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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

INTERNATIONAL MEDICAL
DEVICES, INC., et al.

Plaintiffs

v.

ROBERT CORNELL, M.D., et al.,

Defendants.

Case No.: 2:20-cv-03503-CBM (RAOx)

ORDER RE: CIVIL CONTEMPT

The matter before the Court is Plaintiffs’ Ex Parte Request for an Order to Show Cause Why Defendants Should Not Be Held in Civil Contempt. (Dkt. Nos. 393.) The Court granted Plaintiffs’ request and issued an Order to Show Cause (“OSC”). (Dkt. No. 421.) Defendants filed a response to the OSC (which they labeled as an “Opposition”). (Dkt. No. 422.) Plaintiffs filed a Reply after the Court granted their request to do so. (Dkt. Nos. 428, 429.) The Court denied Defendants’ request to file a Sur-Reply, and permitted Defendants to address their arguments at the hearing. (Dkt. No. 432.) The Court granted Plaintiffs’ request to file a supplemental notice, and Defendants’ request to respond to the supplemental notice. (See Dkt. Nos. 465, 469).

1 **I. BACKGROUND**

2 **1. Preliminary Injunction**

3 On January 20, 2021, the Court granted Plaintiffs’ Motion for Preliminary
4 Injunction (the “Preliminary Injunction”). (Order – Dkt. 137.)

5 Paragraph 1(a) of the Preliminary Injunction enjoins Defendants from
6 “[u]sing or disclosing Plaintiffs’ trade secret information,” including “(1) the
7 design concept for internal pockets or voids of space to increase softness in a
8 cosmetic penile implant; (2) the design concept for use of mesh tabs imbedded in
9 or around the distal tip of a cosmetic penile implant to assist with implantation;”
10 and “(3) the design concept for the use of absorbable sutures in coordination with
11 the mesh tabs imbedded in or around the distal tip of a cosmetic penile implant.”
12 (Preliminary Injunction – Dkt. 138, ¶ 1(a).)

13 Paragraph 1(b) of the Preliminary Injunction also enjoins Defendants from
14 “[c]ommericalizing, marketing, advertising, promoting, offering for sale and/or
15 profiting from the Augmenta implant, U.S. Patent No. 10413413 (“’413 Patent”),
16 and Patent Application No. 16/238,821 (“’821 Application”).” (*Id.*, ¶ 1(b).)

17 Finally, The Preliminary Injunction explicitly states that “the Court is not
18 ordering Defendants to abandon the ‘821 Application or preventing Defendants
19 from pursuing any pending Food and Drug Administration 510(k) submission.”
20 (*Id.*, ¶ 4.)

21
22 **2. Defendants’ Article**

23 On November 19, 2021, Plaintiffs discovered that Defendants had
24 an article entitled “The Augmenta Implant: A Cadaver Model of Novel Anatomic
25 Subdermal Implant for Cosmetic Penile Enhancement” accepted for publication in
26 the journal *Sexual Medicine* (the “Article”). (Article, Ex. A to Baker Decl. – Dkt.
27 No. 392-1). The Article is available online at the following link:
28 [https://www.smoa.jsexmed.org/article/S2050-1161\(21\)00127-6/fulltext](https://www.smoa.jsexmed.org/article/S2050-1161(21)00127-6/fulltext).

1 According to its abstract, the Article was submitted on July 9, 2021 and accepted
2 for publication on September 10, 2021 for publication in the December 2021 issue
3 of Sexual Medicine (*Id.* at 1.)

4 Plaintiffs contend that the Article violates the Preliminary Injunction in two
5 ways: it discloses Plaintiffs' alleged trade secrets (in violation of paragraph 1(a) of
6 the injunction) and markets, advertises, and/or promotes the Augmenta implant (in
7 violation of paragraph 1(b) of the preliminary injunction).

8 As to the disclosure of Plaintiffs' trade secrets, the Article references
9 Augmenta's purportedly unique "Honeycomb Technology," which the Article
10 states is "characterized by sub-centimeter pockets that comprise the under surface
11 of the device throughout its body, designed to reduce the weight of the implant
12 and optimize device elasticity and compressibility." (Baker Decl., Ex. A at 2,
13 emphasis added.) The article also states that Augmenta "possesses multiple
14 polyester mesh tabs embedded within the ventral-most margins of device," which
15 "permits the use of absorbable sutures to secure the implant, minimizing device
16 migration and rotation until tissue ingrowth into the mesh is complete." (*Id.*
17 (emphasis added.)

