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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHRIS DEMEYER, DENNIS WIJNKER, RON DIXON,
HAYATO IRIUMI, DENNIS KOCHANSKI, NATHAN LOWE,
and SOLOMAN S. SHACTER

Appeal 2016-007321
Application 11/963,734
Technology Center 3600

Before ANTON W. FETTING, KENNETH G. SCHOPFER, and
AMEE A. SHAH, *Administrative Patent Judges*.

SHAH, *Administrative Patent Judge*.

DECISION ON APPEAL¹

The Appellants² appeal under 35 U.S.C. § 134(a) from the Examiner's final decision rejecting claims 1–40. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

¹ Throughout this decision, we refer to the Appellants' Appeal Brief ("Appeal Br.," filed Nov. 19, 2015), Reply Brief ("Reply Br.," filed July 21, 2016), and Specification ("Spec.," filed Dec. 21, 2007), and to the Examiner's Answer ("Ans.," mailed June 9, 2016) and Final Office Action ("Final Act.," mailed Mar. 12, 2015).

² According to the Appellants, the real party in interest is "PAREXEL International Corporation and its wholly-owned subsidiary Clinphone PLC." Appeal Br. 2.

STATEMENT OF THE CASE

The Appellants' invention "relates generally to the field of data management, and specifically clinical trial data management." Spec. ¶ 2.

Claims 1, 29, and 35 are the independent claims on appeal. Claim 1 (Appeal Br. 21–22 (Claims App.)) is exemplary of the subject matter on appeal and is reproduced below.

1. A system capable of managing incoming and existing clinical trial data relating to a plurality of clinical trials through compartmentalization across disparate clinical trials, the system comprising:

at least one computer readable medium encoded with a plurality of code bases each configured to control entry and management of data in a clinical trial data store;

a plurality of clinical trial data stores, each of the plurality of clinical trial data stores associated with a clinical trial;

at least one processor programmed to:

present a login screen associated with the plurality of clinical trials, including a first clinical trial and a second clinical trial;

receive a user credential entered via the login screen;

receive a user request to access data associated with a clinical trial;

select based, at least in part, on the user credential, a selected clinical trial data store from among the plurality of clinical trial data stores and a selected code base from among the plurality of code bases to execute to process the user request, wherein execution of a first code base of the plurality of code bases by the at least one processor is constrained to components of said first code base such that execution of said first code base does not affect components of a second code base of the

plurality of code bases, and wherein execution of said second code base by the at least one processor is constrained to components of said second code base such that execution of said second code base does not affect components of said first code base.

THE REJECTION

Claims 1–40 stand rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter. Final Act. 3.

ANALYSIS

Under 35 U.S.C. § 101, a patent may be obtained for “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” 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.” *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014) (quoting *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 588–89 (2013)).

The Supreme Court in *Alice* reiterated the two-step framework, set forth previously in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 78–79 (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.* (emphasis added) (citing *Mayo*, 566 U.S. at 79). If so, the second step is to consider the elements of the claims “individually and ‘as an ordered combination’” to

determine whether the additional elements “transform the nature of the claim’ into a patent-eligible application.” *Id.* (quoting *Mayo*, 566 U.S. at 78–79).

In other words, the second step is to “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.* (alteration in original) (quoting *Mayo*, 566 U.S. at 72–73). The Court acknowledged 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 itself is the abstract idea, and merely invoke generic processes and machinery, *i.e.*, “whether the focus of the claims is on [a] specific asserted improvement in computer capabilities . . . or, instead, on a process that qualifies as an ‘abstract idea’ for which computers are invoked merely as a tool.” *See Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335–36 (Fed. Cir. 2016).

Under the first step of the *Alice* framework, the Examiner determines that the claims are directed to the abstract idea of “managing incoming and existing trial data,” a method of organizing human activities. Ans. 3; *see also* Final Act. 3. Conversely, the Appellants contend that the claims are “directed to enabling upgrading of software executing on [a] computer” that is “inextricably tied to computer technology,” and thus not directed to an abstract idea. (Appeal Br. 10–11 (citing *DDR Holdings v. Hotels.com*, 773 F.3d 1245 (Fed. Cir. 2014))).

