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

25 February 2010

Our Credo

We believe our first responsibility is to the doctors, nurses and patients,
to mothers and fathers and all others who use our products and services.
In meeting their needs everything we do must be of high quality.
We must constantly strive to reduce our costs
in order to maintain reasonable prices.
Customers' orders must be serviced promptly and accurately.
Our suppliers and distributors must have an opportunity
to make a fair profit.

We are responsible to our employees,
the men and women who work with us throughout the world.
Everyone must be considered as an individual.
We must respect their dignity and recognize their merit.
They must have a sense of security in their jobs.
Compensation must be fair and adequate,
and working conditions clean, orderly and safe.
We must be mindful of ways to help our employees fulfill
their family responsibilities.
Employees must feel free to make suggestions and complaints.
There must be equal opportunity for employment, development
and advancement for those qualified.
We must provide competent management,
and their actions must be just and ethical.

We are responsible to the communities in which we live and work
and to the world community as well.
We must be good citizens – support good works and charities
and bear our fair share of taxes.
We must encourage civic improvements and better health and education.
We must maintain in good order
the property we are privileged to use,
protecting the environment and natural resources.

Our final responsibility is to our stockholders.
Business must make a sound profit.
We must experiment with new ideas.
Research must be carried on, innovative programs developed
and mistakes paid for.
New equipment must be purchased, new facilities provided
and new products launched.
Reserves must be created to provide for adverse times.
When we operate according to these principles,
the stockholders should realize a fair return.

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1. Submission Information

Organisation: Janssen-Cilag Pty Limited

Type of Organisation: Proprietary Limited Company

Address: 1 – 5 Khartoum Road, Macquarie Park NSW 2113

Declaration of Interest:

Janssen is engaged in business located in Australia and is the sponsor of a number of medicines listed on the Pharmaceutical Benefits Schedule, including biological medicines.

2. Janssen Overview

"Caring for the world, one person at a time".

Driven by our Statement of Caring, Janssen embraces research and science - bringing innovative ideas, products and services to advance the health and well-being of people. Janssen is a leading research-based pharmaceutical company, employing more than 300 staff across Australia.

Janssen provides prescription medicines for a range of conditions including mental health, neurology, women's health, haematology, gastroenterology, and pain management. Four Janssen medicines are included in the World Health Organisation's Essential Drug list.

The research conducted by Janssen has resulted in a number of critical medicines being developed and made available to the Australian public. Biological medicines are important treatments in Janssen's present range of medicines as well as being important within our pipeline of new medicines.

3. Janssen and Medicines Regulation

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to mother and fathers and all others who use our products and services…

Our Credo

As reflected in our Credo, we believe our first responsibility is to patients, and ensuring continued research and development of, and sound community access to, safe, efficacious and cost effective new medicines is fundamental to this.

In order to continue to develop new and innovative products, companies such as Janssen seek strong, clear and effective regulatory and reimbursement systems.

We therefore welcome the opportunity to contribute to discussions concerning the patenting of biological materials to ensure their effective regulation in Australia.

In this submission we comment on the Bill and its implications for the development of and treatment by medicines in Australia.

We have not raised every issue related to the Bill that concerns us. It is not feasible to do so and other submissions will address further issues.

We have noted, contributed to and strongly support the submission of Medicines Australia (MA).

It should be noted that in this submission we restate many of our submissions made in our March 2009 to the Senate Community Affairs Committee.

4. Executive Summary

Janssen is very concerned by the Bill and considers it to be a dangerous proposition for a range of reasons that will be outlined.

It should be rejected because its consequences would be most detrimental and would include:

1. Limiting access for Australian patients to many innovative medical treatments;
2. Reducing treatment options for Australian healthcare professionals;
3. Stifling scientific research and development in Australia;
4. Constraining business and investment within, and trade from, Australia;
5. Contravening globally accepted principles and practices surrounding intellectual property;
6. Breaching Australia's international trade obligations;
7. Overriding no less than four comprehensive and considered legal and government reports that have recommended against the content of the Bill.

These themes are addressed in further detail below.

We also provide an example of a class of biological medicines that hold a great deal of promise in treating a range of human health conditions. Should be Bill proceed, it would be unlikely that medicines from this class would be further developed or marketed in Australia.

5. Janssen's Response and Position

The Bill is a dangerous proposition for a range of regards that we will address.

