IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL TECHNOLOGIES, INC., Plaintiff, v. KURIN, INC., Defendant.	Civil Action No.19-97-CFC

Rodger Dallery Smith, II, Anthony David Raucci, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, Delaware; Ashok Ramani, David J. Lisson, Micah G. Block, Philip T. Sheng, Ian Hogg, Serge A. Voronov, DAVIS POLK & WARDELL LLP, Menlo Park, California; Kathryn Bi, Alena Farber, DAVIS POLK & WARDELL LLP, New York, New York

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MEMORANDUM OPINION

May 14, 2024
Wilmington, Delaware

COLM F. CONNOLLY
CHIEF JUDGE

Plaintiff Magnolia Medical Technologies, Inc. sued Defendant Kurin, Inc. for patent infringement. Magnolia alleged and a jury found at the conclusion of the first phase of the trial that Kurin directly infringed claims 1 and 24 of U.S. Patent No. 10,039,483 (the #483 patent) by making, selling, using, and offering for sale in the United States a blood sequestration device called the Kurin Lock. D.I. 437 at 2. (For ease of reference, I will at times refer to the Kurin Lock as "the Lock."). In the second phase of the trial, the jury rejected Kurin's defenses that the asserted claims were invalid and awarded Magnolia damages of $2,144,093. D.I. 443 at 3.

Pending before me is Kurin's Motion for Judgment of Non-Infringement as a Matter of Law. D.I. 519.

I. BACKGROUND

A. The #483 Patent

The #483 patent is titled "Fluid Diversion Mechanism for Bodily-Fluid Sampling." D.I. 5-3 at 2 (#483 patent at 1). According to the patent's "Summary," the patent covers "[d]evices for parenterally-procuring bodily-fluid samples with reduced contamination from microbes exterior to the bodily-fluid source, such as dermally-residing microbes[.]" #483 patent at 2:14–16. The "Background" section of the patent notes that "[o]ne way in which contamination of a patient

sample may occur is by the transfer of microbes from a bodily surface (e.g., dermally-residing microbes) dislodged during needle insertion into a patient and subsequently transferred to a culture medium with the patient sample." #483 patent at 1:56–61.

Claim 1 of the patent reads as follows:

> A blood sequestration device, comprising:
>
> a housing having an inlet port configured to be fluidically coupled to a patient and an outlet port configured to be fluidically coupled to a sample reservoir;
>
> a fluid reservoir disposed in the housing and at least partially defined by a seal member, the fluid reservoir configured to receive an initial volume of blood withdrawn from the patient; and
>
> a vent disposed in the housing and configured to allow air to exit the housing as blood enters the fluid reservoir;
>
> the blood sequestration device further configured to allow a subsequent volume of blood to flow from the inlet port toward the outlet port via a sampling flow path, thereby bypassing the fluid reservoir and the initial volume of blood sequestered therein.

#483 patent at claim 1.

Claim 24 reads:

> A blood sequestration device, comprising:
>
> a lumen-containing device configured to be fluidically coupled to a patient; and a housing having an inlet port configured to be fluidically coupled to the lumen-containing device, and an outlet port

> configured to be fluidically coupled to a sample reservoir,
>
> the housing defining a first fluid flow path and a second fluid flow path, the housing configured to transition from a first operating mode in which an initial volume of blood is allowed to flow from the inlet port toward a seal via the first fluid flow path, to a second operating mode in which a subsequent volume of blood is allowed to flow from the inlet port toward the outlet port via the second fluid flow path,
>
> the housing including a vent configured to allow air to exit the housing as blood enters the first fluid flow path,
>
> the seal configured to transition from a first state to a second state to place the housing in the second operating mode such that the subsequent volume of blood can flow toward the outlet port via the second fluid flow path and bypass the initial volume of blood sequestered in the first fluid flow path.

#483 patent at claim 24.

B. The Kurin Lock

The Kurin Lock is a blood sequestration device used in conjunction with needles, tubes, vials and other medical devices to collect blood samples. In Kurin's words, the Lock itself is used to "sequester[] the initial draw of blood upon initial venipuncture." PTX-19 at 4; 7.25.22 Trial Tr. 139:20–21 (docketed as D.I. 504).

