BAYER PHARMA AKTIENGESELLSCHAFT v. MYLAN PHARMACEUTICALS INC., Appeal No. 2023-2434 (Fed. Cir. September 23, 2025). Before Moore, Cunningham, and Scarsi. Appealed from the PTAB.

Background:

Bayer owns a patent with claims describing the dosage and administration of rivaroxaban with and without aspirin for the prevention of major adverse cardiac events.

Mylan Pharmaceuticals, Teva Pharmaceuticals, and Invagen Pharmaceuticals filed substantially identical petitions for inter partes review challenging the claims and asserting that the claims are anticipated or rendered obvious by the prior art. The PTAB combined the three inter partes reviews and held the challenged claims unpatentable. In making its final written decision, the PTAB found that the limitation "clinically proven effective" was a functionally unrelated limitation, and thus non-limiting. The PTAB also found the limitation "a first product comprising rivaroxaban and aspirin" as not being limited to administering rivaroxaban and aspirin together as one dose, and if rivaroxaban and aspirin are administered separately, they may be administered simultaneously or sequentially. The PTAB additionally construed "a first product" to be synonymous with the broader term "combination therapy" instead of "a combination dosage containing both rivaroxaban and aspirin." Bayer appealed the final written decision of the PTAB to the Federal Circuit.

Issues/Holdings:

Did the PTAB err in (1) construing "clinically proven effective" as non-limiting and (2) construing "first product comprising rivaroxaban and aspirin" to encompass administration of rivaroxaban and aspirin as separate dosage forms?

The Federal Circuit affirmed-in-part, vacated-in-part, and remanded for further proceedings.

Discussion:

In response to the first question, the Federal Circuit affirmed the PTAB's decision largely because the claims already specify the exact dosages of rivaroxaban and aspirin to be administered to a patient. In essence, the court determined that "clinically proven effective" has no "functional relationship" with the claimed method because, even if the phrase required clinical proof of efficacy, such proof "in no way transforms the process of taking the drug[s]" at the amounts and frequency already recited in the claim. Therefore, "clinically proven effective" – even if limiting – does not breathe patentability into the claims because this limitation is a functionally unrelated limitation.

In answering the second question, the Federal Circuit found that the PTAB erred in construing the claim limitation "a first product comprising rivaroxaban and aspirin." In particular, the Federal Circuit found that the plain language of the claims requires a single dosage form that includes *both* rivaroxaban and aspirin due to the "and" in "a first product comprising rivaroxaban and aspirin." Consequently, the Federal Circuit agreed with Bayer in that "a first product" more closely mirrors "a combination dosage containing both rivaroxaban and aspirin." Thus, the Federal Circuit vacated and remanded the second issue to be considered under the correct construction of the claim limitation.

Bayer's Patent Claims at Issue:

1. A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, comprising administering to the human patient rivaroxaban and aspirin in amounts that are clinically proven effective in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial dis-ease, 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.

5. A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, the method comprising administering to the human patient rivaroxaban and aspirin in amounts that are clinically proven effective in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial disease, wherein the method comprises once daily administration of a first product comprising rivaroxaban and aspirin and a second product comprising rivaroxaban, and further wherein the first product comprises 2.5 mg rivaroxaban and 75-100 mg aspirin and the second product comprises 2.5 mg rivaroxaban.

(Empasis added).