UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ADMINISTRATORS OF THE TULANE EDUCATIONAL FUND (A/K/A TULANE UNIVERSITY), *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Case No. 09-2428 (RJL)**
IPSEN PHARMA, S.A.S. (F/K/A SOCIETE CONSEILS DE RECHERCHES ET D'APPLICATIONS SCIENTIFIQUES SAS), *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION
(March 23, 2011) [#21]

Plaintiffs in this case, the Administrators of the Tulane Educational Fund (a/k/a Tulane University) ("Tulane") and David H. Coy ("Dr. Coy") (collectively, "plaintiffs") filed this action against Ipsen Pharma, S.A.S. ("Ipsen Pharma") and Ipsen, S.A. ("Ipsen") for correction of inventorship of several U.S. patents pursuant to 35 U.S.C. § 256. The complaint also alleges three claims under Massachusetts state law for unfair business practices, unjust enrichment, and constructive trust. Ipsen Pharma has alternatively moved to dismiss the complaint for failure to state a claim or for a more definite statement. For the following reasons, the motion to dismiss is GRANTED in part and DENIED in part, and the motion for a more definite statement is DENIED.

BACKGROUND

The facts of this case, and the particular patents at issue, have previously been described in an earlier opinion. *See* Memorandum Opinion, Mar. 14, 2011, ECF No. 46. The following relate specifically to Ipsen Pharma and the claims that are subject to its motion to dismiss.

Ipsen Pharma, a subsidiary of Ipsen, is a Société par Actions Simplifiee organized and existing under the laws of France. Compl. ¶ 12, ECF No. 1. Ipsen Pharma is engaged in the business of, among other things, holding intellectual property rights for Ipsen, including the GLP-1 patents. *Id.* It was formed in November 2008 as successor by merger of Société Conseils, de Recherches et d'Applications Scientifiques ("SCRAS") and another Ipsen affiliate. *Id.* ¶ 13. Biomeasure, a Massachusetts corporation, is Ipsen Pharma's majority-owned subsidiary. *Id.* ¶ 14.

The initial research collaborations between Dr. Coy, Tulane, and Biomeasure were governed by a Research Funding Agreement dated July 1, 1984. *Id.* ¶ 15. On November 16, 1990, Dr. Coy, Tulane, and Biomeasure entered into an Amended and Restated Research Funding Agreement ("RFA") that superseded the 1984 agreement. *Id.* ¶ 16. The RFA was further modified by several addenda in 1997 and 1998. *Id.* ¶ 18.

Under its terms, the RFA covered various peptide research and studies conducted by, or under the supervision and control of Dr. Coy. *Id.* ¶ 17. Tulane and Dr. Coy also agreed to undertake a joint research project on "glucagon like peptides," or GLP-1 analogs. *Id.* ¶ 18. In Section 6 of the RFA, the parties agree that "all Results shall be the property of Tulane subject, however, to the rights of Biomeasure therein." *Id.* ¶ 19. The

RFA allows Biomeasure to "prepare, file and prosecute patent applications . . . subject to the approval of Tulane." *Id.* ¶ 20. It also grants Biomeasure (or an affiliate) the right to an exclusive, worldwide license from Tulane and Dr. Coy of any results or any patent or patent application covering the results subject to notification requirements. *Id.* ¶¶ 21-22. Biomeasure is also required to pay Tulane a royalty fee, depending on the degree of collaboration between the parties. *Id.* ¶¶ 22-23.

During the relevant time period, Biomeasure and Tulane held routine joint meetings. *Id.* ¶ 25. One was held on October 10, 1997 in the United Kingdom (the "UK meeting") and another was held on March 20, 1998 in Milford, Massachusetts (the "Milford meeting"). *Id.* Representatives from Tulane and Biomeasure (including joint officers of Biomeasure and Ipsen Pharma's predecessor company, SCRAS) attended both meetings. *Id.* ¶¶ 25-26.

