

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, Ian Hogg, Serge A. Voronov, DAVIS POLK & WARDELL LLP, Menlo Park, California; Kathryn B. Bi, Alena Farber, DAVIS POLK & WARDELL LLP, New York, New York

Counsel for Plaintiff

Kelly E. Farnan, Nicole Kathleen Pedi, RICHARDS, LAYTON & FINGER, PA, Wilmington, Delaware; Catherine Nyarady, Kripa Raman, PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP, New York, New York; Nicholas Groombridge, GROOMBRIDGE, WU, BAUGHMAN & STONE LLP, New York, New York; Jonathan Hangartner, X-PATENTS, APC, La Jolla, California

Counsel for Defendant

MEMORANDUM OPINION

August 4, 2023
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, and offering for sale in the United States a blood sequestration device called the Kurin Lock. (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.

Pending before me is Kurin’s posttrial motion for judgment that the asserted claims are invalid for indefiniteness. D.I. 451. “[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). Kurin argues that the asserted claims are indefinite because they contain three indefinite terms, one of which is “reservoir.”

I have spent many days studying the parties’ briefing on Kurin’s motion and the trial transcripts and exhibits. I have reviewed carefully as well the dozens of other filings made by the parties and transcripts of pretrial hearings that touched on

the meaning of “reservoir.” As a result of those efforts, I have concluded that the better course of action is to stay resolution of the pending motion until I have decided the renewed motion for judgment as a matter of law (JMOL) of noninfringement that Kurin has said it intends to bring. I explain in this Memorandum Opinion my reasoning.

I. 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, 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, 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, 20:48–65 (emphasis added). Thus, claim 1 tells you three—and only three—things about the structure of the fluid reservoir in the claimed device: (1) it is disposed (i.e., it physically exists) in the device’s housing; (2) it is “at least partially defined by a seal member”; and (3) it is “configured to receive an initial volume of blood withdrawn from the patient.” Claim 1 also tells you what the function of the reservoir is in the event the device is used to collect a blood sample: The reservoir receives the initial volume of blood taken from the patient and sequesters that initial volume of blood from a subsequent volume of blood taken from the patient.

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, 22:32–54. Thus, claim 24 tells you only one thing about the “sample reservoir” in the claimed device—i.e., that it is fluidically coupled to an outlet port.

II. 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 Tr. 139:11–21.

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.

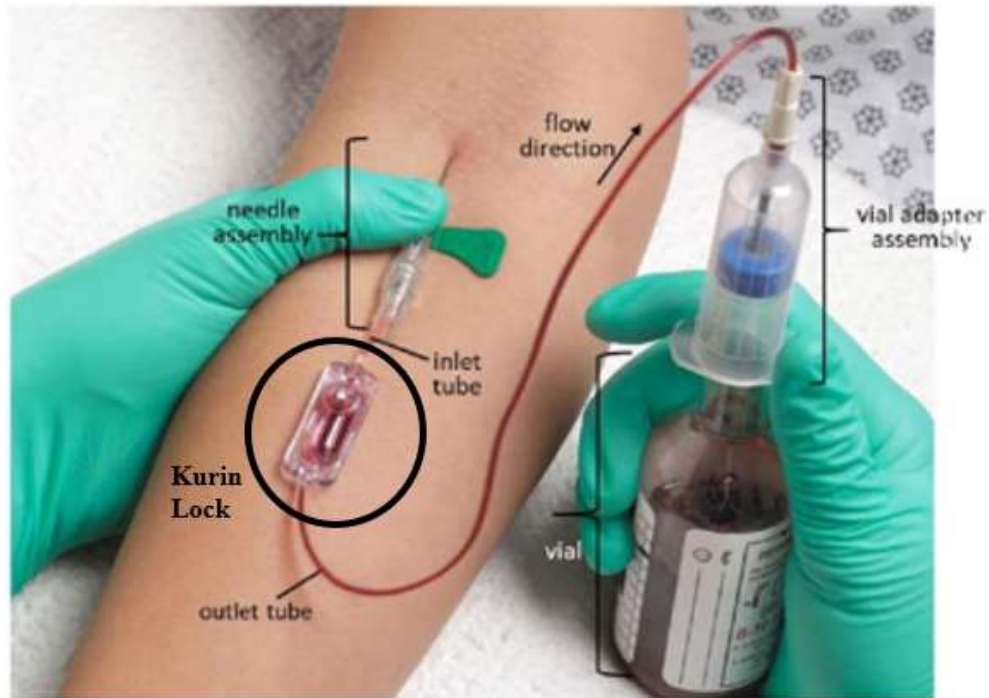
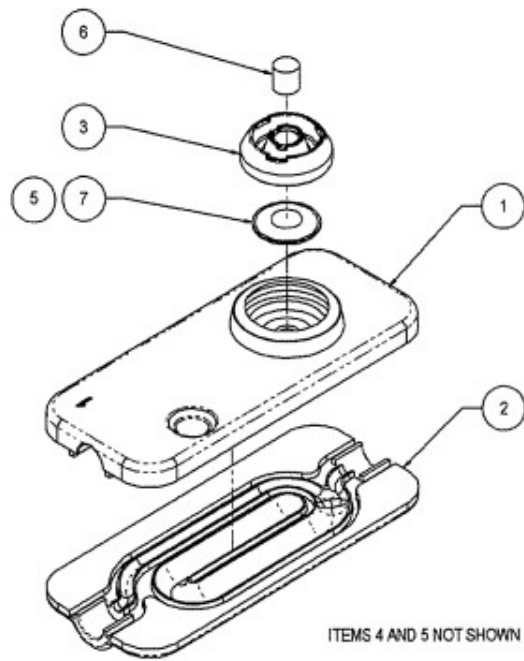


Figure 1

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, MICROCORE 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	REF ID

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:

