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Committee Secretary
Senate Legal and Constitutional Committee
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

25 February 2011

Dear Sir/Madam,

Re Proposed Amendments to the Patents Act 1990

As a company currently pursuing the clinical development of a cellular based therapy for the treatment of cancer, we wish to make a submission in response to the private Senator's Bill to amend Section 18 of the **Patents Act 1990 (Clth),** hereinafter the Patent Act, to prevent the patenting of human genes and "biological materials, including DNA, RNA, protein, cells and fluid, which are identical or substantially identical to such material as they exist in nature".

In summary, Prima BioMed Ltd (Prima) supports the proposal to ban patenting of gene sequences that have been merely isolated; however we do not support the extension of this ban to prohibit patenting of biologicals created by innovative and inventive means. We believe that using words such as "substantially" creates a high level of uncertainty and confusion. We wish to make the following points to the Committee for consideration:

1. The broad manner in which a 'biological' is defined under the proposed amendments in subsection 18(4) to include DNA, RNA, proteins, cells and fluids and the banning of patentable inventions over biological materials which are identical or substantially identical to those in nature in subsection 18(2b) means innovation and development of novel products will be hampered.

2. If the amendments are passed in the currently proposed form we would have concerns about the nature of any new technologies or businesses that we would consider future development of if there were insufficient protective mechanisms in place. This may have the flow on effect of impeding employment of manufacturers and service providers within the Australian market and restricting a highly prospective area of scientific and clinical research and development.

3. Information sharing and collaboration will be reduced and trade secrets will increase

4. We have concerns that larger companies and pharmaceutical businesses will be given unfair advantage due to their ability to afford extended prosecution arguing over subjective definitions of biologicals,

5. Consideration should be made of the use of other legal provisions, for example compulsory licensing or minimisation of exclusive licensing, to control enforcement of patentability in those few instances where a company exploits an invention in a manner that is unfavourable to society

6. Prima supports the views expressed in the US Department of Justice's amicus curiae brief in the Myriad (BRCA 1 and 2 gene) litigation in the United States Supreme Court as displayed at the following link http://graphics8.nytimes.com/packages/pdf/business/genepatents-USamicusbrief.pdf) and attached to email submission with this report (PDF). We support, in particular the DOJ's analysis of the distinction between products of nature and man-made creations.

Background on Prima:
Our company is currently undertaking clinical research into a therapeutic cancer vaccine (CVac™) for women with ovarian cancer. If clinical trials find that CVac™ is an effective treatment for ovarian cancer, and it is approved for clinical use by the relevant regulatory authorities (such as the TGA in Australia) the product will be a groundbreaking treatment for women with a disease with one of the highest mortality rates. CVac™ also has potential to be employed against other forms of cancer.

A second product under development by Prima includes an anti-cancer antibody. Antibodies may also be potentially classified as "substantially naturally occurring" or biological. We are concerned that under the proposed amendments, the major components of both our products would be defined as "substantially naturally occurring" or "substantially identical to such materials as exist in nature, however made" and would therefore be non-patentable.

Comments on proposed amendments and their impact:
The Company's' main concern with the currently proposed amendments is the ambiguity of defining "biological materials" and how they are identical or substantially identical to such materials as they exist in nature. We wish to state that the Company has no objection to the prohibition of patenting genes or materials that occur in nature if the foundation of the patent is merely that of a naturally occurring material without any further intervention or innovation. We do wish to ensure that the proposed amendments do not extend beyond genomic DNA to include manipulated biological materials, cDNA's, vectors, constructs, cells etc. (See also DOJ amicus curiae)

Prima does not specifically rely on a gene patent but our licensed patents are a method of composition (ie a process of generating a vaccine product, CVac™) that uses biological materials which are substantially identical to molecules which do occur in nature; principally the product consists of the patient's own dendritic cells (harvested from their own blood), which are pulsed with a protein antigen (another biological material found in nature). The vaccine product although, **created** by human manipulation is still a substantially naturally occurring product and the proposed amendment to subsection 18(2b) states *"the following should not be patentable: -biological materials including 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 wording of "substantially" is a subjective issue open to argument and interpretation and however made could include man-made. Speaking simplistically, if our product consists of two components, A and B, (both of which are biological) and they undergo manipulation to create a man–made product C – this should be patentable, even if the product C is a biological that is substantially naturally occurring. Product C would not normally be found in nature in these cancer patients therefore the process of generating C should be regarded as novel and inventive. Without the ability to patent the biological product **created** (ie the vaccine itself), our future viability and commercial prospects would be impacted.

