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7	UNITED STATES DISTRICT COURT	
8	FOR THE NORTHERN DISTRICT OF CALIFORNIA	
9	OAKLAND DIVISION	
10	CARL ZEIGG MEDITEG ING	C N 10 41 C2 CD A
11	CARL ZEISS MEDITEC, INC.,	Case No: 19-4162 SBA
12	Plaintiff,	ORDER GRANTING TOPCON'S MOTION TO DISMISS AND
13	VS.	GRANTING IN PART AND DENYING IN PART EMPLOYEE DEFENDANTS AND
14	TOPCON MEDICAL SYSTEMS, INC., TOPCON HEALTHCARE SOLUTIONS,	EMPLOYEE DEFENDANTS AND DR. CHEN'S MOTIONS TO
15	INC., TOPCON CORPORATION, TOBIAS KURKZE, GREG HOFFMEYER,	DISMISS THIRD AMENDED COMPLAINT
16	GENEVIEVE FAY, KATALIN SPENCER, KEITH BROCK, CHARLES GUIBORD, JR.,	PUBLIC VERSION
17	JOSEPH CICCANESI, AND MICHAEL CHEN,	Dkt. 158, 160, 200
18	Defendants.	
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20	This is an action for trade secret misappropriation, patent infringement and related	
21	claims brought by Plaintiff Carl Zeiss Meditech, Inc. ("CZMI") against the following	
22	Defendants: Topcon Corporation, Topcon Medical Systems, Inc., and Topcon Healthcare	
23	Solutions, Inc. (collectively "Topcon," unless specified otherwise); and former CZMI	
24	employees, Tobias Kurzke, Greg Hoffmeyer, Genevieve Fay, Katalin Spencer, Terry Keith	
25	Brock, Charles Guibord, Jr., Joseph Ciccanesi and Michael Chen (collectively "Employee	
26	Defendants"). CZMI accuses Topcon and Employee Defendants, all of whom now work	

for Topcon, of stealing its trade secrets and confidential information in order to develop

competing, "knockoff" ophthalmic software products.

The operative pleading is the Third Amended Complaint ("TAC"). Dkt. 193-4. The parties are presently before the Court on Topcon, Employee Defendants and Dr. Chen's separate motions to dismiss the TAC, pursuant to Federal Rule of Civil Procedure 12(b)(6). Dkt. 158, 160, 200. Having read and considered the papers filed in connection with this matter and being fully informed, the Court hereby GRANTS Topcon's motion and GRANTS IN PART and DENIES IN PART Employees Defendants and Dr. Chen's motions to dismiss. The Court, in its discretion, finds this matter suitable for resolution without oral argument. See Fed. R. Civ. P. 78(b); N.D. Cal. Civ. L.R. 7-1(b).

I. <u>BACKGROUND</u>

A. FACTUAL SUMMARY

The parties are familiar with the facts of this case, which are summarized briefly herein to the extent they bear upon the instant motions.

CZMI develops and supplies ophthalmic diagnostic products ("ODx") used to diagnose and treat a variety of eye diseases. TAC ¶ 35. Such products include Glaucoma Workplace, Retina Workplace and FORUM, among others. Id. ¶ 10, 53. These products facilitate the testing and treatment of various eye diseases, such as glaucoma, cataracts and retinal disorders. Id. ¶ 36. Glaucoma Workplace and Retina Workplace are eye care data management products that have been approved by the Food and Drug Administration ("FDA"). Id. ¶ 56.

In early 2018, Topcon Corporation launched a new subsidiary, Topcon Health Care Systems, to develop software products intended to compete with CZMI's ODx products. Id. ¶ 2. To that end, Topcon, allegedly with the help of former CZMI employees John Trefethen and Grant Schmid (who are not parties to this action), identified specific CZMI employees to recruit. Id. ¶¶ 3, 14, 84. Topcon's goal was to hire CZMI employees who could help recreate CZMI's ODx products, replicate CZMI's product strategy, utilize

¹ Although Chen and the remaining Employee Defendants filed separate motions to dismiss, all references to "Employee Defendants" will include Chen, unless otherwise stated.

its marketing documents, and market Topcon's "knockoff" products to the ophthalmologic industry. <u>Id.</u> ¶¶ 14, 84. To that end, Topcon focused on recruiting employees "with different types of experience" who had knowledge of CZMI's trade secrets and confidential information pertaining to CZMI's ODx products. <u>Id.</u> ¶¶ 64, 3.

