UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

The Cleveland Clinic Foundation, et al.,	)	**CASE NO. 1:15 CV 2331**
	)	
Plaintiff,	)	**JUDGE PATRICIA A. GAUGHAN**
	)	
Vs.	)	
	)	
True Health Diagnostics, LLC	)	**Memorandum of Opinion and Order**
	)	
Defendant.	)	

INTRODUCTION

This matter is before the Court upon the Motion of Defendant True Health Diagnostics LLC to Dismiss (Doc. 25). This is a patent infringement case. For the reasons that follow, the motion is GRANTED.[1]

[1] Plaintiff's request for judicial notice is GRANTED in PART and DENIED in PART. The Court will take judicial notice of the patent prosecution history excerpts and the prior art identified by plaintiff. The Court cannot, however, take judicial notice of the facts contained in the "TRO motion and its supporting papers." Simply because a particular fact is filed in a court document does not mean that it is "not subject to reasonable dispute."

FACTS[2]

Plaintiffs, The Cleveland Clinic Foundation ("CCF") and Cleveland HeartLab ("HeartLab") (CCF and Heartlab, sometimes, collectively "plaintiff") filed this lawsuit against defendant, True Health Diagnostics. In 2003, researchers at CCF developed a test that assesses a patient's risk for cardiovascular disease ("CVD"). The test, called Myeloperoxidase or "MPO" testing, analyzes inflammation of the blood vessels. MPO is an enzyme released by white blood cells when inflammation occurs in the body. When an artery wall is damaged or becomes inflamed, MPO is released into the blood stream in an effort to kill bacteria. Thus, MPO is an early symptom of many types of CVD.

CCF filed a series of patent applications relating to MPO. The Patent and Trademark Office ("PTO") granted CCF's applications, and it is currently the owner of the four patents at issue in this lawsuit: U.S. Patent No. 7,223,552 ("the '552 patent"); U.S. Patent No. 7,459,286 ("the '286 patent"); U.S. Patent No. 8,349,581 ("the '581 patent"); and U.S. Patent No. 9,170,260 ("the '260 patent"). The '552 patent, which issued on May 29, 2007, has since been the subject of validity challenges by competitors in two reexamination proceedings before the PTO. The '552 patent was confirmed valid in both proceedings, most recently in 2011.

The '552 patent, '286 patent, and '581 patent teach a method of analyzing MPO biomarkers in a patient's blood sample[3] to predict a patient's potential for CVD. They do so by

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[2] Although the factual recitation contains some citations to materials that are outside the scope of the Complaint, those citations are for background purposes only and are not relied on by the Court in assessing defendant's motion to dismiss.

[3] For ease of reference, the Court uses the phrase "blood" or "blood sample" to include "blood, serum, plasma, blood leukocytes selected from the group

comparing the level of MPO found in the patient's blood sample with levels of MPO in control subjects to see if the patient has elevated levels of MPO. The '552 patent does so with regard to a typical patient, while the '286 patent and the '581 patent are directed at patients presenting with chest pain.

The '260 patent issued after the filing of this lawsuit. Plaintiff filed an amended complaint to add a claim of infringement regarding this newly issued patent. The '260 patent teaches a method for administering a lipid lowering agent based on elevated levels of MPO. In addition, the amended complaint added a claim for infringement of U.S. Patent No. 9,164,095 ("the '095 patent"), which also issued after the filing of this lawsuit.

Shortly after filing the amended complaint, plaintiff voluntarily dismissed count four, which asserted infringement based on the '095 patent. Each of the four remaining claims assert a claim for infringement for each of the remaining patents. The Court previously denied plaintiff's motion for a temporary restraining order and preliminary injunction. Defendant now moves to dismiss this lawsuit and plaintiff opposes the motion.

