	Case 2:22-cv-00490-SRB	Document 1	Filed 03/29/22	Page 1 of 58
1	Eric M. Fraser, 027241			
2	Phillip W. Londen, 032488			
3	OSBORN MALEDON, P.A. 2929 North Central Avenue, Suite	2100		
4	Phoenix, Arizona 85012 (602) 640-9000			
5	efraser@omlaw.com			
6	plonden@omlaw.com			
7	Todd G. Miller (<i>pro hac vice to be</i> Oliver J. Richards (<i>pro hac vice to</i>			
8	FISH & RICHARDSON P.C.	be filea)		
9	12860 El Camino Real, Suite 400 San Diego, California 92130			
10	(858) 678-5070 miller@fr.com			
11	ojr@fr.com			
12	Frank E. Scherkenbach (pro hac vi	ice to be filed)	
13	FISH & RICHARDSON P.C. One Marina Park Drive			
14	Boston, Massachusetts 02210-187	78		
15	(617) 542-5070 scherkenbach@fr.com			
16	Attorneys for Plaintiff			
17				т
18			STRICT COUR	1
19	DI	ISTRICT OF	ARIZONA	
20	Treace Medical Concepts, Inc.,	N	No.	
21	Plaintiff,		COMPLAINT F	
22	VS.		NFRINGEMEN NFRINGEMEN	NT, TRADEMARK NT, UNFAIR
23	Fusion Orthopedics, LLC,		COMPETITION NFRINGEMEN	N AND COPYRIGHT
24	Defendant.			
25				
26				
27				
28				

1	Plaintiff, Treace Medical Concepts, Inc. ("Treace Medical"), by its attorneys,	
2	brings this Complaint against defendants Fusion Orthopedics, LLC ("Fusion"). Treace	
3	Medical alleges as follows:	
4	NATURE OF THE ACTION	
5	1. This is a civil action arising out of Fusion's: (a) patent infringement in	
6	violation of the Patent Laws of the United States, 35 U.S.C. §§ 271 and 281-285; (b)	
7	trademark infringement under 15 U.S.C. § 1114(a); (c) federal unfair competition; (d)	
8	common law trademark infringement and unfair competition, and (e) federal copyright	
9	infringement under 17 U.S.C. § 101, et seq.	
10	THE PARTIES	
11	2. Treace Medical is a Delaware corporation having its principal place of	
12	business at 203 Fort Wade Rd., Suite 150, Ponte Vedra, Florida, 32081.	
13	3. On information and belief, Fusion is an Arizona limited liability company	
14	having its principal place of business at 4135 S. Power Rd., Ste. 118, Mesa, Arizona,	
15	85212.	
16	JURISDICTION AND VENUE	
17	4. This Court has subject matter jurisdiction over Treace Medical's patent	
18	infringement claims under 28 U.S.C. § 1331 and 1338(a).	
19	5. This Court has subject matter jurisdiction over Treace Medical's federal	
20	trademark infringement claim under 15 U.S.C. § 1121(a), and under 28 U.S.C. §§ 1331	
21	and 1338.	
22	6. This Court has subject matter jurisdiction over Treace Medical's common	
23	law trademark and unfair competition claims under 15 U.S.C. § 1121(a) and under 28	
24	U.S.C. §§ 1331 and 1338(b).	
25	7. This Court has subject matter jurisdiction over Treace Medical's federal	
26	copyright infringement claim under 28 U.S.C. §§ 1331 and 1338(a).	
27		
28		
	1	
1	1	

22 13. In 2015, Treace Medical introduced surgeons to a better way to surgically 23 treat bunions. Treace Medical's novel methods led to greatly improved patient outcomes and caused a paradigm shift in the way surgeons performed bunion surgery. Treace 24 Medical's patented surgical methods seek to restore the natural biomechanical structure of 25 the foot by restoring the tri-planar alignment of the patient's big toe, or more specifically, 26 the relative orientation of the medial cuneiform and first metatarsal bones and the 27

issue. They are a deformity that can result in painful disability. 12. Bunions often progress to the point of requiring surgical intervention. For 17 decades, traditional bunion surgery produced mixed results. With traditional bunion 18 19 surgery techniques, the relevant bones of the foot were cut, reshaped and the cosmetic bump addressed. These traditional techniques, however, did not restore the foot's natural 20 biomechanical structure. 21

Treace Medical is the world's leading designer, developer and manufacturer 11 11. of surgical instruments and surgical methods focused on the management of bunion 12 deformities and related midfoot correction through its Lapiplasty[®] 3D Bunion 13 CorrectionTM procedure. Bunions are the most commonly encountered forefoot problems. 14 Recognizable as a bump on the side of the big toe, bunions are not merely a cosmetic 15 16

Treace Medical's Revolutionary LAPIPLASTY[®] 3D Bunion Correction[™]

FACTUAL BACKGROUND

6 additional bases for the Court's exercise of personal jurisdiction over Fusion. 7 Venue is proper in this district under 28 U.S.C. §§ 1391(b), (c), and 1400(a) 10. 8 and (b).

9. On information and belief, Fusion is doing business in this judicial district and has committed one or more of the acts complained of in this judicial district, providing

2 3

4

5

9

10

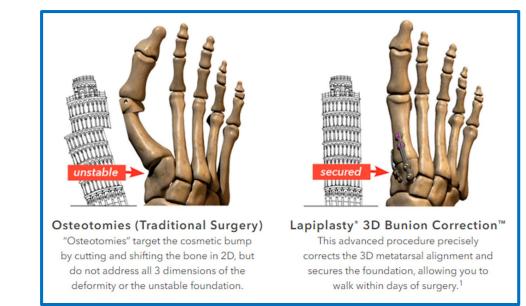
1

8. This Court has personal jurisdiction over Fusion because Fusion is an Arizona limited liability company and has a registered agent for service of process in this state.

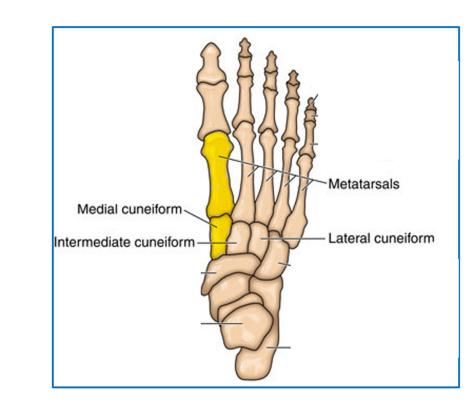
Case 2:22-cv-00490-SRB Document 1 Filed 03/29/22 Page 3 of 58

cuneiform-metatarsal joint. Treace Medical's procedure allows patients to walk in a
 surgical boot within days of the surgery.

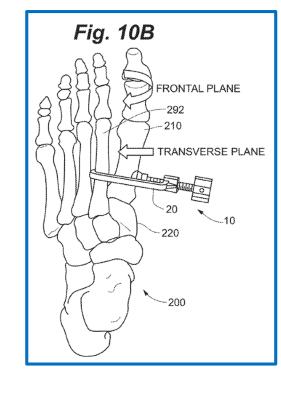
14. A simplified comparison of traditional bunion surgery with Treace Medical's LAPIPLASTY[®] 3D Bunion Correction[™] surgical procedure is shown below:



15. The bones of the foot most relevant to this case are the first metatarsal and the medial cuneiform. The first metatarsal and medial cuneiform bones (highlighted in yellow in the figure below) and the joint (cuneiform-metatarsal joint) between them are the general focus of bunion surgery using Treace Medical's patented methods.

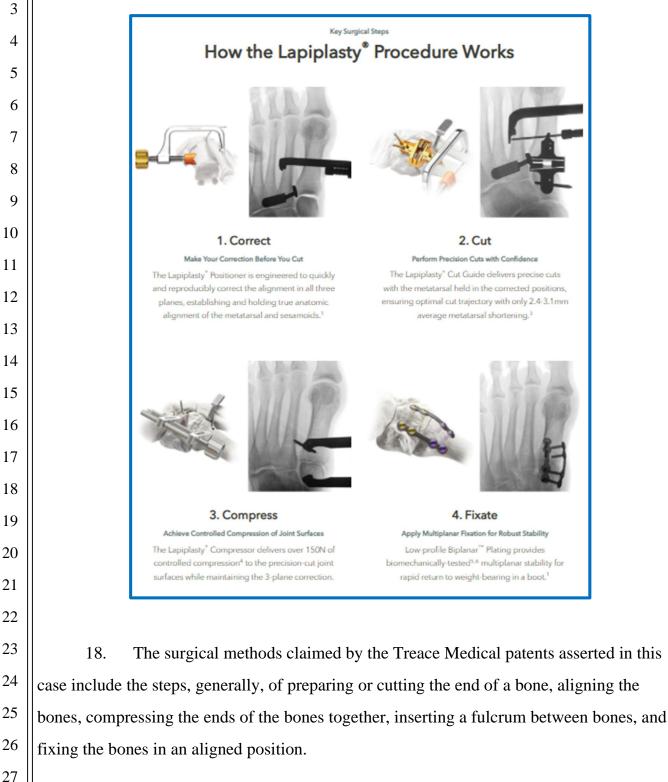


16. Treace Medical's LAPIPLASTY[®] 3D Bunion Correction[™] corrects the alignment of the first metatarsal in three planes: the transverse plane (right to left direction in the figure below), the sagittal plane (into and out of the page in the figure below) and the frontal plane (the big toe is rotated clockwise when viewed end on by the surgeon).





Treace Medical's LAPIPLASTY[®] 3D Bunion Correction[™] allows the 17. patient to quickly return to weight-bearing use (in a boot) of the treated foot (see below).



19. Treace Medical's surgical method has received extensive industry praise. As a result, surgeons have increasingly chosen to change the way they treat bunions, moving away from traditional surgical methods to Treace Medical's LAPIPLASTY[®] 3D Bunion CorrectionTM.

20. Unfortunately, along with praise and the commercial success of Treace Medical's LAPIPLASTY[®] 3D Bunion Correction[™], have come copyists like Fusion, seeking to capitalize on Treace Medical's pioneering technology, Treace Medical's impressive clinical data and Treace Medical's commercial achievements for their own financial gain. Fusion has infringed Treace Medical's patent, trademark and copyright rights.

Fusion's Infringing LapiLock 4D Bunion Correction System and Method

21. Fusion has an internet website at <u>www.fusionorthopedics.com</u>. On that website, Fusion promotes its LapiLock 4D Bunion Correction System to both patients and surgeons. For example at, <u>https://lapilockbunionsurgery.com/?radius=25</u>, Fusion promotes its LapiLock 4D Bunion Correction and implant options to patients and provides a patientdirected video describing its LapiLock 4D Bunion Correction Surgery.

The LapiLock 4D Correction Surgery

Break-through Bunion Surgery is finally here with the FDA cleared LapiLock 4D Correction System.

Bunion surgery requires the realignment of your toe and a surgical implant to fuse the unstable joint. The patent pending LapiLock 4D Correction System by Fusion Orthopedics provides the necessary realignment and 11 unique implant options for bunion surgery depending on patient preference and needs.

FIND A DOCTOR

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

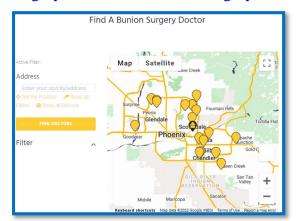
22. While the above excerpt from Fusion's website states that LapiLock 4D Correction System is FDA cleared, there is no record of a clearance of this system in the FDA's 510(k) database (see below).

FDA U.S. FOOD & DRUG	Follow FDA	En Español SEARCH
Home Food Drugs Medical Devices F	Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterina	ry Cosmetics Tobacco Products
510(k) Premarket Notific FDA Home Medical Devices Database		6 B 🔤
New Search	No records were found with Device Name: Lap.Lock Decision Date T	o: 02/28/2022
Page Last Updated: 02/21/2022 Note: If you need help accessing information in diffe	arent file formats, see Instructions for Downloading Viewers and Players	
Note: If you need help accessing information in diffe Language Assistance Available: Español 繁體中文 English	arent file formats, see Instructions for Downloading Viewers and Players. Tiểng Việt 한국어 Tagalog Pyccoxit بحرية Kreyöl Ayisyen Français Polski Po onfact FDA Careers FDA Basics FOIA No FEAR Act Nondis	-
Note: If you need help accessing information in diffe Language Assistance Available: Español 繁體中文 English	[Tiẩng Việt [한국아] Tagalog Pyccoxit ਪ _ਿ ਪ੍ਰਮੇ Kreyði Ayisyen Français Polski Pc ontact FDA Careers FDA Basics FOIA No FEAR Act Nondis	-

23. While the above except from Fusion's website also states that the LapiLock
4D Correction System is patent pending, there are no published patent applications
available on the United States Patent and Trademark Office's ("USPTO") website
assigned to Fusion that describe or claim Fusion's LapiLock 4D Correction System or the
method of its use.

