



21 February 2011

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

Dear Sir/Madam,

**Submission to the Senate Legal and Constitutional Committee on
Patent Amendment (Human Genes And Biological Materials) Bill 2010**

Bayer CropScience, a subsidiary of Bayer AG with annual sales of about EUR 6.5 billion, is one of the world's leading innovative crop science companies in the areas of crop protection, non-agricultural pest control, seeds and plant biotechnology. In Australia, the company employs about 270 people and has its head office in Melbourne. The Australian BioScience division of Bayer CropScience has been involved in research and development of genetically modified canola and cotton, developing better varieties to suit the requirements of Australian farmers.

It is our belief that the current patent laws are robust, contain a number of checks and balances and work well to serve the common good. We do not claim that existing patent laws are perfect and believe they could be revised to improve their applicability. In particular, government should take note of the comprehensive review of the patentability of genes that was completed by the Australian Law Reform Commission in 2004 and implement the recommendations of the Australian Law Reform Commission Report on Gene Patents.

The *Patent Amendment (Human Genes and Biological Materials) Bill 2010* proposes to amend subsection 18 (2), to exclude the patentability of specific technologies, viz:

- (2) *The following are not patentable inventions:*
- (a) *human beings and the biological processes for their generation;*
 - and*
 - (b) *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.*

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This proposal is extremely concerning and unwarranted. The current debate in Australia has centred around the medical field, in particular, issues related to access to medical genetic testing (e.g. BRAC1 and BRAC2 gene testing). The amendments, while purporting to redress imbalances in these fields, will be more far reaching in their impact and will affect all biotechnology fields, including the role patents play in agriculture biotechnology.

The Bill as it is currently drafted, bans patents on all biological materials and also bans patents on compounds that are considered to be substantially identical to biological materials. In its current form, the blanket ban will have a devastating effect, not only on the agricultural biotechnology industry, but also on newer chemistries in pesticide science that aim to imitate naturally occurring compounds.

It will have a serious dampening effect on innovative investment into biotechnology research and development in Australia. This would lead to a curtailment of new and important biotechnology products which are important for keeping Australia's rural industries competitive. In consequence, the competitiveness of Australian agriculture would be greatly reduced, delivering a serious blow to a crucial part of the economy already facing challenges from overseas competition and climate change.

In addition, we believe the current Bill, by concentrating on "biological materials" almost certainly infringes on Australia's international obligations under the TRIPS (*cf* article 27) and AUSFTA treaties and would reverse decades of work aimed at harmonising Australian and International approaches to patents.

Our current system has already served Australia well but the proposed amendment as stated above is unnecessary and an over-reaction. Instead, the government should be encouraged to make the amendments recommended by the Australian Law Reform Commission in 2004 to ensure that no patents are granted on inappropriate subject matter – whatever that subject matter may be – rather than singling out specific materials to create special rules.

**Submitted on behalf of Bayer CropScience
Regulatory Affairs Manager
BioScience**