STANDARD OF REVIEW

When considering a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, the allegations of the complaint must be taken as true and construed liberally in favor of the plaintiff. *Lawrence v. Chancery Court of Tenn.,* 188 F.3d 687, 691 (6th Cir. 1999). Notice pleading requires only that the defendant be given "fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Conley,* 355 U.S. at 47. However, the complaint

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consisting of neutrophils, monocytes, subpopulations of neutrophils, and subpopulations of monocytes, or any combination thereon."

must set forth "more than the bare assertion of legal conclusions." *Allard v. Weitzman* (*In Re DeLorean Motor Co.*), 991 F.2d 1236, 1240 (6th Cir. 1993). Legal conclusions and unwarranted factual inferences are not accepted as true, nor are mere conclusions afforded liberal Rule 12(b)(6) review. *Fingers v. Jackson-Madison County General Hospital District*, 101 F.3d 702 (6th Cir. Nov. 21, 1996), *unpublished*. Dismissal is proper if the complaint lacks an allegation regarding a required element necessary to obtain relief. *Craighead v. E.F. Hutton & Co.*, 899 F.2d 485, 489-490 (6th Cir. 1990).

In addition, a claimant must provide "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 569 (2007). A pleading that offers "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1955 (2009). Nor does a complaint suffice if it tenders "naked assertion[s]" devoid of "further factual enhancement." *Id.*

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it stops short of the line between possibility and plausibility of 'entitlement to relief.'

Id. at 1949 (citations and quotations omitted). *See also, Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603 (6th Cir.2009).

ANALYSIS

1. Preliminary issues

A. Timing and burden of proof

As an initial matter, the Court finds that it is procedurally proper to address defendant's

arguments concerning invalidity based on patent-eligibility at the 12(b)(6) stage. *See, Content Extraction and Transmission, LLC v. Wells Fargo National Bank Association*, 776 F.3d 1343 (Fed. Cir. 2014). In addressing defendant's arguments, the Court will presume that the patents are valid and grant the motion only if defendant is able to show invalidity by clear and convincing evidence. Although post-*Alice* courts appear to call into question whether a presumption of validity applies in this context, the Court will nonetheless apply the presumption.

The Court rejects plaintiff's argument that the Court cannot address these issues before claim construction. *See, Cyberfone Sys. LLC v. CNN Interactive Group, Inc.*, 558 Fed. Appx. 988, 991 n.1 (Fed. Cir. 2014). For purposes of this motion, defendant indicates that it is willing to accept plaintiff's proposed claim construction. In connection with its motion for temporary restraining order and preliminary injunction, plaintiff argued to the Court that "[e]xcept for "MPO Activity" and "MPO Mass," all of the claim terms should simply be afforded their plain and ordinary meaning." In its brief in opposition to the instant motion, plaintiff indicates that it is *now* apparent that additional terms need construction. Those terms include "immunological technique," "comparing levels," and "determining levels." Yet, plaintiff offers no proposed construction for these terms. Defendant has stipulated for purposes of this motion to plaintiff's proposed claim construction, yet plaintiff offers none with regard to these terms. Plaintiff's failure will not serve to block the Court from considering defendant's motion. Otherwise, a plaintiff could prevent dismissal before claim construction simply by noting without explanation that claim construction is "necessary." The Court rejects any such rule.

B. Representative claims

The Court further rejects plaintiff's argument that the Court must address each claim in each patent separately. Defendant argues that claims 11, 14, and 15 of the '552 patent are representative of the remaining claims. Similarly, defendant argues that claims 21 and 22 are representative of the claims in the '286 patent and claim 5 is representative of the claims in the '581 patent. Defendant notes that with the exception of claim 14 of the '552 patent, plaintiff's motion for temporary restraining order and preliminary injunction was based solely on these claims. Moreover, plaintiff fails to point out any claim that is not represented by the aforementioned claims. Rather, plaintiff simply argues:

> Importantly in this regard, no one asserted claim is representative of the others. Some claims require "determining levels" while others claim "comparing levels." Some of the dependent claims contain limitations, *e.g.*, "immunological technique," that further ground those claims as patentable subject matter. These limitations each add additional inventive matter, and thus must each be separately considered.

