Before the High Court

D'Arcy v Myriad Genetics Inc: Patenting Genes in Australia

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Abstract

Australian patent law is currently at a crossroad. As it stands, the law lacks the tools and techniques to categorise patentable subject matter: at least in a way that does not appear to be arbitrary or capricious. The forthcoming High Court appeal in *D'Arcy v Myriad Genetics Inc,* which concerns the patenting of human genes*,* offers an important opportunity to fill this vacuum. One of the challenges for the High Court in doing so, will be to confront the limitations of the existing law; particularly the shortcomings of the decision of *National Research Development Corporation v Commissioner of Patents*.[1] In order for Australian patent jurisprudence to move beyond its current malaise, it is important that the High Court reflect on what is meant by 'invention' in Australian law, and also on the criteria to be used when deciding whether something is patent-eligible.

I Introduction

The forthcoming High Court appeal in *D'Arcy v Myriad Genetics Inc*, which concerns the patentability of human genes, is set to be a very important decision, not least because it has the potential to negatively impact the level of health care delivered to women in Australia. The decision is also important because it provides the High Court with the opportunity to consider one of the most important issues in patent law today: namely, how do we determine the eligibility of patentable subject matter?

The controversial patent in dispute grew out of the discovery of the human BRCA1 and BRCA2 genes, and the fact that there was a close relationship between mutations in those genes and the development of breast and ovarian cancer. These discoveries had important ramifications for breast cancer research. They also led to the development of new molecular diagnostic products that test for the risk of hereditary breast and ovarian cancer. Given the economic and public health benefits at stake, it is not surprising that the patent has been challenged in a number of jurisdictions around the world. In essence, three different types of subject matter have been in issue in the litigation. These are:

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1 (1959) 102 CLR 252.

- Genes in their naturally occurring state: the raw genomic or native DNA (gDNA). There is no doubt that this is not patentable.
- Naturally occurring DNA isolated from the body.
- Synthetic DNA (complementary DNA or cDNA) created in a laboratory from messenger RNA (mRNA). It is widely accepted that this is eligible subject matter.

In 2014, the Full Federal Court of Australia held that the isolated DNA *and* the synthetic DNA were both patent-eligible.[2] While the decision to allow the patenting of the synthetic DNA was not controversial, the same cannot be said about the decision to allow the patent over the isolated DNA to stand. It is the fate of the isolated DNA that will be the primary focus of the High Court appeal.

II Categorising Subject Matter

The process of determining whether subject matter is patent-eligible is essentially an exercise of labeling, classifying, and categorising. As the Full Federal Court said in *Myriad*, the 'central question is whether [the subject matter] falls within the category of inventions to which, by definition, the application of the Act is confined'.[3] While the appeal to the High Court will inevitably give rise to a number of issues, the key question is: how should the isolated DNA be categorised?

Typically, the starting (and finishing) point for answering the question of how subject matter is to be categorised is the 1959 High Court decision of *National Research Development Corporation v Commissioner of Patents* ('*NRDC*'),[4] which is a landmark decision that occupies an almost sacrosanct position in Australian patent law. One of the things *NRDC* is often cited for is the point that when determining whether something is patent-eligible, we should ignore the language of s 6 of the 1623 *Statute of Monopolies*[5] and look instead to the principles that have been used to apply the section. We are also told that when construing the law, we need to ensure that the boundaries of patentable subject matter are fluid enough to encompass scientific and technological breakthroughs. Neither of these points (nor their application, for example, to allow protection over agricultural and horticultural inventions) are controversial, surprising, or worthy of more than a cursory mention.

Perhaps the most important thing to take from *NRDC* is the idea that for subject matter to be eligible, there must be human intervention that creates an artificially created state of affairs that has some discernible effect (which is a restatement of the way the invention has traditionally been portrayed in patent law[6]).

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2 *D'Arcy v Myriad Genetics Inc* (2014) 313 ALR 627 ('*Myriad'*). Upholding *Cancer Voices Australia v Myriad Genetics Inc* (2013) 99 IPR 567.

3 *D'Arcy v Myriad Genetics Inc* (2014) 313 ALR 627, 645 [115].

4 (1959) 102 CLR 252.

5 21 Ja 1, c 3.

6 See Brad Sherman and Lionel Bently, *The Making of Modern Intellectual Property Law* (Cambridge University Press, 1999).

