UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	CV 17-5169-GW(FFMx)	Date	February 27, 2018
Title	*Cedars Sinai Medical Center v. Quest Diagnostic Incorporated*		

Present: The Honorable	GEORGE H. WU, UNITED STATES DISTRICT JUDGE	
Javier Gonzalez	None Present	
Deputy Clerk	Court Reporter / Recorder	Tape No.

Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
None Present	None Present

PROCEEDINGS: IN CHAMBERS - FINAL RULING ON DEFENDANT QUEST'S MOTION TO DISMISS CEDARS-SINAI'S SECOND AMENDED COMPLAINT [26]

Attached hereto is the final ruling on the Defendant's Motion to Dismiss. Pursuant to the portion of that decision concerning the patent infringement cause of action, the Court sets a scheduling conference for March 8, 2018 at 8:30 a.m., for which the parties may appear telephonically. The conference will concern expedited discovery and claim construction schedule solely as it relates to the claim term "an assay" as it appears in Claims 3, 4, 9, and 10 of the '884 Patent. The parties will file a joint report by March 6 with either agreed upon dates or the respective versions of the dates proposed by each side.

Initials of Preparer JG

Cedars-Sinai Medical Center v. Quest Diagnostics, Inc., Case No. 2:17-cv-05169-GW-(FFMx)
Final Ruling on Motion to Dismiss

I. Background

Plaintiff Cedars-Sinai brings this action against Defendants Quest Diagnostics, Inc. and Quest Diagnostics Nichols Institute (collectively, "Quest") alleging four claims: 1) trade secret misappropriation, in violation of the Defend Trade Secrets Act ("DTSA"), 18 U.S.C. § 1836; 2) trade secret misappropriation, in violation of the California Uniform Trade Secrets Act ("CUTSA"), Cal. Civ. Code § 3426; 3) breach of contract; and 4) patent infringement. *See generally* Second Amended Complaint ("SAC"), Docket No. 23. Quest moves to dismiss the SAC in its entirety and, in the alternative, moves for a more definite statement regarding Cedars-Sinai's alleged trade secrets. *See generally* Motion to Dismiss SAC ("Motion"), Docket No. 26-1; Reply to Opposition to Motion ("Reply"), Docket No. 37. Cedars-Sinai opposes the Motion. *See generally* Opposition to Motion ("Opp'n"), Docket No. 35.

Cedars-Sinai alleges the following relevant facts:

Cedars-Sinai is a nonprofit academic medical center. SAC ¶ 16. It has supported decades of research into the pathophysiology of Irritable Bowel Syndrome ("IBS") and development of diagnostics and treatments for IBS, licensing the results of this research to generate revenue to fund its research operations. *Id.* Briefly, Cedars-Sinai: 1) discovered that the detection of particular antibodies above control levels − including anti-vinculin and "anti-CdtB" antibodies − indicates the presence of IBS, 2) that the symptoms of IBS may be attributed to small intestinal bacterial overgrowth ("SIBO"), and 3) that SIBO may be treated with rifaximin. *Id.* ¶ 25. At the time of the Cedars-Sinai team's discovery, there was no existing diagnostic test for IBS using anti-vinculin antibodies − or any other type of antibodies − on the market. *Id.* ¶ 31. Beginning on February 11, 2009, Cedars-Sinai filed a series of provisional patent applications for blood tests for IBS based on these discoveries that ultimately matured into United States Patent No. 9,702,884 ("'884 Patent"), in addition to other patents in the United States and in foreign jurisdictions. *Id.* ¶ 33.

In November 2013, Cedars-Sinai and Quest opened discussions about licensing Cedars-Sinai's diagnostic technology to commercialize the research. *Id.* ¶ 34. On or about November 24, 2013, the parties entered into "Confidentiality Obligations" to facilitate those discussions.

Id. ¶ 35. During the course of these discussions, Cedars-Sinai disclosed "confidential details" of Cedars-Sinai's diagnostic technology. *Id.* ¶¶ 37, 38, 41. Additionally, Cedars-Sinai provided to Quest a confidential presentation[1] (*id.* ¶ 36), unpublished patent applications (*id.* ¶¶ 37, 43), a confidential manuscript (*id.* ¶ 40), and confidential market research (*id.* ¶ 42). On or about December 23, 2014, after a year of discussions and the receipt of the aforementioned materials, Quest informed Cedars-Sinai that it was not interested in pursuing the licensing agreement further. *Id.* ¶ 44.

Cedars-Sinai subsequently learned that on or about July 9, 2015, Quest filed an application to register a trademark for "medical diagnostic testing services; medical information services." *Id.* ¶ 47. "On information and belief, therefore, as of and before July 9, 2015, Quest was creating, designing, developing, and/or using an IBS assay and/or doing IBS testing and/or making preparations for delivery of IBS services and the use of an IBS assay or diagnostic." *Id.* In April 2017, Cedars-Sinai learned that Quest was performing IBS diagnostic testing services under the trademark it applied for in July 2015. *Id.* ¶ 48. "Upon information and belief, Quest's diagnostic IBS testing services and IBS testing are based on unauthorized and unlawful use of Cedars-Sinai's patented inventions, trade secrets, and other confidential information subject to the Confidentiality Obligations, without any authorization by or compensation to Cedars-Sinai." *Id.* ¶ 49.

II. Legal Standard

A. Motion to Dismiss (Rule 12(b)(6))

Under Rule 12(b)(6), a defendant may move to dismiss for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A complaint may be dismissed for failure to state a claim for one of two reasons: (1) lack of a cognizable legal theory; or (2) insufficient facts under a cognizable legal theory. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th Cir. 2008) ("Dismissal under Rule 12(b)(6) is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory.").

