UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

MARICAL INC., et al.,	)	
	)	
Plaintiffs	)	
	)	
v.	)	1:14-cv-00366-JDL
	)	
COOKE AQUACULTURE INC., et al.,	)	
	)	
Defendants	)	

DECISION AND ORDER ON DEFENDANTS' MOTION TO AMEND ANSWER

In this action, Plaintiffs and Counter-claim Defendants Marical Inc., Europharma AS, and Europharma Inc. Canada ("Plaintiffs"), allege that Defendants and Counter-claim Plaintiffs Cooke Aquaculture Inc., Cooke Aquaculture USA Inc., True North Salmon Co. Ltd., True North Salmon US Inc., True North Sales US Inc., and Salmones Cupquelan SA ("Defendants"), produce and import salmon raised by methods that infringe Plaintiffs' United States patents, which patents teach methods for raising pre-adult anadromous fish. (Complaint, ECF No. 1.) In their counterclaim for declaratory judgment, Defendants seek a judgment of invalidity and non-infringement. (Answer and Counterclaims, ECF No. 16.)

The matter is before the Court on Defendants' Motion for Leave to Amend Their Answer. (ECF No. 214.)[1] Through the motion, Defendants seek to add an affirmative defense and five counterclaims in which they allege that the patents-in-suit are unenforceable under the doctrine of inequitable conduct and "infectious unenforceability."

[1] The public version of the motion (ECF No. 214) is redacted.

(Answer ¶¶ 13 – 66, 159 – 243.) Defendants assert they would "limit the inequitable conduct claims to those 'representative' claims in the litigation, and claim 46 of the '792 patent."[2]

Following a review of the record, and after consideration of the parties' written arguments, the Court grants the motion.

BACKGROUND

"Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent. This judge-made doctrine evolved from a trio of Supreme Court cases that applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct …." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). Through a claim of inequitable conduct, a patent infringement defendant asserts that the patentee obtained the patent-in-suit by making material misrepresentations to the PTO or by taking measures to suppress evidence that, if disclosed, would have prevented issuance of a patent. *Id.* at 1285 – 87. "Inequitable conduct occurs when a patentee breaches his or her duty to the PTO of candor, good faith, and honesty." *U.S. Water Servs., Inc. v. Novozymes A/S*, 843 F.3d 1345, 1352 (Fed. Cir. 2016) (quoting *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1186 (Fed. Cir. 2006), and citing 37 C.F.R. § 1.56(a) (2015) (explaining that a party appearing before the PTO has "a duty to disclose ... all information known to that individual to be material to patentability")).[3]

[2] June 30, 2017, Letter of Michael McGraw, counsel for Defendants.

[3] Claims of inequitable conduct involve "particularly egregious misconduct, including perjury, the manufacture of false evidence, and the suppression of evidence." *Therasense*, 649 F.3d at 1287. As explained in *Therasense*, inequitable conduct claims have a significant impact on patent litigation:

Defendants argue that information obtained on the final day of fact-related discovery supports their request to assert the inequitable conduct defense and counterclaims. On February 28, 2017, Defendants deposed Dr. William Harris, the lead inventor of the patents-in-suit. Dr. Harris testified, in part, as Plaintiffs' Rule 30(b)(6) designee. According to Defendants, Dr. Harris testified that he knew of material prior art that he did not disclose to the United States Patent and Trademark Office ("PTO") during the patent prosecution process. (Motion at 1.) Based on the testimony, Defendants argue they can state an actionable claim of inequitable conduct and that the timing of the revelation justifies an amendment despite the expiration of the scheduling order deadline for amendment of the pleadings. Plaintiffs argue Defendants lack good cause for the late motion to amend and have not stated an actionable claim.

> A charge of inequitable conduct conveniently expands discovery into corporate practices before patent filing and disqualifies the prosecuting attorney from the patentee's litigation team. Moreover, inequitable conduct charges cast a dark cloud over the patent's validity and paint the patentee as a bad actor. Because the doctrine focuses on the moral turpitude of the patentee with ruinous consequences for the reputation of his patent attorney, it discourages settlement and deflects attention from the merits of validity and infringement issues. Inequitable conduct disputes also increase the complexity, duration and cost of patent infringement litigation that is already notorious for its complexity and high cost.

