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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte YONATAN GERLITZ and ALEXANDER OSTRITSKY

Appeal 2017-002398¹
Application 12/883,063
Technology Center 3700

Before RICHARD M. LEBOVITZ, JEFFREY N. FREDMAN, and
RYAN H. FLAX, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims directed to a method of non-invasively measuring a substance in a body. The Examiner rejected the claims under 35 U.S.C. § 101 as directed to patent ineligible subject matter and under 35 U.S.C. § 103 as obvious. We have jurisdiction under 35 U.S.C. § 6(b). The § 101 rejection is affirmed; the § 103 rejection is reversed. All claims remain rejected as unpatentable.

We affirm.

¹ The real party in interest is identified in the Appeal Brief (“Appeal Br.”) as GlucoVista, Inc. Appeal Br. 3.

STATEMENT OF THE CASE

Claims 1–18 and 21–24 stand rejected by the Examiner as follows:

1. Claims 1–18 and 21–24 under 35 U.S.C. § 101 because the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more.

Examiner’s Answer (“Ans.”) 2.

2. Claims 1–18, 21, 22, and 24 under pre-AIA 35 U.S.C. § 103(a) as obvious and unpatentable in view of U.S. Pat. No. 5,900,632, issued May 4, 1999 (“Sterling”), U.S. Pat. No. 6,198,949 B1, issued Mar. 6, 2001 (“Braig”), and U.S. Pat. Pub. No. 2005/0043630 A1, pub. Feb. 24, 2005 (“Buchert”). Ans. 5.

3. Claim 23 under pre-AIA 35 U.S.C. § 103(a) as obvious and unpatentable in view of Sterling, Braig, Buchert, and U.S. Pat. Pub. No. 2002/0133065 A1, pub. Sept. 19, 2002 (“Lucassen”). Ans. 13

Claim 1 is representative and is reproduced below:

1. A method comprising:
 - decreasing a temperature of a surface of a body from a first temperature to a second temperature less than the first temperature;
 - thereafter, recovering to the first temperature by increasing the temperature of the surface of the body from the second temperature to the first temperature;
 - measuring a first amount of infrared radiation absorbed or emitted from the body in a first wavelength band at predetermined time intervals during the recovery increasing the surface of the body from the second temperature to the first temperature, the first wavelength band being a wavelength band or bands in which a substance in the body emits or absorbs infrared radiation;
 - measuring a second amount of infrared radiation absorbed or emitted from the body in a second wavelength band

at predetermined time intervals during the recovery increasing the surface of the body from the second temperature to the first temperature;

measuring a temperature of the surface of the body;

measuring an ambient temperature;

calculating a normalized ratio parameter based on the first amount, the second amount, the body surface temperature, and the ambient temperature; and

determining a concentration of a substance in the body non-invasively by using a correlation with the normalized ratio parameter.

SECTION 101 REJECTION

The Examiner found that the claims are directed to a judicial exception to patentability as being directed to a law of nature, natural phenomenon, or abstract idea “without significantly more.” Final Office Action (“Final Act.”) 2. The Examiner found the claim involved routine data collection and generic processing functions and steps which do not add anything significantly more to the mathematical relationship (*id.*) between the concentration of the substance in the body and the measured infrared radiation and temperatures.

Appellants contend that the claims improve the technological field “by affirmatively determining concentration of a substance in a body using IR radiation,” distinguishing the claims from those in *Parker v. Flook*, 437 U.S. 584 (1978) found to be ineligible for a patent because they were directed to a mathematical equation with insignificant post-solution activity for updating an alarm limit. Appeal Br. 7, 13. Appellants also contend that the claims are distinguished from those held in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012), found by the Supreme Court to “simply tell a doctor about the relevant natural laws.” Appeal Br. 7.

Instead, Appellants contend that the claims are like those found to be patent eligible in *Diamond v. Diehr*, 450 U.S. 175 (1981), because there is a physical change of “decreasing surface temperature followed by recovering surface temperature during measurement of infrared radiation.” Appeal Br. 9. Appellants also argue that the claims “do something significant beyond merely stating a law of nature” by modifying “measurement conditions in a manner that improves application of that law to yield a concentration value for the substance in the body.” *Id.* at 9, 11, 12 (identifying steps in claims said to qualify as ““significantly more”” under PTO Guidelines. With respect to claim 24, Appellants further argue that it is eligible for a patent because it is directed to a data product. *Id.* at 9.