Mr. Kurzke was among the first CZMI employees solicited by Topcon. Id. ¶ 31. While at CZMI, Mr. Kurzke worked in "key roles" over the course of thirteen years. Id. ¶¶ 3, 58. Since 2012, he served at various times as a Product Manager for CZMI's Glaucoma Workplace and had responsibility for said product up to the time of his departure in April 2018. Id. He was responsible for Retina Workplace from 2016 to 2018. Id. During his tenure at CZMI and its parent entity, Mr. Kurzke was closely involved with the research and development/engineering, sales, clinical, and regulatory groups, and at times had global responsibility for market introduction of integrated software solutions for both glaucoma (Glaucoma Workplace) and retinal diseases (Retina Workplace). Id. ¶ 60. In addition, Mr. Kurzke was the lead inventor on U.S. Patent No. 9,968,251 (the "'251 Patent")—the patent-in-suit—which is "generally directed toward methods of displaying certain types of data, and more particularly, displaying information of a patient's eye, including receiving certain measurements and generating a side by side display of those measurements." Id. ¶ 129.

Mr. Kurzke resigned from CZMI on April 27, 2018. <u>Id.</u> ¶ 139.

<u>Id.</u> ¶ 13.

<u>Id.</u> ¶ 6, 10, 15, 48, 82, 90, 91, 95, 102, 103.

<u>Id.</u> ¶¶ 12, 91.

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27 28 Id. ¶ 49.

After Mr. Kurzke left CZMI, Mr. Hoffmeyer, another longtime employee resigned from CZMI on July 6, 2018. Id. ¶ 139. Mr. Hoffmeyer had served as a sales executive at CZMI with responsibility for many of CZMI's ODx products. Id. ¶ 140. In turn, Mr. Hoffmeyer's resignation was followed by Ms. Fay's on October 12, 2018. Id. Ms. Fay had joined CZMI in 2011, and served as Director of Marketing with responsibility for many of CZMI's ODx products, including Glaucoma Workplace. Id.

Subsequently, the remaining Employee Defendants—Messrs. Spencer, Ciccanesi, Guibord and Brock and Dr. Chen—resigned from CZMI. Id. ¶¶ 62, 63. CZMI alleges that each of these individuals had specific roles and knowledge of CZMI's trade secret and confidential information relating to CZMI's ODx products. Id. Ms. Spencer led the logistical operations of national and international events that involved CZMI ODx products. Id. ¶ 63. Her work included creating presentations, promotions and graphics and assisting with new product launches. Id. Messrs. Ciccanesi and Guibord had product-level and separate geographic responsibility for selling various CZMI ODx products and were part of the CZMI sales team that had included Messrs. Trefethen and Schmid, who, as indicated, had previously left CZMI for Topcon and led the recruitment effort. Id. ¶ 63. Lastly, Mr. Brock and Dr. Chen had sales and technical roles for fundus imaging, which is a type of important data that is utilized by the CZMI ODx Products. Id. ¶ 62. Together with Mr. Kurzke, Mr. Brock and Dr. Chen possess much of the technical expertise to advise an engineering team and others at Topcon as to CZMI's trade secrets. Id.

All of the Employee Defendants executed employment and/or confidentiality agreements with CZMI during their employment that required them not to disclose any potentially trade secret, confidential or proprietary information. Id. ¶81. Messrs. Kurzke and Brock and Dr. Chen executed a Trade Secret and Confidential Protection Agreement ("Trade Secret Agreement"). TAC Exs. 12, 18, 19. The remaining Employee Defendants

executed either a Non-Solicitation and Confidential Information Protection Agreement or an Employment Agreement (collectively "Employment Agreement"). Id. Ex. 13-17.

B. PROCEDURAL HISTORY

On July 19, 2019, CZMI filed suit in this Court alleging six claims for relief against Topcon and the Employee Defendants (except Dr. Chen) styled as follows: (1) trade secret misappropriation under the Federal Defend Trade Secrets Act ("DTSA"); (2) aiding and abetting trade secret misappropriation under DTSA; (3) trade secret misappropriation under the California Uniform Trade Secrets Act ("CUTSA"); (4) breach of contract; (5) tortious interference with prospective economic advantage; and (6) unfair competition under California Business & Professions Code § 17200.

Topcon and Employee Defendants filed motions to dismiss under Rule 12(b)(6). On November 13, 2019, the Court issued its Order Granting Defendants' Motion to Dismiss with Leave to Amend ("Dismissal Order"). Dkt. 75. On November 27, 2019, CZMI timely filed a First Amended Complaint ("FAC") against the same Defendants but dropped its claim for unfair competition. Dkt. 84-3. Topcon and the Employee Defendants filed motions to dismiss the FAC, asserting that the FAC had cured none of the prior deficiencies identified in the Dismissal Order. Dkt. 103, 104. Rather than oppose the motions, CZMI filed a Second Amended Complaint ("SAC") with the same five causes of action against the same defendants. Dkts. 113, 118. Topcon timely answered, and the Employee Defendants timely moved to dismiss the SAC on similar grounds. Dkt. 122, 123.

