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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LEO T. FURCHT,
CATHERINE M. VERFAILLIE, and
MORAYMA REYES[1]

Appeal 2019-004165
Application 12/907,495
Technology Center 1600

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and
RYAN H. FLAX, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

The claims in this appeal are directed to a method for identifying an agent that affects a desired cellular response. The Examiner rejected the claims under 35 U.S.C. § 101 as reciting patent ineligible subject matter and under § 112 as lacking a written description. Pursuant to 35 U.S.C. § 134(a), Appellant appeals the Examiner's determination that the claims are unpatentable. We have jurisdiction for the appeal under 35 U.S.C. § 6(b).

We REVERSE

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as ABT Holding Company and Regents of the University of Minnesota, the Assignees of an undivided interest in the application. Appeal Br. 3 (entered Dec. 17, 2018).

STATEMENT OF THE CASE

This appeal is related to the appeals in Application Nos. 12/416,627 (Appeal 2017-004349, now issued as U.S. Pat. 9,974,809 B2), 12/416,700 (Appeal 2017-004123, now issued as U.S. Pat. 9,974,811 B2), 12,416,672 (Appeal 2017-004122, now issued as U.S. Pat. 9,974,810 B2), and 12/416,715 (Appeal 2017-004124, now issued as U.S. Pat. 10,006,004 B2). *See* Appeal Br. 4.

Claims 102–110, 112–119, and 121–123 stand rejected by the Examiner as follows:

1. Claims 102–110, 112–119, and 121–123 under 35 U.S.C. § 101 because the claimed invention is directed to an abstract idea. Ans. 5. The Examiner designated the rejection as a new ground of rejection based on the PTO's recently published revised guidance on the application of 35 U.S.C. § 101. USPTO's January 7, 2019 Memorandum, 2019 Revised Patent Subject Matter Eligibility.

2. Claims 102–110, 112–119, 121–123 under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. Final Act. 11.

There are two independent claims on appeal, claims 102 and 114. We select claim 102 as representative of the rejected claims. Claim 102 is reproduced below:

> 102. A method for identifying an agent that affects a desired cellular response, the method comprising:
>
> a) contacting an isolated culture-expanded cell population with a desired agent, wherein the cells of the population are not embryonic stem cells, embryonic germ cells, or germ cells, express oct4 and/or telomerase and are not tumorigenic, and have undergone at least 10-40 cell doublings in culture prior to being contacted with the agent;
>
> b) determining whether said agent affects said cellular response in said cells of the population.

Independent claim 114 has the same limitations as claim 102, but the cell population has additional limitations. Consequently, the same reasoning discussed below for claim 102 applies to claim 114.

SECTION 101 REJECTION

The Examiner rejected claims 102–110, 112–119, and 121–123 under 35 U.S.C. § 101 as directed to a judicial exception to patent eligibility. Ans. 3. The Examiner found that the claims are directed to an abstract idea.

Principles of Law

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," however, not every discovery is eligible for patent protection. *See Diamond v. Diehr*, 450 U.S. 175, 185 (1981). "Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas." *Id.* The Supreme Court articulated a two-step analysis to determine whether a claim falls within an excluded category of invention. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014); *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 566 U.S. 66, 75–77 (2012).

In the first step, it is determined "whether the claims at issue are directed to one of those [laws of nature, natural phenomena, and abstract ideas] patent-ineligible concepts." *Alice*, 573 U.S. at 217. If it is determined that the claims are directed to an ineligible concept, then the second step of the two-part analysis is applied in which it is asked "[w]hat else is there in the claims before us?" *Id.* The Court explained that this step involves

> 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, 573 U.S. at 217–18 (citing from *Mayo*, 566 U.S. at 75–77).

Alice, relying on the analysis in *Mayo* of a claim directed to a law of nature, stated that in the second part of the analysis, "the elements of each claim both individually and 'as an ordered combination'" must be considered "to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Alice*, 573 U.S. at 217.

The PTO has published revised guidance on the application of 35 U.S.C. § 101. USPTO's January 7, 2019 Memorandum, *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50, 51–57 (2019) ("2019 Eligibility Guidance"). This guidance provides additional direction on how to implement the two-part analysis of *Mayo* and *Alice*.