Discussion

A two-step analysis has been promulgated by the U.S. Supreme Court to determine whether a claim is eligible for a patent under 35 U.S.C. § 101. The test is set forth in *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355 (2014):

First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts [, e.g., a law of nature, natural phenomenon, or abstract idea]. If so, we then ask, what else is there in the claims before us? . . . 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. (alterations, citations, and quotation marks omitted).

Claim 1 involves decreasing the temperature of a body, and “thereafter,” *increasing* it. The claim further requires measuring first and second amounts of radiation absorbed or emitted from a body. The radiation

is measured during the “recovery” when the temperature is *increasing*. A “normalized ratio parameter” is calculated based on the measured amounts of 1) first and 2) second radiation, 3) the body surface temperature, and 4) the ambient temperature. The final step of the claim is “determining a concentration of a substance in the body non-invasively by using a correlation with the normalized ratio parameter.” Independent claims 11, 21, and 24 have similar requirements.

The calculation of the ratio parameter and the subsequent step of using it to determine the concentration of substance in the body constitutes an abstract idea, namely a mathematical relationship, because it is statement of the correlation between infrared radiation and body temperature, each themselves natural phenomena, with the presence and concentration of a substance in the body. The mathematical relationship is an “abstract idea” and a judicial exception to Section 101, because it is not associated with a concrete object, but rather it is a mathematical process that uses measured values to determine a correlation based on a lookup table (Spec. ¶ 42).

In *Digitech Image Technologies, LLC v. Electronics for Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014), the claims were directed to “a process of taking two data sets and combining them into a single data set, the device profile,” where the two data sets were “generated by taking existing information—*i.e.*, measured chromatic stimuli, spatial stimuli, and device response characteristic functions—and organizing this information into a new form.” The *Digitech* court found, relying on *Flook*, that the method claims were drawn to “an abstract idea because it describes a process of organizing information through mathematical correlations and is not tied to a specific structure or machine.” *Id.* at 1350.

The claims in this case are analogous to those at issue in *Digitech* because they merely cover the selection of data (temperature, radiation) obtained from known and existing technology and then using the data to make a correlation. The determination and application of the normalized ratio parameter has no relationship to specific structure or machine, and does not change how the temperature and infrared radiation measurements are made. “If a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory.” *Parker*, 437 U.S. at 595 (internal quotations omitted).

Diehr

Appellants contend that the claims are eligible for a patent for the same reason as in *Diamond v. Diehr* (“*Diehr*”), namely, there is a transformation to a different state. Appeal Br. 9, 11. This argument does not persuade us that the Examiner erred.

In *Diehr*, the claims were directed to a method of operating a rubber-molding press to mold a compound by curing it in a mold cavity. *Application of Diehr*, 602 F.2d 982, 983–84 (CCPA 1979) (“*Application of Diehr*”; lower court decision; *Diehr* did not reproduce the claims, but *Application of Diehr* did.) The temperature in the mold during the rubber-molding process was constantly determined and provided to a digital computer. *Id.* The computer calculated the Arrhenius equation for the reaction time during the cure to determine when the compound was cured and to automatically open the press. *Id.*

Although the claim recited a mathematical algorithm, the Arrhenius equation, the Court held that the claim was eligible for a patent.

[W]hen 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.

Diehr, 450 U.S. at 192–93.

In this case, while it is not a litmus test for patent eligibility, unlike in *Diehr*, we fail to see a transformation to “a different state or thing” as a part of the claimed invention. It is true that the claims require “changing the surface temperature” as argued by Appellants (Appeal Br. 11), but such a change is not the same as transforming a product into another state by curing it as in *Diehr*. In *Diehr*, an uncured product was transformed into a cured product when raising the temperature caused a chemical change in the physical state of the product. Here, the temperature of the skin is changed when the skin is “recover[ed]” to a first temperature, but the change is only transient and does not involve a chemical change to a different physical state as was the case in *Diehr*.

In addition, *Diehr* did not implicate underlying preemption concerns because *Diehr* addressed a specific rubber-molding process. However, the instant claims are broadly drawn to any body, not even limited to an organism but encompassing any object, and functioning to detect the concentration of any substance in that body. “[P]reemption may signal patent ineligible subject matter.” *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015). Therefore, *Diehr* does not offer an analogous set of facts for the appealed claims.

Does the claim accomplish significantly more than the mathematical relationship?

A claim is eligible for a patent when combination of steps in the claim are “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.” *Alice*, 134 S. Ct. at 2355. Appellants contend that the rejected claims do significantly more than just describe a law of nature. Appeal Br. 12–13. Appellants argue that the “combination of elements imposes meaningful limits in that the later mathematical operations are applied to improve an existing technology.” *Id.* at 13. Appellants identify these elements as including a critical measuring step of measuring the change in surface temperature of the body, determining the concentration of a substance using infrared radiation, and using four measured parameters to calculate a normalized ratio parameter. *Id.* at 11.