As defendant notes, however, the representative claims do include the "determining" and "comparing" limitations referenced by plaintiff. Moreover, to the extent dependent claims 7 and 23 contain the "immunological technique,[4]" the Court will address the limitation below. As such, the Court finds that the claims identified by defendant are representative of the claims in the patents in suit.

C. Claim language

Claims 11, 14, and 15 in the '552 patent provide as follows:

> 11. A method for assessing a test subject's risk of having atherosclerotic cardiovascular disease, comprising:

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[4] Plaintiff notes in its motion that claim 18 contains the "immunological technique" limitation. (Doc. 30 at p. 5). No such limitation appears in claim 18.

comparing levels of myeloperoxidase in a bodily sample from the test subject with levels of myeloperoxidase in comparable bodily samples from control subjects diagnosed as not having the disease, said bodily sample being blood, serum, plasma, blood leukocytes selected from the group consisting of neutrophils, monocytes, subpopulations of neutrophils, and subpopulations of monocytes, or any combination thereon;

wherein elevated levels of myeloperoxidase in the bodily sample from the test subject relative to the levels of myeloperoxidase in the comparable bodily samples from control subjects is indicative of the extent of the test subject's risk of having atherosclerotic cardiovascular disease.

14. A method of assessing a test subject's risk of developing a complication of atherosclerotic cardiovascular disease, comprising:

determining levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or both in a bodily sample of the test subject, said bodily sample being blood, serum, plasma, blood leukocytes selected from the group consisting of neutrophils and monocytes, or any combination thereof;

wherein elevated levels of MPO activity or MPO mass or both in the subject's bodily sample as compared to levels of MPO activity, MPO mass or both, respectively, in comparable bodily samples obtained from control subjects diagnosed as not having the disease indicates that the test subject is at risk of developing a complication of atherosclerotic cardiovascular disease.

15. The method of claim 14, wherein the test subject's risk of developing a complication of atherosclerotic cardiovascular disease is determined by comparing levels of myeloperoxidase mass in the test subject's bodily sample to levels of myeloperoxidase mass in comparable samples obtained from the control subjects.

Claims 21 and 22 of the '286 patent provide as follows:

21. A method of assessing the risk of requiring medical intervention in a patient who is presenting with chest comprising

characterizing the levels of myeloperoxidase activity, myeloperoxidase mass, or both, respectively in the bodily sample from the human patient, wherein said bodily sample is blood or a blood derivative,

wherein a patient whose levels of myeloperoxidase activity, myeloperoxidase mass, or both is characterized as being elevated in comparison to levels of myeloperoxidase activity, myeloperoxidase mass or both in a comparable bodily samples obtained from individuals in a control population is at risk of requiring

medical intervention to prevent the occurrence of an adverse cardiac event within the next six months.

22. A method of determining whether a patient who presents with chest pain is at risk of requiring medical intervention to prevent an adverse cardiac event within the next six months comprising:

comparing the level of a risk predictor in a bodily sample from the subject with a value that is based on the level of said risk predictor in comparable samples from a control population, wherein said risk predictor is myeloperoxidase activity, myeloperoxidase mass, a myeloperoxidase-generated oxidation product, or any combination thereof, and wherein said bodily sample is blood, serum, plasma, or urine,

wherein a subject whose bodily sample contains elevated levels of said risk predictor as compared to the control value is at risk of requiring medical intervention to prevent an adverse cardiac event within 6 months of presenting with chest pain, and

wherein the difference between the level of the risk predictor in the patient's bodily sample and the level of the risk predictor in a comparable bodily sample from the control population establishes the extent of the risk to the subject of requiring medical intervention to prevent an adverse cardiac event within the next six months.

