CLAIMING CLONES

Jason Rantanen[1]
Associate Professor
University of Iowa College of Law

QUICK VIEW

In re *Roslin Institute (Edinburgh)*, 2014 WL 1814014 (Fed. Cir. May 8, 2014),[2] relates to Dolly, probably the most famous baby sheep ever.[3] As most folks know, Dolly was the first successful mammalian clone from an adult somatic cell. This means that her nucleic genetic material is a copy of the adult from which she was cloned. The basic process used to create Dolly is illustrated to the right.

In addition to claims on the cloning process (which were not at issue in this appeal), the University of Edinburgh also sought product claims. Claims 155 and 164 are representative[4]:

> 155. A live-born clone of a pre-existing, nonembryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs, and goats.
>
> 164. The clone of any of claims 155-159, wherein the donor mammal is non-foetal.

The Patent Office rejected these claims on Section 101, 102, and 103 grounds and the University appealed.[5]

The Federal Circuit agreed that the claims were not patent eligible under Section 101. The court began by distinguishing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) (which it treated as a subject matter eligibility case) from *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980), with the latter involving a patent eligible organism because "it was 'new' with "*markedly different characteristics from any found in nature* and one

---

[1] A.B. 99', Brown University; M.A. 00', University of Chicago; J.D. 03', University of Chicago Law School. Contact email: jason-rantanen@uiowa.edu. This article (without footnotes) was originally published at http://patentlyo.com/patent/2014/05/claiming-clones.html.

[2] In re Roslin Institute (Edinburgh), 2014 WL 1814014 (Fed. Cir. May 8, 2014).

[3] Except for possibly Mary's little lamb. *See* Margaret R. McLean, *Much Ado about Cloning in the Public Square*, 32 U. TOL. L. REV. 337 (2001).

[4] *See Roslin Institute*, 2014 WL 1814014, at *1-*2.

[5] *See id.* at *2.

having the potential for significant utility."[6] On the other hand, "any existing organism or newly discovered plant found in the wild is not patentable."[7] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*[8] reinforced this distinction.

Here, the claims covered organisms (such as Dolly) that do not "possess 'markedly different characteristics from any [farm animals] found in nature.'"[9] The emphasis of the court's analysis was on genetic identity: "Dolly's genetic identity to her donor parent renders her unpatentable."[10] The claims thus fell into the product of nature exception to the broad scope of patent eligible subject matter.

Underlying the court's opinion was a policy thread relating to copying generally: that the copying of unpatentable articles is permitted so long as it does not infringe a patented method of copying. In *Sears Roebuck & Co. v. Stiffel Co.*, for example, the Supreme Court wrote that "[a]n unpatentable article, like an article on which the patent has expired, is in the public domain and may be made and sold by whoever chooses to do so."[11] Because the claimed clones are exact genetic copies of the of patent ineligible subject matter, they, too, are not eligible for patent protection.

What about the argument that these clones may be genetic copies of the donor organism, but they aren't exactly the same? For example, environmental factors will produce differences between the phenotypes of the donor and clones and their mitochondrial DNA will differ, since the mitochondrial DNA comes from a different source than the nucleic DNA. The court rejected these arguments because such differences were not claimed: the claims are written in terms of genetic identity, not phenotypic or mitochondrial differences.

What the court appears to be implicitly doing here is to interpret the claims in a manner that is least favorable to the applicant. There is at least a plausible argument that the claims *do* implicate genetic identity but phenotypic diversity by their reference to a "live-born clone of a … mammal." To be sure, the word "clone" contemplate genetic identity. But at the same time the very idea of a live-born mammalian clone suggests that the product will not be an exact duplicate of the donor. In other words, while the claims don't contain the words "phenotypic difference," those differences are inherent in what a clone is: a clone will necessarily exhibit phenotypic

---

[6] *Id.* at *3 (quoting *Chakrabarty*, 447 U.S. at 310 (emphasis added by court)).

[7] *Id.*

[8] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

[9] *Roslin Institute*, 2014 WL 1814014, at *4 (quoting *Chakrabarty*, 447 U.S. at 310).

[10] *Id.*

[11] Sears Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 231 (1964).

differences because it will develop in different environmental circumstances than its donor.

However, even were the claims to expressly include such limitations, the court reasoned that it would not change the outcome. As to phenotypic differences, they "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,' Appellant's Br. 21, uninfluenced by Roslin's efforts."[12] (I guess the fact that the whole process was set in motion by human activity doesn't count.) As to mitochondrial differences, "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."[13] As a result, the claims fail the "markedly different characteristics" language of *Chakrabarty.*

Cited as:

Bluebook Style: Jason Rantanen, *Claiming Clones*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 92 (2014).

APA Style: Rantanen, J. (2014). Claiming clones. *NTUT Journal of Intellectual Property Law & Management, 3*(1), 92-94.

[12] *Roslin Institute*, 2014 WL 1814014, at *5.

[13] *Id.* at *6.