

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 13-10628-RGS

EXERGEN CORPORATION

v.

KAZ USA, INC.

MEMORANDUM AND ORDER ON DEFENDANT'S MOTION
FOR JUDGMENT OF INVALIDITY UNDER 35 U.S.C. § 101

March 25, 2016

STEARNS, D.J.

The court is again confronted¹ with Kaz USA, Inc.'s subject matter patentability challenge to the viability of Exergen Corporation's asserted claims. In addition to the parties' exhaustive briefing, I now have the benefit of the evidence presented at the well-litigated jury trial. Guided by the jury's verdict, and by the pleadings specific to this case, I will affirm the validity of the challenged claims for the reasons that will be explained. *See Internet*

¹ Applying the doctrinal precepts of issue preclusion, the court previously ruled that claims 27, 29, 37, and 56 of the '938 patent were invalid in light of Judge Casper's order granting defendant's motion for summary judgment on the issue of § 101 invalidity as to claims 51, 52, and 54 of the '938 patent in Exergen's infringement suit against Thermomedics, Inc., and Sanomedics International Holdings, Inc. *See Exergen Corp. v. Kaz USA, Inc.*, 2015 WL 8082402 (D. Mass. Dec. 7, 2015); *Exergen Corp. v. Thermomedics, Inc.*, 2015 WL 5579800 (D. Mass. Sep. 15, 2015).

Patents Corp. v. Active Network, Inc., 790 F.3d 1343, 1347 (Fed. Cir. 2015) (noting that a “pragmatic analysis of § 101 is facilitated by considerations analogous to those of §§ 102 and 103 as applied to the particular case.”); *Accenture Global Servs., GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336, 1341 (Fed. Cir. 2013) (the legal determination under § 101 may depend on “underlying factual issues”).

Exergen’s ’685 and ’938 patents are directed to non-invasive methods and devices for accurately determining a person’s deep body temperature by taking measurements of the skin temperature over an artery, preferably, the temporal artery.

[P]rior to inventions of the patents-in-suit, persons skilled in the art were skeptical that accurate internal temperatures could be determined from external measurements taken at exposed locations, such as the forehead. There existed an unmet need in the field, particularly in pediatric medicine, for accurate temperature measurements taken by less intrusive instruments than ear thermometers.

Exergen Corp. v. Kaz USA, Inc., 2015 WL 4974167, at *4 (D. Mass. Aug. 20, 2015). Claim 49 of the ’938 patent, a device claim, is representative.

49. [A body temperature detector comprising:

a radiation detector; and

electronics that measure radiation from at least three readings per second of the radiation detector as a target skin surface over an artery is viewed, the artery having a relatively constant blood flow, and that process the

measured radiation to provide a body temperature approximation, distinct from skin surface temperature, based on detected radiation;]

wherein the artery is a temporal artery.

The other asserted claims – claims 17, 24, 33, 39, 40, 46, 60, and 66 of the '938 patent, and claims 7, 14, and 17 of the '685 patent – are examined in detail in one of the court's earlier opinions. *See Exergen*, 2015 WL 8082402, at *6-9.

Section 101 serves to promote scientific and technological advancement by excluding laws of nature, natural phenomena, and abstract ideas from the realm of patentable subject matter, thus preventing patentees from monopolizing “the basic tools of scientific and technological work.” *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1293 (2012). “[H]owever, 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.” *Id.* In balancing these often competing desirables, the Supreme Court has adopted a two-step inquiry into subject matter eligibility.

First, we determine whether the claims at issue are directed to [a] patent-ineligible concept[.]. [*Mayo*], 132 S. Ct., at 1296-1297. If so, we then ask, “[w]hat else is there in the claims before us?” *Id.*, [] at 1297. 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. *Id.*, [] at 1298, 1297. 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.” *Id.*, [] at 1294.

Alice Corp. Pty. Ltd. v. CLS Bank Int’l, 134 S. Ct. 2347, 2355 (2014).

Guided by *Alice*, the parties focus on whether Exergen’s asserted claims, when stripped of those elements that simply reflect laws of nature, were “well-understood, routine, conventional activity previously engaged in by scientists who work in the field,” and whether singly or in combination, they truly illuminate an “inventive concept.” *Mayo*, 132 S. Ct. at 1298, 1294. The relevant laws of nature, however, do not drop out of the analysis altogether. Rather, they require a nuanced appreciation in the context of the claims taken as a whole.

The evidence received at trial established that Exergen’s “body temperature detector” built on two previously known but unrelated natural laws or phenomena – the absence of arteriovenous anastomoses (AVAs)² that would create a relatively constant blood flow in certain arteries close to the skin surface, including the temporal artery, *see* Tr. Day 2 at 86-89; and the principles of thermodynamics embodied by the heat transfer equations

² AVAs function like valves, adjusting blood flow to the skin to regulate the body’s temperature. Tr. Day 2 at 87.

disclosed in the patents, *see id.* at 104. As asserted, the claims do not attempt to appropriate or cordon off the development by others of ideas based on either or both of these principles. *See Alice*, 134 S. Ct. at 2354-2355 (while allowing patents on building blocks “would risk disproportionately tying up the use of the underlying ideas, . . . [inventions incorporating these fundamental laws] pose no comparable risk of pre-emption, and therefore remain eligible for the monopoly granted under our patent laws.”) (internal quotation marks and citation omitted). An artery’s lack of AVAs may prove useful in medical applications other than temperature measurement, and the heat transfer equations at issue have already been used in ways that are not covered by the patents-in-suit. *See* Tr. Day 2 at 68-70.

