

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
26
27
28

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

EDWARDS LIFESCIENCES
CORPORATION, et al.,

Plaintiffs,

v.

MERIL LIFE SCIENCES PVT. LTD., et al.,

Defendants.

Case No. 19-cv-06593-HSG

**ORDER GRANTING MOTION FOR
SUMMARY JUDGMENT AND
GRANTING IN PART AND DENYING
IN PART MOTIONS TO SEAL**

Re: Dkt. No. 67

Pending before the Court is Defendants Meril Life Sciences PVT. LTD (“Meril Life Sciences”) and Meril, Inc. (collectively, “Defendants,” or “Meril”) Motion for Summary Judgment, for which briefing is complete. Dkt. Nos. 67 (“Mot.”), 82 (“Opp.”), and 90 (“Reply”). The parties have also filed administrative motions to seal (“Motions to Seal”) portions of their briefs and exhibits related to the Motion. *See* Dkt. Nos. 66, 81, 87, 89. On September 24, 2020, the Court held a hearing on the Motion. Dkt. No. 96. For the reasons below, the Court **GRANTS** Defendants’ Motion for Summary Judgment, and **GRANTS IN PART** and **DENIES IN PART** the Motions to Seal.

I. BACKGROUND¹

Meril Life Sciences is an India-based, global medical device company that was founded in 2007. Declaration of Nilay Lad (Dkt. No. 67-3, “Lad Decl.”) ¶ 2. Meril, Inc. is a wholly owned subsidiary of Meril Life Sciences. *Id.* Meril created a “Myval” branded transcatheter heart valve, which is designed to be used with a “Navigator” delivery system (collectively, the “Myval System”). *Id.* ¶ 3; Declaration of Sanjeev Bhatt (Dkt. No. 67-1, “Bhatt Decl.”) ¶ 3. Edwards

¹ The following facts are undisputed unless otherwise noted.

1 Lifesciences Corporation (“Plaintiff” or “Edwards”) is a supplier of medical devices for the
2 treatment of heart disease, including artificial heart valves. Among its best-known products are its
3 “SAPIEN®” transcatheter prosthetic heart valves.

4 The Myval System is intended to treat severe symptomatic native aortic valve stenosis, a
5 condition where the aortic valve narrows and restricts normal blood flow. *Id.* In 2016, Meril’s
6 experimentation with the Myval System led up to a cadaver procedure “to determine the feasibility
7 of implanting the Myval transcatheter heart valve into human subjects” at the University of
8 Washington (“UW”) in January 2017. Bhatt Decl. ¶ 4. In January 2017, Meril shipped six
9 samples of the Myval System to UW to conduct these pre-clinical investigations on cadavers, and
10 to determine whether the Myval transcatheter heart valve could be safely implanted in future
11 clinical studies. *Id.* Members of the UW team successfully implanted the Myval transcatheter
12 heart valve in cadavers, which enabled Meril to plan its clinical studies with human subjects. *Id.*²

13 Meril first began conducting clinical trials for its Myval System in India in June 2017, and
14 received approval from the Drug Controller General of India on October 31, 2018. Lad Decl. ¶ 4.
15 In April 2019, the Myval System was granted the CE marking, which certifies its conformance to
16 health and safety standards for products sold within the European Economic Area. *Id.* In the
17 United States, the Myval System is considered a “Class III” medical device subject to strict
18 regulatory standards. *Id.* ¶ 5; 21 U.S.C. § 360c(a)(1)(C) (classifying a Class III device as “for use
19 in supporting or sustaining human life or for a use which is of substantial importance in preventing
20 impairment of human health”). Therefore, Meril may not lawfully market or sell the Myval
21 System in the United States without first receiving mandatory premarket approval from the United
22 States Food and Drug Administration (“FDA”). Lad Decl. ¶ 5; 21 U.S.C. § 360c; 21 C.F.R. §

23

24 ² Around this time, Meril also began planning a preclinical animal study for Myval with the CRF
25 Skirball Center for Innovation in New York (“Skirball Study”). Dkt. No. 87-6 (“Stephens Decl.”)
26 Ex. 13 at 4:23-28. The Skirball Study was to investigate the feasibility of implanting the Myval
27 System into humans, and whether Meril could do so safely in clinical studies. *Id.* In 2016, Meril
28 sent three samples of the Myval transcatheter heart valve (“THV”) and the Myval System for the
Skirball Study, and six Myval Samples to UW. Bhatt Decl. ¶ 4; Stephens Decl. Ex. 13 at 4:23-28.
The Skirball Study occurred on January 27, 2017, and the results were documented in a written
report. Dkt. No. 90-1 (“Mayer Reply Decl.”) Ex. 15.

1 812.20; 21 C.F.R. § 812.42.

2 To receive premarket approval from the FDA, Meril must first apply for and obtain an
3 investigational device exemption (“IDE”) from the FDA, identify clinical investigators to implant
4 the device in human subjects, collect data from those subjects, and then submit the data to the
5 FDA. Lad Decl. ¶ 5; Bhatt Dec. ¶ 5. IDE applications require sponsors to describe all preclinical
6 testing and include reports of prior investigations. Dkt. No. 67-15, Declaration of Melanie Mayer
7 (“Mayer Decl.”), Ex. 4 at MERIL00000542.

8 The premarket approval process can be lengthy and difficult to navigate, and Meril began
9 preparations ahead of its planned IDE application. First, Meril began preparing for a pre-
10 submission to the FDA, which allows device manufacturers to request formal regulatory feedback
11 on the device before officially engaging in the premarket approval process. Lad Decl. ¶¶ 6-7;
12 Mayer Decl., Ex. 1 at MERIL00000404. The pre-submission program allows device makers like
13 Meril to obtain guidance from the FDA about its premarket submissions, which in turn improves
14 the quality of submissions and shortens total review times. Lad Decl. ¶ 6; Mayer Decl., Ex. 1 at
15 MERIL00000404.

