

**Keywords:** prosecution history estoppel, doctrine of equivalents,

***Amgen, Inc. v. Coherus Biosciences, Inc.***

Court of Appeals for the Federal Circuit

No. 18-1993

Decided July 29, 2019

**I. Facts**

Amgen prosecuted a patent with a claim for a method of purifying proteins using hydrophobic interaction chromatography (“HIC”). The process used a combination of buffered salt solutions containing the protein that is poured into a HIC column. The proteins bind to column matrix and impurities are poured off. Amgen’s patent claimed a process that increases the maximum amount of protein in solution that can be loaded into the HIC column by using certain combinations of salts “chosen from one of three pairs: citrate and sulfate, citrate and acetate, or sulfate and acetate.”

During prosecution, Amgen received a rejection that their claim was obvious over a reference that also utilized salts to accomplish the higher protein yield from the HIC process. Amgen subsequently traversed the rejection by arguing that they were claiming particular salt pairs. The examiner rejected that argument, so Amgen argued that choosing such pairs would be a “lengthy development path” and that “merely adding a second salt” would not result in the invention. The claim was subsequently allowed, without amendment. Amgen then sued Coherus Biosciences for infringement of the patent under a theory of doctrine of equivalents since the exact claimed salt pairs were not utilized by Coherus.

**II. Issue**

1) Does argument-based prosecution history estoppel apply to arguments that ultimately were not required to secure allowance of the claims?

**III. Discussion**

**Argument based prosecution history estoppel applies to each argument separately, regardless if was necessary for allowance or not.**

The Federal Circuit affirmed the application of argument-based estoppel. “To invoke argument-based estoppel, ‘the prosecution history must evince a clear and unmistakable surrender of subject matter.’” Slip Op. at 9, quoting *Conoco, Inc. v. Energy & Env’tl. Int’l, L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006). Here, the court held, argument-based estoppel applies “because Amgen clearly and unmistakably surrendered unclaimed salt combinations during prosecution.” *Id.* at 9. Amgen repeatedly pointed to the *particular* combinations of salts as important in distinguishing the prior art references. As a result, “a competitor would reasonably believe that Amgen surrendered unclaimed salt combinations.” *Id.* at 10.

Amgen’s primary argument, that it asserted other reasons for distinguishing the prior art reference, was not persuaded as “precedent instructs that estoppel can attach to each argument.” *Id.* at 11. The court was similarly not persuaded by Amgen’s argument that its last response before the claims were allowed did not contain the particular-salt-combination argument. But “[t]here is no requirement that argument-based estoppel apply only to arguments made in the most recent submission before allowance.” *Id.* at 11.

The court did appear to leave open the possibility that a submission that disavows the clear and unmistakable surrender of unclaimed salt combinations might be able to negate argument based prosecution history estoppel. However, Amgen made no such statement in any of their submissions.

**IV. Conclusion**

The Court of Appeals for the Federal Circuit held that argument-based prosecution history estoppel applies to all arguments made separately for each separate element. The court affirmed the holding of the District Court.