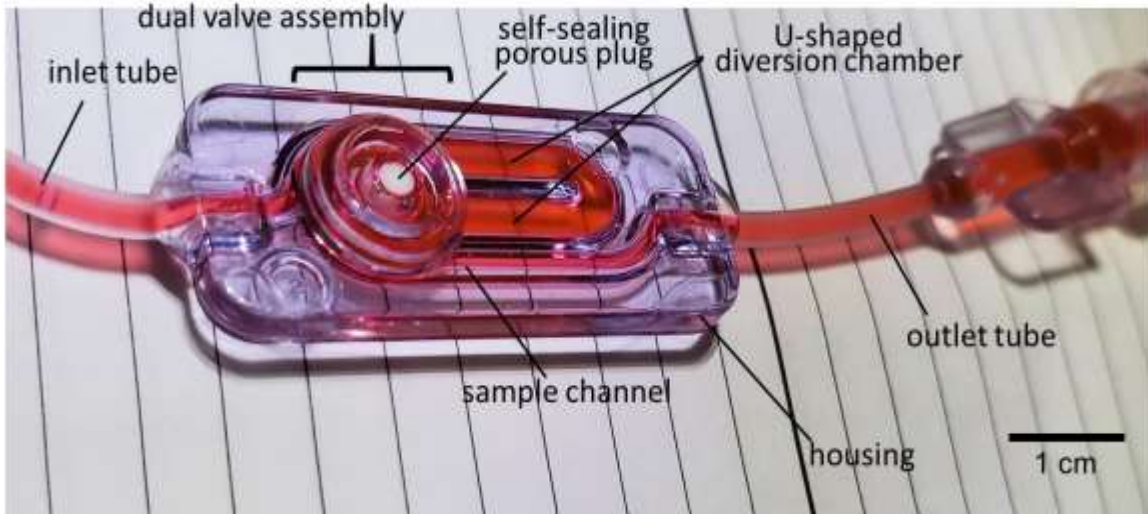


Figure 3

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.

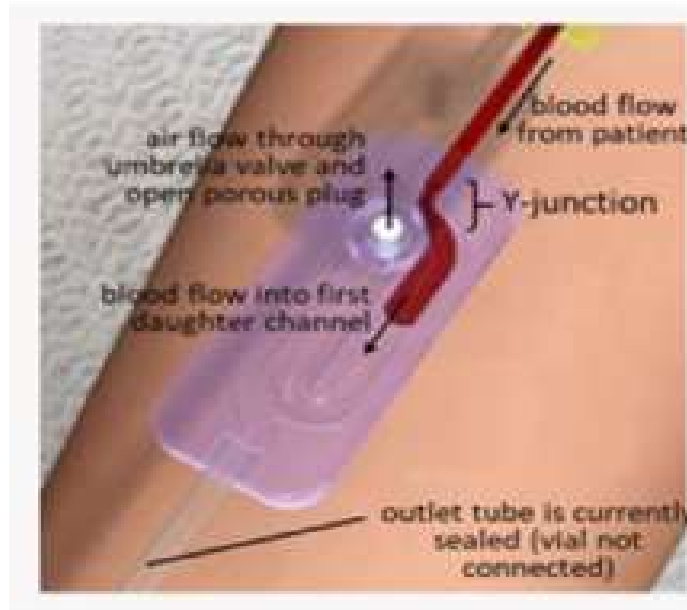


Figure 4

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.

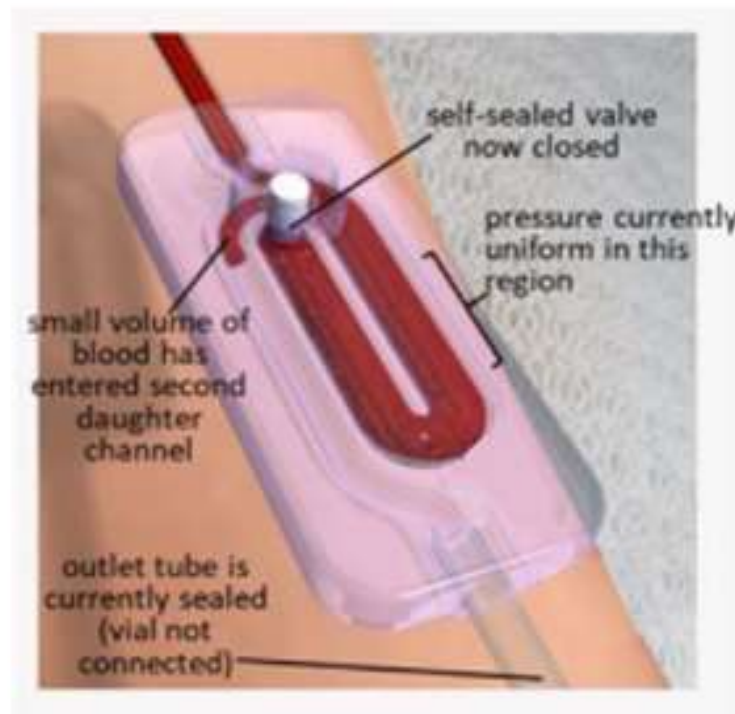


Figure 5

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.

