

IN RE ROSLIN INSTITUTE, Appeal No. 2013-1407 (Fed. Cir. May 8, 2014). Before Dyk, Moore, and Wallach. Appealed from PTAB.

Background:

Roslin is the assignee of a patent application claiming the products (clones) resulting from a genetic cloning method.

The Patent Trial and Appeal Board (PTAB) held all of the claims in the application to be unpatentable subject matter under 35 U.S.C. §101. The PTAB found that although the claimed clones "may be called a composition of matter or manufacture" as required by 35 U.S.C. §101, it concluded that the claimed clones were ineligible for protection under 35 U.S.C. §101 because the subject matter of the claims constitute a natural phenomenon that did not possess "markedly different characteristics than any found in nature." Roslin appealed.

Issue/Holding:

Did the PTAB err in holding that the products from a patented method of cloning mammals were unpatentable subject matter under 35 U.S.C. §101? No, affirmed.

Discussion:

In *Funk Bros. Seed v. Kalo Inoculant*, the Supreme Court held that a natural organism, unaltered by the hand of man, was unpatentable because its qualities are the work of nature. In clarifying the scope of *Funk Bros.*, the Supreme Court further held in *Diamond v. Chakrabarty* that non-naturally occurring discoveries of organisms that possess "markedly different characteristics from any found in nature" are eligible for patent protection. As an example, in *Chakrabarty*, the Court found that a genetically modified bacterium capable of breaking down components of crude oil was patentable because the modified bacterium was "new" with "markedly different characteristics from any found in nature." The Supreme Court added that the patentee's discovery must not be nature's handiwork, but his own.

On appeal, Roslin argued that copies (clones) are eligible for patent protection because they are the product of human ingenuity and not nature's handiwork. The Federal Circuit disagreed. The Federal Circuit found that the clones are not eligible for patent protection because the clones are exact replicas of other organisms, which by themselves do not possess "markedly different characteristics from any organisms found in nature." Moreover, the applicant had not altered any of the genetic information used to make the claimed clones. Although the applicant argued that the clones had phenotypic differences due to environmental factors and mitochondrial DNA differences as a result of the cloning process, these differences were not claimed and, regardless, were not established to confer patent eligible distinctions. For these reasons, the judgment of the PTAB was affirmed.