Therasense, 649 F.3d at 1288. According to the Federal Circuit, "the remedy for inequitable conduct is the 'atomic bomb' of patent law." *Id*. (quoting *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting)). "Unlike validity defenses, which are claim specific, see 35 U.S.C. § 288, inequitable conduct regarding any single claim renders the entire patent unenforceable." *Id.* In addition to the impact such claims have on patent litigation, inequitable conduct claims have had a significant negative impact on the patent prosecution process. *Id.* at 1289. "With inequitable conduct casting the shadow of a hangman's noose, it is unsurprising that patent prosecutors regularly bury PTO examiners with a deluge of prior art references, most of which have marginal value." *Id.* at 1289. The resulting deluge contributes to administrative backlog. *Id.* at 1290. *See also Agfa Corp. v. Creo Products Inc*., 451 F.3d 1366, 1379 (Fed. Cir.2006) (explaining that infectious unenforceability occurs when inequitable conduct renders unenforceable claims in a related application).

U.S. Patent Application No. 09/687,476 (the '476 Application), which issued as the '792 Patent, was filed on October 12, 2000, by Antoinette G. Giugliano of the law firm Hamilton, Brook, Smith & Reynolds, P.C. ("Hamilton Brook firm"). (Proposed Am. Compl. ¶ 14.) David E. Brook of the Hamilton Brook firm is counsel of record for the prosecution of the application. (*Id.* ¶ 15.)

On March 24, 2002, a patent examiner with the PTO issued an office action rejecting all pending claims under the judicially created doctrine of nonstatutory double patenting, citing prior patent number 6,337,391 (the '391 Patent), and explaining that "the claims if allowed, would improperly extend the 'right to exclude' already granted in the ['391] patent." (*Id.* ¶ 16; *see also* ECF No. 213-2.) The patent examiner further wrote: "The subject matter claimed in the instant ['476] application is fully disclosed in the ['391] patent and is covered by the patent since the patent and application are claiming common subject matter, as follows: the patent discloses a method of improving the raising of fish comprising adding magnesium and calcium to increase expression and/or sensitivity of at least one PVCR." (Proposed Am. Compl. ¶ 17.)

In response to the March 24, 2002, Office Action, applicants submitted a reply dated April 23, 2002. (*Id.* ¶ 18; *see also* ECF No. 214-4.) In their reply, applicants stated:

> The claimed methods involve adding magnesium and calcium to the freshwater in which the pre-adult anadromous fish are maintained prior to transfer to seawater, and adding a specially made feed for fish consumption to the freshwater. The feed contains NaCl and at least one PolyValent Cation Sensing Receptor (PVCR) modulator (e.g., an amino acid). The PVCR modulator present in the feed is sufficient to contribute to a significantly increased level of calcium and/or magnesium in serum of these fish, and the magnesium and calcium added to the freshwater increase expression and/or sensitivity of at least one PVCR in the fish.

> ….
> Assuming that the Examiner meant to issue a 102(e) or 102(e)/103 rejection, the disclosure of the '391 patent also does not describe the claimed invention. The '391 patent does not even disclose or mention the specially made feed used in the claimed methods e.g., feed having NaCl and at least one PVCR modulator. The methods that are included in the '391 patent describe slowly adapting fish to different salinities. According to the '391 patent, once the flounder, a non-anadromous fish, were maintained in either a hypersalinity or hyposalinity environment, their body composition changed. See Example 10 of the '391 patent. The claimed invention is used for an entirely different purpose, namely, for transferring anadromous fish to seawater, and it involves steps that are not mentioned or suggested in the '391 patent. There is no mention of preparing anadromous fish for transfer to seawater by adding calcium and magnesium to the freshwater in which the anadromous fish are maintained in sufficient amounts to increase expression and/or sensitivity of at least one PVCR. Also, there is no mention of adding feed to the freshwater, wherein the feed contains a PVCR modulator to significantly increase calcium and magnesium levels in the serum of fish. These two steps work together. The specially made feed causes the fish to ingest increased amounts of freshwater having the additional calcium and magnesium, and as a result, the levels of calcium and magnesium cause increased sensitivity and/or expression of at least one PVCR which, in turn, prepares the fish for transfer to seawater. The invention, as a whole, is not described nor suggested in the '391 patent.
> ….
> For example, there is no support for accomplishing the transfer of anadromous fish to seawater by adding both the magnesium and calcium to increase expression of at least one PVCR, and there is certainly no support for the NaCl/PVCR modulator feed.

