IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

ERESEARCHTECHNOLOGY, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 15-918
	)	Hon. Nora Barry Fischer
CRF, INC, d/b/a CRF HEALTH	)	
	)	
Defendant.	)	
	)	
	)	
	)	
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MEMORANDUM OPINION

I. Introduction

Plaintiff eResearchTechnology, Inc. ("ERT") filed suit against Defendant CRF, Inc., d/b/a CRF Health ("CRF") on July 15, 2015, and filed an amended complaint on October 22, 2015, alleging that CRF's products infringe five of Plaintiff's patents.[1] (Docket Nos. 1, 18). Presently before the Court is Defendant's Motion to Dismiss, Pursuant to Rule 12(b)(6) and related brief, (Docket Nos. 24–25), Plaintiff's response thereto, (Docket No. 29), Defendant's Reply, (Docket No. 34), and Plaintiff's Sur-Reply, (Docket No. 35). The Court has also had the benefit of hearing and oral argument which occurred on January 29, 2016 and March 10, 2016. (Docket Nos. 36, 38). For the following reasons, Defendant's Motion to Dismiss, Pursuant to Rule 12(b)(6) [24] is GRANTED.

[1] Plaintiff asserts Patent Nos. 8,065,180 (the '180 Patent); 8,145,519 (the '519 Patent); 8,433,605 (the '605 Patent); 6,879,970 (the '970 Patent); and 7,415,447 (the '447 Patent) against the Defendant. (Docket No. 18-1 to 18-5).

II. **Background**

Plaintiff ERT is a Delaware corporation with its principal place of business in Pittsburgh, and is a leading cloud platform solutions provider for clinical trials. (Docket No. 18 at 2). ERT advertises that its services and products improve the accuracy and reliability of patient data within the clinical drug trial process. (Docket No. 29 at 1). Defendant CRF is likewise a Delaware corporation, but with a principal place of business in Plymouth Meeting, Pennsylvania. (Docket No. 18 at 2). CRF competes with ERT, and similarly provides mobile technology and services in the clinical trial space. (Docket No. 29 at 1–2).

Participant noncompliance with clinical drug trials is expensive and problematic for pharmaceutical companies trying to navigate the drug approval process. (*See* Docket No. 18-1 at 1:23–48). In the past, trial participants were given paper-based diaries to record their medical information during the course of a clinical trial, but that method of collecting data proved error prone. (*Id.*). Additionally, evaluating participant compliance using the paper-based diaries itself was complicated. (*Id.*). In response, clinical drug trial companies like ERT and CRF started offering electronic solutions to help pharmaceutical companies better record and analyze trial participant data. (*See* Docket No. 29-2; *also* CRF Health (last visited May 6, 2016) http://www.crfhealth.com/platform/; *PRO eCOA Scientific Services*, ERT (last visited May 6, 2016) https://www.ert.com/ecoa/pro-ecoa-scientific-services/). The benefits of using an electronic system appear to be substantial both in terms of cost-savings and increasing the quality of the clinical drug trial process. (*See* Docket No. 29-2). Accordingly, both parties have a strong incentive to police their intellectual property assets; hence, Plaintiff filed the instant lawsuit.

Plaintiff is the owner of the five patents-in-suit, *i.e.*, the ’180, ’519, ’605, ’970, and the ’447 Patents, which are collectively directed to improving clinical trials. (Docket No. 18 at ¶ 2).

Plaintiff asserts that Defendant infringes its patents, and particularly accuses Defendant of infringing them, both directly and indirectly, by way of providing and inducing others to use Defendant's "'eCOA' solution."[2] (Docket No. 18 at ¶ 20).

In the instant motion to dismiss, Defendant contends that Plaintiff's patents are not patent-eligible, and thus, Defendant cannot be found liable for infringement. (Docket No. 24). Plaintiff counters by arguing that its patents are patent-eligible and that Defendant has infringed same. (Docket No. 29).

III. Procedural Posture

Plaintiff initiated this lawsuit against Defendant on July 15, 2015, alleging that the Defendant infringed the '180, '519, and '605 Patents. (Docket No. 1). Shortly thereafter, Plaintiff filed an amended complaint, asserting the '970 and '447 Patents as well. (Docket No. 18). Defendant filed the instant Motion to Dismiss on November 5, 2015, (Docket No. 24), and the parties briefed same. (Docket Nos. 25, 29, 34, 35). As noted, the Court conducted Motion Hearings. (Docket Nos. 36, 38). Hence, the matter is now ripe for disposition.

IV. Legal Standard[3]

When reviewing a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the

[2] Plaintiff defines Defendant's allegedly infringing product as "at least the eCOA solution, alone, in combination, or parts thereof; the parts of the eCOA solution including, but not limited to, the TrialMax Touch, TrialMax Slate, TrialMax Web, TrialMax App, TrialStudio, asma-1 PEF meter, MyGlucoHealth wirelessmeter, TrialManager, TrialMax Synapse, Project Management, Collaborative Design, Data Management, and Data Collection Networks." (Docket No. 18 at ¶20).

