Kluwer Patent Blog

Cloned Sheep And Other Patent Eligibility Issues In The U.S.

Courtenay C. Brinckerhoff (Foley&Lardner LLP) · Monday, May 12th, 2014

Last week, in *In Re Roslin Institute*, the U.S. Court of Appeals for the Federal Circuit held that cloned cattle, sheep, pigs and goats are non-patent eligible subject matter under 35 USC § 101. While the result that these cloned animals cannot be patented may not be surprising, the basis for the court's finding–that the claimed subject matter was ineligible under the "product of nature" doctrine, has some scratching their heads. A more logical way to understand the decision is to read the court's holding as finding that the cloned animals are non-patent eligible subject matter because they cannot be distinguished from naturally occurring animals.

The patent application at issue was 09/225,233, assigned to the Roslin Institute of Edinburgh, Scotland. The court identified claims 155 and 164 as representative:

> 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 inventors are the same inventors who made Dolly the sheep (the first mammal cloned from an adult somatic cell). The Federal Circuit points out that the inventors were granted a patent on their cloning ***methods*** (U.S. 7,514,258) that was not at issue in this case.

In a decision rendered February 7, 2013 (before the Supreme Court's *Myriad* decision), the USPTO Patent Trial and Appeal Board (PTAB) affirmed the examiner's § 101 rejection because the claimed subject matter "constituted a natural phenomenon that did not possess 'markedly different characteristics than any found in nature.'"

The Federal Circuit decision was authored by Judge Dyk and joined by Judges Moore and Wallach. The claims were rejected under 35 USC §§ 101, 102 and 103, but the court focused on the § 101 rejection. The decision reviews the Supreme Court's "product of nature" jurisprudence (e.g., *Myriad*, *Chakrabarty* and *Funk Brothers*) and concludes:

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

The court explains further:

> 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.
>
> *****
>
> Roslin's claimed clones are exact genetic copies of patent ineligible subject matter. Accordingly, they are not eligible for patent protection.

The court rejected Roslin's arguments that phenotypic differences in the cloned animals supported patent eligibility because the phenotypic differences (i) were not recited in the claims and (ii) arose "quite independently of any effort of the [would-be] patentee." The court also rejected Roslin's arguments that differences in mitochondrial DNA supported patent eligibility because any such differences (i) were not recited in the claims and (ii) had not been shown to impart and differences to the cloned animal. The court left open the possibility that "having the same nuclear DNA as the donor mammal may not necessarily result in patent ineligibility in every case," but emphasized that the claims at issue "do not describe clones that have markedly different characteristics from the donor animals of which they are copies."

The USPTO § 101 Patent Subject Matter Eligibility Guidance

U.S. practitioners are seeing more and more Office Actions with new § 101 rejections based on the March 4 Guidance, with rejections applied to isolated product claims, composition of matter claims, method of manufacture claims, and method of treatment claims. In response to stakeholder reactions to the unexpected scope of the Guidance, the USTPO hosted a forum on May 9 to receive public feedback on the Guidance document, including alternative approaches to applying the Supreme Court's "product of nature" and "law of nature" jurisprudence. At the end of the program, the USPTO indicated that while it was open to reconsidering, revising, and supplementing the Guidance, it was not likely to withdraw the current Guidance document altogether. The USPTO advised applicants to respond to the new rejections as they would to any other rejection, using the framework outlined in the Guidance, and appealing rejections that are believed to be contrary to law.

I encourage all practitioners and stakeholders who seek U.S. patent protection in any chemical, biotechnology or pharmaceutical field to review the Guidance and provide feedback to the USTPO as soon as possible, and preferably by the end of June 2014.

To make sure you do not miss out on regular updates from the Kluwer Patent Blog, please subscribe here.

This entry was posted on Monday, May 12th, 2014 at 6:00 am and is filed under Biologics, Exceptions to patentability, United States of America
You can follow any responses to this entry through the Comments (RSS) feed. Both comments and pings are currently closed.