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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BO OLDE and KRISTIAN SOLEM

Appeal 2020-000525
Application 13/519,559
Technology Center 3700

Before BRETT C. MARTIN, MICHELLE R. OSINSKI, and ANNETTE R. REIMERS, *Administrative Patent Judges.*

MARTIN, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1, 21, 24, 25, and 38–46. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as GAMBRO LUNDIA AB. Appeal Br. 2.

CLAIMED SUBJECT MATTER

The claims are directed to an apparatus and method for prediction of rapid symptomatic blood pressure decrease. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A monitoring device operating as part of a blood treatment device including an extracorporeal blood flow circuit configured to be coupled to a cardiovascular system of a subject and at least one pressure sensor configured to generate measurement data based on pressure within the extracorporeal blood flow circuit, the monitoring device for predicting rapid symptomatic blood pressure decrease during the subject's blood treatment, the monitoring device comprising:
>
> an input for receiving the measurement data from the at least one pressure sensor in the extracorporeal blood flow circuit coupled to the cardiovascular system of the subject, the measurement data comprising a time sequence of pulse shape parameters representing pressure variations in at least one blood vessel of the subject;
>
> and a data analysis part configured to repeatedly receive the pulse shape parameters, calculate a pulse measure representing an overall magnitude determined by averaging a plurality of magnitudes from a plurality of the pulse shape parameters within a time window, and cause an output signal to be generated when the pulse measure fulfils a decision criterion, the output signal indicating a predicted rapid symptomatic blood pressure decrease in the subject,
>
> wherein, when the pulse measure fulfils the decision criterion, the output signal causes the blood treatment device to (i) issue an alarm indicating that a treatment parameter of the subject's blood treatment should be adjusted, or (ii) adjust the treatment parameter of the subject's blood treatment.

REFERENCES

The prior art relied upon by the Examiner is:

Name	**Reference**	**Date**
Simard	US 5,476,592	Dec. 19, 1995

Bissler	US 6,780,322 B1	Aug. 24, 2004
Balschat	US 6,804,991 B2	Oct. 19, 2004

REJECTIONS

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**
1, 21, 24, 25, 38–46	112	Written Description
1, 21, 24, 25, 38–46	112	Indefiniteness
1, 21, 24, 25, 38–46	101	Eligibility
1, 21, 24, 38–46	103	Bissler, Simard
25	103	Bissler, Simard, Balschat

OPINION

Standard for Patent Eligibility

In issues involving subject matter eligibility, our inquiry focuses on whether the claims satisfy the two-step test set forth by the Supreme Court in *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014). The Supreme Court instructs us to "first determine whether the claims at issue are directed to a patent-ineligible concept," *id.* at 216–18, and, in this case, the inquiry centers on whether the claims are directed to an abstract idea. If the initial threshold is met, we then move to the second step, in which 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 217 (*quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 79, 78 (2012)). The Supreme Court describes the second step 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.* (quoting *Mayo*, 566 U.S. at 72–73).

The USPTO recently published revised guidance on the application of § 101. USPTO's January 7, 2019 Memorandum, *2019 Revised Patent Subject Matter Eligibility Guidance* ("Memorandum"). Under that guidance, we first look to whether the claim recites:

> (1) any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts, certain methods of organizing human interactions such as a fundamental economic practice, or mental processes); and
>
> (2) additional elements that integrate the judicial exception into a practical application (*see* MPEP § 2106.05(a)–(c), (e)–(h)).

Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then look to whether the claim:

> (3) adds a specific limitation beyond the judicial exception that is not "well-understood, routine, conventional" in the field (*see* MPEP § 2106.05(d)); or
>
> (4) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception.

See Memorandum.

