

BETWEEN:



YVONNE D'ARCY
Appellant

and

MYRIAD GENETICS INC
First Respondent

GENETIC TECHNOLOGIES LIMITED ABN 17 009 212 328
Second Respondent

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AFFIDAVIT

20 I, Grant Ian Shoebidge of Level 21, 60 Margaret Street, Sydney, New South
Wales registered Australian patent attorney, affirm as follows:

1. I am a partner at Shelston IP and have been a registered patent attorney for over 7 years.
2. I am a fellow of the Institute of Patent and Trade Mark Attorneys (IPTA), the proposed intervener in this proceeding, and have been a member of IPTA since 2006.
3. Prior to my entry into the patent attorney profession, I spent 16 years working in medical research or industry-based research laboratories. During this time, I obtained a Bachelor of Science with honours from
30 Macquarie University and a PhD (molecular immunology) from the University of Technology, Sydney. Throughout my research career I have worked on a number of different projects including:
 - (a) the development of tests to determine HIV infection and susceptibility to Alzheimer's disease;
 - (b) breast cancer research; and

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Filed on behalf of:	The Institute of Patent and Trade Mark Attorneys, Intervener
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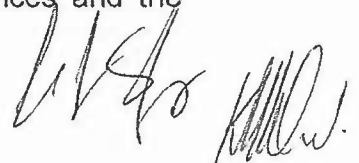
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(c) development of gene-based tuberculosis vaccines.

4. On the basis of my research expertise and work with other colleagues in the fields of research above, it is clear to me, and I believe would be clear to other medical research professionals in Australia, that isolated naturally-occurring material represents valuable technology because the characteristic of being "isolated" permits uses that are not available when such material exists in its natural state.
5. In the course of my work as a medical research professional, at no time was I or, I understand, any of my colleagues restricted in our work by the
10 existence of intellectual property covering isolated naturally-occurring material, for example, isolated nucleic acid sequences or proteins.
6. I entered the patent profession in 2004, working for an Australian start-up biotechnology company, Apollo Life Sciences.
7. I was employed at Apollo Life Sciences as a "patent scientist" and my duties included drafting patent applications, under the supervision of registered patent attorneys, directed to isolated human cytokines and growth factors. These isolated human cytokines and growth factors had potential beneficial uses in research applications as well as medical treatment including treatments of ageing and immune-system disorders
20 such as Alzheimer's disease, rheumatoid arthritis, multiple sclerosis, psoriasis and chronic viral infections such as hepatitis C.
8. Apollo Life Sciences lodged over 50 provisional patent applications directed to isolated human cytokines and growth factors during my time with the company. This intellectual property was a key area of importance for Apollo Life Sciences' business and was considered by me and others in the company as essential to obtaining investment funds through the company's listing on the stock exchange. In light of my experience with Apollo Life Sciences and as a patent attorney since then, I believe that, in the absence of patent applications covering the isolated cytokine and growth factor
30 products which had the expectation of being granted, funds would not have been raised for investing in the growth of Apollo Life Sciences and the



continued development of beneficial research and medical applications of the human cytokines and growth factors the company had synthesized and isolated from human cells.

9. In 2006, I joined Shelston IP as a trainee patent attorney. I was registered as a patent attorney in 2007 and became a partner of the firm in 2015.
10. During my time with Shelston IP, I have drafted patent applications directed to subject matters including:
 - (a) peptides isolated from naturally-occurring proteins for use in diagnosing the autoimmune disease systemic lupus erythematosus (SLE);
 - (b) isolated fluorescent proteins from coral for research and diagnostic applications; and
 - (c) isolated yeast strains for use in wine manufacture.
11. Also during my time with Shelston IP, I have also been involved in patent opposition proceedings before the Patent Office which concerned patent applications covering:
 - (a) exendins (compounds isolated from venom) for modulation of triglyceride levels and treatment of dyslipidemia;
 - (b) isolated fungal lipolytic enzymes for use in baking; and
 - 20 (c) vaccines comprising peptides derived from isolated naturally-occurring proteins.
12. The work that I have been involved with as a patent attorney reinforces the view that I formed during my former career in the research and biotechnology industry, that:
 - (a) isolated products of nature represent new technology by virtue of the fact that the relevant products exist in a form (i.e. isolated) that does not exist in nature;



- (b) isolated naturally-occurring products provide beneficial economic uses that are not available for naturally-occurring material; and
- (c) the availability of patent protection for such isolated naturally-occurring products is crucial to encourage research into the isolation and commercialisation of such products and development of beneficial uses of those products, such as new methods of medical treatment and diagnostics.

13. As an Australian patent attorney, it is important for me to keep up to date with developments in patent law in jurisdictions other than Australia, most
10 importantly the United States and Europe as well as other major jurisdictions.
14. I have taken a particular interest in the recent changes in US laws resulting from the US Supreme Court landmark decisions in *Association for Molecular Pathology v. Myriad Genetics Inc.* (the **Myriad decision**) and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (the **Prometheus decision**). Significantly, the US Supreme Court Myriad decision resulted in the United States Patent and Trade Marks Office (the **USPTO**) adopting a practice of excluding all isolated naturally-occurring material from patentability, not just isolated genes. This practice is detailed
20 in the USPTO guidelines for determining patent eligibility of claims reciting or involving "laws of nature, natural phenomena and natural products". I have written articles on these matters.
15. On the basis of my understanding of the US law following the Myriad and Prometheus decisions and the subsequent USPTO guidelines, in consultation with US patent attorneys, I have provided advice to my Australian clients indicating that inventions involving isolated naturally-occurring material (such as those specifically detailed in paragraph 10 above) would most likely not be patent eligible under US laws. The same invention would, however, be considered patent eligible under the current
30 Australian law.




