

No. 13-_____

IN THE SUPREME COURT OF THE UNITED STATES

ADVANCED BIOLOGICAL LABORATORIES, SA,
AND ABL PATENT LICENSING TECHNOLOGIES, SARL,
Petitioners,

v.

SMARTGENE, INC.,
Respondent.

**On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit**

PETITION FOR A WRIT OF CERTIORARI

ROBERT R. SACHS*
DANIEL R. BROWNSTONE
FENWICK & WEST LLP
555 California Street
12th Floor
San Francisco, CA 94105
(415) 875-2300
rsachs@fenwick.com

Counsel for Petitioners

April 24, 2014

* Counsel of Record

QUESTION PRESENTED

Whether claims to a computerized expert system and method for evaluating treatment options for complex medical conditions which necessarily requires the use of computer, are patent eligible since they do not preempt all practical applications of an abstract idea of “guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition.”

PARTIES TO THE PROCEEDING

All parties to the proceeding are identified in the caption.

RULE 29.6 STATEMENT

Advanced Biological Laboratories, SA and ABL Patent Licensing Technologies, SARL have no parent company, and no publicly held company owns 10% or more of either company's stock.

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PETITION FOR A WRIT OF CERITORARI

Petitioners Advanced Biological Laboratories, SA and ABL Patent Licensing Technologies, SARL (collectively, “ABL”) respectfully petition this Court to grant a writ of certiorari, vacate the opinion of the Federal Circuit below, and remand this case for further proceedings in view of its forthcoming decision in *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, No-1398.

OPINIONS BELOW

The opinion of the United States District Court for the District of Columbia granting summary judgment is reproduced in the appendix to this petition (App. E) 41a-92a and reported at 852 F. Supp. 2d 42. The related order is unreported but is reproduced at App. F 93a-94a. The opinion of the United States District Court for the District of Columbia denying ABL’s motion for reconsideration is reproduced at App. C 15a-38a and is reported at 915 F. Supp. 2d 69. The related order is unreported but is reproduced at App. D 39a-40a. The panel opinion of the United States Court of Appeals for the Federal Circuit panel is unreported but is reproduced at App. A 1a-12a and is available at 2014 U.S. App. LEXIS 1357. The panel’s mandate is reproduced at App. B 13a-14a.

JURISDICTION

The U.S. Court of Appeals for the Federal Circuit entered its judgment on January 24, 2014. (App. 1a-

12a.) This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

“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.

INTRODUCTION

Judge Pauline Newman recently characterized the Federal Circuit as being in a state of jurisprudential “deadlock,” making patent eligibility under 35 U.S.C. § 101 a question “whose result will depend on the random selection of the panel.” *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1280 (Fed. Cir. 2013) (hereinafter *CLS Bank*) (*en banc*) (Newman, J., dissenting), *cert granted*, *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S.Ct. 734 (2013) (hereinafter *Alice*). No better case illustrates the panel-dependent crapshoot that Section 101 jurisprudence has become than this one. Although it is impossible to predict the Court’s forthcoming opinion in *Alice*, there is little doubt that it will significantly impact the law in this area and break the deadlock in the Federal Circuit.

The decision below is a prime example of the current dysfunctional state of the law in the Federal Circuit. Not only did the panel fail to follow this Court’s precedents, it also effectively ignored the

analytical framework that two of its members, Judge Lourie and Judge Dyk, set forth as the proper “integrated approach to § 101” in which “[f]irst and foremost is an abiding concern that patents should not be allowed to preempt the fundamental tools of discovery—those must remain “free to all . . . and reserved exclusively to none.” *CLS Bank*, 717 F.3d at 1280 (Lourie, J., concurring). Judge Lourie, writing for the plurality and expressly relying on this Court’s decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289 (2012), stated that “[w]hat matters is whether a claim threatens to subsume the full scope of a fundamental concept, and when those concerns arise, we must look for meaningful limitations that prevent the claim as a whole from covering the concept’s every practical application.” *CLS Bank*, 717 F.3d at 1281. Even though the *en banc CLS Bank* plurality opinion failed to command a majority of the Federal Circuit, the preemption basis of its approach was supported by a majority of the Federal Circuit—and yet was treated as an afterthought by the panel below in this case.

Instead of using the preemption framework established by this Court and supported by a majority of the Federal Circuit, the panel applied an entirely different test from *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366 (Fed. Cir. 2011), directed to whether the claims recite “mental steps,” an approach that has little meaningful application when considering the technology in this case, a computerized expert system. Crucially, the panel overlooked the critical and distinguishing fact that in *CyberSource* there was an express admission

by the patentee that the steps of their claim could be performed mentally—but no such admission or evidence exists in this case. Only after deciding that ABL's claims covered “the conscious process that doctors can and do perform in their heads”—even though there was absolutely no record evidence to support this strange conclusion—did the panel merely note that “the concern about preempting public use of certain kinds of knowledge, emphasized in *Mayo*, is a grave one.” (App. 11a.) The panel trivially distinguished other Federal Circuit precedent that applied a more appropriate test for computer implemented inventions, where the computer is integral to the operation of the system and method, precisely as in this case.

It is not enough that there is a concern about “preempting public use of knowledge,” even a grave one, at stake. Every patent case that reaches the Federal Circuit presents a potential of preemption of public knowledge because all claims preempt the use of knowledge to some degree. This Court has time and again instructed that the only thing that matters is whether the claims in fact “preempt” all practical applications of an abstract idea, law of nature, or natural phenomenon. *Mayo*, 132 S.Ct. at 1294 (admonishing against “upholding patents that claim processes that too broadly preempt the use of a natural law.”); *Bilski v. Kappos*, 130 S.Ct. 3218, 3231 (2010). (“Allowing petitioners to patent risk hedging would pre-empt use of this approach in all fields”); *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972) (“if the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula”). That factual determination must be based on a factual record, not

the intuitions of an appellate court that are facially inconsistent with evidence of that patented technology.

A GVR order is proper because no matter what test this Court adopts in *Alice*, it is highly unlikely to be the one that the panel below applied. Second, the panel relied instead on premises that would have to be rejected in view the Court's decision. Third, the Court's new test would have a direct impact on the ultimate outcome of this case.

STATEMENT OF THE CASE

In 2008, respondent SmartGene, Inc. filed an action for declaratory judgment that it did not infringe U.S. Patent Nos. 6,081,786 (the "786 patent") and 6,188,988 (the "988 patent") (collectively, the "ABL patents") and that the ABL patents were invalid. ABL counterclaimed for infringement of each patent. The ABL patents describe a computer-implemented method, system, and computer program for a medical expert system for identifying treatment options for treating medical conditions.

Expert systems are one application of "artificial intelligence," a field of computer science that dates back to the early 1950s. The United States Patent and Trademark Office ("USPTO") has long recognized this technology and has issued more than 10,000 patents to various types of expert system

technology.¹ By its nature, an expert system is, first and foremost, a computerized system: It is simply not possible to have an expert system in the absence of a computer and accompanying software program. Expert systems apply computerized databases of rules (written in computer code) to particular data (also expressed in computer code) to categorize, diagnose, or otherwise evaluate complex factual patterns.

The expert systems claimed by ABL's patents make use of rules that define very precise relationships between medical facts regarding a patient and medical treatments.² For example, some rules define specific relationships between different types of drugs for treating HIV. An expert system applies the rules to the initial input facts, and then recursively "chains" together the outputs of these rules until a final conclusion results. In the case of

¹ The USPTO recognizes expert systems as a distinctive type of "artificial intelligence" technology, and classifies it in U.S. Patent Classification, Class 706 (Artificial Intelligence), Subclass 45 (Knowledge processing system; "Note. This subclass and subclasses indented hereunder provide for details of (1) expert systems or (2) operation of expert systems (either stand alone expert systems or expert systems interacting with other systems)."). The USPTO recognizes twenty-five separate subclasses of expert systems (including a specific subclass for medical systems) that have more than 10,000 issued patents classified therein, further demonstrating the beneficial and extensive nature of this technology.

² To be clear, ABL does not claim any law of nature, or correlation of medical facts such as in *Mayo*. Further, SmartGene has never argued that ABL claims any law of nature or natural correlation.

ABL's patents, the output is a recommended treatment regimen, or a ranked listing of possible treatment regimens, for use with patients with challenging medical issues requiring complex management.

Early in the litigation, before any meaningful discovery had been conducted and before claim construction, SmartGene moved for summary judgment seeking a judgment that the ABL patents were invalid for lack of patentable subject matter under 35 U.S.C. § 101. The district court granted SmartGene's motion in early 2012, based primarily on the court's view that the claims recited nothing more than mental steps performed by a doctor, even though there was no evidence to support this conclusion. (App. 67a.)

Following this Court's decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289 (2012), ABL moved for reconsideration of the district court's summary judgment order, on the basis that *Mayo* clarified applicable § 101 standards that required the consideration of evidence relevant to patent eligibility. ABL submitted such evidence in connection with its motion. The district court denied the motion for reconsideration. (App. 40a.)

On appeal, the Federal Circuit affirmed the district court's decisions. The Federal Circuit wrongly applied this Court's jurisprudence in *Benson*, 409 U.S. at 67-68; *Parker v. Flook*, 437 U.S. 584, 589 (1978); and *Mayo* without meaningful discussion of the preemption doctrine. Instead, the panel below held that ABL's patents simply

implemented “familiar” mental steps on a computing device, without adding “enough else.” (App. 11a.)

The Federal Circuit made several serious errors in its short analysis. First, it applied the wrong test, one based on mental steps, rather than preemption. Second, to the extent that it mentioned preemption, it was merely as an afterthought, without any actual analysis of *how* ABL’s claims preempt an abstract idea. (App. 11a.) Third, it failed to consider the *language of ABL’s claims* from the perspective of one of ordinary skill in the art, which is how this Court has consistently analyzed the scope of preemptive impact. Fourth, the panel came to these conclusions on a barren record, without any *evidence* to support either its conclusion regarding mental steps or a preemption analysis, and without regard to the presumption of validity that applies to every patent claim. *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S.Ct. 2238, 2242 (2011) (patent claims may only be invalidated upon clear and convincing evidence). Finally, the panel ignored other Federal Circuit precedent that contradicted the panel’s underlying assumptions and legal theory.

This Court granted certiorari in *Alice* to resolve the chaos in the Federal Circuit’s § 101 jurisprudence pertaining to computer implemented inventions, such as ABL’s invention. That chaos is the result of an unmistakable divide in the Federal Circuit between those who see the integral presence of a computer in a computerized system and method as being sufficient for patent eligibility, and those like the panel below, which give little weight to the presence of a computer, simply because they believe

that computers do nothing more than perform the mental steps of a human. *CLS Bank*, 717 F.3d at 1286 (Lourie, J., concurring) (“At its most basic, a computer is just a calculator capable of performing mental steps faster than a human could.”). No matter the outcome of *Alice*, the Federal Circuit’s analysis will prove unsupported by controlling law, requiring ABL’s patent claims to be revisited.

REASONS FOR GRANTING THE PETITION

- I. **THIS CASE WILL NEED TO BE RECONSIDERED IN VIEW OF THIS COURT’S UPCOMING DECISION IN *ALICE CORP. V. CLS BANK***
 - A. **The Panel Below Failed to Follow This Court’s Precedent For The Proper Test of Patent Eligibility**

This Court’s precedents make clear that the core concern of § 101 is whether the claims preempt all practical applications of an underlying abstract idea, law of nature, or natural phenomenon. In *Benson*, the claims “purported to cover *any use* of the claimed method in a general-purpose digital computer of any type,” such that “the patent would *wholly pre-empt* the mathematical formula *and in practical effect* would be a patent on the algorithm itself.” *Benson*, 409 U.S. at 64, 71-72 (emphasis added). In *Bilski*, the Supreme Court stated that “Claims 1 and 4 in petitioners’ application explain the basic concept of hedging” and that “[a]llowing petitioners to patent risk hedging would pre-empt use of this approach in *all fields*, and would effectively grant a *monopoly*

over an abstract idea.” *Bilski*, 130 S.Ct. at 3231 (emphasis added). In *Mayo*, the Court emphasized that Prometheus’ claims “threaten to inhibit the development of more refined treatment recommendations” because “[t]he determining” step too is set forth in highly general language *covering all processes* that make use of the correlations after measuring metabolites, including later discovered processes that measure metabolite levels in new ways.” *Mayo*, 132 S.Ct. at 1302 (emphasis added). By contrast, in *Diehr*, the claims were patent-eligible because “they do not seek *to preempt the use* of [the Arrhenius] equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.” *Diamond v. Diehr*, 450 U.S. 175, 187 (1981) (emphasis added).

Mayo emphasized that the scope of the claims must be considered not by a lay court, but by the “relevant audience” of scientists or technologists: “First, the “administering” step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs.”; “That is to say, these clauses tell the relevant audience about the laws . . .”; “the claims inform a relevant audience about certain laws of nature”. *Mayo*, 132 S.Ct. at 1297-98.

All of these cases demonstrate that preemption is the essential component of patent eligibility, that the focus is on the actual claims, and that the question is answered by evaluating the *full scope* of the actual claims with respect to any uses and *all practical applications* of the underlying abstract idea, as

understood by the relevant audience, those of ordinary skill in the relevant art.

Despite these express and oft-stated requirements, the panel below confined its analysis to the realm of “mental steps,” (App. 9a.) basing its decision on a survey of this Court’s precedents in *Benson*, *Diehr*, and *Mayo*, as incorrectly interpreted by *CyberSource*. The panel asserted that *CyberSource* and its other precedents rest:

on Supreme Court decisions indicating that section 101 covers neither “mental processes”—associated with or as part of a category of “abstract ideas”—nor processes that merely invoke a computer and its basic functionality for *implementing such mental processes*, without specifying even arguably new physical components or *specifying processes defined other than by the mentally performable steps*.

(App. 9a (citing *Benson*, 409 U.S. at 67-68; *Flook*, 437 U.S. at 589) (emphasis added).)

This interpretation of *Benson* and *Flook* misses the forest for the trees, and is at odds with this Court’s core reasoning in those cases. Further, as applied to ABL’s claimed invention, the panel’s decision entirely begs the question as to the proper interpretation of a patent claim, a question that must necessarily be answered for preemption to be properly evaluated. Specifically, the panel assumed, without any evidence, and contrary to the record, that doctors were the “relevant audience” of the ABL

claims, rather than computer scientists, who in fact would be the ones who would practice the invention. From there, the panel interpreted the claim inconsistently with how the relevant audience would understand the disclosed technology and claims.

B. The Panel Failed to Follow More Relevant Federal Circuit Precedent

The panel's reliance on *CyberSource*, rather than other more recent precedent is just one clue to the panel-dependency of the present outcome. Other than being cited by Judge Lourie in his opinion in *CLS Bank*, *CyberSource* has not been relied upon by any other panel of the Federal Circuit as a controlling or even useful holding.

Another clue to the panel-dependent nature of this case is the court's superficial attempt to distinguish *Ultramercial, LLC v. Hulu, LLC*, 722 F.3d 1335 (Fed. Cir. 2013), which set forth a more appropriate test of patent eligibility for computer implemented inventions. Specifically, the very nature of ABL's computerized expert system requires the use of a physical computer—a computer is fundamentally integral to the invention, which cannot be created or employed without one. Yet, despite this uncontested fact, the panel trivially distinguished *Ultramercial*, where the Federal Circuit held that a “computer being part of the solution, being integral to the performance of the method” was a sufficiently meaningful limitation on a claimed computer-implemented method. This is precisely the case here, where the claims recite a particularly configured computer. The panel below

merely stated that the process in *Ultramercial* was “materially different” but gave no explanation as to why a complex, inherently computer-based technology like that in *Ultramercial*, which necessarily required a computer, was somehow less like ABL’s invention than the admittedly entirely mental process in *CyberSource* that required no computer whatsoever.

C. The Panel Misapplied *CyberSource v. Retail Decisions*

Even if *CyberSource* had been the most relevant precedent, the panel misapplied it to this case. The *CyberSource* holding was that the claimed method could be performed entirely in the human mind:

Thus, claim 3’s steps can all be performed in the human mind. Such a method that can be performed by human thought alone is merely an abstract idea and is not patent-eligible under § 101.

CyberSource, 654 F.3d at 1373.

Crucial to this legal conclusion was a factual record: “CyberSource’s CEO admitted that, before CyberSource created a computer implemented fraud detection system, “[w]e could see just by looking that more than half of our orders were fraudulent.” J.A. 375.” *CyberSource*, 654 F.3d at 1373.

This type of factual record is completely absent in the present case: There is no admission by ABL or the inventors, or any other evidence that the claims

can be “performed by human thought alone,” as in *CyberSource. Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1467 (Fed. Cir. 1998) (“we cannot . . . make findings of fact from a record that cannot support them.”); see *Middleton v. Dep’t of Def.*, 185 F.3d 1374, 1383 (Fed. Cir. 1999) (“[A]s an appellate court, we may not find facts”). And yet, while ABL repeatedly emphasized the lack of a factual record to the Federal Circuit in its briefing, the panel completely ignored this issue in its opinion, and essentially made factual findings that the claimed invention could be performed by human thought alone. (App. 10a (“Our ruling is limited to the circumstances presented here, in which every step is a familiar part of the conscious process that doctors can and do perform in their heads.”).) In the absence of such evidence, the panel’s decision was no minor error, since it effectively wiped out 132 claims in two separate patents.

Finally, if patent eligibility excludes a computer system or program that replaces the logical or mathematical reasoning of a human, then it logically follows that no computer program that performs any logical or mathematical task that a human *could do* is patent eligible. This is because ultimately any algorithm that computer performs is by necessity one that a human programmer originally thought of and “performed entirely” in his or her head. This further demonstrates that the panel’s focus on so-called mental steps fundamentally misunderstands the nature of computers.

This Court’s decision in *Alice* will clarify the details of the patent eligibility doctrine and resolve

the conflict between the different members of the Federal Circuit. An order of GVR will enable the panel to apply the correct test to the ABL claims, rather than its incorrect reading of the mental steps doctrine.

D. ABL's Claims Provide the Federal Circuit with an Opportunity to Evaluate Patent Eligibility Outside of the Narrow Domain of Computer-Implemented Business Methods

The Court should issue a GVR order in this case to provide the Federal Circuit an early opportunity to apply its upcoming decision in *Alice* to computer-implemented inventions outside of business methods. The vast majority of the Federal Circuit's recent cases involve patents claiming some form of business method implemented on a computer, including *CLS Bank* (automated third-party settlement of real time financial transactions); *Ultramerical* (advertising over the Internet), *Accenture Global Services, GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336 (Fed. Cir. 2013) (insurance task management system); *Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Canada*, 687 F.3d 1266 (Fed. Cir. 2012) (system for tracking life insurance premiums), *Fort Props., Inc. v. Am. Master Lease LLC*, 671 F.3d 1317 (Fed. Cir. 2012) (investment tool for buying and selling properties without incurring tax liability.); *Dealertrack, Inc. v. Huber*, 674 F.3d 1315 (Fed. Cir. 2012) (internet based credit application processing); and *In re Ferguson*, 558 F.3d 1359 (Fed. Cir. 2009) (advertising paradigm).