ANALYSIS

Claim Grouping

Although Appellant presents separate argument headings for claims 1, 39, and 42, the arguments for claims 39 and 42 merely refer to the arguments presented for claim 1. App. Br. 22. We select claim 1 as representative of the group, and the remaining claims stand or fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Examiner's Findings and Conclusion

In the first step of the *Alice* inquiry, the Examiner rejects claims 1, 21, 24, 25, and 38–46 "because the claimed invention is directed to a judicial exception, i.e. abstract idea without significantly more." Final Act. 9. The Examiner identifies the claimed device for monitoring blood pressure that uses mathematical formulas based on input of medical data as the abstract idea. *Id.* at 9–10. At *Alice* step 2, the Examiner additionally finds that the claims do not add a meaningful limitation to the abstract idea so as to amount to significantly more than the judicial exception. Final Act. 10.

Analysis According to the Guidelines

Step One: Does Claim 1 Fall within a Statutory Category of § 101?

We first examine whether the claim recites one of the enumerated statutory classes of subject matter, i.e., process, machine, manufacture, or composition of matter, eligible for patenting under 35 U.S.C. § 101. Claim 1 is directed to a device, which is one of the statutory classes (i.e., a machine) under 35 U.S.C. § 101.

Step 2A, Prong One: Does Claim 1 Recite a Judicial Exception?

We next look to whether the claim recites any judicial exceptions, including certain groupings of abstract ideas, i.e., mathematical concepts, certain methods of organizing human activity such as a fundamental economic practice, or mental processes.

In this instance, claim 1, for example, recites a device for monitoring blood pressure. Specifically, the claim recites:

> an input for receiving the measurement data from the at least one pressure sensor in the extracorporeal blood flow circuit coupled to the cardiovascular system of the subject, the measurement data comprising a time sequence of pulse shape parameters representing pressure variations in at least one blood vessel of the subject; and
>
> a data analysis part configured to repeatedly receive the pulse shape parameters, calculate a pulse measure representing an overall magnitude determined by averaging a plurality of magnitudes from a plurality of the pulse shape parameters within a time window, and cause an output signal to be generated when the pulse measure fulfils a decision criterion, the output signal indicating a predicted rapid symptomatic blood pressure decrease in the subject,
>
> wherein, when the pulse measure fulfils the decision criterion, the output signal causes the blood treatment device to (i) issue an alarm indicating that a treatment parameter of the subject's blood treatment should be adjusted, or (ii) adjust the treatment parameter of the subject's blood treatment.

Although these components are claimed in structural form, they essentially amount to computer components for applying a mathematical concept. We therefore determine that claim 1 recites the abstract idea of a using a mathematical formula based on input of medical data, which is a judicial exception to patent-eligible subject matter.

Step 2A, Prong Two: Does Claim 1 Recite Additional Elements that Integrate the Judicial Exceptions into a Practical Application?

Following our Office guidance, having found that claim 1 recites a judicial exception, we next determine whether the claim recites "additional elements that integrate the exception into a practical application" (*see* MPEP §§ 2106.05(a)–(c), (e)–(h)). *See* Memorandum, 84 Fed. Reg. at 54. As noted above, each of the claimed components is merely a conventional tool used to collect and process data using a mathematical formula. As used in the claims, the data analysis part is merely a generic component of a computer system that does not result in an improvement in the functioning of a computer or other technology or technological field. The recitations of the generic structures with which the recited steps are performed are merely instructions to use a computer system as a tool to perform the abstract idea. Thus, the claims do not apply, rely on, or use the mathematical formula in a manner that imposes a meaningful limit on the use of that formula. Rather, the claim is simply a drafting effort designed to monopolize the use of the mathematical formula of claim 1.

The additional elements do not add meaningful limits to the mental process steps recited in claim 1. Instead, the generic data analysis components are no more than instructions to apply the judicial exception (i.e., mathematical formula) using generic computer elements. *See* MPEP § 2106.05(f) ("Use of a computer or other machinery in its ordinary capacity for . . . tasks (*e.g.,* to receive, store, or transmit data) or simply adding a general purpose computer or computer components after the fact to an abstract idea . . . does not provide significantly more.").

