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Should the Australian Patent Office be denying patent eligibility to cDNA inventions?

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In this, the first of a trilogy of articles investigating specific areas of Australian Patent Office examination practice, I consider how the High Court's decision in D'Arcy v Myriad Genetics Inc [2015] HCA 35 (7 October 2015) (the Myriad decision) has been interpreted to render all non-naturally-occurring cDNA compositions patent ineligible. I also question the legitimacy of this current Patent Office practice in view of patent eligibility standards applied to other gene-based inventions.

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Background

When the High Court of Australia ruled against the patentability of isolated human genes in October 2015, biotechnology stakeholders were on tenterhooks as to how the decision would be interpreted and its impact on Australian biotechnology innovation.

It is now history that the Australian Patent Office's narrow interpretation of the Myriad decision manifested only as an exclusion to patentability of isolated gene sequences encompassing "genetic information" that occurs in nature. Isolated naturally-occurring material other than genes, such as proteins and micro-organisms, remain unquestionably patent eligible under Australian law. This contrasts with the US situation, where the Supreme Court "Myriad decision" resulted in a patentability exclusion for all isolated naturally-occurring materials.

Remarkably, however, up until the Myriad decision's first anniversary, the Australian Patent Office implemented examination practice that excluded from patentability certain gene-based inventions that only came about as a result of human activity. These inventions included codon-optimised nucleic acid sequences, and double-stranded interfering RNA compositions. The Patent Office's rationale at the time was that although such compositions do not occur in nature, they encompass "genetic information" that is naturally occurring. This practice was reconsidered by the Patent Office in Cargill Incorporated v Dow AgroSciences LLC [2016] APO 43 (5 July 2016) (the Cargill decision), which confirmed the patentability of codon-optimised nucleic acid sequences) and Arrowhead Research Corporation [2016] APO 70 (13 October 2016) (the Arrowhead decision), which confirmed the patentability of interfering RNA compositions.

Australian Patent Office practice, however, currently maintains a patentability exclusion for all cDNA inventions. It is, however, arguable whether this practice is consistent with the Patent Office's own precedents set down by the Cargill and Arrowhead decisions.

cDNA: the current Patent Office position

According to the Australian Patent Office Manual of Practice and Procedure, if "genetic information" in a man-made molecule, for example cDNA, is the same as that in the genome, the molecule is not patent eligible". cDNA appears to have been specifically excluded from patentability because the Myriad decision states in obiter at paragraph 55:

> The information stored in "… the sequence of nucleotides coding for the mutated or polymorphic BRCA1 polypeptide is the same information as that contained in the DNA of the person from which the nucleic acid was isolated. …. That characteristic also attaches to cDNA, covered by the claims,

which is synthesised but replicates a naturally occurring sequence of exons".

Based on this paragraph, which specifically concerns a prognostic invention and not the expression of a protein, the Patent Office has applied a broad exclusion to the patentability of all cDNA inventions.

cDNA consists of a nucleotide sequence of human-made fused exons (the exons encoding a protein), without intervening non-coding introns. It is well known by molecular biologists that the removal of introns confers a multitude of advantages not exhibited by the corresponding genomic sequence, including ease of cloning and manipulation, and superior protein expression levels. Moreover, it is well understood that intron sequences include genetic information. This is a fact clearly identified by the Myriad decision at paragraph 201, where it is stated "[i]ntrons do not encode a protein but they contain information that helps regulate the utilisation by the cell of the encoded information in the exons". Based on this point alone, it would seem clear that if a cDNA invention relates to the expression of a protein, cDNA could not be considered as encompassing the same information as that which occurs in nature.

Patent Office practice inconsistencies?

Most recently, I challenged the Patent Office's position in a case where the claimed cDNA demonstrably exhibited commercial advantages over the corresponding genomic sequence. The Patent Office acknowledged that the claimed cDNA provided advantages which distinguished it from genomic genetic information. The relevant claims, however, were ultimately rejected because the Examiner formed a view that "[t]he key issue is that in the absence of an appropriate vector, isolated cDNA is in substance genetic information which encodes the same polypeptide as the genomic sequence" The Examiner also stated that the benefits of "efficiency and ease of expression or quantity of expression, arise as a result of a man-made expression construct and expression in a transgenic host". This approach is arguably inconsistent with the position of the Patent Office in the Cargill decision, where the patentability of codon-optimised DNA was confirmed based on its utility. Relevantly, all of the points raised by the Examiner above, to support a case of patent ineligibility, also clearly apply to patent eligible codon-optimised DNA.

Specifically in the Cargill decision, the Delegate stated that codon-optimisation is an important man-made variation to the naturally occurring sequence, notwithstanding that such sequences code for the same protein as a naturally occurring sequence, because it facilitates optimal production of the encoded protein in certain cells above that which could be expected from the naturally-occurring sequence. Such benefits, however, only come about as a result of an expression construct and expression in a transgenic host, which are the identical circumstances that confer the commercial advantages associated with cDNA.

Similarly, in the Arrowhead decision, it was found that the double-stranded nature of the claimed RNA compositions played a significant role in the working of the invention.

In both Cargill and Arrowhead cases, it was the advantages and economic utility of the claimed nucleotide sequences which provided basis for their patentability. However, the advantages and economic utility of cDNA sequences, which are directly comparable to codon-optimised sequences, are currently insufficient to confer patentability to cDNA inventions.

Conclusion

It is difficult to understand how Applicants claiming cDNA inventions that confer significant economic advantages over naturally-occurring sequences are receiving fair treatment from the Patent Office given that codon-optimised DNA sequences, which exhibit similar advantages, are patent eligible. Hopefully, in the future the Patent Office will have the opportunity to consider patent eligibility of cDNA in greater detail to ensure that consistent examination practice is clearly applied.

Grant Shoebridge contributed to this article.

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