16 In May 2019, Meril imported a number of Myval System devices to a large conference in
17 France called EuroPCR. Dkt. No. 84-1, Ex. A (“Lad Depo.”) at 76-78. Edwards appears to have
18 anticipated this importation, and filed a proceeding in France authorizing the seizure of the Myval
19 Devices based on the alleged infringement of Edwards’ European patents. *Id.* A brochure was
20 seized that included an updated new slide on Meril’s Global Clinical Program, with the first
21 mention of a “Landmark Trial.” *See* Stephens Decl. ¶ 82; Ex. 34. This “Landmark Trial” was to
22 be a three-arm trial comparing the Myval System with the market leading devices in Europe,
23 Edwards’ SAPIEN valves and Medtronic’s CoreValve Evolut valves. Dkt. No. 84-2, Ex. B
24 (“Bhatt Depo.”) at 50-51.

25 In late August 2019, Meril contacted the FDA to inquire about the Landmark Trial and the
26 preliminary requirements for filing a pre-submission. Lad Decl. ¶ 7, Exs. A, B. In early
27 September 2019, Meril also contacted CardioMed LLC, a medical device consulting company that
28 provides regulatory and clinical trial consulting services, including for premarket approval

1 submissions, and sought its help in preparing a pre-submission filing to the FDA for the Myval
2 System. *Id.* ¶ 8, Ex. C.

3 Meril then sought out potential clinical researchers at the 2019 Transcatheter
4 Cardiovascular Therapeutics Conference in San Francisco (“TCT Conference”)—an annual
5 scientific symposium hosted by the Cardiovascular Research Foundation (“CRF”) featuring the
6 latest developments in interventional cardiovascular medicine, and attended by leading researchers
7 and clinicians. *Id.* ¶ 10; Mayer Decl., Ex. 3. In advance of the TCT Conference, Meril provided
8 CRF a digital flyer containing information about Meril’s booth and its agenda at the conference.
9 *Id.* ¶ 11. CRF then distributed this flyer to individuals and organizations who had subscribed to
10 receive email updates about the TCT Conference. *Id.* It is undisputed, however, that the Myval
11 System was never shown to anyone after it was imported into the United States. *Id.* ¶ 17; Lad
12 Depo. at 95-96.

13 Nilay Lad, a Meril employee, traveled to San Francisco on September 24, 2019 to attend
14 the TCT Conference. Lad Decl. ¶ 13. He carried with him two Myval THV’s, Myval THV’s with
15 rubber leaflets, and two Navigator delivery systems (collectively, “Myval Samples”) on his flight
16 into San Francisco International Airport. *Id.* The Myval Samples were contained in a bag, and
17 accompanied by a written declaration stating:

18 This is to inform you that the demo samples carried by Mr. Nilay Lad
19 is for the demonstration purpose only.

20 It is consist [sic] of Demo samples of Medical devices. They have no
21 commercial value & hence it is not used for any sales purpose. The
22 demo samples are NON-STERILE. NOT FOR HUMAN USE. NOT
FOR SALE. NOT APPROVED FOR SALE IN UNITED STATES.
FOR DEMO PURPOSE ONLY AT TCT 2019, SAN FRANCISCO.

23 *Id.*, Ex. F.

24 Meril had a booth at the TCT Conference from September 26 to September 28, and
25 provided information on its cardiovascular systems, including the Myval System, in the form of
26 visual displays and presentations to attending physicians. *Id.* ¶ 14, Exs. G-H. For the Myval
27 System, Meril exhibited patient case studies, information on the Myval System and its use in a
28 clinical trial, and information about the placement of the Myval System in patients. *Id.* Meril
stated to conference attendees that the Myval System was not yet approved by the FDA, and that it

1 was not available for sale in the U.S. *Id.* Meril also discussed the details of the Myval System
2 with several U.S. doctors to identify potential clinicians for its premarket approval application. *Id.*
3 ¶ 15.

4 Meril considered showing the physical Myval System in conjunction with a simulation
5 system that would provide potential clinicians with a hands-on opportunity to interact with the
6 physical devices. However, because of alleged technical difficulties with the simulation system,
7 Meril did not show the physical Myval samples at the TCT Conference. *Id.* ¶ 17. Meril also did
8 not offer for sale or sell the Myval System to any non-U.S. customers at the TCT Conference. *Id.*
9 ¶ 15. Because Meril did not exhibit the physical Myval Samples, Mr. Lad maintained the samples
10 overnight in a bag in a storage room at the TCT Conference. The samples were never taken out of
11 the bag or displayed to any conference attendees. *Id.*

12 On September 28, Mr. Lad gave the Myval Samples to another Meril employee, Sanjeev
13 Bhatt, to take to Europe on September 30. *Id.*; Bhatt Decl. ¶ 6. For a short period of time after
14 Meril attended the TCT Conference, Meril’s LinkedIn page stated that 2,000 people visited its
15 booth at the TCT Conference and that Meril had exhibited the Myval System at its booth. Lad
16 Decl. ¶ 18. Meril later removed the LinkedIn post. *Id.*

17 **II. LEGAL STANDARD**

18 Summary judgment is proper when a “movant shows that there is no genuine dispute as to
19 any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a).
20 A fact is “material” if it “might affect the outcome of the suit under the governing law.” *Anderson*
21 *v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). And a dispute is “genuine” if there is evidence
22 in the record sufficient for a reasonable trier of fact to decide in favor of the nonmoving party. *Id.*
23 But in deciding if a dispute is genuine, the court must view the inferences reasonably drawn from
24 the materials in the record in the light most favorable to the nonmoving party, *Matsushita Elec.*
25 *Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986), and “may not weigh the evidence
26 or make credibility determinations,” *Freeman v. Arpaio*, 125 F.3d 732, 735 (9th Cir. 1997),
27 *overruled on other grounds by Shakur v. Schriro*, 514 F.3d 878, 884–85 (9th Cir. 2008). If a court
28 finds that there is no genuine dispute of material fact as to only a single claim or defense or as to

1 part of a claim or defense, it may enter partial summary judgment. Fed. R. Civ. P. 56(a).

