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4 November 2015

Commissioner of Patents
IP Australia
Ground Floor, Discovery House
47 Bowes Street
Phillip ACT 2606

By email only: mdb-patents-consultation-group@ipaaustralia.gov.au

Dear Commissioner,

Examination practice arising from *D’Arcy v Myriad Genetics Inc*

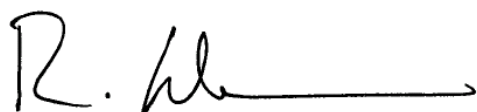
We refer to your proposed examination practice that was first published for public comment on 16 October 2015.

We acted for Ms D’Arcy in the *D’Arcy v Myriad Genetics* proceeding before the High Court of Australia as well as the proceedings of the same name before the Federal Court of Australia.

We are concerned that your proposed examination practice involves a misapplication of the High Court of Australia’s decision and we have sought advice in this regard from David Catterns QC and Dr Peter Cashman who were counsel for Ms D’Arcy in these proceedings. We attach their advice which we adopt in full.

Please do not hesitate to contact me should you wish to discuss this matter further.

Yours faithfully,



Rebecca Gilsenan
MAURICE BLACKBURN

D'ARCY v MYRIAD

JOINT OPINION

We have been asked by Maurice Blackburn, solicitors, to advise on the Proposed Examination Practice issued by the Commissioner of Patents on 16 October 2015, with an invitation to interested parties to comment on the proposed practice by 6 November 2015.

The Proposed Practice follows the Commissioner's consideration of the High Court's decision in *D'Arcy v Myriad Genetics Inc* [2015] HCA 35.

We appeared as counsel for the appellant in *D'Arcy v Myriad*, instructed by Ms Rebecca Gilsenan, of Maurice Blackburn.

The Commissioner's Proposed Practice consists of:

- (a) a list of potential subject matter that she considers are "not patent eligible" and for which she will not accept claims; and
- (b) a list of potential subject matter that "the Commissioner proposes ... remain patent eligible as they do not merely represent information coding for a polypeptide".

In our opinion, the list of "not eligible" subject matter is apparently intended to be confined to the bare minimum that, consistently with her statutory duty and the *ratio decidendi* of *D'Arcy v Myriad*, the Commissioner must refuse to accept.

In our opinion, however, the list of "remaining patent eligible" subject matter contains many examples of subject matter that, on the reasoning of each of the three judgments of the seven members of the High Court, are plainly not patent eligible. That is, claims for such subject matter are not claims to a manner of manufacture within the meaning of s18(1)(a) of the *Patents Act 1990*. It follows that such claims are not claims to a "patentable invention".

The error in the Commissioner's approach, with respect, is her confining of the reasons for decision of the High Court to the rejection of claims to "isolated nucleic acid that merely represents information coding for a polypeptide" (emphasis added). That subject matter is

now certainly not patentable but the reasoning of the Court goes a considerable distance beyond that.

The Federal Court and other prescribed courts are bound to follow not just that narrow *ratio* of the High Court but also the other considered *dicta* of the Court whose members, although they gave three judgments, expressed a considerable measure of agreement on important issues of principle. This constitutes “seriously considered” *dicta*, in terms of the High Court’s judgment in *Farah Constructions Pty Ltd v Say-Dee Pty Ltd* (2007) 230 CLR 89, [134], [147], [158].

For an example in a patents context, see *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 217 CLR 274, at [57], [67], [103]. See also *Telstra Corporation Limited v Phone Directories Pty Ltd* [2010] FCAFC 149, [112]; *Construction Forestry Mining and Energy Union v Endeavour Coal Pty Ltd* [2015] FCAFC 76, [139]. In our opinion, the prescribed courts with jurisdiction in patent cases will undoubtedly apply the reasoning that appears in the judgment given by the plurality, French CJ, Kiefel, Bell and Keane JJ, and will very likely apply the reasoning in the other judgments.

There is also no question that the Commissioner is bound to administer the Act in a manner that is consistent with the decision of “a superior court of record in the exercise of federal jurisdiction declaring the meaning and proper content of a law of the Parliament” – here, the High Court having done so, the Commissioner may not “ignor[e] the views of the judicial branch of government”, by “administering the statute in a manner contrary to the meaning and content as declared by the Court”: *Commissioner of Taxation v Indooroopilly Children Services (Qld) Pty Ltd* (2007) 158 FCR 325, at [3], per Allsop J, Stone and Edmonds JJ agreeing at [1] and [47]-[48].

By s45 of the Act, the Commissioner must examine a patent request and specification and report on compliance with, *inter alia*, s18(1)(a). By s49(1), she must accept a request and specification if she is “satisfied on the balance of probabilities ... (b) that the invention, so far as claimed, satisfies the criteria mentioned in paragraphs 18(1)(a) ...”.

By s49(2), the Commissioner may refuse a request if s49(1) does not apply – that is, as relevant here, unless she is satisfied that the relevant claim claims a manner of manufacture.

In our opinion, in light of *D'Arcy v Myriad*, the Commissioner cannot be satisfied that claims for most of the items on the list of subject matter that she proposes should remain patent eligible satisfy the manner of manufacture criterion. If she cannot be satisfied of this, then by s49(2) she should refuse them.

The current form of s49 is part of a consistent legislative policy to raise the quality of granted patents. It represents a significant shift from the policy that used to apply, namely that the Commissioner “ought not to refuse an application and specification unless it appears practically certain that letters patent granted on the application would be held to be invalid”: *Commissioner of Patents v Microcell Limited* (1959) 102 CLR 232, 244-245. In our respectful opinion, the Proposed Practice departs significantly from that policy and would lead to the acceptance of requests and specifications with claims that are plainly invalid.