24. Fusion's internet website also invites prospective patients to "FIND A DOCTOR". By pressing the "FIND A DOCTOR" button, the prospective patient is able to select from doctors in the greater Phoenix area at the link

https://lapilockbunionsurgery.com/find-a-bunion-surgery-doctor/?radius=25



25. Treace Medical has spent considerable amounts of money educating surgeons about the benefits of LAPIPLASTY[®] 3D Bunion Correction[™] over traditional bunion surgery and on training surgeons in how to correctly perform LAPIPLASTY[®] 3D Bunion Correction[™]. Treace Medical sponsors cadaver labs and other educational seminars where surgeons can learn from and practice LAPIPLASTY[®] 3D Bunion Correction[™] with experienced LAPIPLASTY[®] 3D Bunion Correction[™] surgeons before they perform this surgery on their own.

26. On information and belief, Fusion targeted surgeons who are trained in performing LAPIPLASTY® 3D Bunion Correction[™] as customers for its LapiLock 4D Correction System. By targeting trained LAPIPLASTY[®] 3D Bunion Correction[™] surgeons, Fusion avoids the substantial cost inherent in converting surgeons who perform traditional bunion surgery to a new technique and then ensuring that these surgeons perform the new technique correctly. Fusion's efforts to target surgeons trained in performing LAPIPLASTY[®] 3D Bunion Correction[™] have been most pronounced in Arizona and Utah. Fusion identifies fourteen (14) LAPIPLASTY[®] 3D Bunion Correction[™] trained surgeons from these states at its "FIND A DOCTOR" link.

Case 2:22-cv-00490-SRB Document 1 Filed 03/29/22 Page 10 of 58 LAPILOCK SURGICAL TECHNIQUE Learn More About LapiLock 4D Bunion Correction SUBMIT

8 27. On information and belief, Fusion has also been hiring and attempting to hire 9 sales representatives who represent Treace Medical and have been trained by Treace Medical to understand and sell Treace Medical's LAPIPLASTY® 3D Bunion 10 Correction[™], to promote Fusion's LapiLock 4D Bunion Correction, instead, to Treace 12 Medical's customers and potential customers.

28. Fusion's internet website also includes a "Surgeon Portal" at https://lapilockbunionsurgery.com/surgeons/ where surgeons can download a current version of the "LAPILOCK SURGICAL TECHNIQUE" document ("LapiLock Brochure") or watch a video demonstrating and explaining the LapiLock 4D Bunion Correction System and method of use titled DTP003 Rev 3 Surgical Technique Video ("LapiLock Video") or "Learn More About LapiLock 4D Bunion Correction" by submitting their contact information.

29. Fusion has used and is using and is offering to sell and selling technology that Treace developed over the past eight years at great expense. Treace Medical's LAPIPLASTY® 3D Bunion CorrectionTM has been refined and tested over that time to deliver optimum surgical results for patients. On information and belief, Fusion's LapiLock 4D Bunion Correction has been subject to little or no clinical testing.

1

2

3

4

5

6

7

30. On information and belief, surgeons led to believe that Fusion's LapiLock 4D Bunion Correction will produce the consistently positive results that they achieve with Treace Medical's LAPIPLASTY[®] 3D Bunion CorrectionTM have instead experienced inconsistent results with Fusion's LapiLock 4D Bunion Correction, including failure of bones to fuse post-surgery.

6 31. On information and belief, patients experiencing poor outcomes with 7 Fusion's LapiLock 4D Bunion Correction are unlikely to distinguish between Fusion's 8 surgical method and system and Treace Medical's surgical method and system. On 9 information and belief, these patients are, however, likely to tell their friends and 10 colleagues about their dissatisfaction with the "latest" surgical technique for treating bunions. On information and belief, this bad "word of mouth" taints Treace Medical's LAPIPLASTY[®] 3D Bunion CorrectionTM in the minds of prospective patients. On 12 13 information and belief, this bad "word of mouth" can also cause prospective patients who would otherwise be helped through surgery with Treace Medical's LAPIPLASTY® 3D 14 15 Bunion CorrectionTM to unnecessarily forego care and endure great pain and ongoing 16 disfigurement.

17

1

2

3

4

5

11

Treace Medical Requested Fusion Discontinue its Improper Activities

18 32. On February 16, 2022, Mr. John Treace, the Chief Executive Officer and 19 Founder of Treace Medical and a co-inventor of the '590 Patent, sent a letter to Mr. Adam 20 Cundiff, the Chief Executive Officer of Fusion. Mr. Treace's letter attached a copy of the 21 590 Patent and a detailed claim chart explaining, with citation to the LapiLock Brochure 22 and LapiLock Video, how Fusion's LapiLock 4D Bunion Correction infringed the claims 23 of Treace Medical's '590 Patent. Mr. Treace's letter also explained that Fusion's use of 24 the mark LapiLock 4D Bunion Correction infringed Treace Medical's registered trademark 25 LAPIPLASTY and 3D BUNION CORRECTION mark and was likely to cause 26 confusion—confusion that could lead Treace Medical's customers and potential customers 27 to mistakenly believe that Fusion's LapiLock 4D Bunion Correction is manufactured by 28 Treace Medical, distributed by Treace Medical, associated or connected with Treace

||

1	Medical, or had the sponsorship, endorsement or approval of Treace Medical. Mr. Treace
2	asked that Fusion confirm, no later than March 2, 2022, that it would:
3	1. Stop making, using, importing, offering for sale, and selling in the
4	United States the devices used with [Fusion's] LapiLock;Stop inducing infringement of [Treace Medical's] patents by removing
5	all materials describing LapiLock from its own websites and all affiliated websites;
6	3. Stop distributing all printed and electronic literature related to
7	LapiLock;4. Stop all other activities that describe or encourage the performance of
8	[Treace Medical's] patented methods using Fusion products;5. Stop using the LAPILOCK mark, "4D Bunion Correction" language
9	and all other confusingly similar themes, text and illustrations;6. Produce to Treace [Medical, Fusion's relevant] sales information for the
10	LapiLock system and components; and
11 12	7. Produce to Treace [Medical] all existing LapiLock inventory, training supplies, kits, loaners, demonstration products, related devices and
12	promotional literature (or certify to Treace [Medical] in writing that the same have been destroyed).
14	33. On February 17, 2022, Mr. Sam Rocereta, representing himself as General
15	Counsel for Fusion, acknowledged receipt of Mr. Treace's letter and responded, copying
16	Adam Cundiff, Nathan Peterson (Fusion's President and Co-Founder) and Jason Graff
17	(Fusion's Patent attorney) as follows:
18	John,
19	I am in receipt of your February 16th, 2022 correspondence addressed to Mr.
20	Cundiff. I write as attorney for Fusion Orthopedics and if you are represented by an attorney, please put me in touch with them.
21	Fusion appreciates the positions outlined in the correspondence. To be clear,
22	Fusion respects all intellectual property rights and would never infringe on
23	anyone's intellectual property rights intentionally.
24	Generally, Fusion's position is contrary to the allegations in the correspondence. After cursory review, Fusion disagrees with your
25 26	assessment that the Lapilock product infringes with the two '590 patent
20	independent claims. Perhaps most concerning of the '590 patent claims is the probability that well known prior art existed before your earliest priority
28	date. Intellectual property counsel is further assessing your allegations, claims, patent enforceability, and demands, as well as our pending patents.
	11

	Case 2:22-cv-00490-SRB Document 1 Filed 03/29/22 Page 13 of 58			
1 2	Congratulations on your remarkable success with TMCI. As you envision productive conversations, or opportunities for our companies to work together, always feel free to reach out.			
3	Kind regards,			
4	Killu legalus,			
5	34. On February 18, 2022, Mr. Treace sent the following e-mail to Mr. Rocereta,			
6	copying Adam Cundiff, Nathan Peterson and Jason Graff:			
7	Hi Sam,			
8	Thank you for reaching out and for your kind words about the remarkable			
9	success that Treace continues to enjoy. As you can imagine, our success has			
10	been the result of years of hard work by the entire Treace team.			
11	As a co-inventor of the '590 patent, I am curious about the views you express on infringement and validity. Could you please explain why Fusion			
12	believes that its LapiLock system and method does not infringe the two			
13	independent claims of the '590 patent? Similarly, could you please identify the "well known prior art" that you refer to in your letter. I would very much			
14	enjoy reviewing that art.			
15	I appreciate your prompt response to my previous letter and hope that you			
16	will provide the requested information just as quickly.			
17	Best regards,			
18	35. On February 18, 2022, Mr. Rocereta responded to Mr. Treace, copying			
19	Adam Cundiff, Nathan Peterson and Jason Graff, as follows:			
20	John,			
21	I've calendared your request for the week of the 28th. I'm unavailable some			
22	of the next week due to Presidents Day.			
23	We hope you have a great weekend.			
24	Kind regards,			
25	36. On March 2, 2022, Mr. Rocereta sent an e-mail to Mr. Treace, copying			
26	Adam Cundiff, Nathan Peterson and Jason Graff stating:			
27				
28				
	12			

John,

Fusion has made recent adjustments in their literature to better reflect the distinct differences in the two systems. Your intellectual property attorneys can analyze and advise you on why the LapiLock system does not infringe on the two '590 independent claims.

Regarding the independent literature, with which you have an interest, we will provide the literature at the appropriate time should it be necessary for us to go forward with an inter partes review proceeding on the '590 patent.

As always, should an opportunity arise for our companies to work together in a productive way, feel free to reach out.

Kind regards,

37. Fusion's website at https://lapilockbunionsurgery.com/wp-

content/uploads/2022/02/STG015_LapiLock_2.pdf did indeed direct the viewer to a new version of the LapiLock Brochure. The new brochure is entitled "STG015_LapiLock_2". The previous brochure at this location was entitled "STG015_LapiLock_4D Brochure-c.pdf". Fusion made minor changes, such as replacing the word "fulcrum" in the previous version of the brochure with the word "spacers" at three locations and removing the word "bunion" in the mark "LapiLock 4D Bunion Correction". However, elsewhere on Fusion's website, LapiLock 4D Bunion Correction remains in use. Fusion made minor changes to the described surgical procedure. Specifically, Fusion's literature now instructs surgeons to remove the fulcrum (now "spacer") prior to correction of the intermetatarsal angle ("IMA") and then replace the fulcrum after the IMA is corrected, whereas Fusion previously instructed LapiLock surgeons to leave the fulcrum in place while correcting the IMA. On information and belief, if this change were to be followed by surgeons, it would likely lead to reduced surgical efficacy and adverse outcomes for patients.

38. Whether and to what extent Fusion will ensure that this "new" surgical
procedure will be taught or followed by either new or existing surgeon users of Fusion's
products and surgical procedure is unknown, but unlikely.

