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Inventions are worthy of patents, not mere discoveries

Innovation, research and market competition in the Australian pharmaceutical and biopharmaceutical industries have been unnecessarily stymied because of the increasing reach of patent rights.

By Kate Lynch, CEO Generic Medicines Industry Association

THE GENERIC MEDICINES Industry Association (GMiA) supports the amended Patent Amendment (Human Genes and Biological Materials) Bill as tabled at the Senate Inquiry Public Hearing on 28 April 2011 because it recognises that the thresholds for the grant of a patent in Australia are set too low, suppressing competition and discouraging follow-on innovation.

The GMiA, which represents Australia's generic medicines industry, along with the Cancer Council Australia, the Human Genetics Society of Australasia, the Royal College of Pathologists of Australia, the South Australian Government, the Australian Medical Association, the Department of Health and Ageing to name a few, are supportive of the Bill's central objective, which is to impose a ban on the patenting of human genes and proteins as well as other naturally occurring biological materials if they are "identical" to that which exists in nature.

Recently a critic of the Bill, Dr Anna Lavelle, CEO of AusBiotech, published a rebuke to the Bill, claiming it "has missed the fundamental point" by not "addressing the concerns being expressed by the Australian community" (see *ALS* July/August 2011, page 10).

A patent monopoly over the BRCA genetic mutations per se means that Myriad Genetics, the company that owns the rights to the patents, has a legally enforceable monopoly over the use of the BRCA genetic mutations. If anyone in Australia uses any of the genetic mutations covered by the patents in a genetic test, that use alone would constitute a patent infringement.

Simply put, the patent claims over the genetic test are subservient to the patent

claims to the BRCA 1 and BRCA 2 genetic mutations per se. Moreover, whether the patent claims to the use of those genetic mutations in a diagnostic test are valid and enforceable will depend on whether those specific claims satisfy the remaining patentability thresholds, being an entire different matter.

The real issue that concerns Australians is affordable access to healthcare. Public outrage overflowed in the media and led to Senator Heffernan asking the Senate for an Inquiry in November 2008 when BRCA testing was threatened by Myriad's Australian agent, Genetic Technologies.

Australians feared they would be required to pay \$4,000 to know if they have the genetic mutations. Patents enable those that own them to control both the supply and cost of the things covered by the patents.

GMiA is not anti-patent, and supports the patentability of all inventions that meet fair standards of patentability. GMiA supports the enforcement of valid and infringed patents relating to patentable inventions that the patent owners have invented.

However, GMiA does not support patenting naturally occurring phenomena that have been merely isolated from their natural environments. Without patent claims on the BRCA 1 and BRCA 2 genetic materials per se, others would be free to develop competing tests which would enable the commercial development of better, faster, cheaper and more accurate tests. Such competition would provide Australians with a choice of tests.

Dr Lavelle makes several erroneous claims in her opinion piece. First, the amended Bill does not "threaten the very foundations of scientific research and

development on biological materials", because inventions that are created from the knowledge of the natural world remain capable of being patented.

If the amended Bill is enacted, it will remain possible and legitimate to patent the medicinal use of a new and inventive biotechnological process, new formulation therapy or diagnostic that uses naturally occurring biological materials.

Next, the amended Bill will not adversely "impact... across diverse sections of the Australian community". It will, in fact, do the exact opposite by enabling Australian scientists, both in universities and biotechnology companies, to freely access naturally existing biological materials and use them for any purpose.

Finally, the amended Bill will not undermine Australia's "world-class health system" nor will it deny Australians "safe and cost effective access to essential treatments and life-enhancing medicines".

Rather, by opening up access to human genetic material and proteins information to anyone, the amended Bill will inject much needed competition into the innovation of new and much needed medicines, treatments and diagnostics.

GMiA and AusBiotech concur with regard to the important benefits that will flow on from the *Intellectual Property Laws Amendment ('Raising the Bar') Bill 2011* and GMiA advocates for the speedy passage of this Bill through Parliament. However, the 'Raising the Bar' Bill does not deal with patentable subject matter generally nor the patentability of isolated biological materials specifically and, as such, does not address these other important issues.

Unless the amended Bill is passed, the Australian patent system will not only stifle the ability of Australian scientists to access and work freely with naturally occurring biological materials, but also will slow innovation in the development of new medicines, treatments and diagnostics.