16. I understand that the United States is the only developed western jurisdiction in which isolated products of nature do not represent patentable subject matter. I am aware that the present law in Australia regarding patentability of isolated naturally-occurring material following the decision of the Full Federal Court in *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 115 (5 September 2014) is in line with at least the laws of the UK, Europe, Canada, Japan, China and New Zealand.
17. From interactions with my clients, I consider that the law as it stands in the US has had a chilling effect on the ability of organisations to obtain patent protection on isolated naturally-occurring material in the US. This in turn negatively impacts on the ability of organisations to raise investment funding for the development and commercialisation of products containing isolated naturally-occurring material, such as pharmaceutical and diagnostic products.
18. The current US law introduces substantial uncertainty into the US patent system. Specifically, under the current US law, the possibility that material may exist in nature is not a bar to patentability. If, however, subsequent to the grant of a patent covering isolated material that material is found to be naturally-occurring, the patent could be held to be invalid. This is particularly relevant to patents that cover antibodies, which are molecules of the mammalian immune system involved in fighting infections. Isolated antibodies are at the cutting edge of a new generation of pharmaceuticals for treating diseases such as cancer. However, given the nature of how antibodies are generated in the mammalian immune system, it might be argued that any antibody could potentially exist in nature and, as such, patents covering isolated antibodies should not be allowed.
19. The current US law also introduces unnecessary complexity into the question of patentability. For example, in order for a "nature-based" product to be patent eligible, the product must exhibit "markedly different characteristics" to material that exists in nature. Markedly different characteristics may include structural, functional or other properties. However, the exact threshold of "markedly different characteristics" is not

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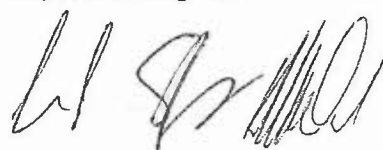
clearly defined under US law. Accordingly, there can be no certainty that even in the event an isolated nature-based material is in some way different to what occurs in nature that it will be eligible for patent protection.

20. For over 8 years, I have advised my local and international clients that isolated naturally-occurring material, such as genes and proteins, represents patentable subject matter in Australia. This understanding has been confirmed, for example, during prosecution of Australian patent applications. In particular, patentable subject matter rejections raised by an Examiner alleging that the subject matter defined in a claim corresponds to naturally-occurring material, can be overcome by specifying that the material defined by the claim is "isolated". Thus a change in the Australian law to exclude isolated naturally-occurring material from patentability would make many patents vulnerable to revocation as well as introduce uncertainty in relation to the allowability of pending patent applications.

21. IP Australia's long-term practice of allowing patents covering isolated naturally-occurring material was endorsed in 2010, when the Senate Committee on Community Affairs Inquiry into Gene Patents (**Senate Gene Patent Inquiry**) made no recommendation to exclude isolated naturally-occurring material from patentability.

22. On the basis of the recommendations of the Senate Gene Patent Inquiry, the Centre for International Economics (**CIE**) was commissioned by IP Australia to investigate the economics of isolated human gene patents in Australia. The independent report produced by the CIE was published in 2013 and one of the key findings in that report was that patents play a key role in promoting innovation and the public-private partnerships required to bring new human gene-based medicines and diagnostics to market. Based on my experience (described above), I concur with that finding.

23. In 2011, the then Prime Ministers of Australia and of New Zealand announced a proposal to implement a single patent examination process for both countries. The Australian parliament recently passed the Intellectual Property Amendment Bill 2014 having provisions to enable the single application and examination process. The next step in implementing the



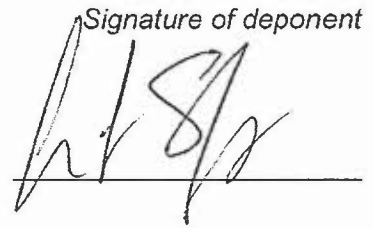
single examination process is for the New Zealand parliament to introduce a complementary Bill. It is widely believed that a single examination process will benefit Australian and New Zealand innovators. A change in the Australian law to exclude isolated naturally-occurring material from patentability would take Australia's laws out of line with New Zealand laws and add complexity to the proposed single examination process.

AFFIRMED by the deponent
at Sydney in New South Wales
on 10 March 2015.

Before me:

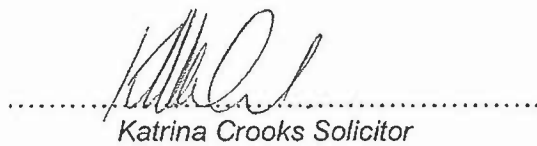


Katrina Crooks, Solicitor

Signature of deponent


10 I Katrina Crooks, a solicitor of Shelston IP certify the following matters concerning the making of this affidavit by the person who made it:

1. I saw the face of the person and
2. I have known the person for at least 12 months



Katrina Crooks Solicitor

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