In deciding a Rule 12(b)(6) motion, a court "may generally consider only allegations contained in the pleadings, exhibits attached to the complaint, and matters properly subject to

[1] The transmission of this presentation would seem to predate the execution of the Confidentiality Obligations. *Compare* SAC ¶ 35 (Confidentiality Obligations entered into on or about November 24, 2013) *with* SAC ¶ 36 (confidential presentation sent on or about November 13, 2013).

judicial notice." *Swartz v. KPMG LLP*, 476 F.3d 756, 763 (9th Cir. 2007). The court must construe the complaint in the light most favorable to the plaintiff, accept all allegations of material fact as true, and draw all reasonable inferences from well-pleaded factual allegations. *Gompper v. VISX, Inc.*, 298 F.3d 893, 896 (9th Cir. 2002); *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001), *amended on denial of reh'g*, 275 F.3d 1187 (9th Cir. 2001); *Cahill v. Liberty Mutual Ins. Co.*, 80 F.3d 336, 337-38 (9th Cir. 1996). The court is not required to accept as true legal conclusions couched as factual allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Where a plaintiff facing a Rule 12(b)(6) motion has pleaded "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged," the motion should be denied. *Id.*; *Sylvia Landfield Trust v. City of Los Angeles*, 729 F.3d 1189, 1191 (9th Cir. 2013). But if "the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not show[n] . . . the pleader is entitled to relief." *Iqbal*, 556 U.S. at 679 (citations omitted).

B. Motion for a More Definite Statement (Rule 12(e))

"A party may move for a more definite statement of a pleading to which a responsive pleading is allowed but which is so vague or ambiguous that the party cannot reasonably prepare a response." Fed. R. Civ. P. 12(e). "Courts have held that a Rule 12(e) motion is proper only where the complaint is *so indefinite that defendant cannot ascertain the nature of the claim* being asserted." O'Connell & Stevenson, *Fed. Civ. Proc. Before Trial, California & 9th Circuit Edition* ("Federal Practice Guide"), § 9:347 (Rutter Grp. 2017) (emphasis in original). The motion "must point out the defects complained of and the details desired." Fed. R. Civ. P. 12(e).

III. Discussion

A. First and Second Claims: Trade Secret Misappropriation

To state a claim for trade secret misappropriation under the CUTSA,

> a plaintiff must allege that: (1) the plaintiff owned a trade secret; (2) the defendant misappropriated the trade secret; and (3) the defendant's actions damaged the plaintiff." *Autodesk, Inc. v. ZWCAD Software Co., Ltd.*, [Case] No. 14-1409, 2015 WL 2265479, at *5 (N.D. Cal. May 13, 2015) (citation omitted). The elements of misappropriation under the DTSA are similar to those under the CUTSA. *Compare* 18 U.S.C. § 1839(5) *with* Cal. Civ. Code § 3426.1(b).

Space Data Corp. v. X, Case No. 16-3260, 2017 WL 3007078, at *2 (N.D. Cal. July 14, 2017).

"A 'trade secret' is defined as information that: (1) derives independent economic value from not being generally known to the public; and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." *Gatan, Inc. v. Nion Company*, Case No. 15-1862, 2017 WL 1196819, at * 6 (N.D. Cal. Mar. 31, 2017) (citing Cal. Civ. Code § 3426.1); *see also Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 476 (1974) ("The subject of a trade secret must be secret, and must not be of public knowledge or of a general knowledge in the trade or business."). Because the pleading standards of Cedars-Sinai's DTSA and CUTSA claims are the same, the Court will analyze those two claims together. *See Rockwell Collins, Inc. v. Wallace*, Case No. 17-1369-AG-(JCGx), 2017 WL 5502775, at *2 (C.D. Cal. Nov. 20, 2017) (analyzing DTSA and CUTSA claims together on a Rule 12(b)(6) motion to dismiss).[2]

The parties halfheartedly suggest that trade secret misappropriation claims are subject to a heightened pleading standard. *See* Motion at 13-14; Opp'n at 10. Although the parties raise the issue only in the context of Rule 12(e) - and not Rule 12(b)(6) - the Court finds that it is necessary to address it here as a heightened pleading standard would necessarily impact the Court's analysis of both the Rule 12(b)(6) and Rule 12(e) issues. The dearth of authority provided by the parties required the Court to conduct its own research, which revealed that the issue is unsettled. After a review of cases in this judicial district, the Court would find that a heightened pleading standard is not applicable to Plaintiff's statutory trade secret misappropriation claims and will not apply one here.

The Court's research revealed as an initial matter that courts often describe the adequacy of trade secret pleadings by using the terms "sufficient particularity" and "reasonable particularity," but it is unclear whether there is a meaningful difference between the two. Some courts use only one or the other while other courts use them interchangeably. *See, e.g., Manchester v. Sivantos GMBH*, Case No. 17-5309-ODW-(JEMx), 2018 WL 587849, at *3 (C.D. Cal. Jan. 29, 2018) (using "sufficient particularity"); *Teledyne Risi, Inc. v. Martin-Baker Aircraft Co., Ltd.*, Case No. 15-7936-SJO-(GJSx), 2016 WL 8857029, at *7 (C.D. Cal. Feb. 2, 2016) (using "reasonable particularity"); *Jun-En Enter. v. Lin*, Case No. 12-2734-PSG-(Ssx), 2012 WL 12886499, at *3 (C.D. Cal. Oct. 17, 2012) (using terms interchangeably); *TMC Aerospace, Inc. v. Elbit Systems of America LLC*, Case No. 15-7595-AB-(Ex), 2016 WL 3475322, at *4 (C.D. Cal. Jan. 29, 2016) (using terms interchangeably); *Sms Signature Cars v. Connects Mktg. LLC*,

[2] The parties similarly analyze these two claims together. *See* Motion at 8-15; Opp'n at 3-12.

