United States Court of Appeals for the Federal Circuit

IN RE ROSLIN INSTITUTE (Edinburgh)

2013-1407

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Serial No. 09/225,233.

Decided: May 8, 2014

SALVATORE J. ARRIGO, Law Office of Salvatore Arrigo and Scott Lee, LLP, of Washington, DC, argued for appellant. With him on the brief was SCOTT M.K. LEE.

AMY J. NELSON, Associate Solicitor, United States Patent and Trademark Office, of Alexandria, Virginia, argued for appellee. With her on the brief were NATHAN K. KELLEY, Deputy General Counsel for Intellectual Property Law and Solicitor, and THOMAS W. KRAUSE, Associate Solicitor.

Before DYK, MOORE, and WALLACH, *Circuit Judges*.

DYK, *Circuit Judge*.

The Roslin Institute of Edinburgh, Scotland (Roslin) is the assignee of U.S. Patent Application No. 09/225,233 (the '233 application) and appeals from a final decision of

the Patent Trial and Appeal Board (Board). The Board held that all of Roslin's pending claims—claims 155-159 and 164—were unpatentable subject matter under 35 U.S.C. § 101. The Board also rejected Roslin's claims as anticipated and obvious under 35 U.S.C. §§ 102 and 103. We affirm the Board's rejection of the claims under § 101.

BACKGROUND

On July 5, 1996, Keith Henry Stockman Campbell and Ian Wilmut successfully produced the first mammal ever cloned from an adult somatic cell: Dolly the Sheep. A clone is an identical genetic copy of a cell, cell part, or organism.

The cloning method Campbell and Wilmut used to create Dolly constituted a breakthrough in scientific discovery. Known as somatic cell nuclear transfer, this process involves removing the nucleus of a somatic cell and implanting that nucleus into an enucleated (*i.e.*, without a nucleus) oocyte. A somatic cell is any body cell other than gametes (egg or sperm). An oocyte is a female gametocyte (an egg cell prior to maturation), and a nucleus is the organelle that holds a cell's genetic material (its DNA). Often referred to as "adult" cells, somatic cells are differentiated, *i.e.*, they are specialized to perform specific functions. For example, liver, heart, and muscle cells are all differentiated, somatic cells.

To create Dolly, Campbell and Wilmut fused the nucleus of an adult, somatic mammary cell with an enucleated oocyte. Specifically, Campbell and Wilmut found that if the donor, somatic cell is arrested in the stage of the cell cycle where it is dormant and non-replicating (the quiescent phase) prior to nuclear transfer, the resulting fused cell will develop into a reconstituted embryo. Once the nucleus of a somatic, donor cell is removed, that nucleus is fused with an oocyte, which develops into an embryo. The embryo can then be implanted into a surrogate mammal, where it develops into a baby animal. The

resulting cloned animal is an exact genetic replica of the adult mammal from which the somatic cell nucleus was taken.

Campbell and Wilmut obtained a patent on the somatic method of cloning mammals, which has been assigned to Roslin. *See* U.S. Patent No. 7,514,258 (the '258 patent). The '258 patent is not before us in this appeal. Instead, the dispute here concerns the Patent and Trademark Office's (PTO) rejection of Campbell's and Wilmut's claims to the clones themselves, set forth in the '233 application, titled Quiescent Cell Populations for Nuclear Transfer.[1]

The '233 application claims the products of Campbell's and Wilmut's cloning method: cattle, sheep, pigs, and goats. Claims 155 and 164 are representative:

> 155. A live-born clone of a pre-existing, non-embryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs, and goats.
>
> 164. The clone of any of claims 155-159, wherein the donor mammal is non-foetal.

J.A. 4. As the Board described, "[c]laims 156-159 depend from claim 155 and further specify that the claimed clones are limited to clones of cattle, sheep, pigs, and goats, respectively." J.A. 4.

On November 10, 2008, the examiner issued a non-final rejection of Campbell's and Wilmut's patent claims

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[1] This application was previously before the Board in *Ex Parte Campbell*, No. 2007-1617 (B.P.A.I. Jan. 30, 2008). In *Ex Parte Campbell*, the Board examined the '233 application as well as a companion patent application, U.S. Patent Application No. 09/658,862 (the '862 application). The '862 application was abandoned on September 16, 2008, and is not at issue in the present appeal.

because she found that they were directed to non-statutory subject matter under 35 U.S.C. § 101 as well as anticipated and obvious under §§ 102 and 103. On February 7, 2013, the Board affirmed the examiner's rejection of all of Campbell's and Wilmut's claims. Although the Board acknowledged that the claimed clones "may be called a composition of matter or a manufacture" as required by § 101, J.A. 18, it concluded that the claimed subject matter was ineligible for patent protection under § 101 because it constituted a natural phenomenon that did not possess "markedly different characteristics than any found in nature." J.A. 21.

