

BETWEEN:



YVONNE D'ARCY
Appellant

and

MYRIAD GENETICS INC
First Respondent

GENETIC TECHNOLOGIES LIMITED ABN 17 009 212 328
Second Respondent

10

20

INTERVENER'S SUBMISSIONS

Part I:

1. I certify that this submission is in a form suitable for publication on the internet.

Part II:

2. The Institute of Patent and Trade Mark Attorneys of Australia (IPTA) seeks leave to be heard as *amicus curiae*.

Part III:

3. IPTA represents the interests of patent attorneys in Australia, who act on behalf of clients in research and industry in Australia and overseas.¹
4. Any decision of this Court in relation to the patentability of isolated genetic material or other isolated natural materials is of importance to those involved in conducting research and innovation especially in the biotechnology industry and to

30

¹ Affidavit of Trevor John Davies affirmed on 10 March 2015 (the **Davies Affidavit**) at [2] and [3].

Date of Document	31 March 2015
Filed on behalf of:	The Institute of Patent and Trade Mark Attorneys, Intervener
Prepared by:	Odette Gourley
Law firm:	Corrs Chambers Westgarth
Telephone:	(02) 9210 6066 Fax: (02) 9210 6611
Email:	odette.gourley@corrs.com.au Ref: 9110227
Address for service:	Level 9, 8-12 Chifley Square, Sydney, New South Wales, 2000
13104805/1	

patent attorneys who advise their clients regarding patent protection of inventions arising out of such research and innovation.²

5. IPTA wishes to make submissions dealing with relevant matters of law and of fact not dealt with by either party³, including:

(a) whether the concept of “patents of inventions” in section 51(xviii) of the *Commonwealth of Australia Constitution Act* (the **Constitution**) encompasses isolated genetic material and other materials isolated from nature;

10

(b) if the answer to (a) is in the affirmative, whether the *Patents Act* 1990 excludes such materials from patentability in Australia; and

(c) the potential impact on research and industry in Australia if isolated genetic material and other materials isolated from nature were to be held not to be patentable subject matter.

Part IV:

6. Section 51(xviii) of the Constitution empowers the Parliament to make laws for the peace, order and good government of the Commonwealth with respect to:

“Copyrights, patents of inventions and designs, and trade marks.”⁴ IPTA has given notice to the Attorneys General pursuant to section 78B of the *Judiciary Act* 1903 on the basis that these submissions give rise to an issue involving interpretation of section 51(xviii) of the Constitution.

20

² See Davies Affidavit and the affidavits of Michael Caine sworn on 10 March 2015 (the **Caine Affidavit**), Grant Ian Shoebridge affirmed on 10 March 2015 (the **Shoebridge Affidavit**), Sherry M. Knowles sworn on 11 March 2015 (**Knowles Affidavit**) and Julian Clark affirmed on 18 March 2015 (the **Clark Affidavit**).

³ An amicus may be heard if it is willing to offer the Court a submission of relevant law or fact which will assist the Court in a way it would not otherwise have been assisted: *Levy v Victoria* (1997) 189 CLR 579 at 604-605; also, for example, APRA and Communications Alliance were given leave to be heard as amici curiae in *Roadshow Films Pty Ltd v iiNet Limited* [2011] HCA 54 at [6] (orders 3 and 5).

⁴ This section of the Constitution has not been amended.

Part V:

7. The starting point for any consideration of whether an invention can be the subject of a patent is section 51(xviii) of the Constitution, which granted the Parliament power to make laws with respect to, *inter alia*, “patents of inventions”.
8. It is necessary to identify the meaning of “patents of inventions” as at 1901. The word “invention” was relevantly defined in 1901 as “[t]he original contrivance or production of a new method or means of doing something, of an art, kind of instrument, etc. previously unknown...; origination, introduction”.⁵
9. The 1883 protocol to the *International Convention for the Protection of Industrial Property* specified that the words “‘Industrial Property’ [were] to be understood in their broadest sense; they [were] not to apply simply to industrial products, properly so called, but also to agricultural products (wine, grain, fruits, cattle etc)...”. In this context, the United Kingdom passed the *Patents, Designs and Trade Marks Act 1883* (UK), which provided the basis for most Australian colonial patents legislation.⁶
10. Under the 1883 UK Act, “patents” meant “letters patent for an invention” and an “invention” meant “any manner of new manufacture the subject of letters patent and grant of privilege within section six of the Statute of Monopolies”: s 46.
11. Section 6 of the *Statute of Monopolies 1623* (UK) permitted the granting of:

