Submission to the Productivity Commission Compulsory Licensing of Patents Inquiry (September 2012)

28 September 2012

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

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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 the community. Janssen is a leading research-based pharmaceutical company, employing more than 350 staff across Australia

Janssen provides prescription medicines for a range of therapeutic areas including mental health, neurology, women's health, hematology, gastroenterology, oncology, infectious diseases 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.

3. Janssen and Intellectual Property

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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.

To continue developing new and innovative products, companies such as Janssen seek strong, clear, effective and consistent patent laws and mechanisms.

We therefore welcome the opportunity to contribute to the Productivity Commission's public inquiry into Compulsory Licensing of Patents. We support the Commission's effort to ensure that Australia has an effective patents system that is consistent with international standards. We believe that this is essential in order for Australia to continue to access key innovations and remain an attractive country for investment.

Medicines are the culmination of a long and costly process of research and development. The medicines industry in Australia invests significant money to both develop new treatments as well as to make existing treatments available to Australians. A country's Patent Laws and enforcement mechanisms are a key component of the decision to invest in such activities.

In this submission we comment on Janssen's experience with making decisions on bringing products to market in Australia and working within the patent system to ensure the broadest possible access to our medicines.

We have not raised every issue of patent law in Australia that is of interest to us. We have sought to highlight the information that we believe will be valuable for the Commission in forming its recommendation and ensuring that Australia will continue to receive investment as well as improve access to medicines for patients in need.

We have noted, contributed to and broadly support the submission of Medicines Australia (MA). Additionally, whilst we have not made direct comments regarding Australia's international obligations we also broadly support the submission from the Biotechnology Industry Association.

4. Executive Summary

Janssen welcomes the opportunity to make a submission to Productivity Commissions review of the Compulsory License provisions under the Patents Act 1990. The patents system is a key element of Australia's innovation system and helps ensure access to the latest technological innovations for all Australians.

We believe that the current provisions are adequate and should **not** be amended for the following reasons:

i. The current Patents Act supports continued investment in research and development in Australia, which is facing increased competition from other countries. Efforts to reduce the effectiveness of Australia's Patent system by making it easier for third parties to acquire innovative technology by way of compulsory license would undermine this position.

ii. Investment by the medicines industry in Australia is predicated on strong, internationally consistent, patent laws and enforcement mechanisms. The current Patents Act 1990 has served Australia well in this respect for many years. This ensures that Australian's have affordable access to the most innovative and effective medicines in the world. Furthermore, the current patent system underpins the viability of the clinical trial industry in Australia, which offers hope to thousands of patients who have exhausted all other options.

iii. The issue of gene patents has been thoroughly dealt with under several other public reviews in Australia. Similar to other areas of medical research, gene sequencing is an inventive and skillful process, requiring the same sorts of patent protection as all other inventions. Efforts to create technology specific requirements are both short-sighted and misinformed. Not only do these have the potential to reduce access to affordable healthcare in Australia, but also may result in Australia not being aligned with its international obligations.

iv. Lastly, the fact that compulsory licenses are difficult to obtain in Australia, and are rarely executed confirms that such mechanisms are, as intended, an effective means of last resort. It can be observed that the market is a highly effective means of dealing with potential patent issues that might impact access to affordable healthcare. Furthermore, those companies processing the skills and resources required to safely manufacture medicines, are considered highly likely to also possess the skills and resources to leverage the existing compulsory licensing provisions.

5. Addressing the primary terms of reference

(a) Janssen response to Australia's system of patents and compulsory licensing

Janssen has been operating in Australia for almost 25 years, and has had significant experience with Australia's patent system. During this time, we have worked effectively with other organizations and institutions to ensure the broadest possible access to our medicines. Critically, we have always resolved any potential market or patent related issues through existing market and legal mechanisms, negating the need to utilise mechanisms of last resort under the current Patents Act 1990.

Australia's Current Patent System

The current patent system has served Australia well, creating an environment that appropriately balances incentives for private innovation with the public's need to access new technology – which is the heart of the patent system. As noted in section 2, research and development in the medicines industry is highly risky and costly, for which adequate protection must be provided in order to encourage innovation that will benefit all Australians.