[3] The Court applies the legal standard articulated by the Court of Appeals for the Third Circuit when deciding this motion. *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 713 (Fed. Cir. 2014) ("We review a district court's dismissal for failure to state a claim under the law of the regional circuit in which the district court sits.").

complaint, the plaintiff may be entitled to relief." *Eid v. Thompson,* 740 F.3d 118, 122 (3d Cir. 2014) (quoting *Phillips v. Cnty of Allegheny,* 515 F.3d 224, 233 (3d Cir. 2008)). A pleading party need not establish the elements of a *prima facie* case at this stage; the party must only "put forth allegations that 'raise a reasonable expectation that discovery will reveal evidence of the necessary element[s].'" *Fowler v. UPMC Shadyside,* 578 F.3d 203, 213 (3d Cir. 2009) (quoting *Graff v. Subbiah Cardiology Associates, Ltd.,* 2008 WL 2312671 (W.D. Pa. June 4, 2008)); *see also Connelly v. Lane Const. Corp.*, 809 F.3d 780, 790 (3d Cir. 2016) ("Although a reviewing court now affirmatively disregards a pleading's legal conclusions, it must still . . . assume all remaining factual allegations to be true, construe those truths in the light most favorable to the plaintiff, and then draw all reasonable inferences from them.") (citing *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 154 n.1 (3d Cir. 2014)).

Nonetheless, a court need not credit bald assertions, unwarranted inferences, or legal conclusions cast in the form of factual averments. *Morse v. Lower Merion School District,* 132 F.3d 902, 906, n.8 (3d Cir. 1997). The primary question in deciding a motion to dismiss is not whether the Plaintiff will ultimately prevail, but rather whether he or she is entitled to offer evidence to establish the facts alleged in the complaint. *Maio v. Aetna,* 221 F.3d 472, 482 (3d Cir. 2000). The purpose of a motion to dismiss is to "streamline [ ] litigation by dispensing with needless discovery and factfinding." *Neitzke v. Williams,* 490 U.S. 319, 326–327 (1989).

A patent case may be dismissed based on a lack of patent-eligibility,[4] under 35 U.S.C. § 101. *See e.g., Genetic Techs. Ltd. v. Merial L.L.C.*, 2016 U.S. App. LEXIS 6407 (Fed. Cir. Apr. 8, 2016) (affirming motion to dismiss based on 35 U.S.C. § 101).

[4] There is some dispute regarding what standard of review should be applied to motions to dismiss for lack of patent-eligibility. *Intellectual Ventures I LLC v. Erie Indem. Co.*, 2015 U.S. Dist. LEXIS 129153, at *51-53, n.37 (W.D. Pa. Sept. 25, 2015) (noting differing views regarding standard of review). This Court will accept all well-

Title 35, United States Code Section 101, recites:

> Whoever 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 therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101. Despite the broad statutory language, "[l]aws of nature, natural phenomena, and abstract ideas are not patent-eligible." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) (quoting *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, ___, 133 S. Ct. 2107, 2116 (2013)). The aforementioned exceptions are deemed unpatentable because otherwise one could "pre-empt" an entire field by monopolizing fundamental building blocks related thereto. *See Alice*, 134 S. Ct. at 2347; *Bilski v. Kappos*, 561 U.S. 593, 610 (2010) ("A contrary holding 'would wholly preempt the mathematical formula and in practical effect would be a patent on the algorithm itself.'") (quoting *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972)). Further, such pre-emption "might tend to impede innovation more than it would tend to promote it, thereby thwarting the primary object of the patent laws." *Alice*, 134 S. Ct. at 2354 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012)); *see* U.S. CONST., Art. I, § 8, cl. 8 (Congress "shall have Power . . . To promote the Progress of Science and useful Arts") (internal quotations omitted). Courts, however, must distinguish between patents that attempt to claim the "building blocks of human ingenuity," and those that use said building blocks to create something more, thereby transforming them into patent eligible inventions. *Alice*, 134 S. Ct. at 2354 (citing *Mayo*, 132 S. Ct. at 1303).

With the forgoing in mind, the Supreme Court has set out a two-part test for distinguishing whether a patent claims patent-ineligible subject matter. First, a court must

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pleaded facts as true, but give no deference to legal conclusions. *Id.* ("Assessing a complaint at the Motion to Dismiss stage requires courts to accept all 'well-pleaded facts as true,' but legal conclusions warrant no deference.") (quoting *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-211 (3d Cir. Pa. 2009)).

determine "whether the claims at issue are directed to one of those patent-ineligible concepts." *Id.* If the court determines that a patent is so directed, then as a second step it must ask "what else is there in the claims before [the court]." *Id.* To answer the question in the second step, the court must consider "the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent eligible application." *Id.* The second step of the analysis is "a search for an inventive concept—*i.e.*, 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.* at 2355.

V. Discussion

A. Procedural Considerations

Plaintiff initially objects to the Court evaluating Defendant's motion to dismiss, asserting that the Court cannot rule on the motion without engaging in claim construction, and that the Court cannot use representative claims to consider the patent-eligibility of the patents-in-suit. (Docket No. 29 at 1).

