IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

No. S28 of 2015

BETWEEN:

YVONNE D'ARCY
Appellant

and

MYRIAD GENETICS INC
First Respondent

GENETIC TECHNOLOGIES LIMITED ABN 17 009 212 328
Second Respondent

AFFIDAVIT

I, Trevor John Davies, of Deutsche Bank Place, 126 Phillip Street, Sydney NSW 2000, registered Australian patent attorney, affirm as follows:

1. I am a Council Member and director of the proposed intervener, Institute of Patent and Trade Mark Attorneys of Australia (ACN 004 194 263) (**IPTA**), and have been since 2002.

2. IPTA is the peak professional body representing Australian patent attorneys and trade mark attorneys. According to the records of IPTA, which I believe to be true and accurate, approximately 84 per cent of registered Australian patent attorneys resident in Australia are members of IPTA. The objects for which IPTA was established, as stated in the IPTA Memorandum of Association, include:

> *"To form a united and representative body of the professions of patent attorneys and trade marks attorneys in Australia for the purpose of promoting improvements in the laws and regulations relating to patents, trade marks, designs and copyrights."*

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Filed on behalf of: The Institute of Patent and Trade Mark Attorneys, Intervener
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3. I, and members of IPTA Council, have been following the progression of the dispute between the Appellant and the Respondents through the Federal Court, and the application for Special Leave to appeal to the High Court. I have discussed the outcome of the Special Leave application, and this resulting appeal proceeding, with members of IPTA Council. I, and members of IPTA Council, consider the outcome of this proceeding to be of importance to the patent attorney profession and its Australian and foreign clients.

4. During my term as a Council Member and director of IPTA I have been involved in the Patents Committee and the Patent Legislation Committee. These committees have the responsibility for liaising with Government and examining, on behalf of the members of IPTA, legislation and proposed legislation in Australia and other countries concerning patent law and patent practice. I frequently discuss matters of patent law and patent practice with my IPTA colleagues.

5. In 2002, I was appointed as an Advisory Committee Member by the Australia Law Reform Commission for its Inquiry on Gene Patenting and Human Health (*Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99, 2004)).

6. In August 2009, I appeared on behalf of IPTA before the Senate Community Affairs References Committee for the Senate Inquiry into Gene Patents.

7. In April 2011, I appeared on behalf of IPTA before the Senate Legal and Constitutional Affairs Legislation Committee during its review of the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*.

8. I am a member of the American Intellectual Property Law Association (**AIPLA**) and am the co-subchair of the International Subcommittee of the AIPLA Biotechnology Committee. I regularly attend the AIPLA Annual Meeting held in Washington DC in October and represented IPTA at the Annual Meeting in 2013 and 2014. Through my involvement in AIPLA and managing my client patent applications in the US I am in regular contact with many US attorneys specializing in biotechnology / life sciences patents.

9. Following a career as a postdoctoral research scientist in the field of protein biochemistry in the US and Germany, I returned to Australia in October 1993 to enter the patent attorney profession as a Technical Assistant with FB Rice & Co to specialise in biotechnology/life sciences inventions. I have been registered as a patent attorney under the *Patents Act 1990* (Cth) (the **Act**) for more than 16 years. Since 2001, I have been a partner of Allens Patent &Trade Mark Attorneys (**Allens PTA**) heading up the pharmaceutical and life sciences patent practice.

10. In the course of my work as a patent attorney acting for Australian clients, I have drafted patent specifications, filed and successfully prosecuted patent applications in Australia and in foreign countries directed to a wide range of inventions including isolated nucleic acids encoding animal and human genes implicated in disease, isolated nucleic acids encoding plant genes imparting desirable crop traits, isolated nucleic acids encoding microbial genes, and isolated nucleic acids encoding proteins such as antibodies, antigens and enzymes having medical, scientific or industrial applications. In each case, the nucleic acid was isolated from a natural organism or natural source by researchers and was novel because it had not previously been isolated from the organism or natural source.

11. In the course of my work as a patent attorney acting for foreign clients, I have prosecuted patent applications before the Australian Patent Office to obtain patents for a wide range of inventions covering isolated biological materials such as cells, nucleic acids, nucleic acid probes and primers, peptides, proteins, vaccines, venoms, antibodies and enzymes having medical, veterinary, agricultural, scientific and industrial applications. Again, the isolated products were each isolated from a natural source.

12. Over my time in the patent profession I have advised foreign attorneys that inventions directed to isolated biological materials are patentable subject matter in Australia. I am aware that other Australian patent attorneys have provided similar advice to foreign attorneys. That advice would have been used by those foreign patent attorneys to guide clients in making a decision

to seek patent protection for their innovation in Australia and potentially commercialise the innovation in Australia.

