US: PATENTS



Fitzpatrick Cella Harper & Scinto
New York

Robert S Schwartz



and Leslie Kushner

Does *Myriad* alter the patentability of natural products?

hether the US Supreme Court's June 13 2013 ruling in Association for Molecular Pathology v Myriad Genetics, Inc, 133 S Ct 2107 (2013) — that "[a] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated" — is narrowly applicable only to nucleic acids or will be broadly interpreted to apply to all naturally occurring biomolecules remains unclear.

The Myriad Court found that Myriad's discovery of breast cancer genes "fell squarely within the law of nature exception" to patentability, long-held by the Court. Under Section 101 of the Patent Act "any new and useful ... composition of matter, or any new and useful improvement thereof" is patentable. Although Myriad's isolated genes were chemically distinct from the naturally occurring genes, the Court found that this structural difference did not confer any "new and useful" property and both the isolated and natural DNA sequence bore the same informational properties. Since Myriad's claims were "focus[ed] on the genetic information" and did not "rely in any way on the chemical changes" resulting from isolation of the DNA segment", Myriad's claims to "genes and the information they encode are not patent eligible under §101 simply because they have been isolated ...".

One interpretation of *Myriad* is that an isolated naturally occurring product may be patentable if the inventors reveal a "new and useful" property of it. Since Judge Learned Hand's 1911 *Parke-Davis & Co v HK Mulford Co* 189 F 95 (SDNY 1911) opinion that purified adrenaline "became for every practical purpose a new thing commercially and therapeutically", purified naturally occurring products, such as blood clotting Factor VIII:C, vitamin

B12 and prostaglandins have been found to be patentable because they possessed some property that provided a therapeutic advantage compared to the natural product.

Whether *Myriad* will be applied broadly to all isolated naturally occurring products and what constitutes a "new and useful" property to render an isolated natural product patentable, will remain unclear until courts sort out the scope of *Myriad* in future cases.