Before determining whether the claims at issue are directed to an abstract idea, we must first determine what the claims are directed to.

The “directed to” inquiry . . . cannot simply ask whether the claims *involve* a patent-ineligible concept, because essentially every routinely patent-eligible claim involving physical products and actions *involves* a law of nature and/or natural phenomenon—after all, they take place in the physical world. *See Mayo*, [566 U. S. at 69] 132 S. Ct. at 1293 (“For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”) Rather, the “directed to” inquiry applies a stage-one filter to claims, considered in light of the specification, based on 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); *see Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1375 . . . (Fed. Cir. 2016) (inquiring into “the focus of the claimed advance over the prior art”).

Enfish, 822 F.3d at 1335.

The step-one analysis requires 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.*, 790 F.3d at 1346. 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).

The Specification is titled “AGGREGATION OF COMPARTMENTALIZED CLINICAL TRIAL DATA” and provides that the invention “relates generally to the field of data management, and specifically clinical trial data management.” Spec. ¶ 2. The Background

section of the Specification discusses the problems of corruption of data that can result in losses of time and money and require “brute force computing to organize often vast amounts of collected data,” and for which finding a time to do so may be impractical. Spec. ¶ 6. An existing solution of compartmentalizing backend databases is still exposed to corruption issues and increased complexity. *Id.* ¶ 7. The invention provides for a solution in the form of “systems for acquiring and managing clinical trial data where a code base and a database is compartmentalized to one or more clinical studies” (*id.* ¶ 8) that “segregates system upgrades and the like from potentially corrupting data across clinical trials” (*id.*) and increases efficiency in conducting trials by allowing new trials to begin with the newer information while allowing older trials to continue with the older information (*id.*). The system for acquiring and managing comprises a clinical data store (*id.* ¶ 22) that “can include a conventional general purpose” microprocessor (*id.* ¶ 51) and can be a server, laptop, or any type of computing device (*id.* ¶ 52), a network such as the Internet (*id.* ¶ 22), and various remote data entry systems, such as a general personal computer with input and output devices (*id.* ¶¶ 22, 56).

Independent claim 1 provides for a “system capable of managing incoming and existing clinical trial data relating to a plurality of clinical trials through compartmentalization across disparate clinical trials, the system comprising:” a computer readable medium with code bases “configured to control entry and management of data,” a plurality of clinical data stores, an a processor programmed to perform the functions of presenting a login in screen, receiving user credential and request data, based on the credential data, and selecting a clinical data store and a code base to

execute to process the user request without affecting components of the other code base. Appeal Br. 21–22. Independent claim 29 provides for a “system capable of managing incoming and existing clinical trial data relating to a plurality of clinical trials through compartmentalization across disparate clinical trials, the system comprising:” a processor programmed to execute the functions of a first code base to control entry and management if data in a first portion of a database, a second code base to control entry and management if data in a second portion of a database, and a selection module to select a code base to process a request. Appeal Br. 25. Independent claim 35 provides for a “method of managing incoming and existing clinical trial data relating to a plurality of clinical trials through compartmentalization across disparate clinical trials, the steps of the method comprising:” capturing first and second clinical data and aggregating the data. Appeal Br. 26.

In light of Specification’s description of the problems and solution, the Specification’s purported advance over the prior art by the claimed invention is to compartmentalize a code base and a database to acquire and manage clinical trial data. This is the heart of the invention. *Cf. Intellectual Ventures I LLC v. Erie Indemnity Co.*, 850 F.3d 1315, 1328 (Fed. Cir. 2017) (“the heart of the claimed invention lies in creating and using an index to search for and retrieve data, . . . an abstract concept”). In that context, considering the claims in light of the Specification and on their “character as a whole” (*Enfish*, 822 F.3d at 1335), the claims are directed to receiving data and, based on the data, selecting a data store and executing a code base to