While this is useful in so far as it provides guidance about the general approach to be adopted when thinking about patentable subject matter, it does not really tell us anything about how we are to determine whether something is 'artificial', nor about the criteria to be used when classifying subject matter more generally.[7] Although *NRDC* provided an important and needed antidote to the restrictive and convoluted way that patents were construed in the mid-20th century, it has largely outlived its usefulness. Moreover, while the decision provides guidance about the general approach that should be adopted when thinking about subject matter eligibility, it provides little, if any, assistance in determining the specific issues at stake in this appeal. In particular, the decision tells us very little about how to determine whether something is 'artificial', nor about the degree and type of human intervention needed to bring about an artificially created state of affairs. In short, *NRDC* provides little guidance in determining how subject matter is to be classified.

Given that *NRDC* has largely outlived its usefulness, the question arises: what should be done? Justice Hayne provided a useful starting point in *Apotex* when he said 'the conception of what is a proper subject for the grant of a patent is not to be understood except as an historical growth. In the development of that conception, "history is likely to predominate over logic or pure reason"'[8]. This means that to understand the subject-matter inquiry in patent law, we need to look at it historically.

One of the lessons that history teaches is that the reasons for the inclusion and exclusion of subject matter cannot be reduced to a set of 'principles' (as was suggested in *NRDC*). Instead, patentable subject matter is determined by an array of factors. One of the most important is the image of invention that underpins the subject-matter inquiry.[9] While there have been occasional exceptions (notably, in relation to immoral inventions), one of the things that the history of patent law shows is that the subject-matter inquiry is based on a specific model of the inventive process.[10] Under this model, the invention is a product of a process in which a human agent (or inventor) exercises their inventive skills to build on, modify, or adapt pre-existing natural materials. In this context, the 'raw materials' (such as the naturally occurring DNA) act as the foundation or building blocks for the inventive process. In turn, the inventive process sees the human inventor, as an agent of change, interact with the pre-existing natural materials to produce something artificial or new. Here, the inventor is tasked with the job of using their 'inventive' skills to change, mould, or re-arrange a pre-existing nature into something new and 'different'. In Australia, this is reflected in the idea that for subject matter to be patent-eligible, it must be the product of 'human intervention that creates an artificial state of affairs'[11] (or that there must be some sort of human interaction with pre-existing materials that creates something artificial).

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7 The question of whether there is an *effect* that is *discernible* is not in issue here.

8 *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* (2013) 304 ALR 1, 29 [81] ('*Apotex*').

9 For a history of the concept of invention in modern patent law, see: Alain Pottage and Brad Sherman, *Figures of Invention: A History of Modern Patent Law* (Oxford University Press, 2010).

10 See Brad Sherman, 'Inventing Nature' (2015) *UC Irvine Law Review* (forthcoming).

11 *D'Arcy v Myriad Genetics Inc* (2014) 313 ALR 627, 629 [11].

Importantly, for an invention to be patentable, the inventor must act in such a way so as to 'individualise' nature (which is reflected in the doctrinal requirement of inventive step). While an inventor may not impose their personality on the resulting invention in the way the Romantic author is presumed to mark the texts that they write, they do shape or mould the resulting invention. In this sense, the notion of individualisation gives rise to the suggestion that the patented subject matter is somehow 'unique'. It is this (relative) uniqueness that allows the logic of the patent doctrine to suggest that patents, by their very nature, do not pre-empt. Under this logic, a patented invention does not monopolise nature, because protected subject matter is something that necessarily builds on, expands, or modifies the underlying raw natural material. As a result of the intervention and action of the human inventor, the resulting invention is necessarily different from the natural materials that it is based on: it is 'artificial'.

In effect, what happens where questions about subject matter arise is that one or more elements of the inventive process are called into question. Given that all elements of the process of invention must be present for there to be a (legal) invention, if one element is missing, the subject matter is deemed to be patent-ineligible. However, if all elements are present, the subject matter will be patent-eligible. In practice, what the courts do when they consider whether something is patent-eligible is that they frame the question so as to focus on those element/s of the inventive process that are in dispute.