Unlike all of the patent claims in those cases, the claims in the ABL patents have nothing to do with business methods or financial systems, or questions of whether some practice is a “fundamental building block” of economics or finance. Instead, the ABL patent claims are clearly directed to an improvement in a traditional area of computing technology, expert systems, and a very specific application in one sub-field thereof, medical expert systems. Expert systems go back to the early 1960s, and some of the very first expert systems were for medical applications. For example, the MYCIN system developed by Stanford University, was used to identify bacteria causing severe infections and to recommend antibiotics; MYCIN was thoroughly considered by the patent examiner in the prosecution history of the ABL patents.

For example, Claim 1 of the '786 patent recites:

- (a) providing patient information to *a computing device comprising:*
 - a first knowledge base* comprising a plurality of different therapeutic treatment regimens for said disease or medical condition;
 - a second knowledge base* comprising a plurality of expert rules for evaluating and selecting a therapeutic treatment regimen for said disease or medical condition;
 - a third knowledge base* comprising advisory information useful for the treatment of a patient with

different constituents of said
different therapeutic treatment
regimens;

(b) generating in said computing device a
ranked listing of available *therapeutic
treatment regimens* for said patient;
and

(c) generating in said computing device
advisory information for one or
more therapeutic treatment
regimens in said ranked listing
based on said patient information
and said expert rules.

(App. 2a-3a (emphases added).)

No appellate court panel is competent to decide, in the absence of a factual record, that particular limitations are insufficient to meaningfully limit the claim to a particular expert system.³ It should go without saying that a panel of the Federal Circuit has no experience and no knowledge of what is *practical, commercially viable, or possible* in this particular field of technology, either as individuals or as an institution from prior experience with cases in this field. While the Federal Circuit has dealt with many business method patents, and many other

³ It is uncontested that the patent examiner specifically considered MYCIN as prior art in the reexamination of the '768 patent, and found that it did not disclose or suggest the claimed combination of the three knowledge bases. This fact alone supports the conclusion that the three knowledge base limitations are meaningful and significant, because they are integral to the invention. ABL's argument in this regard was not addressed by the panel below.

kinds of software patents, *it has never before* substantively addressed patent eligibility for a computerized expert system. In that sense, this was a case of first impression for the Federal Circuit.

The repeated and narrow focus on computer-implemented business methods by the Federal Circuit has failed to yield a workable general framework applicable to all computer implemented inventions. This is because the “business” aspects of the underlying invention are often hard to tease out from the computer-implemented aspects, and as such tend to influence, either directly or indirectly, the court’s perception of what is the “inventive concept.” *Mayo*, 132 S.Ct. at 1294 (citing *Flook*, 437 U.S. at 594). By avoiding the confounding presence of business and financial concepts, the dispute over the eligibility of the ABL patent claims would allow the Federal Circuit to focus instead on the core technological issues that underlie the claim, once it has the benefit of this Court’s guidance in *Alice*.

Further, the logic of the panel’s conclusion—that an expert system simply does what a given human expert would do mentally—proves too much, and while the decision is non-precedential, it presages an approach by the Federal Circuit that could have significant impact on other expert systems patents. By design, expert systems are meant to improve, and in some cases replace, the decision making capabilities of a human. If ABL’s patent claims, which define a specific, novel expert system, are not patent eligible, then it would logically follow that many patents for other types of expert systems in fields ranging from medicine, chemistry, nuclear

engineering, physics, network design, and so forth are likewise invalid because they too merely do the “mental steps” that a person would perform. This approach trivializes the contribution that is involved in developing a specific type of novel and non-obvious expert system, and if followed by district courts and other panels of the Federal Circuit, would jeopardize an increasingly important field of technology.

II. **ANY OUTCOME IN *ALICE* WILL REQUIRE GVR**

A. **The Supreme Court’s Test in *Alice* Will Have to be Applied to ABL’s Claims**

This Court is now considering the case of *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, No. 13-1298, addressing the patent eligibility requirements of computer-implemented inventions. The *Alice* decision will likely articulate a patent eligibility test that will be directly applicable to the ABL patent claims, which are computer-implemented methods and systems. Whatever test the Court develops, whether it is based on preemption or another criterion, it will almost certainly *not* be, verbatim, the mental steps test used by the panel below. Further, because ABL’s patent claims explicitly recite a computer and are directed to non-financial technology, the *specific guidance* issued by this Court in *Alice* will be applicable, but the *specific holding* on the facts of *Alice* will not. Therefore, a GVR order is appropriate for the panel below to apply the forthcoming *Alice* test to a different technological and factual scenario.

Because the Federal Circuit elected not to enter a precedential opinion in *CLS Bank*, this Court’s decision will be a “recent development” in the law that makes GVR appropriate:

Where intervening developments, or recent developments that *we have reason to believe the court below did not fully consider*, reveal a reasonable probability that the decision below rests upon a premise that the lower court would reject if given the opportunity for further consideration, and where it appears that such a redetermination may determine the ultimate outcome of the litigation, a GVR order is, we believe, potentially appropriate.

Lawrence v. Chater, 516 U.S. 163, 167 (1996) (emphasis added).

This Court can either affirm or reverse the Federal Circuit’s *en banc* per curiam holding in *CLS Bank*. Because no opinion commanded a majority, there was no precedential “test” in the *en banc* decision in *CLS Bank* as to the patent eligibility of computer-implemented inventions. Therefore, even an affirmance will necessarily create new precedent, replacing the non-precedential opinion with a binding rule that is applicable to ABL’s patent claims. On the other hand, if the Court reverses, it will again set forth a new precedent. Thus, no matter what the outcome in *Alice*, there will be new, binding precedent from this Court that will govern the ABL patent claims and which was not previously applied.

Second, outside of the remote possibility that the Court's *Alice* decision will be based purely on a mental steps approach, the Court's test will likely be one that reveals that the panel's decision rests upon a premise—that computers simply perform mental steps—that the lower court will have to reject. This Court, mindful of the ubiquity and technological importance of computers in providing humans assistance with everyday tasks, is unlikely to adopt a rule that would render ineligible any computer method that facilitates decision making by humans.

Finally, the clarified test for patent eligibility will critically impact the ultimate outcome in this case. All one-hundred and thirty-two claims in two patents have been declared invalid. Any test that enables even one claim to survive will restore ABL's opportunity to reach the underlying merits of this case.

As such, a GVR order is appropriate to ensure that ABL's patent claims are appropriately considered under a proper test for computer-implemented inventions.

B. An Affirmance of *CLS Bank* Will Refine Current Precedent that Must be Applied to ABL's Claims

There are a limited number of possible outcomes if this Court affirms the *CLS Bank* decision below, and holds Alice's patent claims invalid. In each case, GVR is appropriate.

1. The Court can affirm, and adopt a preemption-based test such as set forth by the Federal Circuit plurality opinion in *CLS Bank*, or along the lines of the concurring opinion of Judge Rader, either of which would be based on an analysis of whether Alice’s patent claims preempt the abstract idea of third-party risk intermediation. Either way, the Court will set forth a series of steps that must be taken to determine the scope of the claim and its preemptive impact.

Before incorrectly applying the “mental steps” doctrine, the panel below appears to have simply adopted the preamble of claim 1 as the abstract idea implicated: a “method for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition.” (App. 9a.) Assuming this is correct, the proper application of the preemption analysis under this Court’s precedent asks: do the claims of the ABL patents “wholly pre-empt” one from “guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition?” *Benson*, 409 U.S. at 72. The question is therefore whether any claim limitations narrow them from “covering the concept’s every practical application,” “*all commercial uses or applications* of that idea” (the processing of evaluation, consideration and construction of such regimens), *CLS Bank*, 717 F.3d at 1332 (Linn, J., dissenting) (emphasis added), or “*cover[ing] all possible ways to achieve the provided result*” (the selection of a treatment regimen), *Id.* at 1301 (Rader, J., concurring-in-part and dissenting-in-part) (emphasis added).

The panel below did not consider this question in any detail, let alone with the particularity that this Court employed in *Mayo* (considering each step individually with respect to its scope and implementation), or by the Federal Circuit in *CLS Bank*. The entirety of the panel’s analysis that touched upon preemption was a single statement: “In this context, the concern about preempting public use of certain kinds of knowledge, emphasized in *Mayo*, is a grave one.” (App. 11a.)

The panel instead used the mental steps doctrine, which is inapplicable to the claimed invention. To reach this conclusion, the panel implicitly had to determine the scope of the claim, since it concluded that “Like the processes claimed in *Benson*, the process of claim 1 ‘can be . . . performed without a computer’ or, alternatively, ‘can be carried out in existing computers long in use, no new machinery being necessary.’” (App. 10a.) However, as noted above, there was no *evidence in the record*, no admissions, no expert testimony, no stipulation of fact, nothing to support the conclusion that in *practical terms*, claim 1 can be performed without a computer. This was simply the panel deciding on its own that such was possible. Unlike financial methods such as disclosed in *Bilski*, *Accenture*, *Fort Properties*, or *Bancorp*, the single, simple equation in *Flook*, or the basic mathematical steps in *Benson*, all of which could in fact easily be performed without a computer, it is by definition *impossible* to have an expert computer system without the computer.

Once the panel wiped out the necessity of a computer, it simply asserted that “a doctor’s mind”

contains “a set of “expert rules for evaluating and selecting” from a stored “plurality of different therapeutic treatment regimens,” as well as “advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens,” as set forth in claim 1. (App. 10a.) Again, there was *no evidence* in the record, such as an expert declaration of a physician, that a “doctor’s mind” contains anything of the sort.

Accordingly, should this Court again endorse preemption as the framework for patent eligibility for computer-implemented inventions, GVR would be appropriate for the panel along with an instruction to remand to the district court for development of a record specifically focused on the facts relevant to preemption.

2. The Court can affirm the result in *CLS Bank*, and adopt a different, non-preemption based test, such as the test set forth by the Solicitor General. The Solicitor General proposed that computer software is patent eligible only if the software innovation “improves the functions of the computer technology” or “is used to improve another technology,” but offering no way of deciding what counts as “technology.” Transcript of Oral Argument at 45, *Alice Corp. Pty. Ltd. v. CLS Bank Int’l* (No. 13-1298).

The panel below did not employ anything approaching this test. Whether an invention “improves” some other technology is a question of fact, not something that the Federal Circuit can

decide without evidence. Indeed, in its motion for reconsideration, ABL submitted to the District Court evidence including clinical data showing that the use of the patented invention demonstrably improved patient treatment outcomes. Unfortunately, the District Court struck this evidence, and the Federal Circuit affirmed that decision. (App. 40a, App. 12a.) This is *precisely the kind of evidence* of an improvement that would become relevant to the question of patent eligibility should the government's approach be adopted in whole or in part. It would be particularly inequitable to ABL if the test for patent eligibility turned on the factual question of whether the computer-implemented method improves a technology and then ABL were denied the opportunity to demonstrate this fact, when its previous efforts to do were rebuffed. A GVR order would prevent such a result.

3. The Court can affirm and adopt some version of a mental steps test. Even in this case, it will almost certainly be a different articulation from that used by the panel below. ABL's patent claims would need to be revisited in view of *this Court's* articulation of the mental steps test. Additionally, any mental steps test would require a factual basis before concluding that the claims could be "entirely performed" by a human. Again, there is no evidence in the record to support this conclusion. Thus, even under this outcome, GVR and, potentially an instruction to remand to the district court for further factual development would be most appropriate.

In any of the foregoing possible outcomes, the Court's *reasoning* would apply to the ABL patent

claims but its *holding* should not control. This is because while the legal issue in this case is essentially the same as in *Alice*—the patent eligibility of computer implemented inventions—the factual and procedural posture of the cases are entirely different. First, the ABL claims are not like those in *Alice*. The ABL claims are not directed to financial processes, such as third party transaction settlement and therefore do not implicate some economic activity. In contrast, the ABL claims are directed to a technological solution for aiding in the selection of medical treatments using computerized technology, a field that is traditionally considered scientific and less “suspect” than business methods.

Second, Alice’s patent claims on their face do not recite any computer elements whatsoever. By contrast, the ABL patent claims expressly recite a computing device that is particularly configured with three specifically recited databases. This is no mere “draftsman effort” to claim an abstract idea, but instead consistent with the way one of skill in the art would claim an expert system. They are therefore much less “abstract” than Alice’s claims under any articulation of whatever test the Court develops to identify patents that directly claim “abstract” ideas.

Third, the factual posture of this case is entirely different from *Alice*. In *Alice*, there was an expert declaration that addressed, *inter alia*, the level of ordinary skill in the art and whether a computer was required to perform the claimed methods *Id.* at 1329. Joint Appendix at 116-131, *Alice Corp. Pty. Ltd. v. CLS Bank Int’l* (No. 13-298). Thus, there was a factual record on which the Federal Circuit, and this

Court could interpret the scope of Alice’s claims and their preemptive impact, whether the claims were directed to technology, or whether the claims were directed to mental steps. In the present case, there are no such expert declarations, and the district court made no factual findings of this nature.

Thus, an affirmance by this Court of *CLS Bank* will create new precedent with a *test* that will apply to ABL’s patent claims, since the direct *holding* of *CLS Bank* will not be applicable. GVR will be appropriate to permit the panel to apply this test to ABL’s patent claims.

C. A Reversal of *CLS Bank* Would Create a Broader Test of Patent Eligibility That Must Be Applied to ABL’s Claims

The Court may choose to reverse the Federal Circuit in *CLS Bank*, and find Alice’s claims patent eligible. In that event, the Court will have *broadened* the scope of eligible computer-implemented patent claims compared to the panel’s understanding when it decided this case, setting a new, expanded outer limit for patent eligibility.

In this event, the Court will also necessarily set forth a test that is broader and more flexible than the mental steps test applied by the panel below. Whether a restatement of the preemption test of *Mayo* and *Bilski* or the development of a different standard, the panel’s mental steps test is unlikely to be the correct one.

Thus, an opinion by this Court reversing the *en banc* decision in *CLS Bank* would undermine the panel's conclusion that the ABL patent claims are not patent eligible. In other words, the panel's decision would be predicated on bad law. The conditions for GVR would be particularly satisfied then, because such a new test would be a recent development that was not considered by the panel below, and which unquestionably impacts the ultimate outcome in this case.

CONCLUSION

On the basis of the foregoing analysis, this Court should grant ABL's petition, vacate the panel decision below, and remand to the Federal Circuit for reconsideration of its opinion in view of the Court's decision in *Alice*.

Respectfully submitted,

ROBERT R. SACHS*
DANIEL R. BROWNSTONE
FENWICK & WEST LLP
555 California Street
12th Floor
San Francisco, CA 94104
(415) 875-2300
rsachs@fenwick.com

Counsel for petitioners

April 24, 2014

*Counsel of Record

APPENDIX A

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

No. 2013-1186

SMARTGENE, INC., *PLAINTIFF-APPELLEE*,

v.

ADVANCED BIOLOGICAL LABORATORIES, SA, AND
ABL PATENT LICENSING TECHNOLOGIES, SARL,
DEFENDANTS-APPELLANTS.

Decided: January 24, 2014

Appeal from the United States District Court for the
District of Columbia in No. 08-CV-0642
Judge Beryl A. Howell

BEFORE LOURIE, DYK, and TARANTO, *Circuit Judges*.

TARANTO, *Circuit Judge*.

SmartGene, Inc. brought this action against Advanced Biological Laboratories, SA, and ABL Patent Licensing Technologies, SARL (collectively, ABL), seeking a declaratory judgment that it did not infringe two of ABL's patents, U.S. Patent Nos. 6,081,786 and 6,188,988, and that both patents were invalid. The district court granted summary judgment that all claims of both patents were ineligible for patent protection under 35 U.S.C. § 101. *See SmartGene, Inc. v. Adv. Biological Labs., SA*, 852 F. Supp. 2d 42, 62 (D.D.C. 2012), *reconsideration denied*, 915 F. Supp. 2d 69 (D.D.C. 2013). We affirm.

BACKGROUND

Each of the two patents here is entitled "Systems, Methods and Computer Program Products for Guiding the Selection of Therapeutic Treatment Regimens." In each, the key claims are independent Claims 1, 23, and 45, which describe a method, a system, and a computer program, respectively, for guiding the selection of a treatment regimen for a patient with a known disease or medical condition. Claim 1 of the '786 patent reads:

1. A method for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition, said method comprising:

(a) providing patient information to a computing device comprising:

a first knowledge base comprising a plurality of different therapeutic treatment regimens for said disease or medical condition;

a second knowledge base comprising a plurality of expert rules for evaluating and selecting a therapeutic treatment regimen for said disease or medical condition;

a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens; and

(b) generating in said computing device a ranked listing of available therapeutic treatment regimens for said patient; and

(c) generating in said computing device advisory information for one or more therapeutic treatment regimens in said ranked listing based on said patient information and said expert rules.

'786 patent, col. 17, line 49, through col. 18, line 4. Claim 1 of the '988 patent is nearly identical. *See* '988 patent, col. 17, line 53, through col. 18, line 12. Claim 23 in each patent claims "[a] system" rather than a method, but otherwise is similar in content.

See '786 patent, col. 19, lines 22-45; '988 patent, col. 23, lines 32-59. Claim 45 in each patent has similar content, but claims a "computer program product comprising a computer usable storage medium having computer readable program code means embodied in the medium." *See* '786 patent, col. 20, line 61, through col. 21, line 22; '988 patent, col. 21, lines 16-48. For reasons to be indicated, we need not be more precise about the claims other than claim 1 of the '786 patent.

In May 2008, *SmartGene* filed this action against ABL, seeking a declaratory judgment that, among other things, the two patents were ineligible for protection under section 101. ABL counterclaimed, asserting infringement of Claims 1 and 23 of both patents. To establish that an actual controversy existed between the parties, SmartGene's complaint identified a prior lawsuit by ABL against SmartGene, in which ABL's complaint alleged infringement of "at least claim 1 of each of the '786 and '988 Patents." J.A. 59. That earlier infringement action, filed in the Eastern District of Texas, had been dismissed for lack of personal jurisdiction before SmartGene initiated this declaratory-judgment action. The present case was stayed until September 2011 while the Patent and Trademark Office reexamined the '786 and '988 patents on prior-art, but not section 101, grounds. The PTO ultimately concluded that all of the patents' claims were patentable over the prior art presented during the reexaminations.

In December 2011, SmartGene moved for summary judgment that "all of the claims" of the

'786 and '988 patents are ineligible for a patent under section 101. Mem. in Supp. of Partial Summ. J. at 1, *SmartGene, Inc. v. Adv. Biological Labs, SA*, No. 08-CV-0642 (D.D.C. Dec. 12, 2011), ECF 47. Expressly asserting that “for the purpose of the § 101 analysis, claim 1 of the '786 patent is representative of all of the claims of the patents-in-suit,” SmartGene’s motion limited its elaboration of its arguments for ineligibility to that claim. J.A. 381. In its responsive briefing opposing summary judgment, ABL never contested SmartGene’s characterization of claim 1 of the '786 patent as representative of all claims of both patents. Opp. to Mot. for Partial Summ. J., *SmartGene*, No. 08-CV-0642 (D.D.C. Dec. 27, 2011), ECF 51. At the oral argument on the summary-judgment motion, ABL did argue that “system” claims require a different analysis from “method” claims. *See* J.A. 2789-91 (“[F]or a system claim, there is a little bit different analysis because claiming an actual system . . . makes it even less abstract because it’s not just a method . . . it is even more intimately connected to the computer, as it is the system.”).