20 “any letters patent and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm to the true and first inventor and inventors of such manufactures, which others at the time of making such letters patent and grants shall not use, so as also they be not contrary to the law nor mischievous to the State by raising prices of commodities at home, or hurt of trade, or generally inconvenient”.

⁵ *A New English Dictionary on Historical Principles* (Vol V, Pt II, 1901). On the use of dictionaries to establish the ordinary meaning of constitutional phrases, see eg *Attorney-General (Vic); Ex rel Black v The Commonwealth* (1981) 146 CLR 559 at 595 per Gibbs J, 606 per Stephen J; cf 616 per Mason J; *Potter v Minahan* (1908) 7 CLR 277 at 301 per O’Connor J.

⁶ For example, the *Patents, Designs and Trade Marks Act 1884* (Q); *Patents, designs and Trade Marks Act 1893* (Tas); *Patents Act 1890* (Vic); *Patent Act 1888* (WA); *Patents Act 1852* (NSW) (repealed by *Patents Act 1899* (NSW)); and *Patent Act 1877* (SA).

12. Commonwealth patents legislation since Federation has defined “invention” by reference to s 6 of the *Statute of Monopolies*.⁷ The breadth of this definition was emphasized in *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 at 271 (NRDC), where Dixon CJ, Kitto and Windeyer JJ stated that:

10 “The truth is that any attempt to state the ambit of s. 6 of the Statute of Monopolies by precisely defining “manufacture” is bound to fail. The purpose of s. 6, it must be remembered, was to allow the use of the prerogative to encourage national development in a field which already, in 1623, was seen to be excitingly unpredictable. To attempt to place upon the idea the fetters of an exact verbal formula could never have been sound. It would be unsound to the point of folly to attempt to do so now, when science has made such advances that the concrete applications of the notion which were familiar in 1623 can be seen to provide only the more obvious, not to say the more primitive, illustrations of the broad sweep of the concept.”

13. In light of the background history outlined above, it can be seen that in 1901 the word “patent” imported the concept of the conferral of a monopoly and the word “invention” encompassed the concept of novelty. This reflects the objects of patent law to encourage inventive ingenuity and disclosure to the public of a new and
20 useful article or process.⁸

14. The High Court considered the head of power in section 51(xviii) of the Constitution in *The Grain Pool of Western Australia v The Commonwealth of Australia* (2000) 202 CLR 479 (*Grain Pool*). The question before the High Court was whether the *Plant Varieties Act 1987* (Cth) and the *Plant Breeder’s Rights Act 1994* (Cth), which permitted the grant of “plant variety rights” in respect of new plant varieties, were beyond Parliament’s power and therefore invalid. The Court unanimously held that the legislation was within power.⁹ In so doing, the High Court unanimously affirmed the breadth of the term “patents of inventions” and, specifically, legislation that permitted the patenting of living plants. This decision
30 is of fundamental importance in the consideration of the patentability of isolated genetic and biological material.

⁷ *Patents Act 1903* (Cth), s 4; *Patents Act 1952* (Cth), s 6; *Patents Act 1990* (Cth), s 18(1)(a).

⁸ *Attorney-General (Cth) v Adelaide Steamship Co Ltd* [1913] AC 781 at 793.

⁹ Gleeson CJ, Gaudron, McHugh, Gummow, Hayne and Callinan JJ delivered a joint judgment, with Kirby J delivering a separate judgment.