Over time, four different (overlapping) approaches have been used when deciding whether something is patent-eligible. With the first approach, subject matter is categorised on the basis that it is by its very nature the type or kind of thing that ought to be classified in a particular way. Where this occurs we are often told that the relevant characteristics are inherent to the subject matter in issue. In the *Myriad* litigation, both in Australia and the United States, this has typically been the case in relation to the raw genomic DNA (gDNA) in the human body, which has been deemed to be the kind of thing that ought to be non-patentable. A second approach classifies subject matter on the basis of the labour used to create the invention. Here, the focus is on the work of the inventor and whether they have exercised the requisite skill to individualise nature. In the *Myriad* litigation (particularly in the US), this argument was used in relation to the synthetic DNA. A third approach focuses on whether there is an inventive concept somehow associated with the subject matter in question. The test for the existence of an inventive concept is similar to the labour-centered approach, except that it is does not focus specifically on the effort of the inventor. Instead, it looks for evidence of the existence of an inventive concept either in the subject matter or in the process by which the subject matter was generated. A fourth approach used to classify subject matter operates on the basis that a nature-based invention will only be patent-eligible if the invention is different from the raw material from which it is derived.[12] The decision of the Federal Court in *Myriad* that the isolated gDNA was

[12] Ibid 663 [211]. US law requires the change be 'markedly different': see *Association for Molecular Pathology v United States Patent and Trademark Office*, 702 F Supp 2d 181, 222 (2010).

patent-eligible was made, in part, on the basis that the isolated DNA was different to the raw gDNA.[13]

Each of the approaches are used at different times, often interchangeably and without explanation. As a result, there is not only diversity between the approaches used in judgments; there is sometimes even diversity within a single judgment. Thus, while most of the discussion about the isolated DNA in *Myriad* has focused on whether — and, if so, how — the isolated DNA differed from its natural counterpart, the discussion about (the synthetic) cDNA tended to focus on the labour that went into the creation of the synthesised materials. The fluid, shifting, and interchangeable way the approaches are employed is not necessarily indicative of some sort of fundamental problem with the law itself. Indeed, the situation would probably be even worse if the courts did not adapt the approach to the particular problem-at-hand. While this makes the task of describing the law more problematic, this fluidity should not be seen as an inherent weakness. Rather, it is an inevitable consequence of the nature of the subject-matter inquiry, of the diversity of the subject matter under scrutiny, and the different ways in which that subject matter is presented to the law for examination. It is also a consequence of the courts selecting the most appropriate approach for the facts-at-hand.

One of the consequences of this is there is not, nor can there be, a single universal test that can be used to determine how subject matter is to be categorised: the approach adopted needs to change depending on the facts in issue. The challenge for the High Court is to find the approach most suited to the facts in issue. While the labour used to generate the isolated DNA may play a role in the High Court's deliberations, it seems likely that the decision will turn on whether the isolated DNA is sufficiently different to the natural material on which it is based for it to be deemed 'artificial'. Before looking at how this question might be answered, I wish to pause and consider another issue that is likely to arise on appeal: namely, what is the role of the United States 'product of nature exclusion' in Australian law?

III What is the Role of the US Product of Nature Exclusion in Australian Law?

The starting point for deciding the eligibility of subject matter in the United States is s 101 of the US patent legislation. This provides that an inventor may obtain a patent for a 'new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof'.[14] An invention that prima facie falls within s 101 may still be ineligible for patent protection, however, if it falls within one of the categories of excluded subject matter: namely, laws of nature, natural phenomena, and abstract ideas.[15] In contrast to the situation in Europe, where the excluded categories have largely been provided by the

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[13] *D'Arcy v Myriad Genetics Inc* (2014) 313 ALR 627, 644 [114], 663–4 [213]–[218].

[14] See *Patent Act*, 35 USC § 101 (West, 1952).

[15] See, eg, *Mayo Collaborative Services v Prometheus Laboratories Inc*, 132 S Ct 1289, 1293 (2012) ('*Mayo*'); *Bilski v Kappos*, 130 S Ct 3218, 3225 (2010) ('*Bilski*'); *Diamond v Chakrabarty*, 447 US 303, 307–10; *Gottschalk v Benson*, 409 US 63, 67–8 (1972); *O'Reilly v Morse*, 56 US 62 (1853).

legislature,[16] the excluded categories in the US have been developed piecemeal by the courts:[17] they are said to be implicit in the relevant legislative provisions. While there are many unanswered questions about the scope and nature of the categories of excluded subject matter, not least how they relate to each other,[18] in recent years they have been treated as givens by American courts. Despite what was said in *Funk* and repeated in *NRDC*,[19] it is clear that the 'laws of nature', 'natural phenomena', and 'abstract ideas' act as de facto statutory exceptions in contemporary US patent law.