1) Claim Construction

Plaintiff's argument that claim construction is necessary prior to resolving Defendant's motion is unpersuasive. Although claim construction is sometimes desirable, it is not necessary. *See Intellectual Ventures I LLC v. Erie Indem. Co.*, 2015 U.S. Dist. LEXIS 129153, at *86 ("[T]he Federal Circuit seems to have concluded that claim construction is desirable, unless in reviewing the patents at issue, a district court concludes that it isn't."); *Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Canada (U.S.)*, 687 F.3d 1266, 1273–74 (Fed. Cir. 2012); *Content Extraction & Transmission LLC v. Wells Fargo Bank, N.A.*, 776 F.3d 1343, 1349 (Fed. Cir. 2014) ("[C]laim construction is not an inviolable prerequisite to a validity determination under §

101."). If the basic character of the subject matter is readily ascertainable, the terms are defined within the patent itself, or they are synonyms to well-known concepts, the Court does not need to engage in claim construction prior to deciding the issue of patentability. *Intellectual Ventures I LLC v. Erie Indem. Co.*, 2015 U.S. Dist. LEXIS 129153, at *86 (citing *MicroStrategy Inc. v. Apttus Corp.*, 118 F. Supp. 3d 888, 891 n.4 (E.D. Va. 2015) ("Claim construction is not necessary to dismiss patent claims at the 12(b)(6) stage or on a 12(c) motion.")). If there are any "factual disputes" during the course of the Court's analysis at the motion to dismiss stage, the Court can remedy same by resolving any such disputes in Plaintiff's favor. *Intellectual Ventures I LLC v. Erie Indem. Co.*, 2015 U.S. Dist. LEXIS 129153, at *85 (citing *Content Extraction*, 776 F.3d at 1349).

If a party asserts that claim construction is needed, it should (1) identify for the Court claims that need to be construed, and (2) explain how construction of such terms could affect the Court's analysis. *CyberFone Sys., LLC v. CNN Interactive Group, Inc.*, 558 Fed. App'x 988, 991 n.1 (Fed. Cir. 2014) ("*CyberFone* argues that claim construction must precede the § 101 analysis, but does not explain which terms require construction or how the analysis would change. It merely points to claim language that we consider here. There is no requirement that the district court engage in claim construction before deciding § 101 eligibility."); *Intellectual Ventures I LLC v. Erie Indem. Co.*, 2015 U.S. Dist. LEXIS 129153, at *88 ("Plaintiffs had ample time in their extensive briefing and during the marathon oral argument to the Court to identify any claim terms they believed required construction *and* to then proffer preferred constructions to the Court. They did not do that. While Plaintiffs have generally referenced terms that they thought may require construction, they have not proffered any proposed constructions or explained how

any proposed construction would affect the analysis.") (citing *CyberFone*, 558 Fed. App'x at 991 n.1) (emphasis in original).

Plaintiff argues that claim construction is necessary in this case, "to obtain a full understanding of the basic character of the claimed subject matter." (Docket No. 29 at 5). Plaintiff has identified two terms, "decision rule" from the '180 Patent, and "Evaluability data categories," from the '519 and '605 Patents, to prove that claim construction must occur prior to the Court's § 101 analysis. (*Id.* at 5). Yet, Plaintiff has not explained to the Court how construction of those terms would alter the Court's § 101 analysis. A conclusory recitation that claim construction is necessary for the Court to fully apprehend the nature of the claims cannot, without some factual basis, prevent the Court from engaging in a pre-claim construction § 101 analysis. *See Intellectual Ventures I LLC v. Erie Indem. Co.*, 2015 U.S. Dist. LEXIS 129153, at *88. Moreover, Plaintiff's proposed constructions are uncontested. (Docket No. 34 at 2 n.2). Having reviewed the claims, the proposed constructions, and considered both parties' arguments, the Court finds that further claim construction is not needed prior to resolving the instant motion to dismiss.

2) Representative Claims

Plaintiff next contends that the Court cannot consider representative claims to evaluate the instant Motion to Dismiss. (Docket No. 29 at 1). To the contrary, a Court may evaluate representative claims when ruling on a motion to dismiss premised on § 101. *See e.g.*, *Intellectual Ventures I LLC v. Erie Indem. Co.*, 2015 U.S. Dist. LEXIS 129153, at *84 (citing *Content Extraction*, 776 F.3d at 1348). If a patent holder objects to such treatment, it bears the burden of persuading the Court that its claims warrant independent review. *Id.* In such an instance, the Court should then review the claims to determine their similarity. *Id.* Given that

there are five patents-in-suit, the Court will consider whether to utilize representative claims relative to each patent individually.

B. Patent-eligibility

1) The '180 Patent

The '180 Patent contains thirty-four claims, eight of which are independent. (Docket No. 18-1). Claim 1 of the '180 Patent generally describes a method of determining whether action is needed in a clinical trial and comprises the following steps:

1. Obtain past data;
2. Apply quantitative analysis to past data to derive a "compliance threshold";
3. Obtain new subject data; and
4. Compare the new subject data to the "compliance threshold" to determine whether some action should be taken.

