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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

PEREGRINE PHARMACEUTICALS, INC., Plaintiff, v. CLINICAL SUPPLIES MANAGEMENT, INC., Defendant.	Case No. SACV 12-1608 JGB (ANx) ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Before the Court is Defendant's motion for partial summary judgment. (Mot., Doc. No. 35.) After considering the papers filed in support of and in opposition to the Motion, and the arguments presented at the July 28, 2014 hearing, the Court GRANTS IN PART and DENIES IN PART the Motion.

I. BACKGROUND

On September 24, 2012, Plaintiff Peregrine Pharmaceuticals, Inc. ("Plaintiff" or "Peregrine") filed a Complaint against Defendant Clinical Supplies Management, Inc. ("Defendant" or "CSM"). (Compl., Doc. No. 1.) The Court granted the parties' stipulation to stay the case for 120 days beginning on March 8, 2013 to allow them to participate in a dispute resolution process required by contract. (Doc. No. 11.)

On March 28, 2014, Plaintiff filed the operative First Amended Complaint which states five causes of action for: (1) breach of contract; (2) negligence; (3) negligence per se; (4) negligent misrepresentation/concealment; and (5) constructive fraud. ("FAC," Doc. No. 26.)

On June 5, 2014, Defendant filed a motion for partial summary judgment. (Mot., Doc. No. 35.) In support of the Motion, Defendant attached:

- Memorandum of Points and Authorities (Mot.);
- Statement of Undisputed Facts ("SUF," Doc. No. 35-1);
- Declaration of Matthew L. Marshall ("Marshall Decl.," Doc. No. 2);
- Declaration of Jennifer Lauinger ("Lauinger Decl.," Doc. No. 35-3);

- Compendium of Exhibits ("Comp.," Doc. No. 35-4) including Exhibits A through G;[1] and
- Request for Judicial Notice ("RJN," Doc. No. 35-5) attaching Exhibits A and B.[2]

On June 23, 2014, Plaintiff opposed the Motion (Opp'n, Doc. No. 38), attaching:

- Statement of Genuine Disputes of Fact ("SGI," Doc. No. 38-4);

[1] Due to the volume of evidence filed in support of and in opposition to the Motion, the Court does not enumerate each attached Exhibit, but describes the documents in subsequent evidentiary citations as needed.

Prior to filing the Motion, Defendant applied to file Exhibits C to G of the Compendium under seal. (Doc. Nos. 31-32.) On May 29, 2014, the Court granted in part Defendant's application finding that compelling reasons existed to seal the documents insofar as they contained confidential financial information of the parties. (Doc. No. 34.) Because Defendant had not articulated a sufficient factual basis justifying sealing the remainder of the documents, the Court ordered Defendant to publicly file redacted versions of the exhibits redacting only confidential financial information. (Id.) In this Order, the Court considers the sealed versions of Exhibits C through G, including the redacted financial information, insofar as necessary.

[2] In its RJN, Defendant requests the Court take judicial notice of the First Amended Complaint and Answer filed in this action. (See generally RJN.) Although the court may take judicial notice of its own records, it is unnecessary for Defendant to file a request for judicial notice of a pleading that has been filed in this action. Therefore, the requests will be DENIED as unnecessary. See Martinez v. Blanas, No. 2:06-CV-0088 FCD DAD, 2011 WL 864956, at *1 n.1 (E.D. Cal. Mar. 10, 2011) (denying request for judicial notice of the complaint as unnecessary as it is "a part of the record in this action"); Low v. Stanton, No. CVS05 2211MCE DAD P, 2007 WL 2345008, at *7 (E.D. Cal. Aug. 16, 2007) (same).

- Declaration of John K. Landay ("Landay Decl.," Doc. No. 38-1);
- Declaration of Jeffrey Masten ("Masten Decl.," Doc. No. 38-2); and
- Declaration of Joseph S. Shan, M.P.H. ("Shan Decl.," Doc. No. 38-3).

Defendant replied on June 30, 2014 (Reply, Doc. No. 39), including its Response to Plaintiff's SGI ("Resp.," Doc. No. 40) and Objections to evidence Plaintiff submitted in support of its opposition ("Obj." Doc. No. 41).

II. LEGAL STANDARD[3]

A court may grant partial summary judgment to determine "before the trial that certain issues shall be deemed established in advance of the trial. The procedure was intended to avoid a useless trial of facts and issues over which there was really never any controversy and which would tend to confuse and complicate a lawsuit." Lies v. Farrell Lines, Inc., 641 F.2d 765, 769 (9th Cir. 1981) (quotation omitted). A motion for partial summary judgment is resolved under the same standard as a motion for summary judgment.

[3] Unless otherwise noted, all references to "Rule" refer to the Federal Rules of Civil Procedure.

See California v. Campbell, 138 F.3d 772, 780 (9th Cir. 1998).

Summary judgment is appropriate if the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A fact is material when it affects the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); Freeman v. Arpaio, 125 F.3d 732, 735 (9th Cir. 1997).

The party moving for summary judgment bears the initial burden of establishing an absence of a genuine issue of material fact. Celotex, 477 U.S. at 323. This burden may be satisfied by either (1) presenting evidence to negate an essential element of the non-moving party's case; or (2) showing that the non-moving party has failed to sufficiently establish an essential element to the non-moving party's case. Id. at 322-23. Where the party moving for summary judgment does not bear the burden of proof at trial, it may show that no genuine issue of material fact exists by demonstrating that "there is an absence of evidence to support the non-moving party's case." Id. at 325.

However, where the moving party bears the burden of proof at trial, the moving party must present

compelling evidence in order to obtain summary judgment in its favor. United States v. One Residential Property at 8110 E. Mohave, 229 F. Supp. 2d 1046, 1047 (S.D. Cal. 2002) (citing Torres Vargas v. Santiago Cummings, 149 F.3d 29, 35 (1st Cir. 1998) ("The party who has the burden of proof on a dispositive issue cannot attain summary judgment unless the evidence that he provides on that issue is conclusive.")). Failure to meet this burden results in denial of the motion and the Court need not consider the non-moving party's evidence. One Residential Property at 8110 E. Mohave, 229 F. Supp. 2d at 1048.

Once the moving party meets the requirements of Rule 56, the burden shifts to the party resisting the motion, who "must set forth specific facts showing that there is a genuine issue for trial." Anderson, 477 U.S. at 256. The non-moving party does not meet this burden by showing "some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). Genuine factual issues must exist that "can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." Anderson, 477 U.S. at 250. When ruling on a summary judgment motion, the Court must examine all the evidence in the light most favorable to the non-moving party. Celotex, 477 U.S. at 325. The Court cannot engage in credibility

determinations, weighing of evidence, or drawing of legitimate inferences from the facts; these functions are for the jury. Anderson, 477 U.S. at 255.