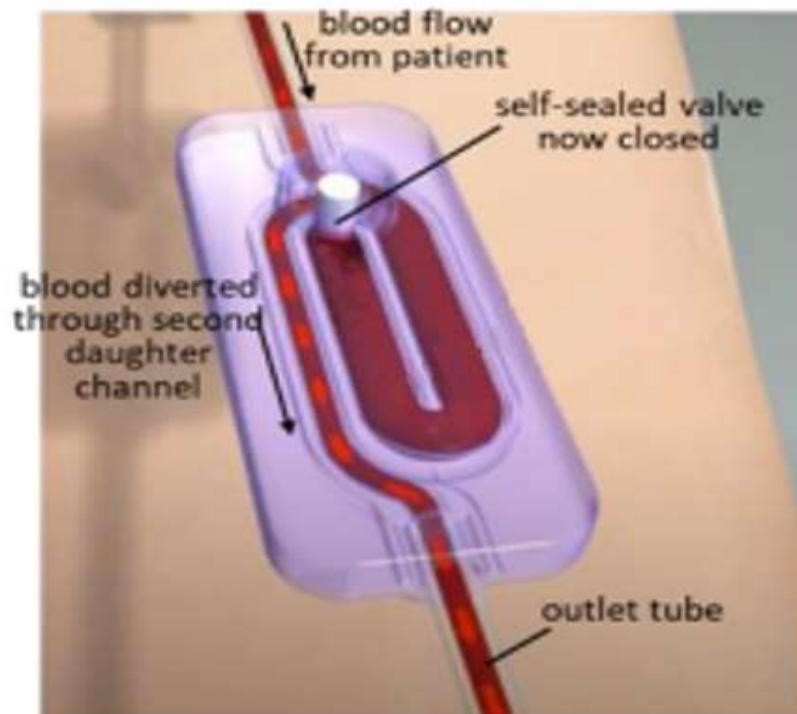


Figure 6

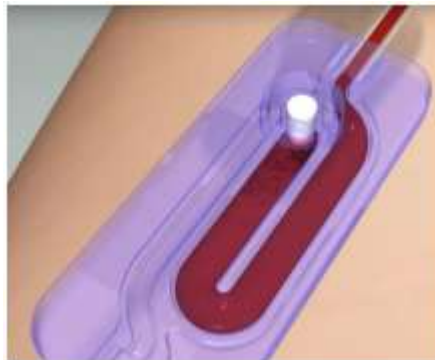
D.I. 318 at 99 (Santiago Opening Report at 29) (irrelevant annotations omitted).

III. The Case's Procedural History with Respect to "Reservoir"

Magnolia has taken various positions over the course of this litigation about the meaning of "reservoir" and how the Kurin Lock meets the reservoir limitations of the asserted claims. Magnolia's shifting positions and Kurin's responses (and lack of responses) to them account for the unusual current posture of the case.

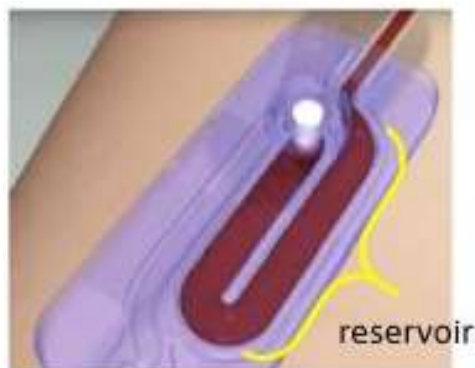
A. Infringement Contentions and Claim Construction

In its initial Infringement Contentions served on Kurin in July 2019, Magnolia identified the entire Kurin Lock as the claimed “reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient” (i.e., the “fluid reservoir” of claim 1):



D.I. 290 at 64.

In revised contentions served on Kurin in September 2019, Magnolia stated that the “reservoir” in claim 18 of the #483 patent “corresponds to at least the ‘U-shaped side channel’ structure,” shown in the diagram depicted below:



D.I. 290 at 71. Magnolia also stated in its revised contentions that “[t]his ‘U-shaped side channel’ structure also satisfies . . . the ‘fluid reservoir’ limitation from

claim[s] 1 and 9 of the [#]483 patent[.]” D.I. 290 at 71. Magnolia never amended or sought leave to amend these revised infringement contentions.

In their Joint Claim Construction Brief filed in February 2020, the parties disputed how I should construe “reservoir” for purposes of claim 18 of the patent. D.I. 59 at 80–90. Claim 18 covers a blood sequestration device that comprises, among other things, a “reservoir configured to transition from a first state such that the initial volume of blood flows from an inlet port toward a seal defining a portion of the reservoir, to a second state such that a subsequent volume of blood can flow from the inlet port toward the outlet port” #483 patent, 22:12–17. Kurin argued that “reservoir” as used in claim 18 was a means-plus-function term that required construction by the Court; that the function of “reservoir” as used in claim 18 was “to transition from the first state to the second state”; and that the corresponding structure for that function was described in specific text and depicted in specific figures in the patent. Kurin emphasized in its claim construction briefing that “reservoir” required construction solely with respect to claim 18. In Kurin’s words:

in many of the asserted claims the term “reservoir” is used in accordance with its plain and ordinary meaning, and to the extent it is required to perform any function, such function is consistent with the term’s plain and ordinary meaning. *For example, claim 1 of the [#]483 patent requires a “fluid reservoir” that is “configured to receive an initial volume of blood withdrawn from the patient.” [[#]483 patent, 20:52-55]. Kurin agrees that*

the term “reservoir” does not require construction and should be given its plain and ordinary meaning with respect to all such claims.

D.I. 59 at 83–84 (emphasis added).

Magnolia countered that “reservoir” should be given its plain and ordinary meaning in all the #483 patent’s claims, including claim 18. It stated in relevant part in its claim construction briefing:

[T]he term “reservoir” is used consistently [in the patent] with its plain and ordinary meaning—i.e., *a receptacle designed to hold fluid*. . . . See also [#]483 Patent, [c]laim 1 (“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”). . . .

. . . .

. . . As Kurin concedes by not seeking construction of this same term in the majority of the asserted claims, “reservoir” is a *quintessentially structural term* and therefore not subject to means-plus-function construction. “Reservoir” has a *well-known structural meaning—namely, a “receptacle designed to hold fluid,”* which Kurin does not contest. And “reservoir” is used consistently throughout the asserted claims

D.I. 59 at 82–83 (citation omitted) (emphasis added).

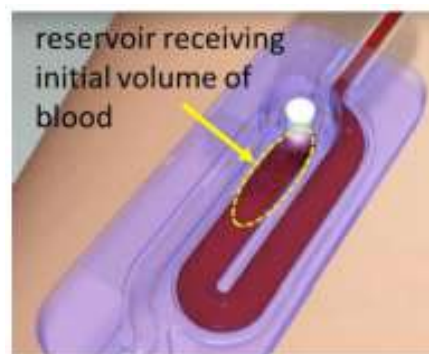
I held a claim construction hearing on April 15, 2020. At the conclusion of the hearing, I said I would defer construction of “reservoir” as used in claim 18 until after I had heard testimony from the parties’ competing experts about the term. 4.15.20 Hr’g Tr. 55:3–10. Later that day, however, Magnolia informed me

by letter that it would no longer assert claim 18. D.I. 70. The parties subsequently submitted, and I signed on May 20, 2020, a stipulation that “reservoir” as used in claims 1 and 24 of the #483 patent and claim 1 of related U.S. Patent No. 9,855,001 (the #001 patent) should be given its plain and ordinary meaning and no construction of the term by the Court was necessary. D.I. 75 at 4.

As Kurin had never disputed in its claim construction briefing or at the claim construction hearing Magnolia’s assertions about the plain and ordinary meaning of “reservoir,” my claim construction order effectively construed “reservoir” to be a structural term that means a receptacle designed to hold fluid.