	Case 2:22-cv-00490-SRB Document 1 Filed 03/29/22 Page 15 of 58
1	39. On March 15, 2022, Mr. Treace responded to Mr. Rocereta copying Adam
2	Cundiff, Nathan Peterson and Jason Graff stating:
3	Sam,
4	I appreciate your response. Unfortunately, you did not sufficiently address
5	any of the concerns raised in my letter. In fact, your response raises even more questions and concerns.
6	
7	First, Fusion's literature changes are tacit acknowledgement that it has infringed on Treace Medical's intellectual property rights. My concern –
8	which remains and is now further validated by your response – is that Fusion has infringed and may still be infringing Treace Medical's '590 patent.
9	has mininged and may still be mininging freace wedical s 590 patent.
10	Second, the changes Fusion made to its literature do nothing to remediate the harm caused to Treace Medical nor do they stop surgeons trained and
11	instructed under Fusion's prior literature from continuing to perform the prior
12	technique, as trained and instructed by Fusion. Consequently, the changes made by Fusion are insufficient to cure the past and continued harm to
13	Treace Medical's proprietary rights.
14	Third, I question the sincerity of the changes made to Fusion's literature.
15 16	Specifically, Fusion's literature now instructs surgeons who use LapiLock to remove the fulcrum (which Fusion renamed "spacer" in its revised literature)
10	prior to correction of the intermetatarsal angle ("IMA") whereas Fusion previously instructed LapiLock surgeons to leave the fulcrum in place while
17	correcting the IMA. I believe that Fusion made this change solely as an
10	attempt to evade clear culpability for infringement of Treace Medical's '590
20	patent because – if the change is actually followed by surgeons – it will obviously lead to poor surgical efficacy and adverse outcomes for patients.
20	This also negatively affects Treace Medical's solid reputation with patients
21	who may not appreciate that their surgeon is using similarly named and described surgical equipment and techniques that are not affiliated with
22	Treace Medical. We therefore believe that Fusion continues to instruct and/or train surgeons who use LapiLock to leave the fulcrum in place while
23	correcting the IMA despite the changes made to its literature to now do the
25	opposite.
26	Fourth, you did not address the other concern I raised in my letter, namely that Fusion's use of LAPILOCK is causing consumer confusion with Treace
27	Medical's well-known LAPIPLASTY® mark. I mentioned in my letter that
28	both marks are very similar and create a similar overall commercial

impression. The similarities are particularly striking given Fusion's use of the language "4D Bunion Correction" in connection with LAPILOCK. Treace Medical routinely uses the mark 3D Bunion Correction[™] in connection with its LAPIPLASTY® mark. This stylization and combination of terms highlights the likelihood of confusion. In fact, many of the themes, illustrations, videos and other materials on Fusion's LapiLock website are very similar to those appearing on Treace Medical's websites, individually and collectively giving the false and misleading impression that Fusion's LapiLock is made by, distributed by, associated with or endorsed by Treace Medical. I remain concerned that Fusion's selection of identifiers for its products and procedure was intended to cause hospitals, surgeons, patients and the public to confuse those products and procedures with those offered by Treace Medical.

Finally, as I mentioned in my letter of February 14, it appears that LapiLock infringes on multiple Treace Medical patents. The '590 patent is merely one example. Other Treace Medical patents practiced by Fusion, its LapiLock products, and the techniques Fusion trains and instructs surgeons to perform include, but are not limited to, United States Patent Nos. 10,561,426; 10,849,670; 10,888,335; and 10,945,764. I am providing claim charts (Exhibits A-D) explaining how Fusion is infringing representative claims of these patents. Of course, Fusion's infringement is not limited to these representative claims.

Accordingly, I ask that you provide to Treace Medical the following by noon (Pacific Time) on March 22, 2022:

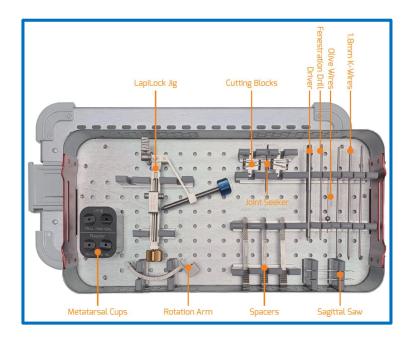
- Confirmation that Fusion now only instructs and/or trains surgeons through its literature, its training modules, labs, cases, procedures and otherwise – to remove the fulcrum (which you now claim to call a spacer) prior to correcting the IMA;
- (2) Confirmation that Fusion no longer instructs or trains surgeons through its literature, its training modules, labs, cases, procedures or otherwise – to leave the fulcrum in place while correcting the IMA;
- (3) Confirmation that Fusion has provided remedial training and instruction to its sales and marketing personnel, including any distributors of LapiLock, educating them that the fulcrum cannot be in place while correcting the IMA;
- (4) Confirmation that Fusion has provided written notice to all surgeons who had previously been instructed and/or trained to leave the fulcrum in place while correcting the IMA or who had previously performed the LapiLock procedure leaving the fulcrum in place while correcting the IMA, that they are required to remove the fulcrum before proceeding to correct the IMA;

П

1	(5)	A copy of the written notice and a complete list of all surgeons
2	(6)	provided with the written notice referenced in (4) above; Confirmation that Fusion will immediately stop making, using,
3		importing, offering for sale, and selling in the United States the
4		devices specifically designed for use in performing any procedure that infringes any Treace Medical patent;
5	(7)	Confirmation that Fusion will immediately stop inducing infringement
6		of any and all Treace Medical patents, including the following U.S. patents: 10,561,426, 10,849,670, 10,888,335 and 10,945,764, by
7		removing all materials from its literature, its own websites and all
		affiliated websites that would induce a surgeon to perform a surgical method covered by Treace Medical's patents;
8	(8)	Confirmation that Fusion will immediately stop distributing all printed and electronic literature that would induce a surgeon to perform a
10		surgical method covered by Treace Medical's patents;
	(9)	Confirmation that Fusion will immediately stop all other activities that
11		describe or encourage the performance of Treace Medical's patented methods using Fusion products;
12	(10)	To the extent Fusion refuses to confirm 6-9, a detailed explanation as
13		to why Fusion is not practicing the claims of the 10,561,426, 10,849,670, 10,888,335 and 10,945,764 patents;
14	(11)	Confirmation that Fusion will immediately stop using the LAPILOCK
15	(12)	mark and "4D Bunion Correction" language; and All existing LapiLock inventory, training supplies, kits, loaners,
16	(12)	demonstration products, related devices and promotional literature for
17		destruction, or written certification that you have destroyed these items.
18	TT 1	
19		s you provide confirmation or performance, as applicable, of the items above by the date and time mentioned above, I am prepared to instruct
20	our at	torneys to take any and all necessary steps to vigorously protect Treace cal's intellectual property rights. Fusion's infringement may subject it
21		s officers to a lawsuit seeking damages for past infringement, enhanced
22		ges for willful infringement, attorneys' fees, costs and injunction to bit Fusion's future patent infringement, as well as all remedies available
23	for Fu	sion's trademark infringement such as Fusion's profits and Treace
24	Media	cal's attorneys' fees and costs.
25	I look	forward to hearing from you promptly.
26	40.	As of the filing of this complaint, Treace has not received a response to Mr.
27	Treace's Ma	rch 15, 2022 communication from Mr. Cundiff, Mr. Rocereta or any other
28	person on Fu	usion's behalf.

Allegations Common to Counts 1 through 5

41. Fusion has made, used, offered for sale, sold and/or imported into the United States medical instruments used in performing bunion surgery. These medical instruments are offered by Fusion for the performance of Fusion's LapiLock 4D Bunion Correction System. The LapiLock 4D Bunion Correction instruments ("Accused Products") are shown in the image below which is found at Page 4 of the LapiLock Brochure.¹



18 42. Treace virtually marks its products through its Internet website at 19 https://www.treace.com/patents to alert competitors, like Fusion, to Treace Medical's 20 issued patents and pending patent applications. Treace Medical's patent marking website 21 states: "One or more implants, instruments, systems, and/or techniques associated with the 22 product names below may be covered by claims in one or more of the United States 23 Patents or Patent Applications as indicated:" United States Patent Nos. 10,561,426; 24 10,849,670; 10,888,335; 10,945,764 and 10,342,590 are listed on Treace Medical's patent 25 marking webpage.

43. Fusion had actual knowledge of United States Patent No. 10,342,590 by at
least February 16, 2022, through its receipt of the letter from Mr. Treace of that date.

28

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

¹ Reference is made to the LapiLock Brochure entitled "STG015_LapiLock_2.pdf".

44. Fusion had actual knowledge of United States Patent Nos. 10,561,426;
10,849,670; 10,888,335; 10,945,764 by at least March 15, 2022, through its receipt of the letter from Mr. Treace of that date.

COUNT 1 – INFRINGEMENT OF U.S. PATENT NO. 10,561,426 BY FUSION

45. Treace Medical incorporates by reference Paragraphs 1-44 of this Complaint as if repeated verbatim in this Paragraph.

46. On February 18, 2020, the USPTO issued United States Patent Number
10,561,426 B2 (the "'426 Patent") to Paul Dayton, Robert D. Santrock, Daniel J. Hatch,
W. Bret Smith, Carlos Eduardo Gil, Sean F. Scanlan, Joe William Ferguson, F. Barry Bays
and John T. Treace. The '426 Patent is entitled "Bone Cutting Guide Systems and
Methods." A true and correct copy of the '426 Patent is attached to this Complaint as
Exhibit A. The '426 Patent remains in force and is assigned to Treace Medical. Treace
Medical has owned the '426 Patent since it issued and still owns the '426 Patent.

47. Attached to this Complaint as Exhibit B is a detailed claim chart explaining
how the Fusion document entitled STG015_LapiLock_2.pdf ("LapiLock Brochure") and
the LapiLock Video describe the performance of the steps of representative independent
claim 1 of the '426 Patent using the Accused Products and thereby instruct and encourage
surgeons to perform the method of those claims. On information and belief, Fusion
continues to instruct and encourage surgeons to perform the method of claim 1 and other
claims of the '426 Patent (the "Claimed Method").

Fusion's Direct Infringement of the '426 Patent

48. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock Video using the Accused Products directly infringe the '426 Patent.

49. On information and belief, Fusion has directly infringed and continues to
directly infringe the Claimed Method by using the Accused Products in the performance of
LapiLock 4D Bunion Correction in violation of 35 U.S.C. §271(a).

50. On information and belief, surgeon consultants to Fusion, tested and performed the Claimed Method using the Accused Products on Fusion's behalf as part of developing the Accused Products and LapiLock 4D Bunion Correction at least before the Accused Products were first offered for sale and sold in the United States.

5

6

7

8

9

10

11

12

13

14

15

18

19

20

21

22

23

24

25

26

1

2

3

4

51. On information and belief, surgeon consultants to Fusion performed the Claimed Method using the Accused Products to perform LapiLock 4D Bunion Correction on Fusion's behalf as part of surgeon education both before and after the Accused Products were offered for sale and sold in the United States.

52. Fusion produced at least the LapiLock Brochure and LapiLock Video showing the Accused Products being used to perform LapiLock 4D Bunion Correction. On information and belief, surgeons working on Fusion's behalf, performed the Claimed Method using the Accused Products on human patients in connection with creating the LapiLock Brochure and LapiLock Video, both of which demonstrate performance of the Claimed Method using the Accused Products.

Fusion's Contributory Infringement of the '426 Patent

16 53. On information and belief, Fusion has contributorily infringed the Claimed
17 Method in violation of 35 U.S.C. §271(c).

54. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock Video using the Accused Products directly infringe the '426 Patent.

55. On information and belief, to the extent Fusion contends that it did not know of the '426 Patent before it commercially released the Accused Products, that contention would be based on Fusion's willful blindness to the '426 Patent.

56. On information and belief, Fusion had actual knowledge of the '426 Patent before commercially releasing its LapiLock 4D Bunion Correction and the Accused Products.

27 57. Devices including at least Fusion's LapiLock Jig, Cutting Blocks and Joint
28 Seeker are material components for use in practicing the Claimed Method.

Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker are especially made 1 58. 2 for use in a manner that infringes the Claimed Method.

59. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker lack substantial noninfringing uses.

60. Fusion has provided materials to hospitals and surgeons demonstrating the use of the Accused Products to perform the Claimed Method. These Fusion provided materials include the LapiLock Brochure and LapiLock Video. Distribution of these materials further shows that Fusion especially made the Accused Products to perform the Claimed Method.

61. On information and belief, Fusion knew that surgeons were performing the Claimed Method using the Accused Products.

62. On information and belief, surgeons have used the Accused Products in a manner that infringes the Claimed Method.

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

24

25

Fusion's Induced Infringement of the '426 Patent

63. On information and belief, Fusion has induced infringement of the Claimed Method in violation of 35 U.S.C. §271(b).

64. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock Video using the Accused Products directly infringe the '426 Patent.

65. On information and belief, to the extent Fusion contends that it did not know of the '426 Patent before it commercially released the Accused Products, that contention would be based on willful blindness to the '426 Patent.

23 66. On information and belief, Fusion had actual knowledge of the '426 Patent before commercially releasing its LapiLock 4D Bunion Correction and the Accused Products.

26 67. On information and belief, Fusion has provided materials to hospitals and 27 surgeons that demonstrate using the Accused Products to perform the Claimed Method. 28 On information and belief, These Fusion provided materials include the LapiLock

Brochure and LapiLock Video. On information and belief, Fusion distributed these 1 2 materials to hospitals and surgeons with the intent to cause surgeons to use Accused 3 Products to perform the Claimed Method.

4 68. On information and belief, Fusion knew that surgeons were performing the 5 Claimed Method using the Accused Products and were directly infringing the Claimed Method. 6

69. On information and belief, Fusion's inducing acts caused surgeons to use the Accused Products in a manner that infringes the Claimed Method.

Fusion's Willful Infringement of the '426 Patent

70. Fusion has willfully infringed the Claimed Method.

71. On information and belief, Fusion has infringed and continues to infringe the Claimed Method with knowledge of Treace Medical's rights in the '426 Patent.

