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Federal Circuit Strengthens Prosecution History Estoppel Principles in Colibri Heart Valve LLC v. Medtronic CoreValve, LLC

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On July 18, 2025, the US Court of Appeals for the Federal Circuit reversed a lower court ruling in *Colibri Heart Valve LLC v. Medtronic CoreValve, LLC*, holding that prosecution history estoppel barred the patentees' doctrine of equivalents (DOE) claim because the asserted equivalent fell within the scope of an independent claim that had been canceled during prosecution.

Background

Colibri Heart Valve sued Medtronic CoreValve alleging induced infringement of US Patent No. 8,900,294 (the '294 patent), directed to methods of partially deploying an artificial heart valve so that clinicians can reposition or recapture the device before full release. The claims recited the use of an artificial heart valve including a "pusher member" and a "moveable sheath" and the step of " … partially deploying a distal portion of the replacement heart valve device within the patient by **pushing out the pusher member** from the moveable sheath to expose the distal portion of the re-placement heart valve device … ." [1] (emphasis added) During prosecution, Colibri also had originally pursued a second independent claim reciting a partial deployment step involving "**retracting the moveable sheath** to expose a portion of the replacement heart valve device."[2] (emphasis added) In response to a rejection for lack of written description under 35 USC § 112,[3] Colibri canceled the second independent claim while retaining the claim, reciting "pushing out the pusher member."

At trial, Colibri dropped its assertion of literal infringement, instead relying on the DOE, arguing that Medtronic's device, in which one retracts a moveable sheath to deploy the heart valve, was substantially the same as "pushing" out the replacement heart valve. The jury found in Colibri's favor and awarded more than $100 million in damages. Medtronic sought judgment as a matter of law, relying primarily on prosecution history estoppel.

Doctrine of equivalents and prosecution history estoppel

Generally, the DOE allows a patentee to extend claim scope to cover insubstantial or equivalent variations of a claimed invention. Prosecution history estoppel, however, is a potent limitation on that doctrine: If an applicant, for example, amends or cancels claims to avoid prior art or otherwise secure allowance, the public is entitled to rely on that surrender of claim scope, rendering the DOE unavailable. In the decision below, the district court held that estoppel did not apply, because, among other reasons, Colibri had not narrowed or amended any claims to exclude the accused equivalent (a method involving the retraction of a moveable sheath), but instead had merely canceled the separate independent claim that had recited the accused equivalent.

The Federal Circuit disagreed, reasoning that estoppel is not limited to subject matter surrendered during prosecution only through claim amendments and narrowing, but also is applicable to subject matter surrendered by wholesale cancellation of claims. Here, there was a "close substantive relationship between the cancelled and retained claims,"[4] so by canceling the separate independent claim specifically reciting partial deployment via "retraction," the patentee signaled that this subject matter was being surrendered to obtain allowance of the closely related remaining claims referencing "pushing."

Takeaways

This case underscores the need for care in prosecution to avoid prosecution history estoppel. For critical patent applications, consider beginning prosecution with a focused, narrow claim set and canceling claims of doubtful patentability before they are rejected. If claims must be canceled following a rejection, consider identifying in the record alternative reasons for the cancellation, or clear statements emphasizing the lack of a “close substantive relationship” between the canceled claims and those remaining. In this opinion, the court emphasized the nearly identical claim language between the canceled claim and the asserted claim, which may be one meaningful way to distinguish this opinion going forward.

In preparation for and during litigation, file history reviews should include a close scrutiny of any claims canceled during prosecution, as well as a consideration of whether such cancellations may limit the availability of DOE infringement theories.

Notes

1. Slip op. at 7.
2. Slip op. at 11.
3. Slip op. at 2.
4. Slip op. at 24.

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Key Contacts

Christopher Hutter Reston	chutter@cooley.com +1 703 456 8506
Sam Matthews Boston	smatthews@cooley.com +1 617 937 2388

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