2 **III. DISCUSSION**

3 Defendants contend that they did not infringe Plaintiff’s patents because (1) Meril did not
4 use or exhibit Myval samples during the TCT Conference, and (2) Meril’s transportation of its
5 Myval-branded transcatheter heart valve system to UW in 2017 and to the TCT Conference was
6 reasonably related to its premarket submissions to the FDA, and is thus protected by the safe
7 harbor exemption under 35 U.S.C. § 271(e)(1).

8 **A. Safe Harbor Application**

9 Congress enacted 35 U.S.C. § 271(e)(1) to address issues created by the legal requirements
10 for pre-market FDA approval of drugs and medical devices, particularly those involving patented
11 inventions. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-70 (1990). One of these issues
12 was that third parties wishing to sell the patented product upon patent expiration had to engage in
13 a lengthy FDA approval process, essentially creating a *de facto* extension of the patent while FDA
14 approval was pending. *Id.* at 670.

15 To address this problem, Congress enacted the safe harbor of Section 271(e)(1), which
16 provides that “[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the
17 United States or import into the United States a patented invention . . . solely for uses reasonably
18 related to the development and submission of information under a Federal law which regulates the
19 manufacture, use, or sale of drugs or veterinary biological products.” Put differently, Section
20 271(e)(1) allows competitors, before the expiration of a patent, to engage in otherwise infringing
21 activities if the use is “reasonably related to” obtaining regulatory approval. Courts routinely
22 decide the applicability of the safe harbor at the summary judgment stage. *See, e.g., Genentech,*
23 *Inc. v. Insmid Inc.*, 436 F. Supp. 2d 1080, 1095 (N.D. Cal. 2006); *Classen Immunotherapies, Inc.*
24 *v. Biogen IDEC*, 659 F.3d 1057, 1059 (Fed. Cir. 2011).

25 Section 271(e)(1) undisputedly can apply to medical devices like the Myval System. *Eli*
26 *Lilly*, 496 U.S. at 661. Section 271(e)(1) “provides a wide berth for the use of patented
27 [inventions] in activities related to the federal regulatory process.” *Merck KGaA v. Integra*
28 *Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005); *see also Med. Diagnostic Labs., L.L.C. v.*

1 *Protagonist Therapeutics, Inc.*, 298 F. Supp. 3d 1241, 1247 (N.D. Cal. 2018). The Supreme Court
 2 has explained that “[Section] 271(e)(1)’s exemption from infringement extends to *all* uses of
 3 patented inventions that are reasonably related to the development and submission of *any*
 4 information under the FDCA [Federal Food, Drug, and Cosmetic Act],” which “necessarily
 5 includes preclinical studies.” *Merck KGaA*, 545 U.S. at 202 (emphasis in original). The safe
 6 harbor also applies regardless of the phase of research, and even if the information is never
 7 ultimately submitted to the FDA as part of an approval application. *Id.* at 202, 205 (“There is
 8 simply no room in the statute for excluding certain information from the exemption on the basis of
 9 the phase of research in which it is developed or the particular submission in which it could be
 10 included.”); *see also Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1027 (Fed. Cir. 1997) (finding
 11 the safe harbor applicable where, “[a]t the time of this litigation, [defendant] had neither filed an
 12 application for approval with the FDA nor otherwise marketed the device”).

13 As the Supreme Court explained, an activity is “reasonably related” to federal regulatory
 14 activities if an accused manufacturer has a reasonable basis for believing that a device may work
 15 to achieve a particular result, and uses the device in research that, if successful, would be
 16 appropriate to include in a submission to the FDA. *Merck KGaA*, 545 U.S. at 207; *see also*
 17 *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1280 (N.D. Cal. 1991) (“*Intermedics I*”)
 18 (proper inquiry is whether “it [would] have been reasonable, objectively, for a party in defendant's
 19 situation to believe that there was a decent prospect that the ‘use’ in question would contribute . . .
 20 to the generation of [] kinds of information . . . likely to be relevant in the processes by which the
 21 FDA would decide whether to approve the product”).

22 Similarly, consistent with the language of the statute, the safe harbor inquiry focuses on
 23 acts or uses, and not on purposes, intent or motive. *See* 35 U.S.C. § 271(e)(1) (extending
 24 protection to “uses reasonably related”). The Federal Circuit has explained that “[t]he breadth of
 25 the exemption [under Section 271(e)(1)] extends even to activities the ‘actual purpose’ of which
 26 may be ‘promot[ional]’ rather than regulatory, at least where those activities are ‘consistent with
 27 the collection of data necessary for filing an application with the [FDA].” *Momenta Pharm., Inc.*
 28 *v. Teva Pharm. USA Inc.*, 809 F.3d 610, 619 (Fed. Cir. 2015) (citing *Abtox*, 122 F.3d at 1027).

1 Plaintiff contends that the safe harbor requires an “actual use.” Opp. at 16. However, as
2 noted, the safe harbor provides that “[i]t shall not be an act of infringement to make, use, offer to
3 sell, or sell within the United States or import into the United States a patented invention . . .
4 solely for uses reasonably related to the development and submission of information” to the FDA.
5 35 U.S.C. § 271(e)(1). The statute lists each of the possibly infringing acts (making, using,
6 offering to sell, selling, and importing) separately, making clear that importation by itself (without
7 actual use) can fall within the safe harbor. The clause “solely for uses reasonably related to the
8 development and submission of information” to the FDA also does not require an “actual use.” As
9 the Federal Circuit has explained, the safe harbor applies “[a]s long as the [allegedly infringing]
10 activity [*e.g.*, making, using, selling, offering for sale, and importing] is reasonably related to
11 obtaining FDA approval.” *Abtox*, 122 F. 3d at 1030.

12 Here, Defendants contend that there can be no genuine dispute that all the accused
13 activities were directed at furthering Meril’s clinical investigation of its Myval System for future
14 FDA approval and thus fall squarely within the scope of the safe harbor. Plaintiff alleges two acts
15 of infringement: (1) Meril “imported” the Myval System into the United States in 2017 so that
16 UW could conduct a pre-clinical cadaver study (Dkt. No. 51 ¶ 40); and (2) Meril “imported” and
17 “exhibited” at least one Myval System at the 2019 TCT Conference. *Id.* ¶ 39.