We believe that the current safeguards under the Patents Act 1990 including; Compulsory Licenses, Crown use provisions and the rights conferred to the Commonwealth, are effective mechanisms of last resort, and provide adequate protection to the public from potential abuses of patent rights. The reason such mechanisms of last resort are so rarely sought is several fold including;

- Existing patent mechanisms and laws in Australia, such as the requirement for 'research freedom' introduced under the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* are highly effective at balancing the needs of the public with the incentives for private investment in innovation.
- Market mechanisms in Australia are highly effective at resolving the vast majority of potential patent abuses that could limit access to important inventions in Australia. For example, in the medicines industry, companies use a range of mechanisms such as technology licensing, distribution agreements, co-investment and acquisitions among others that ensure technology is made available. In the last two years alone Janssen has engaged in over six licensing -agreements relating to our product portfolio.
- In cases of extreme social need, where the provision of technology or services are critical, companies, governments and other institutions are for the most part highly effective at negotiating the socially optimal outcome. When it comes to questions of public health (the current trigger point for compulsory licenses), pharmaceutical companies such as Janssen prefer to work closely with NGOs and Governments to provide optimal solutions. Examples can be seen of this in the area of neglected tropical diseases. Janssen donates mebendazole in many countries to combat intestinal worms and other companies such as Pfizer and

Merck have similar programs.

[Recommendation 1: We therefore recommend that no changes are made to the current Patents Act 1990 concerning the use of Compulsory Licensing of Patents.**]**

Implications for Access to Medicines

As outlined in our Credo, Janssen is committed to meeting the unmet medical needs of patients through the development of innovative new medicines. In order for Janssen to achieve this, as with other innovative pharmaceutical companies, we must be able to make a reasonable return. A reasonable return is required to ensure that we can continue to provide a return to our investors as well as continue to fund further investment in new medicines. Patent mechanisms in Australia are essential to ensuring that such investment continues to occur.

Policy Uncertainty leading to lack of new, innovative medicines

Making it easier to obtain a compulsory license in Australia will not improve access to affordable medicines. If anything, we believe that in the long term it will have the opposite effect as uncertainty surrounding the ability to achieve reasonable returns will leave companies with the choice of either not investing in new medicines and/or raising prices to account for the increased risk and premium required to raise the necessary funds for investment.

Disincentive for Clinical Trial Investment

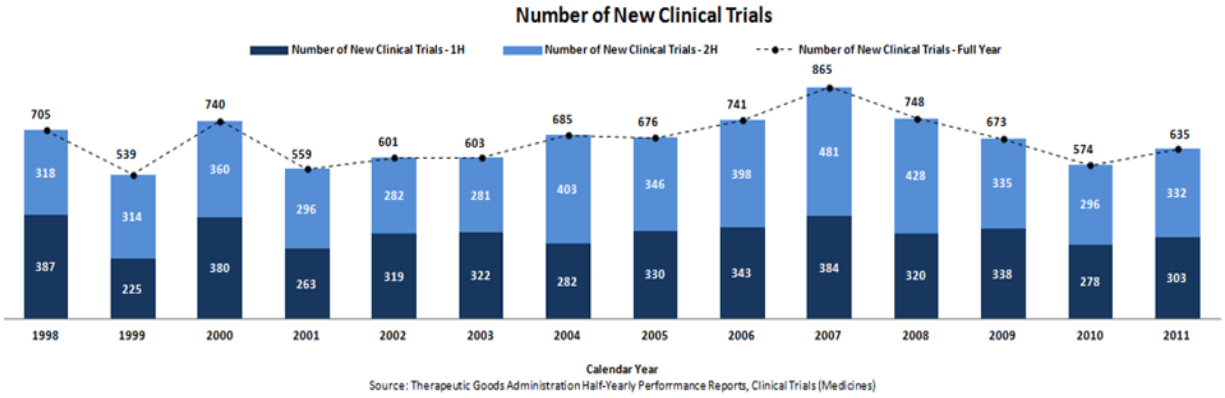
Australia currently enjoys significant investment in medical research and development, including clinical trials for new medicines (see figure 1.0). These trials give patients access to innovative medicines that otherwise would not be available. The Australian medicines industry invests over $450 million a year in clinical trials with more than 18,000 Australians taking part. While some of the world's leading clinical researchers are Australians, the number of new clinical trials in Australia has been declining over the past few years. Australia competes with other countries for these critical investments. One of the key investment decisions for the medicines industry, of which most are international companies headquartered outside of Australia, are the relevant patent laws. While Australia has increased its attractiveness as a result of the recent *Raising the Bar* reforms, any moves to make compulsory licenses easier to obtain would be counterproductive. This is becoming increasingly important as other countries continue to increase their attractiveness through significant investment and industry incentives.

