

**United States Court of Appeals
for the Federal Circuit**

**EMD MILLIPORE CORPORATION
(formerly known as Millipore Corporation),
MERCK CHEMICALS AND LIFE SCIENCE AB
(formerly known as Millipore AB),
AND MILLIPORE SAS,
*Plaintiffs-Appellants,***

v.

**ALLPURE TECHNOLOGIES, INC.
(now known as AllPure Technologies LLC),
*Defendant-Appellee.***

2014-1140

Appeal from the United States District Court for the District of Massachusetts in No. 1:11-CV-10221, Judge Douglas P. Woodlock.

Decided: September 29, 2014

SUSAN G. L. GLOVSKY, Hamilton, Brook, Smith & Reynolds, P.C., of Boston, Massachusetts, argued for plaintiffs-appellants. With her on the brief was LAWRENCE P. COGSWELL, III.

CRAIG R. SMITH, Lando & Anastasi, LLP, of Cambridge, Massachusetts, argued for defendant-appellee. Of counsel was ERIC P. CARNEVALE.

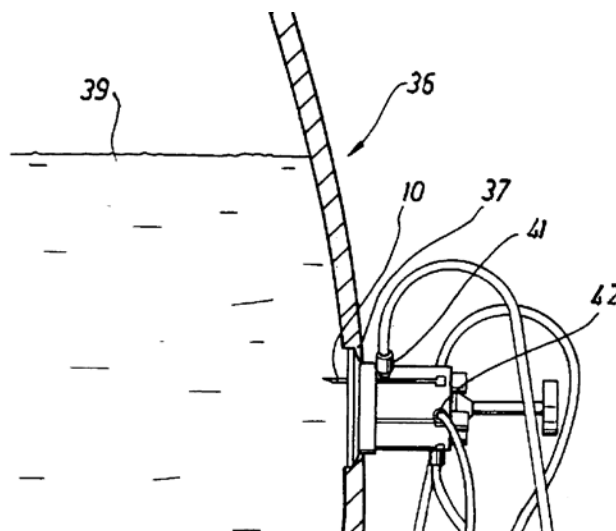
Before PROST, *Chief Judge*, O'MALLEY and HUGHES,
Circuit Judges.

PROST, *Chief Judge*.

Plaintiffs-Appellants EMD Millipore Corporation, formerly known as Millipore Corporation; Merck Chemicals and Life Science AB, formerly known as Millipore AB; and Millipore SAS (collectively, "Millipore") appeal the grant of summary judgment that Defendant-Appellee AllPure Technologies, Inc., now known as AllPure Technologies LLC, ("AllPure") does not infringe the asserted claims of U.S. Patent No. 6,032,543 ("543 patent"). *See EMD Millipore Corp. v. AllPure Techs., Inc.*, No. 11-10221, 2013 WL 5299372 (D. Mass. Sept. 17, 2013) ("*Summary Judgment Order*"). The district court found that AllPure's TAKEONE device neither literally contains the claimed "removable, replaceable transfer member," nor does it provide an infringing equivalent. *Id.* at *9. We agree with the district court that the TAKEONE device does not literally infringe. We also conclude that prosecution history estoppel prevents Millipore from asserting the doctrine of equivalents as to this claim limitation. On these grounds, we affirm the district court's grant of summary judgment.

I. BACKGROUND

Millipore owns the rights to the '543 patent, which discloses a device for introducing or withdrawing a sample from a container holding a fluid without contaminating the fluid. *See* '543 patent abstract, col. 2 ll. 20-24. As Figure 5 depicts, the claimed device is attached to the side of a container holding a fluid medium. *Id.* at col. 1 ll. 54-56.



'543 patent, Fig. 5

To avoid contamination problems, the '543 patent uses individual transfer members to maintain a closed system. '543 patent col. 5 ll. 20-23, col. 5 ll. 35-39, col. 6 ll. 23-26. Each transfer member has a needle embedded in a plastic holder and a seal surrounding the needle which attaches to the holder. '543 patent col. 3 ll. 11-35.