15. At [18] of the joint judgment, the Court stated “it would be expected that what might answer the description of an invention for the purpose of s 51(xviii) would change to reflect developments in technology”.
16. At [22] of the joint judgment, the Court cited *Martin v Hunter’s Lessee* (1816) 1 Wheat 304 at 326 [14 US 141 at 151], noting that Story J “stressed that the legislative powers of the Congress were expressed in general terms’, so as ‘to provide [not] merely for the exigencies of a few years, but...to endure through a long lapse of ages, the events of which were locked up in the inscrutable purposes of Providence”.
- 10 17. The Court acknowledged (at [23] of the joint judgment) “the dynamism which, even in 1900, was inherent in any understanding of the terms used in s 51(xviii)”. Many extraordinary advances had been made in science before 1901 (as is the case since 1901), and therefore the concept of “invention” at that time must also be taken to have encompassed future developments which could not have been predicted, such as in the fields of telecommunications and biotechnology.
18. At [26] of the joint judgment, the Court said “it would be wrong to regard the legislative grant of monopoly rights in new plant varieties as being, in 1900, outside the ‘central type’ of the subject of patents of inventions”, noting that such a broad view would have been apposite to the views of Australian wheat breeders at
20 the time.
19. The Court observed (at [32] of the joint judgment) that the constitutional head of power left it “open to the Parliament to pursue its policies by legislation with respect to various subject matters”.
20. Kirby J expressed similar sentiments at [130] to [135]. At [131], Kirby J observed:

“A universal feature of the twentieth century has been the dynamic progress and momentum of science and technology. The principal inventions of the century, which include flight, applied nuclear fission, informatics and biogenetics were all undiscovered, and for the most part unconceived in 1900. Yet the Constitution certainly envisaged that the Commonwealth was entering an age of special technological inventiveness.”
30

At [132], in the context of the copyright power, his Honour noted that “the science and technology of genetic modification was unknown at that time”.

21. At [133], Kirby J stated:

“The future directions of such inventiveness are unknowable and likely to outstrip even our present vivid imaginations. Whether in particular contexts special and even new forms of such protection are desirable is a matter for argument and dispute. But power being present, the proper place for that debate ordinarily to occur is in the Parliament and in the Australian community which helps to shape the Parliament’s decisions”.

10 22. At [135], Kirby J concluded:

“the lawmaking power with respect to ‘patents of inventions’ within s 51(xviii) involves the provision by the state to the grantee of exclusive rights for a limited time to exploit, and to authorize other persons to exploit, a novel object or process of potential benefit to the community in respect of which a patent may be granted and which is recorded in a public register upon conditions of disclosure. This is the bedrock. Nothing more is required by the ‘really essential characteristics’ of ‘patents of inventions’.”

23. More recently, in *Apotex v Sanofi* (2013) 304 ALR 1; [2013] HCA 50, the High Court reaffirmed that decisions of this kind, involving complex questions of public policy, are “best left to the legislature”: per French CJ at [44], cited by the Full Federal Court at [125] in *D’Arcy v Myriad*.

20 24. By contrast with other major jurisdictions,¹⁰ the Australian legislature has seen fit to exclude only one subject matter from patentability. Section 18(2) of the *Patents Act 1990* excludes “human beings, and the biological processes for their generation” from patentability. For innovation patents, this exclusion is extended to plants and animals and the biological processes for their generation unless they are a microbiological process or product of such a process (s 18(3) & (4) of the *Patents Act 1990*).