As illustrated below in Figure 1, the Lock is connected "upstream" to an inlet tube and a needle assembly that is used to pierce a patient's vein. A "downstream" outlet tube connects the Lock to a vial adapter assembly that has a second needle that is used to pierce the sealed top of a sample collection bottle.

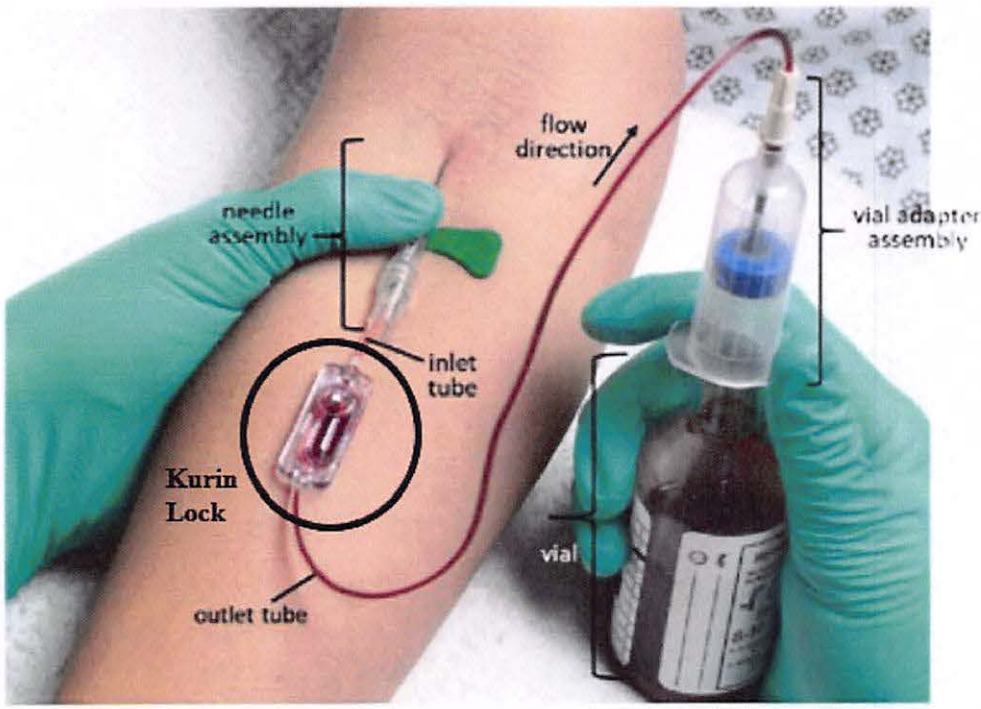
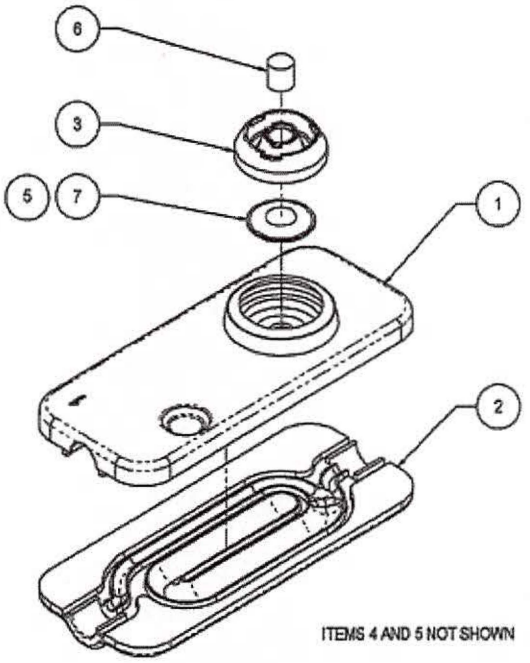


Figure 1

D.I. 322 at 5 (circle and "Kurin Lock" notation added).

