

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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<b>EXERGEN CORP.,</b>	)	
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<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	
	)	<b>Civil Action No. 13-11243-DJC</b>
	)	
<b>THERMOMEDICS, INC., et al.,</b>	)	
	)	
<b>Defendants.</b>	)	
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	)	
	)	

**MEMORANDUM AND ORDER**

**CASPER, J.**

**September 15, 2015**

**I. Introduction**

Plaintiff Exergen Corporation (“Exergen”) has filed this lawsuit against Defendants Sanomedics International Holdings, Inc., and Thermomedics, Inc., (collectively, “Defendants”) alleging patent infringement. D. 1, 17. Defendants have moved for summary judgment on the affirmative defense that the asserted patent claims are invalid. D. 83, D. 84. For the reasons stated below, the Court **ALLOWS** Defendants’ motion for summary judgment of invalidity under 35 U.S.C. § 101, D. 83, and **DENIES** as moot Defendants’ remaining arguments for invalidity under 35 U.S.C. § 102 and/or § 103, D. 84.

**II. Standard of Review**

The Court grants summary judgment where there is no genuine dispute as to any material fact and the undisputed facts demonstrate that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). “A fact is material if it carries with it the potential to affect

the outcome of the suit under the applicable law.” Santiago–Ramos v. Centennial P.R. Wireless Corp., 217 F.3d 46, 52 (1st Cir. 2000) (quoting Sánchez v. Alvarado, 101 F.3d 223, 227 (1st Cir. 1996)). The movant bears the burden of demonstrating the absence of a genuine issue of material fact. Carmona v. Toledo, 215 F.3d 124, 132 (1st Cir. 2000); see Celotex v. Catrett, 477 U.S. 317, 323 (1986). If the movant meets its burden, the non-moving party may not rest on the allegations or denials in her pleadings, Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986), but “must, with respect to each issue on which she would bear the burden of proof at trial, demonstrate that a trier of fact could reasonably resolve that issue in her favor.” Borges ex rel. S.M.B.W. v. Serrano–Isern, 605 F.3d 1, 5 (1st Cir. 2010). “As a general rule, that requires the production of evidence that is ‘significant[ly] probative.’” Id. (quoting Anderson, 477 U.S. at 249) (alteration in original). The Court “view[s] the record in the light most favorable to the nonmovant, drawing reasonable inferences in his favor.” Noonan v. Staples, Inc., 556 F.3d 20, 25 (1st Cir. 2009).

### **III. Factual Background**

Exergen asserts that Defendants’ Caregiver Non-Contact Thermometer has infringed four claims of United States Patent No. 7,787,938 (the “’938 patent”). The ’938 patent, invented by Dr. Francisco Pompei, Exergen’s Chief Executive Officer, describes a method of measuring an individual’s body temperature based upon radiation and temperature measurements taken at the temporal artery at the side of the forehead. The patent sets forth mathematical formulas for converting the measurements into a skin surface temperature reading and then converting the skin surface temperature into an approximation of the subject’s core body temperature, taking into account the ambient air temperature. D. 86-1.

A high-accuracy forehead thermometer had previously not been available due to the challenges presented by the forehead's exposure to varying ambient air temperatures. D. 97-1 ¶ 7. The forehead was targeted because Exergen sought a measurement site that was less invasive than regions targeted by earlier thermometers, such as the eardrum or rectum. D. 97-2 ¶ 7. Temperature measurement at these more invasive sites was time consuming, uncomfortable for patients and inconvenient in clinical environments. D. 97-7 at 33.

Exergen asserts independent claims 51 and 54 and respective dependent claims 52 and 55 of the '938 patent. The independent claims each include a measuring element that involves measuring surface temperature or radiation and a processing element that involves converting that measurement to a core temperature approximation. Claim 51 recites:

A method of detecting human body temperature comprising: measuring temperature of a region of skin of the forehead; and processing the measured temperature to provide a body temperature approximation based on heat flow from an internal body temperature to ambient temperature.

D. 86-1 at 16. Claim 54 recites:

A method of detecting human body temperature comprising: measuring radiation as target skin surface of the forehead is viewed, and processing the measured radiation to provide a body temperature approximation based on heat flow from an internal body temperature to ambient temperature.

Id. The two asserted dependent claims, claims 52 and 55, each limit their corresponding independent claims to a "region of skin over an artery." Id.

The '938 patent also includes many claims that are not asserted in the present litigation, including the method of scanning a thermal radiation sensor across the temporal artery and obtaining multiple radiation readings per second to provide a peak temperature value. Id. at 14-16. The '938 patent notes that many of the individual aspects of the thermometry methods described in the patent "can be found in applicant's prior designs" but the novel invention is the

“unique combination of elements which enable consistent measurements of core temperature by scanning across a superficial artery.” Id. at 14.