¹⁰ See Schedule A

25. Importantly, the Australian legislature specifically rejected a proposal to exclude isolated genetic material and other natural materials from patentability (see [158]-[161] of the decision of the Full Federal Court in *D'Arcy v Myriad*).¹¹
26. The laws of nature exception in the US was introduced by the US Supreme Court in *Diamond v Chakrabarty* (1980)¹², which held that patentable subject matter can be anything under the sun made by man except laws of nature, abstract ideas and physical phenomenon. In that case, the Supreme Court decided that live, human-made, micro-organisms were patentable subject matter within the statutory requirement of an invention or discovery.¹³
- 10 27. In Australia, the decision of the High Court in *NRDC* was to similar effect, requiring an “artificially created state of affairs” for patentability.¹⁴
28. At [38] of the joint judgment in *Grain Pool*, the Court stated, citing *NRDC*:
- “The Statute of Monopolies 1623 (UK) had purported to be declaratory of the common law by indicating the limitations established by the common law upon the exercise of the prerogative of the Crown to grant monopolies. Thereafter, the scope of permissible patentable subject matter involved an inquiry ‘into the breadth of the concept which the law [had] developed by its consideration of the text and purpose of [that statute]’”.*
- 20 29. At [45] of the joint judgment in *Grain Pool*, the Court referred to the decision in *NRDC* as a “celebrated judgment” which held that “the requirement of a ‘vendible product’ for a valid process claim meant no more than that the end produced be of utility in practical affairs”. Similarly, it is not in dispute that isolated genetic material is a “vendible product”, having utility in practical affairs – that is all that is required. Crucially, isolated genetic material does not exist in nature – it is the process of isolation that gives the genetic material novelty and utility. Isolated genetic material is an “artificially created state of affairs”. The same applies to all isolated natural material.

¹¹ See also *Shoebridge Affidavit* at [21].

¹² *Diamond v Chakrabarty* (1980) 447 US 303.

¹³ See *Grain Pool* at [47] and the decision of the Full Federal Court in *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 115 at [127].

¹⁴ *NRDC* at 277.

30. At [46] of the joint judgment, the Court stated that the effect of the decision in NRDC was to confirm “that there is no intrinsic impediment to the patentability of plant varieties”. Similarly, there is no intrinsic impediment to the patentability of isolated genetic material or other isolated natural materials under the Constitution, or the *Patents Act 1990*.
31. Further, the Court in *Grain Pool* held that “a new plant variety” is an “invention in the constitutional sense” (at [75] of the joint judgment). Isolated genetic material and other isolated natural materials (that are novel and inventive) are also “inventions in the constitutional sense”. It is not in dispute that the isolated genetic material claimed in the Myriad patent was novel and not obvious in the sense that it had not been previously disclosed and could not be predicted until it was isolated. Nor is it in dispute that it could not be utilized until it was isolated.
- 10
32. The Constitutional concept of “patents of inventions” is very wide and capable of adapting to advances in human ingenuity. It is wide enough to cover isolated genetic material as claimed in the patent in suit and the *Patents Act 1990* should be construed so as to go to the limits of the Constitutional power.
33. There is no warrant in the background and history of the Constitution and Australian patents legislation for this Court to exclude isolated genetic material or other natural materials from patent protection. To the contrary, the background and history supports the view that they are *prima facie* patentable, provided they otherwise comply with the requirements of the patents legislation.
- 20
34. In order to read down the *Patents Act 1990* as providing less than the amplitude of constitutional power, there would need to be express words of limitation. There is only one legislative exception to patentable subject matter (section 18(2) of the *Patents Act 1990*), which does not apply to the present case. The absence of words of limitation in the Act (other than in section 18(2)) is a powerful argument that the Act occupies the full permissible landscape given by section 51(xviii) of the Constitution.
35. Furthermore, there are powerful policy reasons to permit isolated genetic material and other isolated natural materials to be patented.
- 30

36. As with Australian wheat breeders in 1900, in 2015 the impact on the Australian biotechnology industry is relevant to consideration of the question of whether isolated genetic material and other natural materials can be protected by patents. That potential impact is described in the various affidavits filed by IPTA, which demonstrate that:

