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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SALVATORE ROMANO

Appeal 2018-005470
Application 13/820,853
Technology Center 3700

Before NINA L. MEDLOCK, KENNETH G. SCHOPFER, and
ROBERT J. SILVERMAN, *Administrative Patent Judges*.

SILVERMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision rejecting claims 1–20. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. The Appellant identifies Salvatore Romano as the real party in interest. Appeal Br. 1.

ILLUSTRATIVE CLAIM

1. A method for automatic processing of blood pressure signals, the method comprising at least the following steps:

A. sampling a detected pressure signal detected by a pressure transducer for one or more heartbeats, each heartbeat starting at an initial instant coinciding to that of an initial diastolic pressure and ending at a final instant coinciding to that of subsequent diastolic pressure and comprising a dicrotic point, each heartbeat having a systolic phase comprised between the initial diastolic point and the dicrotic point;

B. automatically analyzing and discriminating a morphology of the sampled pressure signal for each heartbeat, determining an instant and a pressure value of one or more characteristic points of the pressure signal selected from one or more of a point of initial diastolic blood pressure, a point of systolic pressure, a dicrotic point and one or more resonance points, each of which occurs when a second derivative of the pressure signal has a relative maximum, wherein at least a characteristic point of the pressure signal belongs to the systolic phase of the heartbeat and is different from the point of initial diastolic pressure; and

C. for each heartbeat determining an energy efficiency value through the following sub-steps:

determining a direct dynamic pressure wave impedance for each of said one or more characteristic points belonging to the systolic phase of the heartbeat into consideration with an exception of the point of initial diastolic pressure, said direct dynamic pressure impedance being given by a ratio between a value of the pressure signal in the characteristic point and a time interval measured between the respective instant and the initial instant of the heartbeat into consideration, and determining an impedance of a direct pressure wave by adding with alternating signs the values of the dynamic direct impedances ordered according to a direct temporal order starting from the initial instant of the heartbeat into consideration up to the dicrotic instant, applying a positive sign

to the first dynamic direct impedance according to the direct temporal order;

for each of said one or more characteristic points determining a dynamic reflected impedance that is given by the ratio between the pressure at the characteristic point and a time interval measured between the respective instant and the instant of a final beat, and determining the value of an impedance of reflected waves of pressure is obtained by adding the dynamic impedances with alternating signs of the second set of points thus determined, sorted according to a reverse temporal order starting from the instant of the final beat to the instant of the initial diastolic pressure, giving a positive sign to the first dynamic impedance according to the reverse temporal order, the direct temporal order being a first chronological time order starting from the instant of time of the initial diastolic pressure up to the instant of time of the dicrotic point, the reverse temporal order being a second reverse chronological time order starting from the final instant of time of beat down to the instant of time of the initial diastolic pressure; and

determining said energy efficiency as the ratio between the impedance of the direct wave pressure and the impedance of the reflected waves.

REJECTIONS²

I. Claims 1–20 are rejected under 35 U.S.C. § 101 as ineligible subject matter.

II. Claims 14, 15, and 20 are rejected under 35 U.S.C. § 112(a) as failing to comply with the enablement requirement.³

² The Final Office Action (pages 4–7) includes a rejection based on claim indefiniteness, under 35 U.S.C. § 112(b). This rejection is withdrawn. *See* Answer 2.

³ Rejection II refers to independent claims 14 and 15 (*see* Final Action 2–4), but also applies to claim 20 (which depends from claim 14).

FINDINGS OF FACT

The findings of fact relied upon, which are supported by a preponderance of the evidence, appear in the following Analysis.

ANALYSIS

Subject-Matter Eligibility

Under 35 U.S.C. § 101, an invention is patent-eligible if it claims a “new and useful process, machine, manufacture, or composition of matter.” 35 U.S.C. § 101. Yet, subject matter belonging to any of the statutory categories may, nevertheless, be ineligible for patenting. The Supreme Court has interpreted § 101 to exclude laws of nature, natural phenomena, and abstract ideas, because they are regarded as the basic tools of scientific and technological work, such that including them within the domain of patent protection would risk inhibiting future innovation premised upon them. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013).