18 **i. 2019 TCT Conference**

19 Meril contends that the shipment of samples to the TCT Conference falls within the safe
20 harbor because Meril did not exhibit the Myval System during the TCT Conference. *Lad Dec.* ¶
21 17. Meril states that although it transported a number of Myval Samples to the TCT Conference
22 planning to demonstrate the physical device to potential clinical researchers, it had technical
23 difficulties with the simulation system, with the result that the Myval Samples remained stored
24 away during the time they were in San Francisco and were not shown to any conference attendees.
25 *Id.* Accordingly, Meril contends that there can be no infringement.

26 According to the Federal Circuit, demonstrations at medical conferences are covered by
27 the Section 271(e)(1) safe harbor. *Intermedics, Inc. v. Ventritex Co.*, No. 92-1076, 1993 WL
28 87405, at *3 (Fed. Cir. Feb. 22, 1993) (“*Intermedics IP*”) (“Assuming that these nonsale

1 demonstrations at medical conferences constitute an infringing use, we have held they are an
2 exempt use that is reasonably related to procuring FDA approval of the device.”); *Chartex Intern.*
3 *PLC v. M.D. Personal Products Corp.*, 5 F.3d 1505, 1993 WL 306169, at *4 (Fed. Cir. 1993)
4 (affirming summary judgment of non-infringement because exhibition of device at trade show was
5 either a non-infringing act under 35 U.S.C. § 271(a) or exempt under the Section 271(e)(1) safe
6 harbor). And transporting a device to a medical conference is a necessary and predicate act for
7 displaying the device, such that the transportation of an accused device into a country for display
8 at a medical conference is also exempt under the safe harbor. *See Bio-Tech. Gen. Corp. v.*
9 *Genentech, Inc.*, 80 F.3d 1553, 1564 (Fed. Cir. 1996) (importing accused product into the U.S.
10 “for use in clinical trials in support of . . . application for FDA approval” is non-infringing
11 activity); *Merck KGAA*, 545 U.S. at 202 (the safe harbor extends to “all uses” reasonably related to
12 the development of any information for FDA purposes).

13 It is undisputed that as of the time of TCT Conference, Meril had taken significant steps
14 towards obtaining FDA approval for the Myval System, including: (1) preparing a formal clinical
15 trial synopsis for its Landmark Trial, Mayer Reply Decl. Ex. 9;³ (2) preparing a draft
16 presubmission to seek FDA input on its clinical trial, Dkt. No. 84-4 (“Nair Depo.”) at 33:3-24; (3)
17 communicating with the FDA regarding Meril’s proposed clinical study and its presubmission,
18 Lad Decl. Exs. A, B; and (4) hiring an FDA consultant to help with the FDA presubmission. Lad
19 Decl. ¶¶ 8-9; Nair Depo. at 57:10-58:15. Plaintiff does not dispute these facts, and instead
20 contends that because Meril never actually used the devices after their importation, its safe harbor
21 defense fails as a matter of law.

22
23 ³ The Landmark Trial appears to be a post-EU-approval study to be conducted in Europe to
24 compare the Myval System to other leading devices in the European market. Lad Decl. ¶¶ 12, 15.
25 Plaintiff contends that the Landmark Trial is not an “FDA clinical trial” because Meril’s early
26 documents describe it as an “outside the US” trial. Opp. at 17. However, it is undisputed that
27 FDA approval can be supported by clinical trials that include patients both within and outside of
28 the US. Mayer Reply Decl. Ex. 14 at 1, 4; Lad Decl. Ex. A at MERIL00000442-443. Therefore,
even if the Landmark Trial was an entirely “OUS” study at the time of the TCT Conference, and
even if Meril was only identifying investigators at the TCT Conference for this OUS trial, and
even if it was commercially motivated in part, the Landmark Trial was reasonably related to FDA
approval.

1 The Court finds that the undisputed evidence gives rises to no genuine dispute of fact as to
2 whether Meril’s transportation of non-commercial Myval Samples to the TCT Conference is
3 exempt under the safe harbor. Lad Decl. ¶¶ 13-15, 17.⁴ It is undisputed that Meril transported the
4 medical device to the TCT Conference, which was attended by a large number of potential clinical
5 trial investigators. Lad Decl. ¶ 14. It is also undisputed that Meril did not sell or offer to sell its
6 medical device at the medical conference. *Id.* ¶ 15. Therefore, Meril’s transportation of the
7 Myval Samples to the TCT Conference, where Meril did not sell or offer to sell the device, was
8 reasonably related to the submission of information to the FDA, including educating the
9 investigators at the TCT about the Myval System. *See id.* ¶¶ 13, 15; *Telectronics II*, 982 F.2d at
10 1523 (nonsale “demonstrations constitute an exempt use reasonably related to FDA approval”);
11 *Intermedics II*, 1993 WL 87405, at *3 (nonsale demonstrations at medical conferences are
12 reasonably related to FDA approval and exempt under the safe harbor); *see also Proveris*
13 *Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1263 (Fed. Cir. 2008) (“demonstrating an
14 implantable defibrillator at medical conference was ‘reasonably related’ to FDA approval because
15 it facilitated the selection of clinical trial investigators”).