#### **IV. Procedural History**

Exergen instituted this action on May 21, 2013. D. 1. In its preliminary infringement disclosures, Exergen initially asserted multiple claims of two separate patents against two of Defendants’ thermometer products. D. 34.

This case was consolidated with two other cases for claim construction. See Exergen Corp. v. Kaz USA, Inc., No. 13-cv-10628-RGS; and Exergen Corp. v. Brooklands Inc. (“Brooklands”), No. 12-cv-12243-DPW. D. 41, 45. On August 15, 2014, Judge Stearns issued a claim construction order. D. 74.

On October 1, 2014, following an agreement by the parties that removed one of the two challenged products from the case, Exergen filed an amended preliminary infringement disclosure that asserted only claims 51, 52, 54 and 55 of the ’938 patent against a single product, Defendants’ Caregiver Non-Contact Thermometer. D. 78 at 1-2.

Defendants have now moved for summary judgment on the issue of patent validity under 35 U.S.C. §§ 101, 102 and 103. D. 83, D. 84. The Court heard the parties on the pending motions and took the matter under advisement. D. 112.

#### **V. Discussion**

##### **A. Patent Eligibility Under 35 U.S.C. § 101**

###### *1. Legal Framework*

Section 101 of the Patent Act defines patentable subject matter. It states:

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 claims asserted here describe a “process,” defined as a “process, art, or method, and includ[ing] a new use of a known process, machine, manufacture, composition of matter, or material.” Id. § 100(b).

Despite the breadth signaled by the “expansive terms” of § 101, the Supreme Court has long held that certain categories of information are not eligible for patent protection. Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980). “Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.” Gottschalk v. Benson, 409 U.S. 63, 67 (1972). The Court, however, has acknowledged that “too broad an interpretation of this exclusionary principle could eviscerate patent law,” since “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” Mayo Collaborative Servs. v. Prometheus Labs., Inc., \_\_\_ U.S. \_\_\_, 132 S. Ct. 1289, 1293 (2012).

The Court has recently elaborated on the line dividing that which can be patented under § 101 from that which cannot. In Mayo, the Court addressed the patent eligibility of claims covering processes that help doctors determine the appropriate dosage of thiopurine drugs for patients with autoimmune diseases. Mayo, 132 S. Ct. at 1294. The claims described the relationships between the quantity of certain thiopurine metabolites in the blood and the likelihood that a particular drug would be ineffective or produce unwanted side effects. Id. More specifically, the patent in question claimed a method of administering a drug containing a metabolite to a subject and determining the subject’s level of that metabolite, where a certain reading of the metabolite would indicate the need to change the dose of the drug. Id. at 1295.

The Court concluded that the patent claims were invalid under § 101 because the patent effectively claimed a law of nature, “namely, relationships between concentrations of certain

metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm.” Id. at 1296. The Court looked at each element in the patent beyond the recitation of this natural chemical relationship and then all of the elements together to determine whether the claims added enough to qualify as a patent-eligible process “applying” a natural law. The “administering” step simply referred to a pre-existing audience of doctors treating patients with certain diseases. Id. at 1297. The “wherein” clauses informed the doctor of the relevant natural laws: the relationships between the metabolite concentration in the blood and the necessary drug dosage adjustment. Id. The “determining” step instructed the doctor to measure the level of the relevant metabolite through any process of the doctor’s choosing. Id. Finally, the steps together amounted to “nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.” Id. at 1298. The Court found each of these elements insufficient to transform the underlying natural law into something patentable: “the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.” Id.

In Alice Corp. v. CLS Bank Int’l, \_\_\_ U.S. \_\_\_, 134 S. Ct. 2347 (2014), the Court built upon the framework articulated in Mayo for analyzing patent eligibility under § 101. As the Court framed the analysis, a patent claim that covers an abstract idea or natural law is invalid unless the claim recites other features that provide an “inventive concept” beyond the natural law or abstract idea:

First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, “what else is there in the claims before us?” To answer that question, we consider the elements of each claim both individually and “as an ordered combination” to determine whether the additional

elements “transform the nature of the claim” into a patent-eligible application. We have described step two of this analysis as a search for an “inventive concept” — i.e., an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.”

134 S. Ct. at 2355 (quoting Mayo, 132 S. Ct. at 1294-97). The Court applied this standard in Alice to a patent claiming a method of using a third party to mitigate settlement risk. Id. at 2352-53. The Court found that the claims were directed to the abstract idea of intermediated settlement and proceeded to consider whether the elements of the claim, either individually or in combination, were sufficient to transform the claims into a patentable invention. Id. at 2355-57. Finding that the “claims at issue amount to nothing significantly more than an instruction to apply the abstract idea of intermediated settlement using some unspecified, generic computer,” the Court held the patent invalid for want of an inventive concept. Id. at 2360 (internal citation omitted).

In contrast, the Alice Court cited Diamond v. Diehr, 450 U.S. 175, 186 (1981), as an example of a patent claim that added enough of an inventive concept to a natural phenomenon to be eligible for patent protection. 134 S. Ct. at 2358. The patent in Diehr claimed a method for molding raw rubber into cured products using a mathematical formula. Id. The Alice Court explained why the rubber-molding method in Diehr was patentable:

The claim employed a “well-known” mathematical equation, but it used that equation in a process designed to solve a technological problem in “conventional industry practice.” Diehr, 450 U.S. at 177, 178. The invention in Diehr used a “thermocouple” to record constant temperature measurements inside the rubber mold—something “the industry ha[d] not been able to obtain.” Id. at 178 and n.3. The temperature measurements were then fed into a computer, which repeatedly recalculated the remaining cure time by using the mathematical equation. Id. at 178-79. These additional steps, we recently explained, “transformed the process into an inventive application of the formula.” Mayo, 132 S. Ct. at 1299. In other words, the claims in Diehr were patent eligible because they improved an existing technological process, not because they were implemented on a computer.

Id. The Court warned that simply reciting an abstract idea “while adding the words ‘apply it’” was insufficient to “transform a patent-ineligible abstract idea into a patent-eligible invention.”

Id. (quoting Mayo, 132 S. Ct. at 1294).

2. *Step One: Patent-Ineligible Concepts*

The first step in the § 101 analysis asks “whether the claims at issue are directed to one of [the] patent-ineligible concepts,” namely laws of nature, natural phenomena, or abstract ideas. Alice, 134 S. Ct. at 2355. The parties do not seriously dispute that the four claims at issue are directed to patent-ineligible concepts. Claims 51 and 54 recite a method for processing temperature and radiation measurements to estimate body temperature “based on heat flow from an internal body temperature to ambient temperature.” D. 86-1 at 16. The Supreme Court has explained that “if a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features” that supply an inventive concept at step two of the § 101 analysis. Mayo, 132 S. Ct. at 1297. Claims 51 and 54 and their related dependent claims are directed to applying mathematical models of natural thermodynamic relationships, so the § 101 analysis proceeds to the second step.

3. *Step Two: Inventive Concept*

The dispositive question is therefore, as in Mayo: “do the patent claims add enough to their statements of the [natural laws and phenomena] to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?” Mayo, 132 S. Ct. at 1297 (emphases in original). The court must consider the elements of each asserted claim individually and as an ordered combination to determine if the claim contains a patentable inventive concept. Id. at 1297-98. Another district court recently considered the same § 101 question as to claims 51 and 54 of the ‘938 patent and held that the subject matter of these claims was unpatentable.

Brooklands, 2015 WL 5096464, at \*6 (granting summary judgment to defendants under § 101). For the reasons set forth below, this Court agrees with this conclusion and also concludes that the dependent claims 52 and 55 do not recite patent-eligible subject matter.

As discussed above, the independent claims break down into processing and measuring elements. The processing elements recite a method for converting a temperature or radiation reading to a body temperature estimate based on “heat flow from an internal body temperature to ambient temperature.” D. 86-1 at 16. These elements simply describe the application of a heat flow model, which is itself a natural phenomenon akin in Mayo to the natural biological relationship between concentrations of metabolites in the blood and the necessary drug dosage. The Mayo Court held that these elements do not contribute to patentability because these clauses simply “tell the relevant audience about the laws” of nature. Mayo, 132 S. Ct. at 1297.

The measuring elements recite the measurement of temperature or radiation at a region of skin of the forehead. D. 86-1 at 16. The measuring elements include no limit on how temperature or radiation is to be determined, leaving only the measurement of a naturally-occurring phenomenon at a particular location on the body. These elements parallel the “determining” elements in the Mayo patent claims that directed the doctor to determine the level of a certain chemical in the subject. 132 S. Ct. at 1295. The Mayo Court found no inventive concept in these elements because they “simply tell doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists in the field.” Id. at 1298.

Whether there is an inventive concept in the measuring and processing elements considered together presents a closer question. Exergen argues that when taken together, the measurement of body temperature from the surface of the forehead is patent eligible because this practice was thought to be impossible at the time the '938 patent was issued. According to

Exergen's expert Dr. Collins, prior to the issuance of the '938 patent, the notion that body temperatures could be determined from skin temperature was not widely accepted. D. 97-1 ¶ 8. Exergen cites a 1996 study from the Thermoregulation Research Laboratory at UCSF that warned the medical community of the dangers of using skin temperature as a substitute for traditional core-temperature monitoring sites and reported a "poor correlation" between skin temperature and core temperature. D. 97-6 at 3. The American Society for Testing and Materials, an international organization that develops technical standards, concluded in its 2003 and 2009 standards for infrared thermometers that skin temperature could not be independently correlated with core body temperature. D. 97-1 ¶¶ 8-9. Dr. Pompei spent years conducting clinical trials of Exergen's forehead thermometer to overcome skepticism among medical professionals who believed that measuring temperature at the forehead could not lead to accurate estimates of core body temperature. D. 97-2 ¶¶ 5-7.

