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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DENNIS TRIBBLE, ABDUL WAHID KHAN, DENNIS SCHNEIDER, GREGORY T. OLSEN, JAYSON LEE BENDER, BHAVESH S. PADMANI, and MATTHEW A. VALENTINE

Appeal 2017-001269
Application 14/022,415[1]
Technology Center 3600

Before ERIC B. CHEN, IRVIN E. BRANCH, and AMBER L. HAGY, *Administrative Patent Judges*.

BRANCH, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants appeal under 35 U.S.C. § 134(a) from a rejection of claims 45–52 and 56–58, which are all of the claims pending in the application. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

Technology

The application relates to "the receipt, processing, filling on-demand and in anticipation of use, management, and distribution of medication dose

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[1] According to Appellants, Baxter Corporation Englewood is the real party in interest. App. Br. 1.

orders, as well as remote dose inspection for facilitating the practice of telepharmacy." Spec. 1.

Illustrative Claim

Claim 45 is illustrative and reproduced below:

> 45. A medication preparation system for preparing and managing dose orders for compounded doses that have been entered into a first system, comprising:
>
> an order processing server executing software on a processor thereof and connected by a network to the first system and configured to receive the dose orders for compounded doses from the first system, the order processing server including a database configured to store the dose orders and information that relates to the dose orders in a dose record, the order processing server being configured to generate a dose order queue listing all dose orders received by the order processing server;
>
> a dose preparation station for manual preparation of a plurality of compounded doses by a human operator based on received dose orders, the dose preparation station being in bidirectional communication with the order processing server and having an interface comprising a display for providing a human operator with a protocol associated with each received dose order in a human perceivable manner and specifying a set of steps to prepare the compounded dose corresponding to the dose order;
>
> the dose preparation station being configured to present the protocol using the display to the human operator in the human perceivable manner for use by the human operator for manual preparation of a compounded dose corresponding to the dose order and having one or more data input devices operable by the human operator to capture dose preparation information that relates to at least one step of the protocol to prepare the compounded dose to fill the dose order in accordance with the protocol and communicate the dose preparation information to the order processing server for association with the dose record, wherein the dose preparation information includes confirmation

> data entered by the operator to confirm that the at least one step of the protocol was successfully completed and further includes indicia associated with the compounded dose that permits the contents of the compounded dose to be confirmed, and wherein the dose preparation information must be received prior to advancing to a subsequent step of the protocol; and
>
> a portal that is accessible remotely from the dose preparation station and in communication with the database that is configured to access the dose preparation information from the dose record of the database for presentation of the dose preparation information on a display to a remote user for inspection of the prepared compounded dose by review of the dose preparation information in order to verify whether the compounded dose has been prepared in accordance with the protocol, wherein the portal is configured to receive an approval of the release of the compounded dose if the remote user confirms that the dose has been prepared in accordance with the protocol.

Rejection[2]

Claims 45–52 and 56–58 stand rejected 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. Non-Final Act. 2.

ANALYSIS

We review the appealed rejections for error based upon the issues identified by Appellants, and in light of the arguments and evidence

[2] Rather than repeat the Examiner's positions and Appellants' arguments in their entirety, we refer to the above mentioned Appeal Brief, as well as the following documents for their respective details: the Non-Final Action mailed October 20, 2015 ("Non-Final Act."), the Examiner's Answer mailed August 29, 2016 ("Ans."), and Appellants' Reply Brief filed October 26, 2016 ("Reply Br.").

produced thereon. *Ex parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010) (precedential).

Section 101 defines patent-eligible subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. The Supreme Court has "long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012)).

To distinguish "patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts," the Supreme Court has set up an analytical framework. *Alice Corp. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2355 (2014) (citing *Mayo*, 566 U.S. at 71–73). In the first step of the analysis, we determine whether the claims at issue are "directed to" a judicial exception, such as an abstract idea. *Alice*, 134 S. Ct. at 2355. If not, the inquiry ends. *Thales Visionix Inc. v. U.S.*, 850 F.3d 1343, 1346 (Fed. Cir. 2017); *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1339 (Fed. Cir. 2016). If the claims are determined to be directed to an abstract idea, then we consider under step two whether the claims contain an "inventive concept" sufficient to "transform the nature of the claim into a patent-eligible application." *Alice*, 134 S.Ct. at 2355 (citation omitted).

Noting that the two stages involve "overlapping scrutiny of the content of the claims," the Federal Circuit has described "the first-stage inquiry" as "looking at the 'focus' of the claims, their 'character as a whole,'" and "the second-stage inquiry (where reached)" as "looking more

precisely at what the claim elements add—specifically, whether, in the Supreme Court's terms, they identify an 'inventive concept' in the application of the ineligible matter to which (by assumption at stage two) the claim is directed." *Electric Power Grp, LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016). In considering whether a claim is directed to an abstract idea, we acknowledge, as did the Court in *Mayo*, that "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 566 U.S. at 71. We, therefore, look to whether the claims focus on a specific means or method that improves the relevant technology or are instead directed to a result or effect that in itself is the abstract idea and merely invoke generic processes and machinery. *See Enfish*, 822 F.3d at 1336.

