



Dr Anders Hallgren
Director, Sydnovate

25th February 2011

Ms Julie Dennett
Committee Secretary
Senate Standing Committee on Legal and Constitutional Affairs
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

Email: legcon.sen@aph.gov.au



Dear Secretary,

Re: Patent Amendment (Human Genes and Biological Materials) Bill 2010

Sydnovate is the Technology Transfer Office of the University of Sydney. Our mission is to ensure that technologies which are developed during the course of research conducted at the University of Sydney are developed into products and services that are of genuine benefit to the community.

Sydnovate does not support the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* which suggests amendments to Section 18 of the Australian Patents Act 1990; Patentable inventions under which, currently, Human beings, and the biological processes for their generation are excluded from patentable subject matter.

Reasons underpinning our position are detailed below:

1. We understand the amendments have arisen from a parliamentary enquiry raised "to consider the impacts of gene patents on healthcare, medical research and the health and wellbeing of Australians." However we believe that the proposed amendments will not directly achieve the stated objectives of the Bill (as per the Explanatory Memorandum) which include "advancing medical research, the diagnosis, treatment and cure of disease" and "ensuring unfettered access to biological materials for researchers" for reasons including that:
 - A. No evidence has been presented in support of the Bill to demonstrate that the presence of patents in this area is hindering medical research. In fact, the report following the Senate enquiry suggested that evidence on this issue be collected and analysed. Preliminary data we have seen and the experience of the University of Sydney suggests the opposite is true. Patenting is a form of publication of inventions which further promotes research. In any event, we believe the introduction of a robust research exemption into the Patents Act which would facilitate the free conduct of research involving any patented invention is a much more effective way to ensure the unfettered conduct of

research, rather than singling out certain categories of invention from patentable subject matter under the Act.

- B. A key issue raised in the public debate which we believe contributed to the Senate enquiry on this issue was the need for broad availability to patients of diagnostic tests to screen for the presence of genes which have been discovered to indicate a predisposition to particular diseases (such as the BRCA1 and 2 breast cancer genes). The amendments proposed in this Bill will not facilitate the availability of such tests for patients given that on our understand patents over the processes for isolating a particular gene or performing a test to screen for the presence of the gene would still be grantable.

2. The bio-tech industry in general is questioning, as we are, the empirical evidence which undermines the proposed law reform in circumstances where the number companies and development of the pharmaceutical industry in Australia continues to grow as do the number of employed researchers, the dollars spent in research and development and the numbers of Investigational New Drug (IND) submissions.

3. Fundamentally, we believe that biological materials should be subject to the same test for patentability as any other inventions and should not be the subject of a specific exemption.

4. Even if a change were proposed, we believe the definition of “biological materials” proposed by the Bill is extremely broad given that it includes not only “biological materials” but also “their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature”. The suggested definition of “**biological materials**”, in section 18, includes “*DNA, RNA, proteins, cells and fluids*”. Although much of the public debate is around the pros and cons of “gene patents”, in fact the Bill may affect a broader range of patents over biological and materials derived from biologically-generated materials. This would capture many inventions which involve significant intellectual input to develop and apply natural materials in ways which can lead to critical advances in medicine and in our view these inventions should be patentable.

On a broad interpretation of the proposed drafting, the patentability of many inventions generated out of the faculties of Science and Medicine (and a proportion from Engineering) at the University of Sydney may be negatively affected if this Bill was passed. Currently the University of Sydney has 221 active patent families and reviewing these in light of the proposed Bill we have formed the opinion that up to 25% of the University of Sydney's patent portfolio could be adversely affected by the proposed change in legislation.

5. A failure to be able to patent biological inventions in Australia would place Australia out-of-step with other countries and we are concerned this could act as a disincentive to the continued funding of medical and scientific research and innovation Australia and possibly thereby disadvantage Australian universities when compared with international universities.

6. It is our experience that companies that fund research at the University will not invest in research which they hope will lead to developing a drug or related product without a



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period of monopoly provided by patent protection and that the availability of new health treatments in Australia is therefore directly dependent upon biological patents. At least equally relevant to the debate are the terms on which those products are made available to the public, which it can be argued can be regulated other than through the patent legislation, including by compulsory licensing terms, regulating commercialisation deals and government subsidies on health care products and procedures.

Please do not hesitate to contact me if you wish to discuss this matter further.

Yours sincerely,

Dr Anders Hallgren