16 **ii. University of Washington Study**

17 Meril similarly contends that its shipment of Myval Samples to UW for preclinical
18 investigations was protected under the safe harbor. It is undisputed that the UW preclinical study
19 investigated whether the Myval System could be safely implanted in human subjects in future
20 clinical studies. Bhatt Decl. ¶ 4. Plaintiff appears to agree that the UW study was performed by
21 “an internationally respected interventional cardiologist,” who successfully implanted the Myval
22 THV in cadavers and documented the entire procedure on video. Opp. at 20; Bhatt Decl. ¶ 4;

24 ⁴ Plaintiff objects to portions of the Lad Declaration and contends that Mr. Lad lacks personal
25 knowledge of “Meril’s purpose for importing the Myval Device.” Opp. at 15. However, it is
26 undisputed that Mr. Lad personally transported the Myval Samples to the TCT Conference, and he
27 testified that he consulted with counsel and Mr. Bhatt about bringing the Myval System to the
28 TCT Conference. Lad Decl. ¶ 13; Lad Depo. at 34:8-34:17; 60:2-61:7. In addition, Mr. Lad and
Mr. Bhatt explain that Meril brought the Myval samples to the TCT Conference to identify FDA
clinical trial investigators. *See* Bhatt Depo. at 64:1-65:1, 65:21-66:10; Lad Depo. at 83:16-84:1;
see also Bhatt Decl. ¶ 5; Stephens Decl. Ex. 13 at 6:8-11. Accordingly, Plaintiff’s objections to
the Lad Declaration are overruled, and Mr. Lad’s declaration adequately establishes personal
knowledge. *See Fraser v. Goodale*, 342 F.3d 1032, 1036 (9th Cir. 2003).

1 Bhatt Depo. at 40:11-20.

2 The Supreme Court has made clear that preclinical studies appropriate for submission to
3 the FDA during the regulatory process are protected under the safe harbor, even if the results are
4 never ultimately submitted. *Merck KGaA*, 545 U.S. at 202, 205 (“There is simply no room in the
5 statute for excluding certain information from the exemption on the basis of the phase of research
6 in which it is developed or the particular submission in which it could be included.”). Meril
7 presents undisputed evidence that the Myval Samples were related to determining the feasibility
8 and safety of using the Myval System to implant the Myval transcatheter valve in live human
9 subjects, which Meril needed to confirm before it could conduct clinical trials. *Id.* at 193 (safe
10 harbor exempts preclinical studies pertaining to device safety and efficacy in humans); *Genentech,*
11 *Inc. v. Insmid Inc.*, 436 F. Supp. 2d at 1095 (applying safe harbor where third-party consultant
12 research using the accused compound “was for FDA purposes” and where, “[w]ithout FDA
13 approval, Defendants could not sell their drug on the market”); *Intermedics I*, 775 F. Supp. at 1285
14 (where safety certification by a third party was required to conduct FDA clinical tests, such testing
15 was protected by safe harbor).

16 It is also undisputed that the UW clinicians used the Myval System to place a Myval THV
17 in a cadaver. Bhatt Decl. ¶ 4. And Meril used the data collected during this investigation to
18 understand the mechanics of positioning the Myval transcatheter valve in a human body. *Id.*
19 There is also no dispute that, to receive premarket approval for Myval, Meril needed to first obtain
20 an IDE from the FDA, and that the FDA requires the IDE application to include a “report of prior
21 investigations [that] must include reports of all prior clinical, animal, and laboratory testing of the
22 device.” Lad Decl. ¶ 5; Mayer Decl. Ex. 4 at MERIL00000542; *see* Opp. at 19. Therefore, the
23 Court finds that there is no genuine dispute that the UW preclinical study produced (and was
24 therefore reasonably related to) the types of information that are relevant to the FDA approval
25 process.

26 Plaintiff nevertheless contends that “Meril did not submit any information from this study
27 in connection with either of its FDA pre-submissions.” Opp. at 20. Meril counters that Plaintiff
28 misunderstands the FDA process, and that Meril is only at the presubmission stage of the FDA

1 process, during which it is getting FDA input on certain information it plans to submit in its later
2 IDE. Bhatt Depo. at 128:25-129:12; Mayer Reply Decl. Ex. 12. When Meril reaches the IDE
3 stage, the FDA rules require Meril to submit the UW cadaver study video as part of its IDE.
4 Mayer Decl. Ex. 4 at MERIL00000542. In any event, the Supreme Court has made clear that the
5 safe harbor applies to preclinical studies even if the data is not ultimately submitted to the FDA, so
6 Plaintiff’s argument fails as a matter of law. *Merck*, 545 U.S. at 207 (safe harbor “does not
7 become more attenuated (or less reasonable) simply because the data from that experiment are left
8 out of the submission . . . to the FDA”).

9 Plaintiff also contends that Meril did not describe “what information the cadaver study
10 would generate that is relevant to an IDE or PMA.” Opp. at 19. However, Meril explained that it
11 used the data collected during the UW preclinical study to understand the mechanics of
12 positioning the Myval THV in the human body and to determine the feasibility of safely
13 implanting the valve in live human subjects. Bhatt Decl. ¶ 4. Plaintiff does not dispute this, and it
14 is undisputed that the UW study data must be submitted to FDA. In the end, Plaintiff’s argument
15 is unpersuasive, and no more is required for the safe harbor to apply on this record.⁵

16 Lastly, leaving no potentially saving angle unexplored, Plaintiff also asserts that there were
17 a number of additional importations as to which Defendants did not move for summary judgment.
18 Opp. at 18-19. Defendants also appear to move for summary judgment as to the Skirball Study
19 only in their Reply, as there is no mention of the study in the motion. Reply at 6.

20 However, none of these “additional” importations or acts of infringement, including the
21 Skirball Study, are mentioned by Plaintiff in its Amended Complaint, which only addresses the
22 UW study and the TCT Conference. *See, e.g.*, Dkt. No. 51 at ¶¶ 38-40. Although Plaintiff did
23 include boilerplate language saying that “Plaintiffs believe that the factual contentions set forth in

24 _____
25 ⁵ That Meril discussed the UW preclinical study in a Continuing Medical Education presentation
26 in Kolkata, India two years later does not alter the applicability of the safe harbor. *See* Bhatt Dec.,
27 Ex. AA. The Federal Circuit has repeatedly explained that subsequent disclosure or use of
28 information from preclinical or clinical studies—even for commercial purposes—does not negate
application of the safe harbor. *See Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d
892, 898 (Fed. Cir. 2015) (“subsequent disclosure or use of information obtained from an exempt
clinical study, even for purposes other than regulatory approval, does not repeal [the safe harbor]
exemption of the clinical study”).