Of course, “[a]t some level, ‘all inventions . . . embody, use, reflect, rest upon, or apply’” these basic tools of scientific and technological work. *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014). Accordingly, evaluating ineligible subject matter, under these judicial exclusions, involves a two-step framework for “distinguish[ing] between patents that claim the buildin[g] block[s] of human ingenuity and those that integrate the building blocks into something more, thereby transform[ing] them into a patent-eligible invention.” *Id.* (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 88–89 (2012) (quotation marks omitted)). The first step determines whether the claim is directed to judicially excluded subject matter (such as a so-called “abstract idea”); the second step determines

whether there are any “additional elements” recited in the claim that (either individually or as an “ordered combination”) amount to “significantly more” than the identified judicially excepted subject matter itself. *Id.* at 217–18.

In 2019, the USPTO published revised guidance on the application of § 101, in accordance with judicial precedent. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 52 (Jan. 7, 2019) (“*2019 Revised Guidance*”). Under the *2019 Revised Guidance*, a claim is “directed to” an abstract idea, only if the claim recites any of (1) mathematical concepts, (2) certain methods of organizing human activity, and (3) mental processes — without integrating such abstract idea into a “practical application,” i.e., without “apply[ing], rely[ing] on, or us[ing] the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception.” *Id.* at 52–55. The considerations articulated in MPEP § 2106.05(a)–(c) and (e)–(h) bear upon whether a claim element (or combination of elements) integrates an abstract idea into a practical application. *Id.* at 55. A claim that is “directed to” an abstract idea constitutes ineligible subject matter, unless the claim recites an additional element (or combination of elements) amounting to significantly more than the abstract idea. *Id.* at 56.

Although created “[i]n accordance with judicial precedent” (*id.* at 52), the *2019 Revised Guidance* enumerates the analytical steps differently than the Supreme Court’s *Alice* opinion. Step 1 of the *2019 Revised Guidance* addresses whether the claimed subject matter falls within any of the statutory categories of § 101. *Id.* at 53–54. Step 2A, Prong One, concerns whether the claim at issue recites ineligible subject matter and, if an abstract idea is

recited; Step 2A, Prong Two, addresses whether the recited abstract idea is integrated into a practical application. *Id.* at 54–55. Unless such integration exists, the analysis proceeds to Step 2B, in order to determine whether any additional element (or combination of elements) amounts to significantly more than the identified abstract idea. *Id.* at 56.

With respect to Step 1 of the *2019 Revised Guidance*, the Examiner determines that independent claims 1 and 13 (along with respective dependent claims) are within identified categories of § 101, whereas independent claims 14 and 15 are drawn to non-statutory subject matter. Final Action 9.

Claim 14 recites: “A computer program, comprising coded means for executing, when operating in connection with processing means of an apparatus.” Claim 15 recites “A memory support readable by computer means, the memory comprising a program, said program comprising coded means for executing, when operating in connection with processing means of an apparatus.”

If a claim is drawn to subject matter that falls outside the delineated statutory categories of § 101, it is not patent-eligible. *In re Nuijten*, 500 F.3d 1346, 1354 (Fed. Cir. 2007). The Federal Circuit has explained that, with the exception of process claims, “eligible subject matter must exist in some physical or tangible form.” *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344, 1348 (Fed. Cir. 2014). The Board has held that claim limitations, such as a “machine-readable storage medium,” that (under a broadest reasonable interpretation) cover transitory signals, are non-statutory subject matter. *Ex parte Mehwherter*, Appeal 2012-007692,

2013 WL 4477509, at *7 (PTAB, May 8, 2013) (precedential) (citing *Nuijten*, 500 F.3d at 1356–57).

The Examiner states that the “computer program” of claim 14 “is not a specific structure or physical object and could read on a signal per se encoded with the instructions which does not fall into one of the four statutory categories.” Answer 3. Similarly, the Examiner states that, because the “memory support” of claim 15 is characterized in the claim language as comprising at least “a program,” claim 15 also falls outside the statutory categories of § 101. *Id.*

The Appellant does not meaningfully address the Examiner’s position, as to the transitory or non-tangible nature of claims 14 and 15. Accordingly, we sustain the rejection of independent claims 14 and 15, along with dependent claim 20, as constituting non-statutory subject matter, under 35 U.S.C. § 101.

