UNITED STATED DISTRICT COURT
DISTRICT OF MASSACHUSETTS

EDMUND EDWARD WARD,	)	
	)	
Plaintiff,	)	
	)	**Civil Action No.**
v.	)	**16-12543-FDS**
	)	
BRUCE AUERBACH; ERNST J. SCHAEFER, M.D.; ROBERT D. SHAMBUREK, M.D.; ALAN T. REMALEY, M.D.; ALPHACORE PHARMA, LLC; ASTRAZENECA BIOPHARMACEUTICALS, INC.; and MEDIMMUNE, LLC,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER ON DEFENDANTS' MOTIONS TO DISMISS FOR FAILURE TO STATE A CLAIM AND FOR LACK OF PERSONAL JURISDICTION

SAYLOR, J.

This is a tort action arising out of the use of a drug in a compassionate-use protocol. Plaintiff Edmund Edward Ward suffers from a rare genetic deficiency that has resulted in, among other things, severe kidney disease. He alleges that he was fraudulently induced to participate in what he contends was a non-therapeutic, experimental drug trial. He alleges that he was led to believe that the drug, ACP-501, would reverse his kidney disease, but that defendants' true purpose in treating him was to gain data that would be beneficial in selling the company that produced the drug.

Ward has filed suit against the company that originally produced the drug (AlphaCore Pharma, LLC), as well as one of its officers (Bruce Auerbach); the company that later purchased AlphaCore (Medimmune, LLC); a related company (AstraZeneca Biopharmaceuticals, Inc.); and

the doctors involved in his treatment (Ernst Schaefer, Robert Shamburek, and Alan Remaley).[1]

Defendants MedImmune, LLC and AstraZeneca Biopharmaceuticals, Inc., have moved to dismiss the claims against them for the failure to state a claim upon which relief can be granted. Defendants AlphaCore Pharma, LLC and Auerbach have moved to dismiss the claims against them for lack of personal jurisdiction. For the reasons stated below, both motions will be granted.

I. Background

A. Factual Background

1. The Parties

Edmund Edward Ward is a Massachusetts resident and a lawyer. (Compl. ¶ 1; 2d Auerbach Aff. Ex. A at 498). Ward was born with an extremely rare genetic deficiency of a bloodstream enzyme, called lecithin-cholesterol acyltransferase ("LCAT"). (*Id.* ¶ 9). LCAT is associated with high-density lipoprotein cholesterol ("HDL-C"), often referred to as the "good cholesterol." (*Id.* ¶ 11). As a result of his deficiency, referred to as "familial LCAT deficiency" or "FLD," Ward produces virtually no cholesterol. (*Id.* ¶ 9). Ward also suffers from other associated health conditions, including kidney disease. (*Id.*). He is in stage 5 kidney failure, and receives dialysis treatment three times a week. (*Id.*).

Bruce Auerbach is a Michigan resident. He is an officer and principal of defendant AlphaCore Pharma, LLC ("AlphaCore"), a limited liability company based in Ann Arbor, Michigan. (*Id.* ¶ 2). As of 2012, AlphaCore was the sole patent licensee of a form of recombinant human LCAT ("rhLCAT") called ACP-501. (*Id.* ¶ 13). The relevant patent, concerning the "Use of Lecithin-Cholesterol Acytransferase [sic] LCAT) to Reduce

[1] Defendants Shamburek and Remaley have moved to substitute the United States as the named defendant pursuant to 28 U.S.C. § 2679(d).

Accumulation of Cholesterol," is owned by the United States. (*Id.* ¶ 14).

Defendant Ernst Schaefer is a Massachusetts resident. He is a physician at the Tufts University School of Medicine and Boston Heart Diagnostics. (*Id.* ¶ 3). Dr. Schaefer is one of Ward's regular treating physicians. (*Id.* ¶ 18).

Defendants Robert Shamburek and Alan Remaley are physicians employed by the United States Department of Health and Human Services, National Institutes of Health ("NIH"), in Bethesda, Maryland. (*Id.* ¶ 4).

Defendant AstraZeneca Biopharmaceuticals, Inc. ("AstraZeneca") is a corporation with a usual place of business in Delaware. (*Id.* ¶ 7). MedImmune, LLC is a limited liability company and a subsidiary of AstraZeneca. (*Id.*).

2. <u>ACP-501</u>

The claims of the patent for ACP-501 involve "a method for decreasing accumulation of cholesterol in arteries in a human subject not suffering from . . . LCAT . . . deficiency syndrome." (*Id.* ¶ 14). In 2011, Dr. Schaefer and several other physicians published a paper in the Journal of Clinical Lipidology about LCAT deficiency. (2d Auerbach Aff. Ex. A at 498).[2] The paper concluded that "[i]n the future, the use of recombinant LCAT may be of value in patients who develop significant renal impairment."

In 2012, in collaboration with the NIH, AlphaCore conducted a clinical trial of ACP-501 to determine the safety and tolerability of a single injection of the drug in 16 to 18 patients with stable coronary artery disease. (Compl. ¶ 15). Defendants Shamburek and Remaley collaborated with Auerbach in running the trial, and reported that a single injection of ACP-501 was safe and tolerated by the subjects. (*Id.* ¶ 16).

[2] Ward is listed as a co-author of the paper. (2d Auerbach Aff. Ex. A at 498).

3. The Proposal to Ward

According to the complaint, sometime in 2012, Ward was introduced to Shamburek, Remaley, and Auerbach by his treating physician, Dr. Schaefer, as a potential "ideal research subject for ACP-501." (*Id.* ¶ 18).

The complaint alleges that the individual defendants induced Ward to participate as the only subject in a long-term trial of ACP-501 by misrepresenting that the drug would reverse his advanced kidney disease. (*Id.* ¶¶ 22, 46). According to the complaint, the individual defendants withheld their true motivation for the study, which was to test the effect of ACP-501 on the production of HDL-C in an LCAT-deficient patient, "hoping the drug would be considered a potential breakthrough in the prevention of cardiovascular disease," as well as to acquire long-term safety data, in order to accelerate the sale of AlphaCore to a large pharmaceutical company. (*Id.* ¶¶ 23, 46-47).

