How to prosecute biotech patents in Australia after *Myriad*

By Vaughan Barlow[1]

1. Introduction

The Australian High Court decision in *D'Arcy v Myriad Genetics Inc* [2015] HCA 35 in October 2015 ("*Myriad*") was closely aligned with the decision of the United States Supreme Court in *Association for Molecular Pathology v Myriad Genetics, Inc* 569 US 12-398 (2013), holding that the act of isolating a naturally occurring nucleic acid did not confer patentability upon the isolated nucleic acid. Since the High Court's decision, IP Australia has developed practice guidelines that govern examination of relevant subject matter. These guidelines are highly contentious and do not comfortably align with the decision in *Myriad*. This article details the new guidelines and how best to navigate them.

2. Threshold question: does the claim fall within established boundaries of patentability?

Under the new guidelines, examiners are now required to firstly assess whether claims fall within "established boundaries" of patentability per the *NRDC* case[2]; that is, whether they encompass subject matter that has traditionally been regarded as an "artificially created state of affairs". In considering this threshold issue, the *Patent Manual of Practice & Procedure* states that:

> "In general, the Courts have indicated that, subject to other requirements, patents are available for products, methods of making and using products and methods that otherwise result in a new and useful effect. Technical subject matter that has been previously considered by Courts without rejection includes:

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2. *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (the "*NRDC* case");

Recombinant or isolated proteins.
Pharmaceuticals and other chemical substances.
Methods of treatment. …" [3]

If claims do not fall into traditionally allowable subject matter, then they are assessed per the principles enunciated in *Myriad*. In practice, all "composition of matter" claims reciting molecules that can be chemically characterized as nucleic acids, including cDNA, are now shunted into the *Myriad* stream for evaluation. This is regardless of whether or not the claimed nucleic acids are naturally occurring or artificial, what chemical modifications may be included, and whether or not they can be characterized as pharmaceuticals or chemical substances. Claims to compounds and compositions comprising nucleic acids are also shunted into the *Myriad* stream.

Hence, for example, claims reciting modified oligonucleotides with a morpholino backbone will not be shunted into the *Myriad* stream on the basis that the molecules are no longer chemically characterized as nucleic acids. However, claims reciting modified oligonucleotides with, for example, a phosphorothioate backbone will be shunted into the *Myriad* stream on the basis that the molecules are still chemically characterized as nucleic acids.

Claims reciting methods of using a nucleic acid and claims drawn to other associated biological material, such as amino acids, are not subject to *Myriad* considerations. Claims reciting naturally occurring amino acids therefore need only recite that the amino acid is "isolated" in order to satisfy the manner of manufacture requirement, consistent with the traditional requirements that existed prior to *Myriad*.

The practice of IP Australia in assessing this threshold question therefore ignores whether or not nucleic acids recited in claims are (1) naturally occurring or (2) artificial molecules. For the former, such claims are analogous to those considered by the High Court in *Myriad*, where the act of isolation was relied upon for patentability, and hence these claims should indeed be shunted into the *Myriad* examination stream. However, for the latter, and unlike

[3]. Section 2.9.2.1 *Patent Manual of Practice & Procedure*;

the situation in *Myriad*, it is not the act of isolation that is being relied upon for patentability, but rather, the fact that the claimed nucleic acids are artificial molecules, for example, by way of having a chemical modification, etc. Indeed, it is difficult to see how such a molecule cannot be regarded as "an artificially created state of affairs" and therefore properly within the established boundaries of patentability per the *NRDC* case, thereby avoiding *Myriad* considerations.

3. What is the "substance" of the claim?

Once flagged for the *Myriad* stream, a specially formed group of senior examiners then assesses the "substance" of the claim. This involves considering how the invention works, the breadth of the claims / size of the class of compounds covered by the claims, whether the claimed subject matter embodies or conveys genetic information that is of importance to the utility of the invention, the "emphasis" of the claim, and whether a claimed composition of matter is merely a step along the way to a process or method that represents the real invention.

Experience to date suggests that the "substance" of all claims drawn to nucleic acids *per se* will be deemed to be the genetic information carried by the nucleic acids, regardless of the considerations set out above. This is despite cases where, for example, a claimed nucleic acid has a demonstrated therapeutic function, and the invention as a whole is drawn to treating a disease. In this regard, the rationale from examiners is that such functional aspects are irrelevant when considering claims to a composition of matter *per se*. Hence, inherent functional consequences of nucleic acids are disregarded.