The Board also affirmed the examiner's finding that Campbell's and Wilmut's claimed subject matter was anticipated by and obvious in light of the relevant prior art under 35 U.S.C. §§ 102 and 103. Specifically, the Board explained that "'[w]here . . . the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.'" J.A. 21 (quoting *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977)) (alteration and omission in original). The Board then held that the claimed clones were anticipated and obvious because they were indistinguishable from clones produced through prior art cloning methods, *i.e.*, embryotic nuclear transfer and in vitro fertilization.

We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A). We review the Board's legal determinations de novo, and its factual findings for substantial evidence. *In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1361 (Fed. Cir. 2012). Section 101 patent eligibility is a question of law that we review de novo. *Bancorp Servs., LLC v. Sun Life Assurance Co. of Can.*, 687 F.3d 1266, 1273 (Fed. Cir. 2012).

DISCUSSION

I

An inventor may obtain a patent for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101; *see Bilski v. Kappos,* 130 S. Ct. 3218, 3225 (2010). An invention that falls within one of these categories of patentable subject matter may still be ineligible for patent protection if it meets one of three exceptions. Laws of nature, natural phenomena, and abstract ideas are not eligible for patent protection. *See Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012); *Bilski*, 130 S. Ct. at 3225; *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-20 (1854).

Even before the Supreme Court's recent decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), the Court's opinions in *Chakrabarty* and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), made clear that naturally occurring organisms are not patentable.

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 ("[T]here is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed."). Critically, in *Funk Bros.*, the Court explained:

> [w]e do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable. We have here only product claims. [The patentee] does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.

Id. at 130 (citation omitted). Thus, while the method of selecting the strains of bacteria might have been patent eligible, the natural organism itself—the mixture of bacteria—was unpatentable because its "qualities are the work of nature" unaltered by the hand of man. *Id.*

In *Chakrabarty*, 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. 447 U.S. 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), *cert. denied*, 133 S. Ct. 1243 (2013) (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.").

More recently, in *Myriad*, 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. 133 S. Ct. at 2112-13, 2117-18. The Supreme Court concluded that the BRCA genes themselves were unpatentable products of nature.

While Roslin does not dispute that the donor sheep whose genetic material was used to create Dolly could not be patented, Roslin contends that copies (clones) are eligible for protection because they are "the product of human ingenuity" and "not nature's handiwork, but [their] own." Appellant's Br. 17, 18. Roslin argues that such copies are either compositions of matter or manufactures within the scope of § 101. However, Dolly herself is an exact genetic replica of another sheep and does not possess "markedly different characteristics from any [farm animals] found in nature." *Chakrabarty*, 447 U.S. at 310; *see* Reply Br. 13 (stating that "the clones are genetic copies"). Dolly's genetic identity to her donor parent renders her unpatentable.

In *Myriad*, the Court concluded that "isolated," naturally occurring DNA strands are not eligible for patent protection. 133 S. Ct. at 2111. Here, as in *Myriad*, Roslin "did not create or alter any of the genetic information" of its claimed clones, "[n]or did [Roslin] create or alter the genetic structure of [the] DNA" used to make its clones. *Myriad*, 133 S. Ct. at 2116. Instead, Roslin's chief innovation was the preservation of the donor DNA such that the

clone is an exact copy of the mammal from which the somatic cell was taken. Such a copy is not eligible for patent protection.

Related areas of Supreme Court patent case law reinforce this conclusion. For example, Supreme Court decisions regarding the preemptive force of federal patent law confirm that individuals are free to copy any unpatentable article, such as a live farm animal, so long as they do not infringe a patented method of copying. *Sears Roebuck & Co. v. Stiffel Co.* clarified that a state may not "prohibit the copying of [an] article itself or award damages for such copying" when that article is ineligible for patent protection. 376 U.S. 225, 232-33 (1964) (citing *G. Ricordi & Co. v. Haendler*, 194 F.2d 914, 916 (2d Cir. 1952)). In *Sears*, the question was whether the defendant, Sears Roebuck & Co., could be held liable under state law for copying a lamp design whose patent protection had expired. *Id.* at 225-26. The Court explained that "when the patent expires the monopoly created by it expires, too, and the right to make the article—including the right to make it in precisely the shape it carried when patented—passes to the public." *Id.* at 230 (citing *Kellogg Co. v. Nat'l Biscuit Co.*, 305 U.S. 111, 120-22 (1938) and *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896)). The Court further clarified that "[a]n unpatentable article, like an article on which the patent has expired, is in the public domain and may be made and sold by whoever chooses to do so." *Id.* at 231; *see also Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989). Roslin's claimed clones are exact genetic copies of patent ineligible subject matter.[2] Accordingly, they are not eligible for patent protection.