The US product of nature exclusion essentially provides that where subject matter is derived from 'nature', that the subject matter will not be patent-eligible if the grant of a patent would *unduly* restrict access to the underlying material. The mere fact that an invention is based on, or derived from, something in nature does not, of itself, mean that the invention is necessarily excluded. As the US Supreme Court said, 'all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas'.[20] The difficult issue here is deciding how much and what type of restriction is acceptable.

The reason why the question about the standing of the product of nature exclusion in Australian law has arisen is because of the 2013 US Supreme Court decision in *Association for Molecular Pathology v Myriad Genetics Inc*.[21] The Supreme Court, when dealing with a patent virtually identical to the one at issue before the High Court in *D'Arcy v Myriad Genetics*, found that the isolated DNA was *not* patent-eligible.[22] Importantly, the Supreme Court reached its conclusion on the basis of the product of nature exclusion. Given that the US Supreme Court decision was handed down before the Full Federal Court had reached its decision, it is not surprising that the US decision was raised before the Full Federal Court.

In a decision (which occasionally reads as if it is an appeal from the US Supreme Court), the Full Federal Court was clear: there was no product of nature

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16 *Convention on the Grant of European Patents of 5 October 1973* (15th ed, 2013) ('*European Patent Convention* 2000') Art 53.

17 See Christopher Beauchamp, 'Patenting Nature: A Problem of History' (2013) 16 *Stanford Technology Law Review* 257, 264. In *Bilski*, it was suggested that the exceptions go back 150 years: *Bilski*, 130 S Ct 3218, 3225.

18 One of the advantages of the *Alice Corporation* and *Mayo* decisions is that they focus attention on the categories more directly: *Alice Corp Pty Ltd v CLS Bank International*, 134 S Ct 2347, 2354 (2014) ('*Alice Corporation*'); *Mayo*, 132 S Ct 1289, 1293 (2012).

19 Citing Frankfurter J in *Funk Bros Seed Co v Kalo Inoculant Co* (1948) 333 US 127 ('*Funk*'), the High Court said in *NRDC* (1959) 102 CLR 252, 263–4:

> 'It only confuses the issue,' the learned Justice said, 'to introduce such terms as "the work of nature" and the "laws of nature"'. For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed 'the work of nature', and any patentable composite exemplifies in its properties 'the laws of nature'.

20 *Mayo*, 132 S Ct 1289, 1293 (2012).

21 *Association for Molecular Pathology v Myriad Genetics Inc*, 133 S Ct 2107, 2111 (2013).

22 The Court held that while raw DNA and isolated gene sequences were not patent-eligible, synthetic cDNA sequences were: *Association for Molecular Pathology v Myriad Genetics Inc*, 133 S Ct 2107, 2111 (2013).

exception in Australian law.[23] In part, this was because the language of the respective statutes are different. In Australia, the relevant legislation provides that an invention is prima facie a patentable invention if it is a 'manner of manufacture within the meaning of section 6 of the *Statute of Monopolies*'.[24] In contrast, the US legislation provides that an inventor may obtain a patent for a 'new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof'.[25]

When thinking about the relevance in Australia of the product of nature doctrine generally and the Supreme Court decision specifically, it should be noted that many of the early American subject-matter decisions were based on case law about the meaning of 'manufacture' (or 'manufactured article'). Interestingly, many of these decisions, particularly *American Fruit Growers Inc v Brogdex Co*,[26] are routinely cited as the laying the foundation of the product of nature doctrine in the US.

It should also be noted that if we take *NRDC* at its word — namely, that the subject matter examination is 'an inquiry not into the meaning of a word so much as into the breadth of the concept which the law has developed'[27]— then it should not matter that the legislative language is different. It should also not matter that Australian courts have not used the label 'product of nature' to describe their reasoning. Instead, what matters is whether the concept exists in Australian patent law.

While the Full Federal Court was at pains to distance the subject-matter inquiry in Australia from the approach adopted in the US — particularly in relation to the product of nature doctrine — the approach adopted in Australia is conceptually very similar (if not identical) to the approach that has been adopted in the US. Although the categories may be labeled differently and the courts may emphasise different aspects of the inquiry,[28] nonetheless the process of determining whether subject matter is patent-eligible is the same in Australia and the US: it is essentially a taxonomic exercise of labeling, classifying, and categorising. The US product of nature doctrine and the Australian test of artificially created state of affairs are the same question asked from different perspectives. In both cases, they build on an (implicit) image of what it means to invent something; albeit asked from different perspectives: nature and artifice are flip sides of the same coin.