III. FACTS

A. Undisputed Facts

For purposes of this Motion, the parties do not dispute any of the material facts.[4] The following material facts are sufficiently supported by admissible

[4] None of the purported disputes identified in the SGI actually provide or cite to evidence disputing the evidence propounded by Defendant. Instead, Plaintiff challenges Defendant's characterization of the facts as described in the SUF. (See, e.g., SGI ¶¶ 8 ("[D]isputed in part to the extent CSM is implying that the services are not far more detailed."), 11, 24.) Such "disputes" are improper, and the Court relies on the undisputed facts in the SUF to the extent they are adequately supported by the evidence. See Hanger Prosthetics & Orthotics, Inc. v. Capstone Orthopedic, Inc., 556 F. Supp. 2d 1122, 1126 (E.D. Cal. 2008); Contract Associates Office Interiors, Inc. v. Ruiter, No. CIV 07-0334 WBS PAN, 2008 WL 2916383, at *5 (E.D. Cal. July 28, 2008) ("[T]he court will not consider Contract Associates' objections to SSUF Nos. 60, 64, and 75 because these objections are aimed only at Ruiter's characterization and purported misstatement of the evidence-as represented in her SSUF-rather than the actual underlying evidence.").

Similarly, instead of disputing the evidence provided in the SGI, Defendant "disputes" many of Plaintiff's facts by directing the Court to its evidentiary objections. (Resp. ¶¶ 6-7, 9-10, 13-14, 18, 20, 22-26, 28-32, 35-59.) Evidentiary objections disguised as disputes lack merit and do not create genuine issues of fact. See Headley v. Church of Scientology Int'l, No. CV 09-3986 DSF(MANX), 2010 WL 3157064, at *1 n.1 (C.D. Cal. Aug. 5, 2010), aff'd, 687 F.3d 1173 (9th Cir. 2012). Thus these facts are similarly undisputed for purposes of this Motion.

evidence and are uncontroverted; they are "admitted to exist without controversy" for purposes of the Motion.[5] L.R. 56-3.

Peregrine is a clinical-stage biopharmaceutical corporation that develops pharmaceuticals focused on the treatment of cancer and other diseases. (SUF ¶ 1; SGI ¶ 1.) CSM provides clinical supply management services in support of clinical research programs. (SUF ¶ 2; SGI ¶ 2.)

[5] Without providing any argument or explanation, Peregrine objects to nearly every statement made in the Shan and Masten Declarations submitted in support of the Opposition. (Obj.)

As to almost every fact proffered by Peregrine, CSM argues that it is irrelevant and/or speculative. (See, e.g., Obj. ¶¶ 2-7, 9, 10, 13, 15-16, 18-59.) **Error! Main Document Only.**"Objections to evidence on the ground that it is irrelevant, speculative, and/or argumentative, or that it constitutes an improper legal conclusion are all duplicative of the summary judgment standard itself" and are thus "redundant" and unnecessary to consider here. Burch v. Regents of Univ. of California, 433 F. Supp. 2d 1110, 1119 (E.D. Cal. 2006); see Anderson, 477 U.S. at 248 ("Factual disputes that are irrelevant or unnecessary will not be counted."). Thus, the Court OVERRULES CSM's relevance and speculation objections.

With regard to the remaining evidentiary objections, the Court finds that the majority of the objected-to evidence is immaterial to the issue before the Court and does not rely on it here. Insofar as the Court relies on evidence which CSM objects to as hearsay, the Court finds that that evidence could be presented in an admissible form at trial and thus the Court may consider it in deciding the summary judgment motion. Fraser v. Goodale, 342 F.3d 1032, 1036-37 (9th Cir. 2003) (noting that at the summary judgment stage, the Court does "not focus on the admissibility of the evidence's form," but rather on the admissibility of its contents). The Court also finds that as Peregrine employees who designed and executed the Phase II trial (Shan Decl. ¶¶ 5, 8) and carried out the CSM audit (Masten ¶¶ 3-5), Shan and Masten have personal knowledge of the facts the Court relies upon herein.

In 2010, Peregrine initiated a randomized, double-blind, placebo controlled Phase IIb clinical trial of the drug, bavituximab, on 121 late stage lung cancer patients ("Phase II trial"). (SUF ¶ 3; SGI ¶ 3; Shan Decl. ¶¶ 6-7.) The patients in the Phase II trial were divided into three groups. (Id. ¶ 8.) The control or "A" group was to receive docetaxel (chemotherapy) plus a placebo. (Id.) The "B" group patients were to receive 1 mg/kg doses of bavituximab plus docetaxel. (Id.) The third "C" group was to take 3 mg/kg doses of bavituximab plus docetaxel. (Id.)

Peregrine hired eight main vendors to perform the necessary work for the Phase II trial. (SUF ¶ 4; SGI ¶ 4.) Peregrine contracted with CSM to provide supply chain services, including ensuring proper labeling of the drug vials, distribution to the 40 sites, and reconciling the product vials in inventory. (Shan Decl. ¶ 13.)

After several rounds of revisions and negotiations, on March 18, 2010, the parties fully executed the final version of the Master Services Agreement ("MSA"). (Comp., Exh. F.) The MSA provides that the specific service that CSM was to provide in the Phase II trial would be set forth in greater detail in subsequent Work Orders and Change Orders. (MSA ¶¶ 1, 2, 5.) The Work Orders and Change Orders, when finalized and signed by the parties, were subject to the MSA. (MSA ¶¶ 1.A,

2.A.) In exchange for its performance of the Work and Change Orders, Peregrine agreed to pay CSM each month for services rendered. (Id. ¶ 6.) The MSA also included an indemnification provision, which provided that CSM and Peregrine would indemnify each other in certain situations. (Id. ¶ 12.) At two points in the MSA, CSM agreed to provide its services in compliance with the study protocol, written instructions of Peregrine, generally accepted standards of good clinical practice and good manufacturing practice, and all applicable laws, rules, and regulations, including the Federal Food, Drug and Cosmetic Act ("FDCA") and regulations of the Food and Drug Administration ("FDA"). (Id. ¶¶ 3.A, 15.)

Primarily at issue in this Motion is the section of the MSA entitled "Limitations." (Id. ¶ 16.) In relevant part, this section includes two Limitations on Damages ("LOD") clauses which provide:

> **16. LIMITATIONS**
>
> A. Except as expressly set forth in this agreement, CSM does not make any warranty, express or implied, with respect to the services or the results obtained from its work, including, without limitation, any implied warranty of merchantability or fitness for a particular purpose. In no event shall CSM, or any of its affiliates, directors, officers, employees, consultants or agents be liable for consequential, incidental, special, or indirect damages, regardless of whether it

> has been advised of the possibility of such damages.[6]
>
> B. . . .
>
> C. In no event will the collective, aggregate liability of CSM and its affiliates, directors, officers, employees, consultants or agents under this Agreement, the Work Orders or Change Orders exceed the amount of payments actually received by CSM from [Peregrine] for the applicable Work Order(s), including any Change Order(s).

In order to reach the final version of the MSA, the parties engaged in three rounds of revisions and negotiations of contract terms. (SUF ¶ 10; SGI ¶ 10.) In February 2010, CSM sent a draft Master Services Agreement to Peregrine. ("Draft MSA," SUF ¶ 5; SGI ¶ 5.) On February 18, 2010, Peregrine sent a revised, redlined version of the MSA to CSM, which included at least thirty-one changes to the payment terms, the method of preparation of Work Orders, CSM's duties with regard to regulatory compliance, the term of the MSA, termination and indemnification provisions, and the choice of law and force majeure clauses. ("Revised MSA," Comp., Exh. C.) The Revised MSA also deleted a portion of Paragraph 16A which read:

> In no event shall CSM, or any of its affiliates, directors, officers, employees, consultants or agents be liable for consequential, incidental, special, or indirect damages, ~~or for acts of negligence which are not intentional or reckless in nature,~~

[6] In the MSA, Paragraph 16.A was printed in all capital letters. (SUF ¶ 23; SGI ¶ 23.) For ease of reading, the Court omits the capitals in this Order.

