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IP LITIGATION NEWSLETTER

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Safe Harbor Exception Is Available for Uses Reasonably Related – but Need Not ‘Only’ Be Reasonably Related – to the Development and Submission of Information to the FDA

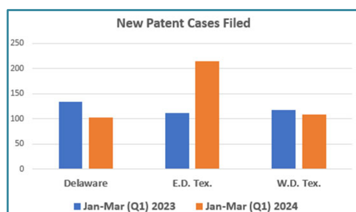
The safe harbor exception in 35 U.S.C. § 271(e)(1) applies “*solely* for uses reasonably related to the development and submission of information” to the Food and Drug Administration (FDA). The Federal Circuit interpreted the word “solely” as modifying “for uses,” finding that “for each act of infringement the safe harbor is available only for acts or uses that bear a reasonable relation to the development and submission of information to the FDA.” *Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd.*, --- F.4th ---, 2024 WL 1243032 (Fed. Cir. Mar. 25, 2024) (Stoll, J., joined by Cunningham, J.). “It is not that the use must *only* be reasonably related to the development and submission of information to the FDA.” Dissenting, Judge Lourie stated, “I believe that ‘solely’ creates a safe harbor only for uses, sales, and importations that solely are for, as the statute says, development of information for the FDA.”

Jury Instructions on the Objective Indicia of Non-Obviousness Must Include All Relevant Objective Indicia for Which There Was Evidence

The Federal Circuit remanded for a new trial on invalidity because the district court made a prejudicial error regarding the jury instructions on the objective indicia of non-obviousness. *Inline Plastics Corp. v. Lacerta Group, LLC*, --- F.4th ---, 2024 WL 1292741 (Fed. Cir. Mar. 27, 2024) (Taranto, J., joined by Chen, J. and Hughes, J.). The jury instructions “mention[ed] only the objective indicia of commercial success and long-felt need, not other objective indicia for which there was evidence.” During the trial, the defendant presented evidence of other objective indicia, such as industry praise for its products, copying, and licensing. “That evidence, taken together, called for an instruction, if properly requested, on the objective indicia to which the evidence pertains, so that the jury could assess its weight as objective indicia and—where the jury was asked for the bottom-line answer on obviousness—in relation to the prima facie case.”

Patent Litigation Trends

The number of new patent cases filed in the first quarter of 2024 nearly doubled in the Eastern District of Texas as compared to the same period last year, whereas the number decreased slightly in both the District of Delaware and the Western District of Texas.



Source: Docket Navigator

Notable Court Decisions

Transfer for Convenience Cannot Be Granted Solely Because of Court Congestion

***In re Clarke*, 94 F.4th 502 (5th Cir. Mar. 1, 2024) (Smith, J., joined by Southwick, J. and Wilson, J.)**

The Fifth Circuit reversed the district court’s order transferring a case involving the Administrative Procedure Act from the Western District of Texas to the District of Columbia due to court congestion. “It is well-settled law that [a 28 U.S.C. § 1404(a)] transfer cannot be granted solely because of court congestion.” Further, the district court erred in analyzing the “local interests” public factor, where “its reasoning consider[ed] only the relationship between the venue and the party,” when the correct analysis focuses “on the events—not the *parties*.” The district court also “clearly abused its discretion by finding that all four private interest factors were ‘neutral,’” where the district court only relied on “conclusory assertions,” and “speculation is all the district court used to consider the private interest factors.”

Pre-Issuance Damages Under Section 154(d) Do Not Apply to Inducement

***Puma Biotech., Inc. v. AstraZeneca Pharms LP*, --- F. Supp. 3d ---, 2024 WL 1157120 (D. Del. Mar. 18, 2024) (Kennelly, J., visiting judge)**

35 U.S.C. § 154(d), which provides some “provisional rights” to patent owners while the patent application is pending, “does not extend *all* post-issuance patent rights to the pre-issuance period; rather, it is a ‘narrow exception’ that permits recovery only for certain conduct that is specifically enumerated in the statute.” Specifically, Section 154(d) does not include any language for induced infringement and thus “does not authorize pre-issuance damages for induced infringement.” Because the defendant is “only accused of induced infringement, it cannot be liable for pre-issuance damages as a matter of law.”

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