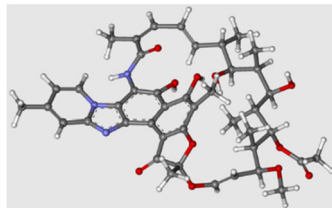


Certainty and Absolute Predictability Are Not Required to Establish a Reasonable Expectation of Success for Obviousness



Rifaximin

The Federal Circuit affirmed the obviousness determination because there was no clear error in finding that the two prior art references, as combined, provided reasonable expectation of success as to the claimed dosage of 1,650 mg/day, administered 550 mg three times per day (TID), of rifaximin, a drug at issue used for irritable bowel syndrome. *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056 (Fed. Cir. Apr. 11, 2024) (Lourie, J. joined by Chen, J.). The two references showed the administration of different dosages up to 1,200 mg/day (400 mg TID), with the second reference

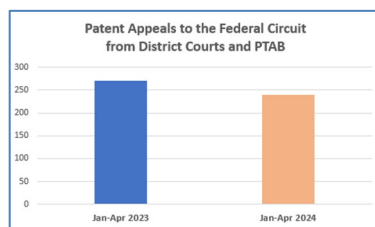
indicating that the optimal dosage may be higher. “The district court did not clearly err in finding that a skilled artisan would have looked to both of those references, considered their limits, and had a reasonable expectation of success as to the efficacy of 550 mg TID dosing. ... Indeed, certainty and absolute predictability are not required to establish a reasonable expectation of success.” Dissenting, Judge Cunningham stated that the evidence does not support the majority’s finding because the reasonable-expectation-of-success analysis was not tied to the scope of the claimed invention – here, the claimed 1,650 mg/day (550 mg TID) dosage.

Obviousness Analysis Incongruent with the Scope of the Claims Is Legally Erroneous

The Federal Circuit vacated and remanded a non-obviousness determination because “the district court asked for a showing of obviousness that went beyond what was claimed.” *Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.*, 97 F.4th 915 (Fed. Cir. Apr. 1, 2024) (Prost, J., joined by Dyk, J. and Hughes, J.). “Nothing in the claims requires that the regimen be used for—let alone be ideal for—the patient population generally or a certain percentage of the patient population. On their face, the claims only recite a dosing regimen for a psychiatric patient.” Therefore, the district court’s requirement that the defendant show that “it would have been obvious to use the recited dosing regimens for the general population of patients—i.e., a generalized dosing regimen” was a legal error.

Patent Litigation Trends

Appeals to the Federal Circuit for patent cases from the district courts and the Patent Trial and Appeal Board (PTAB) decreased more than 10 percent in the first four months of this year from the same period last year.



Source: Docket Navigator

Notable Court Decisions

Evidence of the Impact an Accused Feature Would Have on an Unaccused Product Allowed for Damages Hypothetical Negotiations

IPA Techs. Inc. v. Microsoft Corp., No. 18-cv-00001-RGA, 2024 WL 1797394 (D. Del. Apr. 25, 2024) (Andrews, J.)

The court rejected the defendant’s argument that the plaintiff’s per unit royalty calculation, which was based on sales of an unaccused product (Windows 10), was improper. The court found that “[i]t is undisputed that end users access Cortana, and thereby trigger the accused server code, through Windows 10.” Therefore, “[i]t appears appropriate for the hypothetical negotiators to consider the impact Cortana access would have on the sales revenue of Windows 10. Plaintiff’s damages theory, which purports to estimate the effect of Windows 10 including access to the infringing feature on the average consumer’s purchasing preferences and, subsequently, on Defendant’s Windows 10 sales and pricing strategy, appears to be a reasonable way of measuring this impact.”

Accused Infringer Allowed to Use Evidence of Patent Owner’s Offers to Sell or License the Patented Technology

Acceleration Bay LLC v. Activision Blizzard Inc., No. 16-cv-00033-WCB, Dkt. 848 (D. Del. Apr. 28, 2024) (Bryson, J., circuit judge visiting)

The court rejected the plaintiff’s argument that “evidence of offers to sell or license patents is not admissible to show the value of a license to the patents in suit” under FED. R. EVID. 403. The cases cited by the plaintiff only “relate to efforts by patent owners to introduce evidence of the offers made by the patent owner to sell or license the patents. The courts have regularly rejected such evidence on the ground that the patent owner could offer to sell the patent at a vastly overstated price ...” Here, “by contrast, the offer is not being used by the patent owner, but by the accused infringer to show that the patent owner was willing to license or sell the patents for a particular amount. In that setting, the amount of the offer is quite relevant, as it shows that a license could have been acquired for the price being offered by the patent owner.” However, the accused infringer was not allowed to introduce evidence that such offers were declined.