Case No. 12-1300-JVS-(ANx), 2013 WL 12138992, at *2-3 (C.D. Cal. May 15, 2013) (using terms interchangeably). For its purposes here the Court will consider the two terms to be functionally equivalent.

The Court finds cases applying a heightened standard unpersuasive. Two of the cases find a heightened pleading standard based on Cal. Civ. Proc. Code § 2019.210, which requires a plaintiff to describe trade secrets with "reasonable particularity" prior to the initiation of discovery. *See, e.g., TMC Aerospace*, 2016 WL 3475322 at *4; *Sms Signature Cars*, 2013 WL 12138992 at *3. However, Cal. Civ. Proc. Code § 2019.210 says nothing of pleading and by its very terms is limited to the initiation of discovery. Furthermore, Cal. Civ. Proc. Code § 2019.210 is a California statute and thus could not apply to DTSA claims. To the contrary, the DTSA - enacted in 2016 - makes no mention of any heightened pleading standard. *See* Pub. L. No. 114-153, 130 Stat. 376 (2016). Finally, the Court notes that in an unpublished decision, the Ninth Circuit stated that Cal. Civ. Proc. Code § 2019.210 does not apply at the pleading stage. *Meggitt San Juan Capistrano, Inc. v. Nie Yongzhong*, 575 Fed. App'x. 801, 803 (9th Cir. 2014) ("Appellants cite no state authority for the proposition that Meggitt SJC should have identified the particular trade secrets *at the pleading stage*. Rather, the authorities on which they rely simply require a plaintiff to identify a trade secret "with reasonable particularity" prior to commencing discovery.") (emphasis in original).

The Court finds persuasive the reasoning of cases that decline to apply a heightened pleading standard to CUTSA or DTSA claims. *See, e.g., Id.*; *Rockwell*, 2017 WL 5502775 at *2 (explaining that the "particularity" requirement from Rule 9 does not apply to DTSA claims and that Cal. Civ. Proc. Code § 2019.210 does not apply to pleadings); *New Show Studio LLC v. Needle*, Case No. 14-01250-CAS-(MRWx), 2014 WL 2988271, at *9 (C.D. Cal. June 30, 2014) (explaining that Cal. Civ. Proc. Code § 2019.210 "does not provide grounds for dismissing a trade secret claim at the pleading stage"); *Space Data Corp.*, 2017 WL 3007078 at *3 (declining to apply a heightened pleading standard to CUTSA and DTSA claims because "the [Cal. Civ. Proc. Code] § 2019.210 statement is an issue separate from [defendant's] motion to dismiss").

The two cases cited by Quest do not support requiring a heightened pleading standard. *See* Motion at 13. In *Imax Corp. v. Cinema Technologies, Inc.*, 152 F.3d 1161 (9th Cir. 1998), the appellate court reviewed a district court's decision at the summary judgment stage and thus did not elucidate what is required of trade secret misappropriation pleadings. And in *Rovince*

International Corp. v. Preston, Case No. 13-3527-CAS-(PJWx), 2013 WL 5539430 (C.D. Cal. Oct. 7, 2013) the court did not explicitly address whether a heightened pleading standard applies to trade secret misappropriation claims. *See New Show Studio*, 2014 WL 2988271 at *9 (explaining that *Rovince* does not stand for the proposition that plaintiffs are required to identify their trade secrets with particularity).

In sum, the Court finds that in the context of both Rule 12(b)(6) and Rule 12(e), pleadings for trade secret misappropriation should be held to the standard articulated in Rule 8(a)(2). *See* Fed. R. Civ. P. 8(a)(2) ("A pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief"); *Space Data Corp.*, 2017 WL 3007078 at *3 (applying the Rule 8 standard in determining whether the identification of trade secrets in a complaint is adequate). Accordingly, the Court will not apply a heightened pleading standard here.[3]

1. The SAC Adequately Pleads Trade Secret Misappropriation

Quest contends that no trade secrets exist because all the information allegedly provided to it by Cedars-Sinai was publicly disclosed. *See* Motion at 3-7 (detailing disclosures). Specifically, Quest goes to great lengths to show that the materials Cedars-Sinai identifies as its trade secrets were publicly disclosed through patent applications and the PLoS One article.[4] Motion at 9-13. These disclosures ostensibly include testing methods for IBS by measuring anti-vinculin and anti-CdtB, methods for validating these tests, and Cedars-Sinai's assessment of the potential market for these tests. *Id.* Cedars-Sinai acknowledges that it disclosed some information publicly, but disputes that *all* the information it provided to Quest was disclosed in Cedars-Sinai's patent applications and the PLoS ONE article. *See* Opp'n at 7-9.

The Second Amended Complaint alleges that in the course of confidential

[3] As explained below, the Court finds that Cedars-Sinai adequately pleads its first, second, and third claims and that relief is not warranted under Rule 12(b)(6) or Rule 12(e). This was not a close call and, even were the Court to apply a heightened pleading standard, it would find that Cedars-Sinai has described its trade secrets with "reasonable particularity."

[4] In deciding a Rule 12(b)(6) motion, a court "may generally consider only allegations contained in the pleadings, exhibits attached to the complaint, and matters properly subject to judicial notice." *Swartz*, 476 F.3d at 763. The court may also consider material necessarily relied on by the complaint. *Lee v. City of Los Angeles*, 250 F.3d 668, 688-89 (9th Cir. 2001). The SAC includes the '884 Patent as an exhibit (SAC, Exhibit A) and specifically refers to the patent applications (SAC ¶¶ 33, 41, 43, 74-75), the PLoS One article (SAC ¶ 15), and Quest's trademark application (SAC ¶ 47). Accordingly, the Court will consider those materials in its analysis of the Motion. The other materials that Quest asks the Court to consider are not generally known within the Court's jurisdiction or capable of accurate and ready determination from sources whose accuracy cannot reasonably be questioned and thus the Court declines to take judicial notice and consider those materials. *See* Federal Rule of Evidence 201(b).

communications, Cedars-Sinai provided Quest a confidential presentation (SAC ¶ 36), unpublished patent applications (*id.* ¶¶ 37, 43), a confidential manuscript of a paper to the New England Journal of Medicine (*id.* ¶ 40), technical information on two possible test methods not disclosed in the patent applications (*id.* ¶ 41), a validation method (*id.*), and a confidential IBS diagnostic market research presentation (*id.* ¶ 42). The Court accepts that Cedars-Sinai publicly disclosed some information about its research of IBS diagnostic techniques, but cannot conclude, on a motion to dismiss, that Cedars-Sinai disclosed *everything* about its research in IBS diagnostics. *See T-Mobile USA, Inc. v. Huawei Device USA, Inc.*, 115 F. Supp. 3d 1184, 1191-92 (W.D. Wash. 2015) ("It is simple enough to conclude, based on this host of disclosures, that T-Mobile publicly disclosed much about Tappy. It is another matter entirely to conclude, especially given the limits of a motion to dismiss for failure to state a claim, that T-Mobile disclosed *everything* about Tappy, including trade secret information.") (emphasis in original). The arguments and counterarguments presented by the parties in this case regarding the scope of Cedar-Sinai's trade secrets and its disclosures present highly factual issues that are not properly decided on a motion to dismiss.[5] It is not appropriate for the Court to go through every detail of each of these confidential communications, as well as the published patent applications and the PLoS ONE article, to determine whether or not *every* alleged trade secret was publicly disclosed. Notably, patent applications and scientific articles are highly technical and would likely require expert testimony to decipher. *See id.* at 1192 ("At the threshold, the court is in no position on a motion to dismiss to sift through patent applications and discern whether they fully disclose everything about Tappy."); *see also Emazing Lights LLC v. De Oca*, Case No. 15-1561-AG-(Ex), 2016 WL 3658945, at *3 (C.D. Cal. Jan. 7, 2016) (rejecting defendants' arguments that plaintiff destroyed any relevant trade secrets by publicly disclosing them in its patent and patent application). Furthermore, even if the Court were inclined to engage in the factual inquiry of comparing Cedar-Sinai's public disclosures with Quest's IBS diagnostic technology, it has no information regarding that technology that it could use to make such a comparison.

In summary, the Court would find that Cedars-Sinai has adequately pleaded

[5] As just one example of these highly factual issues, the parties disagree as to the meaning of "as of and before July 9, 2015" and whether Quest used confidential trade secret information from Cedars-Sinai before that date. SAC ¶ 47; Motion at 7. Cedars-Sinai alleges that "as of and before July 9, 2015, Quest was creating, designing, developing, and/or using an IBS assay and/or doing IBS testing and/or making preparations for delivery of IBS services and the use of an IBS assay or diagnostic." SAC ¶ 47. Whether or not Quest actually used confidential information from Cedars-Sinai before that date is a question for the fact-finder, not for the Court on a Rule 12(b)(6) motion.

misappropriation of trade secrets claims under both the DTSA and CUTSA. Cedars-Sinai has alleged that it owns trade secrets relating to its research on IBS diagnostic techniques. Additionally, Cedars-Sinai has alleged that Quest misappropriated these trade secrets (SAC ¶¶ 49, 56) and that Quest's actions have damaged Cedars-Sinai (SAC ¶ 57). Thus, all elements of a trade secret misappropriation claim are plausibly alleged. Accordingly, the Court would deny the Motion in as much as it seeks to dismiss Cedars-Sinai's first and second claims for relief.

2. The SAC Adequately Identifies Cedars-Sinai's Trade Secrets

In the alternative, Quest argues that Cedars-Sinai has failed to identify its trade secrets with reasonable particularity and moves for a more definite statement pursuant to Rule 12(e).[6] *See* Motion at 13-15. Case law indicates that the level of detail required in trade secret pleadings is not high. *See, e.g., TMC Aerospace*, 2016 WL 3475322 at *5 (finding "proprietary design drawings, manufacturing techniques, and manufacturing equipment including moulds and jigs" as an adequate description of trade secrets); *Autodesk*, 2015 WL 2265479 at *5 (finding "source code which comprises AutoCAD 2007 and 2008 is a trade secret, including those portions of code that underlie the commands, interfaces and program files associated with the dozens of specific features which were wrongfully acquired and used in defendants' ZWCAD+ 2012 and 2014 programs" as adequate). Courts have acknowledged that requiring plaintiffs to spell out their trade secrets in great detail would risk public disclosure, the very thing plaintiffs are seeking to prevent. *See Diodes, Inc. v. Franzen*, 260 Cal. App. 2d 244, 252 (1968) ("One who seeks to protect his trade secrets from wrongful use or disclosure does not have to spell out the details of the trade secret to avoid a demurrer to a complaint. To so require would mean that the complainant would have to destroy the very thing for which he sought protection by making public the secret itself."); *see also Autodesk*, 2015 WL 2265479 at *6 ("[C]ourts are 'in general agreement that trade secrets need not be disclosed in detail in a complaint alleging misappropriation for the simple reason that such a requirement would result in public disclosure of the purported trade secrets.'") (citing *Leucadia, Inc. v. Applied Extrusion Technologies, Inc.*, 755 F. Supp. 635, 636 (D. Del. 1991)).