Step 2A, Prong One, of the 2019 Guidelines, instructs us to look at the specific limitations in the claim to determine whether the claim recites a judicial exception to patent eligibility. Step 2A, Prong Two, instructs us to examine the claims to identify whether there are additional elements in the claims that integrate the exception in a practical application, or, put

differently, whether there is a "meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception." 84 Fed. Reg. 54 (2. Prong Two).

If the claim recites a judicial exception that is not integrated into a practical application, then as in the *Mayo/Alice* framework, Step 2B of the 2019 Guidelines instructs us to determine whether there is a claimed inventive concept to ensure that the claims define an invention that is significantly more than the ineligible concept, itself. 84 Fed. Reg. 56. In making this Step 2B determination, we must consider whether there are specific limitations or elements recited in the claim "that are not well-understood, routine, conventional activity in the field, which is indicative that an inventive concept may be present" or whether the claim "simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception, indicative that an inventive concept may not be present." 84 Fed. Reg. 56 (footnote omitted).

With these guiding principles in mind, we proceed to determine whether the claimed subject matter in this appeal is ineligible for patent protection under 35 U.S.C. § 101. As explained in more detail below, we conclude that the claims are directed to patent-eligible subject matter.

Step 2A, Prong One

In Step 2A, Prong One, of the 2019 Guidelines, the specific limitations in the claim are examined to determine whether the claim recites a judicial exception to patent eligibility, namely whether the claim recites an abstract idea, law of nature, or natural phenomenon.

The Examiner found that the claims "encompass an abstract idea, since they broadly claim *in vitro* testing of a cell-type, with almost no true limitation." Final Act. 4. As an example, the Examiner stated that "the claims recite 'contacting a cell with a *desired* agent', and *determining* whether the agent affects the cell," which, because "the *desired* agent is entirely unnamed, the Applicant has, quite literally, abstractly claimed the limitation." *Id.* The Examiner also stated, "a 'desired agent' is not a tangible material, because it require the artisan to 'desire' a particular agent." Ans. 11. The Examiner also stated:

> There is nothing in the claims that provide any direction, because the claims describe the abstract methods of merely "contacting" a cell with an unnamed and unclaimed *agent* in order to acquire an unnamed and unclaimed "desired cellular response."

Final Act. 5.

> The Examiner also found that the "determining" step in the claim,
>
> merely requests the ordinary artisan to determine if a cellular response is present, and since cell viability can be considered a 'desired cellular response,' essentially any cellular physiological reaction to said *agent* would apply. In order to be patent eligible, the claimed method must amount to significantly more than an abstract idea.

Final Act. 10

The Examiner's rejection under 35 U.S.C. § 101 is based on the breadth of the claim. As summarized above, the Examiner considers the claim to be directed to an abstract idea and "abstract research plan" (Ans. 5) because the claims do not specify a specific agent or specific cellular response to it. For this reason, the Examiner states that "the method of using the cell is still claimed as an abstract idea." Ans. 8.

We conclude there is insufficient support for the Examiner's finding that the claim recites an abstract idea because the "agent" and "cellular response" is not specifically identified in the claim. The 2019 Guidance identifies three groupings of abstract ideas — mathematical concepts, certain methods of organizing human activity, and mental process. 84 Fed. Reg. 52. The Examiner did not identify the specific grouping into which the claimed steps fall, let alone explain how claiming an agent and cellular response in broad terms would lead to their classification as an abstract idea as clarified in the 2019 Guidelines. The Examiner's view is that the claim is abstract because it recites "no particular concrete or tangible form." Ans. 10. However, an agent is physical material and a cellular response is a tangible response to the agent. The Specification discloses examples of both. For example, a desired agent can be "[n]ew drugs, antibodies or other compounds." Spec. 21:10-11. It can also be a cytokine, chemokines, hormones, chemotherapeutic agent, or growth factor. *Id.* at 159:2–15. A cellular response can be the expression of genes or proteins induced by the agent. *Id.* at 21:2–5. Thus, after consulting the Specification, one of ordinary skill in the art would understand that the terms recited in the claims are not "abstract ideas" as characterized by the Examiner.

The Examiner's statement that the recited "desired agent" is not "tangible" because it requires the skilled worker to "desire" it (Ans. 11) is not a reasonable reading of the claim. The term "desired"[2] is being used in the claim to mean the "selected" agent, i.e., the agent chosen for the assay.