B. Dr. Santiago’s Report and Deposition

In January 2021, Magnolia served on Kurin Dr. Santiago’s opening expert report on infringement. D.I. 290, Ex. F. Dr. Santiago opined in that report that the oval-shaped region of the inner leg of the U-shaped channel depicted below is “the reservoir of the U-shaped diversion chamber” where “the initial volume of blood . . . remains sequestered.”



D.I. 290 at 100–04.

In a deposition in April 2021, Dr. Santiago testified that this oval-shaped region in the Kurin Lock “meets the reservoir limitations of, for example, claim 1 of the #001 patent.” D.I. 290 at 114. But he also testified in the deposition that “the region in the U[-]tube from the porous plug to the top of the 180-degree turn section . . . is a region and a structure that meets the [‘]reservoir[’] requirement.” D.I. 290 at 117. And he testified that “another part of that inner leg of the U-shaped side channel, say, from a quarter of the way up the inner leg to three-quarters of the way up the inner leg” was a “structure that . . . meets the [‘]reservoir[’] limitation.” D.I. 290 at 118.

Dr. Santiago’s insistence that various areas of the U-shaped channel meet the #001 and #483 patents’ “reservoir” limitations led to this exchange with Kurin’s counsel:

Q. How about if I pick another part of that inner leg of the U-shaped side channel, say, from a quarter of the way up the inner leg to three-quarters of the way up the inner leg, is that a reservoir? In your opinion is that a reservoir that satisfies the requirements of claim 1?

A. The reservoirs that I’ve opined on include the region near the porous plug, and you, I think, purposely excluded that region.

Q. I did. And I’m asking if the region I identified is in your opinion a reservoir that would satisfy the requirements of claim 1?

A. It’s not one of the regions I’ve opined on.

Q. Do you have an opinion on that?

A. I would say that the reservoir that you described, the structure that you described, meets the limitations of claim 1.

Q. Okay. And so you could have just as well offered the opinion that the structure, the area that I described, is the reservoir in the Kurin Lock as what you've done here.

A. I could have. I don't understand. I either did or did not, and I gave my opinion now very clearly. So I don't understand "you could have." I don't understand that.

Q. When you go to trial what opinion will you offer as to the boundaries of the reservoir in the Kurin Lock?

A. So one opinion is depicted here in [paragraph] 136 [of my report].

Q. Okay.

A. Let's call it from the porous plug region until, say, two-thirds of the way up to the 180-degree turn. That is definitely a structure that meets the limitations. A second structure -- so the Kurin Lock meets these limitations in several ways. Another way that it meets the limitations is defining the reservoir or the structure -- or the structure starting from the porous plug to the top of the 180-degree turn.

Q. Any others?

A. I would say from the porous plug to halfway to the 180-degree turn.

Q. So is it fair to say it's your opinion that if we draw the boundaries starting at the porous plug and extending any of the distance down to the 180-degree turn, we can pick any spot in there and say that's the reservoir?

A. I'm saying that the Kurin Lock meets the limitation in at least several ways, and these reservoirs meet the limitation.

Q. That's not my question. Could I start at the porous plug and go into the U-shaped channel beyond the porous plug any distance all the way to the 180-degree turn, just pick a spot, draw a line, and call that the reservoir? . . .

[A.] I think it's most useful to identify specific structures. And for those reasons I said either two-thirds of the way or one-half of the way since these are easy fractions to identify. Also, from the porous plug to the top of the 180-degree. Those three examples I gave you are structures in the Kurin Lock which meet the limitation of reservoir.

Q. How about if I extended it from the porous plug to your line at the apex of the 180-degree turn, and then I went four more millimeters around the corner and drew a line there? Would that -- would that be the reservoir in the Kurin Lock?

A. So four more millimeters in which direction?

Q. Around toward the outer leg of the U-shaped channel.

A. So I didn't offer that opinion.

Q. And I'm asking you would that be a reservoir in the -- in the Kurin Lock?

A. So I'm -- I don't have an opinion about that today or in my report.

Q. Do you have an opinion about that today?

A. No.

Q. How about I took it from the porous plug and went halfway around so that I was halfway up the outer leg of the U-shaped channel and I drew my line there? Would that be a reservoir?

A. I don't have an opinion about that today.

Q. And you haven't offered one in your report, have you?

A. No.

Q. Is there -- is there any other reservoir in the Kurin Lock other than the ones you've already -- you just talked about?

A. I've talked about three possible ones at least. Are you saying are there other regions? Like, for example, the sample channel is not a reservoir. Is not the reservoir.

Q. Okay. I was asking if there's any other region. So in your opinion once it crosses a vertical line at the apex of the turn from the inner leg of the U channel to the outer leg, once we cross that line, in your opinion it's no longer the reservoir?

[MAGNOLIA'S COUNSEL]: Object to form.

THE WITNESS: No, that's not what I said.

Q. You have no opinion as to whether it's the reservoir once you cross that line?

A. That's right. It could be and may or may not be a reservoir.

Q. And how would I determine whether it's a reservoir or not?

A. Well, if— what[] the important question is does it meet the limitations.

D.I. 290 at 118–22 (emphasis added).

For reasons unclear to me, Kurin’s counsel accepted Dr. Santiago’s nonanswer to this last question and never pressed Dr. Santiago during the deposition to define “reservoir” or to explain what the plain and ordinary meaning of “reservoir” is to an artisan of ordinary skill.

C. Kurin’s *Daubert* Motion

About a month after Dr. Santiago’s deposition, Kurin filed a *Daubert* motion to exclude at trial Dr. Santiago’s testimony regarding “reservoir.” D.I. 289. Kurin argued that Federal Rules of Evidence 403 and 702 precluded Magnolia from adducing at trial Dr. Santiago’s infringement opinions because he “does not apply the claim construction agreed [to] by the parties and ordered by the Court” and “[i]nstead, . . . attempts to apply a functional construction of the term ‘reservoir,’ which would have required a means-plus-function claim construction.” D.I. 289 at 1.