This is also the case even where claim language requiring suitability for use is included. For example, reciting "…wherein the nucleic acid is capable of inhibiting mRNA expression, thereby treating disease X" is not persuasive, as such suitability for use is not regarded as limiting the claim to such a use. Similarly, first medical use claims such as "X for use in the treatment of Y" would not be allowable in this context. Conversely, language such as "… when used for …" is regarded as effectively limiting the claim to the use, and hence such claims are allowable. [4]

[4]. Note however that use-type claims cannot support an application for patent term extension;

4. Is the "substance" of the claim "made"?

Examiners must then determine whether the "substance" of the claim is "made". This requires examiners to consider whether the substance of the claim has been created or modified by human action (mere replication is insufficient), whether there are physical differences between the claimed substance and the natural state and what labour was required to produce the product. Unless the sequence of nucleic acid is artificial, for example, a chimeric or other heterologous sequence, then experience to date suggests that the nucleic acid sequence will be deemed not to be "made". Indeed, it appears that as long as the entire nucleobase sequence of the claimed nucleic acid is capable of perfectly hybridizing with a naturally occurring sequence, then the degree to which the nucleic acid molecule is otherwise modified is irrelevant. For example, even claims reciting chemical modifications to the nucleobases themselves, such as 5-methylcytosines, will still be regarded as not "made". This is based on the rationale that the "substance" of the claimed nucleic acid is the genetic information and not the chemical structure.

5. Other considerations

Other broad policy considerations that are to be taken into account by examiners include the breadth of claim scope and any effect on innovation in the art, as well as the ability to define the scope of the claim and hence possible infringement.

Curiously, the new guidelines also state that:

> "A nucleic acid may also provide patentable subject matter when the substance of a claim is determined to be a product and not genetic information. For example, a nucleic acid microarray is more than merely genetic information. Instead, the substance of the claim is a product which has been "made"." [5]

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5. Section 2.9.2.6 *Patent Manual of Practice & Procedure*.

The rationale for the allowability of array claims is that the information provided by a plurality of probes is more than mere genetic information. It has been stated that a claim to a single probe would not be allowable. However, this seems contrary to the position taken in *Myriad* where it was stated:

> "Claim 4 may be taken as an example. In simple terms, it comprises a nucleic acid *probe* in which the nucleotide sequence is a portion of an isolated nucleic acid … The invention in claim 4 carried into effect the idea that specifically identified mutations or polymorphisms in a sequence of the BRCA1 gene suggest a predisposition to breast cancer and ovarian cancer by testing for the presence of one or more of the specifically identified mutations or polymorphisms. That is an invention."

Arguably, a nucleic acid microarray and a probe function on the same principle of hybridization as any other nucleic acid, and it is therefore difficult to reconcile IP Australia's guidelines with continued refusal of claims drawn to nucleic acids that represent only a portion of a gene / open reading frame.

It is also significant to note that the new guidelines are based only on the majority decision in *Myriad*. This is despite the fact that each of the minority decisions also reached the same conclusion on a similar basis (and notably it is one of the minority decisions cited above that held the probe claim allowable).

6. Conclusion: Summary of allowable subject matter

Given the current practice of IP Australia as discussed above, the following points provide a basic guide for navigating objections based on *Myriad*:

(a) Claims to naturally occurring nucleic acids are unpatentable;

(b) Claims to modified nucleic acids should be patentable on the basis that such subject matter is the product of human intervention and therefore within the established

boundaries of patentable subject matter. Hence, such claims should not be subject to a *Myriad* analysis. Even in the event that a *Myriad* analysis is applied, the "substance" of such subject matter should take into account the inherent functional characteristics of the claimed nucleic acids. Furthermore, such modified nucleic acids are potentially analogous to microarrays and probes, and therefore should be regarded as more than mere genetic information, and "carrying into effect" the claimed invention. However, to date, claims to modified nucleic acids have not been allowed, except in cases where examiners appear to have failed to refer the case to the specially formed *Myriad* team within the examination unit;

(c) Claims to other "isolated" biological materials *per se*, such as amino acids, are allowable and are not subject to a *Myriad* analysis; and

(d) Claims to heterologous nucleic acids are allowed, such as vectors or chimeric sequences, as are any uses of nucleic acids, such as methods of medical treatment, Swiss-type claims, product-by-process claims, etc.

It is also worth noting that several cases are scheduled to be heard by IP Australia that will test the boundaries of how *Myriad* is applied to examination. These cases should be determined by the end of 2016. Moreover, IP Australia has openly expressed a desire for a case to be appealed through the court system.