AlphaCore was granted an "orphan drug" designation for ACP-501 and a "compassionate use" protocol was approved. (*Id.* ¶ 20). AlphaCore donated to the NIH the ACP-501 needed for the trial. (*Id.* ¶ 22).

In January 2013, Ward travelled from Massachusetts to the NIH in Maryland to begin treatment. (*Id.* ¶ 27). At the outset of the trial, Auerbach met with Ward and allegedly told him that the process of using ACP-501 to reverse his kidney failure would take a long time, and that he should remain in the trial for the full course of treatment because he would "get out of it what [he puts] into it." (*Id.*).

As of the beginning of 2013, Ward "was considered by his physicians to be in kidney failure," and he was about to receive regular dialysis. (*Id.* ¶ 21). Ward postponed dialysis in order to participate in the trial. (*Id.* ¶¶ 21, 41).

4. The Protocol

At some point (the complaint does not specify when), the NIH created a Clinical Protocol for Ward's treatment. The protocol was titled "Expanded access use of intravenous ACP-501 in one subject with Familial lecithin:cholesterol acyltransferase [rhLCAT] Deficiency." (*Id.* ¶ 36). It appears that AlphaCore and Auerbach played some role in the creation of the protocol, although the details of their roles are unclear. (*See* Pl. Ex. G). Under the protocol, Dr. Shamburek was the principal investigator, Dr. Remaley was the safety-review investigator, and Dr. Schaefer was the medical monitor. (*Id.* ¶ 36(f)).

A draft of the protocol provided for two study sites: one at the NIH facility in Maryland, and another in Massachusetts where Ward would be treated by his regular physician, Dr. Schaefer. (Pl. Ex. E at 23). Under that draft of the protocol, Ward would receive an initial phase of treatment at NIH in Maryland; later, during phase two, he would receive treatments every few weeks in Massachusetts with additional treatments at NIH every few months. (*Id.* at 26-27).

The parties dispute whether that draft became the final operative protocol or whether a later draft, which provided for only one test site in Maryland, was in fact the final approved protocol. (*See* 2d Auerbach Aff. Ex. B at 21; Pl. Surreply at 6-7). It is undisputed that the protocol, whichever version was adopted, did call for Dr. Schaefer to monitor Ward while he was home in Massachusetts. (2d Auerbach Aff. Ex. B at 21 (stating that Dr. Schaefer would "monitor and treat [Ward's] renal dysfunction and other disorders associated with his FLD" while in Massachusetts); Pl Ex. E at 21 (stating that Dr. Schaefer would monitor Ward)).

It appears that in June and July 2013 there was some discussion between Dr. Schaefer and Dr. Remaley concerning the possibility of having ACP-501 sent to Massachusetts so that Ward could be treated there. (Pl. Ex. H). However, it does not appear that any ACP-501

treatments took place in Massachusetts.

5. The Trial

Ward was admitted to the NIH facility in Maryland on January 6, 2013. (*Id.* ¶ 28). According to the complaint, Ward did not receive and sign the NIH's Consent to Participate in a Clinical Research Study until January 24, after he had already been subjected to several days of study. (*Id.* ¶ 29). The complaint further alleges that the consent form was inadequate, because it failed to fully disclose defendants' financial interests in ACP-501. (*Id.* ¶ 35).

The regimen which Ward underwent was "painful, grueling, and confining." (*Id.* ¶ 28). For example, from January 24 to February 27, 2013, Ward remained in one NIH hospital room for 24 hours a day. (*Id.*). He had two intravenous lines continuously inserted, one to administer ACP-501 for one hour in the morning, and the other to draw blood as many as 32 times per day. (*Id.*). From February 27 to June 28, Ward travelled from Massachusetts to Maryland every Tuesday. At NIH, he would check into a hospital room, and Dr. Shamburek would administer ACP-501 on Wednesday morning and then draw his blood six times on Wednesday and another six times on Thursday. (*Id.* ¶ 38).

According to the complaint, Drs. Shamburek and Remaley both told Ward that the ACP-501 was materially improving his kidney function, even though the data as to the drug's effects was at best ambiguous. (*Id.* ¶¶ 39-40). Throughout the trial, at the counseling of Drs. Shamburek and Remaley, Ward did not receive dialysis. (*Id.* ¶ 41).

In April or May 2013, Ward's nephrologist, Dr. Valerie Price, told him that he could no longer go without dialysis. (*Id.* ¶ 50). Nonetheless, he continued with the regimen.

In June 2013, the supply of ACP-501 at NIH was running low. (*Id.* ¶ 52). Drs. Shamburek and Remaley convinced Ward to continue the trial at a lower dose. (*Id.*). That lower

dose caused Ward's HDL-C to plummet. (*Id.* ¶ 53). He expressed a desire to drop out of the trial if he could not continue to receive the higher dose. (*Id.*). According to the complaint, Drs. Shamburek and Remaley induced him to remain in the trial with false promises of a new shipment of ACP-501, meaning a return to the higher dose, and reversing his kidney disease. (*Id.* ¶¶ 54, 56).

From July to September 2013, Ward again travelled from Massachusetts to Maryland every Tuesday for treatment with the lower dose of ACP-501. (*Id.* ¶ 58). According to the complaint, his kidney function deteriorated on the lower dose. (*Id.* ¶ 59). In September, at the urging of Drs. Price and Schaefer, Ward decided to withdraw from the trial in order to receive needed dialysis. (*Id.* ¶¶ 59, 61). The complaint alleges that Dr. Shamburek then tried to convince Ward to remain in the trial by telling him he had "interesting new information" and that the lower dose was working to improve kidney function. (*Id.* ¶ 60). In October, Dr. Shamburek allegedly called Ward and told him that he could not "just leave the program" and that he had to "come back to the NIH." (*Id.* ¶ 61). According to the complaint, in early fall 2013, Ward "learned that the only effect of the ACP-501 experimentation on his kidney condition was to delay, for many months, critical dialysis treatment." (*Id.* ¶ 41).