In its opposition to the motion, Magnolia stated that “Dr. Santiago *identifies structures* in the Kurin Lock device that (1) are ‘reservoirs’ under the Court’s plain-and-ordinary meaning construction and (2) meet the asserted claims’ additional requirements related to such ‘reservoirs.’” D.I. 337 at 2 (emphasis added). Magnolia explained its position as follows:

Kurin represents that Dr. Santiago “does not point to any specific, identifiable ‘reservoir’ structure.” Not true. *Dr. Santiago identifies specific structures that satisfy the “reservoir” requirement* in his opinion. For example, he reads the “reservoir” element on the portion of the U[-]shaped diversion chamber “from the porous plug region until . . . two-thirds of the way up to the 180-degree turn.” That is indisputably a specific, identifiable structure.

Kurin also represents that Dr. Santiago “now opines that the ‘reservoir’ requirement of the asserted claims is met wherever the accused product achieves the function that blood and/or contaminants do not mix with incoming blood flow into the sample channel.” Also not true. To be sure, *having identified structures that a person of ordinary skill in the art would understand to be within the plain and ordinary meaning of the term “reservoir,” Dr. Santiago goes on to analyze the remainder of the claim limitations*, and some of those additional limitations relate to sequestration of blood, bodily fluid or contaminants in the “reservoir.”

D.I. 337 at 8 (citations omitted) (italics and underline added).

I held oral argument on Kurin’s *Daubert* motion on February 10, 2022. Counsel for Kurin framed the issue at the outset of the argument this way: “[W]e have a claim construction dispute, raising . . . [O]2 [Micro] issues, [and] then if their construction is right, we think there is a whole host of implications that flow from that[,] [including that] [t]he claim is fatally invalid [as] indefinite.” 2.10.22 Hr’g Tr. 20:20–24. (The Federal Circuit held in *O2 Micro International Ltd. v. Beyond Innovation Technology Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008), that

“[w]hen the parties present a fundamental dispute regarding the scope of a claim term, it is the court’s duty to resolve it.”)

Consistent with Magnolia’s briefing, its counsel insisted at oral argument that Dr. Santiago would not apply at trial a functional definition of “reservoir” in his infringement analysis, but would instead employ a “structural” definition and “point[] to a particular region in th[e] [Kurin] device bounded in a particular way.” 2.10.22 Hr’g Tr. 34:4–5. More specifically, counsel said that Dr. Santiago would identify at trial the structure as being bounded by the porous plug, the side walls of the U-shaped side channel, and either (1) “the 180-degree turn” of the U-shaped channel, (2) “two-thirds of the way up to the 180-degree turn,” or (3) “halfway” between the porous plug the 180-turn of the U-shaped channel. 2.10.22 Hr’g Tr. 34:21–24. Counsel was adamant that these boundaries were structural. Pointing to the bottom of the U-shaped channel during the argument, counsel said: “The 180-degree turn is defined right here. It’s structural. It’s absolutely consistent with contentions, and it’s workable, all three [possibilities] are.” 2.10.22 Hr’g Tr. 35:2–4. I then asked: “So that’s [i.e., the 180-degree turn is] what he’s going to define at trial[?] That’s the structure, right there[?]” To which counsel responded: “Correct. I don’t know if he will offer all three [possible definitions] at trial. I suspect we will narrow, Your Honor.” 2.10.22 Hr’g Tr. 35:6–9.

I expressed skepticism during the hearing about Dr. Santiago's proposed testimony, but I am not an artisan of ordinary skill and it occurred to me that perhaps skilled artisans might have some special understanding of structure in fluidic devices that would not be apparent to a lay person. When Magnolia's counsel concluded his remarks, I turned to Kurin's counsel and engaged in the following colloquy:

THE COURT: . . . I'm troubled by [Magnolia's position]. I think a jury will be troubled by it, and I don't know how somebody could tell if they are infringing something if they are told that [the reservoir] is, quote, say two-thirds of the way up to the 180-degree turn.

But there is no functional language here.

[KURIN'S COUNSEL]: There's no functional language; I agree.

And where the functional issue comes in is that what is motivating Dr. Santiago to say maybe it's a two-thirds, maybe it's half, maybe it's something else, is that they have done tests, and they think that they can show there is no mixing in some portion of this.

* * * *

Your Honor, and part of the problem here is that if -- if Magnolia was allowed to proceed, what we have now is a claim construction dispute about what is the meaning of "reservoir."

* * * *

THE COURT: Right. Let's stick first with the structure, okay? And I've already said I'm troubled, but I think a jury would be troubled by it.

But the -- they are, on lines 10 through 18 [on a page of Dr. Santiago's deposition transcript], offering an

opinion which is not using functional language. And if they are going to limit themselves to that, then should I not just say, let [the issue] go [to the jury]?

* * * *

THE COURT: . . . They've got an opinion. They say they are going to limit themselves to lines 10 through 17, [of another page of Dr. Santiago's deposition transcript,] which is structure.

All right. It sounds like maybe I should just deny the motion. That's what they get to do.

2.10.22 Hr'g Tr. 35:13–40:2.

Kurin's counsel at this point again invoked *O2 Micro*, but the construction of "reservoir" he offered was not clear to me except insofar as it, like Magnolia's proffered descriptions of the alleged infringing "reservoir," had an opening and therefore was not fully encased by physical boundaries.

[KURIN'S COUNSEL]: Well, Your Honor, I think what we would want to be clear on the record is we think that it implicates a claim construction dispute, late-breaking claim construction dispute, about "reservoir."

I understand Your Honor may not agree with us, but I just want to be clear.

THE COURT: *Well, how would you define "reservoir"?*

[KURIN'S COUNSEL]: I would say that it's a – in the context of these patents when looking – *what the word "reservoir" means in these patents, it is some form of enclosed space that's bounded – its boundaries can't be defined. And it can be – it has an opening for sure, because things have to get into it, but that's what it is. It's boundaries other than the opening, a physical structure. . . .*

2.10.22 Hr'g Tr. 40:3–17 (emphasis added).

Based on Kurin's counsel's concession that Kurin's own definition of "reservoir" allowed for a structure that was not entirely encased by physical boundaries and Magnolia's counsel's insistence that Dr. Santiago would not resort to functionality to define "reservoir," I concluded that the prudent course of action was to proceed to trial and hear from both sides' experts. But I made it a point to warn Magnolia that dire consequences would follow if Dr. Santiago offered and applied a functional definition of "reservoir" at trial:

THE COURT: . . . I don't think that that definition [of "reservoir" that Kurin] proffered implicates [O]2 [M]icro[] because you are talking about an opening. Anytime you have an opening, you do not have a physical barrier. Both sides have defined "structure" [as] having a part, a physical barrier, which is the housing, and – but both sides right now, including what you've just proffered, posit a definition of reservoir which would have at least some portion of the reservoir being undefined by physical barrier.