[2] "deemed correct or proper; selected; required." https://www.dictionary.com/browse/desired (last accessed Sept. 3, 2019).

The Examiner also found that the claimed "determining" step "merely requests the ordinary [skilled] artisan to determine if a cellular response is present." Ans. 5–6. This step recites a mental process, one of the categories of abstract idea recognized in the 2019 Guidelines, because "determining" is an "observation" or "evaluation." 84 Fed. Reg. 52. Thus, we agree with the Examiner that the recited "determining" step recites an abstract idea.

The cell population utilized in the claims are characterized in the claim as follows: "are not embryonic stem cells, embryonic germ cells, or germ cells, express oct4 and/or telomerase and are not tumorigenic, and have undergone at least 10-40 cell doublings in culture prior to being contacted with the agent." If such a cells were a naturally occurring cell population, then there could be basis to find that the claim recites a natural phenomenon because the claimed method determines such cell population's response to an agent – in the same way the body's response to a drug was determined in *Mayo*. *Mayo,* 566 U.S. at 75, 79, 82. In other words, the claims would encompass a naturally-occurring cell's response to an agent as did the claims in *Mayo*. However, Appellant argues that the cells do not exist in nature and that decisions in four *ex parte* appeals before the Board, referenced above, agree that the cell population is novel, non-obvious, and therefore not naturally-occurring. Appeal Br. 7, 29. The Examiner did not respond to this argument or distinguish the claimed cells from those in the prior appeals or establish that the claimed cells are naturally-occurring. As explained in *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980):

> Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His

> discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.

Therefore, we are not persuaded that the claimed cells, and the cellular response evoked in them, constitute a natural phenomenon or law of nature. "That one way of describing the process is to describe the natural ability of the subject matter to undergo the process does not make the claim "directed to" that natural ability." *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1049 (Fed. Cir. 2016)

In sum, we find that the claim recites a mental process, i.e., the recited "determining" step, and therefore proceed to Step 2A, prong 2, to determine whether the exception is integrated into a practical application.

Step 2A, Prong Two

Under Prong Two of Step 2A, when determining whether the exception is integrated into a practical application, as per the *Mayo*/*Alice* framework, we must look at the claim elements individually and "as an ordered combination" to determine whether the additional elements integrate the recited abstract idea into a practical application.

The Examiner stated that the judicial exception is not integrated into a practical application. The Examiner explained:

> This judicial exception is not integrated into a practical application because the claims define *in vitro* cellular testing in their most basic form. The claim(s) does/do not include additional elements that are sufficient to amount to significantly more than the judicial exception because the instant claims are drawn to the cause-and-effect relationship of applying an "agent" to a specific cell, as a means of determining the cells physiological response.

Ans. 5.

Appellant contends that the Examiner erred. Appellant argues that the practical application is "contacting the cells with an agent, assessing the effect of the agent on a physiological response in the cell, and thereby identifying agents that have an effect on a particular physiological response." Reply Br. 6–7. Appellant further states that "the claim as a whole has a practical application because it allows the identification of agents that can affect important cellular processes." *Id.* at 7. Appellant's argument is supported by the disclosure in the Specification.

The Specification discloses various uses of the claimed cells (multipotent adult stem cells or "MASCS"):

> In the method of using MASCs to characterize cellular responses to biologic or pharmacologic agents, or combinatorial libraries of such agents, MASCs are isolated from a statistically significant population of individuals, culture expanded, and contacted with one or more biologic or pharmacologic agents. . . . By comparing the one or more cellular responses of the MASC cultures from individuals in the statistically significant population, the effects of the biologic or pharmacologic agent can be determined. Alternately, genetically identical MASCs, or cells differentiated therefrom, can be used to screen separate compounds, such as compounds of a combinatorial library.

Spec. 159:18–28.

The Specification also discloses:

> Most important, the cells of the present invention provide a source of cultured cells from a variety of genetically diverse individuals who may respond differently to biologic and pharmacologic agents.

Spec. 160:5–8.

The Specification discloses numerous agents that can be tested, including known and unknown agents:

> Cytokines, chemokines, pharmaceutical compositions and growth factors, for example, can therefore be screened in a timely and cost-effective manner to more clearly elucidate their effects. . . . to a range of substances such as, for example, pharmaceutical compositions, vaccine preparations, cytotoxic chemicals, mutagens, cytokines, chemokines, growth factors, hormones, inhibitory compounds, chemotherapeutic agents, and a host of other compounds or factors.