As shown in the design drawing depicted below in Figure 2, the Lock has five parts: two pieces of molded plastic, an umbrella valve, a porous plug, and a cap.



1	KUR-6011	VALVE, UMBRELLA, MATERIAL ML151VMQ, TRANSPARENT	7
1	KUR-6010	PLUG, HYDROPHILIC SELF SEALING	6
AR	KUR-3002	LUBRICANT, MICROCARE MEDICAL, DURAGLIDE DRY	5
AR	KUR-3000	ADHESIVE, LIGHT CURING, TANGENT 7939-V-VT	4
1	KUR-2007	CAP, KURIN LOCK	3
1	KUR-2006	BOTTOM HOUSING, KURIN LOCK	2
1	KUR-2005	TOP HOUSING, KURIN LOCK	1
QTY	PART NUMBER	DESCRIPTION	ITEM NO

Figure 2

DTX-83. The two pieces of plastic are joined to form the housing of the Lock. The plug, valve, and cap are joined to create the so-called "dual valve assembly." The plastic pieces that comprise the housing are molded such that when they are joined together, they accommodate the plug and valve and create two channels: a U-shaped channel and the so-called "sample channel."

The Lock's components and channeling can be seen below in Figure 3, an annotated photograph made by Magnolia's infringement expert, Dr. Juan Santiago:

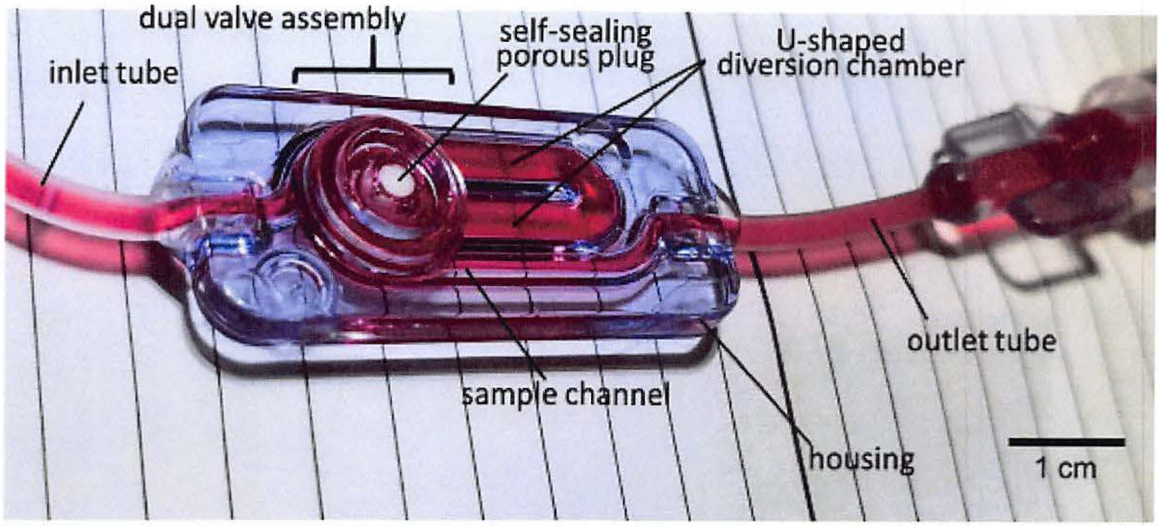


Figure 3

D.I. 455-1 at 23 (Santiago Opening Report at 26). Before taking the photograph, Dr. Santiago filled the Lock with red food dye "to highlight the flow channels." D.I. 455-1 at 23 (Santiago Opening Report at 26). As shown in Figure 3, to use Dr. Santiago's words:

> The [Kurin Lock] includes a housing, connections for inlet and outlet tubes, a Y-junction near the inlet, two daughter channels (the U-shaped diversion chamber and the sample channel), and the dual valve assembly. The dual valve assembly includes a one-way umbrella valve (difficult to see in this image) and a porous self-sealing plug which allows venting of air out of the U-shaped diversion chamber. The Y-junction is not easily visible in this image but includes an inlet channel and two daughter channels.

