

Human gene patents: we need them...

The direction of Australia's current debate on human gene patenting is a major concern, given that human gene patents have served us well through many effective therapeutics.

No doubt, recent unreasonable actions by companies exercising their patent rights have eroded equity of access to genetic tests. Most prominent and widely reported are the attempts by Australia's Genetic Technologies (GTG) to restrict genetic tests for the BRCA1 mutation patented by US company Myriad. Let's be clear, it is critical that breast cancer patients have fast and cost effective access to such tests.

However, Australia's response to the actions of few 'rogue' companies must not jeopardise its standing in the international community and compromise its role in developing new therapies, or ability to access cutting-edge therapies. Equity of access issues should not be solved by changing the patent system. We must retain the benefits of the patent system at the same time as demanding the Australian Government to exercise the powers it already has.

I do not believe that tampering with the well-established system by arbitrarily banning human gene patents would be an appropriate response but I declare a clear conflict of interest: both my parents died from cancer before effective therapies based on human gene sequences were available.

Human gene patents are essential for the development of new therapies. Since 1978 gene patents in the US alone have underpinned the formation of 1,500 companies, investment of more than US\$100 billion in research and more than 150 highly valued therapeutics and vaccines. Some examples: insulin, growth hormone, blood factors, cytokines such as GM-CSF, erythropoietin, interferon, and tissue plasminogen activator - just a few of the biotherapeutics that have been protected by human gene sequence patents.

In Australia, the gene sequences of two cytokines discovered at the Walter and Eliza Hall Institute and Ludwig Institute have resulted in the treatment of more than 10 million cancer and bone marrow transplant patients worldwide. The breast cancer HER2 gene targeted by Herceptin is an excellent example of the results that can be achieved from combining diagnostics and a therapeutic for targeted therapy. It is fanciful to believe that such treatments would have been developed without sequence patent protection.

Further examples are new cancer vaccines such as Dendreon's Provenge. The potential prostate cancer therapy is based on a combination of two patented human DNA sequences, GM-CSF and prostatic acid phosphatase, and is likely to be the first cancer vaccine approved by the US Food and Drug Administration. Similar therapies are in clinical trials for a range of other cancers including "Antisense" Therapies which rely totally on the invention that the "mirror" sequence of human DNA can be used to control gene expression and hence disease.

Oponents of human gene patents believe that patents hinder research but this should also apply to patents in all other areas. Where is the evidence for that? A few anecdotal incidences do not warrant entertaining changes to our patent system.

In my experience, human gene patents have had no negative impact on significant research activities, or the ability to collaborate with other researchers. Take Myriad's BRCA1 patent: more than 20 public Australian organisations have published research related to laboratory studies on the gene sequence since 2002. In spite of Chiron's 1992 Hepatitis C patent, 43 Australian organisations have published research on its gene sequences. To date, WEHI researchers have not experienced any restriction of research due to other's patent claims and most other major Australian medical research institutes continue to research, publish and patent inventions related to human gene sequences.

By contrast, disallowing gene patents would have major negative consequences. Australia has obligations under the World Trade Organisation (TRIPS) and AUS Free Trade agreements and indeed would

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find itself in breach of these agreements - just imagine the claims from investors, inventors and companies for the many patents that have already been granted.

Paradoxically, if gene patents were banned, Australian research organisations would continue to prosecute human gene patents in all the major markets but would not have patent protection in their own domestic market.

Let's get it right. There is no evidence of a systematic problem specifically arising from gene patents, and concerns can and should be addressed through other means. Recently there has been a decline in gene patents submitted, many gene patents have lapsed, and there is a decline in gene patent litigation. Equity of access issues must be addressed by the Australian Government utilising compulsory licensing provisions for cases such as Myriad and GTG. For example, the Government can use powers reserved to it under the Patents Act 1990.

An intelligent approach would be to expand the mandate of the Medical Benefits Scheme to have a system analogous to the Pharmaceutical Benefits Scheme covering genetic testing services - including oversight of pricing and licensing practices. This would allow Australian pathology laboratories be able to conduct such tests without the uncertainty of patent infringement actions. This approach would preserve the benefits of gene patents, send a strong signal to companies to adopt reasonable business strategies, and enhance Australia's standing in the international community. Importantly, it will help Australians access much needed new therapies.