13. Early in my patent attorney career, the rapid development of molecular biological techniques and tools led to the search for genes and genetic mutations that may have involvement in human and animal diseases. Patent protection for these inventions was sought by universities, research organizations and companies around the world to assist with commercial development of new diagnostics and treatments. As the body of public knowledge on the human genome grew over the past 20 or so years, the number of patent applications directed to isolated nucleic acids encoding human genes dropped off dramatically.

14. Although patents directed to isolated nucleic acids encoding human genes are no longer being granted, I consider that patent protection for other isolated biological materials that may exist in nature or modified biological material based on natural material is very important for the development of cancer treatments, antimicrobial therapy, diagnostics, agricultural crops and products, and industrial processes.

15. For my Australian research and biotechnology company clients, patent protection for their biological innovation is essential for commercialization of their technology and success of their businesses. Any change in the long standing practice of the Australian Patent Office to accept patent applications that claim isolated biological material in and of itself as patentable subject matter, that is, being to a manner of manufacture within the meaning of section 6 of the *Statutes of Monopolies* (which has been upheld by six judges of the Federal Court of Australia) would have serious consequences to their commercial endeavors. Furthermore, if isolated biological materials were found not to be a manner of manufacture this would have adverse commercial consequences to owners of existing patent applications and granted patents in this technology. Many patents obtained in good faith may be vulnerable to a validity challenge and if found to be invalid on a manner of manufacture ground, any patented product released

to the Australian market may be copied and commercialized by third parties before the end of the expected patent term.

16. In Europe, the issue of patentability of biological material was dealt with in 1998 under Directive 98/44/EC on the legal protection of biotechnological inventions. The directive has been implemented by all EU member states. The European Patent Convention (**EPC**) contracting states decided to incorporate the directive as secondary legislation into the Implementing Regulations to the EPC. Together with the EPC articles on substantive patent law, these rules provide the basis for deciding on the patentability of biotechnology inventions at the European Patent Office (**EPO**). According to the EPO, the incorporation of the EU directive into the EPC strengthened the practice of the EPO in biotechnology, whilst putting greater focus on ethical considerations. For example, the directive affirmed that isolated biological material is patentable even if it has occurred previously in nature (Rule 27(a) EPC). It also confirmed that plants or animals are patentable if the technical feasibility of the invention (e.g. a genetic modification) is not confined to a particular plant or animal variety (Rule 27(b) EPC). Furthermore, an invention relating to gene sequences can be patented as long as the industrial application of the sequence is disclosed in the application and all other patentability criteria are fulfilled (Rule 29(3) EPC).

17. In the United States of America, up until the Supreme Court's decision *Association for Molecular Pathology v Myriad Genetics, Inc.*, 569 U.S. __ (2013) (***Myriad***) in June 2013 and the "Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products" issued by United States Patent and Trademark Office (**USPTO**) in March 2014 (the ***Guidance***), isolated biological materials were considered to meet the patent subject matter eligibility under 35 USC 101.

18. In my experience, over many years in directing prosecution of biological patent applications before the USPTO for my Australian clients, it was rare to have a 35 USC 101 rejection issue by an examiner in an Office Action for such patent applications.

19. I have been informed by a number of US patent law practitioners and believe that since *Myriad* and the *Guidance* the USPTO has been raising 35 USC 101 rejections on many patent applications directed to inventions involving biological materials isolated from natural sources. I have also been informed and believe that there are many pending patent applications directed to inventions involving biological materials isolated from natural sources that were filed prior to *Myriad* and the *Guidance* that could now be subject to a 35 USC 101 rejection. Furthermore, it is uncertain how many US patents directed to isolated biological materials that issued prior to *Myriad* could now be susceptible to a validity challenge under 35 USC 101 by the courts or the USPTO under re-examination.

20. I have been informed by a number of US patent law practitioners and believe that there is a real concern to the US patent attorney profession and US innovators in the life sciences area that this uncertainty as to patent eligibility in the US will adversely impact on patenting and investment in the biotechnology industry. I have been informed and believe that companies are now reconsidering whether to seek patent protection for their innovation due to the uncertainty in how the USPTO is applying the *Guidance.* There is a concern that without an opportunity for patent protection in the US for some biological inventions, innovation in this area will decrease and there will be a reduction in new products being developed and coming to market.

AFFIRMED by the deponent
at Sydney in NSW
on 10 March 2015.

Before me:

[Signature]

[name and qualification of witness administering oath or affirmation]

Jonathan Adamopoulos
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[Signature of deponent]