manage clinical trial data.³ In this manner, the claim is similar to those deemed to be abstract ideas by our reviewing courts in *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1354 (Fed. Cir. 2016) (process of gathering and analyzing information of a specified content and displaying the result), *Intellectual Ventures I LLC v. Erie Indemnity Co.*, 850 F.3d 1315, 1325–26 (Fed. Cir. 2017) (using an index to locate desired information in a computer database), and *Tranxition, Inc. v. Lenovo (United States) Inc.*, 664 F. App'x 968, 971 (Fed. Cir. 2016) (automating the migration of data between two computers). Here, the claims involve nothing more than receiving data, selecting a data store, and executing a code, without any particular inventive technology — an abstract idea. *See Electric Power*, 830 F.3d at 1354. As such, we find unpersuasive the Appellants' arguments that the claims are not directed to an abstract idea. *See Reply Br. 6–7* (arguing that the Specification was not considered).

We also find unpersuasive the Appellants' arguments that the claims are not directed to an unpatentable abstract idea, because they are analogous to those of *DDR Holdings* in that they “are directed to technology to overcome a problem specifically arising in the realm of computer systems” and are “‘rooted in computer technology,’ as opposed to being ‘divisible’ from a computer.” *Appeal Br. 10*.

In *DDR Holdings*, the Federal Circuit determined that the claims addressed the problem of retaining website visitors who, if adhering to the

³ We note that “[a]n abstract idea can generally be described at different levels of abstraction.” *Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1240 (Fed. Cir. 2016). The Board’s “slight revision of its abstract idea analysis does not impact the patentability analysis.” *Id.* at 1241.

routine, conventional functioning of Internet hyperlink protocol, would be transported instantly away from a host's website after clicking on an advertisement and activating a hyperlink. *DDR Holdings*, 773 F.3d at 1257. The Federal Circuit, thus, held that the claims were directed to statutory subject matter because they claim a solution “necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks.” *Id.* The court cautioned that “not all claims purporting to address Internet-centric challenges are eligible for patent.” *Id.* at 1258. And the court contrasted the claims to those at issue in *Ultracomercial, Inc. v. Hulu, LLC*, 772 F.3d 709 (Fed. Cir. 2014), in that, in *DDR Holdings*, the computer network was not operating in its “normal, expected manner” and the claims did not “recite an invention that is . . . merely the routine or conventional use of the Internet.” *Id.* at 1258–59.

In contrast, here, the Appellants do not show what technical problems the claims address. The Specification discusses that a problem being addressed is the corruption/fraud of data. *See Spec.* ¶¶ 6–8. Although the data is computer-centric, preventing corruption of data is not a problem rooted in technology arising out of computer networks, but one that existed prior to the Internet, for example in ensuring no tampering or loss in paper data files. Also, unlike *DDR Holdings*, here, the solution comprises components of generic servers, processors, module, databases, and devices operating in their normal capacities to receive data, select a database and code, and execute code. *See Spec.* ¶¶ 38, 40, 46, 47, 49, 51–54, and Figs. 1, 2. The Specification states that compartmentalizing databases to prevent corruption from upgrades was conventional at the time of the invention. *See Spec.* ¶ 7. The Appellants do not direct our attention to

where the Specification provides that the components act in a non-conventional manner. Rather, the claims “merely appl[y] a well-known idea using a generic computer ‘to the particular technological environment of the Internet.’” *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1314 (Fed. Cir. 2016) (quoting *DDR Holdings*, 773 F.3d at 1259).

We further find unpersuasive the Appellants’ arguments that the Examiner erred in not following Office guidelines. *See* Reply Br. 4, 11–12 (citing May 4, 2016 Memorandum entitled “Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant’s Response to a Subject Matter Eligibility Rejection” (“May 2016 Memo”). Here, in rejecting the pending claims under § 101, the Examiner analyzes the claims using the *Mayo/Alice* two-step framework. Specifically, the Examiner cites to the intrinsic evidence of the claim language as evidence in determining that the claims are directed to an abstract idea. *See* Final Act. 4; Ans. 3–5. The Examiner further determines that the additional elements of the claims, taken alone and as an ordered combination, do not ensure that the claims amount to significantly more than the abstract idea. *See* Final Act. 4; Ans. 3–7.

Although we agree with the Appellants that additional explanation is always helpful, the Examiner has clearly articulated the reasons for the rejection and has notified the Appellants of the reasons for the rejection “together with such information and references as may be useful in judging of the propriety of continuing the prosecution of [the] application.”

35 U.S.C. § 132. And, we find that, in doing so, the Examiner set forth a prima facie case of unpatentability. *See In re Jung*, 637 F.3d 1356, 1362 (Fed. Cir. 2011); *Chester v. Miller*, 906 F.2d 1574, 1578 (Fed. Cir. 1990) (Section 132 “is violated when a rejection is so uninformative that it

prevents the applicant from recognizing and seeking to counter the grounds for rejection.”). We also note although the guidance suggests comparing the claimed invention to claims already deemed to be directed to an abstract idea (*see* Reply Br. 3–4), it is not always necessary, and is not necessary here.⁴ *See Mortgage Grader, Inc. v. First Choice Loan Servs. Inc.*, 811 F.3d 1314, 1325 (Fed. Cir. 2016) (“[I]t is also possible, as numerous cases have recognized, that a § 101 analysis may sometimes be undertaken without resolving fact issues.”). Thus, we decline to find error in the Examiner’s decision not to recite a judicial decision.

Under the second step of the *Mayo/Alice* framework, we agree with and find supported the Examiner’s determination that the elements of the claims, individually or as an ordered combination, do not amount to significantly more than that abstract idea. *See* Final Act. 4; Ans. 3–7. We are not persuaded of Examiner error by the Appellants’ arguments that assert the opposite. *See* Appeal Br. 12–19; Reply Br. 9–11.

In response to the Appellants’ argument that the claims contain an inventive concept and are patent-eligible under § 101, because the Examiner indicated the claims “as allowable over the prior art” (Appeal Br. 14), we note that an abstract idea does not transform into an inventive concept just because the prior art does not disclose or suggest it. *See Mayo*, 132 S. Ct. at 1304. “Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.” *Ass’n for Molecular Pathology*,

⁴ We further note that the MANUAL OF PATENT EXAMINING PROCEDURE and guidelines are not legal requirements. *Cf. In re Fisher*, 421 F.3d 1365, 1372 (Fed. Cir. 2005) (“The MPEP and Guidelines ‘are not binding on this court’”) (internal citations omitted).

133 S. Ct. at 2117. Indeed, “[t]he ‘novelty’ of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.” *Diamond v. Diehr*, 450 U.S. 175, 188–89 (1981); *see also Mayo*, 132 S. Ct. at 1304 (rejecting “the Government’s invitation to substitute §§ 102, 103, and 112 inquiries for the better established inquiry under § 101”).

Similarly, in response to the Appellants’ argument that “the claims do not preempt all uses of the Office Action’s allegedly-abstract idea of ‘managing clinical trial data.’” (Appeal Br. 14; *see also id.* at 17–19), we note that although the Supreme Court has described “the concern that drives this exclusionary principle [i.e., the exclusion of abstract ideas from patent eligible subject matter] as one of preemption” (*see Alice*, 134 S. Ct. at 2354), characterizing preemption as a driving concern for patent eligibility is not the same as characterizing preemption as the sole test for patent eligibility. “The Supreme Court has made clear that the principle of preemption is the basis for the judicial exceptions to patentability” and “[f]or this reason, questions on preemption are inherent in and resolved by the § 101 analysis.” *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015) (citing *Alice*, 134 S. Ct. at 2354). Although “preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility.” *Id.* The aforementioned concept in the claims here is not sufficiently limiting so as to fall clearly on the side of patent-eligibility.

