The Precedent: Federal Circuit Adds Clarity to Personal Jurisdiction and Obviousness-Type Double Patenting Analyses in *Regeneron Pharms*

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AUTHORED ARTICLE | 3.6.2025

In this edition of *The Precedent*, we outline the decision in *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*

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In *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, the Federal Circuit affirmed the district court's grant of a preliminary injunction, holding that the district court properly found personal jurisdiction over the defendant and properly found Regeneron was likely to succeed on the merits of the suit.

Issues

1. Whether the district court correctly found it had personal jurisdiction over Samsung Bioepis.
2. Whether the district court abused its discretion in issuing a preliminary injunction by finding Samsung Bioepis did not raise a substantial question of invalidity of the '865 patent.

Holdings

1. The district court properly determined that Samsung Bioepis had minimum contacts with the forum state of West Virginia, thus satisfying the personal jurisdiction standard.
2. The district court correctly found that Samsung Bioepis did not raise a substantial question of invalidity and therefore did not abuse its discretion in issuing the injunction.

Background and Reasoning

Regeneron Pharmaceuticals filed patent infringement suits against Samsung Bioepis Co. (SB) and four other defendants based on several patents related to Regeneron's brand-name EYLEA® drug. Under the Hatch-Waxman Act, companies can develop biosimilar products and submit abbreviated Biologics License Applications (aBLAs) with the

FDA to obtain FDA approval on the biosimilar products before the expiration of the patent covering the brand-name product. The filling of an aBLA is treated as an admission that the underlying patent claims read on the biosimilar.

The Judicial Panel on Multidistrict Litigation granted Regeneron's motion to consolidate the actions into the Northern District of West Virginia under 28 U.S.C. § 1407. In the consolidated action, Regeneron filed motions for preliminary injunctions, which the district court granted against SB, enjoining SB from offering for sale or selling in the United States the subject of the aBLA application ("SB15"). On appeal, SB challenged the district court's holding that it had personal jurisdiction over SB and its holding that Regeneron made out its affirmative case for a preliminary injunction.

Regeneron first filed suit against Mylan Pharmaceuticals in West Virginia—Mylan's state of incorporation—and later sued SB in the same forum. SB is a biosimilar-products company headquartered in South Korea. SB granted Biogen—a U.S. company—exclusive rights to commercialize SB's FDA-approved biosimilar (SB15) in the United States. The agreement provided SB with the right to participate in a joint SB-Biogen steering committee by which SB retained involvement in Biogen's commercialization activities in the United States.

On appeal, SB challenged the district court's determination of personal jurisdiction. First, SB argued that a bright-line difference exists between SB doing its own distribution and SB contracting with a national distributor, and thus its contacts should be based only on the sale of SB15 to Biogen, which occurred outside of West Virginia. The Federal Circuit found this argument unavailing, citing *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, for the premise that the "directing of sales into [a state] is sufficient for minimum contacts." SB next argued that Regeneron needed to show evidence of express attention to West Virginia as a target market, which the Federal Circuit rejected by stating "there is simply no good reason . . . for demanding such singling-out evidence as a substitute for persuasive evidence of nationwide targeting without a carve-out."

In rejecting both arguments, the Federal Circuit held that SB's contacts with West Virginia justified the district court's finding of personal jurisdiction. Specifically, the Federal Circuit noted that SB, in filing the aBLA with the FDA, confirmed a plan to engage in real-world marketing of SB15 within the U.S. The agreement with Biogen similarly indicated a commercialization plan to distribute SB15 throughout the United States without any state being excluded from the market.

SB next challenged the district court's grant of a preliminary injunction, which may be granted when a party can show, among other factors, that it is likely to succeed on the merits. If an accused infringer can present an invalidity defense with substantial merit, the preliminary injunction should not issue.

SB argued that it raised a substantial question of validity of Regeneron's '865 patent under an obviousness-type double patenting (ODP) theory in light of Regeneron's earlier '594 patent. ODP prevents a later patent with claims that are obvious variations of claims of an earlier patent from receiving an improper timewise extension. In other words, if the later patent is not patentably distinct, it should terminate at the same time as the earlier patent.

Here, SB argued that the district court erred in finding that the claims of the later ’865 patent were nonobvious variations of the claims of the ’594 patent. Specifically, SB argued that the coverage of the ’865 patent was necessarily within the scope of the ’594 patent, as its claims simply add an “additional property,” and thus the ’865 claims are species of the broader ’594 genus claims. For context, the ’594 patent disclosed a preferred stability of “at least 90%,” which was incorporated into the claim that the VEGF trap be “stable for at least 4 months.” In contrast, the ’865 patent claimed a stability value of 98%. Thus, the ’594 discloses a broader range, which captures or “dominates” the narrower value of the ’865 claims.

The Federal Circuit disagreed with SB’s reasoning, finding the district court properly held that SB did not present a substantial question of invalidity. In doing so, it clarified that patent domination—“where one patent with a broader claim reads on an invention defined by another patent’s narrower claims”—does not render a later patent obvious by itself. Rather, obviousness is a determination of whether the skilled artisan would have been motivated to arrive at the limitation with a reasonable expectation of success, the Federal Circuit clarified. Thus, even if a later claim is necessarily narrower than an earlier claim, claiming it as such may still be non-obvious.

SB also argued that its adequate written description defense—an argument the district court rejected—created a substantial question of invalidity. The written description requirement dictates that the patent document show the inventor “had possession” of the invention at the time of filing. On appeal, SB highlighted its assertion that the ’865 specification did not support the claimed glycosylated aflibercept formulations, and that the district court contradicted itself by finding support for the formulations while also finding that an artisan would have been motivated to use *non-glycosylated* aflibercept under the ODP theory. In affirming the district court, the Federal Circuit provided that the proper inquiry is “whether the patentee has provided an adequate description that ‘in a definite way identifies the claimed invention’ in sufficient detail such that a person of ordinary skill would understand that the inventor had made the invention at the time of filing.” Moreover, the “specification does not need to describe ‘every conceivable and possible future embodiment of [the] invention.’”