D.I. 455-1 at 23 (Santiago Opening Report at 26).

At the start of the blood collection procedure, the downstream end of the Kurin Lock system is sealed and not yet attached to the vial. D.I. 318 at 98

(Santiago Opening Report at 28). The collection procedure begins with the insertion of the upstream needle into the patient's vein. The patient's blood pressure, which is greater than the air pressure in the inlet tube and Lock, causes the blood to flow into the inlet tube and enter the Lock. As illustrated below in Figure 4 (also taken from Dr. Santiago's report), when the blood reaches the Y-junction it flows into the U-shaped channel. According to Dr. Santiago, the blood flows into the U-Shaped channel as opposed to the sample channel because the porous plug allows for air flow and therefore the resistance to flow in the U-shaped channel (i.e., what I will call for ease of reference "air pressure") is less than the resistance to flow (i.e., air pressure) in the sealed sample channel.

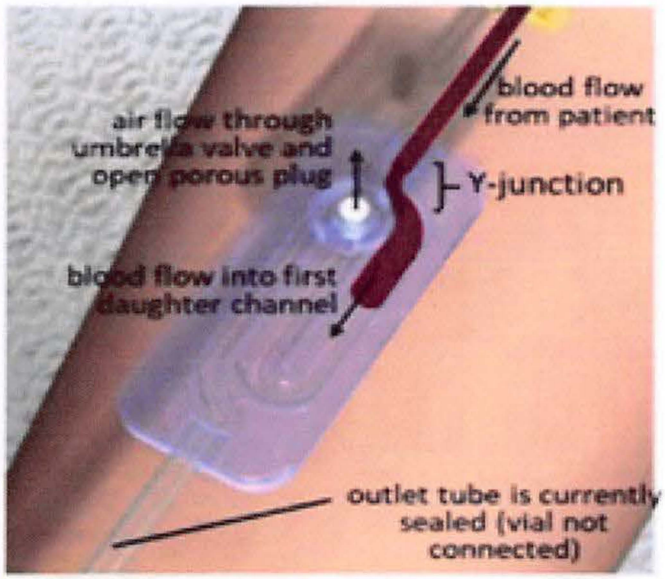


Figure 4

D.I. 318 at 99 (Santiago Opening Report at 29) (irrelevant annotations omitted).

As illustrated below in Figure 5, the blood proceeds down the U-shaped channel, rounds the 180-degree turn at the bottom of that channel, and flows up to the porous plug. When contacted by the blood, the plug's material is activated to seal the channel at that location. Once the U-shaped channel is filled with blood, the blood flowing from the inlet tube enters the sample channel (also referred to as the second daughter channel) and comes to rest when the air pressure in the sealed outlet tube matches the patient's blood pressure.

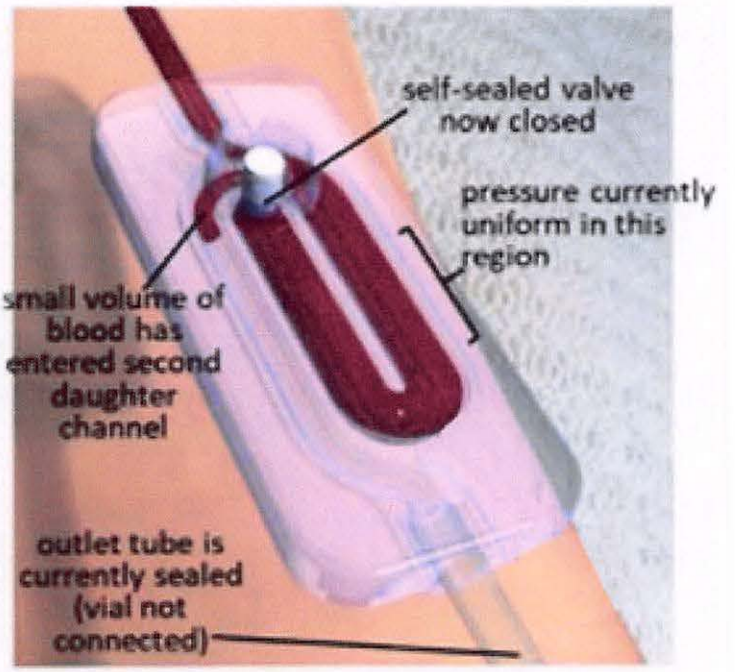


Figure 5

D.I. 318 at 99 (Santiago Opening Report at 29) (irrelevant annotations omitted).