We find unpersuasive the Appellants’ argument that the “[t]he claims recite meaningful limitations demonstrating patent-eligibility,” because they

“recite an ‘improvement to another technology.’” Appeal Br. 14. As the Appellants admit, “[u]sing computers to manage clinical trial data was known.” *Id.* It is not clear what other technology or “technical constraint” (*id.* at 15) the Appellants assert is being improved or addressed. To the extent the Appellants argue that the technology improved is that of upgrading software (*id.* at 14 (“The compartmentalization enables upgraded software to be executed, reducing the risk of errors or security risks, for example.”)), the Appellants do not adequately show how the technology of upgrading software is improved. At best, the improvement is in reducing risks related to errors and security, but not in any specific technology or technical component. The claims do not recite steps regarding performing software upgrades. *See Alice*, 134 S. Ct. at 2355 (looking to the “claims at issue”).

As discussed above, the technology of the claims are generic servers, databases, modules, processor, devices, and computer readable media performing in their ordinary and conventional ways to have encoded data, store data, present data, receive data, select a database and code, and execute code. *See Spec.* ¶¶ 32–57. The Appellants do not provide further support or reasoning as to how these components are technologically improved. There is no indication in the Specification that any technologically novel or inventive hardware is required to perform the method. *See Affinity Labs of Texas, LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1263 (Fed. Cir. 2016); *see also Enfish*, 822 F.3d. at 1336 (focusing on whether the claim is “an improvement to [the] computer functionality itself, not on economic or other tasks for which a computer is used in its ordinary capacity.”).

To the extent the Appellants argue that the computer is not generic because it is specially programmed (Reply Br. 8), a generic computer specially programmed to perform the conventional functions of presenting and receiving data, making a selection, and executing code does not amount to an inventive concept such that the claim is significantly more than the abstract idea. *See Alice*, 134 S. Ct. at 2357–60 (applying an abstract idea, such as an algorithm, on a general purpose computer is not enough to transform a patent-ineligible abstract idea into a patent-eligible invention.); *EON Corp. IP Holdings LLC v. AT & T Mobility LLC*, 785 F.3d 616, 623 (Fed. Cir. 2015) (“A microprocessor or general purpose computer lends sufficient structure only to basic functions of a microprocessor.”).

We further find unpersuasive the Appellants’ argument that although the limitations “alone may appear to be conventional activity, in combination [they] may amount to such ‘meaningful limitations’ when they are used to solve computer-specific problems.” Appeal Br. 15; *see also* Reply Br. 9–10 (“claim 1 reflects an ordered combination of limitations that collectively define an approach for solving a problem that arises from the use of computers to process clinical trial data and involves selecting a data store and a code base to execute in response to a user request.”). As discussed above, the problem addressed by the invention, i.e., that of corrupted/fraudulent data, is not computer-specific.

To the extent the Appellants argue that the claims are significantly more than the abstract idea because of the “multiple detailed limitations regarding a specific computer system” (Appeal Br. 15), we disagree. “None of these . . . individual steps, viewed ‘both individually and ‘as an ordered combination,’ transform the nature of the claim into patent-eligible subject

matter.” *Ultramercial*, 772 F.3d at 715. Having routine steps of presenting and receiving data, making a selection of a database and code, and executing code “do not transform an otherwise abstract idea into patent-eligible subject matter.” *Id.* at 716.

We further find unpersuasive the Appellants’ arguments that the claim limitations “recite[] ‘significantly more’ than the Office Action’s alleged abstract idea” (Appeal Br. 16–17), are “tied to computer technology” (*id.* at 17–19), “further detail how the computer system manages code bases” (*id.* at 17, 18), and/or “specif[y] how data captured with different code bases is used” (*id.* at 18). The Appellants do not provide further support or reasoning as to why or how the limitations are not well-understood, routine, and conventional functions of a generic computer. The Appellants further do not show how the limitations technologically or technically improve the computer itself.

Thus, we sustain the Examiner’s rejection of claims 1–40 under 35 U.S.C. § 101.

DECISION

The Examiner’s rejection of claims 1–40 under 35 U.S.C. § 101 is AFFIRMED.

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