GLP-1 analog development was discussed at the UK meeting. Also at that meeting, Dr. Coy "specifically described to Biomeasure's researchers the genus of GLP-1 analogs that encompasses analogs modified at positions 8 and 35, which includes BIM-51077," the subject of the '186 Patent, and instructed that such analogs should be made and tested. *Id.* ¶ 28. Minutes from the UK meeting "reflect Biomeasure's acknowledgement that substitutions identified by Dr. Coy were unique and likely patentable." *Id.* ¶ 29.

At the Milford meeting approximately six months later, Tulane and Biomeasure researchers "again discussed current data on various GLP-1 analogs being made and tested in cell assays, and how substitutions at various positions affected activity. They

also reviewed pharmaceutical profiles for treating non-insulin dependent (type II) diabetes [] with GLP-1 analogs." *Id.* ¶ 30.

Following those meetings, Tulane and Biomeasure "jointly implemented Dr. Coy's ideas, and made and tested several GLP-1 (7-36) analogs with position 8 and other substitutions." *Id.* ¶ 31. Tulane now sues for correction of inventorship of the patent covering the BIM-51077 compound, which is expected to be effective in diabetes and obesity treatment, as well as for unfair business practices, unjust enrichment, and constructive trust under Massachusetts law.

ANALYSIS

1. Legal Standard

A court may dismiss all or part of a complaint that "fail[s] to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). In considering a motion to dismiss, the court may only consider "the facts alleged in the complaint, any documents either attached to or incorporated in the complaint and matters of which [the court] may take judicial notice." *E.E.O.C. v. St. Francis Xavier Parochial Sch.*, 117 F.3d 621, 624 (D.C. Cir. 1997). To survive a motion to dismiss made pursuant to Rule 12(b)(6), a complaint must "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009). In evaluating a Rule 12(b)(6) motion, the Court construes the complaint "in favor of the plaintiff, who must be granted the benefit of all inferences that can be derived from the facts alleged." *Schuler v. United States*, 617 F.2d 605, 608 (D.C. Cir. 1979) (internal quotation marks omitted). However, factual allegations, even though

assumed to be true, must still "be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Moreover, the Court "need not accept inferences drawn by plaintiff[] if such inferences are unsupported by the facts set out in the complaint. Nor must the court accept legal conclusions cast in the form of factual allegations." *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994).

2. Claim for Inventorship under 35 U.S.C. § 256

Ipsen Pharma contends that plaintiffs' correction of inventorship claim fails for two reasons: first, because 35 U.S.C. § 256 allows only for correction of patents already issued when the complaint was filed, and not the correction of pending patent applications or patents issued during the pendency of the litigation; and second, because plaintiffs have failed to allege "conception" sufficient to state a claim of inventorship.

a. Issued patents vs. patent applications

Plaintiffs seek to have Dr. Coy "named as inventor or co-inventor on the '186, '213, and '628 Patents, and all related U.S. patents and patent applications claiming priority to or through U.S. utility application serial no. 09/206,601 and/or provisional application serial no. 60/111,255." Compl. ¶ 61. Section 256, however, "creates a cause of action in the district courts only to modify inventorship on issued patents." *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1357 n.1 (Fed. Cir. 2004) (noting that plaintiff did not have cause of action under Section 256 for correction of inventorship when the patent had not yet issued at the time plaintiff filed the complaint). Indeed, an entirely separate section of the statute provides for correction of inventorship on patent applications.

Compare 35 U.S.C. § 256 ("Whenever through error a person is named in *an issued patent* as the inventor, or through error an inventor is not named *in an issued patent* and such error arose without any deceptive intention on his part . . . ") (emphases added), *with* 35 U.S.C. § 116 ("Whenever through error a person is named *in an application for patent* as the inventor, or through error an inventor is not named *in an application*, and such error arose without any deceptive intention on his part . . . ") (emphases added).