> regardless of whether it has been advised of the possibility of such damages.

(Revised MSA ¶ 16.A.) On February 18, 2010, Peregrine also sent a "clean copy" of the Revised MSA to CSM which included two additional revisions to the Draft MSA, including a change to CSM's hourly rate and its right to terminate the MSA. (SUF ¶ 17; SGI ¶ 17; Comp., Exh. D.) CSM accepted all of Peregrine's revisions to the MSA. (SUF ¶ 18; SGI ¶ 18.)

According to Peregrine, CSM's role in the Phase II trial was to receive shipments of the placebo, 1 mg/kg bavituximab, and 3 mg/kg bavituximab totaling approximately 8,000 vials, label them as instructed, and distribute them to patient sites. (Shan Decl. ¶ 13.) CSM was also supposed to keep track of the administration of the doses and the patient groups until the study was unblinded. (Id. ¶ 14.)

Peregrine claims that in September 2012, it became aware that the "A" and "B" treatment assignments may have been switched during the trial. (Id. ¶ 16.) Peregrine then undertook an audit of CSM's performance which allegedly revealed that all "C" group patients were correctly treated, but there was evidence of vial mislabeling between the placebo and 1 mg/kg groups. (Masten Decl. ¶ 6.) Peregrine contends that the mislabeling implicated up to 25 percent of the placebo-labeled doses and up to 25 percent of the 1 mg/kg

vials. (Id.) Based on these purported failures, Peregrine claims CSM breached the MSA and failed to comply with good clinical practices, FDA regulations, and industry standards. (Opp'n at 5-7; FAC ¶ 19.)

IV. DISCUSSION

CSM moves for partial summary judgment to enforce the Limitations on Damages ("LOD") clauses in the MSA and thus limit the damages sought by Peregrine in the FAC. (Mot. at 23.) Peregrine argues that the LOD clauses are unenforceable and no damages limitation should apply in this action. (See generally Opp'n.)[7]

Two provisions of the MSA are relevant to CSM's arguments. First, the second sentence of Paragraph 16.A provides: "In no event shall CSM, or any of its affiliates, directors, officers, employees, consultants or agents be liable for consequential, incidental, special, or indirect damages, regardless of whether it has been advised of the possibility of such damages." (MSA ¶ 16.A.) In addition, Paragraph 16.C states: "In no event will the collective, aggregate liability of CSM and its affiliates, directors, officers, employees,

[7] The MSA states that the agreement and any applicable Work Order and Change Orders "will be construed, governed, interpreted, and applied in accordance with the laws of the State of California . . ." (MSA ¶ 17.) In conformity with this provision, the parties rely on California contractual interpretation laws. The Court similarly applies California law.

consultants or agents under this Agreement, the Work Orders or Change Orders exceed the amount of payments actually received by CSM from [Peregrine] for the applicable Work Order(s), including any Change Order(s)." (MSA ¶ 16.C.)

Generally, "a limitation of liability clause is intended to protect the wrongdoer defendant from unlimited liability." Food Safety Net Servs. v. Eco Safe Sys. USA, Inc., 209 Cal. App. 4th 1118, 1126 (2012) (quoting 1 Witkin, Summary of Cal. Law, Contracts, § 503 (10th ed. 2005)). Clauses of this type "have long been recognized as valid in California." Markborough California, Inc. v. Superior Court, 227 Cal. App. 3d 705, 714 (1991); see also Nat'l Rural Telecommunications Coop. v. DIRECTV, Inc., 319 F. Supp. 2d 1040, 1048 (C.D. Cal. 2003) ("Under California law, parties may agree by their contract to the limitation of their liability in the event of a breach.").

A. Interpretation of the LOD Clauses

"Whether an exculpatory clause covers a given case turns primarily on contractual interpretation, and it is the intent of the parties as expressed in the agreement that should control. When the parties knowingly bargain for the protection at issue, the

protection should be afforded. This requires an inquiry into the circumstances of the damage or injury and the language of the contract; of necessity, each case will turn on its own facts." Burnett v. Chimney Sweep, 123 Cal. App. 4th 1057, 1066 (2004) (internal quotation omitted). "The language of a contract is to govern its interpretation, if the language is clear and explicit, and does not involve an absurdity." Cal. Civ. Code § 1638. Under California law,

> [t]he interpretation of a contract is a judicial function. . . . In engaging in this function, the trial court "give[s] effect to the mutual intention of the parties as it existed" at the time the contract was executed. [Cal.] Civ. Code, § 1636. Ordinarily, the objective intent of the contracting parties is a legal question determined solely by reference to the contract's terms. [Cal.] Civ. Code, § 1639 ("[w]hen a contract is reduced to writing, the intention of the parties is to be ascertained from the writing alone, if possible"); [Cal.] Civ. Code, § 1638 (the "language of a contract is to govern its interpretation").

Cachil Dehe Band of Wintun Indians of Colusa Indian Cmty. v. California, 618 F.3d 1066, 1073 (9th Cir. 2010) (citations omitted). However, "contractual clauses seeking to limit liability will be strictly construed and any ambiguities resolved against the party seeking to limit its liability . . . ." Nunes Turfgrass, Inc. v. Vaughan-Jacklin Seed Co., 200 Cal. App. 3d 1518, 1538 (1988); see Queen Villas Homeowners

Ass'n v. TCB Prop. Mgmt., 149 Cal. App. 4th 1, 6 (2007) ("[E]xculpatory clauses are construed against the released party.").

Here, even strictly construed against CSM, the clear, unambiguous and express language of Paragraph 16 limits CSM's liability. The Paragraph provides that "in no event" will CSM be liable for consequential, incidental, special, or indirect damages, nor will its collective, aggregate liability under the MSA exceed the amount Peregrine actually paid to CSM. These provisions clearly limit the amount and types of damages for which CSM can be liable.

Peregrine argues in opposition that the LOD provisions are ambiguous. (Opp'n at 11-12.) "A contract provision is considered ambiguous when the provision is susceptible to more than one reasonable interpretation." S. California Stroke Rehab. Associates, Inc., v. Nautilus, Inc., 782 F. Supp. 2d 1096, 1110 (S.D. Cal. 2011) (citing MacKinnon v. Truck Ins. Exchange, 31 Cal.4th 635 (2003)). First, Peregrine claims that Paragraph 16.A only disclaims liability for breaches of express and implied warranties because the sentence prior to the LOL clause states that CSM does not make any warranty with respect to its services. (Opp'n at 11-12.) However, following the warranty provision, the LOD clause states that "in no event" is CSM liable for consequential, incidental,

special or indirect damages. The court in Food Safety Net Servs. v. Eco Safe Sys. USA, Inc., 209 Cal. App. 4th 1118, 1128 (2012), considered the same argument based on nearly identical contractual provisions and held that "[i]n view of this broad and unqualified language, the clause must be regarded as establishing a limitation on [CSM]'s liability sufficient to encompass [Peregrine]'s claims . . . ."