Based on the failure of ABL’s briefing to contest SmartGene’s characterization of claim 1 of the '786 patent as representative of all claims, the district court found “that the differences between the various method and system claims within the patents-in-dispute are immaterial with respect to whether the patents constitute eligible subject matter under 35 U.S.C. § 101” and, therefore, analyzed only claim 1 of the '786 patent. *SmartGene, Inc.*, 852 F. Supp. 2d at 45-46. The district court concluded that the claim does “no more than describe . . . an abstract mental

process engaged in routinely, either entirely within a physician's mind, or potentially aided by other resources in the treatment of patients." *Id.* at 55. The court held claim 1 of the '786 patent, and hence all asserted claims, "invalid" under section 101. *Id.* at 66.

ABL moved for reconsideration. The court denied the motion. It again reiterated that ABL had not contested the representativeness of claim 1 of the '786 patent in its papers opposing summary judgment and, even at the argument on the motion, had not provided any reason for distinguishing other claims from that one. *SmartGene*, 915 F. Supp. 2d at 75-76.

ABL appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

Review of a grant of summary judgment is de novo. *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1341-42 (Fed. Cir. 2013). Patent eligibility under section 101 is an issue of law. *Bancorp Servs., LLC v. Sun Life Assurance Co. of Can.*, 687 F.3d 1266, 1273 (Fed. Cir. 2012).

A

ABL contends that, even if claim 1 of the '786 patent is invalid, the district court erred in invalidating all claims of the two patents on that basis. Neither of ABL's arguments to support that contention has merit.

First, SmartGene unambiguously moved for summary judgment that all claims of the ‘786 and ‘988 patents— not, as ABL argues, only claims 1 and 23 of both—were ineligible under section 101. *See SmartGene*, 915 F. Supp. 2d at 73-74 (“[ABL’s] assertions in this regard are patently false SmartGene consistently asserted that it was contesting the validity of *all of the claims* in both the ‘786 patent and the ‘988 patent.”). At the outset of this action, SmartGene’s complaint sought a declaratory judgment that the ‘786 and ‘988 patents, without limitation, were ineligible for patent protection. *See* J.A. 60-61. Although ABL *counter*claimed for infringement of only claims 1 and 23 of each patent, SmartGene never narrowed the scope of its declaratory-judgment claims. When later moving for summary judgment, SmartGene expressly placed all claims at issue, asserting that “the *patents-in-suit* are facially invalid as directed to non-statutory subject matter under 35 U.S.C. § 101.” J.A. 366 (emphasis added); *see also* J.A. 374 (arguing in briefing accompanying the summary-judgment motion that “all of the claims of the patents-in-suit are invalid”). Thus, the district court did not err in addressing all claims of the ‘786 and ‘988 patents.

We see no jurisdictional barrier to the district court’s ruling on all of the claims. The eligibility of all claims under section 101 presented a case or controversy. ABL never argued that the district court lacked jurisdiction over any of SmartGene’s claims. And ABL had sued SmartGene in an earlier action, in Texas, alleging infringement of both patents without limitation to particular claims. Given that complaint, we see no reason for

concluding that SmartGene failed to meet its “burden of establishing the existence of an actual case or controversy” as to all claims of both patents. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 140 (2007).

Second, not only were all claims properly before the district court on summary judgment, but the court could properly rest its judgment on its analysis of claim 1 of the ‘786 patent. In its summary-judgment filings, SmartGene expressly asserted that claim 1 was representative and that any differences between the claims are immaterial under section 101, *see* J.A. 381, and ABL did not dispute that characterization in its briefing. It is well established that arguments that are not appropriately developed in a party’s briefing may be deemed waived. *See, e.g., SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006) (collecting cases). During the summary-judgment oral argument, ABL alluded to “a different analysis as to the abstractness issue” between system and method claims. J.A. 2789-91. But the district court acted well within its discretion in concluding, as it explained on reconsideration, that such passing assertions did not amount to a developed argument for different treatment, especially in light of ABL’s complete failure to raise the issue in its briefing. We view the court’s ruling as essentially one that ABL forfeited any argument that any patent claims here are to be treated differently from claim 1 of the ‘786 patent.

B

The district court correctly held that the claim 1 method falls outside the eligibility standards of section 101 as that provision has been construed. This conclusion follows from *CyberSource Corp. v. Retail Decisions, Inc.*, where, based on earlier precedents, this court held that section 101 did not embrace a process defined simply as using a computer to perform a series of mental steps that people, aware of each step, can and regularly do perform in their heads. 654 F.3d 1366, 1373 (Fed. Cir. 2011); *see also In re Grams*, 888 F.2d 835, 840-41 (Fed. Cir. 1989); *In re Meyer*, 688 F.2d 789, 794-95 (C.C.P.A. 1982). As *CyberSource* explains, those precedents rest on Supreme Court decisions indicating that section 101 covers neither “mental processes”—associated with or as part of a category of “abstract ideas”—nor processes that merely invoke a computer and its basic functionality for implementing such mental processes, without specifying even arguably new physical components or specifying processes defined other than by the mentally performable steps. *See Gottschalk v. Benson*, 409 U.S. 63, 67-68 (1972); *Parker v. Flook*, 437 U.S. 584, 589 (1978).

Those precedents cover this case. Claim 1 does no more than call on a “computing device,” with basic functionality for comparing stored and input data and rules, to do what doctors do routinely. In three steps, claim 1 defines a “method for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition.” ‘786 patent, col. 17, lines 49-51. The method (1)

“provid[es] patient information to a computing device” having routine input, memory, look-up, comparison, and output capabilities and that (2) “generat[es] . . . a ranked listing of available therapeutic treatment regimens” and (3) “generat[es] . . . advisory information for one or more therapeutic treatment regimens in said ranked listing.” *Id.* at col. 17, line 52, through col. 18, line 3. Claim 1 places only very broad limitations on a “computing device”: it must contain—like a doctor’s mind—a set of “expert rules for evaluating and selecting” from a stored “plurality of different therapeutic treatment regimens,” as well as “advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens.” *Id.* at col. 17, lines 54-64.

Like the processes claimed in *Benson*, the process of claim 1 “can be . . . performed without a computer” or, alternatively, “can be carried out in existing computers long in use, no new machinery being necessary.” 409 U.S. at 67. The claim does not purport to identify new computer hardware: it assumes the availability of physical components for input, memory, look-up, comparison, and output. Nor does it purport to identify any steps beyond those which doctors routinely and consciously perform. Our ruling is limited to the circumstances presented here, in which every step is a familiar part of the conscious process that doctors can and do perform in their heads.

The Supreme Court’s post-*CyberSource* decision in *Mayo Collaborative Servs. v. Prometheus Labs.*,

Inc., 132 S. Ct. 1289 (2012), reinforces the application of *CyberSource* to decide the present case. The Supreme Court in *Mayo*, though addressing a case involving the “law of nature” exclusion from section 101, recognized that “mental processes” and “abstract ideas” (whatever may be the precise definition and relation of those concepts) are excluded from section 101. *See* 132 S. Ct. at 1289, 1293, 1297-98 (quotation marks omitted). Whatever the boundaries of the “abstract ideas” category, the claim at issue here involves a mental process excluded from section 101: the mental steps of comparing new and stored information and using rules to identify medical options.

Mayo demanded that, when a claim involves an abstract idea (or, in *Mayo* itself, a law of nature), eligibility under section 101 requires that the claim involve “enough” else—applying the idea in the realm of tangible physical objects (for product claims) or physical actions (for process claims)—that is beyond “well-understood, routine, conventional activity.” 132 S. Ct. at 1294, 1298, 1299. The claim here does not do so. It calls on a computer to do nothing that is even arguably an advance in physical implementations of routine mental information comparison and rule-application processes. In this context, the concern about preempting public use of certain kinds of knowledge, emphasized in *Mayo*, is a grave one. *See id.* at 1301-02.

Our decisions since *Mayo* do not undermine *CyberSource* or its application here. None of those decisions calls for validation of a claim, like the

present one, to familiar mental steps performed by or with a computer, without more of significance.

Both the court's decision in *Bancorp, supra*, and its decision in *CLS Bank Int'l v. Alice Corp. Pty*, 717 F.3d 1269 (Fed. Cir. 2013) (en banc), *cert. granted*, 134 S. Ct. 734 (2013), insofar as they involved process claims like the claim here at issue, invalidated certain claims—which involved use of a computer, not defined other than by its function, to perform familiar steps of creating, recording, and altering of certain intangible entities (contracts such as insurance policies or financial obligations). *Accenture Global Servs., GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336 (Fed. Cir. 2013), is similar. *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335 (Fed. Cir. 2013), reversed an invalidation on a motion to dismiss, but the process claimed there was materially different from the one at issue here. Although the parties did not dispute the involvement of an “abstract idea”—getting a kind of confirmation that a viewer has watched advertising as a precondition to sending the viewer desired programming—the process at issue in *Ultramercial* did not involve “mere mental steps.” *See* 722 F.3d at 1349 n.2. And the claims involved a recitation of specifics of computer networks beyond what the present case involves. *See id.* at 1350.

CONCLUSION

For these reasons, the judgment of the district court is affirmed.

AFFIRMED

APPENDIX B

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

CASE No. 13-1186

SMARTGENE, INC., PLAINTIFF-APPELLEE,

v.

ADVANCED BIOLOGICAL LABORATORIES, SA, AND
ABL PATENT LICENSING TECHNOLOGIES, SARL,
DEFENDANTS-APPELLANTS.

ENTERED: MARCH 3, 2014

Appeal from the United States District Court
for the District of Columbia in Case No. 08-CV-0642
United States District Judge Beryl A. Howell

MANDATE

In accordance with the judgment of this Court, entered January 24, 2014, and pursuant to Rule 41(a) of the Federal Rules of Appellate Procedure, the formal mandate is hereby issued.

FOR THE COURT

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

APPENDIX C

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

Civil Action No. 08-00642 (BAH)
Judge Beryl A. Howell

SMARTGENE, INC., PLAINTIFF,

v.

ADVANCED BIOLOGICAL LABORATORIES, SA, *ET AL.*,
DEFENDANTS.

January 3, 2013

MEMORANDUM OPINION

Defendants Advanced Biological Laboratories, SA and ABL Patent Licensing Technologies, SARL (collectively “ABL”) have filed a Motion for Reconsideration under Federal Rule of Civil Procedure 59(e), *see* ECF No. 67, requesting that this Court reconsider its Order granting summary judgment of patent invalidity in favor of Plaintiff SmartGene, Inc. For the reasons explained below, the three grounds proffered by the defendants for reconsideration are unavailing, and the motion is denied.

I. FACTUAL AND PROCEDURAL BACKGROUND¹

Plaintiff SmartGene, Inc., a North Carolina corporation, brought this lawsuit against defendant Advanced Biological Laboratories, SA, a company with its principal place of business in Luxembourg, seeking declaratory judgment as to the invalidity, unenforceability, and SmartGene’s non-infringement of U.S. Patent No. 6,081,786 (the “786 patent”) and U.S. Patent No. 6,188,988 B1 (the “988 patent”) (collectively, the “patents-in-suit”). *See* First Am. Compl. for Declaratory Judgment (“Am. Compl.”), ECF No. 4. After prolonged litigation, including a consensual stay of proceedings of two and a half years, *see* Order, ECF No. 19 (dated February 3,

¹ The Court incorporates by reference the detailed factual and procedural background set forth in its Memorandum Opinion, ECF No. 65. *See SmartGene, Inc. v. Advanced Biological Labs., SA*, 852 F. Supp. 2d 42, 45-48 (D.D.C. 2012).

2009), granting plaintiff's unopposed motion to stay, SmartGene filed a Motion for Partial Summary Judgment, contending that the "patents-in-suit are facially invalid as directed to non-statutory subject matter under 35 U.S.C. § 101." Pl.'s Mot. for Part. Summ. J. of Invalidity Under 35 U.S.C. § 101 ("Pl.'s Mot. for Part. Summ. J."), ECF No. 47.²

This Court granted the plaintiff's Motion for Partial Summary Judgment, finding that "the defendants' Patent Nos. 6,081,786 and 6,188,988 B1 constitute ineligible subject matter under 35 U.S.C. § 101, and are therefore invalid." *SmartGene, Inc. v. Advanced Biological Labs., SA*, 852 F. Supp. 2d 42, 68 (D.D.C. 2012).

Following the Court's decision, the defendants moved for reconsideration under Federal Rule of Civil Procedure 59(e), and submitted in support of

² As the Court explained in its Memorandum Opinion regarding this motion,

SmartGene stated at the March 9, 2012 Motions Hearing that the Motion was framed as a Motion for "Partial" Summary Judgment because the Motion deals only with the validity of the patents-in-dispute and does not address all disputed claims. *See* Motions Hearing Transcript ("Tr") (Rough), Mar. 9, 2012, at 9:30, 42:23-43:1; 43:6-12 No matter the styling of the pending Motion as a "partial" Motion for Summary Judgment, grant of this Motion is dispositive in this matter since the validity of the patents-in-dispute is the *sine qua non* for all the claims and counterclaims.

SmartGene, Inc., 852 F. Supp. 2d at 45 n.1. The Court cited to the court reporter's rough draft of the proceedings in the Memorandum Opinion because the parties had not yet requested formal transcripts. *See id.*

that motion over 1500 pages of declarations and exhibits, including materials not previously provided to the Court for consideration. *See* Defs.’ Mot. for Reconsideration Under F.R.C.P. 59(e) (“Defs.’ Mot.”), ECF No. 67. The plaintiff SmartGene, Inc. opposes the defendants’ Motion for Reconsideration, *see* Pl.’s Opp’n to Defs.’ Mot. for Reconsideration Under F.R.C.P. 59(e) (“Pl.’s Opp’n”), ECF No. 69, and has moved to strike the declarations and exhibits attached to the defendants’ Motion for Reconsideration, *see* Pl.’s Mot. to Strike the Declarations and Certain Exhibits Attached to Defs.’ Mot. for Reconsideration (“Pl.’s Mot. to Strike”), ECF No. 68. Both the defendants’ Motion for Reconsideration and the plaintiff’s Motion to Strike are now pending before the Court.³

II. STANDARD OF REVIEW

“A Rule 59(e) motion is discretionary and need not be granted unless the district court finds that there is an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice.” *Messina v. Krakower*, 439 F.3d 755, 758 (D.C. Cir. 2006) (quoting *Firestone v. Firestone*, 76 F.3d 1205, 1208 (D.C. Cir. 1996)). A motion for reconsideration under Rule 59(e) is “not simply an opportunity to reargue facts and theories upon which a court has already

³ The defendants requested oral argument on their Motion for Reconsideration, *see* ECF No. 67 at 1. Since the parties have extensively briefed the pending motions, however, the Court exercises its discretion under Local Civil Rule 7(f) to decide the motions on the papers.

ruled.” *Fresh Kist Produce, LLC v. Choi Corp.*, 251 F. Supp. 2d 138, 140 (D.D.C. 2003) (quoting *New York v. United States*, 880 F. Supp. 37, 38 (D.D.C. 1995)). Moreover, “the reconsideration and amendment of a previous order is an unusual measure.” *Swedish Am. Hosp. v. Sebelius*, 845 F. Supp. 2d 245, 250 (D.D.C. 2012); *see also Jung v. Ass’n of Am. Med. Colls.*, 184 Fed. Appx. 9, 13 (D.C. Cir. 2006) (noting “the high standard for relief under Rule 59(e)”); *Niedermeier v. Office of Max S. Baucus*, 153 F. Supp. 2d 23, 28 (D.D.C. 2001) (“Motions under [Rule 59(e)] are disfavored and relief from judgment is granted only when the moving party establishes extraordinary circumstances.”). “Rule 59 was not intended to allow a second bite at the apple.” *Oceana, Inc. v. Evans*, 389 F. Supp. 2d 4, 8 (D.D.C. 2005). “In addressing the claims of a party on a motion for reconsideration, the Court is free to expand upon or clarify the reasons supporting its prior ruling.” *Bristol-Myers Squibb Co. v. Kappos*, Nos. 09-cv-1330, 09-cv-2420, 2012 U.S. Dist. LEXIS 134299, at *9 (D.D.C. Sept. 20, 2012).

III.DISCUSSION

The defendants argue that reconsideration of this Court’s Order granting summary judgment for Plaintiff SmartGene, Inc. “is necessary for three reasons.” Defs.’ Brief in Supp. of its Mot. for Reconsideration Under F.R.C.P. 59(e) (“Defs.’ Brief”), ECF No. 67-1, at 1. First, the defendants argue that the Court erred in “invalidating all claims of the patents-in-suit, including unasserted claims.” *Id.* Second, the defendants argue that “invalidating every claim of both patents, or even the four asserted

claims, based solely on an analysis of claim 1 of the ‘786 patent is an error of law.” *Id.* Third, the defendants argue that this Court’s ruling “is premised on a clear error of fact and law given that there was a change in controlling law subsequent to the summary judgment proceedings in this case,” namely the Supreme Court’s decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), which the defendants argue they should have been “provided an opportunity to brief.” Defs.’ Brief at 1. In connection with this third argument, the defendants have submitted evidence that “ABL seeks to present given the *Prometheus* Court’s holdings,” *id.* at 7, in the form of a declaration from a named inventor of the patents-in-suit, a declaration of a patent attorney involved in prosecuting the patents-in-suit, and hundreds of pages of related exhibits. *See* ECF Nos. 67-4, 67-5, 67-6, 67-7, 67-8, 67-9, 67-10, 67-11, 67-12, 67-13, 67-14, 67-15, 67-16, 67-17, 67-18, 67-19, 67-20, 67-21, 67-22, 67-23, 67-24, 67-25, 67-26, 67-27, 67-28, 67-29, and 67-30 (totaling over 1500 pages). The Court addresses these arguments *seriatim* below.