In response, on January 31, 2020, the deadline to amend pleadings, CZMI filed a TAC, which adds a claim for patent infringement, joins Dr. Chen and removes Melissa Goeke as party-defendants.² The TAC alleges causes of action for: (1) misappropriation under DTSA, (2) aiding and abetting misappropriation under DTSA; (3) misappropriation under CUTSA; (4) breach of contract; (5) patent infringement; and (6) tortious interference.

²⁷ Ms. Goeke is identified in the caption of the TAC but is not named in the body of

the pleading. The Court sua sponte amends the caption to omit Ms. Goeke to reflect that she is not a party-defendant.

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These claims are asserted against all Defendants, except the breach of contract claim, which is brought against Employee Defendants only, and the patent infringement claim, which is brought against Topcon only.

Defendants have filed three motions in response to the TAC. Topcon's motion seeks to dismiss the patent infringement and the tortious interference claims. Dkt. 160. Employee Defendants (excluding Dr. Chen) seek the dismissal of claims for misappropriation of trade secrets, breach of contract (except as to Mr. Kurzke) and tortious interference. Dkt. 158. Dr. Chen's motion seeks the dismissal of the same claims at issue in Employee Defendants' motion. Dkt. 200. CZMI opposes each of these motions.³ The matter is now fully briefed and is ripe for adjudication.

II. <u>LEGAL STANDARD</u>

"Dismissal under Rule 12(b)(6) is proper when the complaint either (1) lacks a cognizable legal theory or (2) fails to allege sufficient facts to support a cognizable legal theory." Somers v. Apple, Inc., 729 F.3d 953, 959 (9th Cir. 2013). "Rule 12(b)(6) is read in conjunction with Rule 8(a), which requires not only 'fair notice of the nature of the claim, but also grounds on which the claim rests." Zixiang Li v. Kerry, 710 F.3d 995, 998-99 (9th Cir. 2013) (quoting in part Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556 n.3 (2007)). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 570 (2007)). The court is to "accept all factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." Outdoor Media Group, Inc. v. City of Beaumont, 506 F.3d 895, 899-900 (9th Cir. 2007). Where a complaint or claim is dismissed, leave to amend generally is granted, unless further amendment would be futile. Chaset v. Fleer/Skybox Int'l, 300 F.3d 1083, 1087-88 (9th Cir. 2002).

³ Since Dr. Chen and the other Employee Defendants are similarly situated and are represented by the same counsel, all of their future filings in this action shall be submitted jointly.

III. <u>DISCUSSION</u>

A. TRADE SECRET CLAIMS

CZMI brings three separate claims for trade secret misappropriation under DTSA (first and second causes of action) and CUTSA (third cause of action) against all Defendants. The elements of a claim for misappropriation of trade secrets under DTSA and CUTSA are: (1) the plaintiff owned a trade secret; (2) the defendant acquired, disclosed, or used the plaintiff's trade secret through improper means; and (3) the defendant's actions damaged the plaintiff. Sargent Fletcher, Inc. v. Able Corp., 110 Cal. App. 4th 1658, 1665 (2003) (setting forth the elements under CUTSA); Alta Devices, Inc. v. LG Elecs., Inc., 343 F. Supp. 3d 868, 877 (N.D. Cal. 2018) (stating that the elements under DTSA and CUTSA are essentially the same). Employee Defendants only challenge the second element, claiming that CZMI has failed to adequately allege misappropriation.

Under DTSA and CUTSA, "misappropriation" is defined as either (1) the "[a]cquisition of a trade secret by another person who knows or has reason to know that the trade secret was acquired by improper means," or (2) the "[d]isclosure or use of a trade secret of another without express or implied consent." 18 U.S.C. § 1839(5) (emphasis added); Cal. Civ. Code § 3426.1(b); see Whyte v. Schlage Lock Co., 101 Cal. App. 4th 1443, 1457 (2002) ("'Misappropriation' is, generally speaking, improper acquisition of a trade secret or its nonconsensual use or disclosure.") (citing Cal. Civ. Code § 3426.1(b) & Morlife, Inc. v. Perry 56 Cal. App. 4th 1514, 1523 (1997)). "Improper means" is defined to include "theft, bribery, misrepresentation, breach or inducement of a breach of a duty to maintain secrecy, or espionage through electronic or other means." Cal. Civ. Code § 3426.1(a); 18 U.S.C. § 1839(6).