(*Id.* ¶¶ 19 – 21.)

At his deposition, Dr. Harris testified that he would have reviewed the April 23, 2002, reply to the PTO before it was sent. (*Id.* ¶ 26.) Dr. Harris also stated that the "specially made feed" referenced in the April 23, 2002, reply could be feed with either sodium chloride and a PVCR modulator added, or feed with only sodium chloride added, because sodium chloride is a PVCR modulator. (*Id.* ¶ 27.)

Dr. Harris knew that all prior art feeds contained sodium chloride. (*Id.* ¶ 30.) He also acknowledged that it would have been important to disclose to the Patent Office if he knew that all prior art feed contained sodium chloride. (*Id.* ¶ 31.) 6+6 Freshwater Feed was a feed sold by Moore-Clark from at least 1992-1999 to enhance the smoltification process that contains special salts and Finnstim (betaine and other amino acids). (*Id.* ¶ 32.) 6+6 Freshwater Feed is prior art to the patents-in-suit. (*Id.* ¶ 33.) 6+6 Freshwater Feed was used and offered for sale in the United States before the priority date of the patents-in-suit. (*Id.* ¶¶ 36 – 37.) 6+6 Freshwater Feed contained more than 1% added sodium chloride.[4] (*Id.* ¶ 38.)

Dr. Harris knew at the time the patents were filed that all prior art feeds contained tryptophan, but he did not disclose the information to the Patent Office. (*Id.* ¶ 41.) 6+6 Freshwater Feed contained amino acids. (*Id.* ¶ 42.) Dr. Harris testified that he was familiar with nutritional guidelines for feeds at the time the patent applications were filed. The nutritional guidelines, such as the Nutrient Requirements of Fish, published through the National Research Council in 1993 ("NRC 1993"), existed as written documents at the time the patents-in-suit were filed and were readily available, and as such were prior art. (*Id.* ¶¶ 43 – 44.) NRC 1993 discloses a tryptophan requirement of 0.2% of dry weight for juvenile Chinook salmon.[5] (*Id.* ¶ 45.) Dr. Harris explained that he did not disclose to the

[4] The Court accepted MariCal's proposed construction of "an amount of NaCl sufficient" and construed the term to mean "between about 1% and about 10% NaCl content by weight or a NaCl/feed ratio of between about 10,000 mg/kg and 100,000 mg/kg." (Proposed Am. Compl. ¶ 39.)

[5] As to the construction of the term "amount of NaCl and at least one PVCR modulator sufficient to contribute to," the Court stated that "[i]nsofar as PVCR modulator content in feed is described in Term

Patent Office that all feed contained tryptophan because it was common knowledge. He further explained that protein is a nutritional requirement of fish feed, and all protein contains tryptophan. (*Id.* ¶ 46.) Dr. Harris confirmed that MariCal's feed is "special" only because it contained sodium chloride and tryptophan. (*Id.* ¶ 47.)

The fact that feed manufacturers had been adding NaCl to smolt feeds for many years as of 2002 or that amino acids were added to smolt feeds for nutritional reasons was evidently not disclosed to the Patent Office. (*Id.* ¶ 57.) Dr. Harris testified at his deposition that he did not recall whether he disclosed the nutritional guidelines to the Patent Office, even though he discussed them with his lawyers. (*Id.* ¶ 60.) According to Dr. Harris, the other inventors, who also knew all prior art feeds contained tryptophan, similarly failed to disclose the information to the Patent Office. (*Id.* ¶ 61.) Defendants alleged that Dr. Harris misled the PTO by referring to MariCal's feed as "specially made" instead of disclosing that he believed that all prior art feeds contained sodium chloride and tryptophan. (*Id.* ¶ 59.)