Plaintiffs have conceded in their opposition that they do not seek correction of inventorship of pending U.S. applications. Pls.' Opp'n 11, ECF No. 26. Instead, they maintain that they only seek correction of inventorship for (1) "patent applications claiming priority to or through the Biomeasure Only Applications [that] issue as patents prior to final adjudication of this litigation"; and (2) "international (PCT) patent applications filed as counterparts to issued patents in the Biomeasure Only Patent Family." *Id.* However, as discussed above, Section 256 only creates a cause of action for correction of inventorship of U.S. patents that have already issued at the time of filing of the complaint, and thus plaintiffs' first set of claims regarding U.S. patents that may issue during the pendency of this litigation must be dismissed.

Plaintiffs can, however, seek correction of inventorship for pending foreign applications. *Chou v. Univ. of Chi.*, 254 F.3d 1347, 1360 (Fed. Cir. 2001). Ipsen Pharma argues that plaintiffs, by using the phrase "U.S. patents and patent applications" in the Complaint (Compl. ¶ 61), requested relief only as to U.S. patent applications. However, a reasonable reading of plaintiffs' requests encompasses both U.S. patents and

all—U.S. and foreign—patent applications. Accordingly, plaintiffs have adequately stated a claim only as to foreign patent applications.

b. Sole inventorship vs. co-inventorship

Defendant also contends that plaintiffs have not stated a claim for either sole or co-inventorship. Inventorship requires conception, which is "complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." *Burroughs Wellcome Co. v. Barr Labs. Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). In other words, the inventor must have "a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue." *Id.* (citations omitted).

Plaintiffs contend that Dr. Coy invented the "genus of compounds with substitutions at positions 8 and 35," which "substantially includes the analogs disclosed and claimed in the GLP-1 patents." Pls.' Opp'n 13. To support this claim, plaintiffs included the following allegations in their complaint: in 1997, "Dr. Coy specifically described to Biomeasure's researchers the genus of GLP-1 analogs that encompasses analogs modified at positions 8 and 35, which includes BIM-51077 (the Taspoglutide compound) as well as specific compounds with substitutions at positions 8 and 35, like those in BIM-51077. Dr. Coy further instructed that such substitution analogs should be made and tested for activity and stability." Compl. ¶ 28. The complaint further alleges that in 1998 "Tulane researchers (Drs. David Coy and William Murphy) and Biomeasure researchers . . . again discussed current data on various GLP-1 analogs being made and

tested in cell assays, and how substitutions at various positions affected activity. They also reviewed pharmaceutical profiles for treating non-insulin dependent (type II) diabetes [] with GLP-1 analogs." *Id.* ¶ 30.

As defendant points out, even drawing all inferences in favor of the plaintiffs, these allegations do not allege the level of conception necessary to state a claim for sole inventorship. In particular, plaintiffs fail to allege that the idea for the genus of GLP-1 analogs encompassed by the patents at issue was "so clearly defined" that it could be reduce to practice without extensive research. *Burroughs Wellcome*, 40 F.3d at 1228. Indeed, by the very terms of the complaint itself, Dr. Coy instructed further research and experimentation. *See* Compl. ¶ 28. Thus, plaintiffs' claim for sole inventorship must be dismissed.

Plaintiffs have, however, stated a claim for joint or co-inventorship. The standard for joint inventorship is set forth in 35 U.S.C. § 116, which states in relevant part: "Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent."

As the Federal Circuit has noted, Section 116 was amended in 1984 to codify the principles set forth in *Monsanto Co. v. Kamp*, 269 F. Supp. 818 (D.D.C. 1967). *Vanderbilt Univ. v. ICOS Corp.*, 601 F. 3d 1297, 1302 (Fed. Cir. 2010) (citing *Kimberly-Clark Corp. v. Proctor & Gamble Distrib. Co.*, 973 F.2d 911, 916 (Fed. Cir. 1992)). Accordingly, a joint invention:

> [I]s the product of collaboration of the inventive endeavors of two or more persons working toward the same end and producing an invention by their aggregate efforts. To constitute a joint invention, it is necessary that each of the inventors work on the same subject matter and make some contribution to the inventive thought and to the final result. Each needs to perform but a part of the task if an invention emerges from all of the steps taken together. It is not necessary that the entire invention concept should occur to each of the joint inventors, or that the two should physically work on the project together. One may take a step at one time, the other an approach at different times.