This argument is not persuasive. With respect to the contention that the claims improve an existing technology, even if an improvement is embodied by the claim, we do not find that this “improves” how the technology operates, but rather is an improvement in the application of the mathematical relationship in determining substance concentration, which is, itself, an abstract idea.

“[W]e continue to ‘treat[] analyzing information by steps people [could] go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category.’” *Synopsys, Inc. v. Mentor Graphics Corp.* 839 F.3d 1138, 1146–47 (Fed. Cir. 2016) (quoting *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350,

1354 (Fed. Cir. 2016) (citations omitted)); *see also Electric Power Group*, 830 F.3d at 1353 (“collecting information, analyzing it, and displaying certain results of the collection and analysis” “fall[s] into a familiar class of claims ‘directed to’ a patent-ineligible concept,” that of the abstract idea). The Federal Circuit has recognized that “a claim for a *new* abstract idea is still an abstract idea.” *Synopsys*, 839 F.3d at 1151.

Specifically, the Specification teaches that “it is known that glucose and other blood constituents have strong and distinguishable absorption.” Spec. ¶ 19. The Specification further explains that the “average ratio of the two radiation measurements after normalization for a black body reading is correlated to the concentration of the desired substance in the body, such as the concentration of glucose in the bloodstream of a human body, for example.” *Id.* ¶ 23. Paragraph 43 of the Specification, referenced by Appellants as support for the normalized ratio (Appeal Br. 3–4), describes performing the measurements, calculating a normalized ratio, and then correlating the ratio with the ambient temperature and the body surface temperature using a lookup table. Appellants have not explained how these steps, which constitute the use of an algorithm to determine a concentration, in any way effect the underlying technology used to change and measure temperature and measure infrared application. Rather, the evidence points to any such improvement as being made to the abstract idea and natural law of correlating infrared radiation to substance concentration, a relationship admitted by Appellants to be a natural law (*id.* at 12). The steps of measuring body surface temperature and infrared radiation are routine and conventional as shown in the Sterling and Braig publications discussed below.

Does the asserted improvement establish patent eligibility?

Appellants contend that their claims are patent eligible under 2015 USPTO guidelines because they improve the technological field. Appeal Br. 7.

This argument is not persuasive. In *Amdocs (Israel) Limited v. Openet Telecom, Inc.*, 841 F.3d 1288, 1300–01 (Fed. Cir. 2016), the claims were found to be patent eligible under 35 U.S.C. § 101 because “the claim’s enhancing limitation necessarily requires that these generic components [network devices, etc.] operate in an unconventional manner to achieve an improvement in computer functionality.” However, here the improvement asserted by Appellants is not to a device, but rather to the mathematical relationship between the four natural occurring parameters used to determine the concentration to the substance in the body, particularly the infrared radiation measurements made the heating step.

The rejected claims are also distinguishable from those in *Bascom Global Internet Services, Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350–51 (Fed. Cir. 2016). In *Bascom*, the court held the claims eligible for a patent because:

The claims do not merely recite the abstract idea of filtering content along with the requirement to perform it on the Internet, or to perform it on a set of generic computer components. Such claims would not contain an inventive concept. . . . [Rather] the patent describes how its particular arrangement of elements is a technical improvement over prior art ways of filtering such content.”

Id.

In this case, Appellants have not explained nor provided evidence that the mathematical relationship embodied in the claim is a technological improvement to a device or element used to carry out the claims as it was in *Bascom* and *Amdocs*. Indeed, the broadest claim 1 does not even require a specific device or element for implementing the claimed method.

Claim 24

Claim 24, *inter alia*, adds the limitations of using a memory device configured to store the information utilized to calculate the correlation and of using a processor “operably associated with the memory device so as to access the lookup table therefrom.” Appellants contend that the “data product” stored on a memory device further makes the claim eligible for patent. Appeal Br 9.

We do not agree. The storage of information on a memory device is merely a computer implementation of the claimed method; i.e., using generic computer hardware in its routine and customary way. As held in *Alice*, “simply implementing a mathematical principle on a physical machine, namely a computer, [i]s not a patentable application of that principle.” *Alice*, 134 S. Ct. at 2357–58.

Claim 11

Appellants contend that independent claims 11 is patent eligible because it is tied a specific device, an IR detector, and additionally “selects a specific wavelength (the wavelength characteristic of the substance) and the specific conditions of collection (during temperature recovery) to apply the

laws of nature in a particular circumstance and to achieve a useful result.”

