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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/426,935	03/22/2012	Eileen Morrissey	MDA P0235	3297

122066 7590 07/19/2018

M&B IP Analysts, LLC
500 Headquarters Plaza
Morristown, NJ 07960-7070

EXAMINER
GORT, ELAINE L

ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
07/19/2018	ELECTRONIC

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte EILEEN MORRISSEY and JIM ANDERSON

Appeal 2017-004393
Application 13/426,935[1]
Technology Center 3600

Before CAROLYN D. THOMAS, HUNG H. BUI, and
KARA L. SZPONDOWSKI, *Administrative Patent Judges*.

BUI, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants seek our review under 35 U.S.C. § 134(a) of the Examiner's Final Office Action rejecting claims 1–20, which are all the claims pending in the application. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.[2]

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[1] According to Appellants, MEDICINE DIFFERENTIATION ANALYTICS, LLC is the real party in interest. App. Br. 2.

[2] Our Decision refers to Appellants' Appeal Brief filed May 16, 2016 ("App. Br."); Examiner's Answer mailed November 17, 2016 ("Ans."); Final Office Action mailed November 13, 2015 ("Final Act."); and original Specification filed March 22, 2012 ("Spec.").

STATEMENT OF THE CASE

Appellants' invention relates to "a computer implemented method for determining pharmaceutical asset [] market potential." Spec. ¶ 12. According to Appellants, "[c]ertain exemplary embodiments . . . include a system and method for determining how differentiated a potential medicine (a pharmaceutical asset) will be when it launches on the market compared to its competitors and how aligned the assets differentiation features are to the unmet needs from various customer groups." Spec. ¶ 27.

Claims 1, 12, and 13 are independent. Claim 1 is illustrative of the claimed subject matter, and reproduced below with disputed limitations in italics:

> 1. A computer implemented method for determining pharmaceutical asset market potential, comprising:
>
> collecting asset information about in-line and proposed pipeline products of pharmaceutical assets by a therapeutic category;
>
> retrieving data related to the therapeutic category, wherein the retrieved data includes at least label claims of one or more existing competitor pharmaceutical assets in the therapeutic category, *wherein the at least one label claim is the wording of a label published with the asset*;
>
> determining, by the computer, an unmet need for the proposed pharmaceutical asset by evaluating a plurality of customer value statements (CVS) based on the therapeutic category;
>
> computing, by the computer, a differentiation score based on the evaluated plurality of CVS and contents of the label claims of the of one or more existing competitor pharmaceutical assets in the therapeutic category;
>
> comparing a strength of the proposed pharmaceutical asset against the existing competitor pharmaceutical assets in the therapeutic category; and

> generating an executive summary report of the proposed pharmaceutical asset market potential base, in part, the computed differentiation score.

App. Br. 19 (Claims App.).

EXAMINER'S REJECTIONS & REFERENCES

(1) Claims 1–20 stand rejected under 35 U.S.C. § 101 because the claimed invention is directed to an abstract idea. Final Act. 2–4.

(2) Claims 1–20 stand rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over de Nijs et al. (US 2005/0278185 A1; published Dec. 15, 2005), Koster (US 8,543,411 B2; issued Sept. 24, 2013), and Rao (US 2010/0241459 A1; published Sept. 23, 2010). Final Act. 6–15.

ANALYSIS

§ 101 Rejection of Claims 1–20

Patent eligibility is a question of law that is reviewable *de novo*. *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1333 (Fed. Cir. 2012). The Supreme Court has long held that "[l]aws 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). The "'abstract ideas' category embodies 'the longstanding rule that [a]n idea, by itself, is not patentable.'" *Alice*, 134 S. Ct. at 2355 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

In *Alice*, the Supreme Court reiterates an analytical two-step framework previously set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 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." *Id.* at 2355. The first step in the analysis is to "determine whether the claims at issue are directed to one of those patent-ineligible concepts," such as an abstract idea. *Id.* If the claims are directed to eligible subject matter, the inquiry ends. *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1349 (Fed. Cir. 2017); *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1339 (Fed. Cir. 2016). If the claims are directed to a patent-ineligible concept, the second step in the analysis is to consider the elements of the claims "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." *Alice*, 134 S. Ct. at 2355 (citing *Mayo*, 566 U.S. at 79, 78). 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.* (citing *Mayo*, 566 U.S. at 72–73).

