

# Media Coverage

**Company:** AusBiotech  
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## the pharma letter

### **Australia: raising the bar on patents; Generic drugmakers welcome Copyright bill**

Article | 24 February 2011

**Australia's Senate Legal and Constitutional Committee is being urged to abandon patentable subject matter amendments in favor of the Intellectual Property Laws Amendments by the Institute of Patent and Trade Mark Attorneys of Australia (IPTA) and the trade group AusBiotech.**

In a press conference in Canberra this week, and in submissions to the Committee, AusBiotech and IPTA made the point that pursuing the Patent Amendment (Human Genes & Biological Materials) Bill 2010 will be detrimental to a country endeavoring to promote its intellectual talent, retain its best and brightest, and establish its footprint as an important center for biotechnology development.

Legislation to outlaw the patenting of human genes was introduced into the federal parliament by NSW Liberal senator Bill Heffernan last November. It would expressly exclude from patentability "biological materials which are identical or substantially identical to such materials as they exist in nature, however made." The legislation would cover DNA, RNA, proteins, cells and fluids.

In the past, patents have been granted to biotechnology companies for genes linked to breast and ovarian cancers. The biotech industry argues it needs the patents to protect intellectual property and attract investment that allows vital research and development work to continue.

According to the trade groups, the focus should be on the Intellectual Property Laws Amendment (Raising the bar) Bill 2011, which is far more comprehensive in terms of Australian patent law.

After 20 months of deliberation and considering over 200 submissions, the findings of the Senate Committee Inquiry into Gene Patents released in November 2010 should have put an end to a highly-charged and emotive debate and paved the way for a legislative response based on rational analysis, they argued.

However, it didn't. The Private Members' Bill was introduced in November 2010, seeking to ban the patenting of all biological materials (not just genes) even where they exhibit differences to the original form. This is of great concern to both the IPTA and AusBiotech, who point out that the Bill goes far beyond the terms of reference of the Senate Committee Inquiry and seeks to exclude from patentability all biological materials. It would have huge ramifications across the entire field of medical research in this country and on the future of the Australian biotechnology and medicines industry, they stressed.

**Copyright Act will protect rights of Australians to access generic medicines**

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In a separate announcement by the Generic Medicines Industry Association (GMiA), it was stated that members strongly welcome the Federal Parliamentary Caucus clearing for introduction into Federal Parliament the Therapeutic Goods Legislation Amendment (Copyright) Bill on Tuesday, which is designed to ensure the continued supply of generic medicines to the Australian public.

The Bill will amend the Copyright Act 1968 (Cth) to confirm the legitimacy of the current and future use and reproduction of essential information provided to patients with their medicines that is produced by the sponsors of generic medicines. The supply of the information provided by sponsors of generic medicines in substantially the same form as the originator information is being challenged via the claim of alleged copyright infringement by one sponsor of originator medicines.

Should this originator sponsor be successful in its claim of copyright infringement, suppliers of generic medicines will be unable to provide information substantially similar to the originator information. If nothing is done by government, this would prevent sponsors from not only supplying the information that accompanies the medicine, it would prevent sponsors from supplying generic medicines to the Australian market.

The Copyright Bill is important public policy that efficient and timely market entry of generic medicines brings the public and government important benefits of more affordable medicines and contributes significantly to the sustainability of the Pharmaceutical Benefits Scheme (PBS), says the GMiA. In the last four years the presence of a generic medicines sector has saved the PBS in excess of A\$1.4 billion.