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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HENRY E. YOUNG and PAUL A. LUCAS

Appeal 2018-004405
Application 12/768,471
Technology Center 1600

BEFORE ERIC B. GRIMES, JOHN E. SCHNEIDER, and DAVID COTTA,
Administrative Patent Judges.

SCHNEIDER, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 47–49 and 51. We have jurisdiction under 35 U.S.C. § 6(b).²

¹ We use the word Appellant to refer to “applicant” as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as ABT Holding Company. Appeal Br. 3.

² Appellant notes that the pending appeal for SN 12/768,411 “may be related to, directly affect, or be directly affected by or have a bearing on the Board’s decision in the pending appeal.” We issued our decision in that case, Appeal 2017-002939, on Oct. 10, 2017, affirming the Examiner’s rejections.

We AFFIRM.

CLAIMED SUBJECT MATTER

The claims are directed to pluripotent stem cells. Claim 47, reproduced below, is illustrative of the claimed subject matter:

47. Isolated cells derived from postnatal human cells or tissues and capable of self-renewal and capable of differentiation to cells of endodermal, ectodermal and mesodermal lineages, wherein the isolated cells express SSEA4 and do not express CD13, the isolated cells having been produced by expanding, in culture, a cultured cell clone from a postnatal human tissue.

The prior art relied upon by the Examiner comprises the following:

Name	Reference	Date
Young et al. (Young '735")	US 5,827,735	Oct. 27, 1998
Young et al., <i>Pluripotent Mesenchymal Stem Cells Reside Within Avian Connective Tissue</i> , In Vitro Cell. Dev. Biol. 29A:723–736 (1993) (“Young 1993”)		
Young et al., <i>Mesenchymal Stem Cells Reside Within the Connective Tissue of Many Organs</i> , Devel. Dynamics 202:137-144 (1995) (“Young 1995”)		
Grande et al., <i>Repair of Articular Cartilage Defects Using Mesenchymal Stem Cells</i> , Tissue Eng'g 1:345–353 (1995)		

The Examiner has rejected the pending claims³ as follows:

Claims 47, 48, and 51 have been rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

³ Claim 52 is pending in the application but has been withdrawn from consideration. Final Act. 1.

Claims 47–49 and 51 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Grande in view of Young 1993.

Claims 47–49 and 51 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Young 1995 in view of Young 1993.

Claims 47–49 and 51 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Young 1993.

Claims 47–49 and 51 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Young '735.

NONSTATUTORY SUBJECT MATTER

Issue

The issue is whether a preponderance of evidence supports the Examiner's finding that claims 47, 48, and 51 are directed to non-statutory subject matter.

The Examiner finds that the claims are directed to a natural phenomenon and do not recite additional elements, which amount to something significantly more than a natural phenomenon. Final Act. 9–12.

Appellant contends that the Examiner has not established that the cells recited in the claims exist in nature. Appeal Br. 10. Appellant argues that the recited cells do not exist in nature in that they have adapted to survive in the environment they are placed in after they are extracted. Appeal Br. 10–11, 14–18. Appellant contends that the Supreme Court's decision in *Ass'n for Molecular Pathology v Myriad Genetics, Inc.*, 133 S. Ct. 2017 (2013) is not relevant on this basis. Appeal Br. 11–14, 19. Similarly Appellant argues that the Federal Circuit's decision in *In re Roslin Institute*, 750 F.3d 1333 (Fed. Cir. 2014), is not relevant in that, in *Roslin*, the cells were not changed by environmental factors as in the present case. Appeal Br. 19–21. Finally,

Appellant argues that the claimed stem cells have a new utility. Appeal Br. 22–23.

Analysis

Appellant does not persuade us that a preponderance of the evidence fails to support the Examiner’s conclusion that claims 47, 48, and 51 recite subject matter ineligible for patenting 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.” 35 U.S.C. § 101. However, the Supreme Court has long interpreted 35 U.S.C. § 101 to include implicit exceptions: “[I]aws of nature, natural phenomena, and abstract ideas” are not patentable. *E.g.*, *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014).