1 this claim for relief will likely have further evidentiary support after a reasonable opportunity for
2 further investigation or discovery,” *id.* at ¶¶ 86, 94, this is insufficient to properly plead some
3 unspecified number of additional unnamed potential acts of infringement. Therefore, it is
4 immaterial whether Defendant sought summary judgment as to these unasserted theories.
5 Accordingly, while the Court declines to grant summary judgment as to these acts based on an
6 argument first raised in Defendant’s reply, the Court finds that the additional purported acts of
7 infringement are not presently before the Court in this action. *Hauschild v. City of Richmond*, No.
8 C 15-01156 WHA, 2016 WL 3456620 at *5 (N.D. Cal. June 14, 2016) (disregarding “Plaintiff’s
9 new theory” in a motion for summary judgment where the complaint did not put defendants on
10 notice about the evidence it would need to defend against plaintiff’s new allegations) (citing
11 *Pickern v. Pier 1 Imports (U.S.), Inc.*, 457 F.3d 963, 969 (9th Cir. 2006) (affirming grant of
12 summary judgment in favor of defendant where “the complaint gave the Appellees no notice of
13 the specific factual allegations presented for the first time in [plaintiff’s] opposition to summary
14 judgment.”)); *see also Bell v. F.D.I.C.*, No. C09-0150RSL, 2011 WL 2011497 at *3 (W.D. Wash.
15 May 23, 2011) (“This claim was not asserted in the Amended Complaint, however, and cannot be
16 added to this litigation in response to a summary judgment motion.”); *Gilmour v. Gates*,
17 *McDonald and Co.*, 382 F.3d 1312, 1314–15 (11th Cir. 2004) (“[T]he Supreme Court has
18 mandated a liberal pleading standard for civil complaints ... This standard however does not
19 afford plaintiffs with an opportunity to raise new claims at the summary judgment stage ... At the
20 summary judgment stage, the proper procedure for plaintiffs to assert a new claim is to amend the
21 complaint in accordance with Fed.R.Civ.P. 15(a).”)⁶

22
23 ⁶ In any event, Plaintiff only relies upon a customs declaration for the simulator that lists
24 “Navigator.” Reply at 14; Stephens Decl. Ex. 26. This “Navigator” refers to a modified device
25 that is built into the simulator and that is missing the balloon portion. Mayer Reply Decl. ¶ 34.
26 The Court fails to see the relevance of Plaintiff’s argument when the referenced “Navigator” lacks
27 an “inflatable balloon” as required by Plaintiff’s patent claims. As to the Skirball Study, it is
28 undisputed that the study was a preclinical study to investigate Myval System’s performance and
to inform the feasibility of future clinical trials in live human subjects. Opp. at 4; Stephens Decl.
Ex. 13 at 4:8-15; Bhatt Depo. at 84:15-20. And it is clear that Defendants provided the relevant
discovery surrounding the Skirball Study. Mayer Reply Decl. ¶ 31. Accordingly, it appears that
the safe harbor would also apply to the Skirball Study for the same reasons the Court has found it
applies to the UW study, namely that the FDA requires Meril to submit all Myval preclinical
studies—including the Skirball study—with Meril’s IDE.

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
26
27
28

B. Commercial Purpose

Plaintiff contends that the safe harbor also does not apply because Meril had a commercial purpose when it brought the Myval samples to the UW and to the TCT Conference. Defendants contend that Plaintiff's argument fails for two reasons: (1) Defendants' purported purpose is irrelevant to whether the accused use falls within the scope of Section 271(e)(1), and (2) even if Defendants' purpose was relevant, Meril's purpose in transporting the samples into the U.S. in 2017 and 2019 was to support future clinical trials to seek premarket approval from the FDA.

As discussed above, whether the safe harbor applies turns on the objective question of whether the actions taken with respect to a device are reasonably related to FDA approval, and the only relevant acts are those that would otherwise constitute patent infringement under Section 271. *Eli Lilly*, 496 U.S. at 663 (inquiry is whether the safe harbor "renders activities that would otherwise constitute patent infringement noninfringing"). If Defendants' otherwise infringing act is reasonably related to FDA approval, the safe harbor applies regardless of the purported purpose behind the use. *Momenta Pharm.*, 809 F.3d at 619.

In *Abtox*, the Federal Circuit affirmed the grant of summary judgment of non-infringement, even though plaintiff asserted that the infringing activity was driven by commercial purposes. 122 F.3d at 1027. The plaintiff alleged that the safe harbor did not apply because the defendant's actual purpose behind the testing was to "promote the [device] and other equipment to potential customers" and to offer it for sale. *Id.* The Federal Circuit rejected this argument, explaining that "section 271(e)(1) requires only that the otherwise infringing act be performed 'solely for uses reasonably related to' FDA approval." *Id.* at 1030. "The statute, therefore, does not look to the underlying purposes or attendant consequences of the activity . . . , as long as the use is reasonably related to FDA approval." *Id.* Because the device testing (the allegedly infringing act there) was reasonably related to obtaining FDA approval, the safe harbor applied, regardless of defendant's intent or purpose. *Id.* Therefore, the court's safe harbor analysis focused on uses, not "purposes" or "motives." *Id.* at 1278, 1280 ("Congress did not intend the availability of the exemption to turn on findings about a party's 'purposes' or 'motives'"); see also *Genentech*, 436 F. Supp. 2d at 1095 (even if accused experiments were conducted in part for "commercial reasons," the safe harbor

1 applied because “the experiments would produce information that would be given to the FDA in
2 order to get FDA approval”).