72. On information and belief, Fusion's acts of infringement of the Claimed Method have been and continue to be willful, deliberate and egregious.

73. On information and belief, Fusion acted despite an objectively high likelihood that its actions constituted infringement of a valid patent claim and knew or should have known of this objectively-defined risk of infringement.

74. On information and belief, Fusion flaunted Treace Medical's notice of its rights in and to the '426 Patent by continuing to infringe the claims of the '426 patent, by failing to respond to Mr. Treace's letter at all, let alone by responding to Mr. Treace's letter with an explanation of a commercially reasonable non-infringement defense. In the 22 words of the Supreme Court, Fusion's conduct is of the sort warranting enhanced 23 damages-conduct which has been "variously described in our cases as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or-indeed-characteristic of a pirate."

26

24

25

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

Requested Relief for Fusion's Infringement of the '426 Patent

27 75. Treace Medical is entitled to recover damages that would place Treace 28 Medical in approximately the same financial position that it would have been in had

Fusion's infringement of the '426 Patent not occurred. Treace Medical is entitled to
 recover all profits that it has lost as a result of Fusion's sale of the Accused Products for the
 performance of the '426 Patent.

76. Treace Medical requests pursuant to 35 U.S.C. §284 that damages awarded to Treace in this matter for Fusion's infringement of the '426 Patent be increased by three times the amount found or assessed by the fact finder.

77. On information and belief, in furtherance of its infringement of the '426
Patent, Fusion has targeted as prospective customers, surgeons trained by Treace Medical to perform Treace Medical's LAPIPLASTY[®] 3D Bunion CorrectionTM.

78. On information and belief, Fusion has also targeted sales representatives who were educated by Treace Medical to promote and sell Treace Medical' LAPIPLASTY[®] 3D
 Bunion CorrectionTM to promote and sell Fusion's LapiLock 4D Bunion Correction and the Accused Products.

79. Fusion's misconduct has irreparably injured Treace Medical and will
continue to injure Treace Medical unless and until the Court enters both a preliminary
injunction and permanent injunction prohibiting Fusion and those acting on its behalf from
infringing the '426 Patent, including by prohibiting the making, using, offering for sale,
selling, and importing into the United States of the Accused Products for performing the
'426 Patent.

COUNT 2-INFRINGEMENT OF U.S. PATENT NO. 10,849,670 BY FUSION

80. Treace incorporates by reference paragraphs 1-79 as if set forth verbatim in this paragraph.

81. On December 1, 2020, the USPTO issued United States Patent Number
10,849,670 B2 (the "'670 Patent") to Robert D. Santrock, Paul Dayton, Daniel J. Hatch,
W. Bret Smith, F. Barry Bays, Carlos Eduardo Gil, Sean F. Scanlan, Joe William
Ferguson, and John T. Treace. The '670 Patent is entitled "Bone Positioning and
Preparing Guide Systems and Methods." A true and correct copy of the '670 Patent is
attached to this Complaint as Exhibit C. The '670 Patent remains in force and is assigned

to Treace Medical. Treace Medical has owned the '670 Patent since it issued and still
 owns the '670 Patent.

3 82. Attached to this Complaint as Exhibit D is a detailed claim chart explaining
4 how the LapiLock Brochure and the LapiLock Video describe the performance of the steps
5 of representative independent claim 1 of the '670 Patent using the Accused Products and
6 thereby instruct and encourage surgeons to perform the method of those claims. On
7 information and belief, Fusion continues to instruct and encourage surgeons to perform the
8 method of claim 1 and other claims of the '670 Patent (the "Claimed Method").

Fusion's Direct Infringement of the '670 Patent

83. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock Video using the Accused Products directly infringe the '670 Patent.

84. On information and belief, Fusion has directly infringed and continues to directly infringe the Claimed Method by using the Accused Products in the performance of LapiLock 4D Bunion Correction in violation of 35 U.S.C. §271(a).

85. On information and belief, surgeon consultants to Fusion, tested and performed the Claimed Method using the Accused Products on Fusion's behalf as part of developing the Accused Products and LapiLock 4D Bunion Correction at least before the Accused Products were first offered for sale and sold in the United States.

86. On information and belief, surgeon consultants to Fusion performed the
Claimed Method using the Accused Products to perform LapiLock 4D Bunion Correction
on Fusion's behalf as part of surgeon education both before and after the Accused Products
were offered for sale and sold in the United States.

Fusion produced at least the LapiLock Brochure and LapiLock Video
showing the Accused Products being used to perform LapiLock 4D Bunion Correction.
On information and belief, surgeons working on Fusion's behalf, performed the Claimed
Method using the Accused Products on human patients in connection with creating the

28

9

10

11

12

13

14

15

16

17

18

19

20

21

22

LapiLock Brochure and LapiLock Video, both of which demonstrate performance of the 1 2 Claimed Method using the Accused Products.

Fusion's Contributory Infringement of the '670 Patent

4 88. On information and belief, Fusion has contributorily infringed the Claimed 5 Method in violation of 35 U.S.C. §271(c).

89. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock Video using the Accused Products directly infringe the '670 Patent.

90. On information and belief, to the extent Fusion contends that it did not know of the '670 Patent before it commercially released the Accused Products, that contention would be based on Fusion's willful blindness to the '670 Patent.

91. On information and belief, Fusion had actual knowledge of the '670 Patent before commercially releasing its LapiLock 4D Bunion Correction and the Accused Products.

92. Devices including at least Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker are material components for use in practicing the Claimed Method.

93. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker are especially made for use in a manner that infringes the Claimed Method.

94. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker lack substantial noninfringing uses.

95. Fusion has provided materials to hospitals and surgeons demonstrating the 22 use of the Accused Products to perform the Claimed Method. These Fusion provided 23 materials include the LapiLock Brochure and LapiLock Video. Distribution of these 24 materials further shows that Fusion especially made the Accused Products to perform the 25 Claimed Method.

26 96. On information and belief, Fusion knew that surgeons were performing the 27 Claimed Method using the Accused Products.

28

3

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

97. On information and belief, surgeons have used the Accused Products in a 2 manner that infringes the Claimed Method.

Fusion's Induced Infringement of the '670 Patent

On information and belief, Fusion has induced infringement of the Claimed 98. Method in violation of 35 U.S.C. §271(b).

99. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock Video using the Accused Products directly infringe the '670 Patent.

100. On information and belief, to the extent Fusion contends that it did not know of the '670 Patent before it commercially released the Accused Products, that contention would be based on willful blindness to the '670 Patent.

101. On information and belief, Fusion had actual knowledge of the '670 Patent before commercially releasing its LapiLock 4D Bunion Correction and the Accused Products.

15 102. On information and belief, Fusion has provided materials to hospitals and 16 surgeons that demonstrate using the Accused Products to perform the Claimed Method. 17 On information and belief, These Fusion provided materials include the LapiLock 18 Brochure and LapiLock Video. On information and belief, Fusion distributed these 19 materials to hospitals and surgeons with the intent to cause surgeons to use Accused 20 Products to perform the Claimed Method.

21 103. On information and belief, Fusion knew that surgeons were performing the 22 Claimed Method using the Accused Products and were directly infringing the Claimed 23 Method.

104. On information and belief, Fusion's inducing acts caused surgeons to use the Accused Products in a manner that infringes the Claimed Method.

25

Fusion's Willful Infringement of the '670 Patent

105. Fusion has willfully infringed the Claimed Method.

27 28

24

25

26

1

3

4

5

6

7

8

9

10

11

12

13

106. On information and belief, Fusion has infringed and continues to infringe the Claimed Method with knowledge of Treace Medical's rights in the '670 Patent.

107. On information and belief, Fusion's acts of infringement of the Claimed Method have been and continue to be willful, deliberate and egregious.

108. On information and belief, Fusion acted despite an objectively high likelihood that its actions constituted infringement of a valid patent claim and knew or should have known of this objectively-defined risk of infringement.

109. On information and belief, Fusion flaunted Treace Medical's notice of its rights in and to the '670 Patent by continuing to infringe the claims of the '670 patent, by failing to respond to Mr. Treace's letter at all, let alone by responding to Mr. Treace's letter with an explanation of a commercially reasonable non-infringement defense. In the words of the Supreme Court, Fusion's conduct is of the sort warranting enhanced damages—conduct which has been "variously described in our cases as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate."

Requested Relief for Fusion's Infringement of the '670 Patent

110. Treace Medical is entitled to recover damages that would place Treace
Medical in approximately the same financial position that it would have been in had
Fusion's infringement of the '670 Patent not occurred. Treace Medical is entitled to
recover all profits that it has lost as a result of Fusion's sale of the Accused Products for the
performance of the '670 Patent.

111. Treace Medical requests pursuant to 35 U.S.C. §284 that damages awarded to Treace in this matter for Fusion's infringement of the '670 Patent be increased by three times the amount found or assessed by the fact finder.

25 112. On information and belief, in furtherance of its infringement of the '670
26 Patent, Fusion has targeted as prospective customers, surgeons trained by Treace Medical
27 to perform Treace Medical's LAPIPLASTY[®] 3D Bunion CorrectionTM.

28

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

113. On information and belief, Fusion has also targeted sales representatives who were educated by Treace Medical to promote and sell Treace Medical' LAPIPLASTY[®] 3D Bunion CorrectionTM to promote and sell Fusion's LapiLock 4D Bunion Correction and the Accused Products.

114. Fusion's misconduct has irreparably injured Treace Medical and will continue to injure Treace Medical unless and until the Court enters both a preliminary injunction and permanent injunction prohibiting Fusion and those acting on its behalf from infringing the '670 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the Accused Products for performing the '670 Patent.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

COUNT 3—INFRINGEMENT OF U.S. PATENT NO. 10,888,335 BY FUSION

115. Treace Medical incorporates by reference Paragraphs 1-114 of this Complaint as if repeated verbatim in this Paragraph.

116. On January 12, 2021, the USPTO issued United States Patent Number
10,888,335B2 (the "'335 Patent") to Paul Dayton, Robert D. Santrock, Daniel J. Hatch,
W. Bret Smith, Carlos Eduardo Gil, Sean F. Scanlan, Joe William Ferguson, F. Barry Bays
and John T. Treace. The '335 Patent is entitled "Bone Cutting Guide Systems and
Methods." A true and correct copy of the '335 Patent is attached to this Complaint as
Exhibit E. The '335 Patent remains in force and is assigned to Treace Medical. Treace
Medical has owned the '335 Patent since it issued and still owns the '590 Patent.

117. Attached to this Complaint as Exhibit F is a detailed claim chart explaining
how the LapiLock Brochure and the LapiLock Video describe the performance of the steps
of representative independent claim 1 of the '335 Patent using the Accused Products and
thereby instruct and encourage surgeons to perform the method of those claims. On
information and belief, Fusion continues to instruct and encourage surgeons to perform the
method of claim 1 and other claims of the '335 Patent (the "Claimed Method").

Fusion's Direct Infringement of the '335 Patent

118. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock Video using the Accused Products directly infringe the '335 Patent.

119. On information and belief, Fusion has directly infringed and continues to directly infringe the Claimed Method by using the Accused Products in the performance of LapiLock 4D Bunion Correction in violation of 35 U.S.C. §271(a).

120. On information and belief, surgeon consultants to Fusion, tested and performed the Claimed Method using the Accused Products on Fusion's behalf as part of developing the Accused Products and LapiLock 4D Bunion Correction at least before the Accused Products were first offered for sale and sold in the United States.

121. On information and belief, surgeon consultants to Fusion performed the Claimed Method using the Accused Products to perform LapiLock 4D Bunion Correction on Fusion's behalf as part of surgeon education both before and after the Accused Products were offered for sale and sold in the United States.

122. Fusion produced at least the LapiLock Brochure and LapiLock Video showing the Accused Products being used to perform LapiLock 4D Bunion Correction. On information and belief, surgeons working on Fusion's behalf, performed the Claimed Method using the Accused Products on human patients in connection with creating the LapiLock Brochure and LapiLock Video, both of which demonstrate performance of the Claimed Method using the Accused Products.

Fusion's Contributory Infringement of the '335 Patent

123. On information and belief, Fusion has contributorily infringed the Claimed Method in violation of 35 U.S.C. §271(c).

124. On information and belief, surgeons who have performed and are performingthe surgical method as instructed and encouraged by the LapiLock Brochure and LapiLockVideo using the Accused Products directly infringe the '335 Patent.

