

August 2011

DNA-based diagnostics - the incentives for filing IP are reinforced

A report issued earlier this month by the Human Genetics Commission (HGC) entitled “Intellectual Property and DNA Diagnostics” draws attention once more to the tension between a commercial diagnostics sector, with desire to exploit the financial value of biomarker patents, and a public sector laboratory community which appears reluctant to acknowledge such property rights; it warns that turning a blind eye to relevant IP relies on drivers for inaction by patent holders which seem unlikely to persist, particularly in the light of the predicted increase in the number of private sector genetic screening laboratories. The full report is available on the HGC website:

<http://www.hgc.gov.uk/>

Almost simultaneously with release of that report, the US Court of Appeals of the Federal Circuit (CAFC) issued a decision in the on-going saga of the IP underpinning Myriad BRCA gene testing. This provides useful guidance for drafting of genetic testing claims and provides a further confidence boost to patent holders in the genetic diagnosis field that such claims will continue to be enforceable in the US.

For those not familiar with the history, a US District Court judge ruled in March 2010 that patents held by Myriad, which are directed to isolated BRCA 1 and 2 gene sequences and their use in diagnostic screening, were not patentable. Significantly, the judge ruled that the subject matter covered by these patents was not allowable as a fundamental and general principle of US patent law, not just on the specific issues in this one particular case.

The judge’s reasoning was that isolated genetic material, such as the BRCA 1 and 2 genes, was not sufficiently distinct from the genes as they are found in nature. Thus claims directed to these isolated sequences were to ‘products of nature’ which are not patentable *per se*. In addition, he found that methods of screening genetic information for defects in these genes were also fundamentally non-patentable as they relate to ‘abstract mental processes’. Furthermore, the judge’s comments seriously questioned the patentability of other types of biomolecules.

This ruling went against 30 years of USPTO practice in issuing ‘gene’ patents, and threatened to undermine the foundations of the biotech industry. Hence there has been intense interest and wide speculation about where this case will lead. The latest chapter of this story has now been written - in the form of a 105 page judgement of the Court of Appeals for the Federal Circuit (CAFC).

To sum it up succinctly, the sky has not fallen on biotech patents. The previous patentability position is restored with one notable change. In short:

- Isolated DNA (in this case BRCA cDNA, genes and partial gene sequences) is patentable. The isolation of such sequences from the normal chromosomal environment means they are not products of nature.

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- Methods of screening compounds against cells with altered BRCA genes to identify active agents are patentable. Such methods involve physical steps of administering compounds to cells and thus cannot be regarded as 'abstract mental acts'.
- However, claims reading on to methods of simply analysing and comparing BRCA sequences of subjects are NOT patentable subject matter. Such sequence analysis has been deemed a purely 'abstract mental act'.

The third point is of some concern, but careful reading of the wording of the judgement leaves scope for careful drafting of claims to avoid the difficulty. More specifically, including explicit reference to a physical step, such as detection of a mutation in a patient sample, should side-step the issue.

Will this be the end of the saga? Probably not, but the CAFC has thrown out a strong signal that in its view gene patents are here to stay. As far as the UK and Europe is concerned, the Biotechnology Directive (Directive 98/44/EC) is clear that patents to isolated genes are patentable.

No discussion of patent protection in the genetic diagnosis field would be complete without reference to the Myriad BRCA gene saga, but the recent HGC Report draws attention to the wider scope of IP seekers in the field, particularly universities. The rapidly growing role of genetic biomarkers in such areas as clinical testing may provide attractive licensing opportunities for entities such as universities holding biomarker IP.

Contributors: Douglas Drysdale and Claire Irvine; Dr Irvine was one of the small number of patent attorneys and IP lawyers invited to contribute to the seminar in October 2010 which provided the foundation for the 2011 HGC Report.

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