Firstly, some essential background and context.

Genes, in themselves, as they exist in the human body and in nature more broadly cannot be patented in Australia. This reveals claims of companies 'owning' peoples' genetic make-up to be a misnomer.

Instead what is the subject of the patent is the invention, not 'mere discovery,' of the isolated nucleic acid sequence encoding the genes. In order for patent protection to be secured the material in question has to be patentable subject matter. The *Patents Act 1990* (Cth) provides the definition for this in Australian law as being a 'matter of manufacture, novel, useful and involving an inventive step.' Each of these steps is crucial in justifying why patent law concerning gene patents, as it stands in Australia, should be maintained.

The current patent system has served Australia well and by not specifying different rules for different types of patentable substances it has been able to remain dynamic and flexible to meet the needs of our current environment of fast paced technological change. Any proposal to single out a specific patent area for different regulation would inhibit this flexibility and place Australia out of step with the international community.

Australia has developed a strong position in the healthcare industry as home for many innovator companies. Internationally we are recognised as a country that has produced a number of significant healthcare breakthroughs and inventions. However, it is important to note that in the current economic climate changes to the patent system could prevent innovators from being able to effectively commercialise their invention. This in turn may lead to new, smaller biotech firms considering their location for commercial development. Small innovator companies in the Australian healthcare sector need to continue to have the stability and certainty that has been provided by our intellectual property system. However, this is under increasing pressure in light of economic and policy developments. An effective and balanced patent system can continue to provide a strong policy incentive and supportive environment for these companies to remain in Australia.

Implications for Patients and Healthcare in Australia

The Bill is a dangerous proposition because it will reduce patient access to new medicines.

A strong and balanced patent system ensures that development of new treatments, tests and therapies continues to occur. This in turn ensures that the provision of healthcare remains at the forefront of technological change. The costs associated with the change are more likely to be borne

by private investors relying on the protection of the patent system than by publicly funded research or a 'prize' based system of intellectual property.

A further concern raised by some in regards to gene patents is the effect they may have on the ability for public institutions to provide accurate and effective genetic testing and screening procedures. The recent BRCA-2 case provided an example of such concern. However, it is important to note that thousands of gene patents have been granted in Australia and yet only a small few have raised such concern. Additionally, those that have, have reached an amicable resolution that has not hindered the effective screening of the gene. Additionally, in the unlikely event of an unresolved such situation the Government may seek to more actively employ either Crown use or compulsory licensing provisions within the present legislation.

Some are also concerned that a monopoly will increase costs. However, as the patent is over the sequence itself, not the gene, variances of the sequence can be patented as well. This allows for competition to occur and evidence of this can be seen in the growth of inventions, which reflects a healthy and dynamic market.

Furthermore, costs pressures can be more effectively regulated by the market than by legislation governing the inventions themselves. Once again the BRCA-2 case can be used as an example. The pricing for tests utilising the BRCA-2 patent are varied in different countries, reflecting each environments individual market dynamics. Additionally, the recent announcement in Australia that the tests could be conducted in public hospitals was brought about by general market forces.

Patent protection encourages private investors to support these often risky areas of therapeutic development that might not be sustained by public funding due to their high risk nature. Ultimately the development of new technologies brought about by gene patents results in a net cost benefit to healthcare as more effective treatment methods are developed and early screening and detection tests have contributed towards alleviating the chronic burden of disease.

Implications for Innovation and Research in Australia

The Bill is a dangerous proposition because it will reduce innovation and research in Australia.

Patents are a crucial driver for development and research in the biotechnology industry. The patent system effectively provides an incentive for the high investment required to develop new and innovative products in this area, which in turn has delivered numerous benefits to patients and the Australian community as a whole. While the standard cost of development for an average therapeutic drug is approximately USD1 billion, gene based developments are much more complex and time consuming to develop and have an even higher development cost. Patent protection provides investors with a high level of assurance that they will be able to recover the cost of development. This is particularly crucial in the biotechnology sector in order ensure return on investment a high level of importance is placed on eliminating unpredictability.

A key concern of some surrounding gene patents is that they stifle medical research. However, medical researchers and developers generally support the current patent system as it can provide funding and growth opportunities for them. Without the reasonable incentive of a limited exclusive monopoly many investors would not support such essential research.

