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The Saga of Patenting Dolly

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On May 8, 2014, the United States Court of Appeals for the Federal Circuit unanimously ruled that Dolly the cloned sheep (and clones in general) are unpatentable subject matter and opened a possibility of patenting clones that have “markedly different characteristics from the donor”.¹

Following the Supreme Court’s recent decision in *Association for Molecular Pathology v. Myriad Genetics*, the United States Court of Appeals for the Federal Circuit ruled on May 8, 2014, that clones carrying identical genetic information are unpatentable. Dolly the sheep was the first mammal ever cloned from an adult somatic cell, having the identical genetic information of its donor. Dolly was produced on July 5, 1996 by Keith Henry Stockman Campbell and Ian Wilmut, when Cambell and Wilmut found that once the nucleus of a somatic donor cell is removed, that nucleus is fused with an oocyte and an embryo develops. This embryo, when implanted into a surrogate mammal, develops into a baby animal. The Campbell and Wilmut somatic method of cloning mammals was patented at the USPTO and assigned to Roslin Institute.

The application forming the basis of the appeal on the decision is not this method patent but rather US application No. 09/225,233 filed on April 4, 1999 directed to the clones themselves and titled *Quiescent Cell Populations for Nuclear Transfer*.

The claims under dispute were Claims 155-159 and Claim 164 of this application pertaining to products of the cloning method, and specifically “A live born clone of a pre-existing, non-embryonic, donor mammal...”. During the prosecution of this application, the Examiner rejected the claims at issue as being directed to non-statutory subject matter, and further as being anticipated and obvious. The Patent trial and Appeal Board (Board) affirmed the Examiner’s rejections because it constituted a natural phenomenon.

The Federal Circuit affirmed the rejection of the above claims by the Patent Trial and Appeal Board as relating to non-statutory subject matter. When interpreting the Supreme Court precedents of patent eligibility for claimed subject matter, the Court relied on the recent *Myriad* decision (2013), as well as those issued in the *Mayo* (2012), *Chakrabarty* (1980), the *Funk Bros.* (1948) and *O’Reilly vs. Morse* (1854) decisions, affirming that unless the discoveries possess “markedly different characteristics from any found in nature”, they are not eligible for patent protection. Consequently, it was decided that “Dolly’s genetic identity to her donor parent, renders her unpatentable”.

The Federal Circuit relying on the *Myriad* decision, in which the Court concluded that “isolated, naturally occurring DNA strands are not eligible for patent protection”, stated that Roslin Institute also “did not create or alter any genetic information of its claimed clones”. In fact, the Court concluded that Roslin’s “chief innovation” was in preservation of the donor DNA as an exact copy² and as such, since” the “original” constitutes ineligible patent subject matter, the “copy is not eligible for patent protection”

either. Interestingly enough, although the claimed subject matter does not pertain to genetic information per se, it was found to be analogous to Myriad's isolated gene sequences.

Roslin's attempts to argue that the clone was not identical to the donor as "environmental factors" led to phenotypical differences between the two, differences which in fact should render the claimed subject matter eligible, did not sway the Courts' opinion in Roslin's favor. In this connection the Court asserted that "[a] mammals' phenotype can change constantly throughout the life of that organism"; and drawing support from the decision in Funk Bros. asserted that qualities being the work of nature are not patentable. Notwithstanding the above, the Federal Circuit implied that said differences were not claimed but rather the term "cloned" was used, which in fact was interpreted as "genetic identity"! The Court further stated that nothing in the specification and the claims suggests that the clone is distinct from the donor animal, and that in fact the clones are defined as having nuclear DNA identical to that of the donor.

The Court did provide an opening for future applicants by clarifying that "having the same nuclear DNA as the donor mammal may not necessarily result in patent ineligibility in every case" and that should the claims define clones that "have markedly different characteristics from the donor animals", it might sway patent eligibility in applicant's favor.

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¹ In re Roslin Institute (Edinburgh), Appeal No. 2013-1407, Cir. May 8, 2014, before DYK, Moore, Wallach, Circuit Judges.

² Referencing the contents of the patent application, where it was stated that "[a]nimals produced by transfer of nuclei from a source of genetically identical cells share the same nucleus..."

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