It appears that AlphaCore reimbursed Ward for his travels to and from Maryland, as well as for any lab work conducted in Massachusetts in connection with the trial. (Pl. Ex. D).

6. <u>The Sale of AlphaCore</u>

In April 2013, during the course of the trial, MedImmune purchased AlphaCore for $20,000,000. (*Id.* ¶ 43). According to the complaint, the sale was "based" principally on . . . Ward's HDL-C results." (*Id.*). It further alleges that Ward was not made aware of sale until 2014, almost a year after he had withdrawn from the trial. (*Id.* ¶ 43, 49).

The complaint alleges that the individual defendants, "acting in concert," were AlphaCore shareholders, owned AlphaCore options or warrants, or "otherwise benefitted materially from the sale of [AlphaCore] to [AstraZeneca] in secret." (*Id.* ¶ 45).

7. Allegations as to MedImmune and Astra Zeneca

The allegations of the complaint as to the involvement of MedImmune and AstraZeneca are as follows:

> By virtue of its purchase of [AlphaCore's] assets, including its ACP-501 assets and the ACP-NIH '614 Patent License, Defendant MedImmune, LLC succeeded to the liabilities of [AlphaCore] arising out of the experimental drug trial in which Mr. Ward participated.
>
> As the parent company and owner of MedImmune, LLC, Defendant [AstraZeneca] is and was legally responsible for the liabilities of its subsidiary or division arising out of the experimental drug trial in which Mr. Ward participated.

(*Id.* ¶¶ 69-70).

8. Affidavit of Bruce Auerbach

Bruce Auerbach, the former president of AlphaCore, submitted an affidavit with his motion to dismiss that sets out his (and the company's) relevant contacts with Massachusetts. Among other things, Auerbach stated that he only met with Ward twice, both times at the NIH in Bethesda, Maryland. (1st Auerbach Aff. ¶ 35-36). He never spoke with him by telephone, except once when Ward tried to call him long after the clinical trial had ended, in September 2014; Auerbach, however, refused to speak with him. (*Id.* ¶¶ 30, 35-36). To his knowledge, no other employee of AlphaCore had any communication with Ward between 2007 and 2013. (*Id.* ¶ 36).

According to Auerbach, between 2007 and March 2013, neither he nor AlphaCore (1) transacted any business in Massachusetts; (2) contracted to supply services or things, including, but not limited to, ACP-501, in Massachusetts; (3) regularly did or solicited business in

Massachusetts; (4) engaged in any persistent course of conduct in Massachusetts (including conducting any clinical trials in Massachusetts); or (5) sold ACP-501 or any other product in Massachusetts (or anywhere), and therefore did not derive substantial revenue from goods used or consumed or services rendered in Massachusetts. (*Id.* ¶¶ 31, 33).

During the same period, neither Auerbach nor AlphaCore (1) had an interest in, used, owned, or leased real property in Massachusetts; (2) had any bank accounts in Massachusetts; (3) advertised in Massachusetts; (4) maintained offices in Massachusetts; (5) had any employees in Massachusetts; or (6) had a resident agent in Massachusetts. (*Id.* ¶¶ 32, 34).

B. Procedural Background

Ward filed the complaint in this action in July 2016, in Massachusetts state court. The complaint alleges claims for fraud (Count One); lack of informed consent (Count Two); unjust enrichment (Count Three); violations of the Due Process Clause of the United States Constitution, the Massachusetts Declaration of Rights, and the Nuremberg Code (Count Four); violation of the Massachusetts Civil Rights Act (Count Five); and civil conspiracy (Count Six) against all defendants.

On December 16, 2016, defendants Shamburek and Relamey removed the action to this court on the basis of 28 U.S.C. § 2679(d)(2). Defendants MedImmune and AstraZeneca have moved to dismiss the claims against them under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted. Defendants AlphaCore and Auerbach, who are both citizens of Michigan, have moved to dismiss the claims against them under Fed. R. Civ. P. 12(b)(2) for lack of personal jurisdiction.

II. The Motion to Dismiss for Failure to State a Claim

Ward appears to allege two principal theories of liability as to MedImmune and

AstraZeneca. First, he contends that they are liable for AlphaCore's conduct under a theory of successor liability. (*See* Compl. ¶ 69).[3] He further contends that AstraZeneca is vicariously liable for the obligations of MedImmune. (*Id.* ¶ 70). He also appears to allege that the AstraZeneca defendants should be held directly liable for the claims alleged on the ground that they were aware of the ongoing trial at the time that they purchased AlphaCore. (*See* Pl. Surreply at 2-3). MedImmune and AstraZeneca have moved to dismiss the claims on the ground that the allegations of the complaint as to them are insufficient to allege a viable theory of recovery.

A. Legal Standard

On a motion to dismiss for failure to state a claim made pursuant to Fed. R. Civ. P. 12(b)(6), the Court "must assume the truth of all well-plead[ed] facts and give the plaintiff the benefit of all reasonable inferences therefrom." *Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007) (citing *Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999)). To survive a motion to dismiss, the complaint must state a claim that is "plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). That is, "[f]actual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations omitted). Dismissal is appropriate if the complaint fails to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008) (quoting *Centro Médico del*

[3] According to defendants, AlphaCore was actually purchased by Zeneca, Inc., which purchased all of the membership interests in AlphaCore. (Def. Mem. at 2 n.1). Defendants thus contend that it was not an asset purchase, and the wrong entity has been identified as the acquirer. Those contentions are, of course, outside the four corners of the complaint, but the analysis would not be materially different if the complaint alleged the facts as set forth by defendants.

Turabo, Inc. v. Feliciano de Melecio, 406 F.3d 1, 6 (1st Cir. 2005)).

