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, Julian Clark of 1G Royal Parade, Parkville Victoria 3052, affirm as follows:

1. I am the head of business development at the Walter and Eliza Hall Institute of Medical Research (**WEHI**) Melbourne Victoria.

2. I have more than 35 years international experience in the commercialisation of intellectual property developed in both the public and private sectors and based on gene and other biological substance patent claims.

3. I graduated from Flinders University (First Class Honours and University Medal), University of Glasgow (PhD), am a Doctor of the University of South Australia and a Fellow of the Australian Academy of Technological Sciences and Engineering.

4. I have held senior and chief executive positions in several large and small biotechnology companies in Europe, Asia and Australia, as well as assisting academic organisations in commercialising their research. I am currently a director of Cancer Trials Australia, BioGrid Australia, Nexpep, BACE Therapeutics and Catalyst Therapeutics – all being companies registered in Australia.

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Filed on behalf of:	The Institute of Patent and Trade Mark Attorneys, Intervener		
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5. I have been Head of Business Development at WEHI for more than 10 years and this role includes responsibility for intellectual property capture, management and exploitation through partnership with private and public third parties. WEHI's business development group includes two professional patent counsel and we are deeply involved in research strategy and commercialisation of discoveries from the Institute.

6. WEHI's and my involvement and interest in patent reform and allowable claims is because they lie at the centre of our ability to translate WEHI's investment in research into commercial and community outcomes. We are totally dependent on commercial partners for returns from our intellectual property position and these must be based on a strong and consistent patent environment that respects invention without arbitrary exclusions.

7. WEHI's and my concern that Australia develops a robust, consistent and competitive patent environment is evident from our various submissions related to gene patenting and patent reform. For example, we have made significant submissions to the Australian Law Reform Commission inquiry "Genes and ingenuity" (2004), the IP Australia Consultation: Getting the balance right (2009), the Senate Community Affairs Committee inquiry into gene patents (2010), the Senate Legal and Constitutional Affairs Legislation Committee inquiry into patent amendment (human genes and biological materials) bill (2010), the Intellectual property Law Amendment (Raising the bar) Bill (2011) and IP Australia Patentable Subject Matter (2013).

8. Founded in 1915, WEHI is the oldest research institute in Australia and has earned an international reputation for conducting world class medical research and translation of such research to medical and commercial outcomes in the areas of detecting, preventing and treating diseases, for example solid tissue and blood cancers; rheumatoid arthritis and auto-immunity; coeliac disease; and infectious diseases such as malaria, hepatitis, HIV, HPV and tuberculosis.

9. Currently WEHI innovations underpin more than 100 clinical trials. These include trials of vaccines for type 1 diabetes, coeliac disease and malaria, a

number of which are based on patent claims to naturally occurring gene sequences.

10. WEHI's commercial revenues from collaboration and licensing in recent years have been approximately 5% of total revenue at the Institute (with total revenue currently being approximately $100 million per annum). These revenues (less a 30% distribution to Institute inventors) are reinvested by WEHI in further research at the institute. While these revenues are a small part of WEHI's income, they are very important since Australia's medical research institutes are not fully funded for research infrastructure costs and not at all for costs of obtaining patent protection. Most of WEHI's commercial collaborations, spin out companies and success in the clinic are dependent on strong gene sequence patent claims that are essential to achieve translation from the lab to the market and thus benefits to patients.

11. Since 1983, WEHI has been listed as an owner of over 350 patent applications. Since 2003, we have filed 187 patent families, of which approximately 40% are based on gene sequence claims. In recent times, WEHI files on average one new patent application per month and these patent applications are an essential element of our ability to make medical research innovation available to the public in the form of new products and treatments.

12. Medical research and development is a global industry, meaning that capital essential for development of innovations will move to environments that have a supportive, robust and consistent intellectual property environment. While Australia is approximately 2% of the global healthcare market, our strong medical and clinical research sectors attract "first in class" investments to allow Australians early access to the best possible treatments. In light of my experience set out above, I hold the opinion that, if Australia disallows isolated gene sequence and natural product patent claims, investment will move elsewhere; WEHI and other research entities in Australia will have even greater difficulty in engaging with investors and global collaborators; and incentives for new treatments to be introduced for

the benefit of Australian patients would be diminished. From my experience, I consider that if Australia does rejects the patentability of isolated gene sequence and natural product claims, Australia will suffer economic marginalization with negative impacts on the health, agriculture and potentially environment sectors.

13. I provide examples below of WEHI research and development involving isolated gene sequence patent claims or their fragments which secure an intellectual property position essential for commercialisation, and without such claims WEHI (and consequently Australia) would fail to gain a return and benefits from its investment in medical research.

