Impact of the Myriad Decision on Plant Biotech Patent Applications in Australia

Introduction

Much has been written about the Australian High Court’s decision in *D'Arcy v Myriad Genetics Inc* [2015] HCA (“the Myriad decision”).

This article considers the impact of the decision, and subsequent IP Australia examination guidelines, specifically on the patenting of plant biotech inventions in Australia.

Re-cap on the High Court decision

On 7 October 2015 the High Court of Australia ruled that isolated nucleic acid sequences that encode proteins, or fragments thereof, as found in nature are no longer patent eligible subject matter.

This is a similar decision to that made in the US Supreme court case (*Association for Molecular Pathology v. Myriad Genetics, Inc.*) in June 2013, except that the Australian court went a step further and found that cDNA is also not patent eligible.

The rationale behind the Australian decision is that the informational content, rather than structural content, is the substance of the invention in a claim to an isolated nucleic acid sequence, and that this “information” is not “made” (created or modified) by human action merely through isolation.

IP Australia's reaction to the decision?

Those familiar with US practice will be aware that following the Myriad US Supreme Court decision, the USPTO issued guidelines significantly extending the scope of excluded subject matter, far beyond that considered by the court. The USPTO exclusions cover virtually any naturally occurring biological products including nucleic acid and protein sequences, biomolecules and micro-organisms, regardless of whether they are isolated. This has caused great consternation in the biotech industry. Thankfully, from the patentee’s perspective, IP Australia have reacted more conservatively.

On 15 December 2015, following public consultation, IP Australia issued guidelines (found here) on the examination of patents in light of the Australian Myriad decision. These guidelines were incorporated into the Examiner’s Manual of Practice and Procedure on 11 January 2016.
**Brief summary of some key points from the guidelines**

The guidelines specifically exclude isolated naturally occurring DNA and RNA (whether human, non-human, coding or non-coding) from patent eligibility in light of the Myriad decision, in short because they are considered to relate in substance to “information” and have not been “made”.

In addition, claims to cDNA, synthetic nucleic acids, probes, primers, and isolated interfering/inhibitory nucleic acids are excluded from patentability if they merely replicate the genetic information of a naturally occurring organism.

Uses of such excluded nucleic acids however, can still be patentable.

The guidelines assert that other subject matter which may be affected by the Myriad decision but not expressly excluded from patentability should be assessed on a case by case base with consideration of the following factors:

1. What is the substance of the claim (not merely its form)?
2. Has the substance of the claim been "made" or changed by man, or is "artificial"?
3. Does the invention have economic utility?
4. Does the invention as claimed represent a new class of claim?

The guidelines state that the following subject matter remains patentable:

- Recombinant or isolated proteins;
- Pharmaceuticals and other chemical substances;
- Methods of treatment;
- Methods of applying herbicides; and
- Applications of computer technology.

The guidelines also state that plants, isolated micro-organisms and isolated naturally occurring biomolecules can be patentable, although consideration should be given to whether these are “made”.

The guidelines indicate that isolation can render micro-organisms and biomolecules “made” presumably because IP Australia do not consider that such subject matter relates in substance to “information” in the same way as isolated nucleic acid sequences according to the Myriad decision.

**What does this mean for patenting plant biotech inventions in Australia?**

It appears that following the both Myriad decision, and the IP Australia guidelines, much of the subject matter of plant biotech inventions should remain patentable.

While isolated nucleic acid sequences *per se* as they occur in nature will not be patentable, the following subject matter will likely remain patentable:

- Modified nucleic acid sequences
- Chimeric nucleic acid sequences (e.g. a coding sequence linked to heterologous promoter)
- Isolated polypeptide sequences
• Plant cells and plants transgenic for naturally occurring, modified or chimeric sequences.
• Plants (including non-transgenic plants, if “made” (bred or created via human activity)
• Methods for producing transgenic cells and plants.
• Methods for producing altered phenotypes in transgenic plants
• Methods for editing the genome of plants to introduce new phenotypes
• Methods for producing recombinant products in plant cells and plants
• Pure cultures of (naturally occurring) bio-protection organisms (e.g. bacteria)
• Modified bio-protection organisms (e.g. bacteria)
• Bio-protection methods using naturally occurring or modified organisms

Ultimately it will be for the courts to decide how the Myriad decision is applied, but there should still be many ways to capture plant biotech related inventions as patent eligible subject matter in Australia. It will of course be important to include claims, in patent specification destined for Australia, that are likely to define patent eligible subject matter.

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