We would like to further draw your attention to a number of concerns regarding the implications and economic impact the proposed changes would have to many businesses within the biotechnology industry if the amendment in its present form extends to the

inclusion of the widely defined term "biological" rather than naturally occurring genes themselves. If the restriction applied to any biological material, including material which was developed by novel and innovative processes, this could mean that Australian innovation and research would be stifled severely. This in turn would impact on service providers, manufacturers, consultants, lawyers and any number of third parties indirectly contributing to the generation of novel technologies. Without protection for innovative products under development, Prima would be forced, against its very strong preference, to undertake all relevant research and development offshore - and Australian women would be denied denied early access through clinical trials to a potentially effective treatment for ovarian cancer.

Furthermore, with respect to the antibody development program, Prima (and similar companies considering any new opportunities) would likely reconsider any further investment if the present Bill was passed, as projects at an early proof of concept stage require large investment without a guarantee of return. The high risk of failure and lack of patent protection will deter investment not only in the R&D of the projects but in terms of venture capital and foreign investment in companies themselves. Patents offer businesses a chance to recoup some of the costs they bear in generating potentially beneficial treatments, cures or at the least, knowledge.

While proposed amendments to the Act would have little impact on those companies generating technology platforms that can patent the platform itself, those companies generating specialised unique high risk technologies dependant on biological materials will be severely impeded. The result will be pockets of the industry that will flourish and the higher risk sectors will become dependent on governments to fund their development programs. An increase in the need for trade secrets will likely see a loss of collaboration and information sharing.

The economic impact of the proposed amendments will be further felt by other industry sectors that are service providers and manufacturers that are reliant on performing services and consulting to companies that are developing technology. Employment will be affected as companies choose to abandon projects due to a lack of protection or to stop outsourcing services for fear of loss of proprietary knowledge and the need to keep things in-house.

Should the amendments being considered in the present Bill be passed, it is our concern that a patent system will be created such that larger companies that can afford more skilled, more expensive patent counsel will be able to create convincing arguments to attempt to prosecute claim amendments that overcome subjective interpretation issues. Where larger companies cannot succeed under the patent system, they may resort to keeping trade secrets and stop sharing information. Smaller institutions and government funded organisations that cannot afford protracted prosecution of their intellectual property claims will be disadvantaged.

Finally, interpretation of definitions and law are often a subjective issue that can be argued skilfully. It is important to use caution in defining the scope and definitions of amendments to the Act when considering broad definitions such as the term "biological" and "substantially". The proposed amendments will create a "one size fits all" approach in an industry where it really won't work. There will be some businesses that will not be affected by the proposed amendments if they are passed, however others will be crippled. Rather than accepting an amendment to the Act that may penalise some businesses more than others, a bigger picture solution would address policy reforms or implementing legal mechanisms to regulate patented inventions under conventional laws, national standards or guidelines. Such examples would include clarification of policies surrounding Crown use provisions and compulsory licensing of patent inventions under section 133 of the Patent Act where social needs dominate. Consideration of policy surrounding the ability of firms to negotiate exclusive licenses could also be made. The current proposed amendments are penalising a

large industry for the malicious actions of a few companies not acting in society's best interests.

Conclusion

It is Prima's intention to illustrate to the Committee that passing the currently proposed amendments of the Patent Act Bill will have a multitude of effects on various areas within the industry. Prima does not object to a ban on gene patents but we are opposed to the prohibition of patents on any biologicals where they have been created through innovation and invention. It is our view that adopting a single, more limited amendment which makes it impossible to patent a gene merely because a person has isolated and sequenced a gene is sufficient. Extending the amendments to imposing restrictions on the patentability of all biologicals will have far reaching (and we presume, unintended consequences) and restrict a very high potential new area of clinical research and discovery - the field of cellular -based therapeutic treatments for diseases such as cancers. These therapies have the real potential to enhance the health of Australians with cancer and other life threatening illnesses. It is a vital new area of research and innovation where Australia, through Prima Biomed, has a strong advantage. Developing a strong and sustainable Australian biotechnology industry depends on the capacity of Australians to innovate, commercialise and invest in new ground-breaking therapies. The proposed amendments go far beyond what is either necessary or desirable.

Thank you for your attention in this matter.

Kind regards

Larisa Chisholm

Intellectual Property Manager