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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HENRY E. YOUNG and ASA BLACK

Appeal 2017-006731¹
Application 11/574,622
Technology Center 1600

Before DONALD E. ADAMS, FRANCISCO C. PRATS, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims to isolated stem cells in combination with a liquid serum-free defined medium. The Examiner rejected the claims as being directed to subject matter ineligible for patenting.

We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The sole rejection before us for review is the Examiner's rejection of claims 1, 3–12, and 25–35, as being directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more. Ans. 3–10.

¹ The Real Party in Interest is Moraga Biotech Corporation. App. Br. 2.

Claims 1 and 25, the independent claims on appeal, illustrate the appealed subject matter and read as follows:

1. An isolated stem cell in combination with a liquid medium, comprising:

a viable at least pluripotent and purified post-natal stem cell having a size of equal or less than 1 μm , expressing surface marker CEA-CAM-1, and not expressing surface markers SSEA-1, SSEA-3, and SSEA-4, and wherein the viable post-natal stem cell is further characterized by trypan-blue staining;

wherein the liquid medium is a liquid serum-free defined cell culture medium that is formulated to allow in the absence of differentiation inhibitors cultivation of the stem cell over more than 100 doublings without loss of normal karyotype while preserving totipotent character,

wherein the stem cell is a mammalian cell having surface marker CD66e and not CD10;

wherein the stem cell expresses at least one of, Oct-3/4, Nanog, Nanos, BMI-1, IDE1, IDE3, ABCG2, CXCR-4, and BCL-2, and wherein the cell does not express at least one of CD1 a, CD2, CD3, CD4, CD5, CD7, CDB, CD9, CD11 b, CD11 c, CD13, CD14, CD15, CD16, CD18, CD19, CD20, CD22, CD23, CD24, CD25, CD31, CD33, CD34, CD36, CD38, CD41, CD42b, CD45, CD49d, CD55, CD56, CD57, CD59, CD61, CD62E, CD65, CD68, CD69, CD71, CD79, CD83, CD90, CD95, CD105, CD106, CD117, CD123, CD135, CD166, Glycophorin-A, MHC-I, HLA-DRII, FMC-7, Annexin-V, and LIN; and

wherein the stem cell expresses telomerase, and wherein the cell does not express MHC-I.

25. A stem cell culture, comprising:
an isolated viable at least pluripotent and purified
post-natal stem cell having a size of equal or less
than 1 μm , expressing surface marker
CEA-CAM-1, and not expressing surface markers
SSEA-1, SSEA-3, and SSEA-4, and wherein the
viable post-natal stem cell is further characterized
by trypan-blue staining;
***wherein the stem cell is disposed in a liquid serum-free
defined cell culture medium in the absence of
differentiation inhibitors that allows cultivation
of the stem cell over more than 100 doublings
without loss of normal karyotype while preserving
totipotent character***, wherein the stem cell is a
mammalian cell having surface marker CD66e and
not CD10;
wherein the stem cell expresses at least one of
telomerase, Oct-3/4, Nanog, Nanos, BMI-1, IDE1,
IDE3, ABCG2, CXCR-4, and BCL-2, and wherein
the cell does not express at least one of CD1 a,
CD2, CD3, CD4, CD5, CD7, CDB, CD9, CD11 b,
CD11 c, CD13, CD14, CD15, CD16, CD18,
CD19, CD20, CD22, CD23, CD24, CD25, CD31,
CD33, CD34, CD36, CD38, CD41, CD42b, CD45,
CD49d, CD55, CD56, CD57, CD59, CD61,
CD62E, CD65, CD68, CD69, CD71, CD79,
CD83, CD90, CD95, CD105, CD106, CD117,
CD123, CD135, CD166, Glycophorin-A, MHC-I,
HLA-DRII, FMC-7, Annexin-V, and LIN; and
wherein the stem cell expresses telomerase, and wherein
the cell does not express MHC-I.

Appeal Br. 37–38, 39–40 (emphasis added to show claim limitation at
issue).

STANDARD OF REVIEW

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

[T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .

After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

DISCUSSION

The Examiner's Prima Facie Case

In concluding that claims 1, 3–12, and 25–35 recite subject matter ineligible for patenting, the Examiner found that although the Specification described the isolation and characterization of the stem cells recited in the claims, the Specification nonetheless did not include any “discussion as to markedly different characteristic differences between the stem cell once isolated and the stem cell residing in its tissue counterpart.” Ans. 8–9.

As to the culture medium recited in the claims, the Examiner asserted that isolating stem cells, and their “subsequent culture in medium to prevent differentiation and physical characteristics of the stem cells are each well-understood, routine and conventional in field stem cell biology. All stem cells isolated from tissue are routinely cultured such that remain pluripotent, totipotent or multipotent and are routinely analyzed for physical characteristics.” *Id.* at 9.

Therefore, the Examiner concluded, the rejected claims “do not provide any limitations indicating the claimed isolated stem cell in combination with a liquid medium or a cell culture comprising the isolated stem cells exhibits any characteristics or properties that are significantly

more than the judicial exception, the stem cell residing in its tissue source.”
Id. at 9–10.

Analysis

35 U.S.C. § 101 states that “[w]hoever invents or discovers any new and 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.”

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 Intern.*, 134 S. Ct. 2347, 2354 (2014).