The Court finds that Cedars-Sinai has adequately identified its trade secrets to permit Quest to prepare a responsive pleading. *See* Fed. R. Civ. P. 12(e). Cedars-Sinai describes its

[6] The appropriate pleading standard as to trade secret claims is discussed in a preceding section. The Court notes that even if it applies a heightened "reasonable particularity" standard, Cedars-Sinai's description of its trade secrets would suffice.

trade secrets as "financial, business, scientific, technical, economic, and/or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, tangible and/or intangible, related to IBS diagnostic techniques and validation of the same, as well as how to serve unmet clinical needs associated with IBS." SAC ¶ 52. As discussed above, Cedars-Sinai also identifies the specific confidential communications that allegedly contain these trade secrets. *See id.* ¶¶ 36-43 (listing confidential communications to Quest during licensing negotiations). This alone limits the scope of Cedars-Sinai's alleged trade secrets and gives enough detail for Quest "to prepare a defense and for the court to craft limits on discovery." *Gatan,* 2017 WL 1196819 at *6 (citing *TMX Funding, Inc. v. Impero Techs., Inc.*, Case No. C 10-00202-JF (PVT), 2010 WL 2509979, at *3 (N.D. Cal. June 17, 2010)). In addition, Cedars-Sinai specifically points out as least two aspects of its trade secrets: "two possible test methods that leverage inventions covered in Cedars-Sinai's then pending patent applications but are not themselves disclosed in the patent applications, as well as how to validate tests based on the direct measurement of anti-CdtB and anti-vinculin antibodies and how the same would serve unmet clinical needs" (SAC ¶41) and "confidential IBS diagnostic market research presentation detailing Cedars-Sinai's assessment of the market opportunity for its IBS diagnostic technology and strategies for increasing its acceptance and adoption by patients, physicians, and payers. This included highly valuable and sensitive analysis of pricing and adoption strategies for IBS diagnostics" (SAC ¶ 42). *See T-Mobile*, 115 F. Supp. 3d at 1193 (finding plaintiffs identification of trade secrets adequate because it identified at least two aspects that defendant targeted in its misappropriation). The Court would thus deny the Motion to the extent it seeks to compel a more definite statement regarding Cedars-Sinai's alleged trade secrets.

B. Third Claim: Breach of Contract

The Confidentiality Agreement binding the parties provides that:

> [Quest] agrees to hold and maintain all of [Cedar-Sinai's] Proprietary Information in strictest confidence for a period of five (5) years from the [November 5, 2013]. [Quest] shall not reverse engineer, disassemble or decompile any samples, prototypes, software or other tangible objects provided by [Cedar-Sinai] hereunder other than with [Cedar-Sinai's] express written authorization. [Quest] shall not use any of [Cedar-Sinai's] Proprietary Information other than for the Purpose; provided that [Quest] shall not be liable to [Cedar-Sinai] with respect to the use

> or disclosure of such information as can be established by credible evidence to: (a) *be publicly known, without fault on [Quest's] part, subsequent to the disclosure of such information to [Quest]*.

Confidentiality Agreement, Docket No. 26-3, ¶ 2.a (emphasis added). As an extension of the argument the Court has rejected, Quest argues that because the information it allegedly misappropriated was publicly available, Cedars-Sinai has failed to state a claim for breach of contract. *See* Motion at 16 ("[B]y the terms of the Confidentiality Agreement, Quest is not liable for the use of the information disclosed by the PLoS ONE article and patent applications because Cedars-Sinai made that information public. Therefore, Cedars-Sinai's claim for breach of contract fails as a matter of law because Quest's activities, as pleaded by Cedars-Sinai, are expressly exempted in the Confidentiality Agreement."). For the reasons set forth above, the Court finds that Cedars-Sinai has adequately pleaded that the information provided to Quest included confidential trade secrets and thus rejects Quest's argument. Accordingly, the Court would deny the Motion in as much as it seeks to dismiss Cedars-Sinai's third claim for relief.

C. Fourth Claim: Patent Infringement

1. The '884 Patent and the Asserted Claims

The '884 Patent issued July 11, 2017 and is titled "Methods for Detecting the Presence of Irritable Bowel Syndrome and System for Diagnosing Same." The SAC alleges that Quest infringes Claims 3, 4, 9, and 10 of the '884 Patent ("Asserted Claims"). SAC ¶ 73. The four Asserted Claims recite:

> 3. A system for diagnosing irritable bowel syndrome, comprising:
> an isolated biological sample from a subject desiring diagnosis regarding irritable bowel syndrome (IBS); and
> an assay for detecting in the biological sample, a level of an anti-vinculin antibody.
>
> 4. The system of claim 3, wherein the assay is an enzyme-linked immunosorbent assay (ELISA), wherein the ELISA comprises using vinculin, SEQ ID NO:1 or a fragment thereof as a substrate or reagent to bind the anti-vinculin antibody.
>
> 9. A system, comprising:
> an isolated biological sample from a subject desiring a diagnosis to distinguish between irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD); and
> an assay for detecting in the biological sample, a level of anti-vinculin antibody.

> 10. The system of claim 9, wherein the assay is an enzyme-linked immunosorbent assay (ELISA), wherein the ELISA comprises using vinculin, SEQ ID NO:1 or a fragment thereof as a substrate or reagent to bind the anti-vinculin antibody.