18 As to marketing, advertising, and promotion of the Augmenta implant,
19 Plaintiffs identify the following excerpts as violating the injunction:

- 20 (1) A description of the Augmenta implant as "newly commercially available"
21 (*Id.* at 2);
- 22 (2) "We present the Augmenta, an innovative, technologically advanced
23 subcutaneous elastomer-silicone cosmetic penile implant (CPI), as evaluated
24 by objective structural changes in a cadaveric model." (*Id.* at 1.);
- 25 (3) "The Augmenta CPI could serve as alternative option [sic] for men seeking
26 cosmetic penile enhancement." (*Id.*);
- 27 (4) "Augmenta was designed to permit safe anatomic expansion that enhances
28 the natural cosmetic penile appearance without encumbering normal penile

1 movement and function.” (*Id.* at 2.);

2 (5) “To date, the Augmenta is the only CPI with a hydrophilic coating that
3 can be dipped in antibiotic solution.” (*Id.* at 6.); and

4 (6) “The Augmenta subcutaneous elastomer-silicone [cosmetic penile implant]
5 uniquely features [sic] a structural elasticity/rigidity gradient-producing
6 Honeycomb Technology and embedded soft polyester mesh which may
7 provide multiple clinical advantages to currently available injectable materials
8 and alternative CPIs.” (*Id.*).

9 The Article also states that the Augmenta “is registered with the U.S. Food
10 and Drug Administration (FDA), has received premarket notification and is
11 awaiting FDA 510k clearance for its use in the cosmetic correction of penile soft
12 tissue deformities,” with “[c]ompleted FDA evaluation anticipated 2021.” (*Id.* at
13 2 n.7 and accompanying text.)

14 On December 3, 2021, after Plaintiffs raised the issue that the Article
15 described the Augmenta implant as “newly commercially available,” Defendant
16 Dr. Cornell filed a declaration stating that Defendant reached out to the editors of
17 the journal to “seek a correction” and remove the phrase “newly commercially
18 available” from the Article. (Dkt. No. 397-20 at ¶ 34.) As a result, the Article
19 now includes an Erratum dated February 1, 2022, which states:

20 In the article entitled ‘The Augmenta Implant: A Cadaver Model of a
21 Novel Anatomic Subdermal Implant for Cosmetic Penile
22 Enhancement’ by Clavell-Hernández J et al (Sex Med
2021;9:100447); after publication, the authors asked to clarify the
23 following: the Augmenta is not currently commercially available.

24 However, the Article remains unchanged, including the statement that the
25 Augmenta implant is “newly commercially available.”

26 **3. Plaintiffs’ Requests**

27 Plaintiffs request that the Court do the following:

28 (1) hold Defendants in civil contempt for violating the Preliminary

1 Injunction by publishing the Article;

2 (2) impose a coercive penalty of \$20,000 per day until Defendants file a
3 declaration of compliance with the Court stating that (i) the article has been
4 removed, (ii) the publisher will retract and correct the improper statements, (iii)
5 Defendants have made reasonable efforts to remove the article from the website,
6 and (iv) Defendants will not use the article for any commercial purpose until the
7 Preliminary Injunction is no longer in force;

8 (3) grant Plaintiffs leave to take limited additional discovery to determine
9 the additional damages caused by the Article, including (i) a subpoena to the
10 publisher for documents related to the submission, acceptance, and publication of
11 the article and (ii) a limited set of interrogatories to Defendants regarding the
12 circumstances of the submission, acceptance, and publication of the article;

13 (4) grant Plaintiffs leave to supplemental the expert opinion of Kevin Arst
14 (damages expert) to address damages caused by the publication of the article;

15 (5) grant Plaintiffs leave to file the expert opinion of a marketing expert
16 regarding additional damages arising from the costs of corrective marketing
17 efforts to mitigate harm caused by the publication, with the costs and fees incurred
18 in engaging the expert to be paid by Defendants;

19 (6) award Plaintiffs actual damages suffered to date by the publication (in
20 an amount to be determined at the conclusion of the contempt proceedings);