- (a) The Australian Patent Office and patent profession have for many years proceeded on the basis that isolated genetic material and other materials are patentable, provided that the other requirements of the *Patents Act* 1990 are met, as with any other invention.¹⁵
- 10 (b) The current position in Australia is in line with the laws of the United Kingdom, Europe, New Zealand, Canada, Japan and China.¹⁶ It is only recently that the US has fallen out of step with those countries and that change has garnered significant criticism within and outside the US.¹⁷
- (c) A change to the current position in Australia may affect the validity of numerous existing patents and the patentability of numerous patent applications claiming isolated genetic material or other natural material. It could even affect patents or patent applications claiming synthetically manufactured material that is later found to exist in nature.¹⁸
- 20 (d) If there is no patent protection for isolated genetic material and other natural materials in Australia, research and investment into the isolation and application of such materials will be significantly stifled with resulting reduction in products and methods of utility to mankind.¹⁹

¹⁵ Caine Affidavit at [2]; Davies Affidavit at [10]-[12]; Shoebridge Affidavit at [10]-[12], [15], [20], [21].

¹⁶ Shoebridge Affidavit at [16]; Davies Affidavit at [16].

¹⁷ Shoebridge Affidavit at [15], [16], Davies Affidavit at [17] to [20], Knowles Affidavit at [27] to [33].

¹⁸ Shoebridge Affidavit at [18], Caine Affidavit at [19(d)].

¹⁹ Shoebridge Affidavit at [17], Caine Affidavit at [15], [19(a)], Davies Affidavit at [15], Knowles Affidavit at [33], [34], Clark Affidavit at [12] to [16] and [19] to [26].

Part VI:

37. IPTA estimates that oral presentation of its argument will take one half hour.

Dated 31 March 2015



.....
K. J. Howard SC
T. D. Cordiner

Counsel for IPTA

10

Telephone: 02 9233 5188

Facsimile: 02 9233 1137

Email: khoward@selbornechambers.com.au

SCHEDULE A
(Patentability provisions overseas)

UK:

38. Sections 1 and 4 of the *Patents Act 1977* (UK) provide:

1. Patentable inventions.

- 10 (1) *A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say—*
- (a) *the invention is new;*
 - (b) *it involves an inventive step;*
 - (c) *it is capable of industrial application;*
 - (d) *the grant of a patent for it is not excluded by subsections (2) and (3) below;*

and references in this Act to a patentable invention shall be construed accordingly.

- 20 (2) *It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of—*
- (a) *a discovery, scientific theory or mathematical method;*
 - (b) *a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;*
 - (c) *a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;*
 - (d) *the presentation of information;*

30 *but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such.*

- (3) *A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.*

...

4. Industrial application.

- (1) *Subject to subsection (2) below, an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.*
- (2) *An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.*
- (3) *Subsection (2) above shall not prevent a product consisting of a substance or composition being treated as capable of industrial application merely because it is invented for use in any such method.*

10

Europe:

39. Article 53 of the *European Patent Convention 1973* provides:

European patents shall not be granted in respect of:

- (a) *inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;*
- (b) *plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.*

20

40. Articles 1 to 6 of *Directive 98/44/EC of the European Parliament and of the Council (6 July 1998) on the legal protection of biotechnological inventions* states:

Article 1

1. Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive.

2. This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.

Article 2

30

1. For the purposes of this Directive,

- (a) *'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;*
- (b) *'microbiological process' means any process involving or performed upon or resulting in microbiological material.*

2. *A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.*

3. *The concept of 'plant variety' is defined by Article 5 of Regulation (EC) No 2100/94.*

Article 3

1. *For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.*

10

2. *Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.*

Article 4

1. *The following shall not be patentable:*

(a) *plant and animal varieties;*

(b) *essentially biological processes for the production of plants or animals.*

2. *Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.*

20

3. *Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.*

Article 5

1. *The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.*

2. *An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.*

30

3. *The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.*

Article 6

1. *Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however,*

exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

10

US:

41. 35 U.S.C. Section 101, Patents Act 1952 (US) provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new, useful improvements thereof, may obtain a patent therefor, subject to the conditions and requirements of this Title.

42. Section 33 of the *Leahy-Smith America Invents Act* provides:

Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.

20