Nor do Exergen’s claims succumb to the fatal sin of “simply stat[ing] [a] law of nature while adding the words ‘apply it.’” *Mayo*, 132 S. Ct. at 1294. In *Mayo*, the Supreme Court found ineligible for patentability claims that recited the correlation between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drugs and then added a generic instruction to adjust dosages accordingly. Similarly, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377-1378 (Fed. Cir. 2015), the Federal Circuit found claims that applied “well-known” sequencing techniques to the discovery of fetal DNA in maternal blood to be unacceptable subject matter.

In contrast, the trial evidence presented in this case established that the invention defined in the asserted claims was not a mere appropriation of the laws of nature on which it was based. That certain arteries lacked AVAs was no mystery to the medical community prior to Dr. Pompei's patents, but that knowledge had not been exploited in measuring human body temperature. *See* Tr. Day 2 at 86-87. The heat transfer approach was known and incorporated in Dr. Pompei's own prior art devices measuring body temperature at a protected site (the ear canal), but Dr. Pompei was himself unsure that the approach could be made to work at a location as exposed as the forehead. *Id.* at 68-69. The jury found that combining the two natural phenomena to achieve an accurate noninvasive measurement of human body temperature was not obvious to a person of ordinary skill in the art at the time of the invention. *See* Verdict at 4-5. Indeed, at its unveiling, Dr. Pompei's device received a lukewarm reception among practitioners whose skepticism took some years to overcome. *See, e.g.,* Tr. Day 4 at 68-71.

In applying step one of *Mayo*, the court is persuaded that, while the asserted claims are based in natural phenomena, they do not simply identify some previously unremarked upon natural law, or recite a perfunctory intersection of a couple of previously perceived phenomena; rather, they reveal a novel combination of two previously known but uncorrelated

scientific principles. This is a salient distinction. “[I]n applying the § 101 exception, we must distinguish between patents that claim the buildin[g] block[s] of human ingenuity and those that integrate the building blocks into something more.” *Alice*, 134 S. Ct. at 2354 (quotation marks and citations omitted). “Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented.” *Parker v. Flook*, 437 U.S. 584, 594 (1978).³

The teaching in this case, it should be emphasized, is not that novel combinations of natural phenomena are patentable without more, although they might possibly be in some circumstances. Rather *Mayo* requires that a second question be asked: What else is there in the claims besides the recitation of laws of nature? Kaz notes that the asserted claims each recite a subset of three additional steps – moving while (laterally) scanning (’685 patent claims 7, 14, and 17; ’938 patent claims 17, 24, 33, 60, and 66), obtaining a peak temperature reading (’685 patent claim 7; ’938 patent claims 60 and 66), and obtaining at least three readings per second (’938

³ Many of the most useful human innovations are based on a combination of previously known but unconnected natural phenomena. The relatively modern greenhouse, for example, exploits the transparency and insulating properties of glass to capture and retain the sun’s energy to grow plants outside of their natural season or habitat, while the more ancient water wheel converts the force of gravity’s pull on the fluid dynamics of water to produce usable mechanical power.

patent claims 17, 24, 39, 40, 46, and 49) – but no claim recites the three additional steps ensemble. Pointing to prior art elicited at trial, such as Wortz, Barnes, Hood, Walsall, Exergen’s ’091 patent, and the Exergram and Dermatemp devices, Kaz asserts that these additional elements were familiar accoutrements in the field of thermometry.

As previously noted, that additional claim elements were known in the art does not necessarily defeat subject matter eligibility. “[A] new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.” *Diamond v. Diehr*, 450 U.S. 175, 188 (1981). Here again, the evidence at trial informs the analysis. The additional steps were previously utilized to detect hot spots indicating injury or tumors, or surface temperature differentials. *See, e.g.*, Tr. Day 3 at 62-63 (detecting injury in horses); Tr. Day 4 at 17 (use of motion to scan differential surface temperatures). In the asserted claims, the additional steps solve a different problem. In order to make use of the temporal artery as a suitable location for body temperature measurement, a method or device must accurately locate the artery, which is under the skin surface and invisible to the eye. The temporal artery is small and its exact location varies from person to person. Tr. Day 2 at 101-102. Dr. Pompei devised a method to “cross the T” – by

taking multiple measurements and detecting the highest temperature while scanning laterally across the forehead over the location of the temporal artery. *Id.* at 102. The additional steps of the asserted claims are directed to aspects of this method. There is no evidence in the record that these steps were “well-understood, routine, [or] conventional[ly]” used to detect arterial temperature beneath the skin before the introduction of Exergen’s invention.⁴

As the Supreme Court has said (more than once), “[w]hile a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.” *Mayo*, 132 S. Ct. at 1294, quoting *Diehr*, 450 U.S. at 188, quoting *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939). In *Diehr*, the Court found patent-eligible a claim for a rubber curing process that incorporated a well-known mathematical formula. Why? Because the additional steps “transformed the process into an inventive application of the formula.” *Mayo*, 132 S. Ct. at 1299. Here, in similar fashion, the asserted claims transformed the underlying natural laws into

⁴ Wortz is the only prior art reference directed to detecting temperature above the temporal artery. It discloses detecting the location of the artery by locating its pulse.

inventive methods and useful devices that noninvasively and accurately detect human body temperature. *Ad susceptum perficiendum*.

ORDER

For the foregoing reasons, Kaz's motion for judgment of invalidity under 35 U.S.C. § 101 is DENIED. The Clerk will now enter judgment for Exergen.

SO ORDERED.

/s/ Richard G. Stearns

UNITED STATES DISTRICT JUDGE