Manufacturing Capability

Finally, even if compulsory licenses were made easier they would not open the market to any additional companies. Any company that possesses the skill and technology to produce medical products would also currently have the skill and capacity to leverage the existing compulsory licensing provisions if required.

Therefore we disagree with the assertion that modification to the Patents Act 1900 to allow the easier granting of compulsory licenses would improve access to medicines for Australians.

Figure 1.0 Clinical Trials in Australia



(b) Gene Patents and access to healthcare

Background on Gene Patents

Genes, in themselves, as they exist in the human body and in nature more broadly cannot be patented in Australia. This reveals commonly cited claims of companies 'owning' peoples genetic make-up to be 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 current *Patents Act 1990* 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.

Janssen has previously made submissions concerning the issues surrounding Gene Patents including our Submission to the Senate Legal and Constitutional Affairs Committee Patent Ammendment (Human Genes and Biological Materials) Bill 2010 and the Senate Community Affairs Committee 2009 – Inquiry into Gene Patents.

We believe that questions in this committee's terms of reference have been answered in the previous review and that further enquiry into the validity of gene patents is not required. Continued uncertainty has the potential to negatively affect future investment in critical gene based research as well as access to important medical innovation in Australia. Additionally, as often highlighted in these previous submissions, patent systems are intentionally technology agnostic to ensure they remain relevant and adaptable to rapid changes in technology and attempts to change this

fundamentally undermine the patent system.

Implications for Patients and Healthcare in Australia

Critical advances in effective genetic testing and screening procedures as well as medicines require significant investment, not likely to be effectively borne by public research institutions. The recent BRCA-2 case provided an example of such a 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. Furthermore, those that have, reached an amicable resolution within the bounds of the current patent framework that has not hindered the effective screening of the gene.

As previously noted, 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. Critically, in the current fiscal environment, where public healthcare budgets are under increasing pressure, it is even less likely that public funding will be able to support such innovation.

Therefore, rather than hinder access to affordable healthcare as some contend, the current patent protection for gene sequencing inventions, as with all other patentable discoveries, increases the likelihood of investment and therefore discovery and availability to all Australians.

[Recommendation 2: No changes are made to the current Patents Act 1990 concerning Gene Patents and that further inquiries into this issue may cause a detrimental undermining of policy certainty.**]**

6. Alternative mechanisms proposed

Non-voluntary licensing by a collecting society

In the terms of reference, an alternative to dramatically modifying the compulsory licensing provisions of the *Patents Act 1990* suggests the creation of a collection society similar to Copyright Agency Limited for gene patents.

The proposed system would have many operational difficulties around administration and funding of such a body. Also the presumption that the society could initiate non-voluntary licensing calls into

question the validity of the patent system.

Additionally, the assertion that such a system would make multi-patent dependant technologies easier to license as you would only need one set of negotiations does not reflect the reality outlined in our earlier arguments. In reality, it is most likely that a single healthcare company will own all the related patents to a product, and if negotiations are necessary would be able to license these to another party directly, without the need of an intermediary step.

Such a system could also dramatically impact the viability of bringing innovative medicines to Australia as mentioned in relation to other changes to the Patents Act. However, where this solution is particularly problematic is that it is in essence forming a patent pool.

Such a permanent system in Australia would fail to provide the level of healthcare that Australian's have come to expect from healthcare companies for a range of reasons:

1. It strips the link between ancillary services such as medical education and patient support programs that can only be effectively delivered with a commitment to the therapeutic area and a robust knowledge of the product development

2. It would discourage on-going product monitoring and development and raises questions of responsibility for regulatory monitoring and safety requirements

[Recommendation 3: We would strongly caution against the creation of a collection society for the purposes of administering genetic patents.**]**

7. Recommendations

Recommendation 1

No changes are made to the current Patents Act 1990 concerning the use of Compulsory Licensing of Patents

Recommendation 2

No changes are made to the current Patents Act 1990 concerning Gene Patents and that further inquiries into this issue may cause a detrimental undermining of policy certainty

Recommendation 3

We would strongly caution against the creation of a collection society for the purposes of administering genetic patents

8. 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 for all Australians and ensuring that companies in Australia can continue to provide innovative healthcare solutions.

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