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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte TOAN-THANG PHAN and IVOR JIUN LIM¹

Appeal 2017-002349
Application 11/205,248
Technology Center 1600

Before TAWEN CHANG, JOHN E. SCHNEIDER, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 of the Examiner's rejection of claims to stem cell populations which have been rejected as directed to non-statutory subject matter. We have jurisdiction under 35 U.S.C. § 6(b).²

We REVERSE.

¹ Appellants identify the Real Party in Interest as CellResearch Corporation Pte Ltd. Appeal Br. 4.

We have considered and herein refer to the Specification of Aug. 15, 2005 ("Spec."); Final Office Action of Jan. 20, 2016 ("Final Act."); Appeal Brief of June 30, 2016 ("Br."); and Examiner's Answer of Oct. 4, 2016 ("Ans.").

² An oral hearing was held on Nov. 1, 2018. A transcript of the hearing will be added to the file when it becomes available.

STATEMENT OF THE CASE

“Stem cells are a cell population possessing the capacities to self-renew indefinitely and to differentiate in multiple cell or tissue types.” Spec. ¶ 3. One source of stems cells is umbilical cord tissue, specifically Wharton’s jelly, the matrix of the umbilical cord. Spec. ¶ 8. While umbilical cord tissue has been successfully used to produce stem cells, the tissue has not yielded epithelial stem cells, which can be used for epithelial cell based therapies such as skin resurfacing, liver repair, bladder tissue engineering and the like. Spec. ¶ 9. The Specification describes methods for producing stem cells that can differentiate into epithelial cells. Spec. ¶ 13.

Claims 11, 13–15, 37, 40, and 44–45 are on appeal. Claim 11 is illustrative and reads as follows:

11. An epithelial stem/progenitor cell population isolated from the amniotic membrane of umbilical cord, the epithelial stem/progenitor cell population having the capacity to differentiate in multiple cell types and being isolated by a method comprising:

(a) separating the amniotic membrane from the other components of the umbilical cord *in vitro*;

(b) culturing the amniotic membrane tissue obtained in (a) as a tissue explant, or

culturing amniotic membrane cells separated from the amniotic membrane tissue obtained in (a), under conditions allowing cell proliferation of epithelial stem/progenitor cells without differentiation of the epithelial stem/progenitor cells; and

(c) harvesting the stem/progenitor cells and wherein the stem/progenitor cells have a polyhedral shape, express the following genes: POU5f1, Bmi-1, leukemia inhibitory

factor (LIF), and wherein the stem/progenitor cells secretes Activin A and Follistatin.

Claims 11, 13–15, 37, 40, and 44–45 have been rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter.

DISCUSSION

Issue

The issue raised by this rejection is whether the Examiner has established that the claimed cell population is patent ineligible because it is not markedly different from the amniotic membrane cell population that exists *in vivo*.

The Examiner has determined that the claimed cells are not markedly different from those which exist in nature. Final Act. 3. The Examiner finds that the process limitations in the claims do not amount to something significantly more than the judicial exception in that they do not provide any structural characteristics that are not found in nature. *Id.* The Examiner contends that even if the cells do exhibit differences from those occurring in nature, the cells remain ineligible for patent protection in that they are derived from natural sources. *Id.* at 4.

Appellants contend that the claimed cells present patent eligible subject matter in that the claimed cells do not occur in the absence of human efforts. Appeal Br. 7. Appellants argue that the process steps recited in the claims produce cells with markedly different characteristics than the cells found in nature. *Id.*

In support of their arguments Appellants point to the Declarations of Professor Phan³, one of the inventors. In his fifth declaration, Professor Phan states that the culturing step recited in the claims produces cells which are markedly different from those found in the umbilical cord. 5th Phan Decl. ¶ 5. In his 6th declaration Professor Phan discusses experiments he conducted comparing the traits of the stem cells following the culturing process recited in the claims with cells taken from the source tissue. 6th Phan Decl. ¶¶ 9–11. The Experiments reported by Professor Phan showed that the stem cells produced by the claimed culturing process expressed markers of Oct-4 and Nanog, which are stem cell markers, whereas the cell taken directly from the amniotic membrane without culturing did not. *Id.* Professor Phan concludes that the cells produced by the process recited in the claims are markedly different from those found in nature. 6th Phan Decl. ¶ 12.