(Docket No. 18-1 at 15:40–16:36).[5] Independent claim 4 is similar to Claim 1, but substitutes the "compliance threshold" with a "predictive algorithm" and adds a step of converting the new

[5] Claim 1 recites:

> **A method of determining if action is needed regarding subject compliance** during a current clinical trial, wherein said current clinical trial comprises a group of subjects participating in said current clinical trial, comprising the steps of:
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> **providing data on timeliness of a data entry from a previous clinical trial** and either a) historical subject compliance data from said previous clinical trial or b) historical protocol data from said previous clinical trial, wherein said historical subject compliance data comprise data on a ratio of completed assessments to expected assessments, data on a subject's compliance with a medication regimen, data on a disease episode, or data on a characteristic of a subject's disease state, and wherein said historical protocol data comprise a question posed to a subject, a frequency of prompting of a subject during a day or week, an amount of time allotted for a subject to respond to a question, or a condition mandating removal of a subject from data analysis or from participation in a clinical trial;
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> **generating a preferred compliance threshold** for use during said current clinical trial by quantitative analysis of said data on timeliness of a data entry from said previous clinical trial and either a) said historical subject compliance data from said previous clinical trial or b) said historical protocol data from said previous clinical trial; and
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> **obtaining subject compliance information** from a subject in said group of subjects participating in said current clinical trial comprising using a portable electronic device capable of displaying information and receiving and storing input from a user to obtain

"predictive algorithm" into a "decision rule."[6] (Docket No. 18-1 at 16:42–17:5). Claim 11, is essentially identical to Claim 4 with the addition that it performs the functions specified in Claim 4 on a "portable electronic device," and that it defines some of the actions to be taken in the final step. (*Id.* 18-1 at 17:33–18:14). Independent claims 19 and 21 mirror the steps set forth in claims 1 and 11, but do so as a "computer readable medium," and add a step "prompting said action," referenced in the prior claims. (*Id.* 18-1 at 18:44–19:39, 19:43–20:29). Independent claims 22 and 23 incorporate substantially the same steps as claims 19 and 21, but generate "a spectrum of compliance," a "predictive algorithm," instead of a "compliance threshold" or "algorithm." (*Id.* at 20:30–21:24, 21:25–22:12). Independent claim 24 is virtually identical to claim 21, but without the prompting step. (*Id.* at 22:12–65). The dependent claims merely include specific applications of the terms included in the independent claims. (*See* Docket No. 18-1). Accordingly, claim 1 of the '180 Patent is representative.

> said subject compliance information from said subject in said group of subjects participating in said current clinical trial; and
>
> **comparing said subject compliance information from said subject** in said group of subjects participating in said current clinical trial **to said preferred compliance threshold to determine if said action is needed** for said subject in said group of subjects participating in said current clinical trial, wherein said action comprises removing all or part of data from said subject in said group of subjects participating in said current clinical trial from data analysis, removing all or part of the data from said subject in said group of subjects participating in said current clinical trial from a report, removing said subject in said group of subjects participating in said current clinical trial, prompting said subject in said group of subjects participating in said current clinical trial to view said portable electronic device, alerting clinical staff to contact said subject in said group of subjects participating in said current clinical trial, providing compliance feedback to said subject in said group of subjects participating in said current clinical trial to encourage continued compliance with said current clinical trial, providing compliance feedback to said subject in said group of subjects participating in said current clinical trial to remediate poor compliance with said current clinical trial, providing a report on the compliance of said subject in said group of subjects participating in said current clinical trial to said clinical staff or a clinical trial sponsor, or training said clinical staff in the monitoring and correcting of subject compliance.

(Docket No. 18-1 at 15:40–16:36) (emphasis added).

[6] As there is no contest, the Court adopts Plaintiff's proposed claim construction for "decision rule" to mean "reformatted algorithm." (Docket No. 29 at 5).

a) Alice Step 1

The parties have presented competing views as to on how the Court should decide whether claim 1 is directed to an abstract idea. Plaintiff contends that the Court should look to the purpose of the invention, and suggests the purpose is "to determine if action is needed to increase subject compliance during a clinical trial, in order to increase the reliability and usability of clinical trial results, which would ultimately reduce clinical trial costs, time to complete the clinical trial, and time to get a drug or medical device to market." (Docket No. 29 at 9) (citing Docket No. 18-1 at 1:61–2:3). Defendant argues that distilling the purpose of the invention is not the test for whether a patent is directed to an abstract idea, and instead articulates its version of the nature of the claim as "directed to the simple abstract idea of determining whether a clinical trial participant is entering his data on time consistent with past experience, *i.e.*, 'historical data' and, if not, calling to remind him." (Docket No. 25 at 10).

Whether a claim is directed to an abstract idea is an inquiry that can be considered as one of identifying the "heart of the patented invention/true nature of the claim." *Intellectual Ventures I LLC v. Erie Indem. Co.*, 2015 U.S. Dist. LEXIS 129153, at *55. As noted above, "'preexisting, fundamental truth[s]' such as mathematical equations, and [] 'method[s] of organizing human activity' or 'longstanding commercial practice[s]' like intermediated settlement or risk hedging" are some examples of abstract ideas. *Id.* (quoting *Alice*, 134 S. Ct. at 2356). Understanding the purpose of an invention may aid in identifying the underlying nature of the claim. *See e.g.*, *Cal. Inst. of Tech. v. Hughes Communs., Inc.*, 59 F. Supp. 3d 974, 991 (C.D. Cal. 2014); *Stoneeagle Servs. v. Pay-Plus Solutions, Inc.*, 113 F. Supp. 3d 1241, 1250 (M.D. Fla. 2015); *DataTern, Inc. v. MicroStrategy, Inc.*, 2015 U.S. Dist. LEXIS 118530, at *26 (D. Mass. Sept. 4, 2015); *TimePlay, Inc. v. Audience Entm't LLC*, 2015 U.S. Dist. LEXIS 174781, at *18 (C.D. Cal. Nov. 10, 2015). But, the purpose of the invention is not dispositive on the issue of what defines the

"heart" of the patent and cannot render an otherwise abstract idea patent-eligible. *Parker v. Flook*, 437 U.S. 584, 595 n.18 (1978) ("Very simply, our holding today is that a claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under § 101."); *Bilski*, 561 U.S. at 610–11 ("*Flook* stands for the proposition that the prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant postsolution activity.'") (citing *Diamond v. Diehr*, 450 U.S. 175, 191–92 (1981)).

Moreover, some Courts have found that since computer programs generally comprise sets of instructions or algorithms, they are generally directed to an abstract idea. *See e.g.*, *SRI Int'l, Inc. v. Cisco Sys.*, 2016 U.S. Dist. LEXIS 48092, at *11–12 (D. Del. Apr. 11, 2016) ("Because computer software comprises a set of instructions, the first step of *Alice* is, for the most part, a given; *i.e.*, computer-implemented patents generally involve abstract ideas."); *Intellectual Ventures I, LLC v. Canon Inc.*, 2015 U.S. Dist. LEXIS 151485, at *64 (D. Del. Nov. 9, 2015).

Here, the "heart" of the invention relates to using an electronic device to obtain clinical trial data that would otherwise be collected by pen-and-paper diary, and analyzing the data to decide whether to prompt action. The individual steps comprising the method, *i.e.*, gathering data, analyzing same, and acting pursuant to that data, are similar to others that have been found to be abstract. *See e.g.*, *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1361–62 (Fed. Cir. 2015) (finding a method comprising (1) testing prices, (2) gathering statistics about how customers reacted to the prices, (3) using that data to estimate outcomes, and (4) acting on estimated outcomes (*i.e.*, automatically selecting and offering new prices based on estimated outcome) to be directed to the abstract idea of price optimization.); *see also Intellectual Ventures I LLC v. Erie Indem. Co.*, 2015 U.S. Dist. LEXIS 129153, at *94 (finding a method of

"gathering, storing, and acting on data based on predetermined rules" to be directed to an abstract idea).

Plaintiff nevertheless asserts that the fact that its invention is limited to clinical trials prevents it from being considered abstract. (Docket No. 29 at 9) ("Such purpose cannot be abstract, as it is seeking to solve problems uniquely within the context of conducting clinical trials"). Yet, Federal Circuit and Supreme Court precedents clearly hold that the one cannot circumvent the ban on patenting abstract ideas by attempting to limit them to a particular technological environment. *Bilski*, 561 U.S. at 610–11; *see also OIP*, 788 F.3d at 1362–63 ("And that the claims do not preempt all price optimization or may be limited to price optimization in the e-commerce setting do not make them any less abstract.") (citing *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350, 1355 (Fed. Cir. 2014)).

Plaintiff next contends that the "specific and concrete" claim limitations save the invention from being considered abstract. (Docket No. 29 at 10) (citing *Intellectual Ventures I, LLC v. Canon Inc.* 2015 U.S. Dist. LEXIS 151485). "Specific and concrete" is not the legal standard, however, and Plaintiff implicitly concedes as much. (Docket No. 35 at 3) ("ERT never argued that "specific and concrete" is a legal standard. The adjectives describe limitations found in the claims."). Moreover, patent claims with even more specific steps have been held to be directed to abstract ideas and ultimately found patent-ineligible. *See NexusCard, Inc. v. Kroger Co.*, 2016 U.S. Dist. LEXIS 38857, at *10–12 (E.D. Tex. Mar. 24, 2016) (finding an eighteen-step claim articulating a "membership discount program" nevertheless was directed to an abstract idea). Finally, Plaintiff's reliance on *Intellectual Ventures I, LLC v. Canon Inc.*, is misplaced because the claims at issue there did not recite mathematical formula or attempt to implement any such formula, as opposed to relying on the particularity of the claims themselves. *Intellectual*

Ventures I, LLC v. Canon Inc. 2015 U.S. Dist. LEXIS 151485, at *69–70. Accordingly, the Court finds claim 1 of the '180 Patent to be directed to an abstract idea.

B) Alice Step 2

Given that claim 1 of the '180 Patent is directed to an abstract idea, the Court next considers whether the claim limitations, both individually and in combination, "transform the nature of the claim into a patent eligible application." *Alice*, 134 S. Ct. at 2355 (citing *Mayo*, 132 S. Ct. 1289). "A claim that recites an abstract idea must include "additional features" to ensure "that the [claim] is more than a drafting effort designed to monopolize the [abstract idea]." *Id.* at 2357. "[T]ransformation into a patent-eligible application requires "more than simply stat[ing] the [abstract idea] while adding the words 'apply it.'" *Id.* Further, "appending conventional steps, specified at a high level of generality," was not "enough" to supply an "'inventive concept.'" *Id.* Similarly, "the mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention." *Id.* at 2358.