Quest argues the Asserted Claims are invalid under 35 U.S.C. § 101 because they are drawn to patent-ineligible subject matter. *See* Motion at 16-23.

2. The Mayo/Alice Test for Patent Eligibility Under 35 U.S.C. § 101

An invention or a discovery is patentable if it is a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. "In choosing such expansive terms . . . Congress plainly contemplated that the patent laws would be given wide scope." *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980). Still, the Supreme Court has identified exceptions to this wide scope to "distinguish patents that claim the building blocks of human ingenuity, which are ineligible for patent protection, from those that integrate the building blocks into something more." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2350 (2014) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.,* 566 U.S. 66, 89 (2012)) (internal quotations omitted). These exceptions to patent protection are "laws of nature, natural phenomena, and abstract ideas." *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). While the boundaries of the judicial exceptions remain subject to further development, the Supreme Court has clearly stated the policy underlying those exceptions: avoiding patents that "too broadly preempt the use of a natural law [or abstract idea]." *Mayo*, 132 S. Ct. at 1294. Thus, patent law should "not inhibit further discovery by improperly tying up the future use of laws of nature [or abstract ideas]." *Id*. at 1301.

In *Mayo*, the Supreme Court "set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice*, 134 S. Ct. at 2355. The first step is to ask "whether the claims at issue are directed to one of those patent-ineligible concepts." *Id.* If not, the claims fall within the scope of § 101 and are patent-eligible. If the claims are directed to one of the exceptions, the next step is to search for an "inventive concept" that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself." *Mayo*, 566 U.S. at 72-73. In doing so, a court must "consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Alice*, 134 S. Ct. at 2355

(quoting *Mayo*, 566 U.S. at 78-79).

The question in the law of nature context is whether the claims at issue add more than "'well-understood, routine, conventional activity already engaged in by the scientific community'" to the law of nature. *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1047 (Fed. Cir. 2016) (quoting *Mayo*, 566 U.S. at 79-80). "[G]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 577 (2013).

3. Mayo/Alice Step One

Quest argues that the Asserted Claims are invalid under § 101 because they "are directed to a single natural phenomenon: the correlation between the presence of anti-vinculin antibodies and IBS." Motion at 17. Quest argues, "[t]he Federal Circuit has found substantively identical claims invalid under § 101." *Id.* at 19 (citing *Cleveland Clinic Found. v. True Health Diagnostics, LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017)). Quest also argues that the Asserted Claims represent a "sweeping preemption of the natural phenomenon," as Claims 3 and 9 "preempt all means for detecting the natural phenomenon of elevated vinculin in IBS patients." *Id.* at 20. Quest argues that Claims 4 and 10 fare no better because "the recitation of ELISA to detect anti-vinculin is not sufficiently novel or specific to transform the natural phenomenon into a patent eligible application thereof." *Id.*

Cedars-Sinai argues that Quest fails to prove invalidity of the Asserted Claims of the '884 Patent. Opp'n at 14. Cedars-Sinai first asserts that a person of ordinary skill in the art would understand the term "an assay" as used in the claims to mean "a vinculin-based assay." *Id.* at 15-16. Cedars-Sinai further contends that, "[b]ecause vinculin is an intracellular protein, it must first be ***manufactured*** and isolated in order to prepare the vinculin-based assay of the asserted claims." *Id.* at 19 (emphasis in original). Cedars-Sinai asserts that "vinculin utilized in the claimed assay will have different characteristics and will behave differently in the environment of a diagnostic assay than naturally-occurring vinculin would within the cellular environment." *Id.* at 20. Based on these characterizations, Cedars-Sinai argues the Asserted Claims "cannot be directed to natural phenomena because they each use a non-naturally occurring component: vinculin." *Id.* at 21. Cedars-Sinai argues that preemption is not a concern because the Asserted Claims are "limited specifically to vinculin-based assays." *Id.* at 22.

In reply, Quest again emphasizes the Federal Circuit's decision in *Cleveland Clinic*.

Reply at 12. Quest argues the Asserted Claims are invalid even accepting Cedars-Sinai's construction of "an assay" as "a vinculin-based assay." *Id.* at 15-16. Quest again compares the Asserted Claims to the claims at issue in *Cleveland Clinic* and notes that even though the *Cleveland Clinic* claims implicated manufactured components in commercially-available tests, the claims were still patent-ineligible because the focus of the claims was detecting MPO levels in the body using known techniques. *Id.* at 17. Quest argues that even assuming Cedars-Sinai's construction of "an assay," the preemption analysis does not change because, as Cedars-Sinai represented in its opposition, an assay for detecting a level of anti-vinculin antibody "must necessarily use vinculin as the assay reagent." *Id.* at 18 (quoting Opp'n at 16).

In analyzing the Asserted Claims, it is helpful to consider and compare other claims that have been tested against § 101. *See, e.g.*, *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1334 (Fed. Cir. 2016) ("The Supreme Court has not established a definitive rule to determine what constitutes an 'abstract idea' sufficient to satisfy the first step of the *Mayo/Alice* inquiry. Rather, both this court and the Supreme Court have found it sufficient to compare claims at issue to those claims already found to be directed to an abstract idea in previous cases." (Internal citations omitted).)

