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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/322,898	02/09/2009	Roger L. HUNGERFORD	5360.115516	8862

107568 7590 04/02/2018

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EXAMINER	
PATEL, NEHA	

ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
04/02/2018	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ROGER L. HUNGERFORD and CURT MATTHEW ALLEN

Appeal 2016-005227[1]
Application 12/322,898[2]
Technology Center 3600

Before MICHAEL C. ASTORINO, JAMES A. WORTH, and TARA L. HUTCHINGS, *Administrative Patent Judges*.

HUTCHINGS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134(a) from the Examiner's final rejection of claims 1–4, 6, 7, 11, 12, 14, 16, 17, and 21. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Our decision references Appellants' Appeal Brief ("App. Br.," filed Nov 10, 2015) and Reply Brief ("Reply Br.," filed Apr. 20, 2016), and the Examiner's Answer ("Ans.," mailed Feb. 25, 2016) and Final Office Action ("Final Act.," mailed July 24, 2015).

[2] Appellants identify Baxter Healthcare S.A. and Baxter International Inc. as the real parties in interest. App. Br. 5.

CLAIMED INVENTION

Claims 1, 6, 11, 16, and 21 are the independent claims. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A computer-based method to prevent titration errors in infusion therapies, comprising:
>
> receiving, using a graphical user interface for an interface unit for an infusion pump, first data for a first infusion regimen for a medication, the first regimen including a first unit of measure of dosage of a first parameter in which the first regimen is executed;
>
> initiating, using a processor for the pump, the first infusion regimen;
>
> receiving, using the graphical user interface and the interface unit, and after receipt of the first data and initiation of the first regimen, second data for a second infusion regimen for the medication, the second regimen including a second unit of measure of dosage in which the second regimen is executed;
>
> determining, using the processor in the pump, whether the first and second units of measure of the medication are the same for ensuring the units of measure of dosage are the same; and
>
> initiating, using the processor in the pump, the second infusion regimen responsive to the determination that the first and second units of measure are the same.

REJECTIONS

Claims 1–4, 6, 7, 11, 12, 14, 16, 17, and 21 are rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter.

Claims 1–4, 11, 12, 14, and 21 are rejected under 35 U.S.C. § 103(a) as unpatentable over Condurso (US 2006/0047538 A1, pub. Mar. 2, 2006) and Martucci (US 2004/0172302 A1, pub. Sept. 2, 2004).

Claims 6, 7, 16, and 17 are rejected under 35 U.S.C. § 103(a) as unpatentable over Condurso and Vanderveen (US 2005/0145009 A1, pub. July 7, 2005).

ANALYSIS

Non-Statutory Subject Matter

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. The Supreme Court, however, has long interpreted § 101 to include an implicit exception: "[l]aws of nature, natural phenomena, and abstract ideas" are not patentable. *See, e.g.*, *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014).

The Supreme Court, in *Alice*, reiterated the two-step framework previously set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), "for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice*, 134 S. Ct. at 2355. The first step in that analysis is to "determine whether the claims at issue are directed to one of those patent-ineligible concepts." *Id.* If the claims are not directed to a patent-ineligible concept, e.g., an abstract idea, the inquiry ends. Otherwise, the inquiry proceeds to the second step where the elements of the claims are considered "individually and 'as an ordered combination"' to determine whether there are additional elements that "'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo*, 566 U.S. at 79, 78).

The step-one analysis calls upon us to consider "the claims . . . in their entirety to ascertain whether their character as a whole is directed to excluded subject matter." *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015). The question is whether the claims as a whole "focus on a specific means or method that improves the relevant

technology" or are "directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery." *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1314 (Fed. Cir. 2016).

In this case, the preamble of claim 1, for example, provides for a "computer-based method to prevent titration errors in infusion therapies." The method performs the following five steps: (1) receiving first data for a first infusion regimen for a medication; (2) initiating the first infusion regimen; (3) receiving, after receipt of the first data and initiation of the first regimen, second data for a second infusion regimen for the medication; (4) determining whether the first and second units of measure of the medication are the same; and (5) initiating the second infusion regimen responsive to the determination that the first and second units of measure are the same. The Specification provides that an "error that can occur in the process of delivering medication to a patient is to initiate an infusion in a first unit of measure and then modify the infusion by changing to a different unit of measure without properly adjusting the remaining infusion parameters." Spec. ¶ 21. The claimed invention, thus, seeks to "address[] and prevent[] errors related to changes in units of measure." *Id.* Independent claims 1, 6, 11, 16, and 21, while of differing scope, each focus on addressing such errors. In this context, the character of Appellants' claimed invention as a whole focuses on improving a process for initiating a second infusion regimen by collecting and comparing data, namely units of measure of dosage.

It is well-established that § 101 covers neither "mental processes" — associated with or as part of a category of "abstract ideas" — nor processes that merely invoke a computer and its basic functionality for implementing

such mental processes, without even specifying arguably new physical components or specifying processes defined other than by the mentally performable steps. *See, e.g.*, *SmartGene, Inc. v. Advanced Biological Labs., SA*, 555 Fed. App'x 950, 954 (Fed. Cir. 2014), *cert. denied*, 135 S. Ct. 58 (2014). If a claim recites a mental process or abstract idea, it must recite "enough else—applying the idea in the realm of tangible physical objects (for product claims) or physical actions (for process claims)—that is beyond 'well-understood, routine, conventional activity." *Id.* at 955 (citation and internal quotations omitted). In *SmartGene*, the Federal Circuit held that the claim at issue recited a patent-ineligible mental process involving the mental steps of comparing new and stored information, and using rules to identify medical options. *Id.* The Court determined that the claim "calls on a computer to do nothing that is even arguably an advance in physical implementations of routine mental information-comparison and rule application processes." *Id.*

Here, in rejecting the claims under 35 U.S.C. § 101, the Examiner determines that Appellants' claims are directed to an abstract idea because the claims recite a "series of step[s] that can be perform[ed] manually" and thus, are directed to an abstract idea. Ans. 4 ("For example, [a] care giver or nurse can manually determine the unit of measure of the medication and initiate or block delivery of [the] infusion regimen."). The Examiner finds that the claims do not recite additional elements or a combination of elements that amount to significantly more than the abstract idea. *Id.* at 4–5. In particular, the Examiner finds that the claims recite no more than "generic computer structure that serves to perform generic computer functions that serve to merely link the abstract idea to a particular technological

environment (i.e. infusion pump processor, interface, etc.)." *Id.* at 5 (citing Spec. ¶ 4). The Examiner further finds that the functions recited in the steps (e.g., receiving, determining, initiating) are "well-understood, routine, and conventional activities" previously known to the pertinent industry. *Id.*

Appellants argue that the claims are not abstract because they are directed to an infusion pump used in infusion therapies (claims 11 and 16), and a computer-based method for controlling an infusion pump using a computer processor and graphical user interface (claims 1, 6, and 21). App. Br. 19; *see also id.* at 20 ("the infusion pump, which is clearly a mechanical device"). In the Reply Brief, the Appellants ostensibly argue that the claims satisfy the machine-or-transformation test because they are tied to a machine (e.g., graphical user interface, pump, and processor) and/or transform an operation state of the pump. *See* Reply Br. 7–16 (discussing each of the independent claims, as well as dependent claims 2–4, 7, 12, 14, and 17). As an initial matter, the Supreme Court clarified in *Bilski v. Kappos*, 130 S. Ct. 3218, 3227 (2010) that the machine-or-transformation test, although a useful tool, "is not the sole test for deciding whether an invention is a patent-eligible 'process' [under § 101]."

Here, the focus of Appellants' invention is not on technological improvements to an infusion pump, its processor, or a graphical user interface. For example, the claimed pump does not improve the mechanical delivery of fluids. Instead, it is directed to an improvement to the process for determining whether to initiate a second infusion regimen based on whether the units of measure of dosage in the first regimen are the same as those in the second regimen. *See, e.g.*, Spec. ¶ 21 (invention addresses and prevents errors related to changes in units of measure). Thus, the claimed

method involves the steps of collecting information, analyzing the information, and uses rules to determine how to proceed based on the results of the collecting and analysis, i.e., a mental process comprising steps that are individually abstract. *See, e.g.*, *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353–54 (Fed. Cir. 2016). As such, we agree with the Examiner's determination that the claims are directed to an abstract idea.

Because the claims are directed to an abstract idea, the question before us at step two of the analysis is whether the claims include any additional features constituting an inventive concept. Here, our analysis uncovers no inventive concept in the individual claim limitations or their ordered combinations. The claims recite additional generic computer components (e.g., an infusion pump, a processor, and a graphical user interface), but merely requiring generic computer implementation fails to transform an abstract idea into a patent-eligible invention. *Alice*, 134 S. Ct. at 2357. Here, we are not persuaded that the Examiner erred in determining that these components do no more than provide a particular environment for implementing the abstract idea.

Appellants argue that the claims are analogous to those in *Diamond v. Diehr*, 450 U.S. 175 (1981), which involved the use of mathematical equations in operation of a rubber molding press to cure raw rubber into a product that retains its shape. *See* Reply Br. 14 (citing USPTO Example 25[3]); *see also July Examples* 14–19 (describing Example 25). We disagree. In *Diamond*, the claimed invention improved the operation of a rubber

[3] July 2015 Update Appendix 1: Examples, available at https://www.uspto.gov/sites/default/files/documents/ieg-july-2015-app1.pdf (hereinafter "*July Examples*").

molding press by taking measurements, and feeding those measurements into a digital computer that repeatedly recalculates the cure time based on the Arrhenius equation, resulting in a transformation of raw rubber to a molded, rubber product. *Diamond*, 450 U.S. at 177–179, 184. Appellants contend that claim 1 transforms the infusion pump into a different state, i.e., states for first and second regimens. Reply Br. 15. However, "merely transform[ing] data from one form to another is not patent eligible," as the Supreme Court made clear in *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972). In contrast to the situation in *Diamond*, applying Appellants' claimed steps (e.g., receiving data, and determining whether the units of measure of dosage are the same) does not result in any analogous transformation of matter from one state (i.e., raw ruber) to another (i.e., a molded product). We determine Appellants' claim 1 is more analogous, instead, to the process claim deemed patent-ineligible in *Gottschalk*.

In *Gottshalk*, the Supreme Court held that a process claim that converted binary-coded decimal numbers into pure binary were patent-ineligible. *See Gottschalk*, 409 at 73. In reaching its conclusion, the Court found that the steps of the claimed process "can be performed mentally" and also "can be carried out in existing computers long in use," here, a generic "graphic user interface" and "processor" in a generic "infusion pump," respectively. *See id.* at 67. Similarly, here, Appellants' steps of receiving and determining can be performed mentally, and also can be carried out using existing computers (e.g., an exising graphic user interface, processor, and infusion pump). *See CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1375 (Fed. Cir. 2011) ("[t]hat purely mental processes can be

unpatentable, even when performed by a computer, was precisely the holding of the Supreme Court in *Gottschalk v. Benson*").

We are not persuaded by Appellants' argument that the claims are similar to those described in USPTO Example 26. *See* Reply Br. 10–11; *see also July Examples* 19–21 (describing Example 26). There, the invention solved a problem peculiar to internal combustion engines related to declining engine performance due to increasing exhaust gas recirculation ("EGR"). *Id.* at 19. To address this problem, the invention in Example 26 modifies the amount of EGR using a control system to control the opening and closing of an exhaust gas recirculation valve based upon a rate of change of the engine throttle. *Id.* at 20. We see no comparable adjustment to the operation of Appellants' infusion pump here.

Like the situation in *SmartGene*, we find nothing in the application of the abstract idea that is "arguably an advance in physical implementation of routine mental information-comparison and rule-application processes." *SmartGene*, 555 Fed. App'x at 955. The claims recite the steps of initiating the regimens, but there is no indication in the claims, Specification, or briefing that this step is more than well-understood, routine, additional activity, which is not sufficient for patent eligibility. Although the claims recite various physical components, the focus of the claim is not on the improvement of any technology or technical field, or to the components themselves, but instead on implementing the abstract idea in a particular technological environment (i.e., infusion pump, processor, graphical user interface), which is insufficient. *See Alice*, 134 S. Ct. at 2358. We are not persuaded that the Examiner erred in finding that the elements or combination of elements amount to no more than mere instructions to

implement the idea using generic computer components, such as an infusion pump and graphical interface, in their ordinary capacities (e.g., receiving data, processing data).

Therefore, we are not persuaded that the Examiner erred in rejecting the claims under 35 U.S.C. § 101. Therefore, we sustain the Examiner's rejection.

Obviousness

Independent Claims 1, 11, and 21, and Dependent Claims 2–4, 12, and 14

We are persuaded by Appellants' argument that the Examiner erred in rejecting independent claims 1, 11, and 21 under 35 U.S.C. § 103(a) at least because Martucci does not disclose or suggest "determining, using the processor in the pump, whether the first and second units of measure of the medication are the same for ensuring the units of measure of dosage are the same," as recited in claim 1, and similarly recited in claims 11 and 21. App. Br. 22–26. The Examiner relies on Martucci as disclosing the argued limitation. Final Act. 9 (citing Martucci ¶ 402, Figs. 39A, 52). However, we find nothing in the cited portions of Martucci that discloses or suggests the argued limitation.

Martucci relates to a system and method for verifying operational parameters of medical devices. Martucci ¶ 4. Martucci describes at paragraphs 276–278 that different units of measurements (UOMs) are used by different portions of the patient care system, such that, for example, a physician's UOM is general a different unit than the administering clinician's UOM. With reference to Figures 39A and 52, Martucci describes ensuring pharmacy prescription parameters match programmed pump channels before starting an infusion pump. *Id.* ¶ 402. Stated differently, the

cited portions of Martucci describe comparing two different UOM's to ensure a correspondence before starting an infusion pump. However, we agree with Appellants that the cited portions of Martucci do not disclose or suggest comparing the same UOM (i.e., first and second units of measure of dosage) for two infusion regimes. *See* App. Br. 24–25.

In view of the foregoing, we do not sustain the Examiner's rejection of independent claims 1, 11, and 21, and their dependents under 35 U.S.C. § 103(a).

Independent Claims 6 and 16, and Dependent Claims 7 and 17

We are persuaded by Appellants' argument that the Examiner erred in rejecting independent claims 6 and 16 under 35 U.S.C. § 103(a) at least because Condurso does not disclose or suggest "generating . . . a query regarding inclusion, in the second data, of a volume of the second medication, in contrast to a query of a specified dosage rate of the second medication," as recited in claim 6, and similarly recited in claim 16. The Examiner relies on Condurso for the argued limitation. *See* Final Act. 18–19 (citing Condurso ¶¶ 125, 126, Fig. 1). However, we find nothing in the cited portions of Condurso that teaches or suggests the argued limitation.

Condurso describes at paragraph 125 checking a database to determine if a second drug may be safely delivered to a patient. The inventors in Condurso recognized that drugs in a multiple source infusion region may not be compatible, requiring that mixing of certain drugs be prevented, or that infusion of the second drug be delayed for a period of time. Condurso ¶ 123. To address this problem, the system displays a prompt to a caregiver, inquiring whether the drug is to be delivered using a Y-site connector and, if so, requesting the caregiver to "enter[] the dose rate

and other pertinent parameters into the system." *Id.* ¶ 125. The system determines whether these parameters are appropriate for the patient. *Id.* In particular, the system inputs patient characteristics, such as weight, age, and gender, into a pharmacokinetic (PK) model to help a caregiver generate a proposed dose or schedule. *Id.* ¶¶ 128–29.

Therefore, the cited portion of Condurso describes that a caregiver provides parameters regarding dose rate to the system, but does not disclose or suggest that a processor for the pump generates a query regarding "inclusion in the second data, of a volume of the second medication, in contrast to a query of a specified dosage rate of the second medication."

In view of the foregoing, we do not sustain the Examiner's rejection of independent claims 6 and 16, and their dependent claims under 35 U.S.C. § 103(a).

DECISION

The Examiner's rejection of claims 1–4, 6, 7, 11, 12, 14, 16, 17, and 21 under 35 U.S.C. § 101 is affirmed.

The Examiner's rejections of claims 1–4, 6, 7, 11, 12, 14, 16, 17, and 21 under 35 U.S.C. § 103(a) are reversed.

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