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L.S.PERRON a.m. PATRON

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Senators Coonan, Heffernan, Siewert and Xenophon

**Senate Inquiry into Patent Amendment (Human Genes and Biological Materials)
Bill 2010**

Australian research scientists and industry have made significant achievements in medical research which have improved the quality of life in people in Australia and all around the world, e.g. Relenza anti-influenza drug (Biota), the Cochlear hearing implant (Cochlear), the cervical cancer vaccine (University of Queensland, CSL, Merck).

While the Perth Bone & Tissue Bank (PBTB) agrees that the inclusion of human gene sequences in a patent should never give the patent owner any rights or ownership in relation to the gene(s) that exist in an individuals body, PBTB is concerned that the current poor wording of the legislative amendment, which has included any biological material containing human genes, will have unintended consequences on the development of novel therapies, diagnostics, vaccines and medical devices in Australia.

In conjunction with the University of Western Australia, the PBTB has developed Allogeneic Bone Gel (ABG) from human bone. Studies in animal models have shown that ABG is an excellent and safe medium for carrying mesenchymal stem cells (MSC). When MSCs carried in ABG are surgically implanted, the MSCs mature into osteoblasts which make new bone. PBTB and UWA have several patent applications pending on ABG, to date almost AU\$700,000 has been spent on the developmental research work.

If the Patent Amendment Bill results in these patent applications being considered invalid, we shall be unable to progress this important work. This will mean that clinical studies to confirm the clinical efficacy of MSCs carried in ABG, to create new bone in patients in order to heal ununited fractures, to fuse vertebrae (when required), or to replace bone which has been lost due to severe trauma or the surgical removal of a bone tumour, will not be financially possible.

The PBTB wishes to draw to the attention of the Senate Inquiry the importance of improving the wording of the legislative amendment so that novel biological substances derived from human tissues are not linked with human genes.

ANNE COWIE
Managing Director
PBTB.