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23 The Full Federal Court also made it clear that it preferred the finding of the US Court of Appeals Federal Circuit that the isolated DNA was patent-eligible, rather than the Supreme Court which found otherwise.

24 *Patents Act 1990* (Cth) s 18(1)(a).

25 See *Patent Act*, 35 USC § 101 (West, 1952).

26 283 US 1 (1931). For earlier decisions construing 'manufacture', see *Hartranft v Wiegmann*, 121 US 609 (1887) (shells cleaned by acid and then ground on an emery wheel were not manufactured shells and thus were exempt from duty); *Anheuser-Busch Brewing Association v United States*, 207 US 556 (1908) (assessing whether corks had been 'manufactured' in the US and thus able to receive a rebate).

27 *NRDC* (1959) 102 CLR 252, 269.

28 In both cases, the choice is whether to categorise subject matter as either patent-eligible or as patent-ineligible. The key difference is the focus of attention: while American case law tends to focus on patent ineligibility (the excluded categories), Australian law focuses on patent eligibility (artificial effect).

While the product of nature doctrine may not exist in name, there is little doubt that it exists conceptually in Australian law.

Having said this, the question of whether Australian law recognises the product of nature doctrine is, for the purposes of the appeal, neither here nor there. This is because what matters most about the product of nature doctrine is the way it is applied, and the degree and/or type of derivation from nature that is needed for something to be deemed patent-eligible. As with the test for artificial state of affairs, what really matters is how the test is applied. It is to this question that I now turn.

IV Judging Difference

The process of determining whether a nature-based invention, such as the isolated DNA at stake in *D'Arcy v Myriad*, is artificial requires the court to pass judgment on whether the 'invention' is materially different from the natural raw materials on which it is based.[29] This is a two- or possibly three-step process. First, it is necessary to determine what is being compared. Specifically, it is necessary to determine how the subject matter and the natural material on which it is based are to be characterised. Once this is done, it is then necessary to compare the subject matter and the raw materials as characterised. In some cases, a third step may be needed to determine whether any identified differences are in fact 'marked' (or whatever qualitative threshold is imposed on this difference).

It is clear from the cases that have used 'difference' as a means of categorising subject matter that the outcome often turns on the way the raw material and the subject matter are characterised. One of the notable things about the DNA that is at issue in the appeal is that it can legitimately be construed in both chemical and genetic terms: it is a classic example of a hybrid creation. While this hybridity may be celebrated in science, it creates problems for the law.

At each stage of the litigation, both in Australia and the US, the fate of the isolated DNA has turned on whether the DNA was construed chemically or genetically.[30] Given that the isolated DNA is *chemically* different to the raw material that it was derived from, when the DNA is viewed chemically, it almost inevitably leads to the conclusion that it is different to the naturally occurring DNA and thus patent-eligible. This is the approach adopted by the Australian Full Federal Court[31] and the US Federal Circuit.[32] In contrast, when the DNA is viewed *genetically,* this leads to the conclusion that the isolated DNA is the same as the naturally occurring DNA and thus not patent-eligible. Although the opponents of

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29 It is possible that the question could be addressed using one of the other approaches: the most likely being the labour used to isolate the DNA.

30 I have purposely used 'genetically' instead of 'information' in this context, primarily because a focus on information is misleading. While genes do embody information — which has long been treated as being patent-ineligible — it is not the information per se that is important, so much as the function of genes to shape human development.

31 *D'Arcy v Myriad Genetics Inc* (2014) 313 ALR 627.

32 *Association for Molecular Pathology v United States Patent and Trademark Office*, 689 F 3d 1329 (Fed Cir 2011).