"Because direct evidence of misappropriation and misuse is not always available, plaintiffs can rely on circumstantial evidence to prove their case." M.A. Mobile Ltd. v. Indian Inst. of Tech. Kharagpur, 400 F. Supp. 3d 867, 893 (N.D. Cal. 2019); e.g., UniRAM Tech., Inc. v. Taiwan Semiconductor Mfg. Co., 617 F. Supp. 2d 938, 944 (N.D. Cal. 2007) ("In most cases plaintiffs must construct a web of perhaps ambiguous circumstantial

evidence from which the trier of fact may draw inferences which convince him that it is more probable than not that what plaintiffs allege happened did in fact take place."). Nonetheless, in the event "a plaintiff seeks to plead trade secrets misappropriation based on circumstantial evidence, the allegations must still 'be enough to raise a right to relief above a speculative level." Yeiser Research & Devel. LLC v. Teknor Apex Co., 281 F. Supp. 3d 1021, 1048 (S.D. Cal. 2017) (quoting Twombly, 550 U.S. at 555).

1. Tobias Kurzke

Starting first with Mr. Kurzke, the Court finds that the allegations of misappropriation directed against him are more than adequate to state a claim. TAC ¶¶ 82-122. There is no dispute between the parties that Mr. Kurzke was under a duty to maintain the secrecy of CZMI's trade secrets and confidential information pursuant to the terms of his Trade Secret Agreement with CZMI. Id. Ex. 12, Dkt. 193-12.

Id. ¶¶ 6, 10, 15, 48.

Id. ¶¶ 49.

See WeRide

Corp. v. Kun Huang, 379 F. Supp. 3d 834, 848 (N.D. Cal. 2019), modified in part, No. 5:18-CV-07233-EJD, 2019 WL 5722620 (N.D. Cal. Nov. 5, 2019) (finding that a former employee's misappropriation was evidenced by his copying and retaining his former employer's confidential files) (citing cases).

In response, Employee Defendants dispute that Mr. Kurzke's actions are in any way nefarious,

Dkt. 158

at 16.

Id.

2 3 TAC ¶ 91. <u>Id.</u> ¶ 7. Id. ¶ 49. Drawing all reasonable inferences in favor of CZMI, the Court finds that these and other facts alleged in the pleadings provide at least circumstantial evidence of misappropriation by Mr. Kurzke. **10** 2. Remaining Employee Defendants 11 Employee Defendants argue that the TAC contains no substantive allegations of 12 wrongdoing and therefore the trade secret causes of action should be dismissed. 13 14 —there are sufficient facts alleged from 15 which it can be inferred that they misappropriated CZMI's trade secrets.⁴ **16** According to CZMI, Mr. Kurzke's hiring was the lynchpin in Topcon's strategy to **17** develop products intended to compete with CZMI's ODx products. It was only after 18 Topcon realized that it could hire Mr. Kurzke that Topcon then recruited the Employee 19 Defendants in order to assemble a team capable of replicating CZMI's products and 20 marketing strategies. Id. ¶¶ 14, 31, 64, 84. To that end, Topcon, with help from Mr. 21 22 23 Dkt. 1/8 at 9, 14 (citing Elman Decl. in Supp. Pl.'s Opp'n to Employee 24 Mot. to Dismiss ("Elman Decl.") ¶¶ 5-9 Dkt. 178-1). While such evidence certainly is proof of misappropriation, the Court does not consider it at this juncture. On a 25 motion to dismiss under Rule 12(b)(6), the Court must limit its review to the operative complaint and may not consider facts presented in briefs or extrinsic evidence. See Lee v. 26 City of Los Angeles, 250 F.3d 668, 688 (9th Cir. 2001); Schneider v. Calif. Dep't of Corrections, 151 F.3d 1194, 1197 n.1 (9th Cir.1998) ("new allegations contained in the [plaintiff]'s opposition . . . are irrelevant for Rule 12(b)(6) purposes."). Nonetheless, as 27 will be discussed below, the facts alleged in the TAC are sufficient to avoid dismissal.

Kurzke and other former CZMI employees, targeted Employee Defendants based on their different skillsets (e.g., technical, engineering, sales and marketing) as well as their specific knowledge and experience with CZMI ODx products and related trade secrets and confidential information. <u>Id.</u> ¶¶ 14, 31, 62-63, 74-75. Within a matter of months after Mr. Kurzke's departure from CZMI, the other Employee Defendants followed suit and resigned from CZMI and began working for Topcon. SAC ¶¶ 139, 140. Since then, Topcon has rapidly laid out plans to launch Glaucoma Module to compete with CZMI's Glaucoma Workplace. TAC ¶¶ 92-105.

The forgoing and other facts alleged in the TAC, taken as true and construed in a light most favorable to CZMI, are sufficient to constitute circumstantial evidence of misappropriation by Employee Defendants. E.g., Montana Silversmiths, Inc. v. Taylor Brands, LLC, 850 F. Supp. 2d 1172, 1184 (D. Mont. 2012) (noting that the timing of the employees' acceptance of employment with the defendant and defendant's subsequent development of competing product was circumstantial evidence of trade secret misappropriation). The Court therefore denies Employee Defendants and Dr. Chen's motions to dismiss the misappropriation of trade secret claims.

B. Breach of Contract

CZMI's fourth cause of action alleges that Employee Defendants breached their respective Trade Secret and Employment Agreements. To state a claim for breach of contract, express or implied, under California law, a plaintiff must allege: "(1) the contract, (2) the plaintiff's performance of the contract or excuse for nonperformance, (3) the defendant's breach, and (4) the resulting damage to the plaintiff." CDF Firefighters v. Maldonado, 158 Cal. App. 4th 1226, 1239 (2008).

Here, the pleadings allege that Employee Defendants breached their Employment Agreements and/or Trade Secret Agreements by "improperly acquiring, using and/or disclosing CZMI's trade secret, confidential or proprietary information." Compl. ¶¶ 205-208. The pleadings further allege that Mr. Hoffmeyer breached the non-interference provision and that Mr. Ciccanesi breached the non-solicitation clause of their respective

Employment Agreements. <u>Id.</u> ¶¶ 212-13. Employee Defendants acknowledge that the TAC sufficiently alleges a breach of contract claim as to Mr. Kurzke but contend that the claim should be dismissed as to the rest of them. Dkt. 158 at 20; Dkt. 200 at 17.

As an initial matter, Employee Defendants contend that the breach of contract cause of action, to the extent it is based on CZMI's Employment Agreements, fails on the ground that those agreements contain non-compete and non-solicitation clauses barred under California law. Dkt. 158 at 20.5 As support, they point to California Business & Professions Code § 16600, which provides that "every contract by which anyone is restrained from engaging in a lawful profession, trade, or business of any kind is to that extent void," subject to statutory exceptions not relevant here. Id.; see also id. §§ 16601-607 (codifying exceptions); see, e.g., Edwards v. Arthur Andersen LLP, 44 Cal. 4th 937, 948 (2008) ("The noncompetition agreement that Edwards was required to sign before commencing employment with Andersen was therefore invalid because it restrained his ability to practice his profession.").

Employee Defendants' contention that section 16600 requires dismissal of CZMI's breach of contract claim is uncompelling. Aside from Messrs. Hoffmeyer and Ciccanesi, CZMI is not alleging that Employee Defendants violated any non-compete or non-solicitation provision in their respective Employment Agreements. Rather, CZMI avers that they breached their obligation not to improperly acquire, use and/or disclose CZMI's trade secrets, confidential or proprietary information. TAC ¶ 209. Employee Defendants do not dispute that CZMI's confidentiality requirements are enforceable. Accordingly, any clause that is unenforceable under section 16600 can be severed from the non-objectionable provisions. See Winston Research Corp. v. Minnesota Mining and Mfg. Co., 350 F.2d 134, 140 (9th Cir. 1965) (holding that an offending noncompete provision can be severed,

⁵ Employee Defendants acknowledge that the Trade Secret Agreement is enforceable. Dkt. 158 at 20.

leaving the remainder of contract enforceable); Mercuro v. Super. Ct., 96 Cal. App. 4th 167, 184-85 (2002) (same).⁶

As to Messrs. Hoffmeyer and Ciccanesi, the pleadings accuse them of violating the non-interference and non-solicitation provisions of their respective Employment Agreements, but expressly allege that California law is inapplicable because neither is a California resident. TAC ¶ 159-160, 163; see also Dkt. 178 at 11. Employee Defendants fault CZMI for failing to cite any caselaw holding that non-California residents are not entitled to the protection of section 16600. Dkt. 189 at 10. However, as the parties moving for dismissal, the burden is on Employee Defendants to provide the Court with relevant legal authority establishing that Messrs. Hoffmeyer and Ciccanesi's Employment Agreements are governed by section 16600. See Indep. Towers of Wash. v. Wash., 350 F.3d 925, 930 (9th Cir. 2003) ("It is [the movant's] burden . . . to present the court with legal arguments to support its claims."). Because this particular issue has not been properly briefed, the Court declines to reach the issue whether CZMI's contract claims as to Messrs. Hoffmeyer and Ciccanesi are precluded by section 16600.

