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24 February 2011

Ms Julie Dennett
Committee Secretary
Senate Legal and Constitutional Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Ms Dennett,

Please find attached a submission on behalf of the Peter MacCallum Cancer Centre in response to the Patent Amendment (Human Genes and Biological Materials) Bill 2010. The response has been prepared by Dr Shari Lofthouse, our Acting Director of Commercialisation, in consultation with our senior researchers. We welcome the opportunity to provide our opinion in this matter of great importance to our research and clinical activities.

With many thanks for your attention.

Yours sincerely,

Joseph A. Trapani MBBS, FRACP, FFSc (RCPA), PhD
Executive Director Cancer Research
Head, Cancer Immunology Program
Professor

cc: Mr Craig Bennett, Chief Executive Officer

Submission to the Senate Legal and Constitutional Affairs Committee inquiry regarding the Patent Amendment (Human genes and Biological materials) Bill 2010.

Prepared by Dr Shari Lofthouse, Acting Director of Commercialisation, Peter MacCallum Cancer Centre, St Andrew's Place, East Melbourne 3002 Victoria.

Peter MacCallum Cancer Centre ("Peter Mac") is Australia's only public hospital solely dedicated to cancer. The hospital provides multi-disciplinary patient services including haematology, medical oncology, surgical oncology, radiation oncology, radiation therapy and supportive care. We also offer a broad range of patient support and education programmes. Peter Mac is also one of an elite group of hospitals worldwide to have its own integrated cancer research program encompassing basic, translational and clinical research investigating causes and therapies for cancer.

It is well recognized that the concept of awarding monopolies over products and services is, by definition, anticompetitive. However, it has been necessary to establish patent systems worldwide to provide economic incentive to invest in new inventions. It must also be remembered that patent law was not framed solely to benefit the innovator. In return for being rewarded with a temporaray market monopoly, the innovator must fully disclose the invention, to benefit the base of public knowledge and foster further innovation. Any changes to the patent system must retain this two way benefit as a central theme.

The requirement for a general research exemption.

As a leading specialist centre for cancer research and treatment, the potential impact of this Bill is of some concern. Evidence shows that to date, we and other research organisations have not been significantly impacted by the threat of infringement actions negatively impacting our research activities. Recent case law in Australia and in other countries has however confused the situation regarding research exemptions and there are a handful of examples where patent owners have attempted to enforce their rights over non-commercial researchers. This is in direct conflict with fundamental aspects of the patent system.

Peter Mac, for example, leads the Australian Ovarian Cancer Study. This is a collaborative research program between clinicians, scientists, patients and advocacy groups aimed at improving the prevention, diagnosis, and treatment of ovarian cancer. The Study supports multiple research groups that use genetic information in a significant proportion of their studies. In regard to such work, it is essential that our rights in regard to research use be clarified, so that researchers can be confident that they are working free of any threat of litigation. Public research organisations have no access to funding that would support their legal defence in the case of infringement actions, and must be provided with statutory protection so they can continue their work without such threat. Peter Mac agrees with the wording of the research exemption drafted by IP Australia in a proposed amendment to Part 1, Chapter 11 of the Patent Act (IP Australia consultation paper March 2009; Towards a stronger and more efficient IP rights system). We understand that this change will provide protection for our researchers across all technologies, not merely for genes and other biologicals.

What is a "gene patent" ?

In the specific example of gene patents, any modifications to existing law must be carefully considered, as an ever-increasing proportion of medical therapies rely on knowledge obtained through gene sequencing. A new frontier of medicine in "personalised therapies" may be at risk if the research use provisions, public availability of therapies and the need to foster innovation through financial incentive are not appropriately balanced. There has been much confusion in the public media over the use of the term "gene patents". As such this submission will address the various definitions of this wording in turn.

A common misconception amongst the public is that patents are granted over human genes. This is not the case – we accept that nobody is able to "own" our genes. It is also now understood that patents cannot be granted to isolated gene sequences or fragments of gene sequences in their

own right. A patented invention must demonstrate some utility and Australian patent law is quite clear on this point.

The chief concern of Peter Mac is in regard to patents that are granted with respect to therapies and assays that interact with or rely on the use of gene sequences *and that include claims directed solely to the gene sequence itself*. We are concerned that companies that have been granted such patents may attempt to assert ownership rights over all technologies directed at that sequence. As previously mentioned, we have no access to funding to support any legal defences in such matters, thus the situation urgently needs to be clarified so that we fully understand our freedom to operate with respect to such patents. In many cases, public databases of sequence information have already disclosed such sequences (such as in the "Myriad" patents) and such claims should have been excluded during the examination phase due to lack of novelty. While the underlying invention may still be patentable (again, as would be the case if the gene sequences of the Myriad patents were removed) we would still like clarification of our rights to continue to conduct research on the patented invention using that sequence and to commercially exploit alternative assays, therapies or technologies directed to the claimed sequence, provided our new developments meet the usual standard of novelty, non-obviousness and utility. Our proposal to correct this is the removal of claims directed solely to the gene sequence itself, but instead to incorporate the sequence into claims addressing the assay or therapy. Again, the research exemption would also be necessary to implement. To use common analogies, we have no issue purchasing a drug that affects bone mineralisation, but the invention should not cover the bone itself. An anaesthetic machine is indeed a useful invention, but we do not expect to pay license fees on the oxygen it pumps.

Raising the bar in inventive step.

