IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL TECHNOLOGIES, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. 19-97-CFC-CJB
KURIN, INC.,	)	**[UNDER SEAL]**
Defendant.	)	

REPORT AND RECOMMENDATION

As announced at the telephonic hearing on December 10, 2020, I recommend that the Court DENY Plaintiff's Motion for Leave to Amend the Complaint (D.I. 166). My Report and Recommendation was announced from the bench at the conclusion of the hearing as follows:

> Now we're going to turn to the motion to amend the complaint. I'm going to issue this as a report and recommendation. I am not going to be issuing a separate written opinion, but we will issue a document that incorporates [my] oral recommendation by reference.
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> There was full briefing on [this motion].[1] The parties filed numerous exhibits attached to the briefing and two declarations, and there were many, many exhibits attached to the [proposed] amended complaint.[2] I also heard lengthy oral argument here today.
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> For the reasons I'm going to discuss, I recommend that Judge Connolly deny Magnolia's motion for leave to amend its complaint to add a false advertising claim. This Court has previously treated a denial of a motion to amend the complaint as a claim dispositive motion, which means that the magistrate judge's

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1 *See* D.I. 167, 184, 190.

2 *See* D.I. 166 (Ex. 1), 185, 191.

ruling is issued as a report and recommendation, and I will do that here.[3]

[Background]

. . . [T]his patent infringement action was filed in January 2019. The Court entered its scheduling order on June 21, 2019 and set the deadline for amending the pleadings as December 16, 2019.[4]

Pursuant to the scheduling order, Plaintiff served its list of asserted claims and initial infringement contentions on July 17, 2019. As is clear from Plaintiff's infringement contentions and the parties' briefing on this motion (and the parties' briefing on other motions filed with the court, including's Kurin's motion for leave to file an early summary judgment motion[5]), a hotly disputed issue in [this] patent infringement case is whether Kurin's accused infringing products allow mixing between blood in the first path and blood in the second path.

That factual dispute may have implications for the infringement case in a number of ways. I don't want to oversimplify it, but after examining the record, I think it is fair to say that Kurin says that it doesn't meet certain limitations required by the asserted claims—for example, the diverter limitation, and others—because its product allows mixing between the blood in the two flow paths. Magnolia disputes that. As I understand it, part of Magnolia's evidence that certain claim limitations are met by Kurin's product are Kurin's own marketing materials and statements to the FDA about how its product works. Those materials say that Kurin's product has a first flow path that is, for example, some combination of "locked," "contained," "sealed," "sidelined," "captured," "corralled," "diverted and sequestered," "held in a side chamber," and/or "retained." Essentially, Magnolia intends to argue to the jury that it should find that there is limited or no mixing between the blood in the two flow paths, because that is what Kurin is telling the public and the FDA. And because there is limited or no mixing, certain of the claim limitations are met and Kurin infringes.

But there's a twist to this story. While the patent case has been ongoing, the parties have been fighting with each other about

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[3] *See, e.g.*, *Paoli v. Stetser*, No. 12-66-GMS-CJB, 2013 WL 2154393, at *1 n.1 (D. Del. May 16, 2013).

[4] D.I. 24 ¶ 8.

[5] D.I. 78, 79, 85, 86.

the contents of their respective advertising in the U.S. District Court for the Southern District of California. Prior to Magnolia filing the patent infringement complaint in this case, Kurin sued Magnolia in California for false advertising under the Lanham Act (and asserted other claims).[6]

On August 13, 2018, Magnolia asserted a counterclaim in that case, alleging that Kurin's advertisements constituted false advertising under Section 43(a) of the Lanham Act. Among other things, Magnolia challenged certain Kurin advertisements that suggested that Kurin's products contain a "lock, physical barrier, or any other mechanical isolation capability."[7] Magnolia's counterclaim in that case went on to allege that "upon information and belief, Kurin Lock does not contain a lock, physical barrier, or any other mechanical isolation capability. Upon information and belief, contrary to its representations to consumers and brand messaging, in Kurin's device there is no lock that physically separates the contaminants from the sample blood pathway. Accordingly, Kurin's representations to consumers that Kurin's device contains a 'lock' is false and/or misleading because it implies that its blood collection set employs a physical barrier when, in fact, no such physical barrier exists."[8]

Discovery proceeded in the California case and, on May 24, 2019, Magnolia obtained deposition testimony from Kurin's CEO, Bob Rogers, who testified that blood entering the side channel of the Kurin Lock "could . . . end up in the blood culture bottle."[9] In other words, there could be mixing between blood in the two paths.