In regard to Step 2A, Prong One, of the subject-matter eligibility analysis, the Examiner states:

Claim(s) 1–17 is/are determining the value of an impedance of reflected waves of pressure and determining said energy efficiency as the ratio between the impedance of the direct wave and the reflected wave. The abstract idea in the claim is the idea itself of determining the energy efficiency from the directed and reflected impedance signals.

Final Action 7. The Examiner’s Answer adds: “Similar to the claims in *In re Grams*[, 888 F.2d 835 (Fed. Cir. 1989),] and *Electric Power Group*[, *LLC v. Alstom S.A.*, 830 F.3d 1350 (Fed. Cir. 2016),] the current claims are directed to collecting data, analyzing it and then displaying the results of the analysis.” Answer 4.

The Examiner does not explicitly identify the claim limitations that would describe an abstract idea; although, the Examiner does identify limitations of claim 1 that are said to be the “additional elements” of the claim.⁴ Consequently, at least the following limitations remain, in the Examiner’s analysis, as describing a judicial exception:

determining the value of an impedance of reflected waves of pressure is obtained by adding the dynamic impedances with alternating signs of the second set of points thus determined, sorted according to a reverse temporal order starting from the instant of the final beat to the instant of the initial diastolic pressure, giving a positive sign to the first dynamic impedance according to the reverse temporal order, the direct temporal order being a first chronological time order starting from the instant of time of the initial diastolic pressure up to the instant of time of the dicrotic point, the reverse temporal order being a

⁴ In the Final Office Action (pages 7–8) and the Answer (page 4), the Examiner identifies the following claim 1 limitations as “additional elements”: “automatically analyzing and discriminating a morphology of the sampled pressure signal for each heartbeat, determining an instant and a pressure value of one or more characteristic points of the pressure signal”; “for each heartbeat determining an energy efficiency value [by] determining a direct dynamic pressure wave impedance for each of said one or more characteristic points”; “determining an impedance of a direct pressure wave by adding with alternating signs the values of the dynamic direct impedances ordered according to a direct temporal order starting from the initial instant of the heartbeat into consideration up to the dicrotic instant, applying a positive sign to the first dynamic direct impedance according to the direct temporal order”; and “for each of said one or more characteristic points determining a dynamic reflected impedance that is given by the ratio between the pressure at the characteristic point and a time interval measured between the respective instant and the instant of a final beat.” *See* Final Office Action (pages 7–8); Answer (page 4). In addition, the Examiner refers to “sampl[ing]” as an additional element. Final Action 8; Answer 5. Therefore, in addition to the foregoing, we understand that the Examiner also regards step “A” of claim 1 to be among the additional elements, rather than part of the description of a judicial exception.

second reverse chronological time order starting from the final instant of time of beat down to the instant of time of the initial diastolic pressure; and

determining said energy efficiency as the ratio between the impedance of the direct wave pressure and the impedance of the reflected waves.

As to the categorization of these claim limitations, the Examiner, as noted, likens them to claims considered in *Grams* and *Electric Power*. See Answer 4. The Federal Circuit explained that the identified claim steps at issue in *Grams* included “in essence a mathematical algorithm, in that they represent ‘[a] procedure for solving a given type of mathematical problem.’” *Grams*, 888 F.2d at 837 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 65 (1972)) (footnote omitted). In *Electric Power*, the Federal Circuit explained that the court treats claims for “analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category.” *Electric Power*, 830 F.3d at 1354.

Accordingly, viewed through the lens of the *2019 Revised Guidance* (see 84 Fed. Reg. at 52), we understand the Examiner’s position to be that claim 1 recites either a mathematical concept or a mental process.

The Appellant does not squarely address the criteria for determining whether a claim recites a judicial exception, but instead argues that claim 1, for example, “relates to real world method steps” and that “[p]rocessing blood pressure signals to provide an energy efficiency value provides an indicator of overall patient health.” Appeal Br. 28–29. See also Reply Br. 2–3.

