WHEN SAYING MORE GETS YOU LESS: THE FEDERAL CIRCUIT AFFIRMS THAT SUPERFLUOUS PROSECUTION ARGUMENTS CAN LIMIT DOCTRINE OF EQUIVALENTS INFRINGEMENT

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Prosecution history estoppel can bar a claim of patent infringement under the doctrine of equivalents where a patentee's statements lead a competitor to reasonably believe the patentee had surrendered the relevant subject matter, even if the argument was not actually required to secure allowance of the claim. The Federal Circuit reaffirmed that proposition this week in *Amgen Inc. v. Coherus Biosciences Inc.*, No. 18-1993, slip op. at 9 (Fed. Cir. July 29, 2019). The *Amgen v. Coherus* decision comes after a series of other high-profile cases from the Federal Circuit this year limiting the application of the doctrine of equivalents, including *Amgen Inc. v. Sandoz Inc.*, 923 F.3d 1023, 1029 (Fed. Cir. 2019) ("The 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.'") and *Duncan Parking Techs., Inc. v. IPS Group, Inc.*, 914 F.3d 1349, 1362 (Fed. Cir. 2019) ("[T]he doctrine of equivalents cannot be used to effectively read out a claim limitation . . . Because the public has a right to rely on the language of patent claims.").

The Patent-in-Suit

The patent at issue—U.S. Patent No. 8,273,707 ("the '707 Patent")—is directed to a method of purifying proteins, using hydrophobic interaction chromatography ("HIC") and buffered salt solutions employing specific two-salt combinations. *Amgen*, slip op. at 2. It "claims a process that . . . increases the 'dynamic capacity' of a HIC column," to maximize the protein filtered through the column at any given time without increasing the concentration of a single salt in the buffer solution. *Id.* at 3. Each claim of the '707 Patent requires a salt combination in the buffer solution chosen from: citrate and sulfate, citrate and acetate, or sulfate and acetate. *Id.* at 4.

During examination, the examiner rejected the then-pending '707 Patent claims as obvious in view of U.S. Patent No. 5,231,178 ("*Holtz*"). *Holtz* disclosed using several salts to improve the interaction between proteins and the column matrix, and according to the examiner, "it would have been obvious for a person of ordinary skill to routinely optimize *Holtz* to achieve the claimed invention." *Id.* at 4. In response, Amgen Inc. ("Amgen") made three arguments:

1. *Holtz* does not teach or suggest ***any*** combinations of salts;
2. *Holtz* does not teach or suggest the ***particular*** combinations of salts recited in the pending claims; and

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3. *Holtz* does not teach dynamic capacity, much less increasing dynamic capacity.

Id. at 4–5. Amgen submitted an inventor declaration supporting each of these arguments. The examiner determined that Amgen had not sufficiently overcome his previous rejection. *Id*. at 5–6. Amgen responded again, but did not reiterate its "particular combinations" argument, and the examiner allowed the claims. *Id*. at 6.

The District Court Litigation

The *Amgen v. Coherus* case began in August 2016 after Coherus Biosciences Inc. ("Coherus") filed its abbreviated Biologic License Application ("aBLA") to market a biosimilar version of Amgen's pegfilgrastim product Neulasta, which is a recombinant therapeutic protein that stimulates production of neutrophils, a type of white blood cell. *Amgen*, slip op. at 6. Amgen and Coherus engaged in the "patent dance," exchanging the information required under the Biologics Price Competition and Innovation Act. *Id*. The exchange revealed that while Coherus's manufacturing process included a chromatography buffer with a combination of salts, it did not contain one of the particular salt combinations recited in the '707 Patent claims. *Id*.