The example of “naturally occurring isolated regulatory DNA”, that appears first on the Commissioner’s patent eligible list, shows that the Proposed Practice conflicts directly with the reasoning of the Court. In our opinion, a prescribed court would follow the High Court in holding a claim to a promoter sequence not to be a manner of manufacture.

We point out that, as occurred in *D'Arcy v Myriad*, a claim to a particular practical application of such a sequence might well be in a different category. The Commissioner’s document correctly notes that the High Court did not make any finding with respect to claims of that type.

As the Commissioner’s document also notes, the High Court considered the claims in issue in *D'Arcy v Myriad* as a matter of substance and “decided that the information [embodied in the nucleotides] was an inherent part of the molecule and **not created by human action**” (emphasis added). See, e.g., per the plurality at [16]. This reasoning applies directly to the example of isolated regulatory DNA. The Commissioner’s distinction, apparently based on a view that such DNA does not code for a polypeptide is, in our opinion, far too narrow a basis on which to put aside the High Court’s reasoning – such DNA is not created by human action; it does not involve “making”. It follows that this form of DNA is not a manner of manufacture (assuming, as in *D'Arcy v Myriad*, that the act of isolation does not itself involve invention).

It is significant that the distinguished experts relied upon by the respondent in *D'Arcy v Myriad* explained that, for example, “introns can encode functional RNA molecules of many types. These functional RNA molecules have very diverse effects including the modulation of gene expression.” (Affidavit of Professor John Rasko affirmed 23 September 2011 at [93]. See also the Affidavit of Professor Matthew Brown affirmed 21 December 2011 at [85] to [88]). The proposed distinction based on a narrow view of DNA’s role in coding is, thus, unsound.

See per the plurality at [6], [85], [89], [91]-[93]; Gageler and Nettle JJ at [126]-[128], [137], [139], [158], [160], [169]; Gordon J at [244]-[249], [278]-[282].

In conformity with the plurality’s holding that attributes that are not “made” or “brought about by human action” do not bring an alleged invention within the ambit of a “manner of manufacture”, eg at [6], Gageler and Nettle JJ emphasised the necessity that the inventive concept or inventiveness must make a contribution to the essential difference between the product and nature. See at [128]-[123], [161]-[165].

A further very significant aspect of the High Court’s reasoning, in our opinion, is the Court’s reference to policy considerations, e.g., by the plurality at [28]. These include, relevantly here, the need to enhance “the coherence of the law relating to inherent patentability”. See also [30]. They also include the proposition that it is undesirable to accord patentability to a class of claims that will have a negative or chilling effect on innovation, eg at [93].

This is an answer, we respectfully suggest, to the submissions that the Commissioner will possibly receive, that the refusal of claims to the subject matter suggested by the Proposed Practice as being patent eligible will itself affect innovation. We note that the High Court declined to entertain submissions to that effect from the Institute of Patent and Trade Mark Attorneys of Australia, which applied to intervene in *D'Arcy v Myriad*. Such an approach would fail to distinguish between the patentability of naturally occurring things themselves (whether isolated or not) and the application of those things to a new and useful purpose, such as a method of treatment or diagnosis. See eg *D'Arcy v Myriad* at [126], [137].

In our opinion, the Commissioner’s approach, as reflected in the Proposed Practice, would detract from the coherence of the law relating to inherent patentability – that is, to the law relating to manner of manufacture and s18(1)(a). To confine the High Court’s reasoning as being narrowly limited to “coding for a polypeptide” is antithetical to the objective of coherence. As noted above, the Commissioner’s proposed approach plainly departs from the considered reasoning of each of the reasons for judgment of the High Court: in particular, that of the four justices comprising the plurality.

We note that the Commissioner’s list of patent eligible subject matter contains an apparent cascade of degrees of artificiality. In our opinion, that approach reflects a mechanistic application of the idea of an “artificial effect of economic utility” of the type that the High Court deprecates in *D’Arcy v Myriad*. In our opinion, the reasoning of the High Court would have the result, for example – contrary to the Proposed Practice – that a naturally occurring isolated virus or polypeptide would not be a manner of manufacture if, on the face of the specification, its isolation did not involve invention; but the use of the virus or polypeptide in, say, a vaccine or as an enzyme inhibitor might be. Similarly, there is no valid normative distinction between an isolated polypeptide *per se* and an isolated polynucleotide.

We respectfully suggest that, for the Proposed Practice to have real value in the commercial interest of prospective patentees, and in the public interest, the Commissioner should issue a further proposed practice or engage in a further appropriate process of consultation that describes in much more detail the technology being considered, including the types of claims and whether the claims are for the assertedly eligible subject matter alone – or for applications of that subject matter. The Commissioner could invite comment on the inherent patentability of the various types of subject matter in a manner analogous to the very full consultation adopted by the United States Patent and Trademark Office following the series of recent United States Supreme Court decisions on inherent patentability, including in the counterpart case to *D’Arcy v Myriad*. See *Interim Guidance on Patent Subject Matter Eligibility* 79 FR 74618 (Dec 16, 2014); *July 2015 Update on Subject Matter Eligibility* 80 FR 45420 (July 30, 2015).

The present timetable for comment and the brevity of the Proposed Practice is, in our opinion, likely severely to disadvantage persons who wish to assist the Commissioner in the

proper discharge of her duties in arriving at a legally tenable and practical approach to her statutory function, in the light of the High Court's decision.

To reiterate, it is our opinion that the present form of the Proposed Practice seriously misreads the High Court's reasons. In our opinion, the Proposed Practice is likely to constitute the type of conduct that was unequivocally criticised in *Commissioner v Indooroopilly*.

David Catterns QC

Dr Peter Cashman

4 November 2015