The Appellant’s proposed “real world” (Appeal Br. 28) significance of certain claim limitations does not persuade us of error, as to the inquiry of

Step 2A, Prong One. Indeed, the Supreme Court has explained that such a consideration does not resolve the question of patent eligibility:

The fact that a computer necessarily exist[s] in the physical, rather than purely conceptual, realm, is beside the point. There is no dispute that a computer is a tangible system (in § 101 terms, a “machine”), or that many computer-implemented claims are formally addressed to patent-eligible subject matter. But if that were the end of the § 101 inquiry, an applicant could claim any principle of the physical or social sciences by reciting a computer system configured to implement the relevant concept. Such a result would make the determination of patent eligibility depend simply on the draftsman’s art, thereby eviscerating the rule that [l]aws of nature, natural phenomena, and abstract ideas are not patentable.

Alice, 573 U.S. at 224 (citations and internal quotation marks omitted).

Therefore, the Appellant’s argument does not persuade us of error, in regard to Step 2A, Prong One.

Turning to Step 2A, Prong Two, unless a claim that recites a judicial exception (such as an abstract idea) “integrates the recited judicial exception into a practical application of that exception,” the claim is “directed to” the judicial exception. *2019 Revised Guidance*, 84 Fed. Reg. at 53. The analysis of such an “integration into a practical application” involves “[i]dentifying . . . any additional elements recited in the claim beyond the judicial exception(s)” and “evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application.” *Id.* at 54–55. Among the considerations “indicative that an additional element (or combination of elements) may have integrated the exception into a practical application” is whether “[a]n additional element reflects an improvement in the functioning of a computer, or an

improvement to other technology or technical field.” *Id.* at 55 (footnote omitted). “[W]hether an additional element or combination of elements integrate[s] the exception into a practical application should be evaluated on the claim as a whole.” *Id.* at 55 n.24.

The Appellant contends that “the present invention is an improvement in the technology,” identifying portions of the Specification that refer to the accuracy of blood pressure measurements, measuring blood pressure in a “self-adapting manner” relative to variations in blood pressure, and the “determination of a correction factor that estimates a maximum derivative of ventricular pressure.” Reply Br. 4–5 (citing Spec. p. 4, l. 9 through p. 6, l. 22).

However, even though the Appellant suggests that independent claims 14 and 15 include the “self-adapting” feature (Appeal Br. 37, 40), the Appellant does not adequately relate any of the purported improvements to any specific claim language of any claim. Further, the Appellant does not address other matters relating to Step 2A, Prong Two.

Therefore, in view of the foregoing, we are not persuaded of error in the Examiner’s application of the inquiries relevant to Step 2A, Prong Two.

Under Step 2B of the *2019 Revised Guidance* (84 Fed. Reg. at 56), a claim that recites a judicial exception (such as an abstract idea) might, nevertheless, be patent-eligible, if the claim contains “additional elements amount[ing] to significantly more than the exception itself” — i.e., “a specific limitation or combination of limitations that [is] not well-understood, routine, conventional activity in the field, which is indicative that an inventive concept may be present.” *See Alice*, 573 U.S. at 223

(“[T]he mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention.”)

The Examiner states that claim 1 does not contain significantly more than a judicial exception, explaining that both the “machine recited and automating the processing” are “generic and routine in the art.” Answer 3. *See also* Final Action 8. According to the Examiner, “[t]he machine itself is not any particular machine suited only for this method but could be a general purpose computer and sensor that simply executes the steps.” Answer 3.

The Appellant contends that the claimed use of pressure sensors to determine a dynamic reflected impedance, which is then used to determine an energy efficiency, is not routine and, furthermore, the Examiner “has not provided any evidence to provide that such features are routine and well-understood in the field of diagnostics.” Reply Br. 3. *See also* Appeal Br. 29.

“Whether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination.” *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018). Here, the Examiner’s determination that the additional elements of claim 1 are “generic and routine in the art” (Answer 4) lacks the requisite evidentiary support. Moreover, even if the referenced claim limitations could be executed on a generic computer, this does not necessarily preclude them from amounting to significantly more than a judicial exception. As the Federal Circuit has explained:

Much of the advancement made in computer technology consists of improvements to software that, by their very nature, may not be defined by particular physical features but rather by logical structures and processes. We do not see in *Bilski* or

Alice, or our cases, an exclusion to patenting this large field of technological progress.

Enfish, LLC v. Microsoft Corp., 822 F.3d, 1327, 1339 (Fed. Cir. 2016).