First, the Court turns to the defendants’ contention that “invalidating all claims of the patents-in-suit, including unasserted claims, is an error of law.” Defs.’ Brief at 1. The defendants claim that it is “undisputed that SmartGene chose to contest the validity of only claims 1 and 23 of each of the ‘786 and ‘988 patents” and that the plaintiff “provided no argument regarding any claims other than the four claims at issue, and never alleged a case or controversy existed with respect to any other claims.” *Id.* at 2; *see also id.* at 3 (“In short, there

was never a case or controversy with respect to anything but claims 1 and 23 of the '786 and '988 patents.”). The defendants’ assertions in this regard are patently false, however. The plaintiff made it abundantly clear that it was seeking declaratory judgment of invalidity as to the '786 patent and the '988 patent. *See, e.g.*, Am. Compl., ECF No. 4, at 4 (seeking, in Count II, “Declaratory Judgment of Invalidity of the ‘786 Patent”); *id.* at ¶ 20 (“The ‘786 Patent is invalid for failing to comply with 35 U.S.C. §§ 101-103 and/or 112”); *id.* at 5 (seeking, in Count IV, “Declaratory Judgment of Invalidity of the ‘988 Patent”); *id.* at ¶ 26 (“The ‘988 Patent is invalid for failing to comply with 35 U.S.C. §§ 101-103 and/or 112”); *id.* at 6 (requesting, in Prayer for Relief, “A declaration that each of the claims of the ‘786 Patent are invalid” and “A declaration that each of the claims of the ‘988 Patent are invalid.”); Pl.’s Mot. for Clarification and/or Reconsideration, ECF No. 44, at 1 (noting that “[i]n April 2008, SmartGene filed its original Complaint (Dkt# 1) in this declaratory judgment action seeking a declaration that U.S. Patent Nos. 6,081,786 and 6,188,988 B1 (collectively, the ‘patents-in-suit’) are invalid and that SmartGene does not infringe the patents-in-suit.”); Pl.’s Mot. for Part. Summ. J. of Invalidity Under 35 U.S.C. § 101 (“Pl.’s Mot”), ECF No. 47, at 1 (“[T]he patents-in-suit are facially invalid as directed to non-statutory subject matter under 35 U.S.C. § 101.”); LCvR 7(h) Statement of Undisputed Material Facts in Supp. of Pl.’s Mot. for Part. Summ. J. of Invalidity Under 35 U.S.C. § 101 (“Pl.’s Facts”), ECF No. 47-1, at 1 (noting that the plaintiff “filed this declaratory judgment action seeking a declaration that U.S.

Patent Nos. 6,081,786 and 6,188,988 B1 (collectively, the ‘patents-in-suit’ and individually as ‘the ‘786 patent’ and ‘the ‘988 patent’, respectively) are invalid and unenforceable”); Pl.’s Mem. in Supp. of Part. Summ. J. of Invalidity Under 35 U.S.C. § 101 (“Pl.’s Mem.”), ECF No. 47-2, at 1 (“SmartGene filed this declaratory judgment action seeking a declaration that U.S. Patent Nos. 6,081,786 and 6,188,988 B1 (collectively, the ‘patents-in-suit’) are invalid and that SmartGene does not infringe the patents-in-suit.”); *id.* (“SmartGene now moves for summary judgment of invalidity of the claims of the patents-in-suit on the ground that the claims are directed to non-statutory subject matter under 35 U.S.C. §101”); *id.* (arguing that “*all of the claims* of the patents-in-suit are invalid and this motion should be granted”) (emphasis added); *id.* at 2 (noting that “[t]his motion, if granted, is dispositive of the validity of the patents-in-suit”); *id.* at 10 (arguing that “the claims of the patents-in-suit are clearly directed to subject matter that is ineligible for patenting and summary judgment of invalidity should be granted”); *id.* at 16-17 (“For the reasons stated above, the claims of the ‘786 patent and the ‘988 patent are invalid for failure to claim patent-eligible subject matter.”); Pl.’s Reply to Defs.’ Opp’n to Pl.’s Mot. for Part. Summ. J. of Invalidity Under 35 U.S.C. § 101 (“Pl.’s Reply”), ECF No. 55, at 1 (concluding that the defendants’ opposition “reinforces the compelling case for finding that the *patents-in-suit* are invalid as failing to comply with 35 U.S.C. § 101”) (emphasis added); *id.* at 11 (“Regardless of how the claims of the patents-in-suit are analyzed, whether under the software *per se* rubric, the mental steps rubric, or the

machine or transformation test, they are abstract. Accordingly, this Court should grant SmartGene's motion and invalidate the claims of the patents-in-suit.”).

Rather incredibly in the face of these statements in the record, the defendants characterize as “*undisputed* that SmartGene chose to contest the validity of only claims 1 and 23 of each of the ‘786 and ‘988 patents,” and aver, in particular, that the plaintiff “never argued the invalidity of dependent claims 2-22, 24-44, nor the invalidity of claims 45-66 of both patents, claims directed to various ‘computer program products.’” Defs.’ Brief at 2-3 (emphasis added). Ignoring the plain breadth of the plaintiff’s challenge to the validity of the patents-in-suit, the defendants myopically point to the plaintiff’s statement that “[t]he following comprises the text of the four claims in suit reproduced in their entirety” together with the plaintiff’s listing of claims 1 and 23 of the ‘786 and ‘988 patents, and suggest that “SmartGene acknowledged that ‘[i]n this litigation, ABL is only asserting claims 1 and 23 of the ‘988 patent” *Id.* at 2 n.1. While the LCvR 7(h) Statement of Undisputed Material Facts in Support of Plaintiff’s Motion for Partial Summary Judgment, ECF No. 47-1 — to which the defendants never responded — does focus on those four claims, *see* Pl.’s Facts at ¶¶ 5, 7, 9, 10, plaintiff SmartGene consistently asserted that it was contesting the validity of *all of the claims* in both the ‘786 patent and the ‘988 patent. *See, e.g., id.* at ¶ 1 (noting that SmartGene “filed this declaratory judgment action seeking a declaration that U.S. Patent Nos. 6,081,786 and 6,188,988 B1 (collectively, the

‘patents-in-suit’ and individually as ‘the ‘786 patent’ and ‘the ‘988 patent’, respectively) are invalid and unenforceable”). In fact, the plaintiff made clear that it believed that claim 1 of the ‘786 patent “is representative of *all of the claims* of the patents-in-suit,” Pl.’s Mem. at 8 n.3 (emphasis added), and that, based on a finding of invalidity of claim 1 of the ‘786 patent, the patents-in-suit were thus invalid. While the defendants may not *agree* that the plaintiff was correct in asserting that claim 1 of the ‘786 patent was representative of “all of the claims of the patents-in-suit,” or in requesting declaratory judgment that the patents-in-suit in their entirety were invalid, the defendants’ assertion that “SmartGene provided *no* argument regarding any claims other than the four claims at issue, and never alleged a case or controversy existed with respect to any other claims,” Defs.’ Brief at 2 (emphasis added), is simply disingenuous in the face of the above-cited statements in the plaintiff’s filings.

In any case, the defendants had the opportunity to contest these arguments in their Opposition to the Plaintiff’s Motion for Partial Summary Judgment, and failed to do so. *See generally* Defs.’ Opp’n to SmartGene’s Mot. for Part. Summ. J of Invalidity Under 35 U.S.C. § 101, ECF No. 50.

Even if the defendants somehow did not understand from the plaintiff’s motion and the Amended Complaint that the plaintiff was contesting all of the claims in the patents-in-suit based on an analysis of claim 1 of the ‘786 patent, the Court explicitly brought this issue to the attention of the defendants at the motions hearing

held on the plaintiff's Motion for Partial Summary Judgment by asking the defendants' counsel directly the following question:

THE COURT: Let me clarify one other thing that I promised I was going to ask you You know, because SmartGene does say that for purposes of this Section 101 Analysis that claim 1 of 786 Patent is representative of *all the claims of the patents in suit*, you didn't really address that in your brief. So I wanted to know if that's your position.

Transcript of Oral Argument ("Tr.") (Mar. 9, 2012), ECF No. 70, at 31, lines 11-17 (emphasis added). The defendants' counsel responded, stating:

That is not our position. As SmartGene mentioned, and I don't remember if it was their opening brief or their reply brief, there are two different types of claims at issue in the case, both method claims and system claims. And we believe there would be a different analysis as to abstractness issue and whether it can all be performed in the mind between a method claim and a system claim.

Id. at lines 18-24.⁴

⁴ The Court asked the defendants' counsel for further explanation of "how the analysis under 101 would differ for each of the four claims, if that's what you think I have to do." Tr. at 32, lines 5-6. The defendants' counsel responded as follows:

As the Court noted in its Memorandum Opinion, the defendants' counsel's response to this question at the motions hearing provided the Court no reason to conclude that claim 1 of the '786 patent was *not* representative of all of the claims of the patents-in-suit. *See SmartGene, Inc.*, 852 F. Supp. 2d at 46 n.4 (noting that the defendants "fail to cite any authority that supports their assertion [that "method" and "system" claims require a different standard of review for subject matter patentability], and ignore authority to the contrary") (citing *In re Meyer*, 688 F.2d 789, 795 n.3 (C.C.P.A. 1982) ("for purposes of

Okay. And to clarify, for purposes of this argument we are not arguing that kind of the different kind of steps that are performed are different. It's mainly focused on the method versus the system claim, because cases such as *Bilski*, when they are talking of business method patents, and things that can be completed entirely in the mind, are method patents. That's what they discussed. So you can perform this method entirely in your mind. Not this method, but the method at *Bilski* for example. And for a system claim, there is a little bit different analysis because claiming an actual system, I would argue, makes it even less abstract because it's not just a method where, okay, we will look at who is performing the method, how do you perform the method, and what's performing the method, but rather what we have claimed in Claim 23 is a system, the very specific system that is used to select therapeutic treatment regimen[]s. It's even less abstract.

Id. at lines 7-23. The Court then responded by asking the defendants' counsel, "And it's less abstract, why?," *id.* at lines 24-25, to which the defendants' counsel responded, "Because it is even more intimately connected to the computer, as it is the system. It's not just a method where arguably – well, they have argued that the computing device as used in the claims can be a human mind." *Id.* at 33, lines 1-4.

section 101, [claims reciting “means for” performing the steps set forth in the method claims] are not treated differently from method claims”). Thus, the defendants had the opportunity to address this issue at the motions hearing, and could have provided additional briefing if they believed that the Court had an incorrect understanding of the plaintiff’s position. They failed to do so before, during and even after the motions hearing, and have made only a last gasp effort to address the issue of whether claim 1 in both patents-in-suit is representative of all the claims after the Court issued its ruling and in connection with their motion for reconsideration.

The defendants feign ignorance in urging the Court to grant their Motion for Reconsideration, arguing that “[i]f SmartGene truly believed that all the claims of the two patents were a threat, it should have unambiguously argued the invalidity of all claims in its motion.” Defs.’ Reply Mem. in Supp. of Its Mot. for Reconsideration Under F.R.C.P. 59(e) (“Defs.’ Reply”), ECF No. 71, at 1 (emphasis in original). The plaintiff, as indicated above, did just that. *See, e.g.*, Pl.’s Mem. at 2 (“This motion, if granted, is dispositive of the validity of the patents-in-suit”); *see id.* at 1 (“Accordingly, all of the claims of the patents-in-suit are invalid and this motion should be granted”); Pl.’s Reply at 1 (concluding that the defendants’ opposition “reinforces the compelling case for finding that the *patents-in-suit* are invalid as failing to comply with 35 U.S.C. § 101”) (emphasis added); *id.* at 11 (“[T]his Court should grant SmartGene’s motion and invalidate *the claims* of the patents-in-suit.”) (emphasis added); *see also* Am. Compl. at 4 (seeking, in Count II, “Declaratory

Judgment of Invalidity of the ‘786 Patent”); *id.* at ¶ 20 (“The ‘786 Patent is invalid for failing to comply with 35 U.S.C. §§ 101-103 and/or 112”); *id.* at 5 (seeking, in Count IV, “Declaratory Judgment of Invalidity of the ‘988 Patent”); *id.* at ¶ 26 (“The ‘988 Patent is invalid for failing to comply with 35 U.S.C. §§ 101-103 and/or 112”); *id.* at 6 (requesting, in Prayer for Relief, “A declaration that each of the claims of the ‘786 Patent are invalid” and “A declaration that each of the claims of the ‘988 Patent are invalid.”). That the defendants would not understand from these statements that the plaintiff was challenging each of the claims of the patents-in-suit strains credulity.

Indeed, in its opposition to the defendants’ Motion for Reconsideration, SmartGene reaffirms that, in this lawsuit, it “sought a declaration of invalidity of the *entire* ‘786 and ‘988 patents.” Pl.’s Opp’n at 3 n.2 (emphasis added). The defendants, however, remain adamant in their Reply that “SmartGene does not dispute the critical fact that claims 1 and 23 were the only claims subject to its motion for partial summary judgment.” Defs.’ Reply at 1. That claim is simply untrue. *See* Pl.’s Opp’n at 3 n.2 (SmartGene asserting that it “sought a declaration of invalidity of the *entire* ‘786 and ‘988 patents”) (emphasis added). The plaintiff made amply clear its theory of the case, premised on the invalidity of claim 1 of the ‘786 patent under 35 U.S.C. § 101, and the Court will not reopen the litigation now that the defendants have belatedly realized the implications of the plaintiff’s theory, only after issuance of this Court’s decision. *See, e.g., Daniel v. Fulwood*, No. 10-cv-862, 2012 U.S. Dist.

LEXIS 138549, at *4 (D.D.C. Sept. 27, 2012) (“Motions for reconsideration are not simply an opportunity to reargue facts and theories upon which a court has already ruled.”) (citations and internal quotation marks omitted).

Accordingly, since the defendants’ argument that “[i]nvalidation of [u]nasserted [c]laims [i]s [a]n [e]rror of [l]aw,” is based on the false premise that SmartGene “chose to contest the validity of only claims 1 and 23 of each of the ‘786 and ‘988 patents,” Defs.’ Brief at 2, this argument provides no reason for the Court to reconsider its decision.⁵

⁵ The defendants cite a case from the Federal Circuit for the proposition that “[a] party claiming declaratory judgment jurisdiction ‘has the burden of showing . . . that there is a substantial controversy, between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.’” Defs.’ Brief at 2 (quoting *Streck, Inc. v. Research & Diagnostic Sys.*, 665 F.3d 1269, 1282 (Fed. Cir. 2012)). In response, the plaintiff spends much of its opposition to the defendants’ Motion for Reconsideration articulating why there was a “very real controversy regarding the entire ‘786 and ‘988 patents due to ABL’s use of the ‘786 and ‘988 patents in the marketplace in a manner that is significantly injuring SmartGene’s business.” Pl.’s Opp’n at 2. In their reply, the defendants deem to be “irrelevant” SmartGene’s allegation that the ‘786 and ‘988 patents have been used to ward off SmartGene’s potential clients “since the proper inquiry is what SmartGene argued in its motion for summary judgment.” Defs.’ Reply at 1. Since the Court concludes, from the plain language of SmartGene’s Motion for Partial Summary Judgment that SmartGene challenged the patents-in-suit in their entirety, the Court will not proceed here in analyzing SmartGene’s allegations of injury in the marketplace as outlined in its opposition to the Motion for Reconsideration.

Second, the Court turns to the defendants' related argument that "invalidating every claim of both patents, or even the four asserted claims, based solely on an analysis of claim 1 of the '786 patent is an error of law." Defs.' Brief at 1.

As a threshold matter, the defendants take issue with SmartGene's argument that SmartGene articulated its claim grouping theory – that claim 1 of the '786 patent was representative of all of the claims in the patents-in-suit – in its Motion for Partial Summary Judgment. *See* Pl.'s Mem. at 8 n.3 ("Accordingly, for the purpose of the § 101 analysis, claim 1 of the '786 patent is representative of all of the claims of the patents-in-suit."). Again, the defendants feign surprise, asserting that, "[i]f this was notice that SmartGene was arguing the invalidity of 127 separate claims — the vast majority of which are dependent claims — then it successfully hid an elephant in a mousehole." Defs.' Reply at 1 n.3. The Amended Complaint and the plaintiff's Motion for Partial Summary Judgment are no "mousehole[s]," however. In those filings, the plaintiff made it crystal clear that it sought nothing less than declaratory judgment as to the invalidity of the '786 and '988 patents, and that it believed that, "for the purpose of the § 101 analysis, claim 1 of the '786 patent is representative of all of the claims of the patents-in-suit." Pl.'s Mem. at 8 n.3. The defendants' argument that it did not have notice of the plaintiff's claim grouping theory is thus unavailing.

The defendants' argument that the grouping of claims was not proper in this case is similarly

without merit. The defendants acknowledge that “[c]laims may be grouped together only if they involve the same issues of validity and the claim issues are substantially materially identical.” Defs.’ Brief at 3 (citing *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1370 (Fed. Cir. 2003)). Yet, the defendants argue that in this case the Court improperly grouped the claims of the ‘786 and ‘988 patents together, “thereby ignoring differences in the form, type and limitations of 131 claims in two different patents.” Defs.’ Brief at 3.

The Court did not ignore the differences, however, but concluded in its Memorandum Opinion that the “differences” between the system and method claims, at least, were “immaterial.” *SmartGene, Inc.*, 852 F. Supp. 2d at 46. Specifically, the Court acknowledged SmartGene’s assertion that the “differences between Claim 1 in the ‘786 patent and ‘988 patent are insignificant, and that these first claims are representative of all of the claims of the patents-in-dispute.” *Id.* at 45 (citing Pl.’s Mem. in Supp. of Mot. for Part. Summ. J., ECF No. 47, at 8 n.3). The Court then pointed out that the defendants did not address this assertion at all in their opposition brief. *See id.* at 45-46. The Court also pointed out that when the defendants were asked about this issue at the motions hearing, the defendants’ counsel answered that, “for a system claim, there is a little bit different analysis because claiming an actual system . . . makes it even less abstract because it’s not just a method . . . [I]t is even more intimately connected to the computer, as it is the system.” *Id.* at 46 n.4 (quoting Rough Tr. 30:4-15). The Court rejected this argument, noting

that “[t]he defendants fail to cite any authority that supports their assertion, and ignore authority to the contrary.” *Id.* (citing *In re Meyer*, 688 F.2d 789, 795 n.3 (C.C.P.A. 1982) (“for purposes of section 101, [claims reciting “means for” performing the steps set forth in the method claims] are not treated differently from method claims”).

The defendants now argue that “*even assuming* that the Court could review claims 2-22 and 24-66 of both patents though they were not challenged by SmartGene, there is no basis in the record for the Court to find, for example that the ‘computer readable program code means’ limitations of claims 45-66 are substantially materially identical to claims *that do not recite* these limitations.” Defs.’ Brief at 4 (emphasis in original). First of all, the plaintiff *did* challenge these claims, because it challenged the patents-in-suit in their entirety. *See, e.g.*, Pl.’s Mem. at 1 (“SmartGene now moves for summary judgment of invalidity of the claims of the patents-in-suit on the ground that the claims are directed to non-statutory subject matter under 35 U.S.C. §101.”). Second, the defendants did not raise these arguments while the plaintiff’s Motion for Partial Summary Judgment was pending, and provides the Court no reason to consider them now. As the plaintiff notes, a motion for reconsideration is not an opportunity for “another bite at the apple.” *See* Pl.’s

Opp'n at 4.⁶ Therefore, the Court will not revisit its decision now, when the defendants had the opportunity to address this issue during the summary judgment briefing.