We have no issue with genuine inventions that are directed towards gene sequences that meet all the usual criteria of patentability, but are concerned that the thresholds for inventive step and novelty may be too low during the examination phase. We suggest that rather than altering patent law or excluding specific subject matter, this aspect may be best monitored at the examination phase by employing experts in the field to adequately advise examiners on the state of the art from time to time. Continual new developments will always require re-assessment of the application of law, and we cannot continue to alter patent law as every new field of research develops. Maintenance of the fundamental basis of patent law through monitoring of inventive step thresholds would be a more feasible way of addressing the problems of new technologies.

Gene based therapies and the need for patent protection

Finally, gene patents may also refer to inventions that incorporate gene sequences in themselves, such as DNA and RNA-based therapeutics or assays that incorporate specific gene based primers. Again, provided that these inventions genuinely meet inventive standards and they do not have claims that prevent use of the gene sequence itself for other applications, we have no issue. These inventions are synthetically made compounds and should be treated no differently under law than small molecule compounds directed to specific cellular targets. Indeed it is an unusual proposition to exclude certain new therapies from patent protection when the vast majority of new drugs, assay and surgical and medical equipment are patent protected without issue.

Such gene-based compounds form the basis of the field of personalised medicine that may deliver significant impacts on a range of disease therapies. The development of such new drugs requires an enormous financial investment impacted by the large number of drugs that do not reach the clinic, the complex regulatory issues and high production costs. Without the promise of a temporary monopoly, biotechnology and pharmaceutical companies may shift to a model of trade secrets, for which there are no time limits and no statutory limitations. A worse case still is that in the absence of patent protection, such inventions may never be invented in the first place. There is little data to support this proposal either way; *the effect of the absence of patent protection is not measurable; we will never know what inventions we have missed out on.* Proponents of a ban on gene patents cite examples of therapies that have been developed in the absence of patents, and we have no argument with this, as patents are not the only way in which inventions can be protected. They may include other forms of intellectual property such as know how, or be based on trade secrets. Further, patents do not always create monopolies. Many patents give the holder an exclusive right to produce a product that has many substitutes and therefore normal competitive

markets will restrain the patent holders' pricing. We can only address the impact of patenting on development of Peter Mac's own technologies, and it has been repeatedly confirmed to us that we are unable to obtain commercial support for new technologies for which we do not hold patents or patent applications. This commercial funding support is essential for the transfer of technologies from research to the clinic, as research grant funds are not adequate to support all phases of development.

Reasonable access to patented inventions for clinical use; compulsory licenses and crown use.

The issues with the patent system are not limited to research use but threaten to affect our ability to supply clinical services to the public at reasonable cost. This problem is not limited to gene or biological based patents alone and needs to be clarified for all patented technologies. While the majority of medical drugs and treatments are available to us at reasonable cost and under license to a range of suppliers, some companies have chosen to exploit their rights by refusing to issue non-exclusive licenses or placing excessive costs on inventions under their granted monopoly. This was the central issue in the case of Genetic Technologies, who threatened legal action to a number of Australian medical institutions and insisted upon themselves acting as the only supplier of BRCA diagnostic testing in this country, under license from Myriad. The institutions exerted considerable effort in addressing this injustice before GTG chose to back down on its demands in the face of public disapproval. Exclusion of gene claims would have had no effect on this issue, as the underlying Myriad patents contain a series of claims directed to the diagnostic assay itself, which would have remained even in the proposed gene patent ban proceeded.

The issue here is not with the patent law itself. Australian patent law already includes provisions for crown use and for compulsory licensing, however it appears that these control methods are rarely if ever utilised. We would like the situation regarding compulsory licensing to be clarified, and a process for requests for such licenses to be defined and available at accessible cost. Again, this proposal would cover all patented subject matter.

The proposed ban on patenting of all biological material.

Finally, the Bill seeks to exclude not only gene patents, but all biological materials. Despite the title of the Bill, the wording does not limit this to human based biologicals. Senator Heffernan claims the amendment is narrow, however this is clearly not the case. The amendments, if accepted, may have profound implications not only in the field of medicine (antibiotics, antibodies, synthetic hormones), but also veterinary science, agriculture, industry and the rapidly expanding field of green and renewable energy. The explanatory memorandum to the Bill, Senator Heffernan's readings in the Senate and the media releases from his office all fail to address the issue of other biological inventions at all, and clearly their impact had not been adequately considered. There has been insufficient discussion or evidence available to make any changes to patent law that are so profound in their potential impact at this stage. The changes proposed by Senator Heffernan do nothing to address the concerns of research access, and such widespread changes are also likely to be contravention of our international treaties on patent law. Altering Australian laws out of sync with other international patent laws will only result in investments being transferred offshore, and inhibited access to patented genetic based medicines in this country.

In summary, we see no reason to differentiate gene-based inventions from any other drugs or equipment used in medical treatments. The fundamental basis of the patent system as an incentive for innovation is valid and relevant in the case of genetic inventions. It is however apparent that the law requires clarification to completely define our rights and to allow medical research to continue and for the public to have reasonable access to medical therapies. To this end, our recommendations include;

- A research exemption to be introduced to allow non-commercial research on patented inventions

- Claims addressed only to gene sequences to be disallowed, and such information to be directly linked to the invention by claiming in combination, thereby clarifying that patent holders to no have rights to all inventions targeting the stated sequence.

- The basic premises of inventive step, novelty and utility to be upheld at the examination stage, by setting the thresholds of inventive step on the advice of experts in the field. Stressing the utility issue will continue to support the now-accepted proposition that genes and gene sequenced cannot be patented in their own right.

- A defined and affordable method of access to compulsory licensing and crown use to be established to govern the handful of organisations that choose to assert their rights unfairly under the protection of a legal system that is too expensive to access for public medical institutions.

- The expansion of the gene patent argument to cover all biologicals to be abandoned in the absence of any analysis of the potential impact of this change across a range of industries.