On July 20, 2020, the California court held that Magnolia's counterclaim survived Kurin's motion for summary judgment of no liability.[10] As I will explain more in a minute, the California case is still pending.

Meanwhile, discovery has been proceeding in this case. On August 14, 2020, Kurin produced videos of internal tests conducted

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6 *See* D.I. 185, Ex. M.

7 *See* D.I. 185, Ex. N ¶ 106.

8 *Id.*

9 D.I. 185, Ex. O at 216:12-217:23.

10 *See Kurin, Inc. v. Magnolia Medical Technologies, Inc.*, No. 3:18-cv-01060, D.I. 85 (S.D. Cal. May 29, 2018).

by Kurin a year prior that, according to Kurin, show that the initial volume of blood drawn into the Kurin product's side channel ultimately exchanges with the subsequent blood sample volume.[11] In other words, the blood in the two paths mixes. Magnolia contends—and I assume for purposes of this decision—that those videos were provided to Kurin's CEO, Bob Rogers, in May of 2019 by Kurin's development engineer, Kevin Nason,[12] and should have been produced to Magnolia prior to August 14, [2020].

Subsequently in August 2020, Rogers and Nason testified about mixing between the two flow paths.[13] In his August 18, 2020 deposition testimony, Rogers confirmed, among other things, that everything in the Kurin Lock's side channel will move into the sample channel, ultimately resulting in a "full exchange."[14] On August 20, 2020, Nason testified that based on the internal Kurin testing, certain representations in Kurin's marketing videos were inaccurate.[15]

Kurin's video testing and deposition testimony supports Kurin's apparent theory in this case that it does not infringe because its product allows mixing. However, according to Magnolia, if Kurin is right about that, then Kurin's advertisements suggesting that the blood in the first flow path is "locked," "sequestered," *et cetera*, are false.

Accordingly, Magnolia wants to proceed with a false advertising claim, and it wants to try its false advertising claim to the same jury as its patent infringement claim—its strategy being that if it loses on the patent infringement claim because Kurin's product allows mixing, then it will win on the false advertising claim because Kurin's product allows mixing. Magnolia also contends that the recently produced test results and testimony regarding the operation of Kurin's product should have been produced in this case and the California case long before now. And Magnolia contends

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[11] D.I. 166, Ex. 1 ¶¶ 39, 40.

[12] *Id.* ¶ 41; *see also* D.I. 167 at 7.

[13] D.I. 166, Ex. 1 ¶¶ 36, 37; *see also* D.I. 166-24, 166-25 (Deposition transcripts of Kevin Nason and Bob Rogers attached as Exs. V and W to D.I. 166, Ex. 1).

[14] D.I. 166, Ex. 1 ¶ 36.

[15] *Id.* ¶ 37.

that Kurin is playing games by taking one position in California and another position here.

Instead of proceeding in the California action, on September 4, 2020, Magnolia moved to voluntarily dismiss its Lanham Act claim in the California case.[16] Then, on September 8, 2020, Magnolia filed this motion seeking leave to amend its complaint [in this case].[17] It wants to add a claim of false advertising under Section 43(a) of the Lanham Act. Magnolia alleges that Kurin's recent testimony and the newly produced testing videos show that Kurin had been lying in its public advertising where Kurin described the initial blood drawn into the Kurin Lock is locked, contained, sealed, sidelined, captured, or corralled in the side channel of the Kurin Lock to prevent it from entering the blood collection sample.[18] Magnolia also alleges that Kurin lied to the FDA in filings [that stated] that the Kurin Lock diverts the initial aliquot of blood while the blood is being drawn, and then [Kurin] touted its FDA approval in its advertisements.[19]

[Legal Standards]

"As a general matter, Rule 15(a) governs the amendment of pleadings before trial. That rule provides that '[t]he court should freely give leave [to amend] when justice so requires.'"[20] If we were operating solely under Rule 15(a), I would grant Magnolia leave to amend the complaint.