Claim 46 of the '792 patent is directed to an aquatic food composition that contains NaCl in a concentration of about 10,000 mg/kg to about 100,000 mg/kg (i.e., 1% to 10%) and tryptophan in a concentration of about 1 gm/kg to about 10 gm/kg (i.e., 0.1% to 1.0%). Dr. Harris did not disclose to the PTO that he believed that all prior art feeds contained sodium and tryptophan. According to Defendants, the PTO would have rejected at least

18D, Patent '792 'specifies tryptophan in an amount between about 1 gm/kg and about 10 gm/kg' or another amino acid in the same concentration." (Proposed Am. Compl. ¶ 48.)

claim 46 under 35 U.S.C. §§ 102 and/or 103 if it had been aware of the information that Dr. Harris failed to disclose. (*Id.* ¶ 149.)

Citing Dr. Harris's deposition testimony, in their proposed amended answer, Defendants assert the affirmative defense of inequitable conduct, and counterclaims of "unenforceability" against each of the four patents-in-suit. (*Id.* ¶¶ 159 – 229, Counterclaims 9 – 12.) Defendants allege the information allegedly withheld from the PTO was material to issuance of each of the patents-in-suit. By way of example, concerning the '792 Patent, Defendants allege:

> That the fact tryptophan and NaCl were in the prior art feeds is material to the patentability of claim 46, where claim 46 is directed to an aquatic food composition that contains NaCl in a concentration of about 10,000 mg/kg to about 100,000 mg/kg and tryptophan in a concentration of about 1 gm/kg to about 10 gm/kg. (*Id.* ¶ 176.)

As to the intent to deceive, Defendants assert generally that individuals with a duty to disclose failed to disclose material information with an intent to deceive the Patent Office. (*Id.* ¶ 177.)

Defendants also assert a counterclaim of "infectious unenforceability." According to Defendants, inequitable conduct underlying the issuance of Patent '792 infects each of the other patents-in-suit and renders then unenforceable because they are each either a continuation of, share the same title with, or claim similar subject matter as Patent '792. (*Id.* ¶¶ 230 – 238.) Finally, in the amended counterclaim, Defendants allege the case is "exceptional" due to various circumstances. (*Id.* ¶¶ 230 – 243.)

DISCUSSION

A. Motion to Amend Standard

To amend their answer, Defendants first must demonstrate that they filed their motion timely. Rule 15(a)(1) of the Federal Rules of Civil Procedure permits a litigant to amend a pleading "once as a matter of course," subject to certain time constraints. In the case of an answer, freedom to amend without leave of court is permitted within 21 days of the date on which the answer was filed. Fed. R. Civ. P. 15(a)(1)(A). Thereafter, leave of court is required, though leave should be granted "freely . . . when justice so requires." Fed. R. Civ. P. 15(a)(2); *see also Foman v. Davis*, 371 U.S. 178, 182 (1962).

The standard is elevated when the motion seeking leave to amend is filed after the deadline for amendment of the pleadings set forth in the scheduling order. A motion to amend that is filed beyond the scheduling order deadline requires an amendment of the scheduling order. To obtain an amendment of the scheduling order, a party must demonstrate "good cause." *Johnson v. Spencer Press of Maine, Inc*., 211 F.R.D. 27, 30 (D. Me. 2002); *El–Hajj v. Fortis Benefits Ins. Co*., 156 F. Supp. 2d 27, 34 (D. Me. 2001); Fed. R. Civ. P. 16(b)(4). A court's decision on good cause "focuses on the diligence (or lack thereof) of the moving party more than it does on any prejudice to the party-opponent." *Steir v. Girl Scouts of the USA*, 383 F.3d 7, 12 (1st Cir. 2004). "Particularly disfavored are motions to amend whose timing prejudices the opposing party by 'requiring a re-opening of discovery with additional costs, a significant postponement of the trial, and a likely major alteration in trial tactics and strategy.'" *Id.* (quoting *Acosta–Mestre v. Hilton Int'l of P.R., Inc.*, 156 F.3d 49, 52 (1st Cir. 1998)). It falls to the court's discretion whether to

grant a late motion to amend, and that discretion should be exercised on the basis of the particular facts and circumstances of the case. *Id.*