3 Similarly, Plaintiff contends that *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327 (Fed. Cir.
4 2019), stands for the proposition that that commercial intent can be probative of whether an
5 activity is “reasonably related” to regulatory uses. Opp. at 12. In *Amgen*, a jury instruction
6 correctly instructed the jury to focus on the allegedly infringing activity and whether that activity
7 was reasonably related to the development and submission of information to the FDA. 944 F.3d at
8 1338-39 (“The jury instructions properly asked whether . . . each accused activity[] was for uses
9 reasonably related to submitting information to the FDA.”). Hospira objected to part of the jury
10 instruction, which stated that “[i]f Hospira has proved that the manufacture of a particular batch
11 was reasonably related to developing and submitting information to the FDA in order to obtain
12 FDA approval, Hospira’s additional underlying purposes for the manufacture and use of that batch
13 do not remove that batch from the Safe Harbor defense.” *Id.* at 1338. In finding no legal error
14 with this jury instruction, the Federal Circuit in *Amgen* affirmed that “*underlying purposes do not*
15 *matter* as long as Hospira proved that the manufacture of any given batch of drug substance [the
16 accused activity] was *reasonably related to developing information for FDA submission.*” *Id.* at
17 1339 (emphasis added).

18 Given this guidance from the Federal Circuit, the safe harbor inquiry here focuses only on
19 Meril’s allegedly infringing acts, specifically (1) shipping the Myval Samples to UW; and (2)
20 transporting the Myval Samples to the TCT Conference. As discussed above, both acts fall
21 squarely within the safe harbor. Transportation of the Myval Samples to UW was an exempt act
22 because it generated preclinical data to support Meril’s clinical trials. Likewise, transportation of
23 the Myval Samples to the TCT Conference (with no sales or offers for sale) was an exempt act
24 because Meril is a sponsor “responsible for selecting qualified investigators and providing them
25 with the necessary information to conduct clinical testing.” *Telectronics II*, 982 F.2d at 1523
26 (citing 21 C.F.R. § 812.40). “[Meril’s] intent or alternative uses are irrelevant to its qualification
27 to invoke the section 271(e)(1) shield.” *Abtox*, 122 F.3d at 1030. Accordingly, Defendants’
28 underlying purposes are not relevant to the safe harbor inquiry, and the Court finds that

1 Defendants’ transportation of the Myval System and Myval Samples to UW and the TCT
2 conference fell within the safe harbor, such that there is no infringement.⁷

3 **C. Rule 56(d) Motion**

4 Plaintiff contends that there is an incomplete record regarding Meril’s purportedly
5 infringing acts, and that Meril’s witnesses testified regarding plans surround the Landmark Trial,
6 while Meril refused to produce documents relevant to this purported plan from earlier than May
7 2019.

8 A party seeking relief under Rule 56(d) must show “(1) that they have set forth in affidavit
9 form the specific facts that they hope to elicit from further discovery, (2) that the facts sought
10 exist, and (3) that these sought-after facts are essential to resist the summary judgment motion.”
11 *State of Cal., on Behalf of Cal. Dept. of Toxic Substances Control v. Campbell*, 138 F.3d 772, 780
12 (9th Cir. 1998). Plaintiff must have also diligently pursued the requested discovery. *See Conkle v.*
13 *Jeong*, 73 F.3d 909, 914 (9th Cir. 1995).

14 In December 2019, Plaintiff served its first set of written discovery seeking broad
15 categories of documents relating to all clinical trials for Myval. Mayer Reply Decl. ¶ 12. In April
16 2020, Plaintiff served a second set of written discovery, this time seeking broad categories of
17 documents relating to the Landmark Trial. *Id.* ¶ 19. The parties met and conferred in late June,
18 but it appears Plaintiff waited until July 27 to provide Meril with a draft motion to compel, which
19 it filed after business hours on July 30, one business day before the first scheduled deposition. *Id.*
20 Magistrate Judge Westmore denied Plaintiff’s motion, holding that it was “unreasonable” to
21 expect the Court to resolve the dispute on the “eve of deposition.” Dkt. No. 77.

22 Plaintiff’s failure to diligently pursue discovery is a sufficient basis to deny the Rule 56(d)
23 motion. *Zamora v. City of Oakland*, No. 12-cv-02734 NC, 2013 WL 4103109, at *4 (N.D. Cal.
24 Aug. 12, 2013) (plaintiff’s failure to timely move to compel is ground for denying Rule 56(d)
25 motion). Plaintiff contends that the majority of Meril’s document production came after Meril

26
27 ⁷ Because intent and alternative uses are not relevant to the application of the safe harbor once it is
28 determined that the allegedly infringing acts were reasonably related to FDA approval, the Court
need not reach the issue of Meril’s alleged commercial intent. *See Abtox*, 122 F.3d at 1030;
Amgen, 944 F.3d at 1339.

1 moved for summary judgment, Opp. at 21, 25, but this appears to be a result of the Court’s
2 adoption of Plaintiff’s proposed briefing schedule, which provided for subsequent written
3 discovery after Meril moved for summary judgment. *See* Dkt. Nos. 52, 60; Mayer Reply Decl. ¶
4 22. Finally, the timing of Meril’s five document productions prior to the depositions also appears
5 to be due, in part, to Plaintiff’s delay. For example, on May 27, 2020, Meril disclosed the date
6 ranges Meril used to search ESI and informed Plaintiff that Meril did not agree with Plaintiff’s
7 proposed date ranges. Mayer Reply Decl. ¶ 25, Ex. 23. Plaintiff did not raise this issue with Meril
8 until July 15, 2020. Dkt. No. 72.

9 Accordingly, the Court **DENIES** Plaintiff’s Rule 56(d) motion.

10 **D. Motions to Seal**

11 Meril seeks to seal a number of documents because they contain, characterize, or refer to
12 highly confidential business information. In the Ninth Circuit, a party seeking to file documents
13 under seal in connection with a dispositive motion must establish compelling reasons for doing so
14 to rebut the presumption against public access. *See Foltz v. State Farm Mut. Auto. Ins. Co.*, 331
15 F.3d 1122, 1136 (9th Cir. 2003). The Court will address each request briefly in turn.

