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. BACKGROUND[1]

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.

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

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

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

[2] Around this time, Meril also began planning a preclinical animal study for Myval with the CRF Skirball Center for Innovation in New York ("Skirball Study"). Dkt. No. 87-6 ("Stephens Decl.") Ex. 13 at 4:23-28. The Skirball Study was to investigate the feasibility of implanting the Myval System into humans, and whether Meril could do so safely in clinical studies. *Id.* In 2016, Meril 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.

812.20; 21 C.F.R. § 812.42.

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

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

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

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

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

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

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

> This is to inform you that the demo samples carried by Mr. Nilay Lad is for the demonstration purpose only.
>
> It is consist [sic] of Demo samples of Medical devices. They have no commercial value & hence it is not used for any sales purpose. The 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.

*Id.*, Ex. F.

Meril had a booth at the TCT Conference from September 26 to September 28, and provided information on its cardiovascular systems, including the Myval System, in the form of visual displays and presentations to attending physicians. *Id.* ¶ 14, Exs. G-H. For the Myval System, Meril exhibited patient case studies, information on the Myval System and its use in a 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

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

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

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

## II. LEGAL STANDARD

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

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

## III. DISCUSSION

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

### A. Safe Harbor Application

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

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

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

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

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

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

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

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

**i. 2019 TCT Conference**

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

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

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

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

[3] The Landmark Trial appears to be a post-EU-approval study to be conducted in Europe to compare the Myval System to other leading devices in the European market. Lad Decl. ¶¶ 12, 15. Plaintiff contends that the Landmark Trial is not an "FDA clinical trial" because Meril's early documents describe it as an "outside the US" trial. Opp. at 17. However, it is undisputed that FDA approval can be supported by clinical trials that include patients both within and outside of 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.

The Court finds that the undisputed evidence gives rises to no genuine dispute of fact as to whether Meril's transportation of non-commercial Myval Samples to the TCT Conference is exempt under the safe harbor. Lad Decl. ¶¶ 13-15, 17.[4] It is undisputed that Meril transported the medical device to the TCT Conference, which was attended by a large number of potential clinical trial investigators. Lad Decl. ¶ 14. It is also undisputed that Meril did not sell or offer to sell its medical device at the medical conference. *Id.* ¶ 15. Therefore, Meril's transportation of the Myval Samples to the TCT Conference, where Meril did not sell or offer to sell the device, was reasonably related to the submission of information to the FDA, including educating the investigators at the TCT about the Myval System. *See id*. ¶¶ 13, 15; *Telectronics II*, 982 F.2d at 1523 (nonsale "demonstrations constitute an exempt use reasonably related to FDA approval"); *Intermedics II*, 1993 WL 87405, at *3 (nonsale demonstrations at medical conferences are reasonably related to FDA approval and exempt under the safe harbor); *see also Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1263 (Fed. Cir. 2008) ("demonstrating an implantable defibrillator at medical conference was 'reasonably related' to FDA approval because it facilitated the selection of clinical trial investigators").

**ii. University of Washington Study**

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

[4] Plaintiff objects to portions of the Lad Declaration and contends that Mr. Lad lacks personal knowledge of "Meril's purpose for importing the Myval Device." Opp. at 15. However, it is undisputed that Mr. Lad personally transported the Myval Samples to the TCT Conference, and he testified that he consulted with counsel and Mr. Bhatt about bringing the Myval System to the 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).

Bhatt Depo. at 40:11-20.

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

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

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

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

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

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

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

[5] That Meril discussed the UW preclinical study in a Continuing Medical Education presentation in Kolkata, India two years later does not alter the applicability of the safe harbor. *See* Bhatt Dec., Ex. AA. The Federal Circuit has repeatedly explained that subsequent disclosure or use of 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").

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

[6] In any event, Plaintiff only relies upon a customs declaration for the simulator that lists "Navigator." Reply at 14; Stephens Decl. Ex. 26. This "Navigator" refers to a modified device that is built into the simulator and that is missing the balloon portion. Mayer Reply Decl. ¶ 34. The Court fails to see the relevance of Plaintiff's argument when the referenced "Navigator" lacks an "inflatable balloon" as required by Plaintiff's patent claims. As to the Skirball Study, it is 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.

**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

applied because "the experiments would produce information that would be given to the FDA in order to get FDA approval").

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

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

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

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

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

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

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

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

[7] Because intent and alternative uses are not relevant to the application of the safe harbor once it is 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.

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

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

**D. Motions to Seal**

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

**i. Dkt. No. 66**

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

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

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

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

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

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

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

**iii. Dkt. No. 89**

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

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

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

## 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

United States District Court
Northern District of California