The '543 patent contains 14 claims, including 1 independent claim. Independent claim 1 is reproduced below:

1. A device for one of introduction and withdrawal of a medium into a container having an aperture formed therein for receiving said device, said device comprising:

at least one *removable, replaceable transfer member* for transferring a medium into and out of the container, *said transfer member comprising a holder, a seal for sealing said aperture, a hypodermic needle having a tip, said needle supported within said holder in a longitudinal direction thereof, wherein the seal has a first end comprised of a bellows-shaped*

part sealingly attached to said holder, and a second end comprising a self-sealing membrane portion interiorly formed at an end of said bellows part, said membrane portion for sealing said aperture of said container, wherein said bellows-shaped part surrounds said needle and is deformable in a longitudinal direction, said membrane portion pierceable by the tip of the needle to form a sealable channel;

a fastening device for sealingly securing the transfer member via the seal with the aperture of the container, thereby forming a closed system, said fastening device comprising a flanged part sealingly secured in the aperture and formed with at least one hole therethrough in communication with an interior of said container, a magazine part for removable securement of said at least one transfer member, and a fastening and centering means for removable locking of the magazine part to a flanged part in a position wherein the membrane portion sealingly abuts against the hole of the flanged part so as to accept the hypodermic needle for introduction into and withdrawal from the container through the membrane portion and the hole.

'543 patent, claim 1 (emphases added).

AllPure's accused TAKEONE device is an aseptic sampling system that may be attached to the outside of a container holding a fluid medium and has cannulas that can be inserted into the container to withdraw a sample. The device is delivered fully assembled and sterilized, and it is intended to be disposed of following use. The TAKEONE device, in a disassembled state, is shown

below. *Summary Judgment Order* at *7. The TAKEONE device's transfer member (130) is composed of a holder (150), a seal (comprising a bellows-shaped part (165) and a membrane (166)), and needles (170). *Id.* When disassembled, all components of the TAKEONE device's transfer member can be removed from the magazine part (135). *Id.*



The district court granted AllPure's motion for summary judgment of no infringement of the '543 patent, finding that "the TAKEONE device lacks a 'removable, replaceable transfer member' as claimed in the '543 patent." *Summary Judgment Order* at *7-8. The district court rejected Millipore's argument that a disassembled TAKEONE device satisfies this claim limitation. *Id.* at *8. The district court also found that the TAKEONE device does not provide an infringing equivalent of the limitation. *Id.*¹ We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

¹ In addition, the district court found that the TAKEONE device did not literally possess a seal with a "self-sealing membrane portion interiorly formed at an end of a bellows-shaped part," but it declined to grant

III. STANDARDS OF REVIEW

Summary judgment is appropriate when there is “no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). While we review summary judgment decisions de novo, *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1378 (Fed. Cir. 2008), “[i]nfringement, whether literal or under the doctrine of equivalents, is a question of fact.” *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998). However, “a court may determine infringement on summary judgment ‘when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device.’” *Innovention Toys, LLC v. MGA Entmn’t, Inc.*, 637 F.3d 1314, 1319 (Fed. Cir. 2011) (quoting *Bai*, 160 F.3d at 1353).

Whether prosecution history estoppel applies to a particular argument, and thus whether the doctrine of equivalents is available for a particular claim limitation, is a question of law reviewed de novo. *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1290-91 (Fed. Cir. 2010).

IV. DISCUSSION

This appeal concerns Millipore’s challenges to the district court’s grant of summary judgment of no infringement. The district court found that AllPure’s TAKEONE

summary judgment of no infringement on this limitation under the doctrine of equivalents. *Summary Judgment Order* at *5-6. The district court also declined to grant summary judgment based on AllPure’s argument that Millipore is judicially estopped from taking the position that the TAKEONE device infringes the ’543 patent due to statements it made during prosecution of another patent. *Id.* at *3-4. However, we need not address these findings to resolve this appeal.

device lacked the claimed “at least one removable, replaceable transfer member” both literally and under the doctrine of equivalents. For the reasons discussed herein, we conclude that there is no genuine issue of material fact relating to whether the TAKEONE device literally contains “at least one removable, replaceable transfer member.” We also conclude that the district court should have barred Millipore from asserting that the TAKEONE device contains an equivalent transfer member due to prosecution history estoppel.