To determine if 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.”).

The Supreme Court has made it clear that naturally occurring organisms are not patentable. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). In *Funk Bros.*, the Supreme Court considered a patent that claimed a mixture of naturally occurring strains of bacteria that helped

leguminous plants extract nitrogen from the air and fix it in soil. 333 U.S. at 128–29. The Court concluded that this mixture of bacteria strains was not patent eligible because the patentee did not alter the bacteria in any way. *Id.* at 132.

In *Chakrabarty v. Diamond*, 447 U.S. 303, 305 (1980), the Court clarified the scope of *Funk*. The patent at issue in *Chakrabarty* claimed a genetically engineered bacterium that was capable of breaking down various components of crude oil. *Id.* at 305. The patent applicant created this non-naturally occurring bacterium by adding four plasmids to a specific strain of bacteria. *Id.* at 305 n. 1. Overturning the Board's rejections, the Court held that the modified bacterium was patentable because it was “new” with “*markedly different characteristics from any found in nature* and one having the potential for significant utility.” *Id.* at 310 (emphasis added). As the Court explained, the patentee's “discovery is not nature's handiwork, but his own.” *Id.*

Accordingly, discoveries that possess “markedly different characteristics from any found in nature,” *id.*, are eligible for patent protection. In contrast, any existing organism or newly discovered plant found in the wild is not patentable. *Id.* at 309; *see also In re Beineke*, 690 F.3d 1344, 1352 (Fed.Cir.2012) (holding that a newly discovered type of plant is not eligible for plant patent protection, in part, because such a plant was not “in any way the result of [the patent applicant's] creative efforts or indeed anyone's creative efforts.”).

In *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), the Court held that claims on two naturally occurring, isolated genes (BRCA1 and BRCA2), which can be examined to determine whether

a person may develop breast cancer, were invalid under § 101. *Id.* at 593. The Supreme Court concluded that the BRCA genes themselves were unpatentable products of nature. *Id.*

If the claim is “directed to” a natural phenomenon, 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.* (alterations in original) (quoting *Mayo*, 566 U.S. at 77).

The PTO published revised guidance on the application of § 101. USPTO’s January 7, 2019 Memorandum, *2019 Revised Patent Subject Matter Eligibility Guidance* (“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 2019 Revised Guidance, 84 Fed. Reg. at 54–55. The USPTO’s October 17, 2019 Memorandum, *October 2019 Update: Subject Matter Eligibility* (“2019 October Update”), confirmed that the 2019 revised Guidance is applicable to claims directed to products of nature, laws of nature or natural phenomenon. 2019 October Update 1–2, available at

https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf. 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 2019 Revised guidance, 84 Fed. Reg. at 55.

As discussed more fully below, we have considered the positions of the Examiner and Appellant and conclude that the claims as drafted are directed to a natural phenomenon without anything significantly more. We therefore agree with the Examiner that the claims are not patent eligible.

Step 2A – Prong 1

In the present case, claim 47 recites “[i]solated cells derived from postnatal human cells or tissue, and capable of self-renewal and capable of differentiation to cells of endodermal, ectodermal, and mesodermal lineages, the cells expressing SSEA4, but not CD13, the isolated cells having been produced by expanding, in culture, a cultured cell clone from a postnatal human tissue.” Appeal Br. 31 (Claims App’x).

We, therefore, agree with the Examiner that, as to part 2A, prong 1 of the test, Appellant’s claim 47 recites a natural phenomenon, namely a human cell having certain characteristics.

Appellant’s arguments do not persuade us to the contrary.

