Projected 2022 Patent Litigation Trends

On January 26, 2022, Choate was a sponsor of the BBA IP Year in Review virtual conference. Kevin Quigley, a principal in Choate's Intellectual Property Litigation Group, presented on the panel "Patent Litigation Trends," which provided attendees with important updates and offered insights into what's ahead regarding (1) venue issues; (2) Section 112(a) and genus claims; and (3) skinny labeling.

Below are key takeaways from the panel.

Venue Issues

- In 2021, courts continued to wrestle with what constitutes a "regular and established place of business" under 28 U.S.C. § 1400, which governs venue in patent infringement cases. Venue disputes often are driven by plaintiffs' efforts to bring lawsuits in courts perceived to be plaintiff-friendly, such as the Western District of Texas.

- For example, in *Andra Group, LP v. Victoria's Secret Stores, LLC*, the Federal Circuit held that "[w]here related companies have maintained corporate separateness, the place of business of one corporation is not imputed to the other for venue purposes." 6 F.4th 1283, 1289 (Fed. Cir. 2021).

- The cases continue to demonstrate that venue is fact-intensive inquiry, often requiring the parties to identify relevant witnesses sooner than in a typical litigation timeline.

Section 112(a) and Genus Claims

- Two recent Federal Circuit *decisions—Amgen Inc. v. Sanofi* and *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*—confirmed that biopharma patents claiming a genus of antibodies may be especially susceptible to invalidation for lack of enablement or insufficient written description under 35 U.S.C. § 112(a). Because antibodies often are described by their target antigen rather than by their composition, the literal scope of such a patent claim may encompass millions of antibodies.

- In *Amgen v. Sanofi*, the Federal Circuit affirmed the district court's ruling that Amgen's two antibody patents were invalid, because the functional claims were too broad to satisfy the enablement requirement. 987 F.3d 1080, 1086 (Fed. Cir. 2021). The Federal Circuit emphasized the need to consider the quantity of experimentation required to make and use the *full scope* of the claims—not just the limited number of embodiments that the patent discloses. Id.

- Similarly, in *Juno Therapeutics v. Kite Pharma*, the Federal Circuit vacated a billion-dollar jury verdict and held that Juno's claims did not satisfy the written description requirement because the claims failed to specify which antibodies would bind to which targets. 10 F.4th 1330, 1335 (Fed. Cir. 2021).

- Moving forward, it will be important for life sciences companies to consider how these decisions (including any further appeals to the U.S. Supreme Court) impact not only enforcement of existing claims, but also strategies for protecting newly-developed biopharma intellectual property.

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Skinny Labeling

- So-called "skinny labels" on generic pharmaceuticals recite FDA-approved uses but carve out other uses still covered by the branded competitor's patent. In *GlaxoSmithKline v. Teva*, however, the Federal Circuit held that skinny labels do not offer an ironclad shield against liability for inducing infringement of carved-out uses. 7 F.4th 1320, 1323 (Fed. Cir. 2021). An accused infringer's conduct—like Teva's marketing efforts in that case—may still support a finding of induced infringement.

- Shortly after the Federal Circuit's GSK decision, the Delaware district court in *Amarin v. Hikma*, adopted a more narrow approach in dismissing an induced infringement claim based on an allegedly inadequate skinny label carve out. No. CV 20-1630-RGA-JLH (D. Del. Jan. 4, 2022). The pharmaceutical industry will closely monitor district court decisions interpreting the scope of the GSK holding moving forward.

FOR MORE INFORMATION

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