

## IN RE ROSLIN INSTITUTE: PRODUCTS OF NATURE AND SOURCE LIMITATIONS

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### QUICK VIEW

The Federal Circuit's recent opinion in *In re Roslin Institute*<sup>2</sup> is the court's first decision on the patent-eligibility of natural products after the Supreme Court's *Myriad* decision, which denied patent-eligibility to isolated genomic DNA. The holding itself is probably not significant; cloned animals have little commercial significance at present. But the court's requirement that inventions be "markedly different" from their natural sources casts doubt the patent-eligibility of other biotechnological inventions, such as isolated human stem cells. This comment addresses two issues with the Federal Circuit's analysis in *Roslin*: the court's interpretation of *Chakrabarty*<sup>3</sup> and *Funk Brothers*,<sup>4</sup> and *Roslin*'s requirement that structural or functional differences between natural and synthetic products must be explicitly recited by the claims.

Unaltered by the hand of man: Judge Dyk's opinion in *Roslin* unfortunately perpetuates the view, now found in the PTO's *Myriad* guidelines, that *Chakrabarty* requires a claimed invention to be "markedly different" from a natural product for patent-eligibility under § 101. *Myriad* itself imposed no such requirement: the Court found *BRCA* cDNAs patent-eligible without determining that they were "markedly different" from natural sequences. And though *Myriad* reiterated the "markedly different" language from *Chakrabarty*, *Chakrabarty*'s discussion of "products of nature" was entirely dictum. Only the question of whether living organisms were patent-eligible was before the Court in *Chakrabarty*; the "product of nature" rejection in the case had not been sustained by the Patent Office Board of Appeals.

The *Chakrabarty* Court noted the claimed bacteria differed "markedly"

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<sup>2</sup> *In re Roslin Institute* (Edinburgh), 2014 WL 1814014 (Fed. Cir. May 8, 2014).

<sup>3</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>4</sup> *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

from natural bacteria by way of contrasting the genetically altered bacteria in the case from the mixed culture of naturally occurring bacteria found unpatentable in *Funk Brothers*.<sup>5</sup> The patentee in *Funk* had discovered that certain strains of *Rhizobium* bacteria could be mixed together without inhibiting their nitrogen-fixing capability. Justice Douglas regarded this compatibility as the unpatentable discovery of a natural phenomenon. The claims were unpatentable because the patentee's application of his discovery – a mixed inoculant – required no ingenuity or invention once the discovery itself was known.

As I discuss in a recent article,<sup>6</sup> despite the Court's requirement for 'inventiveness', *Funk* was very much a patent eligibility case rather than a non-obviousness case. It reflects Douglas's view – shared by Justice Stevens in *Flook*, and Justice Breyer in *Mayo* – that obvious applications of scientific discoveries or abstract ideas are not patent-eligible "inventions" within the meaning of the statute.

Whether or not we share that view, understanding Douglas's perspective makes clear that *Funk* was an "inventive application" case, not a "product of nature" case. Douglas made no reference to the "product of nature" doctrine, nor to the recent cases embodying it.<sup>7</sup> Instead, Douglas emphasized the lack of change in the bacteria to establish that the mixed inoculant was obvious (once the patentee's discovery was assumed away). In particular, under the old doctrine of "aggregation," it was not invention to combine old elements where the elements were unchanged, and no new function arose from their combination. It was therefore not inventive for the patentee in *Funk* to combine old bacteria without changing their structure or function.

But just as many combinations of old elements become patentable when a new function emerges, the mixed inoculants of *Funk* would have been patentable – even if the bacteria remained unchanged – had the mixed inoculant acquired new functions not performed by its constituent bacteria. If *Funk Brothers* instead stood for the proposition that a combination is unpatentable if its constituents are "unaltered by the hand of man," then a

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<sup>5</sup> In *Chakrabarty*, the Commissioner of Patents never argued that the claimed bacteria were unpatentable under *Funk* – nor even raised the case. Rather, Chakrabarty, the patent applicant, argued that if living organisms were not patent-eligible, the Court would have said so in *Funk*.

