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Federal Circuit Rules that Dolly the Cloned Sheep is not Patentable

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In a unanimous panel decision, the Federal Circuit affirmed the finding of the USPTO Patent Trial and Appeal Board (PTAB) that claims directed to cloned cattle, sheep, pigs, and goats are directed to non-patent eligible subject matter under 35 USC § 101. The court in effect held that while methods of making a clone may be patentable, the clone generally is not.

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 noted that the inventors were granted a patent on their cloning methods (U.S. 7,514,258), which were not at issue in this case.

In a decision rendered February 7, 2013, the PTAB affirmed the Examiner's § 101 rejection finding the claimed subject matter "constituted a natural phenomenon that did not possess 'markedly different characteristics than any found in nature.'' The Board also affirmed the Examiner's multiple rejections under 35 USC §§102 and 103.

The Federal Circuit's 12 page opinion was authored by Judge Dyk, with Judges Moore and Wallach joining. Although the claims on appeal were rejected under 35 USC §§ 101, 102 and 103, the court did not reach the issues of anticipation and obviousness, disposing of the case solely under § 101. The decision opened with a brief recap of the Supreme Court decisions in *Myriad*, *Chakrabarty*, and *Funk Bros*., collectively being characterized as making it "clear that naturally occurring organisms are not patentable." In *Funk Bros*., "the mixture of bacteria . . . was unpatentable because its 'qualities are the work of nature' unaltered by the hand of man." In *Chakrabarty*, "the modified bacterium was patentable because it was 'new' with 'markedly different characteristics from any found in nature and one having the potential for significant utility.'" Lastly, in *Myriad*, "claims on two naturally occurring, isolated genes . . . were invalid under § 101," because the "genes themselves were unpatentable products of nature." Thus, according to the court, only discoveries that possess "markedly different characteristics from any found in nature" . . . are eligible for patent protection.

Roslin argued that the clones are patent eligible, because they are "the product of human ingenuity" and "not nature's handiwork, but [their] own." However, the court found that "Dolly herself is an exact genetic replica of another sheep and does not possess 'markedly different characteristics from any [farm animals] found in nature.'" The court explained that Roslin's chief innovation was the preservation of the donor DNA such that the clone is an exact copy of the donor. Therefore, Dolly's genetic identity

to her donor parent is what renders her unpatentable.

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.” Future court decisions will likely provide guidance regarding how “markedly different” a clone must be from its donor to render it patent eligible.

If you have any questions about the court’s decision or how it may impact your business, please feel free to contact one of our attorneys.