A. No Literal Infringement

The district court construed the claim limitation “at least one removable, replaceable transfer member” to mean “at least one transfer member that can be removed from the magazine part of the device and replaced with at least one removable, replaceable transfer member.” See *EMD Millipore Corp. v. AllPure Techs., Inc.*, No. 11-10221, 2012 WL 4862772, at *5 (D. Mass. Oct. 11, 2012) (“*Claim Construction Order*”). Neither party has challenged this construction. However, the parties disagree over the meaning of the term “removed,” as contained in the district court’s construction. The district court explained that “remove” means “to move . . . by taking away or off” or to “put aside, apart, or elsewhere.” *Summary Judgment Order* at *7 (citing *Webster’s New International Dictionary* 1921 (3d. ed 1986)). The district court also noted that “[t]ake off” and “put apart” are significantly different from “take apart” or disassemble; “the former implies movement or separation of something as a whole, whereas the latter implies deconstruction.” *Id.*

In examining the TAKEONE device, the district court found that the transfer member lacked the necessary seal once it is removed. *Id.* at *8. “Upon separating the holder [150] from the various other elements, there ceases to be a seal, . . . with two ends comprising a bellows and a membrane, respectively. What Millipore characterizes as

removal of a transfer member from the magazine part is, in fact, disassembly of a transfer member as defined in the '543 patent." *Id.*

On appeal, Millipore challenges the district court's interpretation of its own claim construction. It argues that summary judgment was inappropriate because there remains a genuine issue of material fact relating to whether disassembly of the transfer member could qualify as the claimed removal of the transfer member. Millipore claims that when the TAKEONE device is *disassembled*, all components of the transfer member are still *removed* from the magazine part (135), even if the components of the seal (i.e., the bellows-shaped part (165) and the membrane (166)) are no longer physically connected.

AllPure responds by arguing that there is no triable issue of fact—the TAKEONE device lacks a removable and replaceable transfer member. Claim 1 requires that at least one transfer member have a seal and be “removable, replaceable.” But in order for it to be removable and replaceable, the TAKEONE device must be disassembled. When it is disassembled, no seal exists because the required components are no longer connected. One part of the seal, the bellows-shaped part (165), remains attached to the holder (150), while the second part, the membrane (166), is separated from the rest of the transfer member. AllPure notes that Millipore's counsel even admitted this fact, choosing instead to argue that a transfer member “does not have to still be a transfer member once removed.” J.A. 2519. However, according to AllPure, if the transfer member does not exist when it is removed, then the TAKEONE device does not have the claimed “at least one removable, replaceable transfer member,” so it cannot infringe.

We agree with AllPure and the district court. If a transfer member does not exist when the device is disassembled, as even Millipore's counsel admitted, then there

is no genuine issue of material fact over whether the TAKEONE device contains a “removable, replaceable transfer member” as is literally required by claim 1 of the ’543 patent. As the district court properly noted, “[t]he problem with Millipore’s characterization of ‘removal’ of a transfer member . . . is the absence of necessary component parts of the transfer member once it is removed [T]he part of the device removable from the magazine part must have all of the component parts—a holder, needle, and seal.” *Summary Judgment Order* at *7. Since the TAKEONE device lacks a seal when it is disassembled, it necessarily lacks the claimed “removable, replaceable transfer member.”

B. Prosecution History Estoppel Bars Millipore’s Doctrine of Equivalents Arguments

We next examine whether the district court erred in granting summary judgment of no infringement under the doctrine of equivalents. Even without literal infringement of a certain claim limitation, a patentee may establish infringement under the doctrine of equivalents if an element of the accused device “performs substantially the same function in substantially the same way to obtain the same result as the claim limitation.” *AquaTex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1382 (Fed. Cir. 2005) (citation omitted) (quotation marks omitted). The district court concluded that it was not “possible for Millipore to maintain a claim for infringement under the doctrine of equivalents because the purportedly removable transfer member(s) of the TAKEONE device do not serve the same function or function in the same way as those in the ’543 patent.”² *Summary Judgment Order* at *8.

² As previously stated, the proper inquiry is actually whether the accused device performs *substantially* the

As a preliminary matter, AllPure argues that the district court should not have considered whether Millipore could maintain a claim for infringement under the doctrine of equivalents because prosecution history estoppel bars such a claim. Prosecution history estoppel applies when an applicant during patent prosecution narrows a claim “to avoid the prior art, or otherwise to address a specific concern . . . that arguably would have rendered the claimed subject matter unpatentable.” *Warner-Jenkinson Co. v Hilton Davis Chem. Co.*, 520 U.S. 17, 30-31 (1997). Estoppel then bars the applicant from later invoking the doctrine of equivalents to recapture the surrendered ground. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002).