Similarly, Peregrine argues that the phrase "[e]xcept as expressly set forth in this agreement" is ambiguous. (Opp'n at 12.) Once again, this language is in the first sentence of Paragraph 16.A and does not apply to the LOD clauses. To the contrary, both LOD clauses indicate that they apply more broadly, stating that "in no event" will CSM be liable for additional damages.

Peregrine also contends that the indemnity provisions of the MSA permit unlimited recovery from CSM for any property damage CSM caused. (Opp'n at 12.) The indemnification provisions provide that CSM shall indemnify Peregrine and defend and hold it harmless from and against any liability, loss, or damage because of bodily injury or property damage arising from CSM's actions or inactions under the MSA. (MSA ¶ 12.A.) The language of this provision demonstrates that it is a standard indemnity agreement by which CSM guarded Peregrine against certain third-party claims; it does

not apply to claims between the contracting parties. See Myers Bldg. Indus., Ltd. v. Interface Tech., Inc., 13 Cal. App. 4th 949, 969 (1993) ("A clause which contains the words 'indemnify' and 'hold harmless' is an indemnity clause which generally obligates the indemnitor to reimburse the indemnitee for any damages the indemnitee becomes obligated to pay third persons. [citation omitted] Indemnification agreements ordinarily relate to third-party claims."); Hathaway Dinwiddie Const. Co. v. United Air Lines, Inc., 50 F. App'x 817, 823 (9th Cir. 2002) (holding that a standard indemnity provision in a contract between general contractor and project owner guarded owner against third-party claims and thus did not apply to require contractor to indemnify owner for claims it asserted against owner).

Strictly construing the clauses against CSM, the Court finds that the LOD clauses are unambiguous and contemplate a bar on recovery of consequential, incidental, special, and indirect damages as well as damages in excess of the amount paid by Peregrine to CSM for its work under the MSA. See Coremetrics, Inc. v. Atomic Park.com, LLC, No. C-04-0222 EMC, 2005 WL 3310093, at *4 (N.D. Cal. Dec. 7, 2005) (finding unambiguous a clause which stated "In no event shall either party be liable for any indirect, incidental,

special or consequential damages, including without limitation damages for loss of profits . . . .").

B. Cal. Civ. Code Section 1668

Peregrine dedicates most of its opposition to arguing that the LOD clauses are unenforceable because they violate California Civil Code Section 1668.[8] (Opp'n at 13-24.) Section 1668 provides:

> All contracts which have for their object, directly or indirectly, to exempt anyone from responsibility for his own fraud, or willful injury to the person or property of another, or violation of law, whether willful or negligent, are against the policy of the law.

Cal. Civ. Code § 1668. Specifically, Peregrine argues that Section 1668 prohibits enforcement of the LOD clauses in the MSA as applied to Peregrine's claims for breach of contract, negligence, negligence per se, negligent misrepresentation/concealment, and constructive fraud. (Opp'n at 15.)

[8] Throughout its opposition, Peregrine alternately refers to Section 1668 as § 1668 and § 1688. (See, e.g., Opp'n at 1 ("exculpatory clauses that run afoul of California Code of Civil Procedure § 1668 ('section 1688')"). The relevant section is in the civil code, not the code of civil procedure and is found at section 1668. Similar careless errors can be found throughout the Opposition. (See, e.g., Opp'n at 10 ("section 1668"); id. at 12 (alternating between "1668" and "1688"); id. at 13 (incorrectly quoting a judicial opinion and including the incorrect section number as 1688).) Such errors are distracting, confusing, and misleading to the Court.

Initially, the Court notes the persuasiveness of CSM's argument in Reply. (Reply at 5-6.) Based on the plain language, the Court is skeptical of the applicability of Section 1668 to the claims at issue here. The statute only applies to contracts "which have for their object, directly or indirectly, to exempt anyone from responsibility . . . ." Cal. Civ. Code § 1668. Here, the LOD clauses do not "exempt" CSM from responsibility for any of the causes of action in this litigation. They merely limit the amounts and types of damages available to Peregrine for these violations.

Nevertheless, the Court recognizes that courts applying California law have analyzed damage limitation clauses in light of the restrictions of Section 1668. See Food Safety Net, 209 Cal. App. 4th at 1126-28 (applying analysis of § 1668 to clauses nearly identical to those here); Nunes Turfgrass, 200 Cal. App. 3d at 1538; Civic Ctr. Drive Apartments Ltd. P'ship v. Sw. Bell Video Servs., 295 F. Supp. 2d 1091, 1105-06 (N.D. Cal. 2003); 1 Witkin, Summary of Cal. Law, Contracts, § 660, 737-38 (10th ed. 2005) ("The present view is that a contract exempting from liability for ordinary negligence is valid where no public interest is involved [] and no statute expressly prohibits it []. [citation omitted] Limitation of liability provisions are valid in similar

circumstances."). But see Farnham v. Superior Court (Sequoia Holdings, Inc.), 60 Cal. App. 4th 69, 77 (1997) ("[A] contract exempting liability for ordinary negligence is valid under some circumstances, notwithstanding the language of section 1668. In our view, it follows that a contractual *limitation* on the liability . . . is equally valid where, as here, the injured party retains his right to seek redress from the corporation.").

In Health Net of California, Inc. v. Dep't of Health Servs., 113 Cal. App. 4th 224 (2003), the court considered a contractual clause prohibiting monetary remedies for non-compliance with laws not expressly incorporated into the contract, but permitting equitable remedies. Id. at 228-29. The defendant argued that this provision was not invalid under Section 1668 because the clause is "a limitation on liability and is not a complete exemption." Id. at 239. The court first noted that "section 1668 has, in fact, been applied to invalidate provisions that merely limit liability." Id. Nonetheless, the court went on to find that limiting plaintiff to injunctive relief "surely rises to the level of an 'exemption from responsibility' within the meaning of the plain language of section 1668."[9] Id. The court found it

[9] The Court notes that Peregrine claims that CSM caused Peregrine direct damages totaling $20,000,000. (Opp'n at 8.) According to the evidence submitted, (continued . . .)

necessary to distinguish Farnham and held that "section 1668 affords some leeway in the enforcement of exculpatory clauses" and should apply to the situation presented because it involved the public interest and statutory and regulatory violations. Id. at 240-41. Thus, the court applied an analysis under Section 1668 to the restriction on available remedies. See also Pink Dot, Inc. v. Teleport Commc'ns Grp., 89 Cal. App. 4th 407, 415 (2001) (holding that under § 1668 the terms of the contract "could not have precluded liability for . . . gross negligence up to $10,000 in damages[]").

Even if on its face the statutory language of Section 1668 does not clearly encompass limitations on liability, California courts have frequently applied the statute's analysis to cases in which the clauses at issue merely limited or capped the remedies available to a plaintiff. Although the analysis under Section 1668 is applicable to damage limitation clauses, "Section 1668 is not strictly applied" and does not per

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(. . . continued)

Peregrine paid CSM approximately $600,000 for its services under the MSA. (Comp., Exh. G.) Thus, due to the damages cap in the MSA, Peregrine would be foreclosed from recovering $19,400,000 in direct damages. Peregrine does not quantify its consequential damages but argues that CSM's errors substantially delayed FDA approval of bavituximab and cost Peregrine at least a six month loss in time to market. (Opp'n at 8.) Under the LOD clauses, Peregrine would not be able to recover for these indirect damages, even if proved.

se invalidate limitations on liability as applied to all claims in an action. See Farnham, 60 Cal. App. 4th at 74. The Court turns to the issue of whether Section 1668 prohibits enforcement of the LOD clauses as applied to Peregrine's claims against CSM.