At this point, the clinician uses the second needle to attach a sample collection bottle to the vial adapter assembly; and as illustrated below in Figure 6 (also taken from Dr. Santiago's report), the resulting vacuum causes the blood to

flow from the inlet tube through the sample channel and outlet tube into the collection bottle. The contaminated initial volume of blood remains within the U-shaped channel and thus does not taint the collected blood sample.

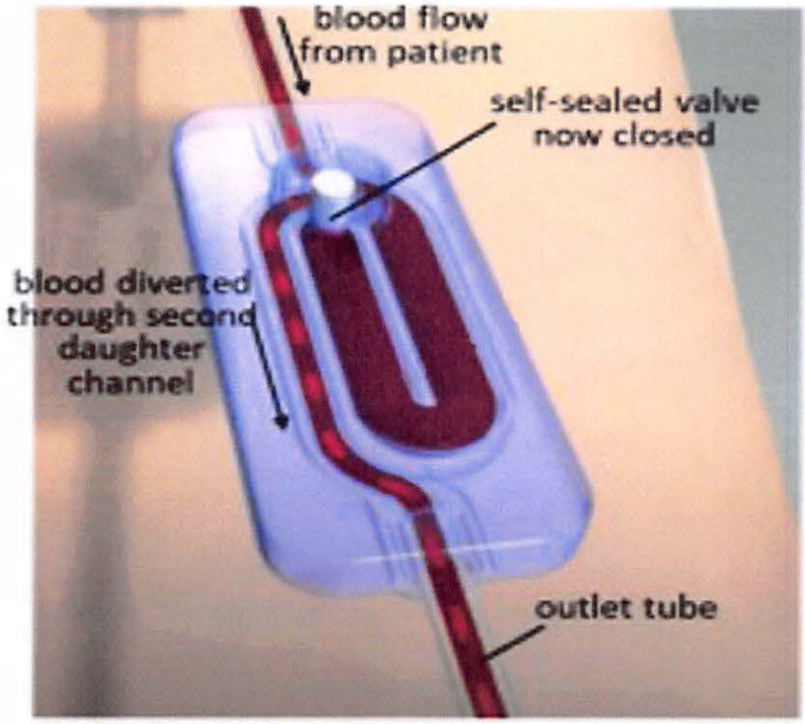


Figure 6

D.I. 318 at 99 (Santiago Opening Report at 29) (irrelevant annotations omitted).

C. Kurin's Rule 50(a) Motion

Immediately after Magnolia concluded the presentation of evidence in its infringement case-in-chief at the end of the first day of trial, Kurin made the following Rule 50(a) motion:

> [KURIN'S COUNSEL]: . . . Kurin has a motion under Rule 50(a) for judgment as a matter of law. I will layout the bases, and I'm happy to go into more detail, but

otherwise, you know, we understand how these things are typically handled.

So Kurin moves for judgment as a matter of law on the issue of infringement on the basis that no reasonable jury would have a legally sufficient evidentiary basis to find for Magnolia on either literal infringement or the doctrine of equivalents, specifically for the following reasons: That having heard the evidence presented by Magnolia of the Kurin device, is not a blood sequestration device, and it does not sequester blood for -- in as much it's open, there's mixing, and the second phase of blood can enter into the U-shaped channel, and can and does; that it does not, because of that same phenomenon, there's no bypassing of the initial volume, there's no initial volume of blood that is sequestered in the fluid reservoir. To the extent that there is a fluid reservoir in the Kurin device it's the entire U-shaped channel not a subportion of it.