Even if a party demonstrates good cause to file a late motion to amend, a court can deny the motion if the court determines that the proposed amendment of the pleading in question would be futile. *Chiang v. Skeirik*, 582 F.3d 238, 244 (1st Cir. 2009). "In assessing futility, the district court must apply the standard which applies to motions to dismiss under Fed. R. Civ. P. 12(b)(6)." *Adorno v. Crowley Towing & Transp. Co*., 443 F.3d 122, 126 (1st Cir. 2006). Accordingly, the Court must accept as true all well-pleaded facts and draw all reasonable inferences in favor of Defendants to determine whether Defendants, through their proposed counterclaim, have stated a claim for which relief may be granted. *Morgan v. Town of Lexington, Mass.*, 823 F.3d 737, 742 (1st Cir. 2016). A pleading fails to state a claim upon which relief can be granted if it does not plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "The relevant question ... in assessing plausibility is not whether the complaint makes any particular factual allegations but, rather, whether 'the [counterclaim] warrant[s] dismissal because it failed in toto to render [defendants'] entitlement to relief plausible.'" *Rodríguez–Reyes v. Molina–Rodríguez*, 711 F.3d 49, 55 (1st Cir. 2013) (quoting *Twombly*, 550 U.S. at 569 n. 14).

B. Good Cause Analysis

Defendants argue good cause exists for the timing of their motion because the motion relies on newly-discovered evidence first obtained at the deposition of Dr. Harris. (Defendants' Motion for Leave to Amend, ECF No. 213-1.) Although the parties initially

contested the scope of the proposed amendment, i.e., whether it implicates claims other than the representative claims and would necessitate a second claim construction hearing (Defendants' Reply, ECF No. 231-1, at 12; Plaintiffs' Sur-Reply, ECF No. 253-1, at 1 – 2), Defendants subsequently agreed to limit the inequitable conduct defense/counterclaims to the representative claims and claim 46 of the '792 patent, which limitation would not require any further claim construction. (June 30, 2017, Letter of Michael McGraw.)

Defendants argue that prior art made Plaintiffs' representations about "specially made feed" specious because, at the time, commercially available feed contained the additions described in the application for Patent '792.[6] Defendants further contend that Dr. Harris's testimony supports the necessary inferences that Plaintiffs understood that their application depended on methods that were already well established in the art, and that their reply to the examiner's rejection of the application for Patent '792 would not have succeeded had they disclosed the prior art methods to the examiner. (Defendants' Motion at 7 – 8; Defendants' Reply at 1 – 2.)

[6] In support of their motion, Defendants include several prior art references. In particular, a 1993 Moore-Clark catalogue offered for sale its 6+6 feed, described as containing "special salts," and recommended for salmon being transferred from freshwater to saltwater. (ECF No. 215-3, PageID # 7795.) A soviet patent application dated 1991 also teaches a fish feed formulation containing sodium chloride between 1 and 12 percent by weight, to "increase the survivability of Atlantic salmon smolt through adaptation to ocean water." (ECF No. 215-8, PageID # 7860 – 61.) Additionally, a 1993 publication titled "Nutrient Requirements of Fish" includes tables indicating the "amino acid requirements" of various fish, including specific amino acids as a percentage of dry diet. The tables specify 0.2 percent tryptophan, the amino acid addition discussed in Patent '792, for juvenile chinook salmon and for juvenile coho salmon. (ECF No. 215-4, PageID # 7823, 7826.) For reference, Patent '792 states, "the methods also involve adding feed having between about 1% and about 10% NaCl by weight and tryptophan in an amount between about 1 gm/kg and about 10 gm/kg to the freshwater and transferring the pre-adult anadromous fish to seawater." (Patent '792, col. 2, ll. 23 – 24.) Also material, Defendants argue, is a 1988 article entitled *Effects of Food Containing Betaine/Amino Acid Additive on the Osmotic Adaptation of Young Atlantic Salmon*, Salmo salar *L*. (Virtanen, et al., ECF No. 215-9.)