In short, the additional elements discussed above: (1) do not improve the functioning of a computer or other technology; (2) are not applied with

any particular machine; (3) do not effect a transformation of a particular article to a different state; and (4) are not applied in any meaningful way beyond generally linking the use of the judicial exception to a particular technological environment. *See* MPEP §§ 2106.05(a)–(c), (e)–(h). Consequently, the claimed invention does not integrate the abstract idea into a "practical application."

For these reasons, the additional elements of claim 1 do not integrate the judicial exception into a practical application. Thus, claim 1 is directed to an abstract idea, which is a judicial exception to patent eligible subject matter under 35 U.S.C. § 101.

Step 2B: Does Claim 1 Recite an Inventive Concept?

We next consider whether claim 1 recites any elements, individually or as an ordered combination, that transform the abstract idea into a patent-eligible application, *e.g.*, by providing an inventive concept. *Alice*, 573 U.S. at 217–18. As noted above, the only additional elements are a data analysis part and an input used for routine computer functionality to enact the data analysis. These additional elements do not provide, either individually or as a combination, improvements to another technology or technical field or the functioning of the computer itself.

According to the Office guidance, under Step 2B, "examiners should . . . evaluate *the additional elements* individually and in combination . . . to determine whether they provide an inventive concept (*i.e.*, whether the additional elements amount to significantly more than the exception itself)." *See* Memorandum, 84 Fed. Reg. at 56 (emphasis added). Thus, the second step of the inquiry (Step 2B) looks at the additional elements in combination. *See*, *e.g.*, Examples accompanying Memorandum (Example 37 (claim 3

analysis) and Example 40 (claim 2 analysis)). *See also BSG Tech LLC v. BuySeasons, Inc.*, 899 F.3d 1281, 1290 (Fed. Cir. 2018) ("It has been clear since *Alice* that a claimed invention's use of the ineligible concept to which it is directed cannot supply the inventive concept that renders the invention 'significantly more' than that ineligible concept.")

As noted above, the data analysis part and input are invoked as conventional tools. Apart from being used to perform the abstract idea itself, these generic computer system components only serve to perform well-understood functions (*e.g.*, storing, selecting, analyzing, and outputting data). *See FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1096 (Fed. Cir. 2016) ("the use of generic computer elements like a microprocessor or user interface do not alone transform an otherwise abstract idea into patent-eligible subject matter"). In our view, claim 1 fails to add a specific limitation beyond the judicial exception that is not 'well-understood, routine, conventional" in the field, but instead "simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception." *See* Memorandum, 84 Fed. Reg. at 56. That is, we are not persuaded that claim 1 is directed to a specific application designed to achieve an improved technological result, as opposed to being directed to merely ordinary functionality of the above-recited additional elements to apply an abstract idea. For the reasons discussed above, we find no element or combination of elements recited in claim 1 that contains any "inventive concept" or adds anything "significantly more" to transform the abstract concept into a patent-eligible application. *See Alice*, 573 U.S. at 221.

Appellant's Contentions

Appellant first briefly argues that the claims are eligible because "use of the time sequence of pulse shape parameters representing pressure variations provides a significant advantage in that Appellants' system allows for the use of 'comparatively small processing resources and sensors [to be] simple and cost-efficient." App. Br. 19. Appellant does not expand on this argument further. This argument does not explain how the use of the mathematical formula and claimed data processing amounts to anything more than the abstract idea of using conventional technology in known ways to process medical data.

Appellant argues that "the claimed elements of a pressure sensor and an input to obtain data from the sensor constitute additional elements that are both non-computer elements, and which operate with the data analysis part of the claim to analyze an extracorporeal or blood circuit." App. Br. 20. Appellant does not explain how the sensor and input are more than extra-solution activity (i.e., data gathering so that the information can be analyzed by mathematical formulas). *See* MPEP § 2106.05(g). Appellant next argues that the claims integrate the abstract idea into a practical application of the judicial exception via the use of an alarm *or* causing treatment parameter adjustment based on the analysis. App. Br. 20–21. We generally agree with Appellant that the treatment parameter adjustment would amount to the integration of the abstract idea into a practical application, but disagree that the mere use of an alarm does so. An alarm is essentially just a notification that a certain result of the data has occurred. It still amounts to nothing more than mere data processing. The Examiner is correct, regarding the alarm, that "such activity has been consistently viewed as extra-solution to the exception by the Courts and not an implementation into a practical

application." Ans. 5.