21 (7) award Plaintiffs reasonable attorney's fees and costs in connection to the
22 contempt proceedings;

23 (8) grant Plaintiffs leave to present evidence of Defendants' violation of the
24 Preliminary Injunction at trial for the purposes of establishing additional damages
25 Plaintiffs have incurred as a result of Defendants' Preliminary Injunction
26 violation;

27 (9) grant Plaintiffs leave to present evidence of Defendants' violation of
28 the Preliminary Injunction at trial for the purposes of establishing willfulness on

1 the part of Defendants or, in the alternative, an entry of judgment in favor of
2 Plaintiffs on Plaintiffs' first and second causes of action for misappropriation of
3 trade secrets.

4 (Proposed Order – Dkt. No. 393-11.)

6 II. STATEMENT OF THE LAW

7 “Civil contempt . . . consists of a party's disobedience to a specific and
8 definite court order by failure to take all reasonable steps within the party's power
9 to comply.” *In re Dual-Deck Video Cassette Recorder Antitrust Litig.*, 10 F.3d
10 693, 695 (9th Cir. 1993). “The contempt need not be willful, and there is no good
11 faith exception to the requirement of obedience to a court order, . . . [b]ut a person
12 should not be held in contempt if his action appears to be based on a good faith
13 and reasonable interpretation of the [court's order].” *Id.* (internal quotations and
14 citations omitted). “Sanctions for civil contempt may be imposed to coerce
15 obedience to a court order, or to compensate the party pursuing the contempt
16 action for injuries resulting from the contemptuous behavior, or both.” *General*
17 *Signal Corp. v. Donalco, Inc.*, 787 F.2d 1376, 1380 (9th Cir. 1986).

18 In a civil contempt action, “[t]he moving party has the burden of showing
19 by clear and convincing evidence that the contemnors violated a specific and
20 definite order of the court. The burden then shifts to the contemnors to
21 demonstrate why they were unable to comply.” *FTC v. Affordable Media, LLC*,
22 179 F.3d 1228, 1239 (9th Cir. 1999) (quoting *Stone v. City and County of San*
23 *Francisco*, 968 F.2d 850, 856 n.9 (9th Cir. 1992)).

25 III. DISCUSSION

26 1. Plaintiffs' Evidentiary Objections

27 Plaintiffs make numerous evidentiary objections to statements made in the
28 Amended Declaration of Mark Duval (Dkt. 422-27) and Declaration of Shahmeer

1 Halepota (Dkt. No. 422-1.) (Objections – Dkt. No. 427.) The Court can decide
2 the issue of civil contempt without considering the statements in dispute and thus
3 overrules the objections as moot.

4 **2. Civil Contempt**

5 Defendant contend that they should not be held in contempt because (1)
6 publishing the Article was necessary for their pursuit of a 510(k) clearance
7 application for the Augmenta implant, (2) they otherwise substantially complied
8 with the Preliminary Injunction, (3) they reasonably believed that publishing an
9 academic article was not “commercializing, marketing, advertising, promoting,”
10 or offering the Augmenta implant “for sale,” and (4) Plaintiffs already disclosed
11 their trade secrets to the public.

12 **2.1. 510(k) Application**

13 Defendants contend that they did not violate the Preliminary Injunction
14 because publishing the Article was a necessary step in obtaining 510(k) clearance
15 in response to the complaints sent to the FDA discussed above. In support of this
16 argument, Defendants provide the declaration of Mark Duval, who was retained
17 by and represents Defendants and specializes in regulatory counseling for medical
18 device companies, in which he opines on the FDA 501(k) application process.
19 Plaintiffs disagree that publishing the Article is necessary. They rely on the
20 declaration of Allison Komiyama, Ph.D., who was retained by and represents
21 Plaintiffs and specializes in regulatory affairs exclusively for the medical device
22 industry. (Reply – Dkt. No. 429.)