Step One: Whether the Claims Are Directed to a Patent-Ineligible Concept (Abstract Idea)

Claim 45, which is representative of the claims before us,[3] is directed to a "medication preparation system," including "an order processing server executing software on a processor thereof," "a dose preparation station," and "a portal" that is remote from the dose preparation station "for inspection of the prepared compounded dose."

The Examiner concludes that the claims "are directed to the abstract idea of comparing new drug preparation information with stored drug preparation [information] and using rules to identify whether the drug has been correctly made." Non-Final Act. 3. In particular, the Examiner

[3] Appellants collectively argue the rejection of all claims with regard to the Examiner's rejection of claim 45 under 35 U.S.C. § 101. *See* App. Br. 4–31. Therefore, based on Appellants' arguments, we decide the appeal of all pending claims based on claim 45 alone. *See* 37 C.F.R. § 41.37(c)(1)(iv).

characterizes "[c]omparing new drug preparation information with stored drug preparation [information] and using rules to identify whether the drug has been correctly made" as an abstract idea "because it is analogous to comparing new and stored information and using rules to identify options." *Id.* The Examiner finds that "claim 45 in the present case is analogous to the abstract idea identified in the *Smartgene* case." *Id.* at 6 (citing *SmartGene, Inc. v. Advanced Biological Labs., SA*, 555 Fed. Appx. 950 (Fed. Cir. 2014) (nonprecedential)).

We agree with and adopt the Examiner's findings and conclusion as our own.

Appellants argue that the Examiner has mischaracterized what the claims are directed to and has incorrectly analogized the claims here to those in *Smartgene*. App. Br. 8–23. Appellants argue, for example, that, unlike the claims in *Smartgene*, "the positive enforcement of a protocol such that the user may only progress in a protocol upon receipt of confirmation data is not capable of being provided by a human user who is inherently subject to error." *Id.* at 20. We are not persuaded.

Claim 45 recites that "dose preparation information must be received prior to advancing to a subsequent step of the protocol." This amounts to an automated checklist or "comparing new and stored information and using rules to identify options," as the Examiner finds. Non-Final Act. 6. Specifically, the system of claim 45 prohibits the "option" to continue with the protocol in the absence of "new information" (received data) satisfying a condition when compared to "stored information." This is also similar to running a mental checklist and advancing to the next item in the checklist only after completing the prior one. A human is capable of mentally

reinforcing a prohibition on advancing to a subsequent step in a checklist only upon completing a current step.

Accordingly, we agree with the Examiner at step one of the *Alice* analysis that the claims are directed to the abstract idea of "comparing new and stored information and using rules to identify options." Non-Final Act. 6.

Step Two: Whether Additional Elements Transform The Abstract Idea Into Patent-Eligible Subject Matter

With respect to the question of whether additional elements transform the abstract idea, the Examiner finds that "[t]his abstract idea is only generally linked to a particular technological environment by reciting the generic computer components that are well known in the art as acknowledged by the [Appellants'] [S]pecification." Ans. 7. The Examiner also finds that "[w]hile utilizing a computer to perform the abstract idea may improve the efficiency of carrying out the abstract idea, the claims do not result in any measurable improvements to the operations of the computer hardware itself, such as reduced memory usage or increased processor speed." *Id.* The Examiner also finds that "[w]hile the claims are directed to manipulating and organizing data, they are not directed to a transformation that changes the fundamental nature of the data." *Id.*

We agree with and adopt the Examiner's findings and conclusion.

In the Reply Brief, Appellants argue that "claim 45 presents something more than the mere abstract idea of determining whether a dose is correctly prepared" because "the system of claim 45 provides functionality simply not possible without the utilization of a system such as that recited in claim 45," namely, "an interlock that goes beyond the mental review of a

user that is inherently subject to error." Reply Br. 3–9 (advancing arguments of similar effect).

Appellants' arguments in this regard are unpersuasive because they overstate the system's role in determining "whether a dose is correctly prepared." Appellants' arguments imply that the system's interlock produces infallibility, which is a desired outcome. We are not persuaded that the system produces infallibility instead of merely following the rules it is programmed to enforce. Moreover, the claim goes on to recite "a portal" at which a "remote user confirms that the dose has been prepared in accordance with the protocol," a superfluous component to the system if the interlock produces the heretofore impossible desired outcome of infallibility. In other words, Appellants' arguments that claim 45 transforms the abstract idea into something more are based unpersuasively on the desired outcome the system is intended to produce, rather than actual claim elements.

We have considered all of Appellants' remaining arguments and have found them unpersuasive.

For the foregoing reasons, we are not persuaded the Examiner erred in rejecting independent claim 45 under 35 U.S.C. § 101 as directed to patent-ineligible subject matter, or in rejecting on the same basis dependent claims 44–52 and 56–58, which Appellants do not argue separately. App. Br. 4–31.

DECISION

For the reasons above, we affirm the Examiner's decision rejecting claims 45–52 and 56–58.

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. § 41.50(f).

AFFIRMED