Our reviewing court has summarized the Supreme Court’s two-part test for distinguishing between claims to patent-ineligible exceptions, and claims to patent-eligible applications of those exceptions, as follows:

Step one asks whether the claim is “directed to one of [the] patent-ineligible concepts.” [*Alice*, 134 S. Ct. at 2354]. If the answer is no, the inquiry is over: the claim falls within the ambit of § 101. If the answer is yes, the inquiry moves to step two, which asks whether, considered both individually and as an ordered combination, “the additional elements ‘transform the nature of the claim’ into a patent-eligible application.” *Id.* (quoting *Mayo [Collaborative Services v. Prometheus Labs, Inc.]*, 132 S. Ct. 1289, 1297 (2012)).

Step two is described “as a search for an ‘inventive concept.’” *Id.* (quoting *Mayo*, 132 S. Ct. at 1294). At step two, more is required than “well-understood, routine, conventional activity already engaged in by the scientific community,” which fails to transform the claim into “significantly more than a

patent upon the” ineligible concept itself. *Mayo*, 132 S. Ct. at 1298, 1294.

Rapid Litigation Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016) (paragraphing added).

In the present case, Appellants persuade us that the preponderance of the evidence does not support the Examiner’s conclusion that the rejected claims recite subject matter ineligible for patenting. In particular, even if we were to agree with the Examiner that the rejected claims are directed to a natural phenomenon, i.e., stem cells, Appellants persuade us (*see* Appeal Br. 25–26; Reply Br. 20–21) that the Examiner has not shown sufficiently that the additional features recited in the claims constitute well-understood, routine, conventional activity already engaged in by skilled artisans in the field of stem cell research.

As seen above, in addition to stem cells, both independent claims on appeal recite compositions that also contain “a liquid serum-free defined cell culture medium that is formulated to allow in the absence of differentiation inhibitors cultivation of the stem cell over more than 100 doublings without loss of normal karyotype while preserving totipotent character.” Appeal Br. 37 (claim 1); *see also id.* at 39–40 (claim 25 reciting “a liquid serum-free defined cell culture medium in the absence of differentiation inhibitors that allows cultivation of the stem cell over more than 100 doublings without loss of normal karyotype while preserving totipotent character”).

In setting out the *prima facie* case, the Examiner asserts that culturing stem cells “in medium to prevent differentiation . . . [is] well-understood, routine and conventional in field stem cell biology. All stem cells isolated from tissue are routinely cultured such that remain pluripotent, totipotent or multipotent and are routinely analyzed for physical characteristics.” Ans. 9.

In setting out the rejection, however, in addition to failing to acknowledge the specific features of the recited culture medium, e.g., that the medium is serum-free, the Examiner did not identify any specific evidence, in the Specification or otherwise, to support the assertion that the culture medium recited in claims 1 and 25 was merely a well-understood conventional element routinely combined with stem cells. *See id.* at 3–20 (Examiner’s statement of the rejection).

In response to Appellants’ arguments in that regard, the Examiner cites the Jiang² and Kim³ references. Ans. 11–12 (citing Jiang 41, Kim 583).

We acknowledge Jiang’s disclosure of several cultures of “MAPCs” (multipotent adult progenitor cells) that produced more than 100 doublings (Jiang 41) as Appellants’ claims 1 and 25 require of the recited culture medium. The Examiner, however, does not identify any specific disclosure in Jiang demonstrating that the culture medium used to produce those doublings was conventionally and/or routinely used with stem cells. Nor has the Examiner identified any specific disclosure demonstrating that the medium used to produce those doublings was serum-free, and did not contain differentiation inhibitors, as required by Appellants’ claims 1 and 25.

As to Kim, we acknowledge the use of a medium to culture stem cells, but that medium contains “10% fetal bovine serum” (Kim 583), contrary to

² Yeuhua Jiang et al., *Pluripotency of mesenchymal stem cells derived from adult marrow*, 418 NATURE 41–49 (2002).

³ Jiyoung Kim et al., *Ex Vivo Characteristics of Human Amniotic Membrane-Derived Stem Cells*, 9 CLONING AND STEM CELL 581–594 (2007).

the requirements of Appellants' claims 1 and 25. Thus, like Jiang, Kim fails to support the Examiner's position that a serum-free medium meeting the requirements of Appellants' claims 1 and 25 was merely a well-understood, conventional element skilled artisans routinely combined with stem cells.

Accordingly, even if we were to agree with the Examiner that the rejected claims involve a natural phenomenon, i.e., stem cells, we are not persuaded that the Examiner has presented a sufficient evidentiary basis to support the factual finding that the additional features recited in the claims, i.e., the claimed culture medium having the recited elements, constitute well-understood, routine, conventional activity already engaged in by skilled artisans in the field of stem cell research. *See Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018) ("Whether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination.").

Because the Examiner, therefore, has not shown by a preponderance of the evidence that the combination of features set forth in Appellants' claims is merely a recitation of a natural phenomenon alongside nothing more than well-understood, routine, and conventional elements already engaged in by skilled artisans in the field, we must reverse the Examiner's rejection.

SUMMARY

For the reasons discussed, we reverse the Examiner's rejection of claims 1, 3–12, and 25–35, as being directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more.

Appeal 2017-006731
Application 11/574,622

REVERSED