In rejecting claims 1–20 under 35 U.S.C. § 101, the Examiner determines these claims are directed to an abstract idea of "generating an executive summary report of the proposed pharmaceutical asset" akin to the abstract idea of collecting and comparing information and using rules to identify options, i.e., which values to be selected for case report. Final Act. 2–3; *see also SmartGene, Inc. v. Advanced Biological Labs., SA*, 852 F. Supp. 2d 42 (D.D.C. 2012), *aff'd* 555 F. App'x 950 (Fed. Cir. 2014)). The Examiner also determines these claims are directed to an abstract idea because the steps recited in these claims "can be perform[ed] manually,"[3]

[3] The Examiner appears to link "steps that can be perform[ed] manually" to "methods of organizing human activities." Final Act. 3. However, these are

i.e., by a human with pen and pencil. Final Act. 3; *see also Cybersource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366 (Fed. Cir. 2011)).

The Examiner further determines the additional elements in the claims do not amount to significantly more than the judicial exception, because (1) the additional elements, whether taken individually or in combination, are "generic computer structure that serves to perform generic computer functions" and (2) the functions recited "are well-understood, routine, and conventional activities previously known to the pertinent industry." Final Act. 3–4. According to the Examiner, "[t]he claims do not recite an asserted improvement to the functioning of the computer itself, another technology, or a technological process but rather recite using a computer to lend speed and efficiency to an abstract idea." Ans. 4.

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two separate categories of abstract ideas as identified by the Supreme Court's decisions in (1) *Gottschalk v. Benson*, 409 U.S. 63 (1972) (holding that "mental steps" as steps that "can be performed mentally" are patent-ineligible under § 101); *see also CyberSource Corp v. Retail Decisions, Inc.*, 654 F.3d 1366, 1373 (Fed. Cir. 2011) (stating that "[m]ethods which can be performed entirely in the human mind are unpatentable because . . . methods which can be performed entirely in the human mind are the types of method that embody the 'basic tools of scientific and technological work'") and (2) *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014) (holding that the concept of intermediated settlement between parties, like the risk hedging in *Bilski*, is patent-ineligible under § 101 and, in the view of the concurrence, the concept of intermediated settlement is akin to "processes for organizing human activity" that (i) do not involve "manufactures, machines, or compositions of matter" and (ii) have never been patent-eligible ever since the English Statute of Monopolies and, as such, (iii) should not be patent-eligible under US modern patent law). Nevertheless, both are examples of patent-ineligible abstract ideas under § 101.

Alice/Mayo—Step 1

Turning now to the first step of the *Alice* inquiry, Appellants do not dispute the Examiner's determination that the claims are directed to an abstract idea of "generating an executive summary report" akin to *SmartGene*. Instead, Appellants contend their "claims are directed to . . . determining pharmaceutical asset market potential" and "do **not** even remotely mention humans or human activity, let alone organizing human activity as alleged." App. Br. 8. (Underlining omitted). According to Appellants, their claims are not directed to "organizing human activities" because:

(1) the USPTO's July 2015 Update: Subject Matter Eligibility clarifies that, the phrase 'certain methods of organizing human activity' is used to describe concepts relating to interpersonal and intrapersonal activities, such as managing relationships or transactions between people, social activities, and human behavior; satisfying or avoiding a legal obligation; advertising, marketing, and sales activities or behaviors; and managing human mental activity and

(2) "the instant claims do not recite or even remotely suggest interpersonal or intrapersonal activities which could be interpreted as organizing human activity."

App. Br. 9–10. (Underlining omitted).

We do not find Appellants' arguments persuasive. At the outset, we note the claims are directed to concepts relating to advertising, marketing, and sales activities in connection with "a pharmaceutical asset (product)" by the USPTO's July 2015 Update and, as such, can be interpreted as directed to "organizing human activity." More importantly, we agree with the Examiner that Appellants' claims are directed to an abstract idea of

"generating an executive summary report of the proposed pharmaceutical asset" akin to collecting and comparing information and using rules to identify options discussed in *SmartGene*. Final Act. 3.

Information, as such, is intangible, and data analysis and data generation are abstract ideas. *See, e.g.*, *Microsoft Corp. v. AT & T Corp.*, 550 U.S. 437, 451 n.12 (2007); *Alice*, 134 S. Ct. at 2355; *Parker v. Flook*, 437 U.S. 584, 589, 594–95 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972). Information collection and analysis, including when limited to particular content, is within the realm of abstract ideas. *See, e.g.*, *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1349 (Fed. Cir. 2015); *Digitech*, 758 F.3d at 1349–50 ("Data in its ethereal, non-physical form is simply information that does not fall under any of the categories of eligible subject matter under section 101").

As also recognized by the Examiner (Final Act. 3), steps recited in claims 1, 12, and 13, including: "collecting asset information", "retrieving data related to therapeutic category", "computing a differentiation score," "comparing a strength of the proposed pharmaceutical asset against the existing competitor" and "generating an executive summary report" can be performed manually using, at most, a pen and paper, without need of any computer or other machine. *See CyberSource*, 654 F.3d at 1372–73 ("[A] method that can be performed by human thought alone is merely an abstract idea and is not patent-eligible under § 101."); *see also In re Comiskey*, 554 F.3d 967, 979 (Fed. Cir. 2009) ("[M]ental processes–or processes of human thinking–standing alone are not patentable even if they have practical application."); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) ("Phenomena of nature . . . , *mental processes*, and abstract intellectual concepts are not

patentable, as they are the basic tools of scientific and technological work" (emphasis added)). Additionally, mental processes remain unpatentable even when automated to reduce the burden on the user of what once could have been done with pen and paper. *CyberSource*, 654 F.3d at 1375 ("That purely mental processes can be unpatentable, even when performed by a computer, was precisely the holding of the Supreme Court in *Gottschalk v. Benson*.").

Accordingly, we agree with the Examiner that claims 1–20 are directed to an abstract idea.

Alice/Mayo—Step 2

In the second step of the *Alice* inquiry, Appellants argue: (1) their "claim limitations offer improvements to the field in which the subject matter of the present application directed by at least one application server configured to perform the pharmaceutical asset differentiation process" and (2) their "claims address a real challenge related to the determination of pharmaceutical asset market potential to evaluate the strength of a proposed pharmaceutical asset" and "to perform the determination requires processing of large amounts of data per therapeutic category" and, as such, "the determination requires complex processing that cannot be performed without machines." App. Br. 10. (Underlining omitted).

We disagree. At the outset, we note that the second step of *Alice* requires 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.'" *Alice*, 134 S. Ct. at 2355 (citing *Mayo*, 566 U.S. at 72–73). According to the Federal Circuit, "the concept of inventiveness is distinct

from that of novelty" and "[t]he inventiveness inquiry of § 101 should therefore not be confused with the separate novelty inquiry of § 102 or the obviousness inquiry of § 103." *See Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1312 (Fed. Cir. 2016). Under current Federal Circuit precedent, an "inventive concept" under *Alice* step 2 can be established by showing, for example, that the patent claims:

> (1) provide a technical solution to a technical problem unique to the Internet, e.g., a "solution [] necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks" (*see DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1257 (Fed. Cir. 2014);
>
> (2) transform the abstract idea into "a particular, practical application of that abstract idea," e.g., "installation of a filtering tool at a specific location, remote from the end-users, with customizable filtering features specific to each end user" (*see Bascom Global Internet Services, Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016)); or
>
> (3) "entail[] an unconventional solution ([e.g.,] enhancing data in a distributed fashion) to a technological problem ([e.g.,] massive record flows which previously required massive databases)" and "improve the performance of the system itself" (*see Amdocs,* 841 F.3d at 1302).

In this case, however, we find no element or combination of elements recited in Appellants' claims 1, 12, and 13 that contains any "inventive concept" and adds anything "significantly more" to transform the abstract concept into a patent-eligible application. *Alice*, 134 S. Ct. at 2357. As discussed *supra*, we are not persuaded the added computer elements such as the computer, storage device or server can transform the abstract idea into a patent eligible invention. As our reviewing court has observed: "[A]fter

Alice, there can remain no doubt: recitation of generic computer limitations does not make an otherwise ineligible claim patent-eligible." *DDR Holdings*, 773 F.3d at 1256 (citing *Alice Corp.*, 134 S. Ct. at 2358)).

Because Appellants' claims 1–20 are directed to a patent-ineligible abstract concept and do not recite something "significantly more" under the second prong of the *Alice* analysis, we sustain the Examiner's rejection of these claims under 35 U.S.C. § 101.

35 U.S.C. § 103(a): Claims 1–20

In support of the obviousness rejection of claim 1 and similarly, claims 12 and 13, the Examiner finds de Nijs teaches tools used to assess pharmaceutical products (assets) with most aspects of Appellants' claimed "method for determining pharmaceutical asset market potential," based on various attributes, scores, and comparison with competitor's product, shown in Figures 1–2, including:

(1) "[c]ollecting asset information . . . by a therapeutic category" (Final Act. 6 (citing de Nijs ¶¶ 40–41));

(2) "retrieving data related to the therapeutic category . . ." (Final Act. 7 (citing de Nijs ¶ 18));

(3) "determining . . . an unmet need for the proposed pharmaceutical asset" (Final Act. 7–8 (citing de Nijs ¶¶ 46, 74)(emphasis omitted);

(4) "computing . . . a differentiation score . . ." (Final Act. 9—10 (citing de Nijs ¶¶ 18, 21)(emphasis omitted));

(5) "comparing a strength of the proposed pharmaceutical asset against [the] existing competitor pharmaceutical assets in the

therapeutic category" ((Final Act. 7 (citing de Nijs ¶ 16)(emphasis omitted)); and

(6) "*generating an executive summary report of the proposed pharmaceutical asset market potential base, in part, the computed differentiation score*." (Final Act. 10–11 (citing de Nijs ¶¶ 16, 20, and 77)).