However, "when a party seeks to amend a pleading after the scheduling order's deadline for pleading amendments has passed, the court will apply Rule 16(b) as opposed to Rule 15(a)."[21] Under Rule 16(b)(4), the scheduling order may be modified "only for good

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16 *See Kurin, Inc. v. Magnolia Medical Technologies, Inc.*, No. 3:18-cv-01060, D.I. 95 (S.D. Cal. May 29, 2018).

17 D.I. 166.

18 D.I. 166, Ex. 1 ¶¶ 33, 34.

19 *Id.* ¶¶ 66, 67.

20 *In re Fisker Auto. Holdings, Inc. Shareholder Litig.*, No. 13-2100-CFC, 2018 WL 5113964, at *3 (D. Del. Oct. 12, 2018) (quoting Fed. R. Civ. P. 15(a)(2)).

21 *Id.*

cause and with the judge's consent."[22] . . . [T]o show good cause, the movant must demonstrate that "despite diligence, the proposed claims could not have been reasonably sought in a timely manner."[23] The focus of the good cause inquiry is therefore on the diligence of the moving party.[24] In assessing diligence, the court asks whether the movant possessed or through the exercise of reasonable diligence should have possessed the knowledge necessary to file a motion before the deadline expired.[25]

[Discussion]

The parties agree that the good cause standard under Rule 16 applies here. They also agree that good cause requires a showing of diligence. Applying that standard, I find that Magnolia has not been diligent in adding the Lanham Act claim in this case because it possessed the knowledge necessary to add the claim before the deadline to amend expired.

To plead an unfair competition claim based on false advertising, a plaintiff must allege, among other things, that the defendant made a false or misleading statement as to its own product or another's, and that the statement actually deceived or at least has a tendency to deceive a substantial portion of the intended audience.[26]

Magnolia contends that it has shown diligence because it only obtained the evidence to show that Kurin's advertising statements were false in August 2020, and it filed its motion shortly after, on September 8, 2020.

Having reviewed the record, I agree with Magnolia [that the new evidence disclosed] in August 2020 [supports] Magnolia's false advertising claim. But the operative facts are [1] the contents of the [advertising] statements and [2] whether they are false or misleading

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[22] Fed. R. Civ. P. 16(b)(4).

[23] *Venetec Int'l v. Nexus Med.*, 541 F. Supp. 2d 612, 618 (D. Del. 2008).

[24] *Glaxosmithkline LLC v. Glenmark Pharms. Inc.*, No. 14-877-LPS-CJB, 2016 WL 7319670, at *1 (D. Del. Dec. 15, 2016).

[25] *See, e.g.*, *Lord v. Consolidated Rail Corp.*, No. 13–0784, 2015 WL 6163951, at *1 (D.N.J. Oct. 19, 2015).

[26] *Incarcerated Enter., LLC v. CNBC, LLC*, 331 F. Supp. 3d 352, 362 (D. Del. 2018).

[because they inaccurately describe how Kurin's product functions]. Magnolia has not disputed that it had access to the statements in Kurin's public advertising that it contends were false before the deadline to amend the pleadings. Moreover, I find that the fact of how Kurin's product actually works is a fact that Magnolia had access to prior to the deadline. It is a product that Magnolia had the tech specs for and samples of as early as June of 2019, and Magnolia could have done the same test that Kurin did to find out how the Kurin product worked. Magnolia may not have had a motivation to perform that test, and I can think of strategic reasons why Magnolia would not have wanted to perform that test. But it could have, through the exercise of reasonable diligence, learned the knowledge necessary to add the false advertising claim prior to the deadline.

