

## **Commissioner's proposed revised examination practice for consultation 16 October 2015 to 6 November 2015.**

The Commissioner has considered the High Court's decision. The decision clearly concludes that a claim to an isolated nucleic acid that merely represents information coding for a polypeptide is not patent eligible. On this basis, the Commissioner considers that the following are not patent eligible and will not accept claims for:

- Naturally occurring (human) nucleic acid sequences encoding polypeptides or functional fragments thereof - either isolated or synthesised
- Naturally occurring (non-human) nucleic acid sequences encoding polypeptides or functional fragments thereof - either isolated or synthesised
- cDNA
- Naturally occurring human and non-human coding RNA - either isolated or synthesised

In light of the High Court's decision the Commissioner proposes the following remain patent eligible as they do not merely represent information coding for a polypeptide:

- Naturally occurring isolated regulatory DNA (e.g. promoters, enhancers, inhibitors, intergenic DNA)
- Isolated non-coding (e.g. "Junk") DNA
- Isolated non-coding RNA (e.g. miRNA)
- Naturally occurring isolated bacteria
- Naturally occurring isolated virus
- Isolated polypeptides
- Synthesised/modified polypeptides
- Isolated polyclonal antibodies
- Chemical molecules purified from natural sources (e.g. new chemical entities, antibiotics, small molecules)
- Isolated cells
- Isolated stem cells
- Probes
- Primers
- Isolated interfering/inhibitory nucleic acids (e.g. antisense, ribozymes)
- Monoclonal antibodies
- Fusion/chimeric nucleic acids
- Transgene comprising naturally occurring gene sequences
- Vectors/microorganisms/animals/plants comprising a transgene