Appellant begins by arguing that the Examiner has not shown that the recited cells exist in nature. Appeal Br. 16. We are unpersuaded. As the Examiner points out

The instantly claimed cells are naturally occurring products. This is evidenced by the disclosure that teaches that the pluripotent embryonic-like stem cells can be isolated from human cells (p. 9, line 20), and specifically from various non-embryonic tissues including muscle, dermis, fat, tendon, ligament, perichondrium, periosteum, heart, aorta, endocardium, myocardium, epicardium, large arteries and veins, granulation tissue, peripheral nerves, peripheral ganglia, spinal cord, dura, leptomeninges, trachea, esophagus, stomach, small intestine, large intestine, liver, spleen, pancreas, parietal peritoneum, visceral peritoneum, parietal pleura, visceral pleura, urinary bladder, gall bladder, kidney; associated connective tissues or bone marrow. See p. 9, lines 23+. Therefore, the cells of the claimed invention are a natural product that is not markedly different in structure from naturally occurring products.

Ans. 5. We agree with the Examiner that the teachings of the Specification support the Examiner's conclusion that the cells exist in nature.

Appellant contends that the recited cells are different from those which exist in nature in that the cells have adapted to exist in vitro. Appeal Br. 12–13. We are unpersuaded. Appellant has not pointed to any specific modifications that have occurred in the recited cells that did not exist in the cells in vivo. Similarly, Appellant has not shown how the isolation and culturing technique used to isolate and culture the recited stem cells induces changes in the cells.

Appellant has submitted evidence that modifications can occur in some cells during the process of culturing the cells, Appeal Br. 14–18, however, Appellant has not established that such changes occur in the

present case. Therefore, we are not persuaded by the articles cited by Appellant.

Appellant's efforts to distinguish the holdings in *Myriad* and *Roslin* are similarly unpersuasive. As the Examiner points out, Appellant has offered no evidence that the specific stem cells recited in the claims are different from those which exist in nature. Ans. 11–12.

Step 2A – Prong 2

With respect to the question of whether there are additional elements which incorporate the exception into a practical application, we find no such elements in the claims as drafted. As noted above, claims 47, 48 and 51 are directed to isolated cells. The claims do not recited any application of the cells. *See* Appeal Br. 31 (Claims App'x).

Step 2B

As to part 2B of the test, we agree with the Examiner that the additional limitations of expanding the cultured cell (claim 47), a culture medium (claim 48), and proliferating the cells beyond 50 cell doublings (claim 51) do not impart something substantially more than the natural phenomenon. The additional limitations recited in claims 47 and 51 do not materially distinguish the cells from those which exist in nature. Final Act. 11–12. The culture limitations of claim 48 do not add something significantly more in that the use of “a medium capable of supporting the proliferation of said cells,” claim 48, Appeal Br. 31, would be a matter of routine, well understood, and conventional activities. *Id.*

Appellant argues that their invention embraces a new use for stem cells. Appeal Br. 22–23. While this may be true, the claims at issue are not

directed to a new use of the cells but to the stem cells themselves and as such, they are directed to patent ineligible subject matter.

We, therefore, agree with the Examiner that, under the Supreme Court's two-part test, claims 47, 48, and 51 recite subject matter ineligible for patenting under § 101.

Conclusion of Law

We conclude that a preponderance of the evidence supports the Examiner's conclusion that claims 47, 48, and 51 are directed to non-statutory subject matter.

OBVIOUSNESS

GRANDE IN VIEW OF YOUNG 1993

Issue

The issue with respect to this rejection is whether a preponderance of the evidence supports the Examiner's conclusion that the rejected claims would have been obvious over Grande in view of Young 1993.

The Examiner finds that Grande teaches using the same starting materials and same method as the present invention. Final Act. 13. The Examiner finds that Grande necessarily produces the same cells as recited in claim 47. *Id.* at 14. The Examiner finds that Grande does not specifically teach diluting the cultured cells its clonal density, culturing the diluted cells, and propagating a single cell to obtain the stem cells recited in the claims. *Id.* The Examiner finds that Young provides such a teaching. *Id.* The Examiner concludes that

it would have been obvious to one of ordinary skill in the art to modify the teachings of Grande, to include clonal analysis of the cells, as taught by Young, with a reasonable expectation of success. One of ordinary skill in the art would have been

motivated to utilize clonal analysis of the cells in order to produce individual cell clones, which would be used to determine pluripotency, or to establish a cell line.