So for that reason, it is not [O]2 [M]icro[], and I'm going to deny the *Daubert* motion because I think they have actually shown that they have structural definition, which they stipulated they are going to limit themselves to. ***And if at any point they try to define or justify the opinion [of infringement of the "reservoir" limitation] by resort to functionality, I will entertain a [] motion in limine to strike it, [and] do whatever we have to.***

I can explain to the jury how they said this is not a "means plus function" term and it was not defined in terms of functionality. They'll pay a price if they d[o]

that [i.e., try to define or justify the opinion by resort to functionality].

* * * *

. . . [The] motion is denied because, in fact, [Magnolia’s counsel] have shown and agreed to be limited by a structural definition of the disputed term and, therefore, I do not think they are violating the claim construction order – and really it was stipulated that it was not a means plus function term.

2.10.22 Hr’g Tr. 40:19–42:8 (emphasis added).

To sum up, then: I denied Kurin’s *Daubert* motion based on Magnolia’s assurances that Dr. Santiago would offer and apply to his infringement opinions at trial a structural definition of “reservoir”; but I also made clear that if Dr. Santiago employed a functional definition of “reservoir” at trial, Magnolia would “pay a price” that included, among other potential remedies, the striking of Dr. Santiago’s testimony from the record.

D. Kurin’s Motions *in Limine* and for Leave to Supplement Its Invalidity Theories

On March 1, 2022, three weeks after my ruling on Kurin’s *Daubert* motion, Kurin served on Magnolia a supplemental report from its infringement and invalidity expert, Dr. Erik Antonsson, in which he stated:

[A]ssuming Dr. Santiago’s opinions related to the “reservoir” are correct, it is my opinion that all asserted claims of the [#]001 and [#]483 patents are invalid for indefiniteness for multiple independent reasons. Applying Dr. Santiago’s opinion, a POSA would not be able to determine the scope of any of the asserted claims

with reasonable certainty as it is unclear whether a device, such as the Kurin device, contains a “reservoir” because it is unclear what structural characteristics define the “reservoir” or how many “reservoirs” there may be in that device. And if there are multiple reservoirs or multiple options for the “reservoir,” it is unclear which “reservoir” is the relevant “reservoir” for determining infringement. Lastly, if the boundaries of the “reservoir” change from patient to patient as conditions such as blood pressure are varied a POSA cannot determine whether a device has the “reservoir” without testing the device under all possible use conditions.

D.I. 422-1 at 8–9.

On June 9, 2022, as part of the parties’ Proposed Pretrial Order, Kurin moved *in limine* to preclude Magnolia from presenting Dr. Santiago’s infringement opinions regarding “reservoir” at trial, arguing that the opinions were not disclosed in Magnolia’s infringement contentions and thus were untimely under the Scheduling Order. I denied its motion at the Pretrial Conference because Kurin failed to articulate how it was prejudiced by not learning of Dr. Santiago’s opinions before it did. 6.30.22 Hr’g Tr. 87:18–20.

Two weeks after the Pretrial Conference, Kurin moved for leave to supplement Dr. Antonsson’s opening report with the opinions on indefiniteness set forth in his March 1, 2022 supplemental report. D.I. 421. I heard oral argument on the motion on July 22, 2022 and ruled that I would not decide the motion until after I had heard Dr. Santiago testify at trial. *See* D.I. 464-1 at 28 (7.22.22 Trial Tr. 36:5–37:9; 38:10–22, 40:12–14).

E. Dr. Santiago's Trial Testimony

On the first day of the infringement phase of the trial, without objection from Kurin, Magnolia offered Dr. Santiago as a “technical expert witness with expertise in the design, development, and analysis of fluidic devices.” 7.25.22 Trial Tr. 172:13–16. Immediately before doing so, Magnolia's counsel had this exchange with Dr. Santiago:

Q. Can you estimate how much of your work involves reservoirs in fluidic devices?

A. Yeah. I would say something like half, roughly half of my publications include a device that have some sort of reservoir. It is a very common feature, very common term in my field.

7.25 Tr. 172:6–11. Magnolia's counsel, however, never asked Dr. Santiago during his direct examination to explain in words what a reservoir is—either generally or as the term is used in the #483 patent; and Dr. Santiago never offered such an explanation during his direct testimony.

Magnolia states in its posttrial briefing, D.I. 463 at 9 (citing 7.25 Tr. 198:16–202:8), that Dr. Santiago “offered and applied” an “understanding of ‘reservoir’” in the following portions of his direct examination:

A. . . . [T]he Court ordered us to interpret that as the initial portion of blood removed from the patient and sequestered.

Q. And how did you approach this requirement that includes the fluid reservoir?

A. So I'll do something similar with many of these requirements. Here, I've highlighted the first three words in yellow. So this -- and I'll just show evidence of that, then we will go through the whole thing, the other parts of this requirement.

So this requirement, the device or -- should have, the device that's claimed, should have a fluid reservoir. And if you remember, this is an image from the Kurin video where the initial volume of blood comes in, it travels down this channel here, and it enters this reservoir region where after it's sealed, it's locked in place.

Q. Shall we proceed?

A. Yes, please.

So you're going to see this same image about four different times. This is the second time now. I've now highlighted more words in the claim. So a fluid reservoir disposed in the housing. And we already talked about housing, but you see, if you remember, this is the -- you're looking at the top housing. It's the entire device, but you can most clearly see the top housing. And the reservoir is clearly in the housing, so it meets that requirement.

Q. Continuing to build, what are you showing here?

A. So adding, now, new words in yellow here, in at least partially defined by a seal member. Okay.

So if you remember, this porous plug, this is porous polymer particles that allow air to pass when it's dry. So when the first blood is flowing into the reservoir, the displaced air goes through the porous plug, or when the moisture of the blood hits it, those particles absorb the moisture and seal.