Finally, the Court turns to the defendants' argument that that this Court's ruling is "premised on a clear error of fact and law given that there was a change in controlling law subsequent to the summary judgment proceedings in this case." Defs.' Brief at 1. Specifically, the defendants contend that they should have been "provided an opportunity" to supplement their briefing after the Supreme Court issued its decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), and that, given the change in law, issues of material fact exist that preclude the granting of summary judgment. This argument does not merit this Court's reconsideration of its decision for at least three reasons.

First, as is relevant to this Court's decision in this case, *Prometheus* was not a "change in controlling law." Instead, *Prometheus*, affirmed or

⁶ Even in this Motion for Reconsideration, the defendants' briefing is incomplete, and only provides hints of the defendants' argument. The defendants state, in a footnote, without elaboration that, "[w]hile not addressed at the Motions Hearing, the computer program product claims 45-66 for each of the patents would also necessarily require a different standard of review." Defs.' Brief at 4 n.2. The defendants provide no further decoding of this statement for the Court, *i.e.*, to what "different standard of review" they are referring. Again, the defendants have simply provided no reason for this Court to reconsider its decision.

clarified earlier Supreme Court precedent related to a 35 U.S.C. § 101 analysis. *See, e.g., SmartGene, Inc.*, 852 F. Supp. 2d at 51 (noting that the Supreme Court in *Bilski v. Kappos*, 130 S. Ct. 3218, 3225, made clear that the 35 U.S.C. § 101 inquiry is a “threshold test,” and, despite indications to the contrary by the Federal Circuit, *Prometheus* “clarified that a 35 U.S.C. § 101 subject matter patentability inquiry is the threshold analysis for determining patent validity”) (emphasis in original); *SmartGene, Inc.*, 852 F. Supp. 2d at 52 (observing that the Supreme Court in *Bilski* “highlighted a trilogy of its decisions – namely *Gottschalk v. Benson*, *Parker v. Flook*, and *Diamond v. Diehr* – as useful ‘guideposts’” and that *Prometheus* “reaffirms the importance of these tools”); *SmartGene, Inc.*, 852 F. Supp. 2d at 55 (finding that, “as in *Benson*, *Flook*, *Bilski II*, and *Prometheus*,” the “patent application here can be rejected under [the Supreme Court’s] precedents”) (citation omitted); *SmartGene, Inc.*, 852 F. Supp. 2d at 58 (explaining that pre-*Prometheus*, the Supreme Court “did not foreclose the use of the machine-or-transformation test” and that *Prometheus* “rejected not the MOT test but the Federal Circuit’s application of that test”); *SmartGene, Inc.*, 852 F. Supp. 2d at 55 (“The Supreme Court in *Prometheus*, however, did not retreat from a transformation analysis as part of a subject matter patentability test under section 101”).

Second, in a related point, *Prometheus* was not determinative of the outcome in this case. Simply stated, this Court’s decision would have been the same even if it had been issued before the Supreme Court released its decision in *Prometheus*. The

defendants are again disingenuous when they argue that “this Court assumed that the steps recited in the claims were ‘well-understood, routine, conventional activity already engaged in by the scientific community’ even though the parties never briefed this precise issue.” Defs.’ Brief at 6. This is just not true. The parties *did* essentially brief this issue. The plaintiff in its Motion for Partial Summary Judgment noted, for example, that “[t]he patents-in-suit . . . claim[], in one form or another, mental processes that a person, *e.g.*, a treating physician or consulting physician, performs in selecting a therapeutic treatment regimen for a known disease.” Pl.’s Mem. at 3; *see also id.* at 6 (“In effect, the claims of the patents-in-suit are directed to nothing more than a mental process in which a person, *e.g.*, a physician, engages when determining a treatment for a patient suffering from a disease or a medical condition” and “[t]his process is an abstraction, as it is a fundamental task in which a physician engages in his/her mind, each time a patient is treated.”); *see id.* at 8-9 (chart describing the human performance equivalent of each claimed method of claim 1 of the ‘786 patent). The defendants thus had the opportunity to respond in any way they saw fit to the plaintiff’s arguments that, *inter alia*, “each limitation of the method claims is readily performable, either entirely mentally within a physician’s mind, or potentially with the aid of pencil and paper,” Pl.’s Mem. at 7, and that “the steps of claim 1 can be performed in the human mind,” *id.* at 9. In fact, they did so in their opposition to that motion, even before the release of *Prometheus*, arguing, for example, that “[o]ne significant

advantage provided by the claimed invention is that a physician has the benefit of more than his or her mind can retain: *i.e.*, the databases can be constantly updated with the most current information in recognition that even the most skilled clinician cannot be expected to know about or memorize every instance of the latest research.” Defs.’ Opp’n at 2; *see also id.* (“Rather than supplanting the role of the physician, as SmartGene suggests, the invention seeks to improve patient treatment by giving the physician reference to a program which can exceed his or her own capabilities.”).⁷ This Court analyzed claim 1 of the ‘786 patent and agreed with the plaintiff in its characterization of the claims of the patents-in-suit. To the extent that the defendants would now like to bolster their arguments with evidence that apparently would have been available

⁷ The defendants did not at that time suggest, as they do now, that *Diamond v. Diehr* stands for the proposition that “evidence of ‘novelty’ of any part of a claim is ‘of no relevance’ for purposes of § 101.” Defs.’ Opp’n to Pl.’s Mot. to Strike Declarations and Certain Exhibits Attached to Defs.’ Mot. for Reconsideration, ECF No. 72, at 2 (quoting *Diamond v. Diehr*, 450 U.S. 175, 189 (1981)). Instead, they simply responded to the plaintiff’s arguments with its own, evidently realizing that the Court may consider these arguments in rendering a judgment. The defendants may not now use *Prometheus* as a vehicle for relitigating these arguments, this time with factual support for their arguments.

to them while the Motion for Partial Summary Judgment was pending, they may not do so.⁸

Finally, the Supreme Court issued its decision on March 20, 2012, and this Court issued its decision on March 30, 2012. Thus, the defendants had ten days in which to apprise the Court of the Supreme Court's decision in *Prometheus*, and how it relates to the instant case, or request an opportunity to brief the case. During that period, the parties provided no notice of supplemental authority regarding *Prometheus*. The defendants now protest that they "never had the opportunity to brief that case." Defs.' Brief at 4. If this were such an important case to the defendants, they could have and should have briefed the case on their own during that period, or at least notified the Court that the case presented new

⁸ In connection with the defendants' argument that they should have been given an opportunity to provide supplementary briefing regarding the *Prometheus* decision, the defendants submit with their Motion for Reconsideration over 1500 pages of declarations and exhibits, that the defendants say "would have been submitted if ABL had been given an opportunity to brief Prometheus." Defs.' Brief at 1-2. The plaintiff has filed a Motion to Strike these declarations, as well as the exhibits attached to the declarations, and any reference to them in the defendants' Motion for Reconsideration. *See* ECF No. 68 at 11. Since the Court denies the defendants' Motion for Reconsideration, disagrees with the defendants' contention that there was a change in controlling law, and finds no other reason that the defendants should now be able to supplement the record in this case with evidence that could have been provided before this Court made its decision on the plaintiff's Motion for Partial Summary Judgment, the Court will grant the Plaintiff's Motion to Strike the Declarations and Certain Exhibits Attached to Defendant's Motion for Reconsideration. *See* ECF No. 68.

controlling authority about which they wished to provide supplemental briefing. They did not do so, and will not now be allowed to use the *Prometheus* decision as a way to reopen this litigation, particularly when that case was not a change in controlling law with respect to the instant case, and not determinative, but rather only supportive, of this Court's decision in this matter.

IV. CONCLUSION

Accordingly, for the reasons explained above, the Defendants' Motion for Reconsideration Under F.R.C.P. 59(e), ECF No. 67, is DENIED, and the Plaintiff's Motion to Strike the Declarations and Certain Exhibits Attached to Defendant's Motion for Reconsideration, ECF No. 68, is GRANTED. An appropriate Order will accompany this Memorandum Opinion.

DATED: January 3, 2013

BERYL A. HOWELL
United States District Judge

APPENDIX D

UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF COLUMBIA

SMARTGENE, INC., PLAINTIFF,

v.

ADVANCED BIOLOGICAL LABORATORIES, SA, *et al.*,
DEFENDANTS.

January 3, 2013

ORDER

Upon consideration of the Amended Complaint in this case, the pending motions, the related legal memoranda, and the applicable law, it is hereby

ORDERED that the Defendants' Motion for Reconsideration Under F.R.C.P. 59(e), ECF No. 67, is DENIED; and it is further

ORDERED that the Plaintiff's Motion to Strike the Declarations and Certain Exhibits Attached to Defendants' Motion for Reconsideration, ECF No. 68, is GRANTED.

SO ORDERED.

DATED: January 3, 2013

BERYL A. HOWELL
United States District Judge

This is a final, appealable Order.

APPENDIX E

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

Civil Action No. 08-00642 (BAH)
Judge Beryl A. Howell

SMARTGENE, INC., PLAINTIFF,

v.

ADVANCED BIOLOGICAL LABORATORIES, SA, *ET AL.*,
DEFENDANTS.

MARCH 30, 2012

MEMORANDUM OPINION

Plaintiff SmartGene, Inc., a North Carolina corporation, brought this lawsuit against Defendant Advanced Biological Laboratories, SA, a company with its principal place of business in Luxembourg, seeking declaratory judgment as to the invalidity, unenforceability, and SmartGene's non-infringement of U.S. Patent No. 6,081,786 (the "786 patent") and U.S. Patent No. 6,188,988 B1 (the "988 patent") (collectively, the "patents-in-dispute"). After prolonged litigation, including a stay of proceedings of two and a half years, SmartGene filed a Motion for Partial Summary Judgment, contending that the "patents-in-dispute" are facially invalid under 35 U.S.C. § 101 of the Patent Act because the subject matter is ineligible for patent protection.⁹

Defendants, Advanced Biological Laboratories, SA ("ABL SA") and ABL Patent Licensing Technologies, SARL ("ABL PLT") (collectively

⁹ SmartGene stated at the March 9, 2012 Motions Hearing that the Motion was framed as a Motion for "Partial" Summary Judgment because the Motion deals only with the validity of the patents-in-dispute and does not address all disputed claims. *See* Motions Hearing Transcript ("Tr") (Rough), Mar. 9, 2012, at 9:30, 42:23-43:1; 43:6-12 (The parties have not requested formal transcripts from the court reporter. Accordingly, the Court's citations to transcripts are from the court reporter's rough draft of the proceedings.). No matter the styling of the pending Motion as a "partial" Motion for Summary Judgment, grant of this Motion is dispositive in this matter since the validity of the patents-in-dispute is the *sine qua non* for all the claims and counterclaims.

“ABL”)¹⁰, oppose the Motion for Partial Summary Judgment, arguing that the patents-in-dispute constitute eligible subject matter under 35 U.S.C. § 101. For the reasons explained below, SmartGene’s Motion for Partial Summary Judgment is granted and this case is dismissed.

V. FACTUAL AND PROCEDURAL BACKGROUND

A. The Patents

The patents at stake in this dispute are Patent Nos. 6,081,786 (the “786 patent”) and 6,188,988 B1 (the “988 patent”), of which the defendants are the undisputed owners. Compl. ¶¶ 7-8.¹¹ The ‘786 patent application was filed with the United States Patent and Trademark Office (“PTO”) on April 1, 1999, and the patent issued on June 27, 2000. *See* LCvR 7(h) Statement of Material Facts in Support of Pl.’s Mot. for Partial Summ. J. at ¶ 4. The application for the ‘988 patent, considered a “continuation” of the application for the ‘786 patent, was filed on March 10, 2000, and the patent issued on February 13, 2001. *Id.* at ¶ 6.

¹⁰ On November 23, 2011, the Court directed that ABL PLT be joined as a defendant in this case pursuant to Federal Rule of Civil Procedure 25(c). *See* Order, ECF No. 43. The Court directed that the party be joined in order to facilitate conduct of the case, because ABL PLT appears to have received rights originally belonging to ABL SA, not because there are distinct, substantive claims against ABL PLT. *See* Minute Order (Jan. 3, 2012).

¹¹ The operative complaint, and the one cited throughout this Opinion, is the First Amended Complaint filed on May 20, 2008. *See* ECF No. 4.

Both patents are entitled “Systems, Methods and Computer Program Products for Guiding the Selection of Therapeutic Treatment Regimens,” and relate “to a system, method, and computer program for guiding the selection of therapeutic treatment regimens for complex disorders . . . by ranking available treatment regimens and providing advisory information.” Defs.’ Mem. in Opp. to Mot. for Partial Summ. J. (“Defs.’ Mem.”), ECF No. 50, at 1-2. Both patents-in-dispute are based on the same patent specifications and disclosures, and relate to methods (*i.e.*, process) and systems for an interactive, computerized program for guiding the selection of therapeutic treatment regimens for a patient based on input provided by a physician. *See* Pl.’s Mem. in Support of Mot. for Partial Summ. J. (“Pl.’s Mem.”), ECF No. 47, at 3; Defs.’ Mem. at 1-2. The defendants sum up their invention as follows: “Element (a) specifies that the physician provide patient information to the computing device which includes prior therapeutic treatment regimen information. This information is then processed against a first knowledge base that contains different treatment regimens and a second knowledge base of expert rules. The computing device then generates available treatments along with advisory information for those treatments. By providing the patient information to the system and allowing interaction with the physician, the Patents describe how therapeutic treatment regimens can be listed with corresponding advisory information.” Defs.’ Mem. at 11.

The Court’s analysis focuses on the patentability of Claim 1 of the ‘786 patent. The language for Claim

1 in both the '786 and '988 patent is nearly identical. SmartGene asserts that the differences between Claim 1 in the '786 patent and '988 patent are insignificant, and that these first claims are representative of all of the claims of the patents-in-dispute. Pl.'s Mem. at 8 n.3. The defendants failed to contest this characterization in their brief.¹² The Court concludes that the differences between the various method and system claims within the patents-in-dispute are immaterial with respect to whether the patents constitute eligible subject matter under 35 U.S.C. § 101. Accordingly, the pending Motion turns on whether Claim 1 of the '786 patent constitutes eligible subject matter under 35 U.S.C. § 101 of the Patent Act. Claim 1 of the '786 patent is directed to:

¹² Although not raised in their brief, the defendants erroneously asserted at the Motions Hearing that the “method” and “system” claims at issue require a different standard of review for subject matter patentability. Tr. 29:6-30:17. Here, Claim 1 in both the '786 and '988 patents is a method claim, while Claim 23 in both the '786 patent and '988 patent is a system claim. *See* Pl.'s Mem. at 11 nn. 5-6. Specifically, the defendants argued that “for a system claim, there is a little bit different analysis because claiming an actual system . . . makes it even less abstract because it’s not just a method . . . [I]t is even more intimately connected to the computer, as it is the system.” Tr. 30:4-15. The defendants fail to cite any authority that supports their assertion, and ignore authority to the contrary. *See, e.g., In re Meyer*, 688 F.2d 789, 795 n.3 (C.C.P.A. 1982) (“for purposes of section 101, [claims reciting “means for” performing the steps set forth in the method claims] are not treated differently from method claims”).

1. A method for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition, said method comprising:
 - (a) providing patient information to a computing device comprising:
 - a first knowledge base comprising a plurality of different therapeutic treatment regimens for said disease or medical condition;
 - a second knowledge base comprising a plurality of expert rules for evaluating and selecting a therapeutic treatment regimen for said disease or medical condition;
 - a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens; and
 - (b) generating in said computing device a ranked listing of available therapeutic treatment regimens for said patient; and
 - (c) generating in said computing device advisory information for one or more therapeutic treatment regimens in said ranked listing based on said patient information and said expert rules.

'786 patent, Col. 17-18, ECF No. 4-1.

B. Procedural History

The litigation between these parties originated in September 2007, when ABL SA filed a lawsuit in the United States District Court for the Eastern District of Texas, Marshall Division, against SmartGene, alleging that SmartGene “manufactures, uses and sells products that infringe the ‘786 and ‘988 Patents.” Compl. ¶ 9. ABL SA alleged specifically that “Smartgene’s IDNS™ HIV program incorporates at least one technology which infringes at least claim 1 of each [of] the ‘786 and ‘988 Patents.” *Id.* The district court in Texas dismissed the case on April 10, 2008 for lack of personal jurisdiction. *Id.* at 10.

SmartGene commenced this action in the District Court for the District of Columbia against ABL SA on April 11, 2008, seeking declaratory judgment of non-infringement, patent invalidity, and patent unenforceability under the Patent Act, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.¹³ SmartGene asserts in its Complaint that the ‘786 patent and the ‘988 patent are invalid

¹³ This Court has jurisdiction to adjudicate this dispute pursuant to 28 U.S.C. § 1331 and 28 U.S.C. § 1338.

“for failing to comply with 35 U.S.C. §§ 101-103 and/or 112.” Compl. ¶¶ 20, 26.¹⁴

ABL SA filed its Answer and Counterclaims on October 6, 2008, alleging that SmartGene’s products “[incorporate] at least one technology which infringes at least claim 1 of each of the ‘786 and the ‘988 patents.” Answer, ECF No. 12, at ¶ 42.¹⁵

On February 3, 2009, SmartGene’s unopposed motion to stay this proceeding, *see* ECF No. 18, was granted due to concurrent patent validity reexaminations brought before the PTO. *See* Order,

¹⁴ SmartGene further claims that “[d]uring Defendant’s prosecution of patent applications PCT US9907171 and EP 999166262.1, which claim priority to the application to which the ‘786 and ‘988 Patents claim priority, the PCT and European Patent Office (“EPO”) search and examination authorities cited prior art references in reports dated October 22, 1999, September 14, 2004, March 9, 2005, October 27, 2005, and March 17, 2006.” Compl. ¶ 11. SmartGene claims that the EPO “determined that the EP 999166262.1 application was “not patentable in view of this prior art . . .” Compl. ¶ 12. The prior art utilized to deny the EPO patent was apparently unavailable during the PTO proceedings because the PTO Board of Appeals “said it would not consider those references” in its reexamination proceeding. Tr. 6:4-8. Accordingly, SmartGene claims that this prior art is “material to the patentability of the ‘786 and ‘988 Patent claims, and, upon information and belief, renders the ‘786 and ‘998 Patents invalid by 35 U.S.C. § 102 and/or § 103.” Compl. ¶ 13. This claim is not at issue in the pending motion.

¹⁵ SmartGene asserts that the counterclaim for infringement is invalid because it was asserted by ABL PLT, rather than ABL SA. Pl.’s Mem. at 1 n.1. The Court need not address this issue because the patents are invalid and the counterclaims are moot.

ECF No. 19. Cumulatively, the defendants advise that the PTO held six reexaminations—three for each of the patents-in-dispute—with two reexaminations combined for each patent. Tr. 45:11-13. None of the reexamination proceedings, however, addressed the subject matter eligibility question under 35 U.S.C. § 101. Tr. 45:16. The PTO completed its reexamination proceedings and issued a final non-appealable denial of further review proceedings on June 14, 2011. Joint Motion to Lift Stay, ECF No. 32, at 1. The PTO concluded that all of the claims of both patents-in-dispute were patentable over the prior art presented during the reexamination. *Id.*

On September 7, 2011, the parties filed a joint motion to lift the stay and submitted a proposed scheduling order. *Id.* This case was then reassigned to the undersigned Judge on September 15, 2011.