Claim 5 of the ’581 patent provides as follows:

5. A method of determining whether a patient who presents with chest pain is at risk of requiring medical intervention to prevent an adverse cardiac event within the next six months comprising:

determining the level of risk predictor in a bodily sample from the subject, wherein said risk preddictor is myeloperoxidase activity, myeloperoxidase mass, a myeloperoxidase (MPO)-generated oxidation product or any combination thereof,

wherein said bodily sample is blood, serum, plasma or urine,

wherein said myeloperoxidase-generated oxidation product is nitrotyrosine or a myeloperoxidase-generated lipid peroxidation product selected from [list of products]...or any combination thereof, and

comparing the level of said risk predictor in the bodily sample of the patient to the level of said risk predictor in comparable samples obtained from a control population,

wherein a subject whose bodily sample contains elevated levels of said risk predictor as compared to the control value is at risk of requiring medical intervention to prevent an adverse cardiac event within 6 months of presenting with chest pain.

2. Invalidity

Defendant argues that three of the four remaining patents in this lawsuit are invalid. According to defendants, the ’552 patent, the ’286 patent, and the ’581 patent are invalid for ineligible subject matter. According to defendant, these patents are directed at a law of nature and contain no inventive step. Plaintiff disagrees.

Pursuant to 35 U.S.C. § 101, [w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore....” Section 101 is limited, however, and does not cover “laws of nature, natural phenomena, and abstract ideas.” *Alice Corp. Pty. Ltd v. CLS Bank International*, 134 S.Ct. 2347, 2354 (2014). In “applying the § 101 exception, we must distinguish between patents that claim the ‘building block[s]’ of human ingenuity and those that integrate the building blocks into something more.” *Id*. (*citing Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289, 1303 (2012)).

In *Alice*, the Supreme Court employed a two-part test “for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.” *Id*. at 2355. Courts must tread carefully because “at some level, all inventions...embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” *Id*. at 2354. First, the court must determine “whether the claims at issue are directed at a patent-ineligible concept.” If the claims are so directed, the Court must proceed to step two, which involves a determination as to whether the patent contains an “inventive

concept," which is described as "an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." *Id*. (Internal citations and quotations omitted).

In *Mayo*, the Supreme Court addressed the validity of a patent designed to "help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high." 132 S.Ct. at 1294. Specifically, the patent described a process of evaluating the safety of the concentrations of a particular metabolite in a person's blood. The Federal Circuit determined that in addition to the natural correlations, the patent claimed specific steps of administering a thiopourine drug and determining the resulting metabolite level. As such, the Federal Circuit determined that the patent was directed at patent-eligible subject matter. The Supreme Court reversed, finding:

> To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.

Id. at 1298.

With regard to the first prong of the *Alice* test, the Court finds that the patents at issue are directed at a law of nature. Defendant claims that the patents recite the relationship between MPO levels in the bloodstream and the risk of having or developing CVD. Plaintiff does not respond to this argument. Upon review, the Court agrees with the defendant that the patents at issue are directed at a natural law, *i.e.*, the correlation between MPO in the blood and the risk of CVD.

The second step in the *Alice* test requires the Court to determine whether the patents contain an "inventive concept," which is described as "an element or combination of elements

that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." Upon review, the Court finds that the patents do not satisfy step two.

The '552 patent and the '581 patent contain a "determining" step. That step, however, simply calls for determining the MPO mass or activity level from the blood sample by whatever method the user chooses. As defendant notes, a myriad of methods well-known in the art existed at the time of invention. The patents themselves acknowledge that such well-known techniques existed. *See, e.g.*, '552 patent, col. 8:32-33 ("[MPO] activity may be determined by any of a variety of standard methods known in the art.") Thus, the "determining" step does not add an inventive concept.

Similarly, the "comparing" step is insufficient to satisfy the *Alice* test. As an initial matter, this step involves a mental process, which does not add an inventive step. This step simply requires comparing the MPO mass or activity level in the test subject to the level in a control population. The control samples are in turn derived from basic statistical techniques and can vary in form. *See, e.g.*, '552 patent, col. 21:11-29. The Court finds that this step does not add an inventive concept. *See, PerkinElmer, Inc. v. Intema Ltd.*, 496 Fed. Appx. 65 (2012)("comparing" step is an ineligible mental process where the statistical information was well-understood, conventional information).