And so it has a reservoir that terminates or it's defined, at least partially defined by a sealed member. So one side of the reservoir has the seal.

Q. Did you personally inspect the seal of the Kurin devices?

A. I did. If you go to the next slide, there will [be] a couple of images that I took from my experiments.

So on the top is this porous plug feature that's in the vent of the Kurin device. Here, you could see the porous plug is made out of these polymer particles that are centered together. Center just means stuck together in such a way that they're still porous through these particles or between these particles. And so air is allowed to pass through these pores. And you need that to happen because you can't fill in a dead-end section of channel like this unless you displace the air.

But, again, when the moisture hits, it absorbs. And in this picture, you can see pretty clearly, the particles have absorbed the moisture, they're swollen. In fact, the whole thing swells and each of the particles swell and now it seals. And as in the video and as in my experiments, this prevents flow of any fluid in or out at this point. Right. So gas can't get in, can't get out, and liquid can't get in or out at that point.

Q. And looking at the remainder of the requirement, did you analyze whether the fluid reservoir you've identified is configured to receive initial volume of blood withdrawn from the patient?

A. Sure. So now this is, again, the same requirement, but I've just highlighted in yellow the last part of it. And that last part is the fluid reservoir configured to receive an initial volume of blood withdrawn from the patient. Okay.

So if you remember, on the left is a Kurin video, on the right is my own experiment. So on the left, we saw the initial volume of blood enter through the -- from the patient through the inlet. It flows through this -- I think the other Kurin lawyer called it a “side channel.” So it enters into this channel, flows around this 180-degree turn. So now it’s flowing back in the direction, but it’s flowing toward the seal, and then it seals.

And so the Kurin devices have this feature which is the fluid reservoir, which is right here, configured to receive an initial volume of blood withdrawn from the patient, and that agrees with their video. It also agrees with my own experiment.

So in my own experiment, the initial amount of blood that comes in was clear, was blood simulant, but it was clear. And you can see that clear liquid here. At this point in the experiment, the seal is already sealed. That is, the porous plug is already sealed. And that’s been, you know, sequestered here in this reservoir.

Q. So we’re back to your roadmap slide. And I can see a check mark next to the fluid reservoir, the requirement that includes a fluid reservoir.

Why did you add that check mark?

A. So that check mark is there to reflect that it’s my opinion that the Kurin devices meet this limitation, this requirement limitation. Yeah.

7.25 Tr. 198:16–202:10.

The quoted testimony speaks for itself. At no point in this testimony (or any other portion of his direct examination) did Dr. Santiago describe or “offer” an “understanding” of the meaning or structure of “reservoir.” Instead, Dr. Santiago merely pointed to an ambiguous “reservoir region” in a demonstrative exhibit that

depicted the Kurin Lock's U-shaped channel. The closest Dr. Santiago came to explaining or defining "reservoir" was saying that the "reservoir region" he pointed to was "at least partially defined by a sealed member." 7.25 Tr. 199:18–200:3.

Consistent with the way Kurin handled Dr. Santiago at his deposition, Kurin's counsel did not press Dr. Santiago during cross-examination at trial about the meaning or structure of "reservoir" or get Dr. Santiago to differentiate what is and what is not a reservoir to an artisan of ordinary skill. It was only at the conclusion of Dr. Santiago's redirect testimony that he was questioned about his "understanding" of the meaning and structure of reservoir:

Q. Would you please explain generally how the term "reservoir" is used in the field of fluidic devices?

A. So you mean like in – not the reservoir of these claims, just the general – or the plain and ordinary meaning?

Q. Correct. The word "reservoir."

A. Yeah. *So a reservoir is a region in a device that holds fluid.* And I say fluid because, I mean, it can hold liquid or it can hold gas. So a region in a device that holds fluid.

Q. *How do you know that the structure you identified as a fluid reservoir in the Kurin Lock for [c]laim 1 from the seal to the 180-degree turn is a "fluid reservoir" as that term i[s] used in the art?*

A. *So this region identified is a region in the device; it holds fluid.*

Q. And is that region also a fluid reservoir that meets the other requirements of [c]laim 1 of the [#]483 patent?

* * * *

Q. Is there any requirement that “reservoir,” as that term is used in the art, is enclosed by a solid boundary?

A. No. In fact, in microfluidics . . . in almost all cases [reservoirs] are not enclosed by solid boundary. There is liquid in the reservoir and there’s liquid in a channel and they are contiguous, right. There’s no solid boundary.

7.25 Tr. 295:9–296:1, 296:15–21. Kurin did not object to this testimony, move to strike it, or seek any other form of relief to address Dr. Santiago’s functional definition (i.e., holding fluid) of the vague “region” of the U-shaped channel he said was the “fluid reservoir” recited in claim 1 of the asserted patent.

F. The Jury Verdict and Kurin’s Request for Posttrial Adjudication of Its Indefiniteness Theory

Kurin moved for judgment as a matter of law on the issue of infringement after Magnolia rested its case. 7.25 Tr. 297, 338. In support of that motion, Kurin argued among other things that, “[t]o the extent that there is a fluid reservoir in the Kurin device it’s the entire U-shaped channel not a subportion of it.” 7.25 Tr. 338:19–21. I did not rule on the motion and instead let the case go to the jury. 7.25 Tr. 349:6–7. The jury found that Kurin’s Lock directly infringed claims 1 and 24 of the #483 patent. D.I. 436 at 2.

Before we began the invalidity and damages phase of the trial, Kurin proposed that instead of submitting its indefiniteness defense to the jury as it had

originally intended, it “would . . . be perfectly happy” for me to decide the issue. 7.26 Trial Tr. 234:3–6. Accordingly, without objection from Magnolia, I denied Kurin’s motion for leave to supplement Dr. Antonsson’s report without prejudice and allowed Kurin to file the pending motion. *See* 7.26 Tr. 243:24–244:6.

I warned Kurin, however, that based on Dr. Antonsson’s credible testimony at trial that the U-shaped channel of the Kurin Lock was a reservoir, *see* 7.26 Tr. 99:9–22, I found it hard to see how Kurin could establish that “reservoir” was indefinite. As I said at the time:

This is going to be really tough [for you], because I’m probably – if you move for it, I’m probably going to basically go back and quote at length Dr. Antonsson and say, “He pretty much knew what [a] reservoir was. He was very credible. He had no problem doing it.” So I think you should really think about whether this is a worthwhile argument to pursue.