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[2] The '233 patent application clarifies that "[a]nimals produced by transfer of nuclei from a source of

II

However, Roslin argues that its claimed clones are patent eligible because they are distinguishable from the donor mammals used to create them. First, Roslin contends that "environmental factors" lead to phenotypic differences that distinguish its clones from their donor mammals. A phenotype refers to all the observable characteristics of an organism, such as shape, size, color, and behavior, that result from the interaction of the organism's genotype with its environment. A mammal's phenotype can change constantly throughout the life of that organism not only due to environmental changes, but also the physiological and morphological changes associated with aging.

Roslin argues that environmental factors lead to phenotypic differences between its clones and their donor mammals that render their claimed subject matter patentable. However, these differences are unclaimed. *See* J.A. 17. Indeed, the word "cloned" in the pending claims connotes genetic identity, and the claims say nothing about a phenotypic difference between the claimed subject matter and the donor mammals. Moreover, Roslin acknowledges that any phenotypic differences came about or were produced "quite independently of any effort of the patentee." *Funk Bros.*, 333 U.S. at 131; *see id.* at 130 ("Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature."); *Chakrabarty*, 447 U.S. at 310 ("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

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genetically identical cells share the same nucleus," J.A. 101, *i.e.*, they share the same nuclear genome.

subject matter under § 101."). Contrary to Roslin's arguments, these phenotypic differences do not confer eligibility on their claimed subject matter. Any phenotypic differences between Roslin's donor mammals and its claimed clones are the result of "environmental factors," Appellant's Br. 21, uninfluenced by Roslin's efforts.[3]

Second, Roslin urges that its clones are distinguishable from their original donor mammals because of differences in mitochondrial DNA, which originates from the donor oocyte rather than the donor nucleus. Mitochondria are the organelles (cellular bodies) that produce the energy eukaryotic cells need to function. Mitochondria possess their own DNA, which is distinct from the DNA housed in the cell's nucleus. In the cloning process, the clone inherits its mitochondrial DNA from its donor oocyte, instead of its donor somatic cell. Therefore, Dolly's mitochondrial DNA came from the oocyte used to create her, not her donor mammary cell. Roslin argues that this difference in mitochondrial DNA renders its product claims patent eligible.

But any difference in mitochondrial DNA between the donor and cloned mammals is, too, unclaimed. Furthermore, Roslin's patent application does not identify how differences in mitochondrial DNA influence or could

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[3] Roslin itself explained that "[c]loned offspring may vary phenotypically due to environment." Appellant's Br. 3; *see also id.* ("[E]nvironmental factors, such as uterine environment, generate differences that prevent a clone and its parent from being phenotypically identical. . . . [Therefore,] [a] clone that contains the same set of chromosomes as a single parental mammal can be distinguished from the parental mammal due to these environmental influences."), 21 ("[E]nvironmental influences . . . result in phenotypic differences."), 23.

influence the characteristics of cloned mammals. As the Board found below,

> [a]s for the influence of the oocyte into which the donor nucleus is transferred, the ']233 Specification teaches that "[a]nimals produced by transfer of nuclei from a source of genetically identical cells share the same nucleus, but are not strictly identical as they are derived from different oocytes. The significance of this different origin is not clear, but may affect commercial traits." The Specification cautions further that "[i]t remains . . . to consider whether it is possible or necessary in specific situations to consider the selection of oocytes." Thus . . . the Specification does not disclose any systematic differences in the clones that arise from the capture of the recipient oocyte.

J.A. 12 (third, fourth, and fifth alterations in original) (citations omitted). There is nothing in the claims, or even in the specification, that suggests that the clones are distinct in any relevant way from the donor animals of which they are copies. The clones are defined in terms of the identity of their nuclear DNA to that of the donor mammals. To be clear, having the same nuclear DNA as the donor mammal may not necessarily result in patent ineligibility in every case. Here, however, the claims do not describe clones that have markedly different characteristics from the donor animals of which they are copies.

Finally, Roslin argues that its clones are patent eligible because they are time-delayed versions of their donor mammals, and therefore different from their original mammals. But this distinction cannot confer patentability. As the Board noted, "[t]he difficulty with the time-delayed characteristic is that it is true of any copy of an original." J.A. 18. Thus, we affirm the Board's finding that

Roslin's clones are unpatentable subject matter under § 101.

AFFIRMED