In *Cleveland Clinic*, the Federal Circuit affirmed a district court's determination that claims from three patents were invalid because they were not directed to patent-eligible subject matter. *Cleveland Clinic*, 859 F.3d at 1355. The Federal Circuit specifically concluded that the claims were "directed to multistep methods for observing the law of nature that MPO [(myeloperoxidase)] correlates to cardiovascular disease." *Id.* at 1360. One of the *Cleveland Clinic* patent claims, for instance, recited:

> 21. A method of assessing the risk of requiring medical intervention in a patient who is presenting with chest pain, comprising
>
> characterizing the levels of myeloperoxidase activity, myeloperoxidase mass, or both, respectively in the bodily sample from the human patient, wherein said bodily sample is blood or a blood derivative,
>
> wherein a patient whose levels of myeloperoxidase activity, myeloperoxidase mass, or both is characterized as being elevated in comparison to levels of myeloperoxidase activity, myeloperoxidase mass or both in a comparable bodily samples obtained from individuals in a control population is at risk of requiring medical intervention to prevent the occurrence of an adverse cardiac event within the next six months.

Id. at 1356-57 (citing U.S. Patent No. 7,459,286). Other dependent claims of the same patent

limited myeloperoxidase ("MPO") detection "by flow cytometry and further require[d] detection of another compound, troponin." In concluding particular independent patent claims were representative, the Federal Circuit noted that the dependent claims in the three patents "merely recite[d] known methods of detecting MPO or MPO derivatives and applie[d] the correlation between these biomarkers and cardiovascular health." *Id.* at 1360. The Federal Circuit noted that the plaintiff "has not created a new laboratory technique; rather, it uses well-known techniques to execute the claimed method. The specification of the testing patents confirm that known testing methods could be used to detect MPO, and that there were commercially available testing kits for MPO detection." *Id.* at 1361.

The Asserted Claims in this matter appear initially to be highly analogous to the claims invalidated by the Federal Circuit in *Cleveland Clinic*. The Asserted Claims essentially recite the combination of an assay for detecting an anti-vinculin antibody and a biological sample "from a subject desiring diagnosis" of IBS. The crux of the claims thus relies on the fact that there is a correlation between IBS and a subject's levels of anti-vinculin antibody. In other words, the claims are directed to systems for observing the law of nature that anti-vinculin antibody correlates to IBS.

This conclusion at *Alice/Mayo* Step 1 is not impacted by Cedars-Sinai's argument that the claim phrase "an assay" in the Asserted Claims must be construed as "a vinculin-based assay." Assuming the claim term "an assay" means "a vinculin-based assay," and even further assuming the claimed vinculin-based assay utilizes manufactured or non-naturally-occurring vinculin, does not change the analysis. The focus of the Asserted Claims is not on the assay itself, but on the system's goal of diagnosing IBS. *See, e.g.*, '884 Patent, Claim 3 ("A system for diagnosing irritable bowel syndrome, comprising . . ."). Whether the system can diagnose IBS, in turn, is dependent on the correlation between IBS and anti-vinculin antibody. This core law of nature persists even where the claimed diagnostic assay is a vinculin-based assay. Cedars-Sinai attempts to distinguish *Cleveland Clinic* and other cases on the basis that the Asserted Claims "provide a vinculin-based assay that utilizes . . . non-naturally occurring components, and the subject vinculin and anti-vinculin antibody were not known or expected to be predictive of IBS in assays." Opp'n at 22-23 n.8. But this argument is an exercise in misdirection. Like the *Cleveland Clinic* claims, the Asserted Claims "purport[] to detect naturally-occurring [anti-vinculin antibodies] through well-known techniques based on a known correlation between [anti-

vinculin antibodies] and the disease state." *See id.* (Cedars-Sinai's parenthetical describing patents at issue in *Cleveland Clinic*); *Cleveland Clinic*, 859 F.3d at 1362 ("Cleveland Clinic does not purport to have invented colorimetric-based assay, flow cytometry, or ELISA, or any of the claimed methods to 'see' MPO and its derivatives in bodily samples. Rather, the claims here instruct that MPO levels be detected or determined using any of these known techniques."). Specifically, the '884 Patent states, "[o]ne of ordinary skill in the art will readily appreciate methods and systems that can be used to detect the presence or absence of an antibody that binds specifically to vinculin, SEQ ID NO: 1 or a fragment thereof. These methods and systems include but are not limited to ELISA, immunohistochemistry, flow cytometry, fluorescence in situ hybridization (FISH), radioimmuno assays, and affinity purification." *Id.* at 12:28-36.

The fact that the correlation between vinculin and IBS was not known before Cedars-Sinai's discovery is also irrelevant. As a law of nature, this correlation has always existed. Simply because Cedars-Sinai was the first to discover it, *i.e.*, make a "breakthrough" in the field, does not change its inherent character as a law of nature. For this reason, any attempt by Cedars-Sinai to distinguish *Cleveland Clinic* based on the argument that the correlation between MPO and cardiovascular health was already known before *Cleveland Clinic's* patent issued is also unpersuasive. As stated, "groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." *Myriad Genetics*, 569 U.S. at 577. Accordingly, the Asserted Claims are directed to a law of nature under *Mayo/Alice* Step One.