Finally, Employee Defendants argue that the TAC fails to allege sufficient facts to demonstrate that they breached their respective Employment or Trade Secret Agreements by improperly acquiring or disclosing CZMI's confidential and trade secret information. Dkt. 158 at 20-21; Dkt. 200 at 17. But as discussed above, the pleadings allege sufficient facts from which it can be inferred that Employee Defendants breached their respective obligations under the Employment Agreements and Trade Secret Agreements. In sum, the Court finds that Employee Defendants have not presented compelling grounds for

⁶ It also bears noting that section 16600 does not automatically preclude the enforcement of a non-competition agreement where an employer is seeking to protect its confidential information. See <u>Asset Mktg. Sys., Inc. v. Gagnon</u>, 542 F.3d 748, 758 (9th Cir. 2008) (non-competition agreements are unenforceable [under Cal. Bus. & Prof. Code § 16600] unless necessary to protect an employer's trade secret"); E.D.C. Techs., Inc. v. Seidel, 216 F. Supp. 3d 1012, 1015-16 (N.D. Cal. 2016) (finding that the plaintiff had adequately pled the existence of a contract, notwithstanding a non-compete provision, where "[m]any of the facts alleged in the amended complaint center around [defendant's] unauthorized use of [plaintiff's] 'intellectual property and confidential information'").

dismissing CZMI's breach of contract cause of action at this stage of the proceedings. Employee Defendants and Dr. Chen's motions to dismiss the breach of contract claim are therefore denied.

C. PATENT INFRINGEMENT

In its fifth cause of action, CZMI alleges that Topcon's new Glaucoma Module infringes Claim 1 of the '251 patent with respect to "testing the method as testified to by Mr. Kurzke [during his deposition]." TAC ¶ 132 (citing Elman Decl. in Supp. of Pl.'s Admin. Mot. to File Under Seal ¶ 9 & Ex. 3 (("Elman Depo."), Dkt. 193-1); see id. ¶¶ 13, 127-138, 216. This software "testing" is related to Topcon's plan to seek FDA approval for Glaucoma Module. Elman Depo. at 163:1-164:15; TAC Ex. 7.

1. "Safe Harbor"

Topcon asserts that CZMI's patent claim fails because the only act of infringement alleged—testing the software used in the Glaucoma Module—is protected by the safe harbor of 35 U.S.C. § 271(e)(1). The statute provides:

It 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.

35 U.S.C. § 271(e)(1). The Supreme Court has construed the safe harbor to apply to drugs as well as medical devices and other products subject to FDA approval. <u>Eli Lilly and Co. v. Medtronic, Inc.</u>, 496 U.S. 661, 669-74 (1990); <u>see also Merck KGaA v. Integra Lifesciences, I. Ltd.</u>, 545 U.S. 193, 202 (2005) (recognizing that section 271(e) provides a "wide berth" for activities related to regulatory approval and "extends to all uses … that are

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reasonably related to the development and submission of any information under the FDCA.") (emphasis in original).⁷

To avoid dismissal under the safe harbor, the operative pleading must allege facts demonstrating that the defendant is currently engaging, or has engaged, in infringing activities that are not protected by section 271(e). Med. Diagnostic Labs., L.L.C. v. Protagonist Therapeutics, Inc., 298 F. Supp. 3d 1241, 1254 (N.D. Cal. 2018) ("Although whether challenged activity is reasonably related to the development and submission of information for FDA approval may in some circumstances be a fact question, there must be specific facts alleged to create a plausible claim to the contrary in order to escape dismissal under the safe harbor provision.") (citing Iqbal, 556 U.S. at 678-79) (Chen, J.).

2. **Contentions**

Topcon contends that the software testing that is alleged to infringe the '251 Patent is in anticipation of its plan to file a 510(k) notification with the FDA to obtain regulatory approval for Glaucoma Module. Dkt. 177 at 2, 127-5 at 163:1-17. CZMI counters that a testing in connection with a 510(k) notification is outside the scope of the section 271(e) safe harbor. The Court finds that Topcon's position is more compelling.

⁷ The safe harbor was enacted in response to the Federal Circuit's decision in Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984), which held that a drug manufacturer engaging in bioequivalency testing could be sued for patent infringement, even if the testing were related to obtaining FDA approval. Intermedics, Inc. v. Ventritex, Inc., 775 F. Supp. 1269, 1272 (N.D. Cal. 1991), aff'd sub nom. Intermedics, Inc. v. Ventritex Co., 991 F.2d 808 (Fed. Cir. 1993). Under Roche, a competitor drug manufacturer could not, without facing potential liability for patent infringement, commence the requisite clinical testing to obtain FDA approval until after the expiration of the branded drug's patent term. Intermedics, 775 F. Supp. at 1272-73. "Because such

activities could not begin until patent expiration, patent owners enjoyed a de facto patent term extension while competitors spent time following patent expiration obtaining FDA premarket approval necessary for market entry." <u>Proveris Sci. Corp. v. Innovasystems</u>, Inc., 536 F.3d 1256, 1261 (Fed. Cir. 2008). To address this windfall, Congress enacted the

Drug Price Competition and Patent Term Restoration Act of 1984 ("1984 Act"), 98 Stat. 1585, which, inter alia, authorizes competitors, prior to the expiration of a patent, to engage in otherwise infringing activities reasonably related to obtaining regulatory approval. Id. Under the 1984 Act, a competitor may, during the lifetime of an existing patent, begin

testing that is reasonably related to seeking FDA approval without being exposed to liability for patent infringement. Id. Such protection allows the competitor to begin selling the competing product immediately upon the patent's expiration. Id.