The Supreme Court has warned that "limiting an abstract idea to one field of use" is not enough to make the concept patentable. Bilski v. Kappos, 561 U.S. 593, 612 (2010). In Parker v. Flook, the patent at issue provided a method for measuring, calculating and adjusting "alarm limits" in the catalytic conversion of hydrocarbons. 437 U.S. 584, 585 (1978). The Court found the claimed process unpatentable because all steps in the claimed process were well known and the patent application "simply provide[d] a new and presumably better method for calculating alarm limit values." Id. at 594-95. As the Court later summarized in Diehr, the prohibition against patenting abstract ideas "cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment." Diehr, 450 U.S. at 191 (citing Flook, 437 U.S. at 584).

The Court finds persuasive the district court's analysis in Brooklands of Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015), a recent Federal Circuit decision. See Brooklands, 2015 WL 5096464, at \*6. The patent in question in Ariosa claimed a method for detecting fetal DNA in the blood of a pregnant woman. The Federal Circuit accepted that "no one was using the plasma or serum of pregnant mothers to amplify and detect" fetal DNA before the issuance of the patent in question and that the discovery "reflect[ed] a significant human contribution." 788 F.3d at 1379. The Brooklands court explained, however, that "[t]he discovery of a law of nature, such as the method for non-invasive fetal testing in Ariosa . . . , no matter how novel, cannot on [its] own amount to patentable subject matter." 2015 WL 5096464, at \*6. The Brooklands court continued, applying this analysis to the patentability of claims 51 and 54:

Exergen may well be correct that Dr. Pompei's discovery that surface skin measurements taken at the forehead reliably can be converted to accurate body temperature is novel and valuable. However, the additional step of measuring the surface skin of the forehead is a necessary, conventional step involving collecting the data needed to be plugged into the mathematical equations in the processing step. Measuring temperature or radiation is simply not an inventive or unconventional step in the field of thermometry.

Id. This Court agrees with this analysis. No matter how novel the concept of measuring body temperature from forehead skin temperature or how valuable the contribution to the medical community, this idea as set forth in the asserted claims is fundamentally a discovery of a natural relationship between skin temperature and body temperature. "Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013) (holding in part that discovery and isolation of naturally occurring segment of DNA, while "important and useful," is not patentable under § 101).

It is clear that the dependent claims, claims 52 and 55, do not provide the inventive concept missing in the independent claims. Each dependent claim adds the element to its corresponding dependent claim that “the region of the skin is over an artery.” Defendants correctly observe that an artery is a natural element and does not add an inventive concept. D. 87 at 26. The asserted claims lack an inventive concept outside of the laws of nature and are not eligible for patent protection.<sup>1</sup>

4. *Machine-or-Transformation Test*

Finally, Exergen looks to the machine-or-transformation test to bolster the patent-eligibility of its asserted claims. D. 97 at 21. This test remains “a useful and important clue” for considering § 101 invalidity challenges, but it is not the definitive test for patent eligibility. Bilski, 561 U.S. at 604. Under this test, a claimed process is “patent-eligible under §101 if: (1) it is tied to a particular machine or apparatus; or (2) it transforms a particular article into a different state or thing.” Id. at 602 (internal citation omitted). Exergen argues that the claims in question “transform data, namely, temperature or radiation measurements taken from forehead skin, into a body temperature reading.” D. 97 at 22. However, the Court finds no transformative element here, where the claims simply apply a mathematical formula to temperature or radiation measurements and do not change the measurements “into a different state or thing.” Bilski, 561 U.S. at 602.

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<sup>1</sup> In reaching this conclusion, the Court has not placed weight on Defendants’ argument that measuring temperature at the forehead is not an “inventive concept” because it was anticipated by prior art. D. 87 at 30. The question of whether a particular invention is novel is “wholly apart from whether the invention falls into a category of statutory subject matter.” Diehr, 450 U.S. at 190 (internal quotation and citation omitted).

**VI. Conclusion**

As the asserted claims are invalid under § 101, the Court need not reach Defendants' alternative arguments for invalidity on the grounds of anticipation and obviousness under §§ 102 and 103. For the foregoing reasons, the Court **ALLOWS** Defendants' motion for summary judgment of invalidity under 35 U.S.C. § 101, D. 83, and **DENIES** as moot Defendants' motion for summary judgment of invalidity under 35 U.S.C. § 102 and/or § 103, D. 84.

**So Ordered.**

/s/ Denise J. Casper  
United States District Judge