Appeal Br. 14.

This argument is not persuasive. The IR detector is unaffected by how the algorithm operates. There is no evidence it is used in any way other than the routine and customary way IR detectors are used. Thus, there is no improvement or change in the function of the device.

Dependent claims

Appellants contend that certain dependent claims are separately patent eligible. *Id.* at 13–14. However, other than listing the additional limitations in the claims, Appellants have not explained how the recited elements confer patent eligibility on the claims. Merely stating the different limitations of dependent claims does not constitute separate argument. *See* 37 C.F.R. § 41.37(c)(1)(vii); *In re Dance*, 160 F.3d 1339, 1340 n.2 (Fed. Cir. 1998)

Summary

The rejection of 1–18 and 21–24 as unpatentable under 35 U.S.C. § 101 is affirmed.

OBVIOUSNESS REJECTIONS OVER STERLING AND BRAIG

Claim 1 involves decreasing the temperature of a body, and “thereafter,” *increasing* it. The infrared radiation is measured during the “recovery” when the temperature of the surface of the body is *increasing*. A “normalized ratio parameter” is calculated based on the measured amounts of 1) first and 2) second infrared radiation, 3) the body surface temperature, and 4) the ambient temperature. The final step of the claim is “determining

a concentration of a substance in the body non-invasively by using a correlation with the normalized ratio parameter.”

The Examiner found that substantially all the steps of the claimed method are described in Sterling, but acknowledged that Sterling does not describe measuring the infrared radiation during the recovery step when the body surface is *increasing*. Final Act. 6. Rather, the Examiner found Sterling teaches measuring infrared radiation when the body surface is *decreasing* during cooling. *Id.* To reach the “increasing” limitation of the claim, the Examiner relied upon the following teaching in Braig in which optical energy is measured after a heater is “momentarily” energized:

A typical operating sequence is shown below.

Step 1. Bring chilled thermal mass window in contact with patient’s forearm.

Step 2. Energize heater momentarily.

Step 3. Optical energy is detected, selected, and analyzed by the system signal processor to determine glucose concentration per the algorithm discussed in at least one of the incorporated references.

Step 4. Allow chilled thermal mass to re-cool patient’s forearm.

Step 5. (Optional, where more than one cycle is required to effect an accurate reading.) Repeat steps 2 through 4 above until the requisite number of separate glucose determinations have been made.

Braig, col. 12, ll. 53–67.

Appellants contend that the Examiner interpreted the cited passage “in isolation, abstracted from the remainder of Braig and from the additional prior art incorporated therein by reference.” Appeal Br. 16. Appellants contend that, when this passage is considered in the context of the full disclosure of Sterling and Braig, one of ordinary skill in the art would not

have understood it to mean that optical energy is measured when the body surface temperature is increasing.

Appellants point out that Sterling, as acknowledged by the Examiner, teaches measuring infrared radiation during the cooling period, not when the body surface temperature is *increased* as recited in all the rejected claims.

Appeal Br. 18–19. In this regard, Sterling teaches:

The spectrometric method taught therein for the noninvasive generation and capture of thermal gradient spectra from living tissue comprises the steps of:

cooling an infrared transmissive mass;

placing the infrared transmissive mass into a conductive heat transfer relationship with the tissue thereby to generate a transient temperature gradient in the tissue;

detecting infrared emissions emanating from the tissue and passing through the infrared transmissive mass;

providing output signals proportional to the detected infrared emissions; and

sampling the output signals as the transient temperature gradient progresses into the tissue.

Sterling, col. 10, l. 65–col. 11, l. 11 (emphasis added).

The present invention employs cooling to promote “self-absorption” by letting the temperature gradient propagate to selected layers typically between 40 and 150 microns below the surface. When the temperature gradient has sufficiently propagated, the present technique can, non-invasively, deliver absorption spectra of the tissue, blood, and interstitial fluid containing glucose or other analytes.

Id. at col. 14, ll. 18–24.

Braig, in its Background section, references the cooling method of Sterling (cited as “U.S. Ser. No. 08/820,378”). Braig, col. 2, ll. 45–64. Braig also describes the black body infrared radiation that underlies the technology as arising from the natural condition in which “[t]here is a

temperature gradient within a body, the deeper layers being warmer than the outer layers, which causes further deviation from the theoretical black body emissions.” *Id.* at col. 1, ll. 54–57. Thus, the non-invasive technology of measuring the concentration of a substance in a body is based on the skin surface being natural colder than the deeper layers. Cooling of the skin is used to enhance the temperature gradient. Sterling, col. 14, ll. 18–24; Braig, col. 2, ll. 5–67.