I could deny the motion on that basis alone, but I also agree with Kurin that the record demonstrates that Magnolia did have actual notice prior to the amendment deadline that there could be mixing going on in the Kurin product. Magnolia's false advertising claim in California is based in part on Magnolia's assertion that there is no physical barrier between the two blood flow paths in Kurin's product. For purposes of the argument, I'll accept [Magnolia's counsel's] representations that the case there is different, because it's about physical barriers as opposed to mixing (although I'm not entirely convinced). However, Kurin points to other documents in the record that establish that Magnolia had actual notice of potential mixing, including, for example, a prior deposition of Kurin's CEO.[27]

Magnolia argues that there's a difference between what it knew before August 2020, that there was a risk of mixing between the side and sample channels, and what it learned in August, which is that Kurin had determined that there was full exchange. But the operative fact that needed to be discovered to bring a false advertising claim is not how Kurin *believes* its product functions. That is certainly evidence that could support a finding of how the product functions. But the operative fact is how the product *actually* functions. And Magnolia could have discovered that fact prior to the deadline to amend the pleadings.

I reviewed the cases cited by Magnolia, including the *Fisker*, *Home Semiconductor*, and *Cordance* cases, and I conclude that they are inapposite.[28] Essentially, the parties seeking to amend in those

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[27] *See supra* n.9; *see also* D.I. 185, Exs. C, D, K, L.

[28] *See Fisker*, 2018 WL 5113964, at *8; *Home Semiconductor*, 2019 WL 2135858, at *5; *Cordance Corp. v. Amazon.com, Inc.*, 255 F.R.D. 366, 372-73 (D. Del. 2009).

> cases learned information after the deadline that they needed to establish as an element of the claim they sought to add. Here, in contrast, Magnolia could have discovered information about how Kurin's product worked prior to the deadline simply by testing the product. I'm certainly troubled by the picture Magnolia paints of what went on here. But the question of whether Kurin sat on evidence that should have been produced in the California case and earlier in this case is not before me. The question I am asked to decide is whether the disclosure of that evidence reveals new facts that Magnolia could not have discovered earlier that provide a basis for the false advertising claim it now seeks to add in this case, and I conclude that it did not.
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> In sum, I find that Magnolia possessed, or through the exercise of reasonable diligence should have possessed, the knowledge necessary to file its motion for leave to amend before the deadline expired. Accordingly, I conclude that Magnolia has not shown good cause under Rule 16(b) to add [the false advertising] claim to this case. Because I find that Magnolia has not shown good cause, I don't reach Kurin's claim splitting argument. And I therefore recommend that the Court deny Magnolia's motion for leave to amend the complaint.
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> Finally, I'm not ruling that Magnolia can't bring a case against Kurin for false advertising based on the evidence it now has. All I'm saying is that it's too late to add that claim to this case.
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> That concludes my report and recommendation.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), (C), Federal Rule of Civil Procedure 72(b)(1), and District of Delaware Local Rule 72.1. Any objections to the Report and Recommendation shall be filed within fourteen days and limited to ten pages. Any response shall be filed within fourteen days thereafter and limited to ten pages. The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the district court.

The parties are directed to the Court's "Standing Order for Objections Filed Under Fed. R. Civ. P. 72," dated October 9, 2013, a copy of which can be found on the Court's website.

This Report and Recommendation relies on material set forth in filings that remain under seal. Accordingly, I am issuing this Report and Recommendation under seal, pending review by the parties. In the event that any party contends that portions of this Report and Recommendation should be redacted, the parties shall jointly submit a proposed redacted version no later than 6:00 p.m. on January 7, 2021, for review by the undersigned, along with a motion supported by a declaration that includes a detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted)). The Court intends to issue a public version of this Report and Recommendation on or around January 11, 2020.

Dated: December 28, 2020

The Honorable Jennifer L. Hall
United States Magistrate Judge