Myriad's US patent may have been willing to recognise that the DNA could be described in chemical terms, they nonetheless argued that the defining and distinguishing characteristic of DNA was its ability to 'be our instruction book on life'.[33] As such, they argued that the DNA should be viewed genetically. This was reflected in the argument that '[g]enes are chemicals, but they are unique because they are much more; they embody the information and instructions the body uses to function'.[34] James Watson made a similar point in his amicus curia to the US Supreme Court, when he described human DNA as 'a chemical entity, but DNA's importance flows from its ability to encode and transmit the instructions for creating humans'[35] and that the 'human genome's ability to be our instruction book on life distinguishes it from other chemicals covered by the patent laws'.[36] On the basis that the gene sequences were the same when they were in the body as when they were isolated, the opponents argued that the subject matter in issue (the isolated gDNA) was no different to the raw materials on which it was based (gDNA in the human body).[37] As such, it was not patent-eligible. While this argument was accepted by the US Supreme Court, to date it has achieved little traction in Australia.

One of the problems with the Full Federal Court decision is that we were given no explanation as to why the decision was made to read the claims chemically, rather than genetically. While there was a lot of talk about how we should read the language of the *Statute of Monopolies* — which did not really bear on the outcome of the decision — the same cannot be said for the way the isolated DNA was construed. Without doubt, this is the one of the most important questions to be addressed in the appeal to the High Court.

It would be normal to expect that the answer to the question of how subject matter is to be characterised would be resolved on the basis of a straightforward reading of the language in the patent claims. One of the reasons why this has proved to be problematic for some is that there is a sense of suspicion about Myriad's patent claims and whether they properly represent what is sought to be protected:[38] a concern that is magnified with product claims.[39] Here, the concern is

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33 'Brief for James D Watson, PhD as Amicus Curiae in Support of Neither Party', Submission in *Association for Molecular Pathology v Myriad Genetics Inc*, 133 S Ct 2107 (2013), 8.

34 'Brief for Petitioners', Submission in *Association for Molecular Pathology v Myriad Genetics Inc*, 133 S Ct 2107 (2013), 5.

35 '[N]o other molecule can store the information necessary to create and propagate human life the way human DNA does': 'Brief for James D Watson, PhD as Amicus Curiae in Support of Neither Party', Submission in *Association for Molecular Pathology v Myriad Genetics Inc*, 133 S Ct 2107 (2013), 2.

36 Ibid 8.

37 The US Solicitor General argued that structural changes that left the natural substance's operative properties entirely untouched were not sufficient in themselves to support patent-eligibility. Otherwise, the removal of a kidney from the body might render the extracted kidney patent-eligible. See 'Brief for the United States as Amicus Curiae in Support of Neither Party', Submission in *Association for Molecular Pathology v Myriad Genetics Inc*, 133 S Ct 2107 (2013), 22.

38 This was reinforced in the US by the view that Myriad's claims were drafted so as to be difficult to invent around; that they did not claim 'the specific chemical composition of a particular molecule', but instead the information 'encoded in the BRCA1 and BRCA2 genes': *Association for Molecular Pathology v Myriad Genetics Inc*, 133 S Ct 2107, 2118 (2013).

39 One of the problems is the lack of symmetry between the criteria used to determine subject-matter eligibility (a product claim construed as a chemical could be held to be different to nature, thus

that patent agents should not be allowed to dress up patent-ineligible subject matter in such a way as to a make it appear as if was patent-eligible. A key question for the High Court is whether to trust the language of the patent. Certainly the US Supreme Court did not, while the Australian Federal Court did.

V Conclusions

The *Myriad* litigation clearly highlights the limitations and shortcomings of the way subject matter is evaluated in Australian patent law. It shows that there is no clear mechanism to decide how subject matter is categorised: no clear sense of whether a gene should be seen chemically or genetically, nor about how difference is to be judged and evaluated. In particular, there is no clear sense of the degree or type of difference that is needed for something to qualify as patent-eligible subject matter, and whether the difference should, as the applicant (D'Arcy) has suggested, be 'interesting', 'important',[40] or something else? If the decision is made to move away from a literal reading of the claims, it is also not clear what criteria should be used to determine what should be the 'correct level of analysis of the claim'.[41]

Australian patent law is currently at a crossroad. As it stands, the law lacks the tools and techniques to categorise subject matter: at least in a way that does not appear arbitrary or capricious. The decision by the High Court to hear the appeal in *D'Arcy v Myriad Genetics* offers an opportunity to fill this vacuum. One of the challenges for the High Court in doing so will be to confront the limitations of *NRDC*.[42] We do not need to be told, yet again, that we should eschew a verbal analysis of the *Statute of Monopolies* in favour of an investigation of the principles used in its application. Nor do we need to hear about how it is necessary to read the statute broadly to ensure that patent law is able to accommodate new innovations. What we do need, however, is for the High Court to reflect on what is meant by 'invention', and to consider the criteria that we might use to decide whether something is patent-eligible.