Vanderbilt, 601 F.3d at 1302 (quoting *Monsanto*, 269 F. Supp. at 824). These guidelines were refined in *Kimberly-Clark*, which held that "[f]or persons to be joint inventors under Section 116, there must be some element of joint behavior . . . . [Individuals] cannot be totally independent of each other and be joint inventors." *Id.* at 1303 (quoting *Kimberly-Clark*, 973 F.2d at 917 (alterations added)).

Thus, each joint inventor "must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice." *Burroughs Wellcome*, 40 F.3d at 1229. But, "each contributor need not have their own contemporaneous picture of the final claimed invention in order to qualify as joint inventors." *Vanderbilt*, 601 F. 3d at 1303. For example, by statute, joint inventors need not contribute to every claim of a patent—"[a] contribution to one claim is enough." *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998); 35 U.S.C. § 116. Indeed, "[o]ne need not alone conceive of the entire invention, for this would obviate the concept of joint inventorship." *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997). However, "[o]ne who simply provides the inventor with well-known principles or explains the state of the

art without ever having 'a firm and definite idea' of the claimed combination as a whole does not qualify as a joint inventor." *Ethicon*, 135 F.3d at 1460.

Thus, Tulane researchers' discussions with Biomeasure researchers regarding the "current data on various GLP-1 analogs being made and tested" do not rise to the level of joint inventorship because they were nothing more than discussions on the current state of the art. But, because plaintiffs claim that Dr. Coy described specific compounds with substitutions at positions 8 and 35 consistent with what was ultimately developed and patented, they have successfully stated a claim for joint inventorship.

3. Massachusetts State Law Claims

As discussed in the Memorandum Opinion granting Ipsen's Motion to Dismiss in this case, the Eastern District of Louisiana has already adjudicated the issue of whether Ipsen Pharma is Biomeasure's alter ego. The standards for establishing the preclusive effect of a prior holding are: (1) "the same issue now being raised must have been contested by the parties and submitted for judicial determination in the prior case"; (2) "the issue must have been actually and necessarily determined by a court of competent jurisdiction in that prior case"; and (3) "preclusion in the second case must not work a basic unfairness to the party bound by the first determination." *Yamaha Corp. of Am. v. United States*, 961 F.2d 245, 254 (D.C. Cir.1992). "[I]f a court makes a substantive determination in order to arrive at a jurisdictional holding, the substantive determination can have issue preclusive effect so long as it was 'actually litigated and determined in the prior action.'" *NextWave Pers. Commc'ns, Inc. v. FCC*, 254 F.3d 130, 148 (D.C. Cir.

2001) (quoting *I.A.M. Nat'l Pension Fund, Benefit Plan A v. Indus. Gear Mfg. Co.*, 723 F.2d 994, 947 n.3 (D.C. Cir. 1983)).

For the same reasons discussed in the earlier Memorandum Opinion in this case, plaintiffs are barred from re-litigating this question by issue preclusion. Thus, in resolving Ipsen Pharma's motion to dismiss the remaining state law claims, the Court will look only to actions of Ipsen Pharma, not those of Biomeasure.

a. Unfair business practices

A party may be liable under Section 11 of Massachusetts General Laws chapter 93A for using or engaging in "an unfair method of competition or an unfair or deceptive act or practice." Mass. Gen. Laws ch. 93A § 11; *see also id.* § 2; *Mass. Eye and Ear Infirmary v. QLT Phototherapeutics, Inc.* (*"MEEI II"*), 552 F.3d 47, 69 (1st Cir. 2009). To be liable, those actions must "occur[] primarily and substantially within the commonwealth." Mass. Gen. Laws. ch. 93A § 11. Moreover, the inquiry under the statute is fact-specific: "[b]ecause '[t]here is no limit to human inventiveness in this field,' Massachusetts courts evaluate unfair and deceptive trade practice claims based on the circumstances of each case. In so doing, Massachusetts leaves the determination of what constitutes an unfair trade practice to the finder of fact, subject to the court's performance of a legal gate-keeping function." *MEEI II*, 552 F.3d at 69 (citations omitted.).

"An act or practice is 'unfair' within the meaning of the statute if it is (1) within the penumbra of a common law, statutory, or other established concept of unfairness; (2) immoral, unethical, oppressive, or unscrupulous; or (3) causes substantial injury to

competitors or other business people." *Vieira v. First Am. Title Ins. Co.*, 668 F. Supp. 2d 282, 292 (D. Mass. 2009) (quotations omitted); *see also MEEI II*, 552 F.3d at 69. In other words, "the objectionable conduct must attain a level of rascality that would raise an eyebrow of someone inured to the rough and tumble of the world of commerce." *Mass. Sch. of Law at Andover, Inc. v. Am. Bar Ass'n*, 142 F.3d 26, 41-42 (1st Cir. 1998) (citation omitted).

Plaintiffs claim that "[t]he knowing and willful misrepresentations by Ipsen and/or Ipsen Pharma regarding inventorship and ownership of the Biomeasure Only Patent Family constitute unfair methods of competition and unfair and deceptive acts and practices." Compl. ¶ 65; *see also id.* ¶ 6. In addition, they allege that Ipsen Pharma engaged in unfair business practice by acquiring the patent rights of its Massachusetts subsidiary, Biomeasure and subsequently entering into the exclusive licensing agreement for Taspoglutide without notifying Tulane. Pls.' Opp'n 15-16. Ipsen Pharma urges the Court to dismiss this claim because plaintiffs have not pled that any of Ipsen Pharma's acts occurred within Massachusetts. Def.'s Mot. 17. However, plaintiffs point to following allegations in the complaint regarding the conduct of Ipsen Pharma (and its predecessor) in Massachusetts to argue that their cause of action arises out of the agreements between Ipsen Pharma and its subsidiary: (1) Ipsen Pharma's funding of Biomeasure's research that led to the GLP-1 patents; and (2) Ipsen Pharma's acquisition of the GLP-1 patent rights from a Massachusetts company. Compl. ¶¶ 24, 45-46. Thus, plaintiffs have pled that the allegedly unfair practices substantially occurred in the Commonwealth.

Ipsen Pharma further argues that plaintiffs' allegations fail to rise to the necessary "level of rascality" sufficient to state a claim because they have pled no facts regarding Dr. Coy's inventorship. However, for the reasons discussed above, plaintiffs' claim for co-inventorship is sustained. Accordingly, defendant's motion to dismiss plaintiffs' claim for unfair business practices must also be DENIED.

b. Unjust enrichment

"Unjust enrichment is defined as 'retention of money or property of another against the fundamental principles of justice or equity and good conscience.'" *Santagate v. Tower*, 833 N.E.2d 171, 176 (2005) (quoting *Taylor Woodrow Blitman Constr. Corp. v. Southfield Gardens Co.*, 534 F. Supp. 340, 347 (D. Mass. 1982)). "A claim of unjust enrichment is appropriate 'where an agreement is too indefinite to be enforced ... [or] where no contract is made because each of the parties had a materially different understanding of the terms.' Unjust enrichment provides an equitable stopgap for occasional inadequacies in contractual remedies at law by mandating that '[a] person who has been unjustly enriched at the expense of another is required to make restitution to the other.'" *Mass. Eye and Ear Infirmary v. QLT Phototherapeutics* (*"MEEI I"*), 412 F.3d 215, 233 (1st Cir. 2005) (citations omitted) (alteration in original). Thus, to state a claim of unjust enrichment under Massachusetts law, a plaintiff must allege the following: "(1) a benefit conferred upon [the defendant] by Plaintiffs; (2) an appreciation or knowledge of the benefit by [the defendant]; and (3) the acceptance or retention of the benefit by [the defendant] under circumstances which make such acceptance or retention inequitable."

Vieira, 668 F. Supp. 2d at 294 (citation omitted).[1] At the pleading stage, plaintiffs may plead inconsistent alternative theories of liability even if they can only recover under one. *Id.* at 295 (citing Fed. R. Civ. P. 8(d)).

Plaintiffs allege that Tulane and Dr. Coy provided Ipsen Pharma with the benefit of the conception of the research that led to the GLP-1 patents, which Ipsen Pharma has appreciated by patenting the rights to the compound. Plaintiffs further allege that Ipsen Pharma has inequitably retained the benefit by refusing to acknowledge Tulane as a co-inventor and pay royalties pursuant to the RFA. It is difficult to see why, if Tulane's claim is successful, it would not be adequately compensated through that contract. However, at this stage of the litigation, plaintiffs are entitled to plead an inconsistent theory and, making all inferences in their favor, they have successfully stated an unjust enrichment claim.

c. Constructive trust

Constructive trust is imposed to avoid "unjust enrichment resulting from fraud, a violation of a fiduciary duty or confidential relationship, mistake, or 'other circumstances' in which a recipient's acquisition of legal title to property amounts to unjust enrichment." *Maffei v. Roman Catholic Archbishop of Boston*, 867 N.E.2d 300, 312 (Mass. 2007) (citing *Fortin v. Roman Catholic Bishop of Worcester*, 625 N.E.2d

[1] The District Court of Massachusetts has also alternatively described an unjust enrichment claim as requiring: "(1) an enrichment, (2) an impoverishment, (3) a relation between the enrichment and the impoverishment, (4) the absence of justification and (5) the absence of a remedy provided by law." *Moore v. La-Z Boy, Inc.*, 639 F. Supp. 2d 136, 143-44 (D. Mass. 2009) (quoting *In re Lupron Mktg. and Sales Practices Litig.*, 295 F. Supp. 2d 148, 182 (D. Mass 2003)).

1352, 1358-59 (Mass. 1994), *cert. denied*, 511 U.S. 1142 (1994)). Plaintiffs have failed to allege fraud, existence of a fiduciary or confidential relationship, or mistake. They have, however, alleged unjust enrichment. Thus, because that claim survives, so does their claim for constructive trust based on unjust enrichment.

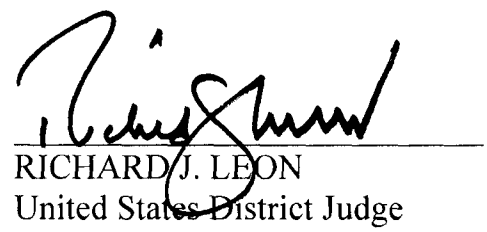
4. More Definite Statement

In the alternative, Ipsen Pharma moves for a more definite statement pursuant to Federal Rule of Civil Procedure 12(e). Though Rule 8(a) requires only a "short and plain statement of the claim showing that the pleader is entitled to relief," it must nevertheless be "detailed enough to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests[.]'" *Dorsey v. Am. Express Co.*, 499 F. Supp. 2d 1, 3 (D.D.C. 2007) (quoting *Twombly*, 550 U.S. at 555) (alteration in original). Under Rule 12(e), the Court may grant the requested relief if the complaint "is so vague or ambiguous that the party cannot reasonably prepare a response." Fed. R. Civ. P. 12(e).

Given the generous nature of Rule 8, the complaint gives Ipsen Pharma fair notice of the claims plaintiffs make against it. The complaint is not "so vague or ambiguous" that Ipsen Pharma cannot respond. Accordingly, the motion for a more definite statement is DENIED.

CONCLUSION

For all the foregoing reasons, Ipsen Pharma's Motion to Dismiss is hereby GRANTED in part and DENIED in part, and its Motion for a More Definite Statement is DENIED. An appropriate order shall accompany this memorandum opinion.



RICHARD J. LEON
United States District Judge