1. Breach of Contract

"With respect to claims for breach of contract, limitation of liability clauses are enforceable unless they are unconscionable, that is, the improper result of unequal bargaining power or contrary to public policy." Food Safety Net, 209 Cal. App. 4th at 1126 (applying section 1668); Civic Ctr. Drive Apartments, 295 F. Supp. 2d at 1106 (noting that a limitation of liability clause may be enforced where a plaintiff alleges a breach of contract claim unless, in contravention of § 1668, "the provision is unconscionable or otherwise against public policy").

Peregrine does not argue that the LOD clauses are unconscionable. Under California law, a contract provision is unenforceable due to unconscionability only if it is both procedurally and substantively unconscionable, but the elements need not be present in the same degree. Shroyer v. New Cingular Wireless Servs., Inc., 498 F.3d 976, 981 (9th Cir. 2007). Here, there is no evidence of procedural unconscionability,

as CSM admits that the MSA was not presented on a take-it-or-leave-it basis (SUF ¶ 6; SGI ¶ 6), the parties negotiated the terms of the contract (SUF ¶ 10; SGI ¶ 10), and there is no evidence of unequal bargaining power. Moreover, clauses limiting damages generally are not substantively unconscionable. See Simulados Software, Ltd. v. Photon Infotech Private, Ltd., No. 5:12-CV-04382-EJD, 2014 WL 1728705, at *4 (N.D. Cal. May 1, 2014) ("Many contracts contain . . . limitation-of-liability clauses and courts have not found these clauses to be substantially unconscionable as a matter of law. The contract does not, as Simulados argues, prevent Simulados from recovery in the event of a breach. The limitation-of-liability clause expressly allows for recovery of the total amount received by Photon. As such, the Contract is not unconscionable and not a contract of adhesion."). Without any evidence of unconscionability, the Court turns to whether the LOD clauses are contrary to public policy.

The California Supreme Court in Tunkl v. Regents of University of California, 60 Cal.2d 92 (1963) provided an outline of the characteristics which mark a contract as involving the public interest under Section 1668:

> [1] It concerns a business of a type generally thought suitable for public regulation. [2] The party seeking exculpation is engaged in performing a service of great importance to the public, which is often a matter of practical necessity for some members of the public. [3] The party holds

> himself out as willing to perform this service for any member of the public who seeks it, or at least for any member coming within certain established standards. [4] As a result of the essential nature of the service, in the economic setting of the transaction, the party invoking exculpation possesses a decisive advantage of bargaining strength against any member of the public who seeks his services. [5] In exercising a superior bargaining power the party confronts the public with a standardized adhesion contract of exculpation, and makes no provision whereby a purchaser may pay additional reasonable fees and obtain protection against negligence. [6] Finally, as a result of the transaction, the person or property of the purchaser is placed under the control of the seller, subject to the risk of carelessness by the seller or his agents.

Id. at 98-101 (footnotes omitted). Peregrine argues that the MSA and the TOD clauses at issue satisfy the Tunkl characteristics. (Opp'n at 15-18.) CSM disagrees. (Reply at 8-9.)

Of primary importance to the second and third factors in Tunkl is the classification of the transaction between Peregrine and CSM. Peregrine characterizes the transaction as one involving essential medical services that are a matter of necessity. (Opp'n at 17.) CSM conversely insists that this is a commercial contract for services involving two sophisticated corporations. (Reply at 6.)

Peregrine relies on Tunkl, Health Net, and Westlake Cmty. Hosp. v. Superior Court, 17 Cal. 3d 465, 480 (1976) to support its position. However, this case,

unlike those cited by Peregrine, does not involve the provision of medical services to the general public. Tunkl and Westlake involved contracts between a patient or doctor and hospital, respectively. Both courts focused on the fact "[t]hat the services of the hospital to those members of the public who are in special need of the particular skill of its staff and facilities constitute a practical and crucial necessity is hardly open to question." Tunkl, 60 Cal. 2d at 101; Westlake, 17 Cal. 3d at 480 ("Hospitals . . . provide a service of great importance to both the public and to doctors seeking to use their facilities."). The MSA did not involve a medical facility and was several steps removed from the provision of health care services to patients. (See Shan Decl. ¶ 14 (describing that a third-party vendor, Perceptive, directed CSM to distribute doses "to the trial sites, to thereafter be processed by pharmacists and distributed to physicians to administer to the patients in the study").) Health Net presents a closer case, but remains distinguishable. There, a health plan provider contracted with the Department of Health Services ("DHS") to be one of two health plans providing managed care services to Medi–Cal patients in a particular county. However, in violation of a statute, DHS assigned all patients who failed to select a plan to the competing health plan. The court found the

transaction affected the public interest because it involved provision of "managed care for Medi–Cal beneficiaries." Health Net, 113 Cal. App. 4th at 238. Comparatively, CSM and Peregrine contracted to provide clinical services, specifically labelling and tracking of drug vials, to trial sites serving 121 patients in the Phase II trial. Peregrine argues that the clinical trials "are of great importance to the public" and the outcome of the Phase II trial is "a matter of 'necessity,' indeed urgency, for certain members of the public." (Opp'n at 17.) However, the service at issue here is not provision of clinical trial services to patients, but rather labeling and distribution of drug vials to trial sites.[10] While the Court recognizes the

[10] In Gardner v. Downtown Porsche Audi, 180 Cal. App. 3d 713 (1986), the court stated that "this element of the Tunkl test appears to boil down to the following question: Is the service merely an optional item consumers can do without if they don't want to waive their rights to recover for negligence or is it something they need enough so they have little choice if the provider attaches a liability disclaimer?" Gavin W. v. YMCA of Metro. Los Angeles, 106 Cal. App. 4th 662, 672 (2003) (quoting Gardner, 180 Cal. App. 3d at 718). Here, CSM's services were clearly optional to Peregrine, as Peregrine could have obtained another vendor to perform clinical supply management services. Unlike Peregrine, clinical trial patients are not subject to the MSA and did not waive their rights to recover for negligence against CSM. See Philippine Airlines, Inc. v. McDonnell Douglas Corp., 189 Cal. App. 3d 234, 243 (1987) ("The damage to PAL was economic, and PAL expressly contracted to limit its remedies for economic loss. The injured passengers may still seek recovery from MDC should they so choose."); Delta Air Lines, Inc. v. Douglas Aircraft Co., 238 Cal. App. 2d 95, 104 (Cal. Ct. App. 1965) ("The upholding of the exculpatory clause will not adversely affect rights of future passengers. They are not parties to the

(continued . . .)

importance of clinical trials to the safety, effectiveness, and eventual public utilization of curative or therapeutic pharmaceuticals, the Court cannot find that a contract concerning the labeling and distribution of vials used in such a trial of 121 patients transforms the contract into one which renders limitation of liability clauses unenforceable under § 1668. See CAZA Drilling (California), Inc. v. TEG Oil & Gas U.S.A., Inc., 142 Cal. App. 4th 453, 469 (2006) ("While the production of oil is of great importance to the public, the drilling of a particular oil well is generally only important to the party who will profit from it."). Thus, the Court finds that the second Tunkl factor weighs only slightly in favor of implicating the public interest.