14. Isolated gene sequences underpin the intellectual property positions of an antibody originating from WEHI which targets the GM-CSF receptor (Australian patent 1990061896). Derivatives of the antibody are in clinical trials (Phase 3) for treating inflammation, partnered with MedImmune/AstraZeneca through CSL Ltd.

15. WEHI was also responsible for the invention of an antibody targeting IL-13 to treat asthma. WEHI has partnered with Aslan Pharmaceuticals, through CSL Ltd to develop the antibody. The antibody will soon enter Phase 1 clinical trials and protection relies on isolated gene sequence claims included in Australian patent 1996072668.

16. The above examples are illustrative of WEHI research and development that are or have been protected by isolated gene sequence claims and that I believe have been and are essential to establishing the exclusivity required to attract commercialisation partners and bring much needed treatments to the community.

17. In 2011, I authored a paper which was published in the Australian Economic Review titled "*Do patents and intellectual property protection hinder biomedical research? A practical perspective*". This paper examined the Australian and international evidence and specifically evaluated publication patterns exemplified by BRCA and GM-CSF research. I concluded in the paper (and hold the view) that there is no evidence of patents to isolated

genetic material having any negative impact on research publication in Australia. My study was conducted before the Australian patent law was clarified to have an explicit research exemption. In fact, my study concluded that research activity and publishing is to the advantage of the patent holder since they add weight to the intellectual property position, provide additional validation and can also indicate potential for new intellectual property claims.

18. I know from my long experience as a company executive in the therapeutic, diagnostic and research tools space that it would be extremely unwise to take any action against research use. Importantly, from my experience at WEHI, one of Australia's largest and highest profiled medical research institutes, in more than ten years there has not been a single incidence of intervention by any patent holder or doubts that our research would infringe on the rights of others. The Institute has never taken action against a researcher for potential infringement of the Institute's patent claims. Since 2003, the Institute has grown from 500 to 1,000 people, published more than 3,000 highly cited papers and filed approximately 187 patent families.

19. Due to the potential size of the market and location of development partners the Institute always files patents in the US. The US Supreme Court Myriad (2013) ruling to disallow gene patents was translated well beyond the boundaries of the court decision by the US Patent and Trademark Office (USPTO) into Interim Guidelines (2014, 2015) to US patent examiners to also disallow natural product claims. As a consequence, in our dealings with the USPTO, we have experienced a period of nearly two years of uncertainty with the USPTO now needing public consultations; changing guidelines which still remain uncertain and interpreted differently by individual examiners; delays in prosecution; and increased costs due to more office actions.

20. As an example, we have reviewed the costs of three recent Institute patent applications at the USPTO. When compared with similar actions prior to the US Supreme Court Ruling and subsequent USPTO Interim Guidelines, costs have more than doubled. Without even considering the negative

down stream consequences of this ruling on development, we are now experiencing an increased cost of $10,000 per patent application in the US. An equivalent increase would be likely in Australia should it decide to follow a similar path. These costs are major issues for Australian medical research since there are no public funds provided for patent prosecution. I believe a likely consequence would be fewer patent applications from Australia's investment in research.

21. In one example, an application involving a WEHI vaccine invention experienced an increased number of USPTO office actions, leading to a final rejection, then to a continuation filing, and then back to a starting examination with further office actions – all of which would not have occurred prior to the US Supreme Court Myriad ruling. If finally rejected by the USPTO, we will have lost an opportunity to commercialise a vaccine against a major disease that kills nearly one million people per year.

22. In another situation, WEHI has experienced USPTO examiner rejection with respect to peptide fragments even though these do not occur in nature. This relates to a ground breaking invention to target specific immune cells for cancer vaccines and if the soluble fragment we claim is not allowed, there will be no possibility of attracting a partner prepared to invest the hundreds of millions of dollars needed to take such a vaccine to market.

23. Implementation of the USPTO Interim Guidelines has led to great uncertainty in what is allowable with respect to the number of diagnostic markers claimed (for example one, two, three or more), the type of antibody claimed, computer designed molecules, and allowable mode of immunisation to raise antibodies.

24. Based on WEHI's experience, I believe that the current situation in the US is leading to unnecessary objections and rejections that are damaging commercialisation of research prospects in the US.

25. In my discussion with international peers, I observe that the Myriad ruling in the US has meant that the US is no longer seen as a leader in global patent

policy and is contrary to the global move towards harmonisation in recent years.

26. I believe that the apparently simple decision to not allow gene patent claims would have no positive impact on equity of access, would delay introduction of new treatments for the benefit of Australians, would discredit a well-functioning patent system, and would add significant costs to Australia's research sector.

AFFIRMED* by the deponent
at Parkville in Victoria
on March 18, 2015

Before me:

Signature of deponent

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An Australian Legal Practitioner within the meaning of the Legal Profession Act 2004