Spec. 159:2–15.

Based on such disclosure, Appellant argues that they invented a *non-naturally occurring cell population*, which is useful in a practical application to elucidate the effects of known and unknown biologic or pharmacologic agents and to determine the different response to agents by genetically diverse individuals from which the cells are derived. The cellular responses are rooted in a non-naturally occurring cell line. Therefore, the claim does not attempt to monopolize any exception based on a mental process or a natural phenomenon because it is integrated and an improvement to the particular technology based on the non-naturally occurring cell line. 84 Fed. Reg. 55.

In response, the Examiner stated that "there does not appear to be any practical applications claimed for the instant method" (Ans. 14). However, the Examiner did not address Appellant's express statement in the Appeal Brief (at 11–12) or the disclosure in the Specification explaining how the claimed cells can be used in a practical application. The Examiner did not explain why the uses disclosed in the Specification for the non-naturally occurring cell population are not practical applications.

In sum, the mental concept of "determining whether said agent affects said cellular response in said cells of the population" is integrated into a practical application because it is an observation performed after the claimed

manipulative steps of the method are carried out. The manipulative steps of the claim impose a meaningful limit on the abstract idea.

Summary

Because the Examiner did not establish that the claims as a whole are directed to an abstract idea, the rejection of independent claim 102 and 114, and dependent claims 103–110, 112, 113, 115–119, and 121–123 under § 101 is reversed.

WRITTEN DESCRIPTION REJECTION

The Examiner rejected the claims as lacking a written description because "[g]iven the broadest reasonable interpretation of 'an agent,' and a 'desired cellular response,' and given that the instant specification does not present with enough detail to suggest that all of the embodiments of the instant claim were in possession of the inventor at the time of filing." Final Act. 11.

35 U.S.C. § 112 requires a written description of the claimed invention that allows a person of skill in the art to recognize that the inventor invented what is claimed. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). To that end, to satisfy the written description requirement, the inventor "must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563−64 (Fed. Cir. 1991). "One shows that one is 'in possession' of

the invention by describing the invention, with all its claimed limitations." *Lockwood v. Am. Airlines, Inc*., 107 F.3d 1565, 1572 (Fed. Cir. 1997) (internal citation omitted).

In this case, what is "claimed" is a method of contacting a cell population with a "desired agent" and then determining whether the agent "affects" a cellular response of the recited cell population. The Specification describes such a method. Spec.21:1–13,158:21–159:15 (section titled "20. MASCs Provide a Variety of Differentiated and Undifferentiated Cultured Cell Types for High-Throughput Screening").

The Examiner states, however, there is insufficient detail about the method disclosed in the Specification. We do not agree. The Specification describes a list of agents that can be used in the claimed method. These agents are disclosed in the Specification at pages 21and 159, and include new drugs, antibodies, cytokines, chemokines, hormones, chemotherapeutic agent, and growth factor. Spec. 159:2–15 (disclosure reproduced *supra*). Thus, the Specification provides a disclosure evidencing that Appellant had possession of the claimed group of "desired agents." Cellular responses are also disclosed, for example, gene and protein expression responses to an agent. Spec. 21:2–5.

The claimed method, as discussed by Appellant, is not directed to a new agent or cellular response, but rather is directed to a method of determining the response of the claimed non-naturally occurring cell population to an agent to determine. It is not necessary to list all possible agents in the specification in order for one skilled in the art to describe the claimed method because the characteristics of the individual agents are irrelevant to how they are evaluated using the claimed testing method.

Unlike *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), where the court required the written description to sufficiently define the genus to allow one skilled in the art to "visualize or recognize the identity of the members of the genus," the agents in this appeal are not asserted to be novel or the inventive concept of the claims as they were in *Lilly*.

For the foregoing reasons, the written description of claims 102–110, 112–119, and 121–123 is reversed.

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
102–110, 112–119, and 121–123	§ 101		102–110, 112–119, and 121–123
102–110, 112–119, and 121–123	§ 112		102–110, 112–119, and 121–123
Overall Outcome			102–110, 112–119, and 121–123

REVERSED