Turning to the remaining Tunkl factors, the first factor is satisfied because CSM's business of labeling, warehousing, and distributing drugs is regulated by the FDA.[11] (See Opp'n at 5-6 (citing 21 C.F.R. §§ 210, 211).) The third factor weighs against finding public interest as CSM does not hold itself out as providing services to the public, but only for a small number of

(. . . continued)

contract and their rights would not be compromised. They retain their right to bring a direct action against Douglas for negligence."); see also Cont'l Airlines, Inc. v. Goodyear Tire & Rubber Co., 819 F.2d 1519, 1527 (9th Cir. 1987).

[11] CSM does not dispute that its business is regulated by the FDA.

clinical-stage pharmaceutical corporations. See CAZA, 142 Cal. App. 4th at 469; Appalachian Ins. Co. v. McDonnell Douglas Corp., 214 Cal. App. 3d 1, 29-30 (1989) ("The high price of obtaining the service, in and of itself, precludes nearly all members of the public from obtaining the service. . . . None of the sales were to an individual member of the general public; all were to large, sophisticated commercial and governmental entities.").

Most importantly here, the fourth through sixth factors demonstrate the absence of a public interest in this transaction. Here, it is undisputed that there was no unequal bargaining power, the parties fully negotiated the contract – including revising several provisions of the MSA, and no property was under the control of the CSM.[12] (See Shan Decl. ¶¶ 12, 14.)

[12] At the hearing, Peregrine argued that it was under the control of CSM because the double-blinded nature of the study meant CSM was "on [its] own" and Peregrine was subject to the risk of CSM's careless errors. (See Shan Decl. ¶ 14 ("Due to the blinded nature of the study, Peregrine . . . was dependent on CSM to strictly floor the protocol . . . ."). The sixth factor asks the Court to consider whether Peregrine's property was placed under the control of CSM and subject to its carelessness. Like in Appalachian, several parties took control of Peregrine's vials after CSM and Peregrine hired a "clinical trial consultant" to coordinate all the vendors, including CSM, and oversee their work. (Shan Decl. ¶ 10.) Thus, Peregrine has not made the requisite showing of control. See Appalachian Ins. Co. v. McDonnell Douglas Corp., 214 Cal. App. 3d 1, 31 (1989) ("Once the satellite was placed in the Space Shuttle, McDonnell Douglas no longer had control; the satellite and the PAM were under NASA's control.").

"Although the Supreme Court [in Tunkl] did not specifically exclude contracts between relatively equal business entities from its definition of contracts in the public interest, it is difficult to imagine a situation where a contract of that type would meet more than one or two of the requirements discussed in Tunkl." CAZA, 142 Cal. App. 4th at 468-69; see Philippine Airlines, 189 Cal. App. 3d at 237 ("Commercial entities, such as PAL and MDC, are entitled to contract to limit the liability of one to the other, or otherwise allocate the risk of doing business."); Delta Air Lines, Inc. v. Douglas Aircraft Co., 238 Cal. App. 2d 95, 102 (1965) ("Perhaps more important, the case at bench involves none of the elements of inequality of bargaining on which the cited cases, and other recent cases of the same sort, have laid their stress."); Reudy v. Clear Channel Outdoors, Inc., 693 F. Supp. 2d 1091, 1116 (N.D. Cal. 2010), aff'd sub nom. Reudy v. CBS Corp., 430 F. App'x 568 (9th Cir. 2011) (finding no public interest where "the Release in question between Plaintiffs and Defendants was between two business entities with equal bargaining power, and not a consumer and a larger entity"). Finally, several California court have held that where the provisions of the contract are negotiable, the exculpatory clause should not be invalidated on public policy grounds. See Food Safety, 209 Cal. App. 4th at

1127; McCarn v. Pac. Bell Directory, 3 Cal. App. 4th 173, 182 (1992) ("The existence of an offer to negotiate the limits of liability in the preprinted contract is fatal to plaintiff's public policy claim. . . . The limitation in Directory's contract was simply not compulsory-it was negotiable."). Since Peregrine was free to and did negotiate thirty-one terms of the MSA, including the LOD clauses, it cannot post facto seek to invalidate the terms it freely negotiated with a relatively equal business entity.

Considering all of the Tunkl factors, the Court concludes that the MSA and the LOD clauses contained therein are not contrary to public policy. Only the first and second factors weigh in favor of invalidating the limitations clauses, and they are strongly outweighed by the third through sixth factors. Accordingly, the LOD clauses apply to the breach of contract claim and limit Peregrine's damages thereunder to direct damages in an amount equal to or less than the payments made to CSM. (MSA ¶¶ 16.A, 16C.) See Food Safety, 209 Cal. App. 4th at 1127 (finding that clauses similar to those here did not affect the public interest where the defendant claimed plaintiff failed to properly conduct a laboratory study of the efficacy of defendant's food disinfection equipment as required by their agreement); Cont'l Airlines, 819 F.2d 1519 at 1527 ("[I]t makes little sense in the context of two

large, legally sophisticated companies to invoke the Tunkl . . . doctrine."); see also Fosson v. Palace (Waterland) Ltd., 78 F.3d 1448, 1455 (9th Cir.1996) ("[A] clear and unambiguous contractual provision providing for an exclusive remedy for breach will be enforced.") (citations omitted).

2. Negligence[13]

Peregrine makes a contractual interpretation argument specific to its negligence claim. (Opp'n at 11-12.) "[T]he law does not look with favor upon attempts to avoid liability or secure exemption for one's own negligence, and such provisions are strictly construed against the person relying upon them." Burnett v. Chimney Sweep, 123 Cal. App. 4th 1057, 1066 (2004) (quotation omitted). "'For an agreement to be construed as precluding liability for 'active' or 'affirmative' negligence, there must be express and unequivocal language in the agreement which precludes

[13] For the first time at the hearing, CSM argued that under the economic loss rule, Peregrine's tort claims should be barred because they rely exclusively on a breach of the contract. See United Guar. Mortgage Indem. Co. v. Countrywide Fin. Corp., 660 F. Supp. 2d 1163, 1180 (C.D. Cal. 2009) ("The economic loss rule generally bars tort claims for contract breaches, thereby limiting contracting parties to contract damages."). Because this argument was raised for the first time at the hearing, it was untimely and shall not be considered by the Court. See Day v. Sears Holdings Corp., 930 F. Supp. 2d 1146, 1168 n.84 (C.D. Cal. 2013) (citing cases).

such liability. [citations omitted] An agreement which seeks to limit generally without mentioning negligence is construed to shield a party only for passive negligence, not for active negligence. [Citations.]'" Id. (quoting Salton Bay Marina, Inc. v. Imperial Irrigation Dist., 172 Cal. App. 3d 914, 933 (1985)). Notably, the Burnett court applied this rule to an exculpatory clause which shielded the defendant from liability for all property damage or personal injury and to a damages limitation clause which precluded payment for lost profits resulting from any cause of action. Id. at 1066-67.[14]

Here, neither of the LOD clauses in Paragraph 16 "specifically mention negligence." Id. at 1066. Accordingly, barring any evidence to the contrary, these provisions are construed as shielding CSM from damages liability "only for passive negligence, not for active negligence." Salton Bay, 172 Cal. App. 3d at 933; see also Philippine Airlines, 189 Cal. App. 3d at 239 ("There is in the limitation of liability clause no mention of negligence and the writing must be strictly

[14] At the hearing, CSM argued that this rule applies only to indemnity clauses. However, Burnett did not involve an indemnity clause or any claims for indemnity. See Burnett, 123 Cal. App. 4th at 1061 (lessee of commercial space sued lessor for negligence, breach of contract, and other claims where the lease shielded lessor from liability for injury or damage and limited lessor's damages liability); see also CAZA, 142 Cal. App. 4th at 466-67 (applying Burnett to portion of the contract limiting contract damages and allocating liability for tort damages).

construed, with the result that it does not cover defendant's own negligence.") (quotation omitted).