Separately, there are some issues based on the vent and seal terminology. One is with respect to Claim 1. The claim requires a fluid reservoir, at least partially defined by a seal member. And it also requires a vent. We heard testimony that the porous plug in the Kurin device can be, first, a vent, and then a seal, but it is not -- it cannot reasonably be considered to be both a vent and a seal at the same point in time, and that, as a matter of law, a device claim like this requiring a seal and a vent would have -- those things would have to be present at the same time in order for all claim elements to be met; they can't be present sequentially. It not a method claim.

And similarly, that the housing, at least partially defined by a seal member, a fluid reservoir disposed in a housing at least partially defined by a seal member, the fluid reservoir configured to receive an initial volume of blood, again, at the time when the fluid reservoir is configured, that porous plug is not a seal; it's a vent.

> And, therefore, that limitation is not met based on the evidence we've heard.
>
> The -- with respect to Claim 24, there is no housing configured to transition from a first operating mode to a second operating mode. What Dr. Santiago testified to was that the vent or plug was -- would transition, but the housing, he identified as a different part, the plastic part, and there's no evidence that that plastic part was configured to so transition.
>
> And with respect to the final limitation of Claim 24, which requires that the initial -- an initial volume of blood sequestered in the first fluid flow path, we heard testimony that the first fluid flow path is the entire channel from inlet to seal, and it is undisputed that within that channel, there is blood that is not sequestered, so that there is no, then, initial volume of blood sequestered in the first fluid flow path as required by Claim 24.
>
> Lastly, with respect to the doctrine of equivalents, the law requires a particularized showing on an element-by-element basis. The testimony was not so particularized and simply reflected a generalized comparison between the Kurin device as a whole and the claim as a whole, and is, therefore -- therefore, not provide a legally sufficient basis in order to support a verdict of infringement under the doctrine of equivalents. And I think -- I'm hoping I've not missed something.

7.25 Tr. 338:1–340:17.

I then questioned both sides' counsel about various matters and we adjourned for the day. I did not grant the Rule 50(a) motion.

II. LEGAL STANDARDS

"If the court does not grant a motion for judgment as a matter of law made under Rule 50(a), . . . the movant may file a renewed motion for judgment as a matter of law and may include an alternative or joint request for a new trial under Rule 59." Fed. R. Civ. P. 50(b). "The grant or denial of a JMOL motion is a procedural issue not unique to patent law, reviewed under the law of the regional circuit in which the appeal from the district court would usually lie." *TI Grp. Auto. Sys. (N. Am.), Inc. v. VDO N. Am., L.L.C.*, 375 F.3d 1126, 1133 (Fed. Cir. 2004) (citations omitted).

A party that does not have the burden of proof is entitled to a judgment as a matter of law "only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993) (citation omitted).

III. DISCUSSION

Kurin argues that it is entitled to judgment of noninfringement as a matter of law under Rule 50(b) for four reasons: (1) Magnolia failed to adduce at trial substantial evidence that the Kurin Lock has claim 1's "fluid reservoir"; (2) Magnolia failed to adduce at trial substantial evidence that the Kurin Lock has

claim 24's "sample reservoir"; (3) Magnolia's expert, Dr. Santiago, "conceded" noninfringement of Claim 24; and (4) Magnolia failed to adduce at trial substantial evidence that the Kurin Lock "includes both the 'seal' and 'vent' limitations of the Asserted Claims." D.I. 520 at 1–3. I address the arguments in turn.

A. Claim 1's "Fluid Reservoir" Limitation

Kurin argues in its Rule 50(b) briefing that Magnolia's infringement expert, Dr. Santiago, "disregarded" my construction of "fluid reservoir" at trial and that his testimony therefore cannot support the jury's verdict of infringement of claim 1. D.I. 520 at 1. For the reasons outlined in *Magnolia Med. Techs., Inc. v. Kurin, Inc.*, 2023 WL 5000562 (D. Del. Aug. 4, 2023), I agree with this argument, as the infringement opinion Dr. Santiago offered at trial was based on a purely functional (as opposed to structural) definition of "fluid reservoir." But I also agree with Magnolia that Kurin failed to preserve this argument in its Rule 50(a) motion as required by Rule 50(b).