Because Dr. Harris was a principal inventor who directly participated in the patent prosecution process,[7] it was appropriate for Defendants to depose him before advancing a claim of inequitable conduct. *Baxter Int'l, Inc. v. CareFusion Corp*., No. 15-CV-9986, 2017 WL 1049840, at *9 (N.D. Ill. Mar. 20, 2017). Given that Defendants' proposed amendment is based on information disclosed during the deposition of Dr. Harris, which deposition was conducted at the close of the discovery period, and because the information (i.e., Dr. Harris's knowledge of the prior art) was unknown to Defendants before the deposition, good cause exists to permit an amendment of Defendants' answer to Plaintiffs' complaint after the deadline for the amendment of pleadings.[8]

C. Futility of the Amendment

Plaintiffs argue that the inequitable conduct claim is futile because the allegations are not sufficiently particularized, the allegedly omitted prior art was actually disclosed, the alleged omissions were not material because they are cumulative of the disclosed prior art, and the allegations do not support an inference of intent to deceive. (*Id.* at 16 – 19.)

Inequitable conduct claims are subject to the heightened pleading standard of Rule 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009). "A pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b)." *Id.* at 1326 – 27. "Rule 9(b) requires identification of the specific who, what, when, where, and

[7] See Defendants' Motion at 4.

[8] Plaintiffs' contention that they would be prejudiced by the amendment is unconvincing. Insofar as the amendment is based on information known to and disclosed by the principal inventor of one the patents-in-suit, Plaintiffs were presumably aware of the information well before the deposition of Dr. Harris.

how of the material misrepresentation or omission committed before the PTO." *Id.* "Although 'knowledge' and 'intent' may be averred generally, [Federal Circuit] precedent, like that of several regional circuits, requires that the pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind." *Id.* at 1327. Defendants seek to particularize their allegations of inequitable conduct by reference to Dr. Harris's deposition testimony.[9] The issue is whether Defendants' allegations are sufficiently particularized to support inferential findings of a material nondisclosure of prior art and an intent to deceive the patent examiner.

a. Materiality

Affirmative misrepresentations to the PTO typically satisfy the materiality standard as one form of "affirmative egregious misconduct." *Id.* at 1292. "After all, a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent." *Id.* Defendants have not alleged any affirmative allegations that would be actionable. Instead, Defendants' allegations involve the nondisclosure of prior art.

[9] At his deposition, Dr. Harris testified that all feed contains tryptophan (ECF No. 231-2 at 105:12); that Plaintiffs' claimed invention is "about more than twofold higher than" the nutritional requirement for tryptophan, which requirement he characterized as 0.02 percent (*id.* at 106:2 – 9); that the tryptophan used by Plaintiffs is a "free amino acid" rather than a peptide, which difference he described as "very big … in terms of PVCR modulators" (*id.* at 106:13 –16); that additions of calcium and magnesium to hatchery water were used by "[s]ome hatcheries and under certain circumstances" (*id.* at 107:7 – 12); that he did not disclose to the PTO that all feed had tryptophan, or that hatcheries raising salmon were already adding calcium and magnesium to water, or that all feed had "some sodium chloride" (*id.* at 108:6 – 24); and that he did not investigate the actual levels of sodium chloride and tryptophan in prior art feed before pursuing the Patent (*id.* at 109:5 – 110:7).

For a nondisclosure to meet the materiality standard, the nondisclosure must be the "but for" cause for issuance of the patent. *Id.* at 1291. Nondisclosure of prior art meets this standard "if the PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Id.* A patentee does not commit inequitable conduct by withholding a reference if the patent examiner in fact considered the reference, *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991), *overruled on other grounds by Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009), or if the allegedly withheld reference would have been less relevant than other information already before the PTO, *Larson Mfg. Co. of S. Dakota v. Aluminart Prod. Ltd.*, 559 F.3d 1317, 1327 (Fed. Cir. 2009).

Defendants' materiality argument is premised on the basic assertion that essentially any prior art feed used in salmon aquaculture would have contained NaCl and tryptophan in amounts sufficient to come within the minimum ranges set forth in the representative claims (1% NaCl and 0.1% tryptophan) and that the patent examiner would have denied the claims if this information had been disclosed. For example, with respect to the representative claims involving tryptophan, the salient omitted reference is Nutrient Requirements of Fish, which states that feeds for juvenile salmon should have 0.2 percent tryptophan. The tryptophan / feed ratio set forth in the patent teaches a range between 1gm/kg (0.1 percent) and 10gm/kg (1 percent) tryptophan.

"A finding of inequitable conduct as to 'any single claim renders the entire patent unenforceable' and may "render unenforceable other related patents and applications in the same technology family." *U.S. Water Servs.*, 843 F.3d at 1352 (quoting *Therasense*, 649

F.3d at 1288). Arguably, Defendants' claim of inequitable conduct with the most potential involves the tryptophan element of claim 46 of the '792 Patent.

Upon review of the claim, the Court concludes that Defendants have adequately alleged materiality based on Nutrient Requirements of Fish (1993). As alleged, the tryptophan nutritional requirements for juvenile salmon are within the scope of the tryptophan requirements taught in the claim. Additionally, for purposes of pleading, i.e., for purposes of assessing the available reasonable inferences, the Nutrient Requirements of Fish is not cumulative. In short, there is a plausible inference that "the PTO would not have allowed [claim 46] had it been aware of the undisclosed prior art." *Therasense*, 649 F.3d at 1291. [10]

b. Intent to deceive [11]

"The relevant 'conditions of mind' for inequitable conduct include: (1) knowledge of the withheld material information or of the falsity of the material misrepresentation, and (2) specific intent to deceive the PTO." *Exergen*, 575 F.3d at 1327. "Although 'knowledge' and 'intent' may be averred generally, … the pleadings [must] allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind." *Id.* For example, the pleadings should include facts from which it would be reasonable to infer that a particular person subjectively believed a

[10] Dr. Harris testified that he understood prior art feeds to contain only .02 percent tryptophan and that the claimed invention involved additions of a "free amino acid" rather than a peptide.

[11] "Intent and materiality are separate requirements." *Therasense*, 649 F.3d at 1290. A strong showing of materiality will not demonstrate intent to deceive. *Id.*

disclosure would prevent a patent from issuing. *Cf. id.* at 1328 ("knowledge …, standing alone, was not enough to infer that the [applicant] also subjectively believed" (discussing analogous inquiry in trademark context)). Facts depicting gross negligence or negligence will not suffice. *Therasense*, 649 F.3d at 1290.

Contrary to Plaintiffs' contentions, Defendants have alleged facts with sufficient particularity and facts that support a plausible claim for relief. *Twombly*, 550 U.S. at 570. Intent can be established inferentially. Here, Defendants have alleged facts from which a fact finder could conclude that one of the principal inventors (Dr. Harris) was aware of the prior art, including that the minimum specifications for NaCl and amino acid content in the feed necessarily encompassed prior art feed, was aware that the prior art was relevant to Claim 46 of Patent '792, and did not disclose the prior art due to concerns that a candid disclosure regarding the scope of the NaCl and amino acid feed specifications would undermine the applications.

CONCLUSION

Based on the foregoing analysis, the Court grants Defendants' motion to amend. (ECF No. 214). Defendants shall file amended answer and counterclaim within seven days of the date of this order.

NOTICE

Any objections to this Order shall be filed in accordance with Federal Rule of Civil Procedure 72.

/s/ John C. Nivison
U.S. Magistrate Judge

Dated this 31st day of July, 2017.