# Association For Molecular Pathology V Myriad Genetics – An *Isolated* Local Difficulty?

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How does yesterday's Supreme Court decision match international opinion on the patentability of biological material? From a European and indeed from an Australian standpoint it can be said with some confidence: not so well.

The USPTO has now made its policy clear in a letter from Andrew H Hirshfeld, Deputy Commissioner for Patent Examination Policy to the Patent Examining Corps:

> "As of today, naturally occurring nucleic acids are not patent eligible merely because they have been isolated. Examiners should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. § 101. Claims clearly limited to non-naturally-occurring nucleic acids, such as a cDNA or a nucleic acid in which the order of the naturally occurring nucleotides has been altered (e.g., a man-made variant sequence), remain eligible. Other claims, including method claims, that involve naturally occurring nucleic acids may give rise to eligibility issues and should be examined under the existing guidance in MPEP 2106, Patent Subject Matter Eligibility.

Is there a straightforward work-around? Some assistance might, it is suggested, be gleaned from the common law of real property. *Fructus naturales* refers to vegetation growing e.g. in a field without human intervention as in a crop of grass which is the natural and permanent produce of land, renewed from time to time without cultivation and cannot be divided from the land on which it is grown. In contrast corn, wheat, oats, barley, potatoes, etc., being *fructus industriales*, are considered as the representatives of the labour and expense bestowed upon them, and regarded as chattels[1]. The rule in *Myriad* covers sequences extracted from living plants and animals, but should it apply to amplified or recombinant versions of those sequences, as in the UK litigation concerning recombinant tPA[2]? Everything other than that which is extracted from an organism is created by human labour and is therefore better regarded as *fructus industriales*. In argument the Supreme Court was anxious that patents should not cover gold extracted from the ground or wood cut from a tree, but should the same prohibition apply to gold made by an alchemist (if that were possible) or cellulosic material identical to natural wood but grown by cell culture?

The position in the US is now radically different from that in Europe. A debate in the 1990's resulted in the passage of the *European Biotechnology Directive* of 6 July

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[1] Rogers, Henry Wade, "The Law in Relation to Crops – Fructus Industriales" (1882). Faculty Scholarship Series. Paper 4043. http://digitalcommons.law.yale.edu/fss_papers/4043

[2] *Genentech Inc's Patent* [1989] R.P.C. 147 (U.K. Court of Appeal)

1998, [1998] OJL 175/1[3]. The preambles are worth consulting for the underlying philosophy, but the bottom line is set out in in Article 3:

> 1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.
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> 2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

In Australia the patentability of such materials has recently been confirmed by the Federal Court of Australia in *Cancer Voices Australia v Myriad Genetics Inc*[4], a well-reasoned and detailed decision that considers relevant US and UK opinions including *Kalo v Funk*. The Australian court explained that its findings were consistent *inter alia* with a report of the Australian Law Reform Commission of June 2004 entitled *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99, 2004). That report concluded that it would be difficult, on any rational basis, to confine reform to genetic materials and technologies, and that the extension of the reform to other fields – where the patenting of pure and isolated chemicals that occur in nature was uncontroversial – could have unknown consequences.

More immediately, the question arises what should patent practitioners do in response to the *Myriad* decision. It is highly unlikely that practitioners in Europe and other non-US countries will eliminate form their specifications claims to isolated nucleic acids or fragments because such claims remain widely allowable. It is suggested that US practitioners should at least at the first filing stage ignore *Myriad* and the recent USPTO guidance in its entirety (subject to such work-arounds that they may subsequently devise and adopt for the US).

As is widely known the added subject-matter provisions of a.123(2) EPC are strictly interpreted at the EPO, and generalizations not found in an application as filed cannot be added subsequently. If a claim to an isolated sequence is not presented in an application as filed, or if a corresponding statement of invention does not appear in the description, then the right to claim that sequence is at risk of being irreversibly lost. Less well-known is the attitude of the EPO to priority as set out in Enlarged Appeal Board decision G 2/98 *Priority of the "same invention"/PRESIDENT'S REFERRAL* which also applies a strict novelty test. Omission from a US provisional application of a claim or statement of invention directed to a sequence could also result in loss of priority for that sequence. Similar very strict attitudes apply in other countries e.g. China, where the issue of added subject-matter is, if anything, even more difficult than

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[3] http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31998L0044&model=guichett

[4] [2013] FCA 65; http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2013/2013fca0065

before the EPO. The above comments should not be interpreted as an indication that adverse consequences will inevitably follow, but a risk-averse drafting approach dictates that the necessary language for isolated sequence claims should continue to appear in US-filed provisional and utility applications and PCT specifications.