Furthermore, looking at the claims as a whole, the steps in combination do not make the ineligible mental steps and natural law patent-eligible.[5] Here, like the claims at issue in

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[5] The Court has reviewed each of the representative patent claims in all three of the patents. Each claim, however, contains no step or combination of steps that contain an inventive element. Rather, all

PerkinElmer, do not require that a doctor act on any risk. Rather, the steps in combination simply instruct a user to apply a natural law, *i.e.*, that an increase in MPO mass or MPO activity in a blood sample correlates to an increase in CVD risk.

Plaintiff argues that the prosecution history shows that the patents-in-suit claim a non-routine way of measuring and using MPO to achieve a new and useful result. According to plaintiff, it invented a specific way to "see" MPO. Rather than rely on the myeloperoxidase intracelleular index ("MPXI"), plaintiff's patents allow for "new measurement" techniques, namely using "MPO mass" and "MPO activity" to detect CVD. Upon review, the Court disagrees. As defendant notes, plaintiff defines "MPO activity" to mean "that a substrate is provided to assess the enzymatic activity of the MPO." Similarly, "MPO mass" means the amount of MPO molecules in a sample, measured, for example, in picomoles per liter (pmol/L)." In other words, these terms refer to naturally occurring measurements, *i.e.*, enzymatic activity level and amount of MPO molecules. Thus, even assuming plaintiff was the first to discover that the amount of MPO molecules in blood or the enzymatic activity level in the MPO can be correlated to CVD, this does not amount to an "inventive" step.[6] As noted in *Association for Molecular Pathology v. Myriad Genetics*, 133 S.Ct. 2107 (2013), " [g]roundbreaking,

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representative claims contain combinations of the "comparing" or "determining" limitations that, when read in combination, do not amount to an inventive concept.

[6] Defendant argues that the prior art shows that, contrary to plaintiff's position, it was *not* the first to look at MPO mass in the blood. Defendant appears correct in this regard. The United States Patent Office ("USPTO") rejected certain claims in the '552 patent as being anticipated by Minota, which "teaches detecting MPO mass in blood from vasculitis patients."

innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." Thus, even though plaintiff may have been the first to "see" MPO by looking at the amount of MPO molecules and/or the enzymatic activity level, these values are naturally occurring and their discovery does not render the patents eligible under § 101. *Id.* ("Discovering important and useful gene and separating it from its surrounding genetic material is not an act of invention."). *See also, Ariosa Diagnostics, Inc v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015)(as it is undisputed that cffDNA is naturally located in maternal blood, the fact that plaintiffs were the first to "see" it does not in and of itself satisfy § 101).

Plaintiff repeatedly argues that the PTO issued the patents and, therefore, they must contain an inventive concept. Plaintiff points out that the '552 patent was reexamined twice and the PTO determined that measuring MPO with MPXI was the prior conventional approach for detecting MPO and that the '552 patent claims "non-routine techniques that could measure MPO in a different way." For the aforementioned reasons, the Court rejects plaintiff's argument. The fact that the PTO issued the patent is not sufficient, standing alone, to satisfy § 101. All of the patents challenged in invalidity proceedings were issued by the PTO and presumably the PTO found them "different from" and "improvements over" prior art. Plaintiff points to nothing in the prosecution history showing that the PTO addressed § 101.

