Federal Circuit Improves the Short-Term "Forecast" for the Doctrine of Equivalents

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On Tuesday, September 3, 2019, in response to a petition for rehearing en banc, the Federal Circuit issued an order withdrawing language in the panel decision in *Amgen Inc. v. Sandoz Inc.*, 2018-1551, stating that the doctrine of equivalents "applies only in exceptional cases." Although the phrase was dicta, it had caused concern that the Court was signaling a shift in the law. The Court's *per curiam* order removes the cloud that had been cast over the doctrine of equivalents as a viable alternative for proving patent infringement. That said, establishing liability based on the doctrine of equivalents presents challenges, and the availability of the judicially-created doctrine of equivalents could be limited by ongoing legislative reform efforts.

In the May 2019 panel decision written by Judge Lourie, the Court rejected Amgen's doctrine of equivalents argument seeking to enforce its patent directed to methods of purifying certain proteins. In dicta, the opinion stated, "[t]he doctrine of equivalents applies only in exceptional cases and is not 'simply the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims.'"

Following that decision, Amgen petitioned for rehearing en banc, arguing that the panel applied an "exceptional case" standard that was contrary to both Supreme Court and Federal Circuit precedent. In its response, Sandoz defended the panel's decision, urging that the panel applied only well-settled law, not any new "exceptional case" standard. In a pair of *per curiam* orders this week, the Federal Circuit withdrew the "exceptional case" phrase without further comment, and otherwise denied the petition.

While the Court's decision to remove the language offers some assurances about the continued viability of the judicially-created doctrine of equivalents, patent practitioners should be aware of a May 2019 draft bill that would amend Section 112 as part of proposed legislation to alter the eligibility standard of Section 101. The draft bill was the subject of several hearings before the Senate Judiciary Subcommittee on Intellectual Property in June 2019, but no bill has been formally introduced to date. If enacted as written, the proposed Section 112 changes could impact the equivalents analysis for functional claim elements. In particular, the May 2019 proposed amendment would restrict the scope of any functional claim term to the corresponding structure, material, or acts described in the specification and "equivalents thereof." If enacted, the proposed change to Section 112 could create uncertainty as to the interplay of the statute with current doctrine of equivalents case law as the application and parameters of these doctrines play out on a case-by-case basis in courts. In short, the long-range forecast on the doctrine of equivalents may not be so clear for those practitioners trying to draft claims, evaluate enforcement of issued claims, or conduct freedom-to-operate analyses in the face of third-party patents.

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