The FDA applies different levels of scrutiny to different types of medical devices before approving or clearing them for market. Triant v. Am. Med. Sys. Inc., No. CV-12-00450-PHX-DGC, 2020 WL 4049844, at *1 (D. Ariz. July 20, 2020) (citation omitted). Medical devices are divided into three classes (Class I, II or III) based on the level of risk they present. 21 U.S.C. § 360c(a)(1). Each Class is subject to different regulations. Id. Class I devices are the lowest risk category, while Class III is the highest. Id. § 360c(a)(1)(A)-(C). Class II devices are subject to approval under the 510(k) "premarket notification" process. Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996). "Under the 510(k) process, if the Class II device is deemed 'substantially equivalent' to a pre-existing device with prior clearance, 'it can be marketed without further regulatory analysis."

PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 925 (9th Cir. 2010) (quoting Lohr, 518 U.S. at 478); 21 U.S.C. § 360c(f)(1)(A). Review of a 510(k) notification is less rigorous than the FDA's "premarket approval" process, which is required, inter alia, for Class III medical devices. See 21 U.S.C. § 360e(a); Riegel v. Medtronic, Inc., 552 U.S. 312, 315 (2008).

CZMI contends that because the FDA's review under a 510(k) notification is less comprehensive than a premarket approval, the section 271(e) safe harbor is inapt. CZMI cites no cases—nor has the Court located any— holding that application of the safe harbor is limited to products undergoing premarket approval. To the contrary, the Federal Circuit has rejected the notion that application of the safe harbor is dependent on the level of regulatory scrutiny germane to a particular device. See Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1028 (Fed. Cir.), opinion amended on reh'g, 131 F.3d 1009 (Fed. Cir. 1997) (holding that section 271(e) applied to Class II medical devices, notwithstanding that Class II devices are subject to an "abbreviated approval process" compared to Class III medical devices, which are subject to premarket approval). Thus, in the absence of controlling authority to the contrary, the Court rejects CZMI's contention that section271(e) does not apply to section 501(k) notifications because of the less rigorous FDA review process.

Next, CZMI contends that dismissal under the safe harbor is improper because Topcon's "internal testing is undoubtedly for Glaucoma Module's commercialization

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efforts, not for FDA approval." Dkt. 177 at 12. There are no facts alleged to that effect in the pleadings. See Med. Diagnostic Labs., 298 F. Supp. 3d at 1254 (requiring the plaintiff allege "specific facts" demonstrating that the challenged activity is not "reasonably related to the development and submission of information for FDA approval ... in order to escape dismissal under the safe harbor provision"). That aside, application of the safe harbor does not turn on whether Topcon eventually intends to commercialize the Glaucoma Module. Rather, "[a]s long as the activity is reasonably related to obtaining FDA approval," the court "does not look to the underlying purposes or attendant consequences of the activity." Abtox, 122 F.3d at 1030; see also Momenta Pharma., Inc. v. Teva Pharma. USA Inc., 809 F.3d 610, 619 (Fed. Cir. 2015) ("The breadth of the exemption extends even to activities the 'actual purpose' of which may be 'promotional' rather than regulatory, at least where those activities are 'consistent with the collection of data necessary for filing an application with the [FDA] ... for approval."")." Here, Topcon asserts—and CZMI does not dispute that it is seeking FDA approval to launch Glaucoma Module. Dkt. 177 at 2. As such, it is clear that that Topcon's product testing bears some reasonable relation to obtaining FDA approval.

Finally, CZMI contends that Topcon cannot invoke the section 271(e) safe harbor until the '251 Patent is about to expire in 2036. Dkt. 177 at 14. This contention lacks merit. As explained above, the safe harbor only protects Topcon with respect to testing of the Glaucoma Module that is reasonably related to its planned 510(k) notification. See AbTox, 122 F.3d at 1030. If and when Topcon receives FDA clearance and begins selling Glaucoma Module, the safe harbor will no longer apply and CZMI may pursue an action for patent infringement against Topcon.

The Court concludes that CZMI's patent infringement claim is barred by the safe harbor set forth in section 271(e). Topcon's motion to dismiss said claim is therefore granted. Because further amendment would be futile, the dismissal is without leave to amend.

