

Door Open For Animal Clone Patents Despite Dolly Ruling

By Ryan Davis

Law360, New York (May 08, 2014, 8:42 PM ET) -- The Federal Circuit ruled Thursday that the research institute that created the famous cloned sheep known as Dolly cannot receive a patent on cloned animals because they are identical to natural animals, but attorneys say the ruling leaves open the possibility that some clones may be patent-eligible.

The appeals court rejected the argument by the Roslin Institute at Scotland's University of Edinburgh that clones like Dolly are the result of human ingenuity and are not "nature's handiwork." The court ruled that only inventions that are "markedly different" from what is found in nature can be patented.

"Dolly herself is an exact genetic replica of another sheep and does not possess markedly different characteristics from any farm animals found in nature," the court wrote. "Dolly's genetic identity to her donor parent renders her unpatentable."

The decision closely follows other recent court decisions that inventions need to be different from natural products to be eligible for a patent under Section 101 of the Patent Act, but it notably did not completely foreclose any patents on cloned mammals, says Sharon Roberg-Perez of Robins Kaplan Miller & Ciresi LLP, who has followed the case.

The court wrote that Roslin's patent application for Dolly must be rejected because it described clones that were genetically identical to the natural donor animals, but it noted that "to be clear, having the same nuclear DNA as the donor mammal may not necessarily result in patent ineligibility in every case."

Roberg-Perez said, "That leaves the door open a little in an interesting way. We might see a lot of creative claim drafting."

The challenge for anyone seeking patent protection on a cloned animal or tissue will be to claim something that is an identical clone of what exists in nature yet is patentably distinct from it, and it's not clear whether that can be done, she says.

One possibility would be to claim a particular, useful application, such as cloned replacement tissue for people with degenerative diseases, rather than to claim the cloned material alone, she says.

The Dolly decision was not surprising given recent precedent, especially the U.S. Supreme Court's **landmark ruling** last year that human DNA isolated by Myriad Genetics Inc. is a product of nature that is not patent-eligible, says Patrice Jean of Kenyon & Kenyon LLP.

"This is a very, very straightforward application of what the courts have done under 101 for biotechnology," she said.

What was unusual is that the Federal Circuit did not make a blanket statement that clones can't be patented, Jean says.

"That's good for innovation," she said. "Myriad was somewhat harsh on the biotechnology industry and didn't leave much of a window."

Roslin's attorney, Salvatore Arrigo of the Law Office of Salvatore Arrigo and Scott Lee LLP, says the institute is reviewing the ruling and considering options for further review.

He says that while Section 101 prohibits patents on natural phenomena, laws of nature and abstract ideas, Dolly clearly does not fit into any of those categories, since she never existed in nature and was created by scientists.

"Instead of putting her into the product-of-nature category, the court appears to have created a fourth exception, for man-made copies of natural products," Arrigo said. "It's certainly surprising that they decided to create a new category, since the three categories have been well-established for many years."

Although the court did not foreclose patents on clones completely, he says it is difficult to imagine what kind of identical clone would be patent-eligible. It is also not clear how broadly the ruling applies, he says, and whether other man-made copies of natural products like antibodies would also be ineligible for a patent.

Dolly, the first mammal ever cloned from an adult cell, was born in 1996 and announced by Roslin with great fanfare in 1997, in what the Federal Circuit ruling describes as a "breakthrough in scientific discovery." Dolly died in 2003 after developing lung cancer.

Roslin already has obtained a U.S. patent on its method of cloning animals, which was not at issue in the appeal. Instead, the court was reviewing the U.S. Patent and Trademark Office's decision to reject the institute's application for a patent on cloned animals themselves.

The patent specifically claimed "a live-born clone of a pre-existing, nonembryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs and goats."

Roslin made several arguments about why Dolly and other cloned mammals are different from the donors used to create them and therefore patent-eligible, but the Federal Circuit rejected all of them.

For one, it noted that the clones have observable differences in shape, size, color and behavior due to environmental factors. The appeals court said that may well be the case, but the patent application did not claim those differences and instead used the word "clone," which "connotes genetic identity."

In addition, the institute said that Dolly had different mitochondrial DNA from her donor parent, since the cloning process meant that this DNA came from the egg cell used to create her, not the donor. Again, the court said the patent application did not claim that difference and that nothing in the claims "suggests that the clones are distinct in any relevant way from the donor animals of which they are

copies."

It is not clear whether the application would have been successful if Roslin had claimed those differences, but future applicants could explore the possibility, Jean says.

"I feel like the court may have bought into the idea that that the clones might be a little different" in terms of their characteristics or DNA, she said.

Roslin's third argument, that clones are "time-delayed versions" of the donor mammals, was flatly rejected by the Federal Circuit, which noted that the same "is true of any copy of an original."

Even though Dolly was a scientific breakthrough, the fact that she was identical to her donor parent sank Roslin's chances of obtaining a patent, the court concluded.

"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," it said. "Such a copy is not eligible for patent protection."

The patent application at issue is number 09/225,233.

Federal Circuit Judges Timothy Dyk, Kimberly Moore and Evan Wallach heard the appeal.

Roslin is represented by Salvatore Arrigo and Scott Lee of the Law Office of Salvatore Arrigo and Scott Lee LLP.

The patent office is represented by USPTO Solicitor Nathan Kelley and Associate Solicitors Amy Nelson and Thomas Krause.

The case is In re: Roslin Institute (Edinburgh), case number 2013-1407, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Richard McVay.