"A post-trial Rule 50 motion can only be made on grounds specifically advanced in a motion for a directed verdict at the end of plaintiff's case." *Kars 4 Kids Inc. v. Am. Can!*, 8 F.4th 209, 220 (3d Cir. 2021) (quotation and citation omitted). The Rule 50(a) motion must have been "sufficiently specific to afford the party against whom the motion is directed with an opportunity to cure possible defects in proof which otherwise might make its case legally insufficient."

Brokerage Concepts, Inc. v. U.S. Healthcare, Inc., 140 F.3d 494, 519 n.18 (3d Cir. 1998) (quotation and citation omitted).

Kurin did not state or imply in its Rule 50(a) motion that Dr. Santiago's testimony was inconsistent with my claim construction order. Nor did it object at trial to Dr. Santiago's testimony about the "fluid reservoir" limitation. Moreover, as I now appreciate having had the benefit of Magnolia's Rule 50(b) briefing, Kurin's own expert, Dr. Antonsson, identified at trial a "fluid reservoir" in the accused device that also was not defined in structural terms. *See* 7.26.2022 Trial Tr. 99:9–99:22 (docketed as D.I. 505); DTX-82. And consistent with Dr. Antonsson's testimony, the only substantive statement Kurin made with regard to noninfringement of the "fluid reservoir" limitation in its Rule 50(a) motion was: "To the extent that there is a fluid reservoir in the Kurin device it's the entire U-shaped channel not a subportion of it." This statement in no way expressed or implied the argument or even the tenor of the argument Kurin is now making in support of its Rule 50(b) motion with respect to claim 1's "fluid reservoir" limitation. Accordingly, Kurin has waived the argument.

B. Claim 24's "Sample Reservoir" Limitation

Magnolia argues, and I agree, that Kurin also failed to preserve in its Rule 50(a) motion its argument that Magnolia failed to adduce evidence to establish that the Kurin Lock satisfied the "sample reservoir" limitation of claim 24. *See*

D.I. 525 at 17. Kurin did not mention claim 24's "sample reservoir" limitation in its Rule 50(a) motion or imply in any way in its Rule 50(a) motion that it was challenging the sufficiency of the evidence of the Kurin Lock's infringement of the "sample reservoir" limitation. Accordingly, Kurin has waived the argument.

C. Dr. Santiago's Alleged "Concession" That the Kurin Lock Does Not Infringe Claim 24

Claim 24 requires that the "subsequent volume of blood can flow toward the outlet port via the second fluid flow path *and bypass the initial volume of blood sequestered* in the first fluid flow path." #483 patent at claim 24 (22:51–54) (emphasis added). Kurin argues that the following trial testimony of Dr. Santiago constituted an "unequivocal admission" that "the initial volume of blood is not sequestered (and thus not bypassed)":

> Q. And in this claim, at the end it says, "The initial volume of blood has to be sequestered in the first fluid flow path." Correct?
>
> A. That's what those words say, yes.
>
> Q. And can we agree that there is blood in the first fluid flow path that is not sequestered?
>
> A. Yes.

D.I. 520 at 13 (quoting 7.26 Tr. 292:7–13).

This argument, however, is based on a false premise—namely, that *all* the blood in the first fluid path is "the initial volume of blood sequestered in the first

fluid flow path." Dr. Santiago did not admit and claim 24 does not require that the initial volume of blood sequestered in the first fluid flow path is the only blood in the first fluid flow path. Accordingly, Kurin's argument that Dr. Santiago conceded at trial that the Kurin lock does not infringe claim 24 fails.