Final Act. 14–15.

Appellant contends that there is no motivation to combine the references, as the specific stem cells claimed were not known to exist at the time the invention was made. Appeal Br. 23. Appellant argues that even if there were a motivation to combine the references, one skilled in the art would not have a reasonable expectation of success. *Id.* at 23–25. Appellant also argues that the present claims are distinguishable over the teachings of the references in that they call for a specific selection step not found in the references. *Id.* at 26–27.

Principles of Law

[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. 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.

In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure.

In re Dow Chemical Co., 837 F.2d 469, 473 (Fed. Cir. 1988) (citations omitted).

Analysis

We adopt the Examiner's findings of fact, reasoning on scope and content of the prior art, and conclusions set out in the Final Office Action and Answer regarding this rejection. We find the Examiner has established that the claims would have been obvious over Grande combined with Young 1993. Appellant has not produced evidence showing, or persuasively argued, that the Examiner's determinations on obviousness are incorrect. Only those arguments made by Appellant in the Briefs have been considered in this Decision. Arguments not presented in the Briefs are waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2015). We have identified claim 47 as representative; therefore, all claims fall with claim 47. We address Appellant's arguments below.

Appellant contends that there is no motivation to combine the references as the claimed cells were not known to exist at the time the invention was made. Appeal Br. 24. We are unpersuaded. As Appellant's Declarant, Dr. Henry E. Young,⁴ admits, the cell mixtures produced by the method of Grande and of Young 1993 contains the claimed cells. Young Decl. 4 ("The Examiner states that Grande's cell mixture (and Young's cell mixture) contains the instantly claimed PPELSCs. This is true."). Appellant has merely used the isolation and culturing techniques disclosed in Young 1993 to isolate the specific stem cells recited in the claims.

Appellant's argument that one skilled in the art would not have a reasonable expectation of success is also unpersuasive. Appeal Br. 24–25. Appellant contends that because of the random nature of Young 1993's

⁴ Declaration of Dr. Henry E. Young, signed June 11, 2013 ("Young Decl.").

cloning technique and the low number of the desired cells in the initial culture, the likelihood of success is very small. *Id.* at 24. We agree with the Examiner that one skilled in the art would have a reasonable expectation of success. Ans. 27–28. The screening of a significant number of samples or clones appears to have been well within the skill of one skilled in the art and would not suggest that isolation of the claimed cells would not be successful. For example, Young 1993 discusses the cloning and analysis of over 1000 clones. Young 1993, Abstract, 728.

Appellant argues that the invention calls for a specific selection step not recited in the references. Appeal Br. 26–27. We remain unpersuaded. As the Examiner points out, the claims do not recite a specific selection technique but merely recite the same technique as taught by the references. Ans. 28.

Conclusion of Law

We conclude that a preponderance of the evidence supports the Examiner’s conclusion that claim 47 would have been obvious over Grande combined with Young 1993.

Claims 48, 49, and 51 have not been argued separately and therefore fall with claim 47. 37 C.F.R. § 41.37(c)(1)(iv).

THE REMAINING OBVIOUSNESS REJECTIONS

Appellant has presented essentially the same arguments against the rejections based on Young 1995 combined with Young 1993, Young 1993 alone, and Young ’735. Appeal Br. 27–28. For the reasons stated above, we affirm these rejections.

CONCLUSION

The Examiner's rejection under 35 U.S.C. § 101 is affirmed.

The Examiner's rejections under 35 U.S.C. § 103(a) are affirmed

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
47, 48, 51	101	Eligibility	47, 48, 51	
47-49, 51	103	Grande, Young 1993	47-49, 51	
47-49, 51	103	Young 1995, Young 1993	47-49, 51	
47-49, 51	103	Young 1993	47-49, 51	
47-48, 51	103	Young '735	47-49, 51	
Overall Outcome			47-49, 51	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED