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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GORAN NESHICH,
IZABELLA AGOSTINHO PENA NESHICH,
JOSE GILBERTO JARDINE, LETICIA NISHIMURA,
IVAN MAZONI, and JOSE SALIM

Appeal 2018-006259
Application 13/821,792[1]
Technology Center 1600

Before DONALD E. ADAMS, ROBERT A. POLLOCK, and ELIZABETH A. LAVIER, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This Appeal under 35 U.S.C. § 134(a) involves claim 1 (Final Act.[2] 2). Examiner entered rejections under the written description provision of 35 U.S.C. § 112, first paragraph and 35 U.S.C. § 101. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] Appellants identify "EMPRESA BRASILEIRA DE PESQUISA AGROPECUARIA - EMPRAPA" as the real party in interest (Appellants' February 2, 2018 Appeal Brief ("Br.") 2).

[2] Examiner's August 8, 2017 Final Office Action.

STATEMENT OF THE CASE

Appellants' disclosure "relates to a method for identifying target regions existing in the interface of monomers constituting the PilT protein with a view to design molecules that are potentially applicable in impairing the activity of this protein, thus controlling infectious processes" (Spec. 1:5–8). Appellants' claim 1 is representative and reproduced below:

> 1. A method for identifying drug candidates that inhibit motility of PilT-expressing *Xylella fastidiosa*, comprising:
>
> (a) selecting at least one interface-forming residue from a PilT protein from a PilT-expressing *Xylella fastidiosa* as a therapeutic target site, wherein said at least one interface-forming residue is selected from the group consisting of residue D184, E89, K187, E258, E74, K235, K249, R35, R90, D33, E248, R36, H152, E336, K58, R212, R335 and E65 from *Xylella fastidiosa* PilT; and
>
> (b) identifying at least one drug candidate predicted to bind to said therapeutic target site, wherein said identifying comprises one or more of *de novo* drug design and virtual screening.

(Br. 18.)

Grounds of rejection before this Panel for review:

Claim 1 stands rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

Claim 1 stands rejected under 35 U.S.C. § 101.

Written Description:

ISSUE

Does the preponderance of evidence on this record support Examiner's finding that Appellants' Specification fails to provide written descriptive support for the claimed invention?

ANALYSIS

To satisfy the written description requirement, "the specification must describe an invention understandable to [the] skilled artisan and show that the inventor actually invented the invention claimed." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). "The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence." *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

On this record, Examiner does not dispute that step (a) of Appellants' claim identifies the therapeutic target site of a PilT protein from a PilT-expressing *Xylella fastidiosa* as at least one interface forming residue is selected from the group consisting of residue D184, E89, K187, E258, E74, K235, K249, R35, R90, D33, E248, R36, H152, E336, K58, R212, R335 and E65 from *Xylella fastidiosa* PilT (*see* Br. 18). In addition, Examiner does not dispute that Appellants disclose the proposed method steps and direct attention to patents and printed publications describing the *de novo* drug design and virtual screening methodology required by step (b) of their claim (*see generally* Spec. 5–11 and 17–20).

Instead, Examiner asserts that "there is no showing in the application that [Appellants] knew to be a fact that instructions to identify compounds to

bind to one of [the recited] . . . residues would be sufficient to identify a drug candidate that inhibits motility of a PilT-expressing proteobacteria" (Ans. [3] 6; *see also* Final Act. 5–7). Stated differently, Examiner finds that Appellants' claimed invention lacks written descriptive support because Appellants' Specification fails to disclose a working example of Appellants' claimed invention. We are not persuaded.

"[T]he written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement." *Ariad Pharms.*, 598 F.3d at 1352 (citing *Falko–Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366–67 (Fed. Cir. 2006)).

In addition, Examiner failed to establish an evidentiary basis to this record to support a finding that a person of ordinary skill in this art would not have expected Appellants' disclosed and claimed method to result in the identification of a drug candidate that inhibits motility of a PilT-expressing proteobacteria or that such a person would have reasonably considered a molecule of water to represent a drug candidate within the scope of Appellants' claim (*see* Ans. 6 ("One can argue that following such generic instruction a molecule of water can be identified as a drug candidate that inhibits motility of PilT-expressing *Xylella fastidiosa* because a molecule of water can certainly be predicted to form hydrogen bonds with (bind to) any of the recited residues")).

CONCLUSION

The preponderance of evidence on this record fails to support Examiner's finding that Appellants' Specification fails to provide written

[3] Examiner's March 27, 2018 Answer.

descriptive support for the claimed invention. The rejection of claim 1 under the written description provision of 35 U.S.C. § 112, first paragraph is reversed.

Subject Matter Eligibility:

ISSUE

Does the preponderance of evidence of record support Examiner's finding that Appellants' claimed invention is directed to patent ineligible subject matter?

PRINCIPLES OF LAW

An invention is patent-eligible if it claims a "new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. However, the Supreme Court has long interpreted 35 U.S.C. § 101 to include implicit exceptions: "'[l]aws of nature, natural phenomena, and abstract ideas'" are not patentable. *E.g.*, *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (quoting *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013)).

