

INTELLECTUAL PROPERTY LITIGATION NEWSLETTER

JANUARY 2025

A publication from Alston & Bird's Intellectual Property Group

Case Highlights

Patents Listed in the FDA's Orange Book Must Claim at Least the Active Ingredient Identified in the Drug Application

Teva Branded Pharmaceutical Products R&D Inc. v. Amneal Pharmaceuticals of New York LLC, No. 24-1936 (Fed. Cir. Dec. 20, 2024) (Judge Prost, joined by Judges Taranto and Hughes) (appeal from D. N.J.).

The Federal Circuit affirmed the district court's order that the plaintiff delist certain patents from the Orange Book, which is used by the Food and Drug Administration to decide whether a generic drug would infringe a patent. The plaintiff argued that so long as patents claim any part of the New Drug Application (NDA) product, even if it only claims device parts, they are properly listed in the Orange Book. However, the natural reading of 21 U.S.C. § 355(b)(1)(A)(viii)(I) requires that, to be listed in the Orange Book, "a patent must both claim the drug and be infringed by the NDA product." Contrary to the plaintiff's argument, it is not enough for the listed patent to be infringed. That patent also must "claim the drug for which the applicant submitted the application and for which the application was approved. And to claim that drug, the patent must claim at least the active ingredient."

Merely Incorporating the Provisional Application by Reference Insufficient to Bring Back Subsequently Deleted Definition

DDR Holdings LLC v. Priceline.com LLC, 122 F.4th 911 (Fed. Cir. Dec. 9, 2024) (Judge Chen joined by Judges Mayer and Cunningham) (appeal from D. Del.).

The Federal Circuit found that the plaintiff's argument—that the patentee acted as its own lexicographer in providing an "explicit definition" of "merchants" to include "both goods and services" in a provisional application, which was incorporated by reference in the asserted patent's specification—unpersuasive. This is because the patent drafter deleted the reference to "products or services" between the provisional application and the patent specification. As a result, the patent specification only discussed merchants as purveyors of "goods" alone. Accordingly, the Federal Circuit agreed with the district court's construction that "merchants" are purveyors of goods, not services. The incorporation by reference did not undermine this conclusion because the deletion "was conspicuous and unambiguous," which would indicate to a skilled artisan that the patentee intended "merchants" to exclude services.

Other Notable Cases

For Divided Infringement, the Direction and Control Analysis of a System Claim Must Be Analyzed by Looking at the Entire System Claim

CloudofChange LLC v. NCR Corp., 123 F.4th 1333 (Fed. Cir. Dec. 18, 2024) (Judge Stoll, joined by Judges Dyk and Reyna) (appeal from W.D. Tex.).

The district court erred in concluding that the defendant directed or controlled its merchants' use of the claimed system in ruling that there was direct infringement. The district court erroneously focused the analysis on only one element of the whole claimed system—internet access. "[D]irecting the merchants to perform one element of a system claim is not the proper test for analyzing vicarious liability for use of a system

claim." Notably, the analysis of a method claim (step-by-step analysis) is fundamentally different from the analysis of a system claim (system as a whole). "Specifically, the issue is whether [the defendant] directed or controlled its merchant-customer's actions in putting the entire claimed system to service to build or edit [the point-of-sale] systems."

Limited Apex Deposition Allowed for the CEO with Percipient, First-Hand Knowledge of License Negotiations

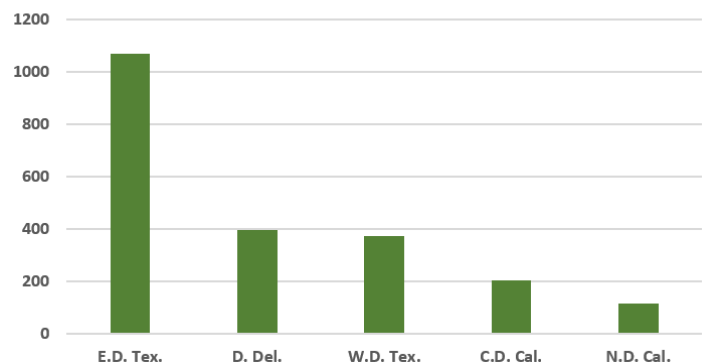
Largan Precision Co. v. Motorola Mobility LLC, No. 4:21-cv-09138 (N.D. Cal. Dec. 30, 2024) (Chief Magistrate Judge Ryu).

Finding that the plaintiff failed to meet the burden to obtain an order preventing an apex deposition, the court allowed a limited two-hour deposition of the plaintiff's CEO. The CEO "was materially involved in negotiating [the license agreement at issue] and has percipient, first-hand knowledge of the reasons for certain positions taken in those negotiations that may be relevant to damages." Although the parties disputed whether the license at issue was comparable to the technology in the case, that question will be vetted through the merits later. For purposes of discovery, there was enough to support the apex deposition.

IP Litigation Trend

In 2024, the Eastern District of Texas led in the number of new patent complaints filed in district courts, almost three times the number of new patent cases filed in the District of Delaware, which came in second, followed closely by the Western District of Texas.

New Patent Complaints Filed in 2024



Source: Docket Navigator

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