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Federal Circuit Patent Bulletin: *In re Roslin Inst.*

May 8, 2014

"[A]n exact genetic replica . . . does not possess "markedly different characteristics from [the original animal] found in nature [and thus the clone's] genetic identity to her donor parent renders her unpatentable."

On May 8, 2014, in *In re Roslin Inst.*, the U.S. Court of Appeals for the Federal Circuit (Dyk,* Moore, Wallach) affirmed the Patent Trial and Appeal Board decision upholding the patent examiner's lack of statutory subject matter rejection under 35 U.S.C. § 101 of the claims of U.S. patent application Serial No. 09/225,233, which related to somatic cell nuclear transfer cloned cattle, sheep, pigs, and goats such as Dolly the Sheep. The Federal Circuit stated:

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." 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. [N]aturally occurring organisms are not patentable. [D]iscoveries that possess "markedly different characteristics from any found in nature" are eligible for patent protection. In contrast, any existing organism or newly discovered plant found in the wild is not patentable. . . .

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." 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." Dolly's genetic identity to her donor parent renders her unpatentable. . . . 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. . . .

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. 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." 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," uninfluenced by Roslin's efforts.

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 influence the characteristics of cloned mammals. . . . 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." Thus, we affirm the Board's finding that Roslin's clones are unpatentable subject matter under § 101.