In determining whether a claim falls within an excluded category, we are guided by the Supreme Court's two-step framework, described in *Mayo* and *Alice*. *Id.* at 217–18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). In accordance with that framework, we first determine what concept the claim is "directed to." *See Alice*, 573 U.S. at 219 ("On their face, the claims before us are drawn to the concept of intermediated settlement, *i.e.,* the use of a third party to mitigate settlement risk."); *see also Bilski v. Kappos*, 561 U.S. 593, 611 (2010) ("Claims 1 and 4

in petitioners' application explain the basic concept of hedging, or protecting against risk.").

Concepts determined to be abstract ideas, and thus patent ineligible, include certain methods of organizing human activity, such as fundamental economic practices (*Alice*, 573 U.S. at 219–20; *Bilski*, 561 U.S. at 611); mathematical formulas (*Parker v. Flook*, 437 U.S. 584, 594–95 (1978)); and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 69 (1972)). Concepts determined to be patent eligible include physical and chemical processes, such as "molding rubber products" (*Diamond v. Diehr*, 450 U.S. 175, 191 (1981)); "tanning, dyeing, making water-proof cloth, vulcanizing India rubber, smelting ores" (*id.* at 183 n.7 (quoting *Corning v. Burden*, 56 U.S. 252, 267–68 (1854))); and manufacturing flour (*Gottschalk*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876))).

In *Diehr*, the claim at issue recited a mathematical formula, but the Supreme Court held that "[a] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula." *Diehr*, 450 U.S. at 176; *see also id.* at 191 ("We view respondents' claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula."). Having said that, the Supreme Court also indicated that a claim "seeking patent protection for that formula in the abstract . . . is not accorded the protection of our patent laws, . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment." *Id.* (citing *Gottschalk* and *Parker*); *see, e.g.*, *id.* at 187 ("It is now commonplace that an *application* of a law of nature or mathematical

formula to a known structure or process may well be deserving of patent protection.").

If the claim is "directed to" an abstract idea, we turn to the second step of the *Alice* and *Mayo* framework, where "we must examine the elements of the claim to determine whether it contains an inventive concept sufficient to transform the claimed abstract idea into a patent-eligible application." *Alice*, 573 U.S. at 221 (quotation marks omitted). "A claim that recites an abstract idea must include 'additional features' to ensure 'that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].'" *Id.* (quoting *Mayo*, 566 U.S. at 77). "[M]erely requir[ing] generic computer implementation[] fail[s] to transform that abstract idea into a patent-eligible invention." *Id.*

The PTO recently published revised guidance on the application of § 101. USPTO, *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50 (January 7, 2019) ("Revised Guidance"). 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 activity 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)).

See 84 Fed. Reg. 54–55. 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 are 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 84 Fed. Reg. 51.

ANALYSIS

> Examiner finds that Appellants' claimed
>
> method includes the steps of selecting target amino acid residues corresponding to residues of interest and of identifying drug candidates predicted to bind thereto. Selecting an amino acid residue is a decision-making step, and a *de novo* drug design and virtual screening are steps of processing information through mathematical concepts such as algorithms and calculations.

(Final Act. 3.) Thus, Examiner finds that Appellants' claim is directed to a mental process and mathematical concept (*see id.* at 3–4). Specifically, Examiner finds that "selecting an amino acid residue is a decision-making step, and [the] de novo drug design and virtual screening are steps of processing information through mathematical concepts such as algorithms and calculations" (*id.* at 4; *see* Ans. 4 ("step b) [of Appellants' claim] is viewed as merely a step of processing information by using mathematical algorithms")). In addition, Examiner finds that Appellants' claim contains "no additional elements that would amount to significantly more than the above-identified judicial exception" (*id.* at 3; *see id.* at 4 ("There are no elements in the claims which are in addition to the elements drawn to judicial exception and which are not drawn to generic technology and are well understood, routine, or conventional")). We are not persuaded.

Examiner has not established that Appellants' claim is directed to certain methods of organizing human activity that are recognized in the Revised Guidance. Examiner also failed to establish an evidentiary basis on

this record to support a finding that Appellants' claim is a mental process capable of being performed in the human mind. In this regard, we find no evidence of record to support a finding that a person of ordinary skill in this art would have considered a method of identifying drug candidates that inhibit motility of PilT-expressing *Xylella fastidiosa* to represent a mental process capable of being performed in the human mind.

In addition, even if we interpret Appellants' claim 1 to recite a mathematical concept and, therefore, an abstract idea, we find that Appellants' claimed invention integrates any such recited mathematical concept into a practical application, specifically, the identification of drug candidates that inhibit motility of PilT-expressing *Xylella fastidiosa* (*see* Br. 18). Thus, Appellants' claim 1 is a chemical process and is, therefore, a patent eligible process. *See Diehr*, 450 U.S. at 192.

CONCLUSION

The preponderance of evidence of record fails to support Examiner's finding that Appellants' claimed invention is directed to patent ineligible subject matter. The rejection of claim 1 under 35 U.S.C. § 101 is reversed.

REVERSED