As for the adjustment of treatment parameters, this limitation is claimed in the alternative such that it is not required by the claims. As such, the claims may be read to encompass nothing more than input of data, data processing, and a notification of a certain result achieved by the data processing. As the Examiner states "inclusion of the 'OR' for the treatment prevents such result from being required, and thus does not implement the exception in a practical application of treatment." Ans. 4. We agree with the Examiner that "[i]t seems that for claims 39/42, if the treatment were required as opposed to an alternative, then the claims would be a practical application." Ans. 6. This assessment applies equally to claim 1, which also includes the potential practical application in the alternative.

Lastly, Appellant asserts "that the underlying measurement data from the at least one pressure sensor of the present claims has been enhanced." App. Br. 22. We disagree. The claims merely use conventional components to process data as discussed above, and then utilize the result of that data to sound an alarm or adjust treatment. Because the claims do not require the treatment adjustment and the alarm by itself does not integrate the abstract idea into a practical application, we are not persuaded that the Examiner erred in finding the claimed subject matter ineligible. *See also Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013) ("Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."); *Parker v. Flook*, 437 U.S. 584, 594–96 (1978) (determining claims to "a new and presumably better method for calculating alarm limit values," which were of undisputed usefulness, were nevertheless directed to patent-ineligible subject matter).

Written Description

The Examiner asks, "What positively claimed structure[s] of the blood treatment device are capable of issuing an alarm and adjusting treatment?" Ans. 7. The Examiner further states that "the claimed functions are unlimited functional claims that extend to all means or methods of resolving the problem of issuing an alarm and adjusting treatment parameter not [commensurate with] the original disclosure." Ans. 8. As Appellant correctly argues, Claim 1 is directed toward a monitoring device as part of a blood treatment device and "that the positively claimed structure for issuing the alarm is the blood treatment device or dialysis machine." Appeal Br. 23. Indeed, as Appellant points out, the Specification explains that "[t]he monitoring device 120 **and/or the alarm device 27 may alternatively be incorporated as part of the dialysis machine 110**." Appeal Br. 24 (quoting Spec. 13, ll. 16–26). We agree that "one of skill finds direct support in clear terms for the language in claim 1 calling for the blood treatment device to issue an alarm." *Id.* The same argument applies equally to claims 39 and 42.

The Examiner likewise rejects claim 38 regarding the specifically claimed options for adjusting the treatment parameter. As with claim 1, Appellant points out that the claims recite the analysis portion of a generalized dialysis machine. Appeal Br. 25. The Specification states that the dialysis device may perform a series of "actions to counter-act the occurrence of a hypotension event and/or reducing negative consequences to the subject where [a] hypotension event is unavoidable." Spec. 12, l. 27–13, l. 12. We do not agree that the claims require some specific structure claimed to perform each of these various functions as long as one of skill in the art understands the capabilities of a typical dialysis machine and that the

claimed tasks are within those capabilities. In the same manner as an applicant does not need to claim a steering wheel and all the components of a drive train when claiming an analysis component of a car that may affect how the car's steering operates, we see no need for Appellant to claim each and every structure in a generic dialysis machine to have written description support for generic functions understood by those of skill in the art to be within the normal capabilities of a dialysis machine. Accordingly, we do not sustain the Examiner's rejections.

Indefiniteness

Regarding claim 1, the Examiner asserts that the claim is indefinite essentially for the same reasons discussed above regarding what structure activates the alarm. Because we consider the alarm function to be supported by the overall dialysis device we do not agree that any specific structure is necessary. For the same reasons as discussed above, we do not sustain this rejection.