B. Applicable Law

As a preliminary matter, there is a question as to what law governs this aspect of the dispute.[4] While defendants contend that Massachusetts law applies, Ward contends that, under the internal-affairs doctrine, Delaware law applies. Under that doctrine, "the law of the State of incorporation governs claims concerning the internal affairs of a corporation." *Harrison v. NetCentric Corp.*, 433 Mass. 465, 472 (2006). Here, because defendants are incorporated under the laws of Delaware, Ward contends that Delaware law should govern.

The Restatement (Second) of the Conflict of Laws states that "the rights and liabilities of a corporation with respect to a third person that arise from a corporate act of a sort that can likewise be done by an individual are determined by the same choice-of-law principles as are applied to non-corporate parties." For all other issues involving the rights and liabilities of a corporation, the law of the state of incorporation will be applied unless "some other state has a more significant relationship to the occurrence and the parties, in which event the local law of the other state will be applied." RESTATEMENT (SECOND) OF CONFLICT OF LAWS §§ 301, 302 (1971).

Here, the theory of liability is either successor liability (that is, liability of both defendants for the act of a predecessor entity) or vicarious liability (that is, liability of AstraZeneca for the act of a subsidiary) for personal injuries allegedly caused by AlphaCore. That is not an issue of internal corporate affairs. Although, in this context, successor liability and vicarious liability are premised on piercing the corporate veil, the law of the state of incorporation is not applicable. Instead, because this is a personal injury case, the law of the

[4] This appears to be a purely technical matter, as the relevant law concerning successor liability appears to be the same in Massachusetts and Delaware.

state where the plaintiff is domiciled should apply, as that state has a greater interest in the litigation than the state where the corporate defendant is incorporated. *See Chrysler Corp. v. Ford Motor Co.*, 972 F. Supp. 1097, 1102-03 (E.D. Mich. 1997) (collecting cases and holding that law of state of incorporation does not apply to issue of successor liability). The Court will therefore apply Massachusetts law to determine the liability of AstraZeneca and MedImmune.

C. Successor Liability

The complaint alleges that MedImmune purchased the assets of AlphaCore in April 2013, during the course of the clinical trial. "Massachusetts courts generally 'follow the traditional corporate law principle that the liabilities of a selling predecessor corporation are not imposed upon the successor corporation which purchased its assets.'" *DeJesus v. Park Corp.*, 530 Fed. App'x 3, 6 (1st Cir. 2013) (Souter, J.) (unpublished opinion) (quoting *Guzman v. MRM/Elgin.*, 409 Mass. 563, 566 (1991)). However, under Massachusetts law, there are four exceptions to that general rule. Liability will be extended to the successor corporation if "(1) the successor expressly or impliedly assumes liability of the predecessor, (2) the transaction is a de facto merger or consolidation, (3) the successor is a mere continuation of the predecessor; or (4) the transaction is a fraudulent effort to avoid liabilities of the predecessor." *Guzman*, 409 Mass. at 566. Plaintiff appears to rely upon the theories of *de facto* merger and mere continuation, which are often used interchangeably and refer to the same basic concept. *See Milliken & Co. v. Duro Textiles, LLC*, 451 Mass. 547, 556 n.15 (2008). However, the complaint fails to allege any facts suggesting that either of those exceptions are applicable here.

The theories of *de facto* merger and "mere continuation" generally apply in situations where the successor corporation is, in essence, the same as the predecessor corporation. The theory of *de facto* merger is usually applied when "the ownership, assets and management of one

corporation are combined with those of another, preexisting entity." *National Gypsum Co. v. Continental Brands Corp.*, 895 F. Supp. 328, 336 (D. Mass. 1995). In determining whether an asset sale should be characterized as a *de facto* merger, courts generally consider the following factors:

> whether (1) there is a continuation of the enterprise of the seller corporation so that there is continuity of management, personnel, physical location, assets, and general business operations; whether (2) there is a continuity of shareholders which results from the purchasing corporation paying for the acquired assets with shares of its own stock, this stock ultimately coming to be held by the shareholders of the seller corporation so that they become a constituent part of the purchasing corporation; whether (3) the seller corporation ceases its ordinary business operations, liquidates, and dissolves as soon as legally and practically possible; and whether (4) the purchasing corporation assumes those obligations of the seller ordinarily necessary for the uninterrupted continuation of normal business operations of the seller corporation. . . . No single factor is necessary or sufficient to establish a de facto merger.

Cargill, Inc. v. Beaver Coal & Oil, Co., 424 Mass. 356, 359-360 (1997) (internal citations omitted).

The "mere continuation" theory generally applies when the successor corporation is, in essence, the same entity as the predecessor. *See Milliken*, 451 Mass. at 557-58. "[T]he indices of a 'continuation' are, at a minimum: continuity of directors, officers, and stockholders; and the continued existence of only one corporation after the sale of assets." *Id.* at 557 (internal quotation marks omitted) (alteration in original). "Similar to the considerations underlying a 'de facto merger,' the factors characterizing a continuing corporation are traditional indicators, but no single factor is dispositive . . . ." *Id.* at 558.

Under either theory, "the principles of successor liability will be imposed where a corporation ceases all of its ordinary business operations, which are assumed by another corporation, and liquidates its assets." *Id.*

The complaint here does not allege that AlphaCore has ceased its ordinary business

operations, nor does it allege any facts from which such a conclusion may be drawn. Indeed, plaintiff's opposition concedes that AlphaCore "appears not to have ceased to exist operationally." (Pl. Opp. at 9). As a basis for successor liability, the complaint alleges only that "[b]y virtue of [their] purchase of [AlphaCore's] assets . . . [the AstraZeneca defendants] succeeded to the liabilities of [AlphaCore] arising out of the experimental drug trial in which Mr. Ward participated." (Compl. ¶ 69). Such legal conclusions—without any supporting factual allegations—are insufficient to state a claim for successor liability. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009).

Ward contends that jurisdictional discovery must be permitted in order to ascertain whether any of the exceptions to the rule against successor liability should apply. (*See* Pl. Opp. at 9). He contends that while AlphaCore does not appear to have ceased its operations, the full nature of the asset acquisition cannot be known without access to the Acquisition Agreement, which is not publically available. But the mere possibility that information disclosed during discovery may show a basis for liability cannot act as a substitute for sufficiently pleaded factual allegations. *See Iqbal*, 556 U.S. at 678-79 ("Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions."); *DM Research, Inc. v. College of Am. Pathologists*, 170 F.3d 53, 55 (1st Cir. 1999) ("[T]he price of entry, even to discovery, is for the plaintiff to allege a *factual* predicate concrete enough to warrant further proceedings, which may be costly and burdensome.") (emphasis in original).

D. Vicarious Liability

The complaint further alleges that AstraZeneca, "[a]s the parent company and owner of MedImmune LLC, is and was legally responsible for the liabilities of its subsidiary or division arising out of the experimental drug trial" in which Ward participated. (Compl. ¶ 70). Even if

there were any potential liability as to MedImmune, "the concept that 'a parent corporation (so called because of control through ownership of another corporation's stock) is not liable for the acts of its subsidiaries,' is 'deeply ingrained in our economic and legal systems.'" *Scott v. NG U.S. 1, Inc.*, 450 Mass. 760, 766 (2008) (quoting *United States v. Bestfoods*, 524 U.S. 51, 61 (1998)). However, "the corporate veil between parent and subsidiary corporations may be pierced when, 'inter alia, the corporate form would otherwise be misused to accomplish certain wrongful purposes, most notably fraud.'" *Id.* (quoting *Bestfoods*, 524 U.S. at 62). Pervasive control alone is insufficient to disregard corporate formalities. *Id.* at 767-68. Rather,

> the decision to disregard settled expectations accompanying corporate form requires a determination that the parent corporation directed and controlled the subsidiary, and used it for an improper purpose, based on evaluative consideration of twelve factors: "(1) common ownership; (2) pervasive control; (3) confused intermingling of business assets; (4) thin capitalization; (5) nonobservance of corporate formalities; (6) absence of corporate records; (7) no payment of dividends; (8) insolvency at the time of the litigated transaction; (9) siphoning away of corporation's funds by dominant shareholder; (10) nonfunctioning of officers and directors; (11) use of the corporation for transactions of the dominant shareholders; and (12) *use of the corporation in promoting fraud*."

Id. at 768 (quoting *Attorney Gen. v. M.C.K., Inc.*, 432 Mass. 546, 555 n.19 (2000)) (emphasis in original).

The complaint does not allege a single fact that would justify piercing the corporate veil and extending liability to AstraZeneca. The sum total of the complaint's vicarious liability allegations are that "Defendant AZ is and was legally responsible for the liabilities of its subsidiaries or divisions arising out of the experimental drug trial in which Mr. Ward participated." (Compl. ¶ 70). That is plainly insufficient to set aside the "deeply ingrained" principle that parent corporations are not liable for the acts of their subsidiaries.

E. <u>Direct Liability</u>

In his surreply to defendants' motion to dismiss, Ward contends that MedImmune and

AstraZeneca had direct knowledge of his treatment. On that basis, he appears to contend that the AstraZeneca defendants can be directly liable for the alleged wrongful acts of AlphaCore, Auerbach, and Drs. Schaefer, Shamburek, and Remaley in inducing him to participate in the trial. However, mere knowledge of Ward's treatment—which is all that is alleged in the complaint (*see* Compl. ¶ 61)—is not sufficient to impose liability for any fraud alleged to have induced him to participate in the clinical trial nor any harm caused by the trial. There is no allegation in the complaint that the AstraZeneca defendants, or their agents, played any role in either inducing plaintiff to participate in or running the trial.[5]

F. Conclusion

Because the complaint fails to allege any factual basis for a finding of successor, vicarious, or direct liability as to MedImmune or AstraZeneca, the motion to dismiss as to those entities will be granted.

III. The Motion to Dismiss for Lack of Personal Jurisdiction

Defendants Auerbach and AlphaCore have moved to dismiss the claims against them for lack of personal jurisdiction, based on the fact that they had no relevant contacts with Massachusetts, the forum state.

A. Personal Jurisdiction Generally

The exercise of personal jurisdiction over a defendant must be authorized by statute and

[5] Based on an exhibit attached to his surreply, Ward contends that AstraZeneca knew about his treatment because Dr. Schaefer had, since 2010, held a consultant or advisory role for and had received honoraria from AstraZeneca. (Pl. Surreply at 2 & Ex. A). However, that document was neither attached to the complaint nor expressly incorporated in it, and therefore is not properly before the court on a motion to dismiss. *See Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993). The complaint does not allege any relationship between AstraZeneca and Dr. Schaefer. Furthermore, the mere fact that Dr. Schaefer may have served as a consultant for or received honoraria from AstraZeneca is not, itself, sufficient to establish that he was an agent of AstraZeneca for purposes of vicarious liability. In any event, Ward does not appear to suggest that such a theory of liability should apply; rather, he appears to contend merely that, because of the relationship between AstraZeneca and Dr. Schaefer, AstraZeneca was likely aware of his treatment. The mere knowledge that Ward was being treated with ACP-501 does not equate to liability for the wrongful conduct alleged.

be consistent with the due process requirements of the United States Constitution. *Nowak v. Tak How Invs., Ltd.*, 94 F.3d 708, 712 (1st Cir. 1996); *Intech, Inc. v. Triple "C" Marine Salvage, Inc.*, 444 Mass. 122, 125 (2005). The Massachusetts long-arm statute provides as follows:

> A court may exercise personal jurisdiction over a person, who acts directly or by an agent, as to a cause of action in law or equity arising from the person's
>
> (a) Transacting any business in this commonwealth;
>
> (b) Contracting to supply services or things in this commonwealth;
>
> (c) Causing tortious injury by an act or omission in this commonwealth;
>
> (d) Causing tortious injury in this commonwealth by an act or omission outside this commonwealth if he regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered, in this commonwealth;
>
> (e) Having an interest in, using or possessing real property in this commonwealth;
> . . . .

