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CLIENT MEMORANDUM

In re Roslin Institute: Federal Circuit Finds Cloned Animals Not Patent Eligible

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AUTHORS

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THE FEDERAL CIRCUIT HOLDS THAT CLAIMS COVERING DOLLY THE SHEEP ARE NOT PATENT ELIGIBLE WITHOUT ELEMENTS MARKEDLY DIFFERENT FROM THE ANIMAL FOUND IN NATURE

On May 8, 2014, the Federal Circuit issued its opinion in *In re Roslin Institute*,[1] holding that, absent claim elements that cover aspects of the invention that are "markedly different" from that which is found in nature, a cloned animal is not patent eligible subject matter under 35 U.S.C. § 101.

Background

On July 5, 1996, Ian Wilmut and Keith Campbell became the first researchers to successfully clone a mammalian cell using a process known as somatic cell nuclear transfer. In this process, Wilmut and Campbell created a clone embryo by removing the nucleus of a donor somatic cell and implanting that nucleus into an enucleated oocyte (egg cell). The somatic-cell nucleus, now contained in the egg, reprogrammed the host egg cell and, once stimulated, began to divide and grow in the same manner as a normal embryo grows into a fetus. The clone embryo was then implanted into a surrogate to develop.

[1] Appeal No. 2013-1407 (Fed. Cir. May 8, 2014).

Dolly the Sheep, cloned from a mammary cell of a donor sheep, was the first mammal successfully cloned using this technique. Since then, this process has successfully cloned a number of mammals, including pigs, deer, horses and bulls. Clones produced through this process have genetic identity with the donor animal.

Campbell and Wilmut pursued patent protection for a number of aspects of their discovery, including the method of cloning and the cloned animal itself. Although the researchers obtained a patent for their method of cloning (now assigned to the Roslin Institute), the U.S. Patent and Trademark Office examiner rejected their claims to the cloned animal as not patent eligible under 35 U.S.C. § 101 and not patentable under 35 U.S.C. §§ 102 and 103. The researchers appealed the rejection to the Patent Trial and Appeal Board (PTAB), which affirmed the examiner's rejections, finding that the claimed clone was a natural phenomenon that did not possess "markedly different characteristics than any found in nature." The researchers appealed this decision to the Federal Circuit.

Patent Eligibility and Products of Nature

"[A]ny new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" is eligible for patent protection under 35 U.S.C. § 101. However, a judicially-created exception to this rule exists where the claimed invention is (1) a law of nature; (2) a natural phenomenon; or (3) an abstract idea.

Regarding natural phenomena, the Federal Circuit noted that Supreme Court precedent has made clear that naturally occurring organisms are not patent eligible. For example, in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, the Supreme Court found that a specific mixture of naturally occurring bacteria was not patent eligible because the patentee did not alter the bacteria in any way.[2] In contrast, the bacteria in *Diamond v. Chakrabarty*,[3] which were altered through plasmids to break down components of crude oil, were "markedly different" from any product found in nature and thus eligible for patent protection.

More recently, the Supreme Court has extended these decisions in *Association for Molecular Pathology v. Myriad Genetics, Inc.*,[4] finding two naturally occurring, isolated genes (BRCA1 and BRCA2) ineligible for patent protection because they were unaltered products of nature. The Court noted that with regard to the isolated genes, "Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes . . . Myriad did not create anything." However, with regard to the cDNA also at issue, which was chemically altered from the naturally occurring gene to remove non-DNA coding regions, the Court found that because cDNA was not naturally occurring, it was patent eligible.

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[2] 333 U.S. 127, 132 (1948).

[3] 447 U.S. 303, 305 (1980).

[4] 133 S. Ct. 2107, 2112-13, 2117-18 (2013).

Dolly the Sheep Not Eligible for Patent Protection

The Federal Circuit found that here, as in *Myriad*, the researchers "did not create or alter any of the genetic information." Instead, the invention 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." Because the cloned animal was an exact copy of the animal found in nature, the cloned animal was not eligible for patent protection.

Although it conceded that the donor animal used to create Dolly could not be patented, the Roslin Institute argued that the cloned animal is patent-eligible because it is "the product of human ingenuity" and "not nature's handiwork, but [their] own." Specifically, the Roslin Institute argued that a cloned animal is distinguishable from the donor animal and thus is eligible for patent protection because although the donor and clone share the same DNA, environmental factors lead to phenotypic differences that change the observable characteristics in the cloned animal. Because these aspects of a cloned animal were not claimed, however, the Federal Circuit did not find the Roslin Institute's arguments persuasive. The Federal Circuit further noted that because any phenotypic differences occurred naturally, they could not make these claims patent eligible under § 101.

In addition, the Roslin Institute argued that a clone is patent eligible because in contradiction to what the PTAB found, the donor and the clone do not share complete genetic identity. Because mitochondrial DNA is not transferred through the nucleus but rather through the egg cell, every clone will have the mitochondrial DNA of the egg cell, not the donor cell. For example, although Dolly the Sheep has the DNA of the donor mammary cell, she inherited her mitochondrial DNA from a different donor egg cell. However, the Federal Circuit again did not find this argument persuasive because this aspect of a clone was not claimed. The Federal Circuit further noted that even if this aspect was claimed, there was nothing in the claims or specification to indicate that this difference would make the clone "markedly different" from the donor animal.

The Roslin Institute also argued that the cloned animals are patent eligible because they are time-delayed versions of the original donor mammals. The Federal Circuit found that this distinction could not confer patent eligibility because the same is true of any copy.

Notably, the Federal Circuit stated in dicta that having the same nuclear DNA as a donor mammal may not necessarily result in patent ineligibility. However, because in this case "the claims do not describe clones that have markedly different characteristics from the donor animals of which they are copies[,]" the Federal Circuit affirmed the PTAB's decision, finding the claims ineligible under 35 U.S.C. § 101.

If you have any questions regarding this memorandum, please contact Michael Johnson (212 728-8137, mjohnson1@willkie.com) or the Willkie attorney with whom you regularly work.

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