This Court lifted the stay on October 21, 2011, and subsequently entered a scheduling order to govern the proceedings in this matter. *See* Minute Order (Oct. 21, 2011); Scheduling Order, ECF No. 39. SmartGene filed the instant Motion for Partial Summary Judgment on December 12, 2011, alleging that the '786 patent and the '988 patent constituted ineligible patent subject matter under 35 U.S.C. § 101 and pursuant to *Bilksi v. Kappos*, 130 S. Ct. 3218 (2010). *See* ECF No. 47. Both parties agree that the resolution of this motion does not

depend on the disposition of any facts. Pl.’s Mem. at 2; Tr. 28:10-15.¹⁶

This Court held a hearing on the Motion for Partial Summary Judgment and a Markman Hearing to resolve disputes over claim construction on March 9, 2012 (“Motion Hearing”). For the reasons explained below, SmartGene’s Motion for Partial Summary Judgment is granted.¹⁷

VI. LEGAL STANDARD

A. Summary Judgment

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, summary judgment shall be granted “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(a); *Anderson v. Liberty Lobby*, 477 U.S. 242, 247 (1986); *Estate of Parsons v. Palestinian Authority*, 651 F.3d 118, 123 (D.C. Cir. 2011); *Tao v. Freeh*, 27 F.3d 635, 638 (D.C. Cir. 1994). Summary judgment is properly granted against a party who, “after adequate time for discovery and upon motion, . . . fails to make a

¹⁶ While the defendants state in their opposition brief that “there are several issues of material fact that should preclude the granting of summary judgment,” *see* Defs.’ Mem. at 1, they did not file a separate statement of disputed material facts, as required by Local Civil Rule 7(h), and clarified at the Motions Hearing that there are no outstanding material facts that prevent adjudication of this Motion for Partial Summary Judgment. *See* Tr. 28:10-15.

¹⁷ Since the Court grants summary judgment for SmartGene, the Court need not proceed with claim construction.

showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The burden is on the moving party to demonstrate that there is an "absence of a genuine issue of material fact" in dispute. *Celotex Corp.*, 477 U.S. at 323.

In ruling on a motion for summary judgment, the court must draw all justifiable inferences in favor of the nonmoving party, and shall accept the nonmoving party's evidence as true. *Anderson*, 477 U.S. at 255; *Estate of Parsons*, 651 F.3d at 123; *Tao*, 27 F.3d at 638. The court is only required to consider the materials explicitly cited by the parties, but may on its own accord consider "other materials in the record." FED. R. CIV. P. 56(C)(3). For a factual dispute to be "genuine," *Estate of Parsons*, 651 F.3d at 123, the nonmoving party must establish more than "[t]he mere existence of a scintilla of evidence" in support of its position, *Anderson*, 477 U.S. at 252, and cannot simply rely on allegations or conclusory statements. *Greene v. Dalton*, 164 F.3d 671, 675 (D.C. Cir. 1999). Rather, the nonmoving party must present specific facts that would enable a reasonable jury to find in its favor. *Id.* If the evidence "is merely colorable, . . . or is not significantly probative, . . . summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (citations omitted).

B. Subject Matter Patentability under the Patent Act

SmartGene's Motion for Partial Summary Judgment challenges the subject matter eligibility of the patents-in-dispute under 35 U.S.C. § 101. *See* Pl.'s Mot. for Part. Summ. J. ("Pl.'s Mot."), ECF No. 47. Congress has defined which inventions are patentable in Section 101 of the Patent Act, which states in its entirety:

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.

The Patent Act defines the term "process" as "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." 35 U.S.C. § 100.

The Supreme Court has further elaborated on what constitutes a patentable process claim, noting that

a process may be patentable, irrespective of the particular form of the instrumentalities used . . . A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject matter to be transformed and

reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery.

Diamond v. Diehr, 450 U.S. 175, 182-83 (1981) (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877)).

While the Patent Act covers a broad range of subject matter, there are three important subject matter exceptions from patentability: “laws of nature, physical phenomena, and abstract ideas.” *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (“*Bilski II*”) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). The Supreme Court has found that these categories of exceptions “are not patentable, as they are the basic tools of scientific and technological work.” *Benson*, 409 U.S. at 67. “Thus, the Court has written that a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are manifestations of . . . nature, free to all men and reserved exclusively to none.” *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1293 (2012) (“*Prometheus*”) (citations and quotation marks omitted). “While these exceptions are not required by the statutory text,” the Supreme Court has noted, “they are consistent with the notion that a patentable process must be ‘new and useful.’ And, in any case, these exceptions have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years.” *Bilski II*, 130 S. Ct. at 3225

(citation omitted). Still, the Supreme Court has recognized that “too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” *Prometheus*, 132 S. Ct. at 1293. The issue before this Court is whether the patents-in-dispute are abstract such that they do not constitute patentable subject matter. Pl.’s Mem. at 1.

C. Level of Deference to the PTO

Patents issued by the PTO, and their underlying claims, are presumed valid. *See* 35 U.S.C. § 282. “[T]his presumption can only be overcome by clear and convincing evidence to the contrary.” *Unique Indus. v. 965207 Alta. Ltd.*, No. 08-1095, 2012 U.S. Dist. LEXIS 19621, at *2 (D.D.C. Feb. 16, 2012); *Eli Lilly & Co. v. Barr Labs*, 251 F.3d 955, 962 (Fed. Cir. 2001); *Apple Computer v. Articulate Sys.*, 234 F.3d 14, 20 (Fed. Cir. 2000).

The determination of whether a claimed invention is invalid for lack of subject matter patentability under 35 U.S.C. § 101 is a “threshold inquiry” and a matter of law. *See In re Bilski*, 545 F.3d 943, 950-51 (Fed. Cir. 2008) (“*Bilski I*”). “[A]ny claim of an application failing the requirements of § 101 must be rejected even if it meets all of the other legal requirements of patentability.” *Id.* at 950. The Court may conduct a section 101 analysis before the Court conducts a formal construction of claims. *See Ultramercial, LLC v. Hulu, LLC*, 657 F.3d 1323, 1325 (Fed. Cir. 2011) (“claim construction may not

always be necessary for a § 101 analysis”). “Only after an invention has satisfied § 101, will it be analyzed under the remaining hurdles of the Patent Act, which include the requirement that an invention be novel, *see* § 102; nonobvious, *see* § 103; and fully and particularly described, *see* § 112.” *CLS Bank Int’l.*, 768 F. Supp. 2d at 221, 233 (citing *Bilski II*, 130 S. Ct. at 3225).

The fact that the PTO conducted reexaminations of the patents-in-dispute does not trigger higher deference on the issue of subject matter patentability because the PTO cannot review subject matter eligibility during a reexamination proceeding. 37 C.F.R. § 1.552. This lawsuit, therefore, is not dealing with matters previously covered during the reexamination proceedings. *Id.* Titled “Scope of reexamination in *ex parte* reexamination proceedings,” § 1.552 states, in relevant part, that upon *ex parte* reexamination, the PTO may only examine the contested patent “on the basis of patents or printed publications and, with respect to subject matter added or deleted in the reexamination proceeding, on the basis of the requirements of 35 U.S.C. § 112.” It further states that “[i]ssues other than those indicated . . . will not be resolved in a reexamination proceeding. If such issues are raised by the patent owner or third party requester during a reexamination proceeding, the existence of such issues will be noted by the examiner in the next Office action, in which case the patent owner may consider the advisability of filing a reissue application to have such issues considered and resolved.” 37 C.F.R. § 1.552. “Thus, other challenges to the patentability of original claims — such as

qualification as patentable subject matter under § 101 or satisfaction of the written description and enablement requirements of § 112—may not be raised in reexamination proceedings.” *In re NTP*, 654 F.3d 1268, 1275-76 (Fed. Cir. 2011); *see also* 35 U.S.C. § 302 (reexaminations may be conducted on “the basis of any prior art”). Since this issue cannot be raised in a reexamination proceeding, no additional deference is accorded to the PTO as to subject matter patentability.¹⁸ *See, e.g., In re NTP*, 654 F.3d at 1275-76.

VII. DISCUSSION

In its Motion for Partial Summary Judgment, SmartGene contends that the patents-in-dispute constitute ineligible patent subject matter because they are (1) “directed to abstract ideas and mental processes,” and because (2) the patents-in-dispute fail the “machine or transformation” (“MOT”) test articulated in *Bilski*, and are thus invalid. Pl.’s Mem. at 1. In support of this contention, SmartGene asserts that the patents-in-dispute are “directed to nothing more than a mental process in which a person, *e.g.*, a physician, engages when determining

¹⁸ Procedurally, the parties could have raised with the Court the issue of subject matter patentability before requesting a stay of this patent action pending PTO reexamination proceedings. If that issue had been taken up earlier in this case, the PTO may have been spared six reexaminations of the patents-in-dispute.

a treatment for a patient suffering from a disease or a medical condition.” Pl.’s Mem. at 6.11¹⁹

The defendants respond that (1) the claims at issue are not directed to an abstract idea, and (2) although the MOT test is “not the sole test for patentability,” the patents-at-issue satisfy that test. Def.’s Mem. at 7-8. According to the defendants, the patents-in-dispute “describe an interactive system, method, and computer program to assist the physician in keeping track of potential treatment regimens and optionally ranking those regimens based on the patient’s personal information.” Defs.’ Mem. at 1-2. “Rather than supplanting the role of the physician, as SmartGene suggests, the invention seeks to improve patient treatment by giving the physician reference to a program which can exceed his or her own capabilities.” *Id.* at 2.

Guided by Supreme Court and Federal Circuit precedent in this area, the Court proceeds with its analysis by (A) examining 35 U.S.C. § 101 as a “threshold” inquiry into patent validity; (B) reviewing Supreme Court caselaw “guideposts”

¹⁹ As noted, Claim 1 of the ‘786 patent discloses a “method for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition” by: (a) having the user input information into a “computing device” comprised of three databases, including (i) a medical conditions database, (ii) a database containing expert rules for selecting a treatment regimen, and (iii) an advisory information database; (b) having the computing device generate a ranked listing of therapeutic treatment regimens for the patient; and (c) generating advisory information based on patient information and expert rules. *See* ‘786 Patent, Col. 17-18, ECF No. 4-1.

on the subject of patent subject matter eligibility; and then examining whether the patents-in-dispute (C) satisfy the MOT test, and (D) constitute eligible subject matter irrespective of the MOT test. Finally, although the Court does not formally construct the claims on which there is disagreement between the parties, the Court (E) examines the claim construction proposals to inform its section 101 analysis. The Court concludes that the relevant precedent and tests demonstrate that the patents-in-dispute constitute ineligible subject matter and are thus invalid.

A. 35 U.S.C. § 101 as a Threshold Inquiry Into Patent Validity

As the Supreme Court noted in *Bilski v. Kappos*, the 35 U.S.C. § 101 inquiry is a “threshold test.” *Bilski II*, 130 S. Ct. 3218, 3225 (2010). “It is well-established that [t]he first door which must be opened on the difficult path to patentability is § 101.” *CLS Bank Int’l. v. Alice Corp. Pty. Ltd.*, 768 F. Supp. 2d 221, 233 (D.D.C. 2011) (citation and quotation marks omitted). A recent Federal Circuit decision, however, cast doubt on this approach, sharply questioning the wisdom of utilizing the § 101 subject matter inquiry as a threshold question. *See MySpace, Inc. v. Graphon Corp.*, No. 2011-1149, 2012 U.S. App. LEXIS 4375 (Fed. Cir. Mar. 2, 2012). In a majority decision, the Federal Circuit cautioned that lower courts should avoid the “swamp of verbiage that is § 101 by exercising their inherent power to control the processes of litigation, . . . and insist that litigants initially address patent invalidity issues in terms of the conditions of

patentability defenses as the statute provides, specifically §§ 102, 103, and 112.” *Id.* at *24 (internal citation omitted). The decision asserts that this approach would alleviate the necessity of entering “the murky morass that is § 101 jurisprudence.” *Id.*; *see also Classen Immunotherapies, Inc. v. Biogen Idec*, 659 F.3d 1057, 1073-75 (Fed. Cir. 2011) (urging judicial restraint in the face of a plethora of section 101 litigation).

Following the Motions Hearing in this case, however, the Supreme Court, in *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289 (2012), clarified that a 35 U.S.C. § 101 subject matter patentability inquiry is the threshold analysis for determining patent validity. The Supreme Court explicitly rejected that the “screening function” of 35 U.S.C. § 101 may be performed by determining the novelty, *see* 35 U.S.C. § 102, non-obviousness, *see* 35 U.S.C. § 103, or the adequacy of the written specification, *see* 35 U.S.C. § 112, of a patentable claim. *Id.* at 1303-04. The Court cautioned that “[shifting] the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.” *Id.* at 1304. Conducting a patent eligibility inquiry under any of the alternative sections “would make the ‘law of nature’ exception to §101 patentability a dead letter. The approach is therefore not consistent with prior law.” *Id.* at 1303; *see also Bilski II*, 130 S. Ct. at 3235; *CLS Bank Int’l.*, 768 F. Supp. 2d at 233; *see also* H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952) (“A person may have ‘invented’ a machine or a manufacture, which may

include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled”) (quoted in *Prometheus*, 132 S. Ct. at 1303-04). Accordingly, this Court treats the § 101 subject matter patentability inquiry as the threshold inquiry for patent validity. In this case, the section 101 analysis begins and ends the Court’s inquiry as it reveals that the patents-in-dispute are not patentable.

B. “Guideposts” for Adjudicating Subject Matter Patentability

The Supreme Court has highlighted a trilogy of its decisions – namely *Gottschalk v. Benson*, *Parker v. Flook*, and *Diamond v. Diehr* – as useful “guideposts” when considering exceptions to patent subject matter eligibility under 35 U.S.C. § 101. *Bilski II*, 130 S. Ct. at 3231. The Court notes that “[i]n searching for a limiting principle, [the Supreme Court’s] precedents on the unpatentability of abstract ideas provide useful tools.” *Id.* at 3229. The most recent Supreme Court decision on this topic, *Prometheus*, reaffirms the importance of these tools, focusing its section 101 analysis, inter alia, on this trilogy of cases as well as *Bilski II*. See *Prometheus*, 132 S. Ct. at 1298-1301. This Court follows suit. The Court reviews these guideposts below, and finds that, under this instructive precedent, the patents-in-dispute are not patent-eligible processes.

1. *Gottschalk v. Benson*

The Supreme Court's decision in *Benson* is the first of these patent subject matter eligibility cases. *Gottschalk v. Benson*, 409 U.S. 63 (1972). There, the Supreme Court held that "a method for converting binary-coded decimal (BCD) numerals into pure binary numerals" that was "not limited to any particular art or technology, to any particular apparatus or machinery, or to any particular end use" was not a process covered by the Patent Act. *Id.* at 64, 71-73. The claimed method sought patent protection over an "algorithm" that represented "a generalized formulation for programs to solve mathematical problems of converting one form of numerical representation to another." *Id.* at 65. The Supreme Court observed that "[t]he mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly preempt the mathematical formula and in practical effect would be a patent on the algorithm itself." *Id.* at 71-72. The Court expressed concern that "the 'process' claim is so abstract and sweeping as to cover both known and unknown uses," which could "vary from the operation of a train to verification of drivers' licenses to researching the law books for precedents" and "be performed through any existing machinery or future-devised machinery or without any apparatus." *Id.* at 68. Accordingly, the Supreme Court denied the claim and found that computer algorithms that encompass methods for mathematical conversion are "procedure[s] for solving a given type of mathematical problem" and are ineligible patent

subject matter that erroneously seeks to patent the “basic tools of scientific and technological work.” *Id.* at 67.

2. *Parker v. Flook*

“In *Flook*, the Court considered the next logical step after *Benson*.” *Bilski II*, 130 S. Ct. at 3230. There, the patent-holder asserted patent rights protection over a “method for updating alarm limits,” which indicated the point at which the catalytic conversion conditions in the petrochemical and oil-refining industries can produce inefficiencies or danger. *Parker v. Flook*, 437 U.S. 584, 585. As the Court noted, “[t]he only novel feature of the method is a mathematical formula.” *Id.* “In [*Benson*], we held that the discovery of a novel and useful mathematical formula may not be patented. The question in this case is whether the identification of a limited category of useful, though conventional, post-solution applications of such a formula makes respondent’s method eligible for patent protection.” *Id.* The Court found that the “only difference between the conventional methods of changing alarm limits and that described in respondent’s application rests in the second step – the mathematical algorithm or formula” and that “a claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under § 101.” *Id.* at 595 & n.18.

Moreover, the Court found that incorporation of “post-solution” activity did not render the formula patentable, because a “competent draftsman could attach some form of post-solution activity to almost

any mathematical formula.” *Id.* at 590. The Court rejected the idea that post-solution activity, “no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process,” finding that would “[exalt] form over substance.” *Id.* The Pythagorean theorem, for example, would not have been patentable even if a final step had been added “indicating that the formula, when solved, could be usefully applied to existing surveying techniques.” *Id.* The patent thus constituted ineligible subject matter because the claim sought patent protection over an improved method for computing alarm limits, which were otherwise computable by hand. *Id.* As the Court explained in *Diehr* and *Bilski II*, “*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.’” *Bilski II*, 130 S. Ct. at 3230 (quoting *Diehr*, 450 U.S. at 191-92).

3. *Diamond v. Diehr*

In *Diehr*, the Supreme Court “established a limitation on the principles articulated in *Benson* and *Flook*.” *Bilski II*, 130 S. Ct. at 3230. The Court upheld as patentable subject matter a process for molding, or “curing,” raw synthetic rubber into a product that would retain its shape. This process involved using the well-known components of time, temperature and a mathematical formula, but combined them with a previously uncontrollable variable (*i.e.*, the temperature inside of a rubber press) and use of a programmed computer. *Diamond*

v. Diehr, 450 U.S. 175, 187 (1981). When implemented in a series of steps, the claimed process took the “guess work” out of the proper curing time. Although the invention incorporated a well-known mathematical formula, the Supreme Court concluded that the patent constituted eligible subject matter because it sought process protection over the formula’s use solely in conjunction with the other steps of the process. *Id.* “These other steps apparently added to the formula something that in terms of patent law’s objectives had significance – they transformed the process into an inventive application of the formula.” *Prometheus*, 132 S. Ct. at 1299.

Unlike in *Benson*, where the “sole practical application of the algorithm was in connection with the programming of a general purpose digital computer,” *Diehr*, 450 U.S. at 185-86, the claimed invention in *Diehr* used a mathematical equation tied to “all of the other steps in their claimed process,” which itself was limited to curing synthetic matter. *Id.* at 187. The Supreme Court acknowledged that although, “[o]bviously, one does not need a ‘computer’ to cure natural or synthetic rubber,” when the computer significantly reduces the probability of damaging the rubber, the process is not rendered unpatentable solely because of the use of a mathematical formula or computer. *Id.*

The Supreme Court articulated the following guidance: “A mathematical formula as such is not accorded the protection of our patent laws [citing *Benson*], and this principle cannot be circumvented by attempting to limit the use of the formula to a

particular technological environment [citing *Parker*]. Similarly, insignificant post-solution activity will not transform an unpatentable principle into a patentable process. *Ibid.*” *Diehr*, 450 U.S. at 191-92. The Court went on to say, however, that, “when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101.” *Id.* at 192.

4. *Bilski II*

In *Bilski II*, the Supreme Court held that the trilogy of cases discussed above – *Benson*, *Flook*, and *Diehr* – made “clear that petitioner’s application [for a business method for hedging risk in the energy commodities market] is not a patentable process.” 130 S. Ct. at 3231 (quotation marks omitted). The Court stated that the patent application sought protection over a “fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class.” *Id.* at 3231 (citation omitted). The Court found that “[t]he concept of hedging, described in claim 1 and reduced to a mathematical formula in claim 4, is an unpatentable abstract idea, just like the algorithms at issue in *Benson* and *Flook*. Allowing petitioners to patent risk hedging would preempt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.” *Id.* The Court drew this conclusion “narrowly on the basis of this Court’s decisions in *Benson*, *Flook*, and *Diehr*, which show

that petitioners' claims are not patentable processes because they are attempts to patent abstract ideas." *Id.* at 3229-30.

5. *Prometheus*

The most recent guidance from the Supreme Court on section 101 analysis concerns patent claims covering a process aimed to aid doctors administering thiopurine drugs to treat patients with autoimmune disease. "The claims purport to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012). In *Prometheus*, the Court concluded, based on the Court's precedent detailed above, that the process claims were directed to natural law and were thus unpatentable.

Specifically, the *Prometheus* Court distilled the guideposts from its earlier section 101 cases into the following "warnings." The Supreme Court warned "against interpreting patent statutes in ways that make patent eligibility 'depend simply on the draftsman's art' without reference to the 'principles underlying the prohibition against patents for [natural laws]," *id.* (quoting *Flook*, 437 U.S. at 593), and warned against "upholding patents that claim processes that too broadly preempt the use of a natural law." *Id.* (citing *O'Reilly v. Morse*, 56 U.S. 62, 112-120). A "process that focuses upon the use of a natural law" must "contain other elements or a

combination of elements, sometimes referred to as an ‘inventive concept,’ sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.” *Id.* (quoting *Flook*, 437 U.S. at 594). The Court found that the patent at issue failed this test, explaining that “the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field.” *Id.* The Court further observed that “upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries,” and thereby allowing monopolies of unforeseeable scope. *Id.*

***6. Patents-in-Dispute Are Unpatentable
Abstract Ideas Under Supreme Court
Precedent***

This Court finds that, as in *Benson*, *Flook*, *Bilski II*, and *Prometheus*, the “patent application here can be rejected under [the Supreme Court’s] precedents . . .” *Bilski II*, 130 S. Ct. at 3231. Mental processes and abstract intellectual concepts are simply not patentable for the sound reason that “monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.” *Prometheus*, 132 S. Ct. at 1293. The patents-in-dispute do no more than describe just such an abstract mental process engaged in routinely, either entirely within a physician’s mind, or potentially aided by other resources in the treatment of patients.

Specifically, the claim here, like the claim in *Prometheus*, “presents a case for patentability that is weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*.” *Id.* at 1299. In *Diehr*, as noted, the parties sought patent protection over the use of a mathematical equation “in conjunction with all of the other steps in their claimed process. These include[d] installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time.” *Diehr*, 450 U.S. at 187. The Court found that the invention was patentable under section 101 because it was not “an attempt to patent a mathematical formula, but rather [was] an industrial process for the molding of rubber products.” *Id.* at 192. Unlike the patent-eligible claim in *Diehr*, the claim at issue here, as described below, involves no “transformation of an article” nor a “step-by-step method for accomplishing such [transformation].”²⁰ *Id.* at 184. The claim here is more like the claim in *Flook* (and *Prometheus*) because it is merely a recitation of abstract steps, rather than an innovation that adds something “specific to the laws of nature [or abstract ideas] other than what is well-understood, routine, conventional activity, previously engaged in by those in the field.” *Prometheus*, 132 S. Ct. at 1299.

²⁰ The Court discusses this concept of transformation more fully below in the discussion of the “machine or transformation” test.

The claims at issue here are also analogous to the claim in *In re Meyer*, 688 F.2d 789 (C.C.P.A. 1982), a case before the United States Court of Customs and Patent Appeals. There, the patent applicant sought patent protection over a process for gathering neurological testing data, imputing it into a computer, and using a formula to infer whether certain neurological elements are functioning. *In re Meyer*, 688 F.2d at 793. The United States Court of Customs and Patent Appeals rejected the patent owner’s assertion that the invention was “concerned with replacing, in part, the thinking processes of a neurologist with a computer,” and instead concluded that, “the process recited is an attempt to patent a mathematical algorithm rather than a process for producing a product as in [*Diehr*].” *Id.* at 794. Here, the defendants have stated that “the purpose of [their] invention was to provide the practitioner with help, to give the practitioner more than he could have just in his mind.” *See* Tr. 35:16-18. This Court rejects this argument where the patents-in-dispute are even more abstract than in *Meyer*, which at least involved a mathematical algorithm.²¹

Before proceeding to the machine-or-transformation test that the Supreme Court has highlighted as an “important tool” in section 101 analysis, the Court first examines the ‘786 patent

²¹ The defendants were given the opportunity to distinguish *In re Meyer* at the Motions Hearing and were unable to do so, with counsel for the defendants simply reiterating counsel’s view of the purpose and function of the invention at issue here, rather than specifically addressing how this case is distinguishable from *Meyer*. Tr. 34:22-35:25.

step-by-step in the context of the Court’s precedent, as the Court did in *Prometheus*. Set against this binding precedent, the Court concludes that nothing in Claim 1 of the ‘786 patent transforms the everyday abstract ideas on which it is based into patentable processes.

a. An Examination of Each Step in Claim 1 of the ‘786 Patent

“[W]hen a court examines whether a claim is directed to an abstract idea, the court must view each claim as a whole.” *CLS Bank Int’l v. Alice Corp. Pty, Ltd.*, 768 F. Supp. 2d 221, 232 (D.D.C. 2011). The Court views Claim 1 as a whole but still finds it useful to examine the claim in steps for the purposes of its analysis of the claim as a whole. The first step of Claim 1 of the ‘786 patent describes “[a] method for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition, said method comprising.” As SmartGene highlights, the language of the claim is directed to “nothing more than a mental process . . .” Pl.’s Mem. at 6. In fact, this process is one that is performed in doctors’ offices everyday. A doctor speaks with a patient, who describes his or her ailments. The doctor recalls or looks up possible treatment regimens, and then advises the patient about the treatment regimen options, and the doctor’s recommendation for the patient. Indeed, the patent specification itself admits that the invention “can simulate the judgment and behavior of a human or organization that has expert knowledge and experience in a particular field.” ‘786 patent, Col. 7, lines 47-49.

The second step of Claim 1 of the '786 patent addresses "(a) providing patient information to a computing device comprising [three knowledge databases]." The Court sees nothing in this step that is any different than the process a doctor goes through in real time when a doctor evaluates a patient by taking a medical history and obtaining information pertinent to the patient's condition and documenting the same in a medical chart. Similarly, the patents' reference to three databases also mimics the evaluative process involved in the treatment of patients. Specifically, after collecting patient information, a doctor would consider "therapeutic treatment regimens for said disease or medical condition" (as in the first knowledge base), consult "expert rules for evaluating and selecting a therapeutic treatment regimen for said disease or medical condition" (as in the second knowledge base), and review "advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens" (as in the third database). The claim itself does not add anything to the process that doctors regularly engage in mentally when evaluating and treating patients.

The next step of Claim 1 of the '786 patent is "(b) generating in said computing device a ranked listing of available therapeutic treatment regimens for said patient." The Court views this step as describing what goes on in the mind of a doctor in evaluating and ranking possible treatment options for a patient based upon the benefits and counter-indicators of each option.

The final step of Claim 1 of the ‘786 patent is “(c) generating in said computing device advisory information for one or more therapeutic treatment regimens in said ranked listing based on said patient information and said expert rules.” The Court understands this step as corresponding to a doctor generating a treatment plan for a patient.

**b. An Examination of Claim 1 of the ‘786 Patent
As A Whole**

In essence, these four steps describe abstract ideas that are commonly performed by medical professionals in evaluating, considering and constructing treatment options for a patient presenting a specific medical condition. As with the claim examined in *Prometheus*, these “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. For these reasons [this Court believes] that the steps are not sufficient to transform unpatentable [abstract ideas] into patentable applications” *Prometheus*, 132 S. Ct. at 1298. In short, the claims track the abstract mental processes of a doctor treating a patient. Accordingly, analyzing Claim 1 of the ‘786 patent under the Supreme Court’s precedent, this Court finds that the claims of the patents-in-dispute are abstract ideas and unpatentable.

C. Claims are Invalid under the Machine-or-Transformation Test

The Court also finds that the patents-in-dispute are invalid under the “machine-or-transformation” or “MOT” test utilized in some of the Supreme Court and Federal Circuit precedent. Different tests have been employed over time to analyze claims under section 101. *See, e.g., State St. Bank & Trust Co. v. Signature Fin. Group*, 149 F.3d 1368, 1373 (Fed. Cir. 1998) (finding that a transformation “constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces ‘a useful, concrete and tangible result’”). The most recent test developed in *Bilski I* is the MOT test. The Federal Circuit, sitting en banc in *Bilski I*, articulated the standards for determining whether a claimed method constituted a patentable “process” under section 101. There, the Federal Circuit clarified that the “machine-or-transformation” test was the “governing test” for determining patent eligibility under section 101. *In re Bilski*, 545 F.3d 943, 955-56 (Fed. Cir. 2008).

In *Bilski II*, the Supreme Court notably rejected the Federal Circuit’s decision that the “machine or transformation” test was the “sole test for governing § 101 analysis.” 130 S. Ct. at 3227. The Court found that while “[i]t is true that patents for inventions that did not satisfy the machine-or-transformation test were rarely granted in earlier eras . . . times change.” *Id.* The Court reflected generally that “[w]ith ever more people trying to innovate and thus seeking patent protections for their inventions, the patent law faces a great challenge in striking the

balance between protecting inventors and not granting monopolies over procedures that others would discover by independent, creative application of general principles.” *Id.* at 3228. The Court, however, did not foreclose the use of the machine-or-transformation test. *Id.* at 3227. Indeed, while the Supreme Court emphasized that the MOT test is “not the sole test for deciding whether an invention is a patent-eligible ‘process,’” the Court noted that the Supreme Court’s “precedents establish that the [MOT] test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101.” *Id.* Most recently, in *Prometheus*, the Supreme Court rejected not the MOT test but the Federal Circuit’s application of that test. There, the Federal Circuit concluded that the transformation prong of the MOT test was satisfied because the claimed process involved “transforming the human body by administering a thiopurine drug and transforming the blood by analyzing it to determine the metabolite levels.” *Prometheus*, 132 S. Ct. at 1302. The Court described as “irrelevant” the transformation on which the Federal Circuit upheld the patent at issue since no part of the so-called “transformation” required the claimed process. *Id.* Accordingly, this Court employs the MOT test as a useful investigative tool.

Under the MOT test, a process claim is patentable if “(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.” *Bilski I*, 545 F.3d at 954; see also *Flook*, 437 U.S. at 589 n. 9 (“An argument can be made [that the Supreme Court] has

only recognized a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a different state or thing.”) (internal quotation marks and citations omitted). The “use of a specific machine or transformation of an article must impose meaningful limits on the claim’s scope to impart patent-eligibility” and, furthermore, “the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity.” *CLS Bank Int’l*, 768 F. Supp. 2d at 234 (citations and quotation marks omitted). SmartGene claims that the patents-in-dispute “[a]ll fail” the MOT test because (1) “they are not tied to a particular machine or apparatus that imparts meaningful limitations on the claims” and (2) “they do not transform a particular article into a different state or thing.” Pl.’s Mem. at 11. The defendants argue, in response, that “[e]ven though the [MOT] test is no longer preferred for inventions of the Information Age,” see *Ulramercial*, 657 F.3d at 1327, “the invention of the Asserted Claims satisfies both prongs of the test.” Defs.’ Mem. at 10. The Court first addresses the machine prong and then the transformation prong, and finds that the patents-in-dispute do not satisfy either one of them. The Court also finds that the computing device referenced by the claims does not impose any meaningful limit on the scope of the claims.

1. *Claims of the Patents-in-Dispute Are Not Tied to a Particular Machine*

To satisfy this prong, a claimed process must be “tied to a particular machine or apparatus.” *Bilski I*,

545 F.3d at 954. SmartGene argues that “[t]he claims of the patents-in-suit are essentially methods for providing and generating information, and do not identify a particular machine for performing the recited claim steps. While the claims reference a ‘computing device,’ this generic token reference does not identify any particular machine or provide any indication of what particular type of machine is to be used . . .” Pl.’s Mem. at 12. The defendants argue in response that the claims meet the machine prong of the MOT test “because the claims are tied to a particular machine that has [three databases]” and “[i]t can hardly be argued that the computing device is incidental to the invention, rather the computing device allows the invention to pull information from three databases.” Defs.’ Mem. at 12-13. The Court finds that the patents-in-dispute do not satisfy the machine prong for two reasons.

First, the claims of the patents-in-dispute do not refer to any “particular” machine. While the claims reference a “computing device,” these references are insufficient to satisfy the machine test. The defendants argue that “the figures and specification specify how the computer is to be specially programmed to implement the method covered by the Asserted Claims,” but the Court is not

persuaded. Defs.’ Mem. at 13.²² The patents-in-dispute include no special programming code, nor provide any specific algorithms that the computers would use to perform the database matching or synthesis of expert rules, advisory information, treatment regimens, and patient information. Moreover, unlike in *Ex Parte Brown*, Appeal 2009-012201, 2011 Pat. App. LEXIS 15902 (BPAI Feb. 8, 2011), on which the defendants rely, *see* Defs.’ Mem. at 9-10, there is no specific “server” specified in the claims.

To the extent that the claims reference a machine at all, they reference a “general purpose computer,” which does not satisfy the machine prong. *See, e.g., CLS Bank Int’l.*, 768 F. Supp. 2d at 237 (“With evolving guidance on this issue, district courts have determined that a method claim that is directed to a general purpose computer is not tied to a particular machine under the MOT test.”) (citations omitted);

²² Counsel for the defendants made an argument at the Motions Hearing that “figure one, a flow-chart” may be “considered [an algorithm].” Tr. 36:23-37:3. The chart simply shows boxes labeled with descriptions of the data and the verbs “generate,” “provide,” “examine,” “enter,” and “modify.” The Court is not at all convinced that the flow chart in figure one is an “algorithm,” and counsel has provided no authority for this figurative leap. Counsel further argues that “under the system description there is a lengthy discussion of the system architecture, the essential server, the local server and exactly what steps are carried out to perform the method [in columns 7, 8, 9, 10]. So although [there] wasn’t any code that was included in the patent, there doesn’t have to be code for there to be an algorithm disclosed in the specification.” Tr. 39:8-14. SmartGene argues in response that columns 7 through 10 do not contain an algorithm. Tr. 43:19-22. The Court agrees.

Graff/Ross Holdings LLP v. Fed. Home Loan Mortg. Corp., No. 07-796, 2010 U.S. Dist. LEXIS 141399, at *20 (D.D.C. 2010) (finding that a “computer processor” referenced in method claim is not a “particular machine” under the MOT test); *Accenture Global Services, GMBH v. Guidewire Software, Inc.*, 691 F. Supp. 2d 577, 597 (D.Del. 2010) (“data processing system”, “claim folder”, “display device”, and “screen” referenced in claim did not constitute a “particular machine” for the purposes of the MOT test); *see also* ECF No. 55, Ex. A, July 8, 2009 Office Action for Patent Application No. 10/857, 105 (“105 Application”) (application where the PTO found that the term “computing device” did not refer to a particular machine and rejected claims on that basis).²³

²³ SmartGene notes that the difference between the ‘105 Application and the patents-in-dispute “is that the PTO applied the MOT test to the claims of the ‘105 Application and not to the patents-in-suit as the MOT was not the law at the time the patents-in-suit issued.” Pl.’s Reply at 7. PTO states as a reason for the rejection of claims in the ‘105 Application: “Claims 1-15 remain rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory matter. This is a new grounds of rejection necessitated by the recent decision in [*In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008)]. . . In the instant case, the method claims are not so tied to another statutory class of invention because the method steps that are critical to the invention are ‘not tied to any **particular apparatus or machine**’ and therefore do not meet the machine-or-transformation test . . . The instantly recited ‘computing device’ is not a specific computing device and the claims are therefore non-statutory. The rejection could be overcome by reciting a ‘suitably programmed computing device’ or ‘appropriately programmed computing device’ provided such is supported in the specification as originally filed.” ECF No. 55, Ex. A at 2-3

The defendants argue that the Court should look to *VS Techs, LLC v. Twitter, Inc.*, No. 2:11-cv-43, 2011 U.S. Dist. LEXIS 114998 (E.D. Va. Oct. 4, 2011), as “[a] good example of the proper application of the machine prong . . .” Defs.’ Mem. at 12. There, the court found that a claim satisfied the machine prong because “the patent constitutes a practical application of an idea.” *VS Techs, LLC*, 2011 U.S. Dist. LEXIS 114998, at *14-15. The Court finds, to the contrary, that the caselaw is clear that allowing a process to become patentable simply because it is computer aided and constitutes a practical application would render the subject-matter eligibility criteria contained in section 101 meaningless. *See Dealertrack, Inc. v. Huber*, Nos., 2012 WL 164439, at *16 (concluding that claims drawn to a “computer-aided” method of processing information through a clearinghouse were ineligible abstract ideas under section 101); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1375 (Fed. Cir. 2011) (emphasizing “that the basic character of a process claim drawn to an abstract idea is not changed by claiming only its performance by computers, or by claiming the process embodied in program instructions on a computer readable medium”).

Furthermore, the fact that the ‘786 claim relies in part on four other patents for its inference database does not save the defendants’ claim under section 101. The defendants argued at the Motions Hearing

(emphasis in original). PTO may have come to the same conclusion if it had examined the patents-in-dispute under the same criteria.

that “the means plus function language is relevant [to the machine prong analysis], because it provides even further support that the claims are intimately tied to the computer for as you know, for means plus function language, we have to disclose the structure.” Tr. 39:16-20. In turning to the defendants’ proposed claim construction of the term “means for generating,” which they cited at the Motions Hearing to satisfy the machine prong of the MOT test, the Court notes that the defendants propose the following construction: “Inference engine and its equivalents.” Defs.’ Cl. Constr. Br., ECF No. 54, at 6. The defendants describe the “corresponding structure” as follows:

The inference engine 26 may be implemented as hardware, software, or combinations thereof. Inference engines are known and any of a variety thereof may be used to carry out the present invention. Examples include, but are not limited to, those described in U.S. Pat. No. 5,263,127 to Barabash et al. (Method for fast rule execution of expert systems); U.S. Pat. No. 5,720,009 to Kirk et al. (Method of rule execution in an expert system using equivalence classes to group database objects); U.S. Pat. No. 5,642,471 to Paillet (Production rule filter mechanism and inference engine for expert systems); U.S. Pat. No. 5,664,062 to Kim (High performance max-min circuit for a fuzzy inference engine).