As to claims 39 and 42, the Examiner finds that it is unclear whether the pressure sensor is just measuring pressure within the extracorporeal circuit or is actually in the circuit. Ans. 10. We agree with Appellant "that it could be either." Appeal Br. 27. This claim language does not conflict with any other recited limitation and merely amounts to broad language that could cover more than one way for the sensing to occur. This does not make the claim indefinite; it merely provides broad coverage to Appellant. *See SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1341 (Fed. Cir. 2005) (breadth is not indefiniteness). Accordingly, we do not sustain this rejection.

Lastly, the Examiner rejects claim 38 essentially for the same reasons related to the written description rejection. We do not sustain this rejection for the same reasons as stated above.

§ 112, Sixth Paragraph

Although the Examiner has given no reason as to why the rejection requires an interpretation of the claims under 35 U.S.C. § 112, sixth paragraph, the Examiner nonetheless determines that certain claim language, namely "an input" and "a data analysis part," should be interpreted as means plus function claim language and thus limited to the disclosure found in the Specification. The Examiner asserts that the language used amounts to nonce terms modified by functional language. Ans. 13.

First, we note that the data analysis part is essentially a generic computing device used to perform the data analysis found in the claims. According to the Examiner's reasoning, all claims that include a generic computer for performing data analysis would have to be considered means plus function language. Additionally, Appellant is correct that a rebuttable presumption exists against interpreting claims as means plus function when the term "means" is not found in the claims. Appeal Br. 31. We agree that the Examiner has provided no evidence as to why this presumption is or should be rebutted. Appeal Br. 32. We also agree that the term "input" amounts to a structural part and should not be interpreted as the Examiner has done. Although there is no rejection associated with this interpretation, we do not support the Examiner's use of means plus function interpretation in applying the claim terms at issue.

Double Patenting

As Appellant points out, the proper standard for double patenting is that "[w]hen two claims in an application are duplicates, or else are so close

in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to other claims under 37 CFR 1.75 as being a substantial duplicate of the allowed claim." App. Br. 16–17. Appellant is correct that claim 39 claims a "monitoring device," which is not found in claim 42. Appeal Br. 33. This alone is sufficient such that Double Patenting would not apply. Accordingly, we do not sustain the Examiner's rejection.

Obviousness

The Examiner's combination relies on Simard to teach at least averaging a plurality of magnitudes from a plurality of the pulse shape parameters within a time window, which the Examiner admits is missing from Bissler. First, we note that Simard is a pumping device used to inject a sterile and anti-pyrogenic fluid and has nothing to do with monitoring blood pressure as claimed. As Appellant states, "*Simard* concerns filter integrity, not patient symptomatic blood pressure decrease" and is concerned with checking a filter during use of the device. Appeal Br. 34. Simard is concerned with measuring pressure drops within the injection system that may indicate a clogged filter. This has nothing to do with measuring blood pressure of a patient.

Appellant is also correct that Bissler "does not disclose or identify any components in its system having variations in pressure" and that "[t]here would have been NO motivation for the skilled artisan to make the argued combination." Reply Br. 14. We do not see how introducing pressure monitoring of an injection device related to filter integrity would cure a deficiency of a device that has nothing to do with varying pressure in the first place. Accordingly, we do not sustain the Examiner's rejections, all of which rely on this improper combination.

CONCLUSION

The Examiner's rejection is AFFIRMED.

More specifically,

DECISION SUMMARY

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
1, 21, 24, 25, 38–46	112	Written Description		1, 21, 24, 25, 38–46
1, 21, 24, 25, 38–46	112	Indefiniteness		1, 21, 24, 25, 38–46
1, 21, 24, 25, 38–46	101	Eligibility	1, 21, 24, 25, 38–46	
1, 21, 24, 38–46	103	Bissler, Simard		1, 21, 24, 38–46
25	103	Bissler, Simard, Balschat		25
Overall Outcome			**1, 21, 24, 25, 38–46**	

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