Plaintiff also argues that certain dependent claims contain an inventive step because they call for the use of an "immunological technique." (*See, e.g.*, claims 7 and 23 of the '552 patent) Plaintiff initially argues that this term requires construction, yet provides the Court with no proposed construction. As set forth above, plaintiff's failure in this regard will not prevent the Court from addressing defendant's motion to dismiss. Nor does plaintiff provide any specific

argument as to why the inclusion of an "immunological technique" satisfies § 101. On the other hand, defendant argues that this limitation does not amount either singularly or in combination with other limitations to an inventive concept because it simply instructs that the levels of MPO mass are "determined by an immunological technique." The Court agrees with defendant that this does not add an inventive step. The patent identifies that one type of immunological technique is ELISA and "commercial kits for MPO quantification are available." *See*, '552 patent col. 9:30-33. Regardless, in the face of defendant's position to the contrary, plaintiff offers no argument as to why the inclusion of an "immunological technique" satisfies § 101. Accordingly, any such argument is rejected.[7]

Plaintiff argues that the patent satisfies § 101 because it does not preempt the entire field since it does not foreclose the use of other current or future MPO measuring techniques. The argument is rejected. *See, Ariosa Diagnostics*, 788 F.3d at 1379 ("Where a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot.").

3. Sufficiency of the allegations

In count five, plaintiff asserts a claim for indirect infringement of the '260 patent. Defendant argues that count five fails to state a claim for indirect infringement based on either contributory or induced infringement. In response, plaintiff argues that the allegations are sufficient and, in the alternative, requests leave to amend the claim.

A. Contributory infringement

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[7] To the extent plaintiff argues that the patent requires use of a "new" testing kit, the argument is rejected. Nowhere in the claim language does the patent require use of any particular "new" kit.

Upon review, the Court finds that the complaint fails to state a claim for contributory infringement under 35 U.S.C. § 271(c). "Contributory infringement occurs if a party sells or offers to sell, a material or apparatus for use in practicing a patented process, and that 'material or apparatus' is material to practicing the invention, has no substantial non-infringing uses, and is known by the party to be especially made or especially adapted for use in an infringement of such patent." *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1337 (Fed.Cir.2012). "Under the plain language of the statute, a person who provides a service that assists another in committing patent infringement may be subject to liability under section 271(b) for active inducement of infringement, but not under section 271(c) for contributory infringement." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1357 (Fed. Cir. 2007).

The Court agrees with defendant that the complaint does not state a claim for contributory infringement because plaintiff fails to identify any "material or apparatus" sold by defendant. Plaintiff argues that it identifies and attaches to its complaint five lab-reports, which plaintiff claims constitute a "material or apparatus" for purposes of 35 U.S.C. § 271(c). The Court disagrees. To the contrary, plaintiff expressly alleges that defendant purchases (as opposed to sells) the MPO testing kits. (Doc. 20 at ¶ 30). Plaintiff further alleges that defendant infringes by "using MPO test kits and performing and/or selling MPO testing services." (Doc. 20 at ¶¶ 39, 45). At best, the lab reports attached to the complaint reflect the manner in which defendant reports the results of the service it provides. The Court finds that, based on the allegations in the complaint, the lab reports do not constitute a "material or apparatus" for purposes of a contributory infringement claim. Having failed to allege this element of the claim,

the Court agrees with defendant that dismissal is warranted.

B. Induced infringement

> Under section 271(b), whoever actively induces infringement of a patent shall be liable as an infringer. To establish liability under section 271(b), a patent holder must prove that once the defendants knew of the patent, they actively and knowingly aided and abetted another's direct infringement. However, knowledge of the acts alleged to constitute infringement is not enough. The mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven.

DSU Medical Corp. v. JMS Co. Ltd., 471 F.3d 1293 (Fed. Cir. 2006)(internal citations and quotations omitted). Here, defendant argues that plaintiff fails to state a claim for induced infringement because there are no facts supporting plaintiff's bare allegations that defendant "intended that its actions would induce direct infringement by others" or that defendant "knew or should have known that its actions would induce direct infringement by others."