Ideally, it would also be useful if the Court could reflect on whether the subject-matter inquiry is the appropriate mechanism to debate the merits of Myriad's patent, or whether this could be better dealt with elsewhere. There are a number of options here.

One option is to continue with the approach that has been adopted to deal with the isolated DNA to date; which is to determine patent eligibility on the basis of whether the isolated DNA is *different* to the natural substance from which it is derived. Here the key issues are: what criteria should be used to judge difference and how should the subject matter in dispute be characterised? If this approach is adopted, which is likely, it is important that the High Court provide clear guidance

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artificial and potentially patentable), and the protection available when granted (protection could cover both the gene as chemical and the gene as a hereditary unit). Similar problems of asymmetry also exist between the test for inventive step and scope of protection.

40 *D'Arcy v Myriad Genetics Inc* [2015] HCATrans 12 (13 February 2015), (D K Catterns QC) (during argument).

41 Ibid (D K Catterns QC) (during argument).

42 (1959) 102 CLR 252.

about how these questions are answered. We need to be told why one particular reading of the claims has been adopted over another. It would also be important to get a sense of whether there were any quantitative or qualitative limitations on the type of difference that is needed for something to qualify as 'artificial' and thus patent-eligible. As recent experience in relation to originality in copyright law shows (particularly in light of the question of whether it is necessary to show something more than the sweat of the brow for a work to be original[43]), this potentially has an important bearing on what is protected.

Yet another option would be to abandon the doctrinally-focused approach that Australian courts have favoured to date, to look at the consequences of granting or not granting protection (which is what most of the critics of Myriad's patents have urged). As this would constitute a radical change of approach for Australian courts and require detailed and substantial policy analysis to ensure evidence-based decision-making, it is unlikely to be adopted. At best, it seems that policy considerations will be indirectly taken into account as part of the doctrinal analysis.

A third option would be to apply the law in a way that minimises the need to pass judgment or, more accurately, shifts the locus of judgment away from a general discussion about subject matter — are genes, software etc patent-eligible? — to one about specific features of a specific invention (as part of an inquiry into inventive step and novelty). As well as using a literal reading of the claims to characterise the subject matter, the court could also eschew attempts to impose qualitative limits of the subject matter. So long as it could be shown, for example, that the subject matter was different or that the inventor had exerted some influence over the resulting subject matter, the subject matter would be patent-eligible. This is, in effect, the approach that has been adopted by the European Patent Office, which has downplayed the importance of the subject-matter inquiry and shifted attention towards more specific (and evidence-based) criteria such as inventive step and novelty.[44] Faced with problems not dissimilar to those currently facing the High Court (albeit in relation to computer-related inventions), the European Patent Office adopted the 'any hardware approach' to patentable subject matter, whereby the existence of *any* type of technology is sufficient for something to be deemed patent-eligible. Under this approach, the mere presence of a technological artifact or process, no matter how old or lacking in inventiveness (such as a cup, a nail, or a personal computer), is sufficient for something to pass the subject matter threshold. Importantly, this has *not* led to an increase in the number of patents being granted; so much as a change in the reasons why patents are excluded (from subject matter to inventive step). While this approach may not be as useful for biological inventions as it is with computer-related inventions (primarly because of the uncetartinty about whether biological innovations are technical), a change of focus would not only provide more certainty and transparency, it might also mean

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[43] See Abraham Drassinower, 'Sweat of the Brow, Creativity, and Authorship: On Originality in Canadian Copyright Law' (2003–2004) 1 *University of Ottawa Law and Technology Journal* 105.

[44] See Lionel Bently and Brad Sherman, *Intellectual Property Law* (Oxford University Press, 4th ed, 2014), 465–71.

that fewer inappropriate patents are granted. Given the ongoing problems with the subject-matter inquiry, this is perhaps the most preferable option. Its effectiveness, however, will depend on a range of factors including how the other patentability thresholds are applied (notably inventive step, which, at least in Australia, is currently very uncertain). No matter which approach is adopted, it is clear, as Catterns said in the application for special leave to appeal to the High Court, that it is 'hard to imagine a more important question in patent law'.[45]

[45] *D'Arcy v Myriad Genetics Inc* [2015] HCATrans 12 (13 February 2015), (D K Catterns QC) (during argument).