

The Secretary
Intellectual Property and Competition Review Committee
Attorney General's Department
Robert Garran Offices
BARTON ACT 2600

Dear Secretary,

I refer to your Interim Report and your request for comments on the Interim Report.

I note I have already provided a submission setting out in detail the reasons and justification for reviewing the scheme for gene and gene sequence patenting. My comments here restate my concern that the present gene and gene sequence patenting practices undermine the basic intentions of patenting to the detriment of the broader Australian community. These are key concerns in analysing the competition effects of biotechnology patenting and need to be canvassed in your review.

I refer to my earlier submission and submit the following issues require further consideration by the Committee:

- (i) Public interest and patenting – section 18 of the *Patent Act* 1990 makes various references to section 6 of the *Statute of Monopolies* including the requirement that the invention not be “mischievous to the state by raising prices of commodities at home, or hurt trade”. Given the focus of the *Patents Act* 1990 was directed to “how the patent system can best contribute to the efficiency and progressiveness of the Australian economy” and the apparent failure when assessing gene and gene sequence patent claims to undertake this assessment, the Committee might review the need to make such an assessment. The Committee might also consider the Australian submissions to the WTO dispute concerning the Patent Protection for Pharmaceuticals (WT/DS114/1) and the reliance on *Attorney General (Cth) v Adelaide Steamship Co* which traced the origin of the *Statute of Monopolies* from the strict limits the common law applied to monopolies and identified the requirement at common law that consideration move to the public for the derogation of the right to freedom of trade – a bargain between the community and the inventor. This assessment seems necessary given there are delays in releasing information or information is not released to ensure that the patent application is not harmed, the Australian experience in the *Chiron case* which shows how a patent right was to be used to prevent an arguably superior product from being made available to the community, the abandonment of research when gene sequences are patented, and the unclear consequences of limiting the use of gene and gene sequence data which may be significant given broad sequence and sequence applications claims (discussed below);
- (ii) Cost of innovation – a key justification for biotechnology patenting is that strong patent laws are needed to protect investments in and funding of research and development. However, without data to justify this claim it is unclear how much biotechnology innovation costs and whether the grant of the patent (with its monopoly returns) is adequate or excessive. The true cost of innovation might be determined (both the cash outlays and timing) by a large and representative sample of projects followed from instigation to the marketing. This has *not* been undertaken or required for biotechnology patents and without this information informed decisions about biotechnology patenting policy cannot be made (such as patent term extensions);
- (iii) Broad claims – once the Patent Office and court accept the gene or gene sequence is patentable, broad claims for both the sequence and its applications are allowed. The breadth of both the sequence claims and sequence application claims restrict the potential for further innovation. It is

submitted the breadth of these claims undermines the policy justifying the grant of a patent monopoly. This might be addressed in part by the rules governing selection and combination patenting, except that current Patent Office and court decisions show this solution to be very limited. These practices are of particular concern in Australia as the value of Australia's genetic resources are being undermined by such broad sequence and application claiming practices; and

- (iv) Extending patent terms – for those advocating patent extensions...show us the data and arguments which justifies patent extensions, and this must be more than mere assertions...as Loughlan states:

“The political process by which the decision on patent term is actually made is, however, skewed by the fact...that patent decisions are not widely seen as political decisions involving winner and losers and possible conflicts between the public interests, but rather as technical, economic decisions suitable to be made by experts. The process is further skewed by the related fact that, as Manderville pointed out, those who would benefit from a strengthening of the patents system such as an extension of the patent term, ‘are concentrated, powerful and active defenders of their interests. In contrast, those who would gain by patent reform are diffuse and hardly aware of their interests in the matter’”.

The assistance of Dr Catherine Pickering is acknowledged and you are referred to our recent paper outlining some of these arguments:

C Lawson and C Pickering, “Patenting genetic materials – failing to reflect the value of variation in DNA, RNA and amino acids” (2000) 11 *Australian Intellectual Property Law Journal*, in press.

If you have any queries please do not hesitate to contact me.

Yours sincerely,

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