loading doses" in the deltoid muscle (an initial 150 mg dose and a 100 mg dose a week later) followed by 25 – 150 mg maintenance doses once a month.

Teva asserted the claims should be presumed obvious over several prior art references that taught administering at least three **equal** doses of 50, 100 or 150 mg of paliperidone palmitate at certain time intervals, and administering a therapeutically effective amount of paliperidone palmitate, including a range encompassing both 100 mg and 150 mg.[3]

The district court rejected Teva's arguments. It found that a presumption of obviousness did not apply because the claimed invention is composed of a unique combination of elements that are not all easily defined with numerical values that can be found in the prior art.[4] Having found against Teva on the remaining factual issues in the obviousness analysis, the district court held that Teva failed to prove that the challenged claims were obvious.

The Federal Circuit decision

The Federal Circuit affirmed. The court first rejected Teva's argument that a presumption of obviousness should apply simply because the prior art ranges "overlapped" with the claimed ranges. The Federal Circuit explained that, while a presumption of obviousness "typically exists" when the claimed range or value overlaps or falls within ranges taught in the prior art, the presumption is not applied without considering the invention's context, how wide the prior art range is and the general expectations of skilled artisans.

Here, the claims did not simply recite an amount of drug already disclosed within a prior art range, but instead included other intertwined elements, such as the timing of the doses, their loading dose nature and the decreasing amounts from the first to second dose that were not included in the prior art "range." As a result of these variables, the claimed dosing regimen "does not *clearly* fit within the presumption's focus on simply selecting a number or range overlapping a prior-art range of a variable or, even, a plurality of variables that overlap with prior-art ranges where the variables are properly considered separately from each other."[5] While it focused on the amounts and timing of the specified doses, the court also noted that the claimed deltoid muscle administration might make the range presumption inapplicable.

After finding no presumption applied, the Federal Circuit found no motivation to combine the prior art references and no reasonable expectation of success. Teva asserted that the prior art references taught the exact amounts of drug claimed in the '906 patent, rendering the claimed regimen obvious. The Federal Circuit found that neither prior art reference disclosed a loading-dose regimen as required by the claims, and that Teva had not shown that a skilled artisan would have been motivated to use a higher initial loading dose followed by a decreased second loading dose.[6] In so holding, the Federal Circuit underscored the importance of expert testimony, noting that the lower court had adequate basis for rejecting Teva's arguments based, in part, on expert testimony that a skilled artisan would not use long-acting injectables to "load" patients or treat acutely agitated patients, and, instead, if anything, would have been motivated to speed up drug absorption by reducing particle size.[7]

On reasonable expectation of success, the Federal Circuit found no clear error in the lower court's determination that, based on expert testimony, a skilled artisan would not have reasonably expected a multidose regimen, like the ones claimed, to be safe and effective.[8] In doing so, the court rejected the argument that unclaimed factors, such as safety and regulatory approval, could be considered in assessing expectation of success.

Finally, the Federal Circuit found that Teva failed to prove motivation, and therefore obviousness, for similar claims to dosing regiments for patients with renal impairment. The lower court found, based on Teva's expert testimony, that Invega Sustenna was contra-indicated for patients with moderate to severe renal impairment, and that Teva's theory of motivation focused on patients with mild renal impairment.[9] Because the prior art was silent on dosages for patients with mild renal impairment and only recommended lowering doses for patients with moderate-to-severe renal impairment, the Federal Circuit found no clear error in the lower court's analysis of the expert testimony of what the prior art would have taught a skilled artisan.[10]

Implications of the Federal Circuit decision

Janssen is an important precedent for parties drafting patent claims or litigating obviousness where the prior art has potentially overlapping ranges for a claimed element, particularly in the pharmaceutical field. Patent applicants aware of overlapping ranges in the prior art should consider drafting claims to include numerous interrelated elements (such as dosage, timing and administration route) that differentiate the claims from the range disclosed in the prior art. In litigation, patentees must be prepared to present facts showing why a presumption of obviousness should not apply if there is overlapping prior art. *Janssen* also provides a good precedent for patentees defending the validity of method of treatment claims, particularly those with loading doses or different dosing regimens for particular patient populations.

[1] *Janssen Pharmaceuticals, Inc. et al. v. Teva Pharmaceuticals USA, Inc.*, Appeal No. 2025-1228 (Fed. Cir. July 8, 2025).

[2] *See, e.g., Genetics Institute, LLC v. Novartis Vaccines & Diagnostics, Inc., 655 F.3d 1291, 1306 (Fed. Cir. 2011).*

[3] Id. at 9.

[4] Id. at 10 (citation and quotation marks omitted).

[5] Id. at 19 (emphasis in original).

[6] Id. at 23 – 24.

[7] Id. at 24 – 26.

[8] Id. at 28 – 29.

[9] Id. at 30 – 31.

[10] Id. at 31.

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