7.26 Tr. 243:17–23.

IV. Kurin’s Pending Motion

Consistent with Dr. Antonsson’s supplemental report, the thrust of Kurin’s indefiniteness theory is that the “[f]luid reservoir’ [limitation] in Claim 1 is indefinite because, *as this term was defined by Magnolia and adopted by the jury*, a person of ordinary skill in the art (‘POSA’) could not, with reasonable certainty, identify the ‘fluid reservoir’ in a blood sequestration device.” D.I. 451 at 1 (emphasis added). The problem with this theory is its logic. The initial (and

explicit) premise of the theory’s syllogism—that the definition of “reservoir” offered and applied by Dr. Santiago does not inform a skilled artisan about the scope of the claimed “fluid reservoir”—is true. But the second (implicit) premise of the syllogism—that Dr. Santiago’s definition of “reservoir” bears on whether the “reservoir” limitation in the #483 patent is indefinite—is not. The syllogism is therefore not valid. *See generally* ARISTOTLE, *PRIOR ANALYTICS* bk. A, at 24b18–20 (R. Smith trans., Hackett Publishing Company ed. 1989) (c. 350 B.C.E.) (“A deduction is a discourse in which, certain things having been supposed, something different from the things supposed results of necessity *because these things are so.*” (emphasis added)).

Indefiniteness “is a matter of claim construction,” *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1319 (Fed. Cir. 2008), *abrogated on other grounds by Nautilus*, 572 U.S. at 901; and it is the Court—not a party or the jury—that construes the claims of a patent, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). In this case, the definition of “reservoir” offered and applied in Dr. Santiago’s infringement analysis was *not* the claim construction of “reservoir” I adopted by stipulation of the parties.

I ruled that “reservoir” was to be given its plain and ordinary meaning; and, as acknowledged by the parties in their claim construction briefing and arguments, the plain and ordinary meaning of “reservoir” is a receptacle designed to hold

fluid. A receptacle is—to use Magnolia’s words—“quintessentially structural.” Dr. Santiago, however, testified at trial that the plain and ordinary meaning of “reservoir” is “a region in a device that holds fluid.” This definition is functional, not structural. It defines “reservoir” by what it does—hold fluid—not by its physical or structural attributes. Dr. Santiago’s use of the word “region” at trial compounded the problem because “region” connotes an indefinite area, and thus using that term further suggested to the jury that the claimed “reservoir” need not be structural. *See Region*, Merriam-Webster, <https://www.merriam-webster.com/dictionary/region> (defining “region” as, among other things, “an indefinite area of the world or universe,” “an indefinite area surrounding a specified body part,” and “a sphere of activity”).

Magnolia intimated in its concluding questioning of Dr. Santiago on redirect examination that the flow of the patient’s blood through the Kurin Lock gives structure to and thus creates the claimed reservoir. *See* 7.25 Tr. 296:15–21 (“Q. Is there any requirement that ‘reservoir,’ as that term is used in the art, is enclosed by a solid boundary? A. No. In fact, in microfluidics, . . . in almost all cases [reservoirs] are not enclosed by solid boundary. There is liquid in the reservoir and there’s liquid in a channel and they are contiguous, right. There’s no solid

boundary.”). But Dr. Santiago did not elaborate on this concept at trial; nor did he ever apply this concept to identify a structure for the claimed “fluid reservoir.”¹

Dr. Santiago’s testimony does not render “reservoir” as used in claim 1 and 24 of the #483 patent indefinite, but because it was the only expert infringement testimony Magnolia offered at trial, it seems likely that Kurin will prevail on its renewed motion for JMOL of noninfringement of at least claim 1 and perhaps claim 24 as well. Since Kurin agreed to dismiss its invalidity counterclaims if it

¹ Dr. Santiago opined at trial that contiguous forces of fluid resistance within the flow of the patient’s blood through the Kurin Lock cause the sequestration of the initial volume of blood inside the vague region in the Lock’s U-shaped channel he identified as the “reservoir.” *See* 7.25 Tr. 216:9–23; *see also* 7.25 Tr. 346:8–15 (Magnolia’s counsel noting that “Professor Santiago’s opinion[] was that to sequester is merely to set aside, and fluid dynamics, it’s known in the art, [has] many different ways to set aside. You do not need a solid barrier in order to do that. And, in fact, the way that a particular volume is sequestered and set aside in the Kurin Lock is a way that’s very common in fluid dynamics. And it does not require a solid barrier.”). If Magnolia were in fact asserting that the sequestration of the patient’s blood creates the “fluid reservoir,” that would be problematic for at least three reasons. First, the asserted claims’ “sequestration” limitation is separate and distinct from the claims’ “reservoir” limitation. *See* D.I. 75 at 2; D.I. 448 at 10. Second, such an assertion would effectively define “reservoir” in functional terms—i.e., by where the initial volume of blood is sequestered. Third, if the fluidics of the patient’s blood flow created the claimed “fluid reservoir,” then the manufacture and sale of the Kurin Lock would not directly infringe claim 1’s “fluid reservoir” limitation. Magnolia, however, accused Kurin only of direct infringement of claim 1; it did not accuse Kurin of inducing clinicians or patients to infringe claim 1. (Of course, one might similarly argue that the U-shaped channel does not become a “reservoir” unless and until the porous plug is turned into a seal by contact with a patient’s blood; but Kurin has not disputed that the U-shaped channel meets the “reservoir” limitation of the asserted claims.)

prevails on infringement, *see* D.I. 401 at 3, I think it prudent to stay resolution of the pending motion until the parties have briefed and I have resolved Kurin's renewed JMOL motion.

* * * *

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 Fourth day of August in 2023, for the reasons set forth in the Memorandum Opinion issued this day, **IT IS HEREBY ORDERED** that resolution of Defendant Kurin, Inc.'s motion for judgment of invalidity of Claims 1 and 24 of U.S. Patent No. 10,039,483 for indefiniteness (D.I. 451) is **STAYED** until resolution of Kurin's renewed motion for judgment as a matter of law of noninfringement.



CHIEF JUDGE