D. TORTIOUS INTERFERENCE

The sixth cause of action for tortious interference with prospective economic advantage is directed against all Defendants. In California, the elements of a tortious interference with prospective economic advantage claim are: "(1) an economic relationship between the plaintiff and some third party, with the probability of future economic benefit to the plaintiff; (2) the defendant's knowledge of the relationship; (3) intentional [wrongful] acts on the part of the defendant designed to disrupt the relationship; (4) actual disruption of the relationship; and (5) economic harm to the plaintiff proximately caused by the acts of the defendant." Sybersound Records, Inc. v. UAV Corp., 517 F.3d 1137, 1151 (9th Cir. 2008) (quoting Korea Supply Co. v. Lockheed Martin Corp., 29 Cal. 4th 1134, 1153 (2003)).

All Defendants argue that the tortious interference claim is preempted by CUTSA. Dkt. 158 at 18; Dkt. 160 at 17; Dkt. 200 at 14. California Civil Code § 3426.7(b) "preempts common law claims that are based on the same nucleus of facts as the misappropriation of trade secrets claim for relief." K.C. Multimedia, Inc. v. Bank of Am. Tech. & Operations, Inc., 171 Cal. App. 4th 939, 958 (2009). In its Dismissal Order, the Court dismissed CZMI's tortious interference claim upon finding that it was predicated on Employee Defendants' use of CZMI's trade secrets. Dismissal Order at 10. In response to the Court's ruling, CZMI amended its tortious interference claim to allege facts that are distinct from those giving rise to its trade secret claims. Compare TAC ¶¶ 139-152 (tortious interference) with id. ¶¶ 53-126 (trade secret). Notably, Defendants make no effort to establish any overlap between CZMI's trade secret allegations and the amended version of its tortious interference claim.⁸ As pled, CZMI's amended tortious interference cause of action is not preempted by CUTSA.

⁸ Employee Defendants cite paragraph 1 of the TAC which, states, in part, that the instant action arises from "Defendants' unlawful scheme to steal CZMI's confidential information" TAC ¶ 1. However, that snippet of the pleadings is clearly intended to provide the reader with an overview of the lawsuit, as opposed to a statement that the tortious interference and trade secret causes of action arise from the same conduct.

More compelling is Defendants' argument that the tortious interference claim fails to adequately allege facts showing "actual disruption" of its customer relationships or damages. Dkt. 158 at 19; Dkt. 160 at 16-17. The actual disruption element requires CZMI to "plead facts either showing or allowing the inference of actual disruption to its relationship with [it customers]." Sybersound Records, 517 F.3d at 1151. Here, CZMI's allegations of actual disruption are conclusory. CZMI first cites two instances where Topcon asked CZMI customers to share CZMI's proprietary information and devices to assist Topcon's development of its Glaucoma Module. FAC ¶ 144-45. However, in both cases, CZMI stops short of alleging facts showing how its customer relationships were actually disrupted or what damages resulted from the alleged solicitations.

Also insufficient are CMZI's allegations that Topcon communicated with two doctors associated with various universities with whom its apparently had some relationship. TAC ¶ 146. Although CZMI contends that those communications amount to "interference," no facts are presented regarding the nature of those communications, how those communications were wrongful, the actual disruption caused or how CZMI suffered damages as a result. Similarly, CZMI's allegations that Topcon disrupted "customer relationships" by appearing "at various conferences to promote Glaucoma Module" is devoid of facts showing what conduct Topcon engaged in to cause actual disruption or otherwise what particular customer relationships were harmed.

The Court finds that CZMI has failed to state a claim for tortious interference and therefore grants Topcon and Employee Defendants and Dr. Chen's motions to dismiss said claim. In light of CZMI's prior opportunities to amend, the Court dismisses said claim without further leave to amend. See Salameh v. Tarsadia Hotel, 726 F.3d 1124, 1133 (9th Cir. 2013) ("A district court's discretion to deny leave to amend is 'particularly broad' where the plaintiff has previously amended."). Accordingly,

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IV. CONCLUSION

For the reasons stated above,

IT IS HEREBY ORDERED THAT:

- 1. Topcon's motion to dismiss is GRANTED, and Employee Defendants and Dr. Chen's motions to dismiss are GRANTED IN PART and DENIED IN PART. The claims for patent infringement and tortious interference with prospective economic advantage are dismissed without leave to amend.
- 2. Because this Order may contain information within the scope of the parties' protective order, this Order shall remain under seal pending further Order of the Court. Within 14 days of the date this Order is filed, the parties shall jointly advise the Court which facts, if any, they contend should be redacted from the public version of this ruling. To the extent any party seeks redaction of any portion of the Court's ruling, such party shall provide the Court with a proposed redacted order for public disclosure.

IT IS SO ORDERED.

Dated: 08-21-2020

SAUNDRA BROWN ARMSTROS (Senior United States District Judge