Principles of Law

35 U.S.C. § 101 states that “[w]hoever invents or discovers any new useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

“Laws of nature, natural phenomena, and abstract ideas are not patentable.” *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S.

³ Declaration Under 37 C.F.R. 1.132: Fifth Declaration of Professor Toan-Thang Phan, MD, PhD, filed Apr. 7, 2015, (“5th Phan Decl.”) and Declaration under 37 CFR 1-132: Sixth Declaration of Professor Toan-Thang Phan, MD, PhD, filed Dec. 9, 2015 (“6th Phan Decl.”). —

66, (2012) (citation omitted). The Supreme Court articulated a two-step test for patent eligibility under § 101 that “distinguish[es] patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.” *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014) (citing *Mayo*, 566 U.S. at 72–73). “First,” *Alice* instructs us to “determine whether the claims at issue are directed to one of those patent-ineligible concepts.” *Id.* (citation and quotations omitted). If the claims are directed to a patent ineligible concept then the court must proceed to the second step of the test: the “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.* (internal quotation marks and brackets omitted).

When the invention is alleged to be a product of nature (*i.e.*, a natural phenomenon), the patent-eligibility inquiry concerns whether the product is “new ‘with markedly different characteristics’” than anything found in nature. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 577, 589–590 (2013).

“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

Analysis

We have considered the parties' arguments and conclude that the Examiner has not set forth a prima facie case that the claimed subject matter falls within one of the judicial exceptions. The Examiner has not provided persuasive scientific reasoning or evidence sufficient to show that the cells found in nature have the same properties as the cells flowing from the recited cultivation steps. Moreover, even if the Examiner has presented a prima facie case, Appellants have presented persuasive rebuttal evidence that the cells produced by the process recited in the claims are markedly different than the cells found in nature.

The Examiner contends that the cells' ability to express the specific markers recited in the claims are innate properties of the cells. Ans. 5. The Examiner contends that

Appellant merely provides the cells a different environment by culturing them in vitro using a culture medium, which is a different environment from in vivo, and as a result, the cells adapt to the environment, and modify by themselves the expression profile of their genes and gene products accordingly, and this is independent of Appellant's intension [sic].

Ans. 6.

We have considered the Examiner's arguments and find them unpersuasive. To begin, the Examiner has produced no persuasive evidence to show that the amniotic membrane cells have the recited characteristics in vivo. *See*, Ans. 4–5. In contrast, Appellants have shown that the amniotic cells do not exhibit the recited traits without the culturing steps recited in the claims. As shown in Professor Phan's 6th declaration, amniotic cells were

tested for Oct-4 and Nanog expression. 6th Phan Decl. ¶ 10–11. No expression to Oct-4 or Nanog could be detected in the amniotic tissue cells. *Id.* Thus the weight of the evidence of record supports a finding that the cells in vivo do not express the recited characteristics.

The Examiner contends that even though the amniotic cells do not express the recited characteristics in vivo, the amniotic membrane cells are used as the source of the recited cells and thus represent a product of nature. Ans. 4–5. The Examiner contends that Appellants have not manipulated the cells to make them express specific markers or possess the claimed phenotype. Ans. 5. Again we are not persuaded.

Referring again to Professor Phan’s 6th declaration, Appellants have submitted evidence that after culturing the cells as required by the claims, the cells do express the recited markers and express a different phenotype than found in vivo. 6th Phan Decl. 11. We agree with Appellants, based on the argument and evidence of record, that the claimed cells are markedly different from the amniotic membrane cells found in nature.

Conclusion

We conclude that the Examiner has failed to establish that the claimed cell population is not patent eligible.

SUMMARY

We reverse the rejection under 35 U.S.C. § 101.

REVERSED