This interpretation is confirmed by the intent of the parties as expressed in the negotiations of the MSA. In the Revised MSA, Peregrine deleted a portion of Paragraph 16.A which could have exempted CSM from liability for "acts of negligence which are not intentional or reckless." (Revised MSA ¶ 16.A.)[15] By erasing that phrase, the MSA eliminates any reference to CSM's negligence, making it liable for active negligence. See Ferrell v. S. Nevada Off-Rd. Enthusiasts, Ltd., 147 Cal. App. 3d 309, 318 (1983) ("We, therefore, conclude that to be effective, an agreement which purports to release, indemnify or exculpate the party who prepared it from liability for that party's own negligence or tortious conduct must be clear, explicit and comprehensible in each of its essential details.").

"Whereas passive negligence involves 'mere nonfeasance, such as the failure to discover a dangerous condition or to perform a duty imposed by

[15] At the hearing, Peregrine incorrectly argued that the erasure of negligence from Paragraph 16.A applied only to CSM's liability for consequential, incidental, special or indirect damages resulting from negligence. However, the language of the unamended sentence makes clear that the original version would have exempted CSM from any liability for negligence. (See Revised MSA ¶ 16.A ("In no event shall CSM . . . be liable for consequential, incidental, special, or indirect damages, *or for acts of negligence* . . . .").)

law,' active negligence involves 'an affirmative act,' knowledge of or acquiescence in negligent conduct, or failure to perform specific duties." Frittelli, Inc. v. 350 N. Canon Drive, LP, 202 Cal. App. 4th 35, 48 (2011) (quotation omitted). The facts put forth in the SGI raise a triable issue of fact as to whether CSM was actively negligent in failing to perform the specific duties under the MSA and Work Orders.

The cases relied upon by CSM – which enforced liability limitation clauses against negligence claims – all included contractual provisions which expressly and unequivocally stated the parties' intent to limit liability for negligence. See Food Safety, 209 Cal. App. 4th at 1126-27; CAZA, 142 Cal. App. 4th at 466-67; Markborough California, Inc. v. Superior Court, 227 Cal. App. 3d 705, 709 (1991); Nat'l Rural Telecommunications, 319 F. Supp. 2d at 1047. Because there is no similar expression of contractual intent in the MSA, the Court finds that the LOD clauses leave CSM open to unlimited liability for active negligence.

The question remains then whether Section 1668 bars the damages limits in the LOD clauses as applied to CSM's passive negligence, if proved. Like with the breach of contract claim, "a contract exempting from liability for ordinary negligence is valid where no public interest is involved . . . and no statute expressly prohibits it . . . ." Blankenheim v. E. F.

Hutton & Co., 217 Cal. App. 3d 1463, 1472 (1990) (quotation omitted); Frittelli, 202 Cal. App. 4th at 43. As discussed above, the MSA and LOD clauses do not implicate the public interest. Other than Section 1668, CSM does not present the Court with any statute which invalidates the limitation on damages for negligence. Accordingly, the LOD clauses apply to Peregrine's claims for passive negligence and limit its recovery in accordance therewith.[16]

3. Negligence Per Se

Section 1668 bars as against public policy "[a]ll contracts which have for their object, directly or

[16] At the hearing, the parties discussed whether Peregrine's claims for gross negligence, subsumed under its negligence claim, would survive. Certainly if the language of the TOD clauses does not encompass affirmative negligence, it also could not reach gross negligence. See Wallace v. Busch Entm't Corp., 837 F. Supp. 2d 1093, 1101 (S.D. Cal. 2011) ("Gross negligence is different from ordinary negligence in that ordinary negligence 'consists of a failure to exercise the degree of care in a given situation that a reasonable person under similar circumstances would employ to protect others from harm,' whereas gross negligence requires 'a want of even scant care or an extreme departure from the ordinary standard of conduct.'") (quotation omitted). In any event, limitations on liability for gross negligence are generally unenforceable. See City of Santa Barbara v. Superior Court, 41 Cal. 4th 747 (2007) (holding an agreement purporting to release liability for future gross negligence unenforceable as a matter of public policy); Rosencrans v. Dover Images, Ltd., 192 Cal. App. 4th 1072, 1081 (2011) ("[w]hile plaintiffs' claims for ordinary negligence are barred by the Release, their claim for gross negligence would not be barred by the Release due to public policy concerns.").

indirectly, to exempt anyone from responsibility for . . . violation of law, whether willful or negligent . . . .” Cal. Civ. Code § 1668. Relying on this portion of the statute, Peregrine argues that the LOD clauses do not apply to its cause of action for negligence per se, as it incorporates violations of law. (Opp’n at 18-20.) Specifically, Peregrine claims CSM violated several FDA regulations contained in 21 C.F.R. §§ 211.125, 211.130, 211.142, and 211-150. (FAC ¶¶ 14, 19, 33.) CSM does not dispute that its alleged conduct violated FDA regulations or that these regulations constitute “violation[s] of law” under Section 1668. See Health Net, 113 Cal. App. 4th at 234 (“The statute's prohibition against contractual provisions that exculpate violations of statutory law has also been construed to include regulatory violations.”).[17] The only issue to be decided is whether the LOD provisions are invalid under Section 1668 as applied to Peregrine’s negligence per se claims.

[17] As opposed to claims for active negligence, the Court was unable to find and the parties have not identified any case where the court required express and unequivocal language limiting liability for negligence per se. Cf. Burnett, 123 Cal. App. 4th at 1066. The Court finds negligence per se claims more closely resemble passive negligence, which involves “mere nonfeasance, such as the failure . . . to perform a duty imposed by law.” Frittelli, 202 Cal. App. 4th at 48. Accordingly, like passive negligence, the LOD clauses need not expressly state their intent to apply to negligence per se claims in order for the damages limitations to apply.

There is a split in the case law regarding whether a party can limit its liability for negligent violations of statutory law. See Morris v. Zusman, 857 F. Supp. 2d 1082, 1094 (D. Or. 2012) (examining California law and stating "[t]here appears to be a degree of ambiguity in the case law construing Section 1668 as to whether the statute operates to void contractual provisions which do not entirely exculpate statutory violations . . . , but purport instead merely to limit the money damages available to an aggrieved party arising out of such violations or conduct."). Peregrine relies on Health Net, 113 Cal. App. 4th at 234 and Capri v. L.A. Fitness Int'l, LLC, 136 Cal. App. 4th 1078, 1084 (2006), for the proposition that "[i]t is now settled—and in full accord with the language of the statute—that notwithstanding its different treatment of ordinary negligence, under section 1668, 'a party [cannot] contract away liability for his fraudulent or intentional acts or for his negligent violations of *statutory* law,' regardless of whether the public interest is affected." Health Net, 113 Cal. App. 4th at 234 (citations omitted); Capri, 136 Cal. App. 4th at 1084. However, as the Court previously discussed, here, CSM did not contract away its liability for regulatory violations, it merely limited its liability for damages resulting from those violations. Making this point, CSM cites CAZA, 142

Cal. App. 4th at 472, and Farnham, 60 Cal. App. 4th at 74, which uphold "contractual limitations on liability, even against claims that the breaching party violated a law or regulation." CAZA, 142 Cal. App. 4th at 472.