Mass Gen. Laws. ch. 223A, § 3. The due process inquiry requires that there be "minimum contacts" between the defendant and the forum state. *Sawtelle v. Farrell*, 70 F.3d 1381, 1388 (1st Cir. 1995) (quoting *International Shoe Co. v. State of Wash.*, 326 U.S. 310, 316 (1945)). Consistent with that requirement, a court may exercise general jurisdiction over "a defendant who has maintained a continuous and systematic linkage with the forum state," and may exercise specific jurisdiction over a cause of action that "relates sufficiently to, or arises from" the defendant's forum-state contacts. *Phillips Exeter Acad. v. Howard Phillips Fund*, 196 F.3d 284, 288 (1st Cir. 1999).

"The jurisdictional requirements imposed by the Massachusetts long-arm statute are quite similar to, though not completely congruent with, the jurisdictional requirements imposed by the Due Process Clause." *Baskin-Robbins Franchising LLC v. Alpenrose Dairy, Inc.*, 825 F.3d 28,

34 (1st Cir. 2016). Thus, the requirements of both must be satisfied in order to establish jurisdiction over a defendant. *Cossart v. United Excel Corp.*, 804 F.3d 13, 18 (1st Cir. 2015).

The plaintiff bears the burden of showing that the court has personal jurisdiction over the defendant. *Daynard v. Ness, Motley, Loadholt, Richardson & Poole, P.A.*, 290 F.3d 42, 50 (1st Cir. 2002). When a district court considers a motion to dismiss for lack of personal jurisdiction without first holding an evidentiary hearing, the *prima facie* standard governs its determination. *United States v. Swiss Am. Bank*, 274 F.3d 610, 618 (1st Cir. 2001). In conducting a *prima facie* analysis, the court is required to take specific facts affirmatively alleged by the plaintiff as true (whether or not disputed), construing them in the light most favorable to the plaintiff; the court, however, should not credit "conclusory allegations or draw farfetched inferences." *Ticketmaster-New York, Inc. v. Alioto*, 26 F.3d 201, 203 (1st Cir. 1994). "The 'plaintiff must go beyond the pleadings and make affirmative proof,'" and "may not rely on unsupported allegations in their pleadings to make a *prima facie* showing of personal jurisdiction." *Boit v. Gar-Tec Prods., Inc.*, 967 F.2d 671, 675 (1st Cir. 1992) (quoting *Chlebda v. H.E. Fortna & Nro Inc.*, 609 F.3d 1022, 1024 (1st Cir. 1979). The court can "add to the mix facts put forward by the defendants, to the extent that they are uncontradicted." *Daynard*, 290 F.3d at 51. Although the court will construe the facts in the light most favorable to the plaintiff in a motion to dismiss, the plaintiff still has the burden of demonstrating each jurisdictional requirement. *See Swiss Am. Bank*, 274 F.3d at 618.

B. <u>The Exercise of Jurisdiction over Auerbach and AlphaCore</u>

It is clear that neither Auerbach nor AlphaCore is subject to personal jurisdiction in Massachusetts on the basis of their own in-forum contacts. According to the uncontradicted affidavit of Auerbach, during the relevant time period, neither he nor AlphaCore transacted any

business in Massachusetts; contracted to supply services or things in Massachusetts; regularly solicited business, engaged in any persistent course of conduct, or derived substantial revenue from goods used or consumed or services rendered in Massachusetts; or had an interest in, used, or possessed any real property in Massachusetts. (1st Auerbach Aff. ¶¶ 31-34). Furthermore, Ward has not alleged, much less produced any evidence, that either Auerbach or ACP caused tortious injury by their acts or omission in Massachusetts. He does not allege that either Auerbach or anyone else at AlphaCore reached out to him in Massachusetts regarding the possibility of using ACP-501 to treat his kidney disease; the evidence instead suggests that Dr. Schaefer initiated contact with Auerbach about that possibility. (1st Auerbach Aff. ¶ 1). Nor does he allege that Auerbach or anyone else at AlphaCore made any fraudulent statements about the purpose of the treatment in Massachusetts; rather, the only allegations of fraudulent statements made by Auerbach occurred in Maryland. (*See* Compl. ¶ 25).

Thus, taking the allegations in the complaint as true, while Auerbach and AlphaCore may have caused a tortious injury inside Massachusetts by their acts or omissions outside the Commonwealth, there is no allegation nor any evidence that either Auerbach or AlphaCore regularly transacted or solicited business, or engaged in any other persistent course of conduct, or derived substantial revenue from goods used or consumed or services rendered in Massachusetts.

1. Theories of Vicarious Personal Jurisdiction

Ward nonetheless contends that the exercise of personal jurisdiction over Auerbach and AlphaCore is proper because their "concerted activities" with the other defendants make it reasonable to impute the Massachusetts contacts of the other defendants, particularly Dr. Schaefer, to them. Ward appears to assert two potential theories of personal jurisdiction here: a joint-venture theory and a conspiracy theory.

a. The Joint-Venture Theory of Personal Jurisdiction

The First Circuit recognized a joint-venture theory of personal jurisdiction in *Daynard v. Ness, Motley, Loadholt, Richardson & Poole, P.A.*, 290 F.3d 42 (1st Cir. 2002). There, the plaintiff, a Massachusetts law professor, alleged that two law firms retained him to assist in their joint tobacco-litigation efforts and then failed to pay him a promised percent of the substantial settlement that they ultimately received. *Id.* at 45-48. The relationship began when a representative of the firm Ness Motley travelled to Massachusetts to retain Daynard's services. *Id.* at 46. Daynard then communicated regularly with individuals at both Ness Motley and the Scruggs Millette firm concerning legal theories and strategies for the litigation. *Id.*

According to Daynard, Ness Motley and Scruggs Millette were working together in a litigation joint venture and, on at least one occasion, a representative of Scruggs stated that he was speaking on behalf of both Scruggs and Motley regarding Daynard's compensation. *Id.* at 46, 47. When the firms refused to pay Daynard the promised percent of their eventual recovery, he filed suit against both firms in Massachusetts. The Scruggs defendants moved to dismiss for lack of personal jurisdiction, contending that Scruggs had not solicited Daynard's services nor travelled to Massachusetts in connection with his work. *Id.* at 49.

The First Circuit held that the Massachusetts contacts of Ness Motley could be imputed to the Scruggs defendants for the purposes of establishing personal jurisdiction. *Id.* at 52. The court framed its analysis not in terms of whether the two firms were in a formal joint-venture or agency relationship, but "whether the relationship between the Scruggs defendants and the Motley defendants, however one labels it, is sufficient to attribute any of the Motley defendants' contacts to the Scruggs defendants for the purpose of reaching the Scruggs defendants under the Massachusetts long-arm statute as cabined by the Due Process Clause of the Fourteenth

Amendment." *Id.* at 53. The court's analysis ultimately rested on the principle that "[f]or purposes of personal jurisdiction, the actions of an agent may be attributable to the principal." *Id.* at 55.[6] It concluded that, based on traditional common-law principles, the two firms were in an agency relationship—or something close enough such that the exercise of jurisdiction was consistent with the Due Process Clause—based on the firms' representations to Daynard and the public that they were joint venturers. *Id.* at 56-67. In essence, the court concluded that Ness Motley acted with the apparent authority of Scruggs Millette when it retained Daynard in Massachusetts and, thus, that that Massachusetts contact could be imputed to the Scruggs defendants for the purposes of establishing personal jurisdiction. *Id.* at 59. The court further reasoned that, even if Ness Motley did not initially act with the apparent authority of Scruggs Millette, Scruggs subsequently ratified the agreement between Ness Motley and Daynard when it agreed to compensate Daynard for his work. *Id.* at 60.

Here, there is no allegation (nor any evidence) that Auerbach or AlphaCore ever represented that they acted with the authority of the other defendants, or that Dr. Schaefer or any of the other defendants ever represented that they acted with the authority of Auerbach or AlphaCore. Instead, the complaint simply alleges that the individual defendants and AlphaCore were "acting in concert" when they "fraudulently induced" Ward to participate in the clinical trial (Compl. ¶ 22), and when they "intentionally withheld from [him] any information regarding their institutional, professional, and personal financial interests and conflicts." (*Id.* ¶ 24). It further alleges that "the individual defendants, acting in concert, were [AlphaCore] shareholders, owned [AlphaCore] options or warrants, or otherwise benefitted materially from the sale of

[6] This principle is codified in the Massachusetts long-arm statute itself, which states that "[a] court may exercise personal jurisdiction over a person, *who acts directly or by an agent*, as to a cause of action in law or equity arising from" certain enumerated acts. Mass Gen. Laws. ch. 223A, § 3.

[AlphaCore] to [AstraZeneca] in secret." (*Id.* ¶ 45).

The complaint thus alleges that the individual defendants (including Auerbach) acted in concert to defraud Ward because all of them sought to profit from the sale of AlphaCore.[7] Put another way, the joint-venture theory of liability is that the individual defendants were acting in concert to injure Ward for their own personal financial gain, and that they were agents of one another in that enterprise. On its face, that allegation is not so implausible as to require dismissal. That, however, is not the standard for the exercise of personal jurisdiction.

First, a plaintiff seeking to establish personal jurisdiction may not simply rely on vague or conclusory allegations. *See Ticketmaster New York*, 26 F.3d at 203; *Boit*, 967 F.2d at 675. Here, the allegation that the physician defendants owned AlphaCore stock (or options or warrants), or otherwise stood to benefit financially from the sale of AlphaCore, is made only in conclusory terms, on information and belief, without any factual detail. Indeed, there are no specific allegations that Dr. Schaefer, Dr. Shamburek, or Dr. Remaley had any actual financial interest at all in AlphaCore, or what that interest might have been.

More importantly, a plaintiff seeking to establish personal jurisdiction under the *prima facie* test may not rely on the allegations alone, but must make a showing "based on evidence of specific facts set forth in the record." *Boit*, 967 F.2d at 675. Here, defendants have submitted an affidavit from Auerbach that states the following:

> On or about September 24, 2008, [AlphaCore's] operating agreement was amended to add financial investor members. None of the financial investor members (or any scientific working members of [AlphaCore]) live or reside in Massachusetts. None of the individual Defendants (excluding myself) sued in the Complaint – Dr. Ernest J. Schaefer ("Dr. Schaefer"), Dr. Robert M. Shamburek ("Dr. Shamburek"), and Dr. Alan T. Remaley ("Dr. Remaley") – ever were members of [AlphaCore] or, to my knowledge, ever had a personal financial

[7] The joint venture theory of liability appears to be viable, if at all, only as to the individual defendants. It is unclear, to say the least, how ACP itself could be considered a joint venturer in a scheme to profit from the sale of its stock.

> interest in the successful development of recombinant LCAT. The NIH has a right, as the patent licensor, to royalty payments under the Cardio Patent only, primarily based on commercial sales milestones of recombinant LCAT, which to date has not occurred.

(Auerbach Aff. ¶ 7). Ward has submitted no affidavits, or evidence of any kind, to the contrary.

Thus, the allegations of the complaint as to the existence of a joint venture to defraud Ward for financial gain are entirely conclusory, and the evidence that the physician-defendants had no financial interest in AlphaCore is unrebutted. Furthermore, there is no evidence that Auerbach or AlphaCore had an agency relationship of any kind with any of the individual physicians. Under the circumstances, there is an insufficient basis for the exercise of personal jurisdiction against Auerbach or ACP on a joint-venture theory.

b. <u>The Conspiracy Theory of Personal Jurisdiction</u>

Ward further contends that the defendants were engaged in a civil conspiracy and that, on that basis, the Massachusetts conduct of any of the defendants may be attributed to Auerbach and AlphaCore. Under the conspiracy theory of personal jurisdiction—which has not been adopted in this circuit, *see Glaros v. Perse*, 628 F.2d 679, 682 (1st Cir. 1980)—"a plaintiff must allege both an actionable conspiracy and a substantial act in furtherance of the conspiracy performed in the forum state." *In re Lupron Marketing and Sales Practices Litig.*, 245 F. Supp. 2d 280, 293 (D. Mass. 2003) (internal quotation marks omitted) (applying Illinois law).[8] "The theory gives this court jurisdiction only over any claims which arise from acts within the commonwealth." *Van Schaick v. Church of Scientology of Cal., Inc.*, 535 F. Supp. 1125, 1132 (D. Mass. 1982).

Taking the second requirement first, there is some evidence that acts in furtherance of the

[8] In *Glaros*, the First Circuit neither adopted nor rejected the conspiracy theory of personal jurisdiction. Rather, the court concluded that the plaintiff there had failed to adequately allege personal jurisdiction under that theory as it has been articulated by other courts, and thus declined to decide whether to adopt the theory or not. *See* 628 F.2d at 682.

alleged conspiracy were performed in Massachusetts, though it is unclear whether those acts would properly be considered "substantial." For example, it appears that, under the provisions of the treatment protocol, Dr. Schaefer monitored and treated Ward's kidney disease while he was in Massachusetts. (*See* 2d Auerbach Aff. Ex. B at 21).

However, **t**he first requirement—an allegation of an actionable conspiracy—is problematic. In a so-called "true conspiracy," the conspiracy itself is an independent tort and no other tortious act must be shown. *Fleming v. Dane*, 304 Mass. 46, 50 (1939); *Massachusetts Laborers' Health & Welfare Fund*, 62 F. Supp. 2d 236, 244 (D. Mass. 1999).[9] To rise to the level of an independent tort, the "mere force of numbers acting in unison" must "make a wrong." *Fleming*, 304 Mass. at 50.

> [I]t must be shown that there was some peculiar power of coercion of the plaintiff possessed by the defendants in combination which any individual standing in a like relation to the plaintiff would not have had. The most common illustration of such a 'conspiracy' is to be found in the combined action of groups of employers or employees, where through the power of combination pressure is created and results brought about different in kind from anything that could have been accomplished by separate individuals. . . . Outside of this and related or similar fields instances of conspiracy which is in itself an independent tort are rare and should be added to with caution.

Id. (internal quotation marks and citations omitted).

The complaint here alleges that the defendants had a "peculiar power of coercion over Mr. Ward" that "individually, they would not have had." (*See* Compl. ¶¶ 97-98). At first glance, that allegation appears to be sufficient; it is certainly plausible that defendants, acting together, exercised a "peculiar power of coercion" over Ward, given his illness and their positions as

[9] Massachusetts recognizes two forms of civil conspiracy, "so-called 'true conspiracy' and conspiracy based on section 876 of the Restatement (Second) of Torts." *Taylor v. American Chemistry Council*, 576 F.3d 16, 34 (1st Cir. 2009) (citing *Kurker v. Hill*, 44 Mass. App. Ct. 184, 188 (1998)). "True conspiracy" is itself an independent tort, while conspiracy based upon concerted action simply extends tort liability to those who assist or encourage another in the commission of a separate tort. *See Massachusetts Laborers' Health & Welfare Fund*, 62 F. Supp. 2d at 244. "[O]nly the 'true conspiracy' version defines an independent cause of action; the 'concerted action' version simply defines who may be liable for other torts." *Id.*

physicians and the licensee of what he believed to be a potentially life-saving drug.

The problem, however, is that the alleged wrong (the defrauding of Ward) was not the result of "mere force of numbers acting in unison." *Fleming*, 304 Mass. at 50. Indeed, no Massachusetts case has ever permitted a plaintiff to proceed on a civil conspiracy theory on facts remotely close to those presented here. As noted, the *Fleming* court announced in 1939 that "instances" of such conspiracies were "rare" and "should be added to with caution." 304 Mass. at 50. In the period of nearly eight decades after that opinion, the courts of Massachusetts do not appear to have found a civil conspiracy under any set of facts outside the employer-employee context. Moreover, application of civil conspiracy to a scenario such as this would lead to an enormous expansion of the tort, which the SJC clearly cautioned against in *Fleming*.

Accordingly, and under the circumstances presented here, personal-jurisdiction over Auerbach and AlphaCore cannot be supported under a civil conspiracy theory of liability.

C. Whether Jurisdictional Discovery Is Appropriate

"A diligent plaintiff who sues an out-of-state [defendant] and makes out a colorable case for the existence of [personal] jurisdiction may well be entitled to a modicum of jurisdictional discovery. . . ." *Sunview Condominium Ass'n v. Flexel Intern., Ltd.*, 116 F.3d 962, 964 (1st Cir. 1997). Whether to permit jurisdictional discovery, even when a plaintiff has made a colorable case for the existence of jurisdiction, is within the broad discretion of the court. *See Swiss Am. Bank*, 274 F.3d at 625-26.

The circumstances presented here by this case do not warrant permitting jurisdictional discovery. There is no colorable evidence of jurisdiction under either a joint-venture or civil conspiracy theory, and discovery on the basis of either theory would amount to little more than a fishing expedition. Jurisdictional discovery as to AlphaCore and Auerbach will therefore be

denied.

IV. Conclusion

For the foregoing reasons,

1. The motion of defendants MedImmune, LLC and AstraZeneca Biopharmaceuticals, Inc., to dismiss for failure to state a claim upon which relief can be granted is GRANTED.

2. The motion of defendants Bruce Auerbach and AlphaCore Pharma, LLC to dismiss for lack of personal jurisdiction is GRANTED.

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
Dated: June 23, 2017 United States District Judge