In view of the difference in Coherus's manufacturing process, Amgen sued Coherus in the District of Delaware for allegedly infringing the '707 Patent under the doctrine of equivalents. Coherus moved to dismiss under Federal Rule of Civil Procedure 12(b)(6), for failure to state a claim. The magistrate judge issued a Report and Recommendation that Coherus's motion be granted since "Amgen 'clearly and mistakably—and indeed, repeatedly—indicated to competitors that it surrendered processes using combinations of salts different from the ***particular*** combinations of salts recited in the . . . claims[.]'" *Id*. at 7 (quoting *Amgen Inc. v. Coherus Biosciences Inc*., No. 17-cv-546-LPS-CJB (D. Del. Dec. 7, 2017)). The district court judge adopted the Report and Recommendation finding that prosecution history estoppel precluded Amgen's claims. *Id*. (citing *Amgen Inc. v. Coherus Biosciences Inc*., No. 17-cv-546-LPS-CJB, 2018 WL 1517689, at *1 (D. Del. Mar. 26, 2018)). Amgen appealed this ruling.

The Appeal

On appeal to the Federal Circuit, Amgen argued that it did not distinguish *Holtz* during prosecution based on Holtz failing to disclose the particular claimed combinations. Amgen maintained that it made only two arguments to distinguish over *Holtz*—that *Holtz* did not disclose increasing dynamic capacity and did not disclose any salt combinations at all. *Id*. at 10. As to its discussion of "particular combinations" of salts during prosecution, Amgen asserted that it "'simply observes (correctly) as a factual matter that *Holtz* does not disclose using combinations of salts in the first instance,' and thus does not clearly and unmistakably surrender unclaimed salt pairs." *Id*.

The Federal Circuit, reviewing the issue *de novo*, rejected Amgen's characterization of its three prosecution arguments, finding that estoppel can attach separately to each. *Id*. at 11. "[W]here a patent applicant sets forth multiple bases to distinguish between its invention and the cited prior art, the separate arguments [can] create separate estoppels as long as the prior art was not distinguished based on the combination of these various grounds." *Id*. at 9 (quoting *PODS, Inc. v. Porta Stor, Inc*., 484 F.3d 1359, 1367 (Fed. Cir. 2007) (internal quotations omitted)).

The Federal Circuit also rejected Amgen's argument that prosecution history estoppel does not apply because its statements regarding the particular combinations of salts were not made during its final office action response. The court stated "[t]here is no requirement that argument-based estoppel apply only to arguments made in the

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most recent submission before allowance." *Id*. at 11. Importantly, nothing in Amgen's final submission disavowed the earlier surrender of unclaimed salt combinations. *Id.* at 12.

The relevant inquiry, according to the Federal Circuit is not whether the assertion was required to secure allowance of the claim, but "whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Id*. at 9 (quoting *PODS*, 484 F.3d at 1368). The Federal Circuit agreed with the district court's conclusion that a competitor would reasonably believe that Amgen surrendered unclaimed salt combinations. Based on Amgen's argument that the prior art did not teach "particular combinations" of salts during prosecution, he Federal Circuit held that Amgen "clearly and unmistakably surrendered salt combinations other than the particular combinations recited in the claims," and affirmed the dismissal of Amgen's complaint. *Id*. at 8.

Lessons Learned

The Federal Circuit and District Court opinions in *Amgen v. Coherus* present a number of interesting takeaways for patent prosecutors and litigators alike.

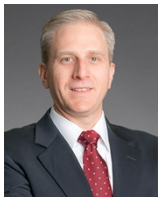
4. Each argument made during prosecution, even if not ultimately the basis for allowance, can independently estop the patentee from asserting certain claim scope down the road in litigation. This cautions in favor of only making arguments necessary to overcome an examiner's rejection during prosecution.
5. Both courts looked not only at the prosecution history of the asserted patent, but also the arguments made during the prosecution of the parent patent. Thus, an awareness of the arguments throughout the patent family could be key to support a claim of prosecution history estoppel.
6. While the order of submissions during prosecution does not necessarily impact the ultimate finding of estoppel, the Federal Circuit left open the possibility that a patentee might avoid prosecution history estoppel by disavowing any surrender of claim scope in a later submission.

NOTES

[1] The court further concluded that, "by disclosing but not claiming the salt combination used by Coherus, Amgen had dedicated that particular combination to the public." *Id*. (citing *Amgen*, 2018 WL 1517689, at *3). This was an independent reason for granting Coherus' motion apart from its prosecution history estoppel arguments. *Amgen Inc. v. Coherus Biosciences Inc*., No. 18-1993, slip op. at 7 (Fed. Cir. July 29, 2019).

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