Plaintiff offers many arguments for why its claims are patent-eligible despite being directed to an abstract idea. Specifically, Plaintiff contends that: (1) the claim limitations add additional inventive features sufficient to render the claims patent-eligible because they improve a technology (clinical trials) and provide enough specificity to meaningfully bind the claims; (2) the claims create a transformation sufficient to save the claims; and (3) that the claims in suit are akin to those in *DDR Holdings*. (Docket No. 29 at 10–14). Defendant disagrees with Plaintiff's contentions, and instead argues that the claim limitations merely incorporate conventional, generic steps that are insufficient to render them patent-eligible. (Docket Nos. 25, 34).

In this Court's estimation, the claim limitations, considered individually and in combination, fail to transform the otherwise abstract ideas into patent eligible applications because they merely recite common, well-known steps. The first and third limitations call for

"providing" or "obtaining" data. (Docket No. 18-1 at 15:44–16:5). Those limitations do not contain any additional inventive steps because they describe "routine data gathering techniques." *OIP*, 788 F.3d at 1363 (finding claim limitations reciting "routine data-gathering steps" did not transform an abstract idea into a patent-eligible application of same.) "[G]enerating a preferred compliance threshold" by quantitative analysis, and comparing the collected data to the threshold as required by the second step similarly does not add inventiveness because it too requires the application of conventional, well-known analytical steps. *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 716 (Fed. Cir. 2014) ("[T]he claimed sequence of steps comprises only 'conventional steps, specified at a high level of generality,' which is insufficient to supply an 'inventive concept.'") (quoting *Alice*, 134 S. Ct. at 2357) (internal citations omitted).

The dependent claims likewise fail to transform the abstract idea into a patent-eligible application. Plaintiff contends that three dependent claims in particular, claims 6, 26, and 28, add a transformative inventive step to the patent. (Docket No. 29 at 11). Claim 6 adds the concept of "creating an evaluability database adapted to store data related to subject compliance." (Docket No. 18-1 at 17:16–18). Claim 26 employs statistical tools to generate algorithms and thresholds. (Docket No. 18-1 at 23:3–6) ("[W]herein said step of generating employs multiple linear regression, discriminant function analysis, logistic regression, neural networks, classification trees or regression trees."). And, claim 28 defines specific data to be used for purposes of data analysis. (Docket No. 18-1 at 23:10–18) ("[W]herein said historical subject compliance data further comprise data on whether a subject had a relationship with a doctor or other medical professional, data on a number or percent of prompts not replied to by a subject, data on a subject's sleep/wake cycle, data on whether a subject had a bowel movement, data on an amount

of time a portable electronic device is in suspend mode, data on a subject's gender, or data on a subject's location.").

Employing a database to store data does not add inventiveness. *See e.g.*, *Intellectual Ventures I LLC v. Capital One Bank (USA)*, 792 F.3d 1363, 1368 (Fed. Cir. 2015) ("[I]t is clear that the claims contain no inventive concept. The recited elements, *e.g.*, a database, . . . are all generic computer elements."). Moreover, applying traditional statistical tools to data cannot possibly provide the inventive step necessary to become patent-eligible. *OIP*, 788 F.3d at 1363 (holding that "well-understood, routine conventional activit[ies]," are insufficient to transform an abstract idea into a patent-eligible application). Finally, the specific data types referenced in claim 28 do not transform the abstract idea claimed in the patent because simply defining the data to be used therein does not supply an inventive concept. *Alice*, 134 S. Ct. at 2357. Thus, the dependent claims do not add any inventive concept that can transform the patent into patent-eligible subject matter.

In a similar vein, to the extent Plaintiff argues that the "computer readable medium" claims or the "system comprising an electronic device" claims add an inventive step, those arguments fail because applying otherwise abstract claims to a computer or translating same into a medium for use in a computer is not inventive. *See Alice*, 134 S. Ct. at 2360 ("Petitioner's claims to a computer system and a computer-readable medium fail for substantially the same reasons.").

Plaintiff next argues that the machine-or-transformation test renders the claims patent-eligible. (Docket No. 29 at 12). As an initial point, the machine-or-transformation test is not dispositive on the issue of patent-eligibility, and is instead just one factor to consider. *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1256 (Fed. Cir. 2014) ("For example, in

Mayo, the Supreme Court emphasized that satisfying the machine-or-transformation test, by itself, is not sufficient to render a claim patent-eligible, as not all transformations or machine implementations infuse an otherwise ineligible claim with an 'inventive concept.'"). In any event, the transformation upon which Plaintiff relies is insufficient to convert the abstract idea into a patent-eligible application of same. *See CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1375 (Fed. Cir. 2011) ("The mere manipulation or reorganization of data, however, does not satisfy the transformation prong.").