<sup>6</sup> Jeffrey A. Lefstin, *Inventive Application: A History*, FLA. L. REV. (forthcoming 2014), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2398696](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2398696).

<sup>7</sup> In particular, the *General Electric* and *Marden* cases, decided in 1928 and 1931, which denied patentability to purified forms of tungsten, uranium, and vanadium. See *General Electric Co. v. De Forest Radio Co.*, 28 F.2d 641 (3d Cir. 1928); *In re Marden*, 48 F.2d 428 (Cust & Pat. App. 1931). The defendant had urged *General Electric* upon the *Funk* court in its brief.

very large number of inventions become patent-ineligible. An artificial structure like an arch, formed by piling stones atop each other, would be ineligible unless the stones themselves were altered by the hand of man. Even as ardent a skeptic of the patent system as Justice Douglas would not have gone that far.

Source limitations and expressly claimed distinctions: The second difficulty with *Roslin* is its demand that the “marked differences” between the natural organism and the invention must be expressly claimed. As Prof. Jason Rantanen discussed,<sup>8</sup> the applicant in *Roslin* argued that cloned animals differ from their natural counterparts at least in having mitochondrial DNA derived from the egg donor, rather than the animal which donated the somatic nucleus. The Federal Circuit rejected such arguments because neither the difference in mitochondrial DNA, nor any functional consequence of that difference, was recited in the claims.

However, the same argument, albeit in the context of § 102, was before the Federal Circuit in the extensive litigation over Amgen’s recombinant erythropoietin (EPO) patents.<sup>9</sup> Much like *Roslin*, Amgen had claims to a “copy” of natural product: in that case EPO produced by mammalian cells in culture. While Amgen’s synthetic EPO differed in glycosylation from the natural product, several of the claims in the case recited only the non-natural source of the EPO, not the structural differences. The Federal Circuit recognized that the novelty of the synthetic EPO claims depended on whether synthetic EPO differed from natural EPO. Yet the court found novelty based on the *unclaimed* structural and functional differences between natural and synthetic EPO, which were demonstrated in part by the specification and prosecution history, and in part by testimony at trial.<sup>10</sup> In effect, the court held that the structural and functional differences characterizing the synthetic product were inherent in the source limitations. (The court did not inquire whether all synthetic EPO molecules falling within the scope of the claims would display similar differences in glycosylation.)

Thus under *Amgen*, a source limitation alone (such as “non-naturally occurring” or “purified from mammalian cells grown in culture”) may establish novelty of a product. Assuming the “clone” limitation in *Roslin* to require derivation from nuclear transfer, then it serves as a source limitation as well. Since *Roslin* cannot overrule *Amgen*, we seem to be in a regime

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<sup>8</sup> See Jason Rantanen, *Claiming Clones*, <http://patentlyo.com/patent/2014/05/claiming-clones.html> (last visited May 21, 2014); see also Jason Rantanen, *Claiming Clones*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 92 (2014).

<sup>9</sup> See *Amgen Inc. v. F. Hoffman-LaRoche Ltd*, 580 F.3d 1340 (Fed. Cir. 2009).

<sup>10</sup> See *id.* at 1370.

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where differences between natural and synthetic products may be unclaimed yet confer novelty under § 102, but must be explicitly claimed to establish “marked difference” under § 101. Of course, if *Roslin* is correct, that doctrinal inconsistency is less significant than the consequence that *Amgen*-type claims – and perhaps a wider category of product-by-process claims involving natural products – are now ineligible under § 101.

Cited as:

Bluebook Style: Jeffrey A. Lefstin, *In re Roslin Institute: Products of Nature and Source Limitations*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 95 (2014).

APA Style: Lefstin, J. (2014). *In re Roslin Institute: Products of nature and source limitations*. *NTUT Journal of Intellectual Property Law & Management*, 3(1), 95-98.