The only reference to heating followed by an infrared radiation measuring step, as acknowledged by the Examiner, is the passage at column 12 of Braig reproduced above. However, as discussed by Appellants, this same passage is followed by disclosure of measuring the infrared emission during the cooling phase, the same technology described in the Background section of the Braig patent and in Sterling. Specifically, Braig discloses:

The contact between cold window **208**, chilled by conductive heat loss to thermal mass window **200**, and the skin of the patient transfers heat conductively from the patient's skin to thermal mass window **200**. This generates a temperature differential between the skin and the interior of the patient, and over the course of the measurement cycle, this temperature differential propagates into the patient's arm in the form of a “cold wave”. As the “cold wave” propagates into the patient's arm, the infrared emissions from the arm vary as described in at least one of the incorporated references.

Braig, col. 14, l. 66–col. 15, l. 9.

Based on these disclosures, Appellants state that it is unreasonable to conclude that Braig suggests detecting optical energy during a period when the surface temperature is increasing as claimed. Appeal Br. 16. Rather, Appellants argue that the reference to *momentarily* energizing the heater

does not actually state that rewarming of the body surface is accomplished and that

Even if energizing occurs before detecting optical energy, other reasons for the timing in doing so include keeping “surfaces of the [measurement] window free of condensate,” as described in column 6, lines 13-16 and also discussed in column 9, lines 9-12 [of Braig].

Appeal Br. 17. Appellants also stated that there would have no reasonable expectation of success because “carrying out the modified method since the modified teaching of Braig inferred by the Office changes the foundational theory for operating in Sterling.” *Id.* Appellants argue:

[T]he proposed modification of Sterling with Braig thwarts the basic assumption under which Sterling operates that “deep infrared emissions pass through layers of tissue that are at a lower temperature” (column 14, lines 6-13). Modification of Braig also thwarts the basic assumption for operation of Braig “per the algorithm discussed in at least one of the incorporated references,” as indicated in column 12.

Id. at 20.

The Examiner did not dispute that Braig describes in its background measuring infrared emissions during cooling. Ans. 23. The Examiner also did not dispute Appellants’ explanation that, in view of the disclosure of measuring infrared during in the Background of the Braig patent and at columns 14–15 of detecting infrared during the cold wave, “momentarily” energizing the heater would include heating to keep the detection window of the device free of condensate. Appellants’ explanation is reasonable because the heater is turned only “momentarily” and is not described as heating the tissue to create a gradient during which infrared emission is measured — which is contrary to the express disclosure elsewhere in Braig that emission is measured during the cold wave.

Furthermore, it is unclear what the purpose of performing a “chilling” step would be, if not to measure the infrared radiation during it as described in both Sterling and Braig. Appeal Br. 20. Braig expressly teaches that chilling is utilized to enhance the temperature gradient during infrared measurement:

In one embodiment of the present invention, heat exchanger **210** is a hollow structure, defining cavity **220**. Cavity **220** is provided with a continuous flow of chilled water by means of a pair of water fittings, one of which is shown at **222**. Thermal mass window **300** is chilled by heat exchanger body **210**. In one preferred embodiment this cooling is to approximately 10° C., but other temperatures may, with equal facility, be implemented for certain metrologic reasons in some applications. This depressed temperature provides an enhanced temperature gradient at the measurement site to enhance the infrared signal to allow detection by detectors

Braig, col. 8, ll. 17–28.

The Examiner did not provide another reason to have measured the infrared radiation during the heating step as recited in the claim, rather than during cooling as expressly described in both Sterling and Braig.

The Buchert publication is cited by the Examiner for its teaching of measuring ambient temperature (Final Act. 7) and, thus, does not make up for the deficiency discussed above in the combination of Sterling and Braig.

Lucassen is cited by the Examiner for its teaching of positioning an optical system (*id.* at 14) and, thus, does not make up for the deficiency discussed above in the combination of Sterling and Braig.

“[T]he examiner bears the initial burden, on review of the prior art ***or on any other ground***, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992)

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(emphasis added). Accordingly, for the foregoing reasons, we conclude that the Examiner did not meet the burden of establishing the obviousness of independent claims 1, 11, 21, and 24, each of which require measuring infrared radiation when increasing the temperature of the body surface. Accordingly, the obviousness rejections of independent claims 1, 11, 21, and 24, and dependent claims 2–10, 12–18, 22, and 23 are reversed.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED