



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

By E-mail ONLY

25 February, 2011

Dear Sir/Madam,

**Re: Proposed Patent Amendment (Human Genes and Biological Materials) Bill
2010 (“Bill”)**

CSL Limited (“CSL”) provides this submission to the Senate Standing Committee on Legal and Constitutional Affairs (“Committee”) in its inquiry on the Bill.

CSL is an Australian listed global specialty biopharmaceutical company that aims to identify, develop and commercialise important, new, biotherapeutic products that prevent or treat serious medical conditions. We are committed to significantly investing in our research and development portfolio in the areas of plasma replacement therapies, vaccines, immunomodulators and therapeutic proteins (using recombinant technology). With major facilities in Australia, Germany, Switzerland and the US, CSL has over 10,000 employees working in 27 countries. CSL is an active user of the patent system in Australia and other jurisdictions, particularly in the biotechnology/biological area.

CSL has had the opportunity to review advanced drafts of the detailed submission being made on behalf of the Institute of Patent and Trade Mark Attorneys of Australia (“IPTA”), Davies Collison Cave (“DCC”) and AusBiotech in response to the Bill. CSL agrees with and supports key points in these submissions, and we join IPTA, DCC and AusBiotech in urging that the Committee reject the Bill. In addition to supporting these more detailed submissions we make the following comments:



1. The Bill does not address the issues, and creates unnecessary uncertainty

The Bill does not reflect the recommendations of the Senate inquiry into gene patents, and fails to take into account various previous and ongoing reviews and reports that have been conducted and which address issues relating to the Bill. Furthermore, the Bill appears unlikely to alleviate the concerns expressed by some members of the community in response to the Senate inquiry into gene patents, for example, access to genetic diagnostic tests. Even if the Bill passes into legislation, patent claims relating to methods involving biological materials may still be granted. If products or services involving such methods are made available in Australia then those patent claims in respect of those methods will continue to impact on the availability of such products or services.

As emphasised in numerous other submissions, the language of the Bill is unnecessarily broad and highly ambiguous. The outcome of the Bill would, therefore, seem to be to provide uncertainty in respect of the range of biological products which will be excluded. Additionally, it would appear that significant legal debate will be required in order to provide any level of clarity as to what is patentable. Such a level of ambiguity does not provide users with any confidence in the system.

The sum of the above is a Bill that does not address the issues it set out to address yet creates uncertainty and ambiguity in respect of patents that serve an important role for those with an interest in biological materials.

2. The effects of the Bill may extend beyond what is intended.

Patents are an important component of the package of rights that provide a period of effective market exclusivity in respect of a product. For many products this period of market exclusivity is vital for driving decisions about research, development and marketing; this is particularly the case for new medicines. Because of its breadth and ambiguity, the Bill appears likely to result in an erosion of the effective market exclusivity in Australia for a wide array of biological products. For some biological products this reduction in market exclusivity may tilt the balance against bringing those products to Australia; either at all or with any level of priority.

We have serious concerns that the Bill will place Australia substantially out of step with many first world countries in respect of what constitutes patentable subject matter, and has the potential to create an impression that Australia does not



adequately respect intellectual property rights. Such a negative impression may impact adversely on decisions as to whether Australia is an appropriate place to conduct certain activities. This impression will be further heightened if Australia is viewed as not complying with its obligations under international treaties or agreements.

3. We favour a technology neutral approach to changes in the patent system.

The Bill is directed only at users of the patent system with an interest in a particular technology area, i.e. biological materials. As a general rule, CSL favours, where ever possible, technology neutral change in the patent system; i.e. change that does not discriminate on the basis of the technology involved but is universally applied. This is certainly the case with respect to matters that impact on the availability of patents and any effective research use exemption where there seems no good reason to discriminate on the basis of the technology involved.

The Bill seeks to deal with issues relating to ensuring patents in respect of biological materials are only granted for “inventions”, and do not impede research. We believe a technology neutral approach can deal adequately with both of these issues not just in the area of biological materials but across all technologies, and that such an approach is more likely to benefit all Australians.

In fact, we understand that changes in respect of what is patentable and research use will form part of the Governments planned Intellectual Property Laws Amendment (Raising the Bar) Bill, and expect this latter Bill will approach the issues on a technology neutral basis. Accordingly, rather than pursuing this technology specific Bill, we believe the focus should be on the planned Intellectual Property Laws Amendment (Raising the Bar) Bill as a means of improving Australia’s patent system.

We thank you for the opportunity to comment on the Bill.

Yours sincerely

Philip Keep PhD
Director of Intellectual Property