16 **i. Dkt. No. 66**

17 Meril seeks to seal certain limited portions of Exhibits A and B to the Lad Declaration; the
18 entirety of Exhibits C, D, I, and K to the Lad Declaration; certain limited portions of Meril’s
19 Corrected Memorandum of Law in support of the Summary Judgment Motion; and certain limited
20 portions of the Lad Declaration. These documents contain sensitive proprietary information
21 concerning Meril’s clinical and regulatory strategies for the Myval System. The Court finds that
22 this information is proprietary and meets the standard to file under seal. *See, e.g. Lucas v. Breg,*
23 *Inc.*, No. 15-cv-00258-BASNLS, 2016 WL 5464549, at *2 (S.D. Cal. Sept. 28, 2016) (sealing
24 510(k) premarket submission to the FDA addressing safety and effectiveness of device); *United*
25 *States ex rel. Ruhe v. Masimo Corp.*, No. 10-cv-08169-CJC(VBKx), 2013 WL 12131173, at *2
26 (C.D. Cal. Aug. 26, 2013) (internal research studies and clinical tests for developing the accused
27 device, and non-public data submitted to the FDA in the course of regulatory approval, were
28 “confidential, proprietary, and [] valuable”); *In re Incretin-Based Therapies Prods. Liab. Litig.*,

1 No.13md2452 AJB (MDD), 2015 WL 11658712, at *3 (S.D. Cal. Nov. 18, 2015) (sealing
2 confidential and proprietary information relating to the “development, testing, and regulation” of
3 proposed drugs, the disclosure of which would result in “significant competitive harm”); *Biovail
4 Labs., Inc. v. Anchen Pharm., Inc.*, 463 F. Supp. 2d 1073, 1083 (C.D. Cal. 2006) (“indisputable”
5 that information contained in abbreviated new drug application to the FDA constituted trade
6 secrets, the disclosure of which to a competitor would be “extremely damaging”). Accordingly,
7 the Motion to Seal (Dkt. No. 66) is **GRANTED**.

8 **ii. Dkt. Nos. 81 and 87**

9 Plaintiff also seeks to file under seal certain information designated by Meril as “HIGHLY
10 CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY” under the Protective Order
11 applicable in this case. Specifically, Plaintiff seeks to file under seal certain limited portions of
12 Edwards’ Opposition brief; certain limited portions of the Declaration of Matthew Stephens in
13 Support of Edwards’ Opposition; and the entirety of Exhibits A-E, K, 10, 13, 19, 21-23, 25-26, 29,
14 36-38, 40, 43-44, 47-48, 50, 51, 53, 55, and 57-59 to the Declaration of Matthews Stephens in
15 Support of Edwards’ Opposition. Plaintiff requests that the Court grant this administrative motion
16 to the extent Defendants’ information qualifies as “privileged, protectable as a trade secret, or
17 otherwise entitled to protection under the law.” However, the parties’ designations alone are
18 insufficient to meet the compelling reasons standard, and the Court therefore **DENIES** this request
19 to seal. Dkt. No. 81.

20 In light of this, Defendants filed a motion to seal (Dkt. No. 87) to identify the limited items
21 it seeks to seal, and to provide a revised proposed order and redacted documents reflecting these
22 changes. Meril seeks to now seal the entirety of Exhibits A, B, C, E, K, 29, 36, 38, 43-44, 47-48,
23 50-51, 53, 55, 57-59 to the Declaration of Matthew Stephens In Support of Plaintiff’s Opposition
24 (“Stephens Declaration”; Dkt. No. 82-1). Meril contends that these documents contain sensitive
25 proprietary information concerning Meril’s clinical and regulatory strategies for its Myval System
26 and its business strategies concerning trade shows. Meril also moves to file the following items
27 under seal with more limited redactions than proposed in the prior motion to seal: certain limited
28 portions of Exhibit D and 13 to the Stephens Declaration, and certain limited portions of

1 Plaintiff's Opposition brief and the Stephens Declaration that describe or reference the
2 confidential documents as summarized above. These documents also contain sensitive proprietary
3 information concerning Meril's clinical and regulatory strategies for its Myval System and its
4 business strategy for trade conferences.

5 For the foregoing reasons, the Court finds that this information is proprietary and meets the
6 standard to file under seal, and the Motion to Seal (Dkt. No. 87) is **GRANTED**.

7 **iii. Dkt. No. 89**

8 Finally, Meril seeks to seal certain limited portions of Exhibits 5, 7 and 8 to the Mayer
9 Reply. Decl., the entirety of Exhibits 9-12 and 15 to the Mayer Reply Declaration, and certain
10 limited portions of Meril's Reply. Meril contends that these documents contain sensitive
11 proprietary information concerning Meril's clinical and regulatory strategies for the Landmark
12 Trial, a clinical trial for Meril's proprietary Myval transcatheter heart valve and delivery system.

13 Exhibit 9 is an internal draft of Meril's trial synopsis for the Landmark Trial; Exhibits 10
14 and 11 are communications with clinical investigators regarding the design of the Landmark Trial;
15 Exhibit 12 is Meril's supplemental presubmission to the FDA for the Landmark Trial as part of its
16 process of receiving FDA approval for the Myval System; and Exhibit 15 is a report for a pre-
17 clinical study for the Myval System. Exhibits 5, 7, and 8 are excerpts of deposition testimony that
18 also describe Meril's confidential strategies for obtaining FDA approval for the Myval System.
19 Exhibits 5, 7, and 8 also contain confidential business strategies for engaging clinicians at trade
20 shows, which also meet the *Foltz* standard.

21 For the foregoing reasons, the Court finds that this information is proprietary and meets the
22 standard to file under seal, and the Motion to Seal (Dkt. No. 89) is **GRANTED**.

23
24
25
26
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
26
27
28


IV. CONCLUSION

For the reasons discussed above, the Court **GRANTS** Defendants’ Motion for Summary Judgment, and **GRANTS IN PART** and **DENIES IN PART** the Motions to Seal.

The claim construction hearing set for November 6, 2020 is **VACATED**. The Court **SETS** a further case management conference for November 3, 2020 to discuss the plan for promptly resolving the remaining causes of action. The parties shall file a case management statement, including a proposed case schedule, no later than October 27, 2020.

IT IS SO ORDERED.

Dated: October 16, 2020


HAYWOOD S. GILLIAM, JR.
United States District Judge