23 Mr. Duval and Dr. Komiyama provide differing opinions on whether
24 submitting the Article for publication was a “necessary” step during Defendants’
25 501(k) application process. The Court, however, can decide the issue of civil
26 contempt without analyzing whether the submission of the Article was a necessary
27 step, and instead focusing on whether the language of the Article constitutes
28 “marketing” or “advertising” in violation of the Preliminary Injunction. Thus, the

1 Court does not address the 501(k) process in this Order.

2
3 **2.2. Substantial Compliance**

4 Defendants contend that they should not be held in contempt because they
5 substantially complied with the Court’s Preliminary Injunction because they (1)
6 shut down the Augmenta website, (2) made no attempt to sell an Augmenta
7 implant to any potential patients or surgeons, (3) have not created or disseminated
8 any marketing materials to promote Augmenta, and (4) have ceased all fundraising
9 for Augmenta, LLC. (Response – Dkt. No. 422 at 18.)

10 The Ninth Circuit has held that “‘substantial compliance’ with [a] court
11 order is a defense to civil contempt, and is not vitiated by ‘a few technical
12 violations’ where every reasonable effort has been made to comply.” *In re Dual-*
13 *Deck Video Cassette Recorder Antitrust Litig.*, 10 F.3d 693, 695 (9th Cir 1993)
14 (citation omitted). Although “technical or inadvertent violations of [an] order will
15 not support a finding of contempt,” a party must take “‘all reasonable steps’ to
16 comply with [a] court order.” *Don’t Shoot Portland v. City of Portland*, 503 F.
17 Supp. 3d 1022, 1036 (D. Or., Nov. 27, 2020) (quoting *Gen. Signal Corp. v.*
18 *Donallco, Inc.*, 787 F.2d 1376, 1379 (9th Cir. 1986)). Moreover, the mere fact
19 that a party “took some steps to ensure compliance” does not relieve it of the
20 obligation to comply with the order as a whole. *Id.*

21 Here, despite Defendants’ efforts, their decision to submit the Article for
22 publication was not a “technical or inadvertent violation” of the Preliminary
23 Injunction — it was a deliberate decision that required time and effort to complete.
24 Accordingly, the Court finds that Defendants have not substantially complied with
25 the Preliminary Injunction.

26
27 **2.3. Advertising, Marketing, and Promoting the Augmenta**

28 Defendants contend that they should not be held in contempt because they

1 reasonably believed that publishing the Article did not violate the Preliminary
2 Injunction’s prohibition on “[c]ommericalizing, marketing, advertising,
3 promoting, offering for sale and/or profiting from the Augmenta implant.”
4 (Preliminary Injunction – Dkt. No. 138 at ¶ 1(b).) First, they contend that
5 “nothing in the injunction states that publishing a scholarly article in [a] peer-
6 reviewed medical journal was forbidden.” Second, they cite to the various
7 dictionary definitions of the words used in the Preliminary Injunction that they
8 believe permit their submission of the Article for publication.

9 The Article, however, includes statements that the Article “present[s] the
10 Augmenta, an innovative, technologically advance subcutaneous elastomer-
11 silicone cosmetic penile implant” and that the Augmenta is “newly commercially
12 available.” The Court finds that these statements violate Section 1(b) of the
13 Preliminary Injunction because a reasonable interpretation of the statements
14 demonstrates that they were made to market, advertise, and promote the
15 Augmenta.

16 Accordingly, the Court holds Defendants in civil contempt for violating
17 Section 1(b) of the Preliminary Injunction.

18 **2.4. Disclosure of Trade Secrets**

19 Defendants contend that they did not violate the Preliminary Injunction’s
20 prohibition of “[u]sing or disclosing Plaintiffs’ trade secret information” because
21 Plaintiffs previously disclosed the design concepts at issue in prior art.

22 First, the Court finds that Defendants violated the Preliminary Injunction by
23 advertising, marketing, and promoting the Augmenta in violation of Section 1(b).
24 Second, the Court denied in part Defendants’ Motion for Summary Judgment
25 (Dkt. No. 527) on the grounds that there are genuine disputes of material fact as to
26 whether the trade secret concepts were indeed disclosed in the prior art. The
27 Court thus does not address whether Defendants disclosed the trade secrets in the
28 Article.

1 **3. Attorney’s Fees**

2 Both parties request an award of attorney’s fees for litigating this contempt
3 issue, which they will fully brief in a separate motion for attorney’s fees.

