



*Johnson & Johnson
Family of Companies in Australia*

Submission to the
Senate Community Affairs Committee
Inquiry into Gene Patents

19 March 2009

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: The Johnson & Johnson Family of Companies in Australia

Type of Organisation: Group of Proprietary Limited Companies

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Declaration of Interest:

Companies in the Johnson & Johnson Family of Companies are engaged in business located in Australia and hold certain genetic and biologically based patents.

Note:

Each product referred to in this submission is the Registered Trademark of Johnson & Johnson.

2. The Johnson & Johnson Family of Companies

Worldwide

Caring for the world one person at a time inspires and unites the people of Johnson & Johnson.

We embrace research and science - bringing innovative ideas, products and services to advance the health and well-being of people.

Employees of the Johnson & Johnson Family of Companies work with partners in health care to touch the lives of over a billion people every day, throughout the world.

Our Family of Companies comprises:

- The world's premier consumer health company
- The world's largest and most diverse medical devices and diagnostics company
- The world's third-largest biologics company
- And the world's sixth-largest pharmaceuticals company.

We have more than 250 operating companies in 57 countries employing 119,200 people.

In 2007 we invested US\$7.68 billion in research.

Our worldwide headquarters is in New Brunswick, New Jersey, USA.

In Australia

Johnson & Johnson Pty Ltd became an Australian corporate entity in 1931.

Today there are more than 1500 J&J employees in Australia and New Zealand and annual turnover of more than AUD\$1.1 billion.

There are five health and medical care focused operating companies in Australia: Johnson & Johnson Medical; Janssen-Cilag; Johnson & Johnson Pacific; Tasmanian Alkaloids; and Ortho-Clinical Diagnostics.

In 2005, Access Economics reported that during 2004, Johnson & Johnson in Australia accounted directly for gross value added of \$327 million, GDP of \$366 million and the employment of 1,313 full-time equivalents (FTE).

In addition, the flow on from inputs of domestically produced goods and services into Johnson & Johnson activities indirectly contributed additional gross value added of \$253 million, GDP of \$259 million and the employment of 2,772 FTE.

Combining the direct and indirect contributions, in 2004 Johnson & Johnson contributed gross value added of \$580 million, GDP of \$624 million and employment of 4,085 FTE to Australia.

We now outline the lines of business and companies within the Johnson & Johnson Family of Companies in Australia.

Medical Devices & Diagnostics

Johnson & Johnson Medical

Johnson & Johnson Medical Pty Ltd (JJM) is a major provider to the Australian health care system through both the provision of products and the development and implementation of support services for the medical community. Each year, JJM reinvests more than ten per cent of its sales in Australia to provide training and other assistance to local doctors. It is focused on a broad range of medical products and through a number of separate groups: Ethicon wound closure and wound management; Ethicon Endo-Surgery minimally invasive technology, laparoscopic instruments and mechanical staplers; Gynecare and Breastcare women's health products and antiseptic products; Cordis cardiology, endovascular, electrophysiology and neuro-radiology; and DePuy Australia, a leading developer of state-of-the-art technologies for joint reconstruction which markets a range of orthopaedic products.

JJM also supports clinical research programs in Australia across all business franchises. From involvement in global programs, first-in-human studies of new innovative technologies, to support original research ideas from Australian clinicians and specialists. JJM is particularly proud to have a long track-record of partnering with Australian surgeons to bring new and innovative devices to the global marketplace.

Ortho-Clinical Diagnostics

Ortho-Clinical Diagnostics (OCD) and Veridex LLC supply professional in vitro diagnostic instrumentation and related supplies to hospital laboratories, private pathology laboratories, and blood donor centres. Products include reagents used for determining patient blood groups and the compatibility of blood units prior to blood transfusions, screening of blood for infectious agents (eg. Hepatitis C), and reagents and instrumentation used for clinical chemistry, endocrinology, serology and oncology blood testing.

Pharmaceuticals

Janssen-Cilag Australia

Janssen-Cilag Pty Ltd (JCA) is a research-based company that markets pharmaceuticals for a range of conditions in mental health, neurology, haematology, gastroenterology, virology, and pain management. One of its key focus areas is biotechnology, which represents the promise of entirely new and highly targeted therapies for a range of diseases. At the same time, innovative genomics tools are already beginning to revolutionise and advance the discovery of pharmaceutical medicines.

Tasmanian Alkaloids

Tasmanian Alkaloids Pty Ltd is an advanced agricultural production and research & development company. It extracts alkaloids (morphine and thebaine extract) from poppies. Some of this product is converted to active pharmaceuticals (codeine phosphate and buprenorphine) with around 99% of the product exported.

In 1995, Tasmanian Alkaloids initiated a project to develop a high-thebaine poppy. In sampling the alkaloid content of thousands of plants, one plant was found to have a high content of thebaine and no morphine, and the first commercial crop of these unique poppies was harvested in 1998. The new plant revolutionised thebaine production and today it has up to 80% of the worldwide market for Oxycodone raw materials.

Tasmanian Alkaloids is presently the largest manufacturer of active pharmaceutical ingredients in Australia and the largest exporter of codeine and thebaine in the world.