27 28

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

On information and belief, to the extent Fusion contends that it did not know 125. 2 of the '335 Patent before it commercially released the Accused Products, that contention 3 would be based on Fusion's willful blindness to the '335 Patent.

4 On information and belief, Fusion had actual knowledge of the '335 Patent 126. 5 before commercially releasing its LapiLock 4D Bunion Correction and the Accused Products. 6

127. Devices including at least Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker are material components for use in practicing the Claimed Method.

Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker are especially made 128. for use in a manner that infringes the Claimed Method.

Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker lack substantial non-129. infringing uses.

Fusion has provided materials to hospitals and surgeons demonstrating the 130. use of the Accused Products to perform the Claimed Method. These Fusion provided materials include the LapiLock Brochure and LapiLock Video. Distribution of these materials further shows that Fusion especially made the Accused Products to perform the Claimed Method.

131. On information and belief, Fusion knew that surgeons were performing the Claimed Method using the Accused Products.

132. On information and belief, surgeons have used the Accused Products in a manner that infringes the Claimed Method.

Fusion's Induced Infringement of the '335 Patent

On information and belief, Fusion has induced infringement of the Claimed 133. Method in violation of 35 U.S.C. §271(b).

25 134. On information and belief, surgeons who have performed and are performing 26 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock 27 Video using the Accused Products directly infringe the '335 Patent.

28

1

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

135. On information and belief, to the extent Fusion contends that it did not know of the '335 Patent before it commercially released the Accused Products, that contention would be based on willful blindness to the '335 Patent.

136. On information and belief, Fusion had actual knowledge of the '335 Patent before commercially releasing its LapiLock 4D Bunion Correction and the Accused Products.

137. On information and belief, Fusion has provided materials to hospitals and surgeons that demonstrate using the Accused Products to perform the Claimed Method.
On information and belief, These Fusion provided materials include the LapiLock
Brochure and LapiLock Video. On information and belief, Fusion distributed these materials to hospitals and surgeons with the intent to cause surgeons to use Accused
Products to perform the Claimed Method.

138. On information and belief, Fusion knew that surgeons were performing the Claimed Method using the Accused Products and were directly infringing the Claimed Method.

139. On information and belief, Fusion's inducing acts caused surgeons to use theAccused Products in a manner that infringes the Claimed Method.

Fusion's Willful Infringement of the '335 Patent

140. Fusion has willfully infringed the Claimed Method.

141. On information and belief, Fusion has infringed and continues to infringe the Claimed Method with knowledge of Treace Medical's rights in the '335 Patent.

142. On information and belief, Fusion's acts of infringement of the Claimed Method have been and continue to be willful, deliberate and egregious.

143. On information and belief, Fusion acted despite an objectively high likelihood that its actions constituted infringement of a valid patent claim and knew or should have known of this objectively-defined risk of infringement.

27 144. On information and belief, Fusion flaunted Treace Medical's notice of its
28 rights in and to the '335 Patent by continuing to infringe the claims of the '335 patent, by

26

failing to respond to Mr. Treace's letter at all, let alone by responding to Mr. Treace's
 letter with an explanation of a commercially reasonable non-infringement defense. In the
 words of the Supreme Court, Fusion's conduct is of the sort warranting enhanced
 damages—conduct which has been "variously described in our cases as willful, wanton,
 malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic
 of a pirate."

7 ||

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

Requested Relief for Fusion's Infringement of the '335 Patent

145. Treace Medical is entitled to recover damages that would place Treace Medical in approximately the same financial position that it would have been in had Fusion's infringement of the '335 Patent not occurred. Treace Medical is entitled to recover all profits that it has lost as a result of Fusion's sale of the Accused Products for the performance of the '335 Patent.

146. Treace Medical requests pursuant to 35 U.S.C. §284 that damages awarded to Treace in this matter for Fusion's infringement of the '335 Patent be increased by three times the amount found or assessed by the fact finder.

147. On information and belief, in furtherance of its infringement of the '335
 Patent, Fusion has targeted as prospective customers, surgeons trained by Treace Medical to perform Treace Medical's LAPIPLASTY[®] 3D Bunion CorrectionTM.

148. On information and belief, Fusion has also targeted sales representatives who were educated by Treace Medical to promote and sell Treace Medical' LAPIPLASTY[®] 3D Bunion Correction[™] to promote and sell Fusion's LapiLock 4D Bunion Correction and the Accused Products.

149. Fusion's misconduct has irreparably injured Treace Medical and will
continue to injure Treace Medical unless and until the Court enters both a preliminary
injunction and permanent injunction prohibiting Fusion and those acting on its behalf from
infringing the '335 Patent, including by prohibiting the making, using, offering for sale,
selling, and importing into the United States of the Accused Products for performing the
'335 Patent.

COUNT 4—INFRINGEMENT OF U.S. PATENT NO. 10,945,764 BY FUSION

150. Treace incorporates by reference Paragraphs 1-149 of this Complaint as if repeated verbatim in this Paragraph.

1

2

On March 16, 2021, the USPTO issued United States Patent Number 151. 10,945,764 B2 (the "'764 Patent") to Paul Dayton and F. Barry Bays. The '764 Patent is entitled "Tarsal-Metatarsal Joint procedure Utilizing Fulcrum." A true and correct copy of the '764 Patent is attached to this Complaint as Exhibit G. The '764 Patent remains in force and is assigned to Treace Medical. Treace Medical has owned the '764 Patent since it issued and still owns the '764 Patent.

152. Attached to this Complaint as Exhibit H is a detailed claim chart explaining how the LapiLock Brochure and the LapiLock Video describe the performance of the steps of representative independent claim 1 of the '764 Patent using the Accused Products and thereby instruct and encourage surgeons to perform the method of those claims. On information and belief, Fusion continues to instruct and encourage surgeons to perform the method of claim 1 and other claims of the '764 Patent (the "Claimed Method").

Fusion's Direct Infringement of the '764 Patent

On information and belief, surgeons who have performed and are performing 153. the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock Video using the Accused Products directly infringe the '764 Patent.

154. On information and belief, Fusion has directly infringed and continues to directly infringe the Claimed Method by using the Accused Products in the performance of LapiLock 4D Bunion Correction in violation of 35 U.S.C. §271(a).

On information and belief, surgeon consultants to Fusion, tested and 155. performed the Claimed Method using the Accused Products on Fusion's behalf as part of developing the Accused Products and LapiLock 4D Bunion Correction at least before the Accused Products were first offered for sale and sold in the United States.

156. On information and belief, surgeon consultants to Fusion performed the Claimed Method using the Accused Products to perform LapiLock 4D Bunion Correction on Fusion's behalf as part of surgeon education both before and after the Accused Products
 were offered for sale and sold in the United States.

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

157. Fusion produced at least the LapiLock Brochure and LapiLock Video showing the Accused Products being used to perform LapiLock 4D Bunion Correction. On information and belief, surgeons working on Fusion's behalf, performed the Claimed Method using the Accused Products on human patients in connection with creating the LapiLock Brochure and LapiLock Video, both of which demonstrate performance of the Claimed Method using the Accused Products.

Fusion's Contributory Infringement of the '764 Patent

158. On information and belief, Fusion has contributorily infringed the Claimed Method in violation of 35 U.S.C. §271(c).

159. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock Video using the Accused Products directly infringe the '764 Patent.

160. On information and belief, to the extent Fusion contends that it did not know of the '764 Patent before it commercially released the Accused Products, that contention would be based on Fusion's willful blindness to the '764 Patent.

161. On information and belief, Fusion had actual knowledge of the '764 Patent before commercially releasing its LapiLock 4D Bunion Correction and the Accused Products.

162. Devices including at least Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker are material components for use in practicing the Claimed Method.

163. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker are especially made for use in a manner that infringes the Claimed Method.

25 164. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker lack substantial non26 infringing uses.

27 165. Fusion has provided materials to hospitals and surgeons demonstrating the
28 use of the Accused Products to perform the Claimed Method. These Fusion provided

materials include the LapiLock Brochure and LapiLock Video. Distribution of these
 materials further shows that Fusion especially made the Accused Products to perform the
 Claimed Method.

4 166. On information and belief, Fusion knew that surgeons were performing the
5 Claimed Method using the Accused Products.

167. On information and belief, surgeons have used the Accused Products in a manner that infringes the Claimed Method.

Fusion's Induced Infringement of the '764 Patent

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

168. On information and belief, Fusion has induced infringement of the Claimed Method in violation of 35 U.S.C. §271(b).

169. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock Video using the Accused Products directly infringe the '764 Patent.

170. On information and belief, to the extent Fusion contends that it did not know of the '764 Patent before it commercially released the Accused Products, that contention would be based on willful blindness to the '764 Patent.

171. On information and belief, Fusion had actual knowledge of the '764 Patent before commercially releasing its LapiLock 4D Bunion Correction and the Accused Products.

172. On information and belief, Fusion has provided materials to hospitals and surgeons that demonstrate using the Accused Products to perform the Claimed Method.
On information and belief, These Fusion provided materials include the LapiLock
Brochure and LapiLock Video. On information and belief, Fusion distributed these materials to hospitals and surgeons with the intent to cause surgeons to use Accused
Products to perform the Claimed Method.

26 173. On information and belief, Fusion knew that surgeons were performing the
27 Claimed Method using the Accused Products and were directly infringing the Claimed
28 Method.

174. On information and belief, Fusion's inducing acts caused surgeons to use the Accused Products in a manner that infringes the Claimed Method.

Fusion's Willful Infringement of the '764 Patent

Fusion has willfully infringed the Claimed Method. 175.

176. On information and belief, Fusion has infringed and continues to infringe the Claimed Method with knowledge of Treace Medical's rights in the '764 Patent.

On information and belief, Fusion's acts of infringement of the Claimed 177. Method have been and continue to be willful, deliberate and egregious.

On information and belief, Fusion acted despite an objectively high 178. likelihood that its actions constituted infringement of a valid patent claim and knew or should have known of this objectively-defined risk of infringement.

179. On information and belief, Fusion flaunted Treace Medical's notice of its rights in and to the '764 Patent by continuing to infringe the claims of the '764 patent, by failing to respond to Mr. Treace's letter at all, let alone by responding to Mr. Treace's letter with an explanation of a commercially reasonable non-infringement defense. In the words of the Supreme Court, Fusion's conduct is of the sort warranting enhanced damages-conduct which has been "variously described in our cases as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or-indeed-characteristic of a pirate."

Requested Relief for Fusion's Infringement of the '764 Patent

180. Treace Medical is entitled to recover damages that would place Treace Medical in approximately the same financial position that it would have been in had Fusion's infringement of the '764 Patent not occurred. Treace Medical is entitled to recover all profits that it has lost as a result of Fusion's sale of the Accused Products for the performance of the '764 Patent.

Treace Medical requests pursuant to 35 U.S.C. §284 that damages awarded 181. to Treace in this matter for Fusion's infringement of the '764 Patent be increased by three times the amount found or assessed by the fact finder.

182. On information and belief, in furtherance of its infringement of the '764
Patent, Fusion has targeted as prospective customers, surgeons trained by Treace Medical to perform Treace Medical's LAPIPLASTY[®] 3D Bunion CorrectionTM.

183. On information and belief, Fusion has also targeted sales representatives who were educated by Treace Medical to promote and sell Treace Medical' LAPIPLASTY[®] 3D Bunion Correction[™] to promote and sell Fusion's LapiLock 4D Bunion Correction and the Accused Products.

184. Fusion's misconduct has irreparably injured Treace Medical and will continue to injure Treace Medical unless and until the Court enters both a preliminary injunction and permanent injunction prohibiting Fusion and those acting on its behalf from infringing the '764 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the Accused Products for performing the '764 Patent.

COUNT 5 - INFRINGEMENT OF U.S. PATENT NO. 10,342,590 BY FUSION

185. Treace Medical incorporates by reference Paragraphs 1-184 of this Complaint as if repeated verbatim in this Paragraph.

186. On July 9, 2019, the USPTO issued United States Patent Number 10,342,590
B2 (the "'590 Patent") to F. Barry Bays, Robert D. Santrock, Paul Dayton, Daniel J.
Hatch, W. Bret Smith, Carlos Eduardo Gil, Sean F. Scanlan, Joe William Ferguson, and
John T. Treace. The '590 Patent is entitled "Tarsal-Metatarsal Joint procedure Utilizing
Fulcrum." A true and correct copy of the '590 Patent is attached to this Complaint as
Exhibit I. The '590 Patent remains in force and is assigned to Treace Medical. Treace
Medical has owned the '590 Patent since it issued and still owns the '590 Patent.

187. Fusion's internet website includes a "Surgeon Portal" at
<u>https://lapilockbunionsurgery.com/surgeons/</u> where surgeons could, before March 2, 2022,
download a version of the "LAPILOCK SURGICAL TECHNIQUE" brochure entitled
STG015_LapiLock_4D Brochure-c.pdf, ("LapiLock Brochure 2") or watch an untitled
video demonstrating and explaining the LapiLock 4D Bunion Correction System and

method ("LapiLock Video 2") or "Learn More About LapiLock 4D Bunion Correction"
 by submitting their contact information.

188. Attached to this Complaint as Exhibit J is a detailed claim chart explaining how the LapiLock Brochure 2 and LapiLock Video 2 describe the performance of the steps of representative independent claim 1 of the '590 Patent using the Accused Products and thereby instruct and encourage surgeons to perform the method of claim 1 and other claims of the '590 Patent (the "**Claimed Method**").

189. On information and belief, Fusion continues to instruct and encourage surgeons to perform the Claimed Method.

190. On information and belief, Fusion has not instructed surgeons to perform the Claimed Method in a non-infringing manner.

Fusion's Direct Infringement of the '590 Patent

191. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiLock Brochure 2 and LapiLock Video 2 using the Accused Products directly infringe the '590 Patent.

192. On information and belief, Fusion has directly infringed and continues to directly infringe the Claimed Method by using the Accused Products in the performance of LapiLock 4D Bunion Correction in violation of 35 U.S.C. §271(a).

193. On information and belief, surgeon consultants to Fusion tested and performed the Claimed Method using the Accused Products on Fusion's behalf as part of developing the Accused Products and LapiLock 4D Bunion Correction at least before the Accused Products were first offered for sale and sold in the United States.

194. On information and belief, surgeon consultants to Fusion performed the Claimed Method using the Accused Products to perform LapiLock 4D Bunion Correction on Fusion's behalf as part of surgeon education both before and after the Accused Products were offered for sale and sold in the United States.

195. Fusion produced at least the LapiLock Brochure 2 and LapiLock Video 2
showing the Accused Products being used to perform LapiLock 4D Bunion Correction.

On information and belief, surgeons working on Fusion's behalf performed the Claimed Method using the Accused Products on human patients in connection with creating the LapiLock Brochure 2 and LapiLock Video 2, both of which demonstrate performance of 4 the Claimed Method using the Accused Products.

1

2

3

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

Fusion's Contributory Infringement of the '590 Patent

196. On information and belief, Fusion has contributorily infringed the Claimed Method in violation of 35 U.S.C. §271(c).

197. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiLock Brochure 2 and LapiLock Video 2 using the Accused Products directly infringe the '590 Patent.

198. On information and belief, o the extent Fusion contends that it did not know of the '590 Patent before it commercially released the Accused Products, that contention would be based on Fusion's willful blindness to the '590 Patent.

199. On information and belief, Fusion had actual knowledge of the '590 Patent before commercially releasing its LapiLock 4D Bunion Correction and the Accused Products.

Devices including at least Fusion's LapiLock Jig, Cutting Blocks and Joint 200.Seeker are material components for use in practicing the Claimed Method.

201. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker are especially made for use in a manner that infringes the Claimed Method.

202. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker lack substantial noninfringing uses.

203. Fusion has provided materials to hospitals and surgeons demonstrating the use of the Accused Products to perform the Claimed Method. These materials include the LapiLock Brochure 2 and LapiLock Video 2. Distribution of these materials further shows that Fusion especially made the Accused Products to perform the Claimed Method.

27 204. On information and belief, Fusion knew that surgeons were performing the 28 Claimed Method using the Accused Products.

205. On information and belief, surgeons have used the Accused Products in a manner that infringes the Claimed Method.

Induced Infringement of the '590 Patent

Fusion has induced infringement of the Claimed Method in violation of 35 206. U.S.C. §271(b).

On information and belief, surgeons who have performed and are performing 207. the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock Video using the Accused Products directly infringe the '590 Patent.

208. On information and belief, to the extent Fusion contends that it did not know of the '590 Patent before it commercially released the Accused Products, that contention would be based on willful blindness to the '590 Patent.

209. On information and belief, Fusion had actual knowledge of the '590 Patent before commercially releasing its LapiLock 4D Bunion Correction and the Accused Products.

210. On information and belief, Fusion has provided materials to hospitals and 16 surgeons that demonstrate using the Accused Products to perform the Claimed Method. On information and belief, These Fusion provided materials include the LapiLock Brochure and LapiLock Video. On information and belief, Fusion distributed these materials to hospitals and surgeons with the intent to cause surgeons to use Accused Products to perform the Claimed Method.

21 On information and belief, Fusion knew that surgeons were performing the 211. 22 Claimed Method using the Accused Products and were directly infringing the Claimed 23 Method.

212. On information and belief, Fusion's inducing acts caused surgeons to use the Accused Products in a manner that infringes the Claimed Method.

Willful Infringement of the '590 Patent

213. Fusion has willfully infringed the Claimed Method.

25 26 27

24

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

17

18

19

214. On information and belief, Fusion has infringed and continues to infringe the Claimed Method with knowledge of Treace Medical's rights in the '590 Patent.

215. On information and belief, Fusion's acts of infringement of the Claimed Method have been and continue to be willful, deliberate and egregious.

216. On information and belief, Fusion acted despite an objectively high likelihood that its actions constituted infringement of a valid patent claim and knew or should have known of this objectively-defined risk of infringement.

217. Fusion flaunted Treace Medical's notice of its rights in and to the '590 Patent. On information and belief, Fusion has taken no steps to ensure that surgeons performing Fusion's LapiLock 4D Bunion Correction are being trained to perform Fusion's LapiLock 4D Bunion Correction in a non-infringing manner. On information and belief, Fusion has not told the surgeons that it previously trained to perform Fusion's LapiLock 4D Bunion Correction in an infringing manner that they must perform Fusion's LapiLock 4D Bunion Correction in a different non-infringing manner. In the words of the Supreme Court, Fusion's conduct is of the sort warranting enhanced damages—conduct which has been "variously described in our cases as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate."

Requested Relief for Fusion's Infringement of the '590 Patent

218. Treace Medical is entitled to recover damages that would place Treace Medical in approximately the same financial position that it would have been in had Fusion's infringement of the '590 Patent not occurred. Treace Medical is entitled to recover all profits that it has lost as a result of Fusion's sale of the Accused Products for the performance of the '590 Patent.

219. Treace Medical requests pursuant to 35 U.S.C. §284 that damages awarded to Treace in this matter for Fusion's willful infringement of the '590 Patent be increased by three times the amount found or assessed by the fact finder.

1

220. On information and belief, in furtherance of its infringement of the '590
 Patent, Fusion has targeted as prospective customers, surgeons trained by Treace Medical
 to perform Treace Medical's LAPIPLASTY[®] 3D Bunion CorrectionTM.

221. On information and belief, Fusion has also targeted sales representatives who were educated by Treace Medical to promote and sell Treace Medical' LAPIPLASTY[®] 3D Bunion CorrectionTM to promote and sell Fusion's LapiLock 4D Bunion Correction and the Accused Products.

222. Fusion's misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters both a preliminary injunction and permanent injunction prohibiting Fusion and those acting on its behalf from infringing the '590 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the Accused Products for performing the '590 Patent.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

25

COUNT 6—FEDERAL TRADEMARK INFRINGEMENT BY FUSION

223. Treace incorporates by reference Paragraphs 1-222 of this Complaint as if repeated verbatim in this Paragraph.

224. On October 28, 2015, Treace Medical filed an application for trademark protection of its LAPIPLASTY mark in International Class 10. Treace alleged a date of first use of January 1, 2016 and a date of first use in commerce of February 23, 2016.

225. Treace Medical's application for protection of its LAPIPLASTY mark published for opposition on August 23, 2016 as Serial No. 86802324.

226. Treace Medical's LAPIPLASTY[®] mark was registered on January 3, 2017 on the USPTO's principal register as U.S. Registration No. 5,115,724.

24

227. Treace Medical is the registered owner of the LAPIPLASTY® mark.

228. Treace Medical's LAPIPLASTY[®] mark is valid and legally protectable.

26 229. Treace Medical's LAPIPLASTY[®] mark is currently in use and has been in
27 use for more than five years since the date of its federal registration.

230. On February 25, 2022, Treace Medical filed a Section 15 Declaration of Incontestability with the USPTO regarding the registered LAPIPLASTY[®] mark.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

231. On April 5, 2021, Treace Medical filed for registration of its 3D BUNION CORRECTIONTM mark in International Class 044 for "providing a website featuring information in the field of bunions and bunion surgery." Treace Medical alleged that its first use and first commercial use of this mark occurred on July 6, 2018. Treace Medical's U.S. Application No. 90/623,428 for the 3D BUNION CORRECTION mark is on the Principal Register of the USPTO.

232. Fusion's infringing LAPILOCK mark is confusingly similar to Treace Medical's federally registered LAPIPLASTY[®] mark in violation of 15 U.S.C. § 1114.

233. Fusion's use of the confusingly similar mark LAPILOCK to identify the Accused Products and methods of their use is likely to create confusion, deception, and mistake by creating the false and misleading impression that Fusion's LapiLock 4D Bunion Correction and the Accused Products are manufactured by Treace Medical, distributed by Treace Medical, are associated or connected with Treace Medical, or have the sponsorship, endorsement or approval of Treace Medical.

234. Fusion's use of the LAPILOCK mark to identify the Accused Products and methods of their use in connection with the phrase "4D Bunion Correction"², increases the likelihood of confusion with Treace Medical's goods and services because Treace Medical uses its LAPIPLASTY[®] mark in connection with the mark 3D BUNION CORRECTION[™].

235. Fusion's use of the confusingly similar mark LAPILOCK and the confusingly similar phrase "4D Bunion Correction" to identify the Accused Products and methods of their use is causing and, unless enjoined by this Court, will continue to cause a

25 26

27

 ² While Fusion recently removed the word "bunion" from this phrase in its
 LapiLock Brochure, Fusion continues to use the phrase "4D Bunion Correction" in its other promotional materials and on its website.

likelihood of confusion and deception of medical personnel, hospitals, patients and the
 public.

236. Fusion's use of the confusingly similar mark LAPILOCK and the confusingly similar phrase "4D Bunion Correction" to identify the Accused Products and methods of their use is causing and, unless enjoined by this Court, will continue to cause injury to Treace Medical's goodwill and reputation, for which Treace Medical has no adequate remedy at law.

237. Fusion's actions demonstrate an intentional, willful, and malicious intent to trade on the goodwill associated with Treace Medical's LAPIPLASTY[®] mark and 3D BUNION CORRECTION[™] mark and to cause Treace Medical great and irreparable harm.

238. Fusion's actions have caused and are likely to continue causing substantial injury to the public and to Treace Medical, and Treace Medical is entitled to injunctive relief and to recover Fusion's profits, actual damages, enhanced profits and damages, costs, and reasonable attorneys' fees under 15 U.S.C. §§ 1114, 1116, and 1117.

COUNT 7—FEDERAL UNFAIR COMPETITION BY FUSION

239. Treace Medical incorporates by reference Paragraphs 1-238 of this Complaint as if repeated verbatim in this Paragraph.

240. On information and belief, Fusion's use of a confusingly similar imitation of Treace Medical's LAPIPLASTY[®] mark and 3D BUNION CORRECTION[™] mark has caused and is likely to cause confusion, deception, and mistake by creating the false and misleading impression that Fusion's goods are manufactured by Treace Medical, distributed by Treace Medical, are affiliated, connected, or associated with Treace Medical, or have the sponsorship, endorsement, or approval of Treace Medical.

25 241. On information and belief, Fusion has made false representations, false
26 descriptions, and false designations of, on, or in connection with its goods in violation of
27 15 U.S.C. § 1125(a). Fusion's activities have caused and, unless enjoined by this Court,
28 will continue to cause a likelihood of confusion and deception of members of the trade and

public, and, additionally, injury to Treace Medical's goodwill and reputation as
 symbolized by Treace Medical's LAPIPLASTY[®] mark and 3D BUNION
 CORRECTIONTM mark, for which Treace Medical has no adequate remedy at law

8

9

10

11

12

13

14

15

22

23

24

25

4 242. Fusion's actions demonstrate an intentional, willful, and malicious intent to
5 trade on the goodwill associated with Treace Medical's LAPIPLASTY[®] mark and 3D
6 BUNION CORRECTIONTM mark and to cause great and irreparable injury of Treace
7 Medical.

243. Fusion's conduct has caused, and is likely to continue causing, substantial injury to the public and to Treace Medical. Treace Medical is entitled to injunctive relief and to recover Fusion's profits, actual damages, enhanced profits and damages, costs, and reasonable attorneys' fees under 15 U.S.C. §§ 1125(a), 1116, and 1117.

<u>COUNT 8—COMMON LAW TRADEMARK INFRINGEMENT</u> <u>AND UNFAIR COMPETITION BY FUSION</u>

244. Treace incorporates by reference Paragraphs 1-243 of this Complaint as if repeated verbatim in this Paragraph.

16 245. On information and belief, Fusion's use of a confusingly similar imitation of
17 Treace Medical's LAPIPLASTY[®] mark and 3D BUNION CORRECTIONTM mark has
18 caused and is likely to cause confusion, deception, and mistake by creating the false and
19 misleading impression that Fusion's goods are manufactured by Treace Medical,
20 distributed by Treace Medical, are affiliated, connected, or associated with Treace
21 Medical, or have the sponsorship, endorsement, or approval of Treace Medical.

246. Fusion's acts constitute common law trademark infringement and unfair competition, and have created and will continue to create, unless restrained by this Court, a likelihood of confusion to the irreparable injury of Treace Medical. Treace Medical has no adequate remedy at law for this injury.

26 247. On information and belief, Fusion acted with full knowledge of Treace
27 Medical's use of, and statutory and common law rights to, Treace Medical's
28 LAPIPLASTY[®] mark and 3D BUNION CORRECTIONTM mark. On information and

belief, Fusion acted without regard for the likelihood of confusion of the public created by
 its activities.

248. On information and belief, Fusion's deceptive and misleading
representations about the FDA clearance status, patent pending status, and efficacy of its
LapiLock 4D Correction System were made with the intention that others would rely upon
these representations and thereby cause great and irreparable injury to Treace Medical.

249. Fusion's actions demonstrate an intentional, willful, and malicious intent to trade on the goodwill associated with Treace Medical's LAPIPLASTY[®] mark and 3D BUNION CORRECTION[™] mark and to cause great and irreparable injury to Treace Medical.

250. As a result of Fusion's acts, Treace Medical has been damaged in an amount not yet determined or ascertainable. At a minimum, however, Treace Medical is entitled to injunctive relief, an accounting of Fusion's profits, damages, and costs. Further, in light of the deliberate and malicious use of a confusingly similar imitation of Treace Medical's LAPIPLASTY[®] mark and 3D BUNION CORRECTION mark, and the need to deter Fusion from engaging in similar conduct in the future, Treace Medical additionally is entitled to punitive damages.

18

19

20

21

22

23

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

COUNT 9—COPYRIGHT INFRINGEMENT BY FUSION

251. Treace Medical incorporates by reference Paragraphs 1-250 of this Complaint as if repeated verbatim in this Paragraph.

Treace Medical's Copyrighted Works

252. In 2017, Treace Medical commissioned Hartman Brink, LLC to create an educational video to promote its LAPIPLASTY[®] 3D Bunion Correction[™] procedure as a work made for hire under 17 U.S.C. § 101 ("2017 Work"). Hartman Brink created the 2017 Work pursuant to this commission. Because Treace Medical specifically

commissioned the 2017 Work as a work made for hire, Treace Medical owns any and all
 copyrights in the 2017 Work.

253. In 2021, Treace Medical commissioned Hartman Brink, LLC to update the
educational video as a work made for hire under 17 U.S.C. § 101 ("2021 Work").
Hartman Brink created the 2021 Work pursuant to this commission. Because Treace
Medical specifically commissioned the 2021 Work as a work made for hire, Treace
Medical owns any and all copyrights in the 2021 Work.

254. In this Complaint, the 2017 and 2021 Works are referred to as the "Copyrighted Works." The Copyrighted Works are original motion pictures containing copyrightable subject matter for which copyright protection exists under the Copyright Act, 17 U.S.C. § 101, et seq. Treace Medical is the exclusive owner of all right, title and interest in the Copyrighted Works.

255. Treace Medical owns valid and subsisting United States Copyright
Registration No. PA 2-339-616 for the 2017 Work, and United States Copyright
Registration No. PA 2-340-075 for the 2021 Work. Proof of registration is attached as
Exhibits K and L.

256. Treace Medical has published and distributed the Copyrighted Works on its website, <u>www.lapiplasty.com</u>. The 2021 Work is presently available to the public on Treace Medical's website. Before the 2021 Work was available to the public on Treace Medical's website, the 2017 Work was available to the public on the website. Treace Medical has also published the Copyrighted Works on social media websites, including YouTube and Facebook, where the Copyrighted Works have been viewed more than 20,000 times.

257. The Copyrighted Works have been tremendously successful in promoting
 Treace Medical's LAPIPLASTY[®] 3D Bunion Correction[™] procedure. The Copyrighted
 Works have been viewed more than one million times on Treace Medical's website.

258. All public depictions of the Copyrighted Works are accompanied by an
 appropriate copyright notice indicating that Treace Medical is the owner of all rights in the
 Copyrighted Works.

259. The Copyrighted Works are of significant value to Treace Medical because
 they increase interest in, and demand for, Treace Medical's LAPIPLASTY[®] 3D Bunion
 Correction[™] procedure.

Fusion's Infringing Conduct

260. Fusion created a video that is a shot-for-shot remake of the Copyrighted Works. The video is available on Fusion's website at

10 <u>https://lapilockbunionsurgery.com/?radius=25</u>, where it is available to the public.

(Hereafter, "Infringing Work").

4

5

6

7

8

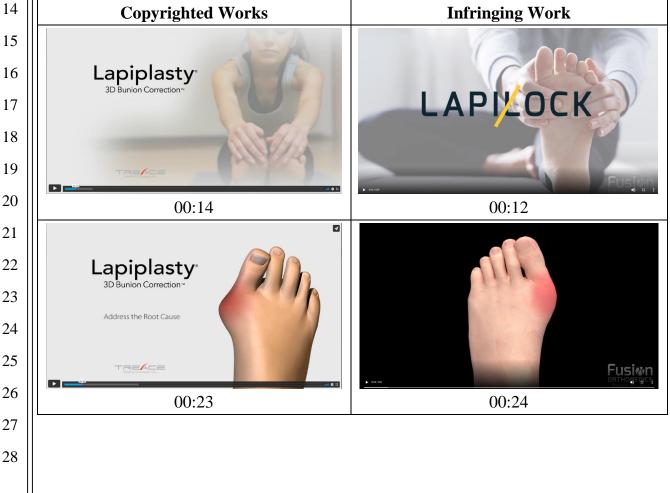
9

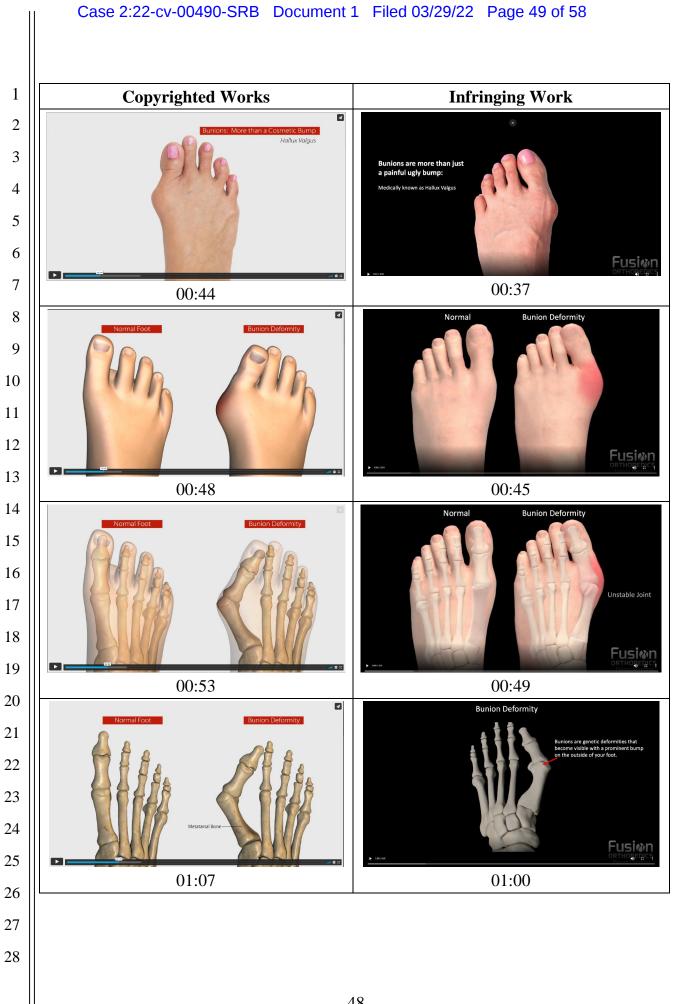
11

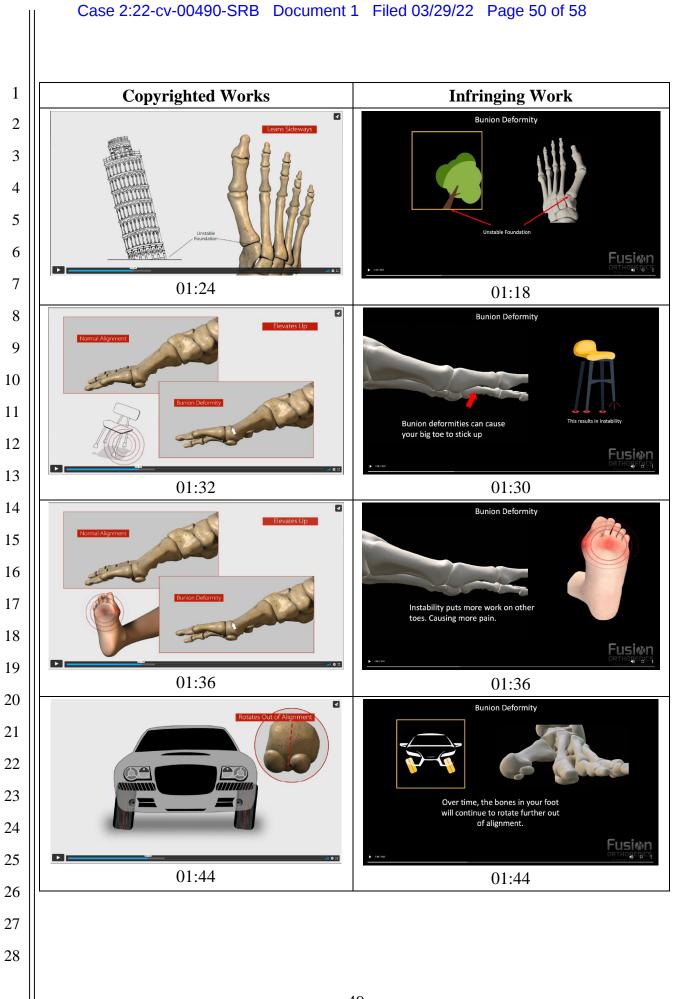
12

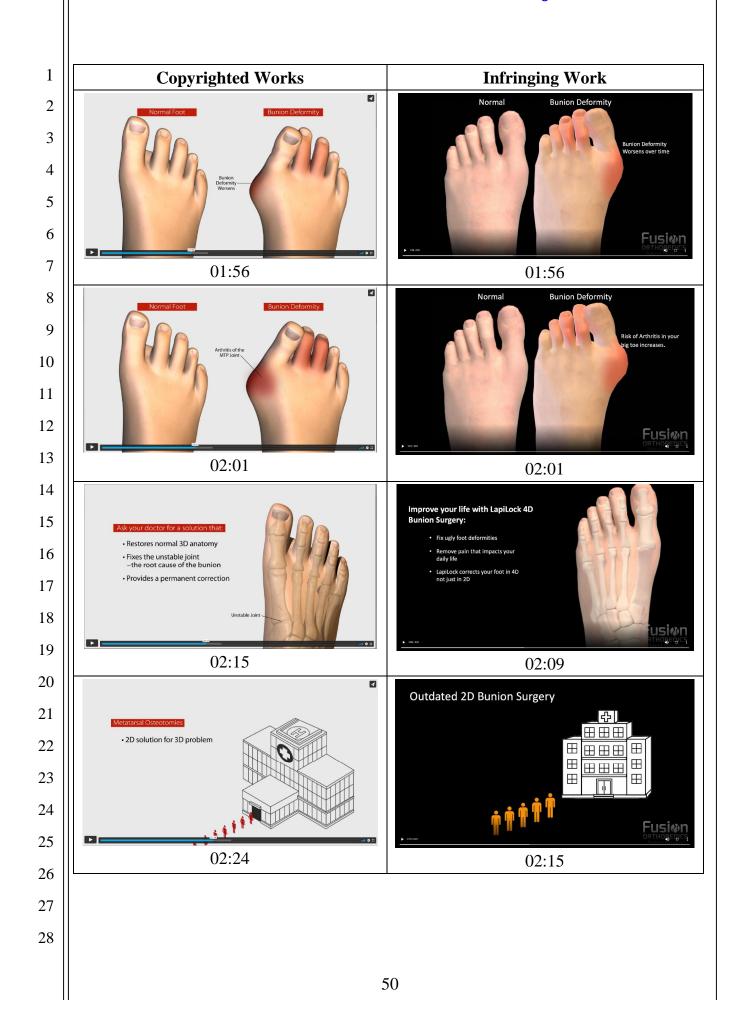
13

261. The Infringing Work uses strikingly similar images arranged in a virtually identical sequence as the Copyrighted Works, as illustrated in the screen shots below.

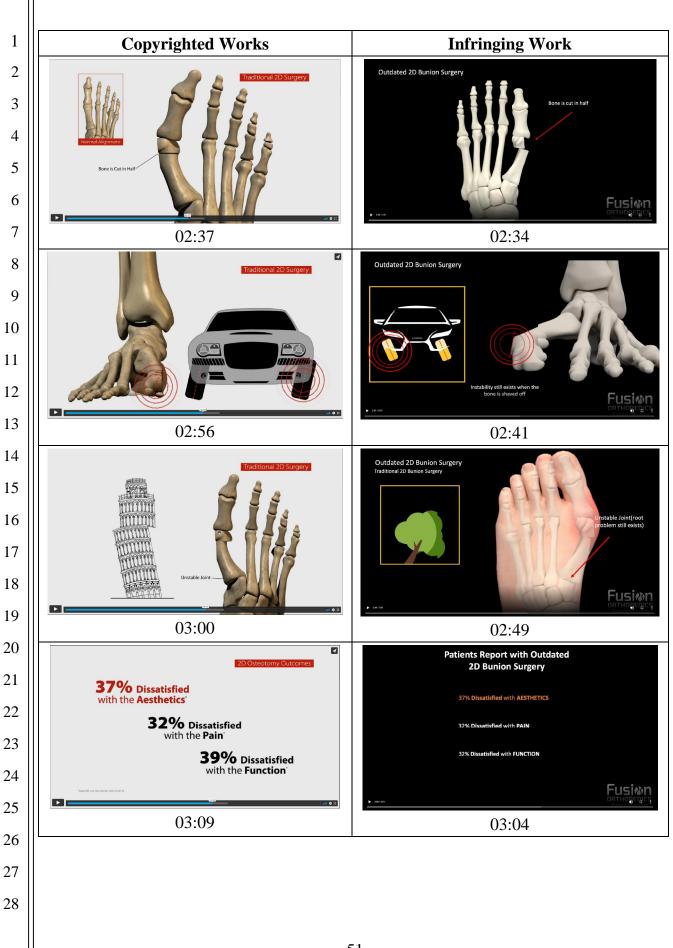




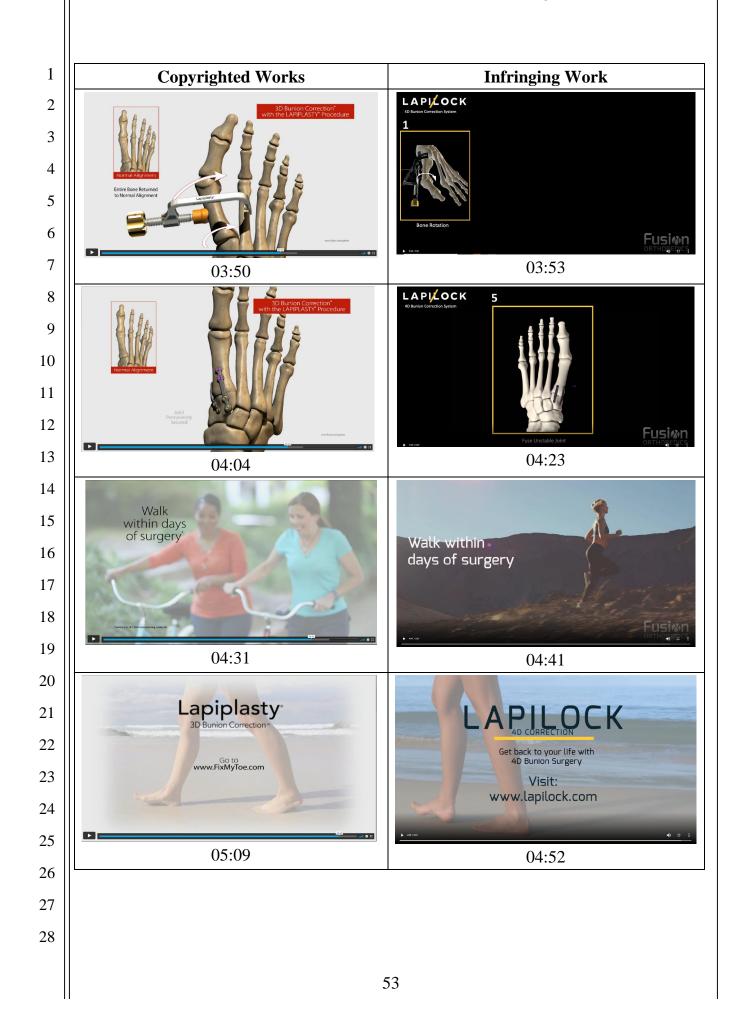












Case 2:22-cv-00490-SRB Document 1 Filed 03/29/22 Page 55 of 58 1 **Copyrighted Works Infringing Work** 2 Only a surgeon can <mark>tell if the La</mark>piplasty[®] Procedure is right for you. As with any medical treatment, individual results may vary There are potential risks and recovery takes time. This video, and its contents are protected by U.S and International copyright laws. Reproduction 3 Potential risks include but are not limited to infection and/or distribution of the video, and its contents, discomfort from the presence of the implant, loosening of the implant, and loss of correction without the express written consent of Fusion vith nonunion or malunion Orthopedics, LLC is prohibited. 4 © 2021 Fusion Orthopedics USA, LLC Go to www.FixMyToe.com DTP002 Rev 1 5 6 © 2018 Treace Medical Concepts, Inc. All rights re inlasty is a registered trademark of Treace Medical C 7 05:16 04:57

262. As the above comparison demonstrates, the Copyrighted Works and the Infringing Work are substantially similar.

263. On information and belief, Fusion viewed Treace Medical's Copyrighted Works and intentionally copied the Copyrighted Works to create the Infringing Work. That Fusion copied the Copyrighted Work when it created the Infringing Work is evidenced by the striking similarities between the Copyrighted Work and the Infringing Work, which cannot possibly be explained other than as a result of copying.

264. Fusion reproduced and distributed the Copyrighted Works without Treace Medical's authorization, consent, or knowledge.

265. Through Fusion's conduct alleged herein, including Fusion's reproduction and distribution of portions of the Copyrighted Works, Fusion has directly infringed Treace Medical's exclusive rights in the Copyrighted Works in violation of Section 501 of the Copyright Act.

266. On information and belief, Fusion's infringing conduct alleged herein was and continues to be willful and with full knowledge of Treace Medical's rights in the Copyrighted Works, and has enabled Fusion to illegally obtain profit.

25 267. As a direct and proximate result of Fusion's infringing conduct, Treace
26 Medical has been harmed and is entitled to damages in an amount to be proven at trial.
27 Pursuant to 17 U.S.C. § 504(b), Treace Medical is also entitled to recover Fusion's profits

28

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

attributable to Fusion's infringing conduct. Treace Medical is further entitled to its
 attorney's fees and costs under 17 U.S.C. § 505.

268. As a direct and proximate result of Fusion's infringing conduct, Treace
Medical has sustained and will continue to sustain substantial, immediate, and irreparable
injury, for which there is no adequate remedy at law. On information and belief, unless
Fusion's conduct is enjoined by this Court, Fusion will continue to infringe the
Copyrighted Works. Treace Medical is therefore entitled to preliminary and permanent
injunctive relief restraining and enjoining Fusion's ongoing infringement.

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Treace Medical Concepts, Inc. prays for the following relief against Fusion:

1. For judgment in favor of Treace Medical that Fusion has infringed and is infringing the claims of the '590, '426, '670, '335 and '764 Patents, both directly and indirectly;

2. For a preliminary and permanent injunction prohibiting Fusion, including its officers, agents, employees, and all persons acting in concert or participation with them who receive actual notice of the Court's Order, from committing further acts of infringement of the '590, '426, '670, '335 and '764 Patents;

3. For an award of damages for Fusion's infringement of the '590, '426, '670, '335 and '764 Patents in the amount of at least a reasonable royalty, together with interest (both pre-and post-judgment), costs and disbursements as fixed by this Court under 35 U.S.C. § 284;

4. For an award of damages for Fusion's infringement of the '590, '426, '670,
'335 and '764 Patents in the amount of Treace Medical's lost profits associated with
Fusion's sale of the Accused Products, together with interest (both pre-and post-judgment),
costs and disbursements as fixed by this Court under 35 U.S.C. § 284;

5. For a determination that Fusion's infringement of the '590, '426, '670, '335
and '764 Patents has been and is willful;

6. For an award of enhanced damages under 35 U.S.C. § 284;

7. For a determination that this is an exceptional case within the meaning of 35 U.S.C. § 285;

8. For an award to Treace Medical of its reasonable attorneys' fees;

9. For an accounting for damages;

10. For a preliminary and permanent injunction prohibiting Fusion, including its officers, agents, employees, and all persons acting in concert or participation with them who receive actual notice of the Court's Order, from committing further acts of trademark infringement and unfair competition associated with Fusion's illegal use of the LAPILOCK mark and 4D BUNION CORRECTION phrase;

11. For an award of Fusion's profits, actual damages, enhanced profits and damages, costs, and reasonable attorneys' fees under 15 U.S.C. §§ 1114, 1116, and 1117 for Fusion's illegal use of the LAPILOCK mark and 4D BUNION CORRECTION phrase;

12. For a preliminary and permanent injunction prohibiting Fusion, including its officers, agents, employees, and all persons acting in concert or participation with them who receive actual notice of the Court's Order, from committing further acts of unfair competition, including deceptive and misleading representations about the FDA clearance status, patent pending status, and efficacy of its LapiLock 4D Bunion Correction;

13. For judgment in favor of Treace Medical that Fusion has infringed and is infringing the Copyrighted Works;

14. For a preliminary and permanent injunction prohibiting Fusion, including its officers, agents, employees, and all persons acting in concert or participation with them who receive actual notice of the Court's Order, from committing further acts of infringement of the Copyrighted Works;

15. For an award of damages for Fusion's infringement of the Copyrighted Works;
16. For an award of the profits Fusion obtained as a result of its infringement of
the Copyrighted Works;

	Case 2.22-00-00490-SRB Document 1 Filed 03/29/22 Page 58 01 58
1	17. Should Treace Medical elect, for an award of statutory damages pursuant to 17
2	U.S.C. § 504(c);
3	18. For an award of reasonable attorney's fees and costs pursuant to 17 U.S.C.
4	§ 505;
5	19. For an award of interest, including pre-judgment and post-judgment interest,
6	on the foregoing sums; and
7	20. For such other and further relief in law or in equity to which Treace Medical
8	may be justly entitled.
9	JURY DEMAND
10	Pursuant to Fed. R. Civ. P. 38(b), Treace Medical demands trial by jury on all issues
11	so triable.
12	DATED this 28th day of March, 2022.
13	OSBORN MALEDON, P.A.
14	By <u>s</u> / Phillip W. Londen
15	Eric M. Fraser Phillip W. Londen
16	2929 North Central Avenue, Ste. 2100
17	Phoenix, Arizona 85012-2793
18	FISH & RICHARDSON P.C.
19	Todd G. Miller (<i>pro hac vice to be filed</i>) Oliver J. Richards (<i>pro hac vice to be filed</i>)
20	12860 El Camino Real, Suite 400
21	San Diego, California 92130
22	FISH & RICHARDSON P.C. Frank E. Scherkenbach (<i>pro hac vice to be filed</i>)
23	One Marina Park Drive
24	Boston, Massachusetts 02210-1878
25	Attorneys for Plaintiff
26	
27	
28	
	57