Therefore, the Appellant persuades us that the Examiner erred in applying the analysis of Step 2B, such that we do not sustain the rejection of independent claim 1 as being directed to an abstract idea without reciting significantly more. Our analysis applies equally to independent claims 13, 14, and 15, as well as the dependent claims in the Appeal.

Altogether — and in view of the considerations discussed above, concerning whether claims 14 and 15 are statutory subject matter, under Step 1 — we sustain the rejection of independent claims 14 and 15 (along with dependent claim 20) and we do not sustain the rejection of independent claims 1 and 13 (along with dependent claims 2–12 and 16–19) under 35 U.S.C. § 101.

Enablement

Each of independent claims 14 and 15 recites, in part, a “*coded means* for executing, when operating in connection with *processing means* of an apparatus, the steps of a method.” (Emphasis added).

The Examiner states that each of the claimed “coded means” and “processing means” invokes the means-plus-function provision, of 35 U.S.C. § 112(f), and that the Specification fails to disclose corresponding structure, material, or acts for performing the claimed function. Final Action 3. Consequently, the Examiner regards claims 14 and 15 as failing to comply with the enablement requirement of 35 U.S.C. § 112(a), because the claimed subject matter is not described in the Specification in a manner that would

enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. *Id.*

The Appellant contends that claims 14 and 15 stand rejected erroneously, because corresponding structure relating to the “coded means” and the “processing means” purportedly appears in WO 2004/084088 A1, which is allegedly incorporated by reference on page 10, lines 14–16, of the Specification. Appeal Br. 16–17. *See also* Reply Br. 1–2.

In response, the Examiner states that the WO 2004/084088 A1 reference fails to provide the required enabling disclosure of the “coded means” and “processing means” and, in any event, the identified reference is not properly incorporated by reference:

The WO 2004/084088 reference seems to only disclose a processing means in its specification but with no associated structure. The WO 2004/084088 reference is also not properly incorporated by reference and is not part of the chain of continuity and fails to meet the requirements of 37 CFR 1.57. Appellants have not clearly addressed the “coding means” or shown how the specification is clear as to what the coding means is or what structure it would have. Even if one surmises the coding means is drawn to some computer related component, it is unclear whether the means refers to hardware, software, or some combination of both.

Answer 2.

Disputing the Examiner’s position, the Appellant contends that the Specification “properly incorporates WO 2004/084088 A1 by reference.”

Reply Br. 1.

In part, 37 C.F.R. § 1.57 (entitled “Incorporation by reference”) states:

an incorporation by reference must be set forth in the specification and must:

(1) Express a clear intent to incorporate by reference by using the root words “incorporat(e)” and “reference” (*e.g.*, “incorporate by reference”); and

(2) Clearly identify the referenced patent, application, or publication.

37 C.F.R. § 1.57(c). “Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112.” MPEP § 608.01(p)(I)(A) (citing *In re de Seversky*, 474 F.2d 671 (CCPA 1973)).

The portion of the Specification that, according to the Appellant, would incorporate by reference particular material of WO 2004/084088 A1 refers to techniques for identifying particular points of a blood-pressure signal, stating:

As a not limitative example, the heartbeat and the corresponding pressure characteristic points can be discriminated and individuated by means of a method as that disclosed in WO 2004/084088.

Spec. 10, ll. 14–16.

We are not persuaded that this remark in the Specification incorporates by reference the identified document WO 2004/084088 A1. Contrary to 37 C.F.R. § 1.57(c), the Specification does not “[e]xpress a clear intent to incorporate by reference by using the root words ‘incorporat(e)’ and ‘reference’ (*e.g.*, ‘incorporate by reference’).”

In view of the foregoing, we are not persuaded of error in the Examiner’s enablement rejection of claims 14 and 15, such that we sustain the rejection of independent claims 14 and 15 (along with dependent claim 20) under 35 U.S.C. § 112(a).

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–20	101	Subject-matter eligibility	14, 15, 20	1–13, 16–19
14, 15, 20	112(a)	Enablement	14, 15, 20	
Overall Outcome			14, 15, 20	1–13, 16–19

TIME PERIOD FOR RESPONSE

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

AFFIRMED-IN-PART