Plaintiff's reliance on *Chamberlain* is inapposite because the transformation that occurred there had nothing to do with data. *Chamberlain Grp., Inc. v. Linear LLC*, 114 F. Supp. 3d 614, 628–29 (N.D. Ill. 2015) (finding a transformation occurred because a garage door changed from an open to a closed position). Similarly, *Card Verification Solutions, LLC v. Citigroup Inc.*, does not apply to the Plaintiff's patents because the patents-in-suit do not add new data. See *Card Verification Solutions, LLC v. Citigroup Inc.*, 2014 U.S. Dist. LEXIS 137577, at *13 (N.D. Ill. Sept. 29, 2014) ("'[T]he mere manipulation or reorganization of data … does not satisfy the transformation prong.' But here, the claimed invention goes beyond manipulating, reorganizing, or collecting data by actually adding a new subset of numbers or characters to the data, thereby fundamentally altering the original confidential information.") (quoting *CyberSource*, 654 F.3d at 1375).

Finally, Plaintiff's reliance on *DDR Holdings* is unavailing because the claims at issue do not address a problem unique to the internet. *See Intellectual Ventures I LLC v. Capital One Bank (USA)*, 792 F.3d at 1371 ("The patent at issue in *DDR* provided an Internet-based solution to solve a problem unique to the Internet that (1) did not foreclose other ways of solving the problem, and (2) recited a specific series of steps that resulted in a departure from the routine and

conventional sequence of events after the click of a hyperlink advertisement. The patent claims here do not address problems unique to the Internet, so *DDR* has no applicability."). Accordingly, the claims in the '180 Patent are not patent-eligible.

2) The '519 and '605 Patents

The '519 Patent is a continuation of the '180 Patent, and the '605 Patent is a continuation of the '519 Patent; therefore, they share a common specification and priority date with the '180 Patent. (Docket Nos. 18-2, 18-3). The '519 Patent contains sixty-three claims, three of which are independent. (Docket No. 18-2). Claim 1 of the '519 Patent is representative and puts forth a two-step method for "classifying clinical trial results" comprising (1) entering "evaluability" data from the participants using "an electronic device," and (2) comparing that data to a "norm" to classify the clinical trial results.[7] Independent claim 22 recites a "computer readable medium" employing the steps articulated in claim 1, and independent claim 43 provides for a "system comprising an electronic device, again comprising almost identical steps to those listed in claim 1." (Docket No. 18-2).

The '605 Patent is substantially similar to the '519 patent, and likewise contains sixty-three claims, three of which are independent. (Docket No. 18-3). Claim 1 describes a method for classifying results from a clinical trial by: (1) electronically accessing evaluability data and storing it on an "electronic device"; (2) comparing the data to a norm to classify results; and (3)

[7] Claim 1 recites: A method for classifying clinical trial results from one or more participants in a clinical trial, the method comprising:

a. Entering evaluability data from the one or more participants on an electronic device, wherein the evaluability data comprise one or more evaluability data categories; and
b. Comparing the evaluability data from the one or more evaluability data categories to a norm to classify the clinical trial results from the one or more participants in the clinical trial based on a type of compliance, wherein the classifying allows analysis of participants with a similar type of compliance.

(Docket No. 18-2 at 15:38–49).

analyzing the classified results from participants with a similar type of compliance.[8] As was the case in the '519 Patent, the two remaining independent claims are a "computer readable medium" claim and a "system" claim. (Docket No. 18-3).

Defendant contends that "it would be hard to find a clearer example of an abstract idea" than claim 1 of the '519 Patent, (Docket No. 25 at 17), and this Court agrees. Classifying clinical trial results by obtaining data using a portable electronic device and comparing same to a norm evidences a common "method of organizing human activity' or 'longstanding commercial practice[s]." *Intellectual Ventures I LLC v. Erie Indem. Co.*, 2015 U.S. Dist. LEXIS 129153, at *55 (quoting *Alice*, 134 S. Ct. at 2356). Accordingly, this Court finds that claim 1 of the '519 Patent is directed to an abstract idea.

Step two of the *Alice* inquiry fails to save these claims. As noted above, routine data gathering, even by using a "portable electronic device" does not provide the inventive step necessary to render an abstract idea patent-eligible. *Alice*, 134 S. Ct. at 2357 ("We conclude that the method claims, which merely require generic computer implementation, fail to transform that abstract idea into a patent-eligible invention."); *OIP*, 788 F.3d at 1363 ("routine data-gathering steps" did not transform an abstract idea into a patent-eligible application of same.). Additionally, comparing data to a "norm" is the epitome of a conventional step specified at a high level of generality. *See Ultramercial*, 772 F.3d at 716 (quoting *Alice*, 134 S. Ct. at 2357).

[8] Claim 1 recites: A Method for classifying results from one or more participants in a clinical trial, the method comprising:

a. electronically accessing evaluability data obtained during the clinical trial, wherein the evaluability data is from the one or more participants in the clinical trial, wherein the evaluability data is stored on an electronic device, wherein the evaluability data comprise data from one or more evaluability data categories;
b. comparing the evaluability data from the one or more evaluability data categories to a norm to classify clinical trial results from each of the one or more participants in the clinical trial based on a type of compliance; and
c. analyzing the classified clinical trial results from the one or more participants with a similar type of compliance.

(Docket No. 18-3 at 15:40–53).

