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The Commissioner of Patents
IP Australia
PO Box 200
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Our Ref: 63542AUM01

Dear Commissioner

Contact:

Jacinta Flattery-O'Brien,
PhD

We thank the Commissioner for her invitation to comment on the proposed examination practice following the High Court decision in *D'Arcy v Myriad Genetics Inc* [2015] HCA 35. The Commissioner has set out a number of biological products which, it is proposed, will remain patent eligible. Plants comprising a transgene are among these products and are the topic of this submission. In brief, we seek to clarify that there is no requirement for a plant to comprise a transgene in order to be considered patent eligible subject matter.

It has long been the practice of the Patent Office to accept claims directed to plants, whether or not those plants include a transgene. Sophisticated breeding programs, mutagenesis and genome-editing can all produce plants that do not comprise a transgene but which still meet the requirements for patentability under Australian law. Indeed, plants that are eligible for protection under the *Plant Breeder's Rights Act 1994* (Cth) may also be patentable, provided they meet the additional thresholds for patentability. As the High Court confirmed in *Grain Pool of Western Australia v Commonwealth of Australia* [2000] HCA 14 "there is no intrinsic impediment to the patentability of plant varieties".

The reasoning of the majority in *D'Arcy v Myriad Genetics Inc* does not affect the status quo when it comes to the patentability of plants. The High Court restricted its decision to the three disputed claims (at [37]) and found that the nucleotide sequences in question could properly be described as information and that the isolated nucleic acid itself is merely the medium in which the information resides (at [89]). This reasoning holds little relevance when considering the patentability of plants. Their honours observed (at [91]) that debates about "products of nature" versus "artificially created products" were distracting from the central issue, that is, whether an essential integer of the claims, the genetic information, renders the claims ineligible for patentability. Plants are clearly not a medium for holding information. They are products, the traits of which can be manipulated by man for the purpose of creating an article of commercial importance.

Their honours also observed that the artificially created state of affairs defined by claims 1 to 3 was "a step along the way" to a process or method of economic significance (at [85]). Clearly this is not so in the context of plants. Plants have immediate economic significance and that fact is not changed by the presence or absence of a transgene.

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In the proposed examination guidelines the Commissioner has, correctly in our view, identified naturally occurring isolated bacteria and naturally occurring isolated viruses as patent eligible subject matter. We ask that the Commissioner make it clear in her updated guidelines that there is no requirement for a plant to comprise a transgene to be considered patentable subject matter.

We look forward to receiving confirmation that our submission has been considered.

Yours respectfully

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