D. The "Seal" and "Vent" Limitations

The devices taught by claim 1 and claim 24 have both a seal and a vent. *See* #483 patent at claims 1 (20:53–56), 24 (22:43–49). But as Kurin argued at trial, in its Rule 50(a) motion, and again in support of its Rule 50(b) motion, *see* 7.25 Tr. 338:22–339:17; 7.26 Tr. 104:24–106:7, 199:9–200:11; D.I. 520 at 16–21, because the porous plug serves as both the Lock's seal (when sufficiently wetted with the patient's blood) and its vent (before it is sufficiently wetted), the Lock never has both a seal and a vent at the same time. For that reason, there is no moment in time when the Lock meets both the seal and vent limitations and therefore, as a matter of law, there is no moment in time when the Lock infringes the asserted claims. *See Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1255 (Fed. Cir. 2010) ("There can be no literal infringement where a claim requires two separate structures and one such structure is missing from an accused device.") (citation omitted); *Lemelson v. United States,* 752 F.2d 1538, 1551 (Fed. Cir. 1985) ("It is [] well settled that each element of a claim is material and essential, and that in order for a court to find infringement, the plaintiff must show the

presence of every element . . . in the accused device.") (citation omitted); *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991) ("[T]he failure to meet a single limitation is sufficient to negate infringement of the claim[.]").

Magnolia insists that the Lock "meets every claim limitation because it contains a structure that is both a seal and a vent" and that "nothing in the patent precludes a single structure from being both a vent and a seal." D.I. 525 at 22–23. But this misses the point. It is undisputed that the porous plug acts as both the Lock's seal and vent. The point, however, is that the plug does not act as both a seal and a vent at any point in time. The plug is a vent until it becomes a seal. Once it becomes sufficiently wet to become a seal, it is no longer a vent, as it no longer allows for the passage of air out of the U-shaped diversion chamber. In the words of Magnolia's expert, Dr. Santiago: the Lock's plug "is a porous plug that at first allows air, and then when liquid hits it, it shuts off and it seals." 7.25 Tr. 238:8–10. At no point in time is the plug both a seal and a vent.

Magnolia also argues that Kurin failed to preserve this argument with respect to claim 24 in its Rule 50(a) motion because Kurin's counsel "raised 'issues based on the vent and seal terminology' *only* 'with respect to Claim 1.'" D.I. 525 at 21 (emphasis in the original). But under Third Circuit law, courts "do not measure [a Rule 50(a) motion's] sufficiency by the text alone, but against the background, as reflected in the record, of what the party now claiming waiver

understood as to the tenor of the Rule 50 movant's position and theory." *Brokerage Concepts*, 140 F.3d at 519 n.18. That background here makes clear that Kurin's Rule 50(a) argument that the Lock's porous plug "cannot reasonably be considered to be both a vent and a seal at the same point in time" was not limited to claim 1. Throughout the trial, both sides treated the vent and seal limitations as being the exact same for both asserted claims. *See, e.g.*, 7.25. Tr. 224:5–225:12, 237:21–240:12; 7.26 Tr. 104:24–106:7, 199:9–200:11, 177:4–180:1. As Magnolia's counsel stated in his closing argument, "about half of Claim 24 is identical to Claim 1," 7.26 Tr. 177:5; and in their questioning of witnesses and their arguments to the jury and Court, both sides' counsel dealt with the vent and seal imitations as if they were identical for both asserted claims. Substantively, there is no difference between Kurin's position with respect to why the Lock does not meet the vent and seal limitations of claim 1 and its position with respect to why the Lock does not meet the vent and seal limitations of claim 24. And for that reason, at the time Kurin's counsel made his Rule 50(a) argument, I understood—and I suspect Magnolia understood—that his discussion of the vent and seal limitations applied equally to both asserted claims.

Accordingly, I find that Kurin is entitled to a judgment of noninfringement of claims 1 and 24 of the #483 patent as a matter of law.

IV. CONCLUSION

For the reasons discussed above, I will enter a judgment of noninfringement of the asserted claims as a matter of law.

The Court will issue an Order consistent with this Memorandum Opinion.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL TECHNOLOGIES, INC., Plaintiff, v. KURIN, INC., Defendant.	Civil Action No. 19-97-CFC

ORDER

At Wilmington on this Fourteenth day of May in 2024:

For the reasons set forth in the Memorandum Opinion issued this day, IT IS HEREBY ORDERED that Kurin's Motion for Judgment of Non-Infringement as a Matter of Law (D.I. 519) is GRANTED.

CHIEF JUDGE