

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

SMARTGENE, INC.,

Plaintiff,

v.

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

Defendants.

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

**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.<sup>1</sup> Defendants, Advanced Biological Laboratories, SA ("ABL SA") and ABL Patent Licensing

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<sup>1</sup> 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.

Technologies, SARL (“ABL PLT”) (collectively “ABL”)<sup>2</sup>, 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.

## **I. 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.<sup>3</sup> 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.

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

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<sup>2</sup> 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).

<sup>3</sup> The operative complaint, and the one cited throughout this Opinion, is the First Amended Complaint filed on May 20, 2008. *See* ECF No. 4.

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.<sup>4</sup> 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

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<sup>4</sup> 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”).

constitutes eligible subject matter under 35 U.S.C. § 101 of the Patent Act. Claim 1 of the '786 patent is directed to:

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.<sup>5</sup> SmartGene asserts in its Complaint that the ‘786 patent and the ‘988 patent are invalid “for failing to comply with 35 U.S.C. §§ 101-103 and/or 112.” Compl. ¶¶ 20, 26.<sup>6</sup>

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.<sup>7</sup>

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, 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

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<sup>5</sup> This Court has jurisdiction to adjudicate this dispute pursuant to 28 U.S.C. § 1331 and 28 U.S.C. § 1338.

<sup>6</sup> 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.

<sup>7</sup> 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.

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.<sup>8</sup>

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.<sup>9</sup>

## **II. 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

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<sup>8</sup> 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.

<sup>9</sup> Since the Court grants summary judgment for SmartGene, the Court need not proceed with claim construction.

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 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.<sup>10</sup> *See, e.g., In re NTP*, 654 F.3d at 1275-76.

### III. 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 a treatment for a patient suffering from a disease or a medical condition.” Pl.’s Mem. at 6.<sup>11</sup>

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.

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<sup>10</sup> 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.

<sup>11</sup> 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.

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” 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 pre-empt 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].”<sup>12</sup> *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.

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

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<sup>12</sup> The Court discusses this concept of transformation more fully below in the discussion of the “machine or transformation” test.

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.<sup>13</sup>

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 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 . . .”

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<sup>13</sup> 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.

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 Ultramercial*, 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.<sup>14</sup> 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

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<sup>14</sup> 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.

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); *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).<sup>15</sup>

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

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<sup>15</sup> 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 (emphasis in original). PTO may have come to the same conclusion if it had examined the patents-in-dispute under the same criteria.

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 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.<sup>16</sup>

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<sup>16</sup> 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 treatment options for them. The patents-

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.<sup>17</sup>

### **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

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<sup>17</sup> 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 Lection*, 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, 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.

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 term "knowledge base" be narrowly constructed to, at a minimum, limit the three databases to human medical information.<sup>18</sup> *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

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<sup>18</sup> 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.

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-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”).

#### IV. 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