As applied to this action, the Court finds the later line of cases more persuasive. Peregrine's cases are largely distinguishable. As the CAZA court recognized, "Capri is significantly different from the present case because it involved personal injury to a consumer. Here, the contract was between two business entities and the damages claimed are entirely economic." CAZA, 142 Cal. App. 4th at 471. In Health Net, the court found that a clause which prohibits "any liability for *any* damages for *any* statutory violation surely rises to the level of an 'exempt[ion] from responsibility' within the meaning of the plain language of section 1668," but left open the possibility that "some contractual limitations over the scope of available remedies need not necessarily run afoul of section 1668." Health Net, 113 Cal. App. 4th at 239. The LOD clauses do not rise to the level of exemption described in Health Net. CSM remains liable for direct damages in an amount equal to the sum it received from Peregrine. See Morris, 857 F. Supp. 2d at 1096 (synopsizing the Health Net rule as: "any limitation of liability that, while facially falling short of an absolute elimination of liability, would

nevertheless be unenforceable under Section 1668 to the extent that it so limited the money damages available as to constitute a *de facto* exemption from responsibility for intentional misconduct or violation of statutory law"). Moreover, unlike in Health Net, the Court found that the transaction at issue does not affect the public interest. Id. at 241.

By comparison, in CAZA, TEG hired CAZA to drill a well and executed a contract that excluded consequential damages and allocated liability for tort damages caused by negligence. 142 Cal. App. 4th at 457, 466. A few days after drilling began, there was a blowout, resulting in the death of a CAZA employee, injury to others, and complete destruction of the well. CAZA filed a complaint against TEG, alleging breach of contract and other causes of action. Id. at 458. TEG filed a cross-complaint contending that CAZA was liable for negligence per se because it violated various statues and regulations in performing drilling activities. Id. at 470. The CAZA court reviewed numerous California cases and held that the challenged provisions "represent[] a valid limitation on liability rather than an improper attempt to exempt a contracting party from responsibility for violation of law within the meaning of section 1668." Id. at 475. The court stated:

> CAZA did not seek or obtain complete exemption from culpability on account of its potential negligence or

> violation of any applicable regulations. It merely sought to limit its liability for economic harm suffered by TEG. The parties foresaw the possibility that a blowout could occur and agreed between themselves concerning where the losses would fall. . . . [T]he limitation of liability provisions did not adversely affect the public or the workers employed by CAZA. . . . [W]here the only question is which of two equal bargainers should bear the risk of economic loss in the event of a particular mishap, there is no reason for the courts to intervene and remake the parties' agreement.

CAZA, 142 Cal. App. 4th at 475. Similarly here, the LOD provisions merely limit CSM's liability for economic harm. The MSA reveals that the parties foresaw the centrality of the FDA regulations and CSM's compliance with professional standards. (See MSA ¶¶ 3A, 15.) The LOD clauses do not adversely affect the patients in the Phase II trial or the general public. Peregrine and CSM, two equal bargainers, apportioned the risk for violations of law in the MSA , and the Court shall not disturb the parties' agreement. See Farnham, 60 Cal. App. 4th at 78 ("[T]he "sole remedy" provision[, which preserved an employee's claims against his corporate employer but waived his right to sue the corporation's officers,] in Farnham's contract does not conflict with any public interest but is instead the result of a private, voluntary transaction in which Farnham simply agreed to look to Sequoia to shoulder a risk that might otherwise have fallen on its

officers, directors and shareholders."); Morris, 857 F. Supp. 2d at 1097 ("[N]egotiated agreements to cap available money damages at reasonable levels would not be within the scope of [Section 1668]."); Reudy, 693 F. Supp. 2d at 1118 (applying CAZA and stating "Presumably two business entities with equal bargaining power should be able to voluntarily enter into a Release Agreement whereby one pays the other in order to continue its' allegedly wrongful conduct. . . . This does not appear to . . . be the sort of Agreement that was meant to run afoul of Section 1668, and is clearly distinguishable from the facts of the cases cited by Plaintiffs in which the parties signed broad contracts releasing new, unknown and unspecified wrongdoing that might happen in the future[.]").

Relying on these cases, the Court finds that Section 1668 does not invalidate the LOD clauses as applied to CSM's alleged violations of law used to support Peregrine's claim for negligence per se. The Court holds that the damages caps in Paragraph 16 apply to this claim.

4. Fraud

Finally, the FAC includes two fraud claims for negligent misrepresentation and constructive fraud. See Blankenheim, 217 Cal. App. 3d at 1472-73 ("[C]ase

law has long held that negligent misrepresentation is included within the definition of fraud."); Cal. Civ. Code § 1573.

Unlike claims involving negligent violations of law under Section 1668, there is no split in the caselaw regarding intentional torts. The cases uniformly hold that "limitation of liability clauses are ineffective with respect to claims for fraud and misrepresentation," regardless of whether the public interest is implicated. Food Safety, 209 Cal. App. 4th at 1126; Blankenheim, 217 Cal. App. 3d at 1471–1473.

None of the cases cited by CSM uphold the application of a liability limitation clause to a fraud claim, even where the clause amounts to a limitation on damages limitations as opposed to an outright exemption. See Farnham, 60 Cal. App. 4th at 71 ("[C]ontractual releases of future liability for fraud and other intentional wrongs are invariably invalidated."); Civic Ctr. Drive, 295 F. Supp. 2d at 1106 ("Under § 1668 of the California Civil Code, contracts which 'have for their object . . . to exempt any one from responsibility for his own fraud . . . are against the policy of the law.'") (quotation omitted).

In accordance with the precedent, the Court holds that the LOD clauses are inapplicable to Peregrine's claims for negligent misrepresentation and constructive fraud. See WeBoost Media S.R.L. v. LookSmart Ltd., No.

C 13-5304 SC, 2014 WL 2621465, at *9-10 (N.D. Cal. June 12, 2014) (holding that "section 1668 renders the T & C's limitation of liability unenforceable to the extent that it would insulate Defendant from intentional tort liability" where the clauses at issue, like those here, barred consequential damages and limited liability to "the total amount paid . . . to Defendant under this Agreement," but did exculpate liability for the claims at issue).

V. CONCLUSION

For the foregoing reasons, the Court GRANTS IN PART and DENIES IN PART Defendant's motion for partial summary judgment. The Court holds that the Limitations on Damages clauses in Paragraph 16 of the Master Services Agreement apply to the FAC's causes of action for breach of contract, passive negligence, and negligence per se. The damages limitations do not apply to the claims in the FAC for active negligence, negligent misrepresentation, and constructive fraud.

Dated: July 30, 2014

Jesus G. Bernal
United States District Judge