Fed. Cir. Denies 'Dolly' Clone Rehearing; Supreme Court Only Option Available

By John T. Aquino

Aug. 14 — The Federal Circuit Aug. 12 denied a rehearing of whether Dolly the cloned sheep can be claimed as patent-eligible subject matter, leaving a petition for Supreme Court review as the appellant's only option (In re Roslin Inst. (Edinburgh), Fed. Cir., No. 2013-1407, petition for rehearing denied 8/12/14).

The U.S. Court of Appeals for the Federal Circuit rejected the Roslin Institute's petition for a panel rehearing or an en banc hearing of the case and didn't issue an opinion.

The deadline for the institute to file a petition for certiorari with the Supreme Court is Nov. 10. Harold C. Wegner of Foley & Lardner told Bloomberg BNA in an Aug. 14 e-mail that he thinks the chance of the Supreme Court granting the case certiorari “is a very long shot given that the Federal Circuit’s holding denying patent-eligibility is not inconsistent with the recent Supreme Court decisions on patent eligibility in recent cases such as Mayo Collaborative Servs. v. Prometheus Labs., Inc. and Ass'n for Molecular Pathology v. Myriad Genetics.”

A Federal Circuit panel May 8 affirmed the rejection of a Roslin patent application by the Patent and Trademark Office's Patent Trial and Appeal Board, citing Supreme Court decisions for the proposition that the requirement of “markedly different characteristics” in a claimed organism can't be met when the invention claimed is identical to the donor animal.

If the Federal Circuit's decision is left undisturbed by the Supreme Court, some attorneys indicated that the decision left some “wiggle room” that applicants in Dolly-like situations could possibly utilize.

Chakrabarty, Funk Cited

Keith Henry Stockman Campbell and Ian Wilmut of the Roslin Institute of Edinburgh created the first cloned mammal from an adult somatic cell in 1996. Claim 155 of their U.S. Patent Application No. 09/225,233 is directed to Dolly and any similar “live born clone of a pre-existing, non-embryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs and goats.”

The board affirmed a PTO examiner's rejection of the claim under Sections 101 (patent eligibility), 102 (novelty) and 103 (obviousness). Roslin appealed.

The Federal Circuit limited its review to patent eligibility under Section 101, and the three-judge panel cited Supreme Court decisions in Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948)—“naturally occurring organisms are not patentable”—and Diamond v. Chakrabarty, 447 U.S. 303 (1980)—an organism is patent eligible if it is “new” with “markedly different characteristics from any found in nature.” The Supreme Court cited Funk and Chakrabarty extensively in Myriad.

The Federal Circuit panel wrote, “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.”

Still Some Wiggle Room?

Matthew McFarlane of Robins, Kaplan, Miller & Ciresi LLP, New York, in an Aug. 14 e-mail to Bloomberg BNA, agreed with Wegner that it would be unlikely for the Supreme Court to grant certiorari in this case given its rulings in Mayo and Myriad.

“That said, a cert petition could be persuasive,” he added. “For example, what if the question presented focused on the obvious internal inconsistency of the Dolly invention? On the one hand, there's the incredible amount of human work required to make the clone and the undeniable value of that clone as a product, but on the other hand, no possibility for patent protection because of its genetic identity. Or maybe that's an issue
best left for Congress to decide.”

If the Supreme Court denies certiorari or affirms the Federal Circuit’s ruling, then the holding of In re Roslin stays in place.

A number of attorneys contacted by Bloomberg BNA noted the “wiggle room” left by the Federal Circuit in Roslin when the court acknowledged that there could be differences unrelated to the somatic cell and that “having the same nuclear DNA as the donor mammal may not necessarily result in patent ineligibility in every case.” In Roslin, however, the claims didn’t describe clones with markedly different characteristics from the donor animals.

McFarlane said, “I think what’s most interesting about the court’s statement is the idea that, despite its holding, the Federal Circuit still sees some wiggle room in those characteristics that define a thing as being ‘identical’ to a thing found in nature. The court seems to be focusing on the only reasonable conclusion after the Supreme Court’s decision in Myriad: a patent claim must feature elements requiring an observable difference from a naturally-occurring product. If that element exists, a claim focusing on it would not have the same infirmity. The Federal Circuit appears to be unwilling to foreclose the possibility that a clone may actually exhibit patent-eligible differences despite genetic identity to a naturally-occurring donor.”

Thomas J. Kowalski and Deborah Lu of Vedder Price, New York, in an Aug. 14 e-mail to Bloomberg BNA, picked up on an idea from the novel and film Jurassic Park and wrote that the court “has even left open the question of whether a clone of an extinct animal, such as a Dodo Bird, may be patent-eligible since having the same nuclear DNA as a donor animal may not necessarily result in patent ineligibility in every case (and the extinct animal arguably does not exist in nature at this time).”

They said that the “takeaway” is: “Biotech patent applicants need to ensure that distinctions (e.g., phenotypic, mitochondrial distinctions) between donor animals and clones are recited in claims before the USPTO—as well as in claims taken up on appeal to the PTAB or the Federal Circuit—so as to recite patent eligible subject matter.”

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