The Examiner then relies on: (1) Koster for teaching "wherein the least one label claim is the wording of a label published with the asset" and (2) Rao for teaching "determining . . . [the] unmet needs for the proposed pharmaceutical asset by evaluating a plurality of customer value statements (CVS) based on the therapeutic category" in order to support the conclusion of obviousness. Final Act. 7–9 (citing Koster's Fig. 3 and Rao's Fig. 1).

Appellants do not dispute the Examiner's factual findings regarding de Nijs. Appellants also acknowledge "Koster teaches, in relevant part, a label containing 'information that is required by federal labelling laws and information added for marketing motivations'" and Koster's "label includes 'a second bar code representing the authenticating data' and 'an RFID tag.'" App. Br. 13 (citing Koster 6:30–31, 6:56–57, 7:1–4, and 45–51). However, Appellants argue "that 'reading' a label by processing and recognizing RFID tags and bar codes for authentication purposes does **not** read on the claimed features of retrieving data including label claims which are wordings of labels published with assets" especially when "Koster does **not** even remotely mention recognition of wording on a label, let alone the claimed at least one label claim." App. Br. 13. (Underlining omitted).

Appellants also argue because "Rao attempts to evaluate the consumer purchase behavior of a certain **consumer** (or group of consumers) seeking to

purchase a pharmaceutical product, but **not** to evaluate the **pharmaceutical product itself**" disclosed by de Nijs, "the Office Action fails to show, given these differences, for example, how the method of Rao can be properly combined with the teachings of de Nijs" and "does not articulate how the two different approaches taken by the reference can be combined to result in the claimed invention." App. Br. 15.

Appellants' arguments are not persuasive. Instead, we find the Examiner has provided a comprehensive response to Appellants' arguments supported by evidence. Ans. 4–8. As such, we adopt the Examiner's findings and explanations provided therein. *Id.* For additional emphasis, we note obviousness is a question of law based on underlying factual findings, *In re Baxter*, 678 F.3d 1357, 1361 (Fed. Cir. 2012), including what a reference teaches, *In re Beattie*, 974 F.2d 1309, 1311 (Fed. Cir. 1992), and the existence of a reason to combine references, *In re Hyon*, 679 F.3d 1363, 1365–66 (Fed. Cir. 2012). When a claimed invention "'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)).

Such is true here. All the elements recited in Appellants' claim 1, including: (1) "the at least one label claim [] the wording of a label published with the asset" and (2) "evaluating a plurality of customer value statements (CVS)" are well-known elements in the context of product market research with each performing the same function it had been known to perform, as evidenced from Koster's label, shown in Figure 3, and Rao's

CVS, described in paragraphs 7, 25–35. As such, we agree with the Examiner that (1) information obtained from patient/panelist described in paragraphs 7, 25–35 of Rao can be considered as the claimed "customer value statements" and (2) incorporating Rao's evaluation of CVS into the tools of de Nijs would have been obvious to those skilled in the art "because customer behaviors will be one of the closet indicator of market need" as articulated by the Examiner. Ans. 7–8.

Lastly, we note Appellants have not presented sufficient evidence or argument that the Examiner's proffered combination of references would have been "uniquely challenging or difficult for one of ordinary skill in the art." *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)). Nor have Appellants provided objective evidence of secondary considerations, which our reviewing court guides "operates as a beneficial check on hindsight." *Cheese Systems, Inc. v. Tetra Pak Cheese and Powder Systems, Inc.*, 725 F.3d 1341, 1352 (Fed. Cir. 2013).

For these reasons, Appellants have not demonstrated Examiner error. Accordingly, we sustain the Examiner's obviousness rejection of independent claims 1, 12, and 13 and claims 2–11 and 14–20 dependent therefrom.

DECISION

As such, we AFFIRM the Examiner's final rejection of claims 1–20 under 35 U.S.C. § 101 and 35 U.S.C. § 103(a).

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