



CAFC creates blueprint for early stage challenges to claims brought under doctrine of equivalents

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In its recent decision in [Amgen Inc v Coherus Biosciences Inc](#), the Federal Circuit held that an argument made during the course of prosecution barred Amgen from asserting infringement under the doctrine of equivalents. This was even though the argument was not necessary to secure allowance of the claims and was one of multiple arguments made during prosecution.

In doing so, the court affirmed the district court's dismissal of Amgen's complaint under Rule 12(b)(6), creating a blueprint for future early stage challenges to claims brought under the doctrine.

Amgen sued Coherus in the District Court for the District of Delaware for infringement of its US Patent No 8,273,707 after Coherus filed an abbreviated Biologic License Application (aBLA) for approval of a biosimilar of Amgen's Neulasta product. The '707 patent claims methods of purifying proteins using hydrophobic interaction chromatography (HIC) that increase the dynamic capacity of the HIC column, ie, reduce the amount of protein lost before elution. In particular, the '707 patent claims methods for purifying proteins on columns that include, as a first step, "mixing a preparation containing the protein with a combination of a first salt and a second salt". The claims further specify that "the first and second salts are selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate, respectively".

During prosecution, the claims of the patent were rejected in view of the Holtz reference, which generally disclosed several salts that can be used to improve the hydrophobic interactions between a protein and a column matrix. Amgen responded that Holtz does not teach (1) combining multiple salts, (2) combining the *particular* salts recited in the claims, or (3) using any combination of salts for increasing the dynamic capacity of a HIC column. It submitted a declaration to the USPTO to further emphasise the importance of the particular combinations of salts in its claims, which improved the cost-effectiveness of commercial manufacturing and increased the dynamic capacity of the column. Amgen argued more broadly that Holtz failed to disclose any combination of salts.

In a response to a second rejection, it reiterated its broader response to Holtz, but did not repeat its emphasis on the particular combination of salts disclosed in the claims. The examiner allowed Amgen's claims after receiving its second response.

Amgen's complaint against Coherus asserted that it infringed the '707 patent under the doctrine of equivalents because Coherus's aBLA indicated that its biosimilar is manufactured using a salt combination other than the three specified in the '707 patent claims. Coherus successfully moved pursuant to Rule 12(b)(6) to dismiss Amgen's complaint in the district court, arguing that the plaintiff was barred from asserting infringement under the doctrine of equivalents based on prosecution history estoppel.

On appeal, the Federal Circuit affirmed the district court's dismissal of Amgen's complaint, holding that it "clearly and unmistakably surrendered unclaimed salt combinations during prosecution". Specifically, Amgen emphasised that Holtz did not disclose the *particular* salt combinations claimed in the '707 patent multiple times during prosecution. The court rejected Amgen's argument that it distinguished Holtz more broadly on the ground that Holtz does not disclose *any combination* of salts.

This case highlights the importance of taking a conservative approach in prosecution to avoid making unnecessary statements that can later limit claim scope. Notably, Amgen made several arguments during prosecution and the argument found to be a disclaimer was not one that resulted in allowance of the claims.

In fact, in reaching its decision, the Federal Circuit noted that prosecution history estoppel applies even though Amgen only included the "particular combinations" argument in its response to the examiner's first rejection, and not the second rejection. This was because: "Clear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim, may also create an estoppel." Furthermore: "While Amgen did assert multiple reasons for why Holtz is distinguishable, precedent instructs that estoppel can attach to each argument."

Although the availability of the doctrine of equivalents is a question of law, the application of prosecution history estoppel frequently requires some resolution of factual disputes. Thus, this case is also noteworthy in that it resulted in dismissal prior to discovery or claim construction despite involving highly technical subject matter.

The result here may provide support for future early challenges to claims brought under a doctrine of equivalents theory - the keys being whether there can be any dispute over the meaning of statements made during prosecution and whether there is any conflicting evidence in the prosecution history that would weigh against disclaimer. Here, there were neither.

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