4 “An award of attorney’s fees for civil contempt is within the discretion of
5 the district court.” *Harcourt Brace Jovanovich Legal & Pro. Publications, Inc. v.*
6 *Multistate Legal Stud., Inc.*, 26 F.3d 948, 953 (9th Cir. 1994). “[T]he cost of
7 bringing the violation to the attention of the court is part of the damages suffered
8 by the prevailing party and those costs would reduce any benefits gained by the
9 prevailing party from the court’s violated order.” *Inst. of Cetacean Rsch. V. Sea*
10 *Shepherd Conserv. Soc.*, 774 F.3d 935, 958 (9th Cir. 2014) (citations omitted).

11 Because the Court finds that Defendants violated the Preliminary Injunction
12 and holds them in civil contempt, the Court finds that Plaintiffs are the prevailing
13 party for purposes of this Motion. The Court thus grants Plaintiffs leave to file a
14 Motion for Attorney’s Fees to recover the attorney’s fees and costs incurred while
15 litigating this issue.

16
17 **4. Sanctions**

18 “District courts have broad equitable power to order appropriate relief in
19 civil contempt proceedings.” *F.T.C. v. EDebitPay, LLC*, 695 F.3d 938, 945 (9th
20 Cir. 2012). “Sanctions for civil contempt may be imposed to coerce obedience to
21 a court order, or to compensate the party pursuing the contempt action for injuries
22 resulting from the contemptuous behavior, or both.” *Toyo Tire & Rubber Co. v.*
23 *Hong Kong Tri-Ace Tire Co.*, 281 F. Supp. 3d 967, 987–88 (C.D. Cal. 2017)
24 (quoting *Gen. Signal Corp. v. Donallco, Inc.*, 787 F.2d 1376, 1380 (9th Cir.
25 1986)). “One of the paradigmatic civil contempt sanctions is a per diem fine
26 imposed for each day a contemnor fails to comply with an affirmative court
27 order.” *United States v. Ayres*, 166 F.3d 991, 995 (9th Cir. 1999); *see also CBS*
28 *Broad. Inc. v. FilmOn.com, Inc.*, 814 F.3d 91 (2d Cir. 2016) (upholding fine of

1 \$10,000 per day for violation of injunction).

2 The party pursuing the contempt action is also entitled to “compensation for
3 any actual damages suffered.” *Inst. of Cetacean Rsch.*, 774 F.3d at 958 (awarding
4 compensation to ship operators for “actual damages suffered and resources (such
5 as fuel and personnel costs) that were wasted as a result of Defendants’ violation
6 of a preliminary injunction).

7 The Court imposes the following sanctions:

8 (1) The Court imposes a coercive penalty of \$5,000 per day from the date of
9 the filing of this order until Defendants file a declaration of compliance with the
10 Court stating that (i) Defendants have made reasonable efforts to remove the
11 article from the publisher’s website, (ii) Defendants have made reasonable efforts
12 to have the publisher retract and correct the improper statements, and (iii)
13 Defendants will not use the article for any commercial purpose until the
14 Preliminary Injunction is no longer in force;

15 (2) The Court grants Plaintiffs leave to take limited additional discovery to
16 determine the additional damages caused by the Article, including (i) a subpoena
17 to the publisher for documents related to the submission, acceptance, and
18 publication of the article and (ii) a set of interrogatories to Defendants limited to
19 the circumstances of the submission, acceptance, and publication of the article;

20 (3) The Court grants Plaintiffs’ request for leave to supplement the expert
21 opinion of Kevin Arst (damages expert) to address damages caused by the
22 publication of the article. The supplemental opinion must comply with Federal
23 Rule of Civil Procedure 26;

24 (4) The Court grants Plaintiffs leave to file the expert opinion of a
25 marketing expert regarding additional damages arising from the costs of corrective
26 marketing efforts to mitigate harm caused by the publication. The expert opinion
27 must comply with Federal Rule of Civil Procedure 26.

28 The additional discovery permitted by this Order must be completed no

1 later than January 1, 2023.

2 **IV. CONCLUSION**

3 Accordingly, the Court holds Defendants in civil contempt for violating
4 section 1(b) of the Court's Preliminary Injunction, grants Plaintiffs leave to file a
5 Motion for Attorney's Fees, and imposes the sanctions as described in this Order.

6
7 **IT IS SO ORDERED.**

8
9 DATED: 11/1/22.


10 **CONSUELO B. MARSHALL**
11 **UNITED STATES DISTRICT JUDGE**