Consumer Healthcare

Johnson & Johnson Pacific

Johnson & Johnson Pacific Pty Ltd (JJP) is the largest over-the-counter supplier to retail pharmacy in Australia serving all community pharmacies and being in the top thirty suppliers for manufactured goods to grocery supermarkets. JJP is committed to providing the best service, programs and advice to consumers, customers and the community, and is dedicated to bringing to market innovative healthcare solutions.

Our broad product range spans across baby, beauty, oral care, smoking cessation, upper respiratory, gastro intestinal, eye care and general medicine categories. Among our most famous brands are the Johnson's Baby® range, Band-Aids®, Listerine® and Reach®.

3. The Promise of Health Care – Our Belief and Our Role

At Johnson & Johnson, we believe that effective, compassionate health care systems are critical to achieving better health for people around the world. Such systems are centred on the needs of individuals, offer access to health care coverage for all, and provide people with information, encouragement, incentives and support to remain healthy, to obtain early diagnoses and to receive quality care and treatment when it is needed. We believe that people everywhere are served best when health care systems:

- Focus attention on prevention and public health measures in addition to acute and chronic care;
- Address the need for access to care across all economic and social circumstances;
- Allow patients and their health care practitioners to choose the best course of treatment;
- Support health choices with scientifically sound clinical and economic evidence;
- Protect the privacy of everyone’s personal medical records;
- Provide for both public and private health care funding solutions;
- Provide incentives for medical progress;
- Promote market-based competition;
- Are characterized by strong and well-respected regulatory authorities;
- Promote transparent and ethical interactions among stakeholders;
- Are adequately funded to support the health care needs of individuals;
- Allow individuals, health care professionals, caregivers and payers to have access to up-to-date health information to help guide decisions; and
- Operate efficiently, providing affordable, quality, timely and continuous care, and maximum, equitable access.

We believe that, as a member of the global health care community, Johnson & Johnson has a responsibility to advance good health care through our actions as well as to work with others to help shape effective health care systems around the world that will serve the needs of people. We recognize that all members of the health care community must collaborate to achieve this goal. Using the vantage point of our broad base in health care, we will:

- Work to address unmet medical needs through science and innovation, using our talents and commitment to improve health care;
- Support efforts to enhance access to health care and health care products;
- Provide appropriate clinical and economic information about our products and treatments, as well as broad health, disease and prevention information, to individuals, health care practitioners, caregivers and payers in ways that facilitate health care decision-making;
- Protect the privacy of personal medical information;
- Lead by example in providing preventive, health-related and lifestyle modification tools and solutions to our employees and their families worldwide;
- Work with others to improve the quality, cost effectiveness and accessibility of health care for people in developed and developing countries;
- Promote strong regulatory bodies; and
- Enhance business models to ensure appropriate incentives and long-term sustainability.

4. Johnson & Johnson and Gene Patents

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...

Our Credo

As reflected in our Credo, we believe innovation will play an essential role in meeting the healthcare needs of the Australian community.

In order to continue to develop new and innovative products, especially in emerging areas such as gene therapies, innovative companies, such as Johnson & Johnson, rely on a strong and balanced patent system.

We therefore welcome the opportunity to contribute to the on-going refinement of Australia's patent system to ensure it remains effective in balancing the rights of the public and innovators.

In this submission we raise ideas and recommendations for possible areas of refinement in the patent landscape surrounding genetic advancements, and note issues of patent protection of medical development more broadly.

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

We have noted and broadly support the submission made by Medicines Australia (MA).

5. The Impact of Gene Patents in Australia

A foundational issue for this Inquiry is an appropriate definition of ‘gene patents.’ Many concerns relating to gene patents stem from a misunderstanding as to the actual patentable subject matter in question.

Genes, in themselves, as they exist in the human body and in nature more broadly cannot be patented. 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.

Patents and Encouraging Innovation and Research

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, reflected in the Inquiry's terms of reference, is that they stifle medical research. However, many researchers in public institutions and universities support the current patent system as it can provide funding and growth opportunities for them. Without the incentives of a limited exclusive monopoly many investors would not support these research institutions.

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.

Patents and Healthcare

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, such as BRCA-2 have reached an amicable resolution that has not hindered the effective screening of the gene.

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.

Modifications to Existing Patent Protections

The patent system in Australia should not be modified to provide special rules for gene patents. Importantly this 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.

Recommendation 5.1

The current patent system in Australia should continue to allow the grant of gene patents

Recommendation 5.2

The current patent system in Australia should retain the current restrictions to the conditions of gene patents

6. Conclusion

The Johnson & Johnson Family of Companies in Australia 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 Senate Community Affairs Committee for the opportunity to submit and we are pleased to commend these ideas and recommendations to the Committee for consideration.

The Johnson & Johnson Family of Companies in Australia 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.

7. Summary of Recommendations

Recommendation 5.1

The current patent system in Australia should continue to allow the grant of gene patents

Recommendation 5.2

The current patent system in Australia should retain the current restrictions to the conditions of gene patents