Plaintiff's argument that the dependent claims provide "specific and concrete limitations," misapprehends the law, and fails to describe sufficient transformation to render the claims patent-eligible applications. *Alice*, 134 S. Ct. at 2355. The claims cited by Plaintiff incorporating quantitative analysis, (Docket No. 18-2 at 15:59–60), discussing "statistical or data mining techniques," (*Id.* at 15:61–64), defining the type of data to consider, (*Id.* at 16:1–4), or identifying the type of database to be used, (*Id.* at 16:20–21), all fail to transform the nature of the claim into a patent-eligible application. *See e.g.*, *Alice*, 134 S. Ct. at 2357; *OIP*, 788 F.3d at 1363 ("well-understood, routine conventional activit[ies]," are insufficient to transform an abstract idea into a patent-eligible application); *Intellectual Ventures I LLC v. Capital One Bank (USA)*, 792 F.3d at 1368 (holding that a database is a "generic computer element"). Accordingly, the '519 Patent is patent-ineligible.

The '605 Patent, fares no better. Given that the only substantive differences between the two patents include that the '605 patent recites "electronically accessing" the data in step one, and that it adds a third step of "analyzing the classified clinical trial results," the Court finds that for the same reasons set forth above, the '605 Patent is not patent eligible.

3) The '970 and '447 Patents

The '970 and '447 Patents are related to, but different from the '180 Patent. (Docket Nos. 18-4, 18-5). The '970 Patent describes a method of "predicting subject noncompliance" in clinical trials, and contains thirty-seven claims, ten of which are independent. (Docket No. 18-4). Claim 1 is representative and states:

> A method of predicting subject noncompliance, comprising the steps of:
>
> providing historical subject compliance data;
>
> generating at least one predictive algorithm for predicting subject noncompliance by quantitative analysis of the historical subject compliance data; and

translating the at least one predictive algorithm into at least one prediction rule for use with a clinical trial.

(Docket No. 18-4 at 10:42–49). For the same reasons as articulated above, obtaining data, generating an algorithm by quantitative analysis, and translating said algorithm into a more useful rule is directed to an abstract idea. *See Alice*, 134 S. Ct. at 2354 ("[A]bstract ideas are 'the basic tools of scientific and technological work.'") (citing *Myriad*, 133 S. Ct. at 2116); *OIP*, 788 F.3d at 1361–62 (finding a method comprising (1) testing prices, (2) gathering statistics about how customers reacted to the prices, (3) using that data to estimate outcomes, and (4) acting on estimated outcomes (*i.e.*, automatically selecting and offering new prices based on estimated outcome) to be directed to the abstract idea of price optimization); *CyberSource*, 654 F.3d at 1371 (finding a patent that (1) obtained information about other credit card transactions, (2) constructed a map of numbers based on transactions, and (3) used the map to determine if the transaction was valid, "fails to recite patent-eligible subject matter because it is drawn to an unpatentable mental process—a subcategory of unpatentable abstract ideas.").

The remaining independent claims are merely variants of claim 1 directed to "determining subject noncompliance," "detecting subject fraud," or describe "a medium suitable for use in an electronic device" comprising substantially similar steps to that articulated above. (Docket No. 18-4). Accordingly, the '970 Patent is directed to an abstract idea.

Turning to step two of the *Alice* inquiry, the Court finds that the claim limitations fail to transform this otherwise abstract idea into a patent-eligible application. As was the case with the '180 Patent, merely obtaining data, applying statistical tools to said data to derive an algorithm, and converting said algorithm by generic means does not add an inventive step. *See OIP*, 788 F.3d 1363 ("routine data-gathering steps"); *Ultramercial*, 772 F.3d at 716 ("'conventional steps,

specified at a high level of generality,'") (quoting *Alice*, 134 S. Ct. at 2357). Thus, the '970 Patent is not patent-eligible.

The '447 Patent is a continuation-in-part of the '970 Patent, and shares a substantially similar specification. (Docket No. 18-5). Claim 1 of the '447 Patent is representative and recites:

> A computer implemented method of determining noncompliance of a participant in a clinical trial, comprising the steps of:
>
> providing historical participant compliance data;
>
> generating at least one predictive algorithm for determining participant noncompliance by quantitative analysis of the historical participant compliance data;
>
> applying the at least one algorithm to determine participant compliance; and
>
> outputting notice of noncompliance.

(Docket No. 18-5 at 15:4–13). Not much differentiates the '447 Patent from the '970 Patent. That the '447 patent attempts to "determine" noncompliance or "predict success," as opposed to "predict noncompliance," does not demonstrate to the Court that the patent is not directed to an abstract concept or otherwise includes sufficient inventive additions to find it to be patent-eligible. Thus, the Court finds the '447 Patent patent-ineligible for the same reasons articulated above. *See Alice*, 134 S. Ct. at 2354; *OIP*, 788 F.3d at 1361–62; *CyberSource*, 654 F.3d at 1371; *Ultramercial*, 772 F.3d at 716.

VI. **Conclusion**

For the forgoing reasons, Defendant's Motion to Dismiss, Pursuant to Rule 12(b)(6) [24] is GRANTED. An appropriate Order follows.

s/ Nora Barry Fischer

Nora Barry Fischer
United States District Judge

cc/ecf: All counsel of record.