There is a presumption that prosecution history estoppel applies when a patentee has filed an amendment seeking to narrow the scope of a claim, and “the reason for that amendment was a substantial one relating to patentability.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366 (Fed. Cir. 2003) (en banc). The patentee bears the burden of rebutting the application of prosecution history estoppel by establishing one of three exceptions: (1) the equivalent was unforeseeable at the time of the application; (2) the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question; or (3) there is some other reason suggesting that the patentee could not

same function in *substantially* the same way to obtain the same result. *Aqua Tex Indus.*, 419 F.3d at 1382. Millipore argues that the district court used the wrong standard, but for the reasons discussed herein, we conclude it was unnecessary for the district court to even undertake a doctrine of equivalents analysis. Therefore, this issue is moot.

reasonably be expected to have described the equivalent. *Festo Corp.*, 535 U.S. at 740-41.

During prosecution of the '543 patent, the applicant amended claim 1's language, adding, inter alia, the requirement that the transfer member's seal have "a first end comprised of a bellows-shaped part sealingly attached to said holder, and a second end comprising a self-sealing membrane portion interiorly formed at an end of said bellows part." J.A. 2143. The applicant stated that the purpose of the amendment was to make claim 1 "allowable and distinguishable over the cited references." J.A. 2148. The district court found that although claim 1 "was narrowed to allow the device to be patented over prior art, it was not narrowed so as to disclaim all multi-part seals." *Summary Judgment Order* at *5. The district court then considered Millipore's doctrine of equivalents arguments on the merits.³ *Id.* at *8.

Millipore argues that the claim language was actually broadened. Prior to amendment, claim 1 required "at least one transfer member . . . whereas the transfer member . . . is removable for replacement thereof *after use*." J.A. 341 (emphasis added). Because the amended claim 1 no longer contains the "after use" language, Millipore suggests that the claim is broader and, therefore, prosecution history estoppel cannot apply. *See* J.A. 440-41.

³ The district court discussed prosecution history estoppel in a separate portion of its summary judgment order. *See Summary Judgment Order* at *5. However, since there is only one seal in claim 1, the district court's statements about prosecution history estoppel and a multi-part seal pertain equally to the "at least one removable, replaceable transfer member" that is at issue.

We disagree with Millipore and conclude that it was unnecessary for the district court to perform a doctrine of equivalents analysis because prosecution history estoppel bars Millipore's arguments. Although the applicant eliminated the "after use" language, the applicant nonetheless added the requirement that the seal have a first and second end with distinct elements. This narrows the seal limitation, which in turn narrows the transfer member limitation. And the applicant even stated in its reasons for amendment that "none of the references show or disclose *a seal formed like the present one.*" J.A. 2148 (emphasis added). Thus, these amendments were added to overcome a previous rejection. And to the extent this statement is ambiguous, we note that the Supreme Court has stated "[w]here no explanation is established . . . the court should presume that the patent applicant had a substantial reason related to patentability for including the limiting element added by amendment." *Warner-Jenkinson*, 520 U.S. at 33.

The district court should have proceeded under the presumption that prosecution history estoppel applies. Millipore then had the burden to rebut the presumption through one of the three enumerated exceptions, but Millipore chose not to present any argument on this issue to the district court. See Oral Arg. 24:06-24:20, *available at* <http://www.cafc.uscourts.gov/oral-argument-recordings/14-1140/all> ("Q: You never argued in the alternative that if in fact there was a conclusion by the trial court that the amendment was narrowing or limiting, that you could rebut the presumption that would arise under *Festo*? A: That is correct, your honor . . ."). Instead it argued that the amendment was not narrowing. See J.A. 2208-09. Since Millipore failed to rebut the presumption, the district court should have concluded that Millipore was barred from arguing that the TAKEONE device infringes the transfer member limitation under the doctrine of equivalents. This error, however, does not change the

outcome of this case, as the district court still proceeded to grant summary judgment of no infringement under the doctrine of equivalents on the merits. *See Summary Judgment Order* at *8-9.

V. CONCLUSION

Since there is no genuine dispute of material fact regarding whether the TAKEONE device contains a “removable, replaceable transfer member,” either literally or under the doctrine of equivalents, we affirm the district court’s grant of summary judgment of no infringement.

AFFIRMED