Another related concern, raised by some, is that gene patents restrict access to key information surrounding the gene sequence. However, the 'trade-off' for the monopoly of patent protection is the publication of the patent, which ensures that the information surrounding the patent can still be used for further research and development. Furthermore, the monopoly granted by the patent system is only for a restricted period, expiring after 20 years.

Broader Implications and Additional Considerations

In addition to the above critical considerations, the Bill would place Australian law at odds with international standards and potentially breach our agreements under TRIPS to not single out specific forms of patents for special regulation.

As previously mentioned, singling out gene patents as a defined category requiring special rules governing their use would undermine the dynamic nature of the patent system. Under the current system gene sequences in themselves and mere discoveries are not patentable and the requirements for novelty and inventive step ensure this. Application of these general patent principles has allowed Australian patent law to remain effective and relevant during the current period of rapid technological development. The courts and patent office are uniquely placed to continue to ensure that the dynamism built into the legislation continues to meet the challenges of technological advancement.

The current restrictions on techniques to isolate individual genes and gene sequences (unless they are inventive or innovative in themselves) ensure that research in these areas continues without raising fundamental issues over licensing.

Many of the concerns raised about gene patents posit theoretical problems that may occur in the future, which have yet to be evidenced in 30 years of biotechnology research. Furthermore, coupled with these concerns there have not been any viable alternative methods for regulating gene technology proposed. Commonly suggested alternatives such as prize based systems of reward or purely government driven research have not proven successful in other economies. The *Patents Act 1990* has a proven record of being able to effectively regulate invention and innovation in Australia in the community's interests. Great caution should be exercised in considering any amendment to this stable and successful system.

Moreover, four major legal and governmental reviews have considered in detail the issues raised by those supporting the Bill. These are:

1. Australian Law Reform Commission 2004 – *Gene Patenting and Human Health*

2. Advisory Council on Intellectual Property (ACIP) 2005 – *Patents and Experimental Law*
3. Senate Community Affairs Committee 2009 – *Inquiry Into Gene Patents*
4. ACIP 2010 – *Patentable Subject Matter*

Not one of these bodies has concluded that local patent laws should be amended to invalidate or prohibit genetic or biological materials from being patented.

The findings of these bodies should carry weight and be considered in addressing the views of those supporting the Bill.

Case Study - Monoclonal Antibodies

A tangible example of the detrimental effects that the proposed Bill would have for Australian patients can be seen in the case of monoclonal antibodies. These treatments are a new biological based category of medicines. Many of the more powerful new cancer agents and anti-viral treatments come from this category of medicines and some commentators have even suggested that this class will one day provide a cure for AIDS. These medications are easily identified by their last three letters being –mab.

In Australia Janssen currently markets one of these products and hopes to bring a further two to market in the coming years. However, if this Bill were to become law it is unlikely that Janssen would be able to effectively provide these important medications to patients.

Furthermore, without the necessary patent incentive these medications would not have been investigated in the first place.

STELARA®

STELARA® (ustekinumab) is currently marketed in Australia for severe plaque psoriasis and has delivered an effective treatment to this debilitating condition for many Australians. Importantly this product works where other treatments have failed and provides another option for sufferers.

Bapineuzimab

Bapineuzimab is currently being investigated for the treatment of Alzheimer's disease, a condition that affects over 125,000 Australians. This is a novel new treatment that actively removes the plaques associated with Alzheimer's Disease.

Siltuximab

Siltuximab is currently in Phase II trials for helping patients with Multiple Myeloma, a form of cancer.

Recommendations

Recommendation 5.1
The Bill should be rejected

Recommendation 5.2
The Parliament should carefully review the present legal arrangements and act upon the considered advice of the four relevant legal and governmental reviews and reports

6. Conclusion

Janssen supports a strong and effective patent system that balances the needs of the community and innovators.

We are deeply committed to working with governments and other stakeholders towards high standards of healthcare to all Australians and ensuring that companies in Australia can continue to provide innovative healthcare solutions.

In this spirit, we thank the Committee for the opportunity to submit and we are pleased to commend these ideas and recommendations to the Committee for consideration.

Janssen would be pleased to assist and work with the Committee and the Government to:

1. amplify and/or clarify these submissions;
2. attend hearings to speak to these submissions;
3. provide expert advice in relation to these submissions or matters of health related patents more generally; and
4. otherwise contribute to the development and implementation of an effective and balanced patent system in Australia.