Defs. Cl. Constr. Br. at 6 (quoting, *inter alia*, ‘786 patent, Col. 8, lines 25-37). The Court finds that general references to other patents as “examples” of

components of a structure without any detail as to implementation or combination is simply insufficient to identify a structure in the claims. This is fatal for the defendants' claims. Accordingly, the Court finds that nothing in the defendants' proposed claim construction helps them satisfy the "machine" prong of the MOT test.

Second, the computing device referenced in the claims is incidental to the claimed invention and is not used for more than "insignificant postsolution activity," and thus does not satisfy the machine prong. *Diehr*, 450 U.S. at 191. As in *Flook*, the computing device is merely a means of improving an existing process, which does not make the claims of the patents-in-dispute patentable. *Flook*, 437 U.S. at 595 n. 18. Indeed, when a computer is functioning simply to speed up a process, this does not make the process patentable. *CLS Bank Int'l*, 768 F. Supp. 2d at 238-39 ("In order for the addition of a machine to impose a meaningful limit on the scope of a claim, it must play a significant part in permitting the claimed method to be performed, rather than function solely as an obvious mechanism for permitting a solution to be achieved more quickly"); *see also Cybersource*, 654 F.3d at 1375-76 (case would be different if "as a practical matter, the use of a computer [was] required"). In the patents-in-dispute, the computing device referenced in the claims appears to be doing nothing more than speeding up the research and mental processes that a doctor normally goes through when evaluating the best treatment options or regimen for a given patient. Thus, Claim 1 of the '786 patent does not satisfy the machine prong of the MOT test.

2. Claims of the Patents-in-Dispute Do Not Satisfy the Transformation Test

To satisfy the “transformation” prong of the MOT test, a claimed process must “[transform] a particular article into a different state or thing.” *Bilski I*, 545 F.3d at 954. SmartGene argues that the claims of the patents-in-dispute “merely take one form of information (i.e., patient information, therapeutic treatment regimens and advisory information) and represent it in a different form (i.e., lists of therapeutic treatment regimens and advisory information)” and that “[s]uch manipulations of information . . . are insufficient to meet the ‘transformation’ prong of the MOT.” Pl.’s Mem. at 16. The defendants counter that “raw patient information is transformed into a treatment regimen which in turn transforms the patient’s body.” Defs.’ Mem. at 11. According to the defendants, this “system creates the ability for a physician to interact with a program and view and develop a treatment regimen for a patient.” *Id.* This Court finds the defendants’ arguments unavailing and concludes that the patents do not satisfy the transformation prong of the MOT test.

The Supreme Court and Federal Circuit have offered some guidance in deciphering whether a process satisfies the transformation prong. First, the “transformation must be central to the purpose of the claimed process” *see Bilski I*, 545 F.3d at 962, and the “mere manipulation or reorganization of data . . . does not satisfy the transformation prong.” *CyberSource*, 654 F.3d at 1375. Second, “[p]urported transformations or manipulations simply of public or

private legal obligations or relationships, business risks, or other such abstractions cannot meet the test because they are not physical objects or substances, and they are not representative of physical objects or substances.” *Bilski I*, 545 F.3d at 963. Finally, as noted, the Supreme Court in *Prometheus* recently rejected the Federal Circuit’s application of “transformation,” where the Federal Circuit concluded that claimed processes were patent eligible where they involved “transforming the human body.” *Prometheus*, 132 S. Ct. at 1302-1303. The Supreme Court in *Prometheus*, however, did not retreat from a transformation analysis as part of a subject matter patentability test under section 101.

The Federal Circuit’s guidance in *CyberSource* is particularly instructive. In *Cybersource*, the Federal Circuit held that a method for detecting credit card fraud in internet commerce constituted ineligible patent subject matter. *Id.* There, the parties sought patent protection over a process that compares databases comprised of credit card transaction history information to determine whether current purchases are indicative of credit card users’ purchasing habits. 654 F.3d at 1367. The Federal Circuit concluded that such an invention does not constitute patent eligible subject matter because it “can be performed by human thought alone . . .” *Id.* at 1373. The Federal Circuit also explicitly stated that the mere use of the internet does not create patentable subject matter, because the internet is utilized as a “source of data,” and “mere [data-gathering] step[s] cannot make an otherwise nonstatutory claim statutory.” *Id.* at 1370 (quoting

In re Grams, 888 F.2d 835, 840 (Fed. Cir. 1989)). The Federal Circuit found that the patents-in-dispute did not satisfy the transformation prong because “[t]he mere manipulation or reorganization of data . . . does not satisfy the transformation prong.” See *CyberSource*, 654 F.3d at 1375. This conclusion indicates that even if computers simplify data gathering and computation functions, a claimed invention is nevertheless unpatentable if it may be entirely performed through mental processes.

Examining the Supreme Court and Federal Circuit precedent, as well as decisions in this Circuit, the Court concludes that, the ‘786 patent does not involve transformation. As in *Bilski*, *Cyberspace*, and *CLS Bank Int’l*, the alleged transformation performed in the defendants’ patents is more akin to a manual reorganization of treatment options. This does not satisfy the transformation prong of the MOT test. See, e.g., *CLS Bank Int’l*, 768 F. Supp. 2d at 234-35 (rejecting argument that “would convert almost any use of a computer, or other electronic device with memory, to a transformation under the MOT test simply because data would necessarily have to be manipulated”) (citations omitted).

The defendants’ arguments to the contrary are not persuasive. Specifically, the defendants note that the Federal Circuit, in *Bilski I*, stated that “the transformation of . . . raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly-claimed process patent-eligible” and that “the electronic transformation of the data itself into a visual

depiction . . . was sufficient.” *See* Defs.’ Mem. at 11 (quoting *Bilski*, 545 F.3d at 963 (referring to *In re Abele*, 684 F.2d 902 (C.C.P.A. 1982)). Defendants’ reliance on *Abele* is misplaced. In *Abele*, the patent applicant sought to patent a process for improving the accuracy and reliability of CAT scan imaging techniques, while simultaneously reducing the X-ray exposure of the patient. *Abele*, 684 F.2d 902, 903 (C.C.P.A. 1982). This process of improving imaging is very different than the data manipulation at issue here. Unlike in *Abele*, the patents here do not manifest any sort of physical transformation, and therefore do not satisfy the transformation prong of the MOT.²⁴

²⁴ The defendants further rely on an Eastern District of Virginia decision, *VS Techs., LLC v. Twitter, Inc.*, No. 2:11-cv-43, 2011 U.S. Dist. LEXIS 114998, at *19 (E.D. Va. Oct. 4, 2011), where the court noted that a claim directed to the creation of an online community “involves a transformation in the sense that it creates the ability for people to interact in real time.” The defendants argue that “[i]n the same way the technology in [*VS Tech*] involved a transformation by creating the ability to interact in real time, the Asserted Claims involve a transformation by creating the ability for the user to interact with the program to develop a treatment regimen.” Defs.’ Mem. at 11-12. The Court does not find this argument convincing as there is nothing in the Supreme Court or Federal Circuit precedent that suggests data matching and ranking, as described in the patents-in-dispute, constitute a “transformation” of that data in a manner that would satisfy the machine or transformation test. Similarly, the argument by the defendants that their invention “transforms the patient’s body,” *see id.* at 11, appears to be exactly the type of transformation expressly rejected by the Supreme Court in *Prometheus*.

D. Patent Claims Do Not Constitute Eligible Subject Matter

A claimed method may still constitute eligible subject matter despite failing to satisfy the MOT test. *See Bilski II*, 130 S. Ct. at 3226. The defendants assert that the MOT test is “disfavored,” and that the Court should instead be guided by the Federal Circuit’s reasoning in *Ultramercial, LLC v. Hula, LLC*, 657 F.3d 1323, 1329 (Fed. Cir. 2011). Defs.’ Mem. at 8. An examination of this Federal Circuit precedent, however, only reaffirms that the defendants’ patents-in-dispute are abstract and do not constitute patent eligible subject matter.

In *Ultramercial*, the Federal Circuit held that a patent claiming a method for “distributing copyrighted products (e.g. songs, movies, books) over the Internet where the consumer receives a copyrighted product for free in exchange for viewing an advertisement, and the advertiser pays for the copyrighted content,” constituted patentable subject matter. 657 F.3d at 1324. The Federal Circuit upheld the patent-eligibility of the mechanism, concluding that this patent “does not claim a mathematical algorithm, a series of purely mental steps, or any similarly abstract concept.” *Id.* at 1329. Rather, it “claims a particular method for collecting revenue from the distribution of media products over the Internet.” *Id.* This invention constituted patentable subject matter because the claim itself required complex computer programming and “controlled interaction with a consumer via an Internet website.” *Id.* at 1330. Unlike the claims in *Cybersource*, the Federal Circuit concluded that the

claims here were “something far removed from purely mental steps.” *Id.* at 1329-1330 (emphasis in original).

While the claims in *Ultramercial* could not be performed as “purely mental steps,” and involved a number of steps, with complex computer programming, the defendants’ claimed inventions can be performed – and, in fact, are routinely performed – in the minds of physicians who are evaluating patients and selecting therapeutic in-dispute are thus more like the claimed invention in *CyberSource* – a process for detecting credit card fraud in Internet transactions – which the court concluded could be performed exclusively in the human mind. *See CyberSource*, 654 F.3d at 1373. As in *CyberSource*, the claims at issue involve the “organization of data” and do “not require the method to be performed by a particular machine . . .” *Id.* at 1370. The claims thus suffer from the same defects as the claims in *CyberSource* and are not patentable.

The Federal Circuit’s recent decision in *DealerTrack* only reinforces that the patents-in-dispute are not patentable. There, the Federal Circuit found that a process for automating credit applications by receiving credit applicant data from a source and then forwarding the data to potential creditors and forwarding the reply data to the first source, constituted ineligible patent subject matter because it sought to “[explain] the basic concept’ of processing information through a clearing-house, just as claim 1 in *Bilski II* [explained] the basic concept of hedging.” *DealerTrack, Inc. v. Huber*,

Nos. 2009-1566, 2009-1588, 2012 U.S. App. LEXIS 1161, at *47 (Fed. Cir. Jan. 20, 2012) (quoting *Bilski II*, 130 S. Ct. at 3231). The Federal Circuit held that the claim was abstract because the method did not “impose meaningful limits on the claim’s scope.” *Id.* at *48 (quoting *Bilski I*, 545 F.3d at 961-62). In so holding, the Federal Circuit rejected the assertion that a computer was critical to the process because “the computer here ‘can be programmed to perform very different tasks in very different ways[.]’” *Id.* at *48 (quoting *Aristocrat Techs. Australia PTY Ltd. v. Int’l Game Tech.*, 521 F.2d 1328, 1333 (Fed. Cir. 2008)). Thus, “it does not play a significant part in permitting the claimed method to be performed.” *Id.* (citations and quotation marks omitted). The Federal Circuit found the patent invalid because the claims were “silent as to how a computer aids the method, the extent to which a computer aids the method, or the significance of a computer to the performance of the method.” *Id.* at *48. In addition, the claims did “not require a specific application” nor were they “tied to a particular machine.” *Id.* at 49.

In light of this precedent, the Court finds that the defendants’ claims mirror the mental processes that a physician performs, and therefore embody the “‘basic tools of scientific and technological work’ that are free to all men and reserved exclusively to none.” *CyberSource*, 654 F.3d at 1373 (quoting *Benson*, 409 U.S. at 67). Furthermore, the computing device references in the defendants’ patents may be “programmed to perform very different tasks in very different ways,” and therefore cannot serve as a significant limitation or constraint on the claimed

invention. *DealerTrack*, 2012 U.S. App. LEXIS 1161, at *48 (quoting *Aristocrat*, 521 F. 3d at 1333). Like the courts in *Cybersource* and *DealerTrack*, the Court finds the defendants' invention unpatentable.²⁵

²⁵ SmartGene argues that another reason the patents-in-dispute are unpatentable is that the patents are directed to software *per se*. Pl.'s Mem. at 13; Pl.'s Reply at 2. Specifically, SmartGene points to the language of the '786 patent specification, which states that the invention may be constituted in "... an entirely software embodiment..." Pl.'s Mem. at 13 (quoting Ex. A., '786 patent, Col. 4, lines 17-20). SmartGene argues that "[s]uch lack of structure renders the claims unpatentable as directed to software *per se*. *Id.*; see also *Ex. Parte Lektion*, Appeal No. 2009-012445, 2011 Pat. App. LEXIS 21213, *4 (BPAI Aug. 10, 2011) ("As such, claim 1 encompasses software *per se* and is therefore directed to nonstatutory subject matter."); *Ex Parte Barbee*, Appeal No. 2009-009777, 2011 Pat. App. LEXIS 20090, at *3 (BPAI June 21, 2011) ("An embodiment that is software *per se* falls outside of the scope of § 101"); *Ex parte Liebl*, Appeal No. 2009-010624, 2010 Pat. App. LEXIS 14403 (BPAI Mar. 16, 2010) (finding that "the subject matter of the claims on appeal may be properly considered to directly and indirectly recite abstract logic, data structures or software *per se* which our earlier noted case law considers not to be within in any statutory category within 35 U.S.C. § 101"); *Ex Parte Venkata*, Appeal 2009-007302 n.1, 2010 Pat. App. LEXIS 18234, at *8 (BPAI Oct. 6, 2010) (noting that the specification "indicates that the service discovery functions performed by the recited agents may be implemented in software, firmware, hardware or a combination thereof" and thus finding "that the claimed agents comprised in the service discovery system can exist solely in software" and that "[r]eciting descriptive material *per se* (e.g., data structures and computer programs) . . . is non-statutory."). The defendants do not directly address SmartGene's software *per se* argument in their brief. When given an opportunity to respond to SmartGene's software *per se* argument at the Motions Hearing,

E. Claim Construction

Finally, while it is not necessary for this Court to formally construct the claims, the Court notes that the defendants' proposed construction of the disputed claims only reinforces that the defendants' claims are unpatentable. The claimed steps of the invention, and not the specification, must "impose meaningful limits on the claim's scope," *see Bilski I*, 545 F.3d at 961-62, in order to cabin the claimed invention's potential reach. The claim language in Claim 1 of the '786 patent fails to enforce any meaningful limits on the scope and breadth of the claimed invention. The defendants propose, for example, that the term "patient information" in Claim 1 of the '786 patent needs no definition. While SmartGene proposes constructing the claim "patient information" to include "gender, age, weight, CD4+ cell information, hemoglobin information, neuropathy information, neutrophil information, pancreatitis, hepatic function, renal function, drug allergy and intolerance information, information for drug treatments for other conditions, historical information on prior therapeutic treatment regimens for a disease or medical condition, and prior patient information," the defendants insist that the plain language of the claim should apply. Defs.' Cl. Constr. Br. at 2. Likewise, SmartGene proposes that the

the defendants argued, *inter alia*, that "the software *per se* objection is mainly one that has been used in the context of prosecution, and is not a doctrine that has been relied on in the court's recent jurisprudence in the 101 issue." Tr. 31:19-22. Since this software *per se* objection is not necessary to resolve in this Motion, the Court declines to address it.

term “knowledge base” be narrowly constructed to, at a minimum, limit the three databases to human medical information.²⁶ *Id.* at 3. The defendants decline any narrow construction and instead propose constructing the term “knowledge base” in Claim 1 of the ‘786 patent simply as “database.” *Id.* Thus, the contours of these patents with no definition as to which information is pertinent, combined with the broadest possible construction of the terms, could encompass far more than the common understanding of therapeutic treatment regimens and could, for example, include financial information about the patient and the most economic treatment options available. This is reminiscent of the situation in *Benson*, as discussed *supra*, where the Supreme Court expressed concern that a claim was “so abstract and sweeping as to cover both known and unknown uses,” which could “vary from the operation of a train to verification of drivers’ licenses to researching the law books for precedents” and “be performed through any existing machinery or future-

²⁶ Specifically, SmartGene proposed that “[t]he term ‘first knowledge base’ should be construed as a database of information accumulated from a body of knowledge of human specialists in the field of therapeutic treatment regimens. The term ‘second knowledge base’ should be construed as a database of information distinct from the first knowledge base, wherein the second knowledge base is accumulated from a body of knowledge of human specialists in the field of expert rules. The term ‘third knowledge base’ should be construed as a database of information distinct from the first knowledge base and the second knowledge base, wherein the third knowledge base is accumulated from a body of knowledge of human specialists in the field of advisory information.” Defs.’ Cl. Constr. Br. at 3.

devised machinery or without any apparatus.” *Benson*, 409 U.S. at 68. Indeed, the breadth of these proposed constructions only underlines the abstractness of Claim 1 of the ‘786 patent. The defendants’ claims are “invalid as being directed to an abstract idea preemptive of a fundamental concept or idea that would foreclose innovation in this area.” *DealerTrack*, 2012 U.S. App. LEXIS 1161, at * 47; *see also MySpace, Inc. v. Graphon Corp.*, 2012 U.S. App. LEXIS 4375, at *39 (Fed. Cir. Mar. 2, 2012) (J. Mayer, dissenting) (noting that patent claims over “abstract” concepts “fall outside the ambit of section 101 because they are too useful and too widely applied to possibly form the basis of any patentable invention”).

VIII. CONCLUSION

For the reasons discussed above, this Court finds that the defendants’ Patent Nos. 6,081,786 and 6,188,988 B1 constitute ineligible subject matter under 35 U.S.C. § 101, and are therefore invalid. Accordingly, SmartGene’s Motion for Partial Summary Judgment, ECF No. 47, is granted. Since the patents at issue are invalid, the remaining claims and counterclaims pending in the suit are dismissed. An Order consistent with this Opinion shall be filed.

DATED: March 30, 2012

/s/ Beryl A. Howell
BERYL A. HOWELL
United States District Judge

APPENDIX F

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

Civil Action No. 08-00642 (BAH)
Judge Beryl A. Howell

SMARTGENE, INC., PLAINTIFF,

v.

ADVANCED BIOLOGICAL LABORATORIES, SA, *et al.*,
DEFENDANTS.

March 30, 2012

ORDER

Upon consideration of the Complaint in this case, the pending motion, the related legal memoranda, and the applicable law, it is hereby

ORDERED that, for the reasons set forth in the accompanying Memorandum Opinion, the plaintiff's Motion for Partial Summary Judgment, ECF No. 47, is **GRANTED**; it is further

ORDERED that, since the patents at issue are invalid, the remaining claims and counterclaims pending in the suit are dismissed.

SO ORDERED.

This is a final, appealable order.

DATED: March 30, 2012

/s/ Beryl A. Howell
BERYL A. HOWELL
United States District Judge