Importantly, as Quest noted in its reply, Cedars-Sinai has represented that "'an assay for detecting . . . a level of anti-vinculin antibody' must necessarily use vinculin as the assay reagent." Opp'n at 16; *see also* Reply at 18. If Cedars-Sinai's position is accepted, under Cedars-Sinai's own interpretation of the claims, any assay relying on detecting anti-vinculin antibodies in order to diagnose IBS would be covered by the claims. In other words, the Asserted Claims, and particularly Claims 3 and 9, would preempt all assays detecting a correlation between anti-vinculin antibody and IBS. Such sweeping preemption concerns confirm the nature of the Asserted Claims. *Mayo*, 132 S. Ct. at 1301 (patent law should "not inhibit further discovery by improperly tying up the future use of laws of nature."). At the first hearing on the Motion, counsel for Cedars-Sinai argued that preemption is not a concern because while the '884 Patent covers vinculin-based assays, it does not cover using CdtB assays to diagnose vinculin. As counsel for Quest correctly noted, however, the question of preemption

asks whether a particular law of nature is tied up by the patented invention. Simply pointing to a different law of nature (*e.g.*, the correlation between CdtB and IBS as opposed to the correlation between vinculin and IBS) does not address the issue. At the supplemental hearing on the Motion, Cedars-Sinai shifted its argument and stated that the Asserted Claims do not preempt the correlation between anti-vinculin antibodies and IBS, in part because, according to Cedars-Sinai, manufactured vinculin has only a single, specific amino acid sequence. Cedars-Sinai's shifting approach will be addressed in the next section, but it is worth noting that again, if true that manufactured vinculin only has a single, specific amino acid sequence, then preemption would remain a problem as others would still be unable to use any vinculin-based assay (*i.e.*, the only available type of vinculin-based assay) to diagnose IBS.

The Court concludes that the claims are directed to a law of nature under *Mayo/Alice* Step 1 and thus proceeds to analyze *Mayo/Alice* Step 2.

5. Mayo/Alice Step Two

In its Motion, Quest argued that the Asserted Claims fail *Mayo/Alice* Step Two because "there is no 'inventive concept' beyond the natural phenomenon." Motion at 22; *see also id.* ("Indeed, at no point, either in the patent specification or during prosecution did Cedars-Sinai argue that an assay for anti-vinculin antibodies was novel.") Similar to its arguments in its Opposition under *Mayo/Alice* Step One, Cedars-Sinai argued the Asserted Claims are patentable under *Mayo/Alice* Step Two "because the claimed vinculin-based assay constitutes a new and unique way of improving IBS diagnoses." Opp'n at 23. Cedars-Sinai appeared to focus its argument on the idea that the claimed assay was specifically a "vinculin-based assay" and noted that claim construction was necessary to construe the term. *See id.* at 15. It emphasized that the vinculin used in the assays had to be manufactured and thus the Asserted Claims could not be directed toward natural phenomena. *Id.* at 19. In reply, Quest argued, "[i]t may be that testing for anti-vinculin is a new way of diagnosing IBS, but even if it is, and even if that discovery were 'pioneering,' it does not constitute a patent-eligible concept because that application of a natural phenomenon was achieved using a conventional assay long known in the prior art." Reply at 20.

At the first hearing on Quest's Motion, held on February 12, 2018, Cedars-Sinai again initially appeared to be focusing the bulk of its argument on the idea that the claim term "an assay" referred to "a vinculin-based assay" that uses manufactured vinculin. However, over the

course of oral argument, Cedars-Sinai began adding further emphasis to an argument that the Asserted Claims recite an inventive concept because vinculin-based assays were purportedly not well-understood, routine, or conventional at the time of filing of the '884 Patent. Cedars-Sinai argued that as emphasized in recent Federal Circuit opinions, whether something is routine, conventional, or well-understood is a question of fact. *See Berkheimer v. HP Inc.*, --- F.3d ---, 2018 WL 774096 (Fed. Cir. Feb. 8, 2018). Notably, in its opposition, Cedars-Sinai specifically did not raise this argument and indeed, failed to respond to Quest's arguments that vinculin-based assays were well-known in the art at the time of filing of the '884 Patent. *See id.* at 12-25.

At the supplemental hearing on Quest's Motion held on February 15, 2018, Cedars-Sinai once again argued that vinculin-based assays were not well-known in the art. Cedars-Sinai distinguished *Cleveland Clinic* in part based on this fact, arguing that the MPO testing kits covered by the *Cleveland Clinic* claims were available on the market before the patent was filed. Cedars-Sinai reiterated the argument that claim construction of the term "assay" is necessary in determining whether the Asserted Claims recite an inventive concept.

The Court is concerned by what appears to be a "shifting sands" approach on Cedars-Sinai's part as to its § 101 arguments. Indeed, the Court notes that Cedars-Sinai's arguments about the non-routine and unconventional nature of manufactured, vinculin-based assays are not reflected in its SAC.

The parties' arguments in briefing and at oral argument, however, lead the Court to conclude that expedited claim construction and expedited claim construction discovery as to the claim term "an assay" would be beneficial before the Court reaches a determination as to patentability under Section 101.[7] Accordingly, the Court would DENY Quest's Motion to Dismiss WITHOUT PREJUDICE as to the patent-eligibility of Claims 3, 4, 9, and 10 of the '884 Patent. The parties would be ORDERED to meet and confer regarding an expedited discovery and claim construction schedule solely as it relates to the claim term "an assay" as it appears in Claims 3, 4, 9, and 10 of the '884 Patent.

IV. Conclusion

Based on the foregoing discussion, the Court would DENY the Motion as to Cedars-

[7] It is this Court's practice during claim construction to require each party to explain what effect, if any, its proposed claim construction will have on the case if adopted. Particularly in this case, the parties will be expected to describe how their proposed constructions will influence questions relating to patent-eligibility, anticipation, obviousness, enablement, and non-infringement.

Sinai's First, Second, and Third causes of action. The Court would DENY Quest's Motion to Dismiss WITHOUT PREJUDICE as to the patent-eligibility of Claims 3, 4, 9, and 10 of the '884 Patent. The parties would be ORDERED to meet and confer regarding an expedited discovery and claim construction schedule solely as it relates to the claim term "an assay" as it appears in Claims 3, 4, 9, and 10 of the '884 Patent.