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Federal Circuit: The Term 'Clinically Proven Effective' Amount Does Not Impart Patentability Over Prior Art for Claims That Also Recite Specific Numerical Dosages

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In considering claims to a method of reducing cardiovascular events, the Federal Circuit held that the term a "clinically proven effective" amount did not render the claims patentable over the prior art. Specifically, the Federal Circuit held that the "clinically proven effective" amount, whether limiting or not, could not be used to distinguish the prior art because the claims also specified the exact amount of the drugs to be administered in the method. The Federal Circuit also rejected patentee's evidence of unexpected results because that evidence was tied solely to the "clinically proven effective" limitation.

In 2022, Mylan Pharmaceuticals Inc. (Mylan) and others filed IPR petitions challenging all claims of Bayer Pharma Aktiengesellschaft's (Bayer) patent covering methods of reducing the risk of cardiovascular events by administering the drugs rivaroxaban and aspirin in amounts that are "clinically proven effective," wherein rivaroxaban is administered in an amount of 2.5 mg twice daily and aspirin is administered in an amount of 75-100 mg daily. The specification disclosed the results of the claimed treatment regimen from a phase III clinical trial. Mylan alleged the claims were anticipated and obvious based on a summary of that clinical trial protocol that described the treatment regimen, but did not disclose any clinical results.

The Board concluded that the term "clinically proven effective" is non-limiting, and, in the alternative, is inherently anticipated by disclosure of the regimen. On appeal Bayer challenged the Board's construction of the term "clinically proven effective," along with its failure to analyze whether proof of clinical efficacy was an unexpected result for obviousness purposes.

The Federal Circuit did not decide whether "clinically proven effective" was limiting or whether the prior art inherently disclosed the claimed efficacy. Instead, it determined that, regardless of whether the term was limiting, it would still be a "functionally unrelated limitation" that fails to render the claims patentable. The court reasoned that, just as a known method of treatment could not be rendered patentable by adding a limitation referencing a later accolade like "Best Drug of 2026," a limitation that the drug subsequently performed well in a method—where that limitation does not actually change the steps of the method—does not render claims patentable.

In reaching its decision, the court distinguished its prior decision in *Allergan Sales, LLC v. Sandoz, Inc.*, 935 F.3d 1370 (Fed. Cir. 2019), a case in which two wherein clauses with specific safety and efficacy requirements were held limiting and relevant to patentability. According to the court, the claims in *Allergan* differed because they used open language and the wherein clauses modified the overall method (which also included administering a certain amount of two drugs). In other words, the limitations narrowed the range of covered compositions. The efficacy limitation here, in contrast, modified only the amount of drug used in the method, an amount already numerically specified in the claim. The limitation "clinically proven effective" did not further define the dosages that are administered, or any other aspect of the claimed methods.

Finally, the court held that because the evidence of unexpected results (the clinical results) related solely to the "clinically proven effective" limitation, there was no nexus between that evidence and the claims. Thus, that evidence did not support nonobviousness.

Practice Tip: As this case demonstrates, limitations directed to the clinical efficacy of specific dosage amounts may not be sufficient to overcome a prior art clinical trial protocol that includes those same dosage amounts. To the extent safety and efficacy requirements are included as limitations in a claim, patentees should endeavor to make them specific with, for example, measurable metrics, as opposed to merely stating an intended result.

Bayer Pharma Aktiengesellschaft v. Mylan Pharms. Inc., No. 2023-2434 (Fed. Cir. Sep. 23, 2025)

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