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Fed. Circ. Gene Therapy Ruling Gives Rare Eligibility Clarity

By **Dani Kass**

Law360 (February 25, 2026, 10:08 PM EST) -- When the Federal Circuit revived the University of Pennsylvania's gene therapy patent last week, it provided a bright-line rule that's often missing in the debate over patent eligibility, attorneys say.

The Federal Circuit on Friday found the university's human-made cell patent, which is licensed by Regenxbio Inc., does not cover naturally occurring phenomena that can't pass established tests for what's eligible.

"It looks like you really have to show that but for human hands, this would not be found naturally," said Robins Kaplan LLP partner Oren Langer.

What's Patentable

Regenxbio sued Sarepta Therapeutics Inc. in September 2020 claiming infringement of the singular patent at issue. That meant when Delaware's U.S. District Judge Richard G. Andrews granted Sarepta summary judgment in January 2024, it was case dispositive.

The patent claims a human-made host cell containing a recombinant nucleic acid molecule, which is a combination of two pieces of genetic material from two different organisms. Judge Andrews determined that combining natural products and putting them in a host cell does not render them patentable, as they're still directed to natural phenomena.

The Federal Circuit disagreed, holding that the recombinant nucleic acid molecule cannot exist in nature, making it patent eligible under Section 101 of the Patent Act.

"On all points of analysis, the Federal Circuit disagreed with the district court. And I think that's going to be the test in every case," said Aydin Harston of Rothwell Figg Ernst & Manbeck PC. "You have to look at what you're really doing. "

Once the molecule is in place, Harston added, "you're going to get certain effects that are markedly different from if you had those sequences just floating around separately somewhere. Not together, obviously, because they don't occur together. You're never going to get the same effect."

That clear human work separates gene therapy from other parts of biopharma like diagnostics, which are extremely hard to patent under Section 101 because judges often say they're just making

connections about what naturally occurring things could mean. The more embattled areas include chemical compositions for drugs.

"It's a good data point to see this case and how it was explained and analyzed," Hartson said. "There is a dividing line between the eligible versus noneligible cases. Oftentimes, if you have, for example, a composition, a solution that just mixes together two natural products and that's essentially it, that could be more leaning toward the patent-ineligible side. So you have to be more careful with those."

Competing Precedent

A key part of the Federal Circuit's decision was considering whether the case was more like Diamond v. Chakrabarty or Funk Brothers Seed Co. v. Kalo Inoculant Co., U.S. Supreme Court decisions from 1980 and 1948, respectively.

In the former, the court allowed a patent for genetically engineered bacteria meant to break down crude oil. In the latter, the court invalidated a patent for bacteria that allowed different legumes to be packaged together where the bacteria would otherwise have killed each other.

Judge Andrews said Penn's patent was more like Funk Brothers, but the Federal Circuit said Chakrabarty fit.

"That is exactly what we have in this case," said Sean Tu of the University of Alabama School of Law. "We have this therapy that combines two different things that doesn't exist in nature."

The Federal Circuit also found the case aligns with the Supreme Court's Association for Molecular Pathology v. Myriad Genetics decision from 2013, which rejected patent claims isolating genes but allowed claims on a complementary deoxyribonucleic acid, or cDNA, sequence that don't exist in nature.

The appeals court's decision in Regenxbio was in line with what many attorneys would have expected, and if the court had decided otherwise, there would have been a "significant disruption" in the industry, said Ryan Hagglund of Loeb & Loeb LLP.

"That would have certainly disrupted the way a lot of companies engage in their patenting strategy regarding gene therapy, especially in terms of the methods of producing viral vector and recombinant viruses," he added, referring to the way modified genes are delivered to treat a condition.

Diseases that can be helped by gene therapy include cystic fibrosis, hemophilia and sickle cell anemia, according to the Federal Circuit.

Under Chakrabarty, the court's eligibility test looks at whether there are "markedly different characteristics from those found in nature," which is the standard Penn met.

The court's analysis only involved a perfunctory review of the most common patent eligibility cases, 2014's Alice Corp. v. CLS Bank and 2012's Mayo v. Prometheus Laboratories. The Supreme Court established in Alice that abstract ideas and in Mayo that natural phenomena cannot be patented without an added inventive concept. The Federal Circuit panel said if it needs to turn to the Alice-Mayo framework, the test ends at step one, based on its other findings that the patent meets eligibility requirements.

The second element of Chakrabarty is whether the claims have "potential for significant utility," such as gene therapy.

Friday's decision "confirms that the more details about utility and the patents, the better, because that is something that the court focused on," said McKool Smith principal Ramy Emad Hanna.

Hagglund noted that the interplays of Alice-Mayo and Chakrabarty-Myriad could become interesting to watch going forward, as the former generally applies to method claims, while the latter tends to focus on composition of matter claims.

"Are there circumstances where you should be looking to both? And then what would happen if the Alice analysis and the 'markedly different' analysis would lead to different results?" Hagglund said. "There isn't any case law addressing that."

The case is Regenxbio Inc. et al. v. Sarepta Therapeutics Inc., case number 24-1408, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Theresa Schliep. Editing by Alanna Weissman and Jay Jackson Jr.