In response, plaintiff argues that the complaint sufficiently alleges that defendant had knowledge of the '260 patent. According to plaintiff, defendant purchased some of the assets of Health Diagnostics Lab ("HDL") in a bankruptcy proceeding. In its bid for HDL's assets, defendant sought HDL's customer list, including HDL's MPO testing customers, but expressly excluded HDL's Laboratory Services Agreement with HeartLab. Thereafter, HeartLab's CEO emailed defendant on September 14, 2015, to advise defendant regarding the patents. The letter provides as follows:

> We understand that you intend on rejecting our contract as part of the conclusion of your asset purchase, however please be advised that although the terms of our agreement may be rejected, our intellectual property rights are not something that can be rejected in a bankruptcy or 363 asset sale process. For background, many of our patents are referenced in Section 7 of our LSA that is referenced in the attached letter. There are multiple issued patents on MPO in our patent family as well as additional patents pending and this IP has been successfully defended multiple times in re-examination. It is also important to know that these are Cleveland Clinic patents and they have an obligation to

protect them.

This email was sent before the ’260 patent issued. Plaintiff also points out that the Laboratory Services Agreement identified the ’799 application, which plaintiff claims became the ’260 patent. Plaintiff further notes that in the context of this litigation, defense counsel acknowledged investigating the ’381 application, which is a continuation of the ’799 application. Therefore, plaintiff claims that the allegations in the complaint are sufficient to meet the knowledge requirement.

The Court finds that assuming *arguendo* that the aforementioned allegations are sufficient to meet the pleading requirements with regard to the knowledge of the ’260 patent, the Court finds that the complaint nonetheless fails to sufficiently allege a claim for induced infringement. As defendant notes, *in addition* to knowledge, plaintiff must allege sufficient factual support to meet the specific intent element:

> Beyond that threshold knowledge, the inducer must have an affirmative intent to cause direct infringement. ...[I]nducement requires that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement. Accordingly, inducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities.”

DSU Medical Corp., 471 F.3d at 306. (Citations and quotations omitted). Moreover, “mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven.” *Id*. at 1305.

Here, plaintiff does not respond to defendant’s argument that the complaint fails to allege facts sufficient to show the specific intent to induce a third-party to infringe. The ’260 patent is a method patent directed at “administering a lipid lowering agent to a human patient based on elevated levels of [MPO] mass and/or activity comprising...” Thus, in generic terms, the third-

party direct infringer must administer a lipid lowering agent based on elevated levels of MPO in order to infringe the ’260 patent. Although the complaint is devoid of any factual allegations regarding the relationship between defendant and these “third party infringers,” it appears to the Court that the third-party infringers are the doctors that order the testing. Thus, in order to be liable, plaintiff must sufficiently allege that defendant specifically intends to induce doctors to administer a lipid lowering agent based on elevated levels of MPO. The complaint is completely devoid of any factual allegations supporting this theory. In fact, the complaint contains no allegations even generally describing defendant’s alleged role in the infringement of the ’260 patent or any manner in which defendant induces such infringement.[8] As such, the Court finds that plaintiff does not allege sufficient facts to satisfy the specific intent element of an inducement claim. Having concluded that plaintiff fails in this regard, the Court need not reach whether plaintiff adequately alleges an act of direct infringement.

The Court notes that plaintiff alternatively seeks leave to amend its complaint in the event the claim is dismissed. The Court denies plaintiff’s request. *PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 699 (6th Cir. 2004).

CONCLUSION

For the foregoing reasons, the Motion of Defendant True Health Diagnostics LLC to Dismiss (Doc. 25) is GRANTED.

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[8] To infringe the ’260 patent, the infringer must perform an “enzyme linked immunosorbent assay (ELISA).” Defendant claims that it does not measure MPO mass or activity in this fashion. The Court notes that it is not accepting defendant’s statement as true for purposes of this motion. Rather, the Court simply notes that plaintiff wholly fails to describe or identify defendant’s role in the alleged “inducement” of any infringement of the ’ 260 patent.

IT IS SO ORDERED.

/s/ Patricia A. Gaughan
PATRICIA A. GAUGHAN
United States District Judge

Dated: 2/23/16