Submission to IP Australia on:

Pharmaceutical Patents Review –
Background and Suggested Issues Paper

January 2013
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1. **AbbVie Overview**

At the core of AbbVie is a belief that the world needs a new approach to address today’s health issues – from life-threatening illness to chronic conditions. Launched in 2013, following separation from Abbott Laboratories, AbbVie represents a new biopharmaceutical company that combines the expertise and stability of a long-standing pharmaceutical company with the focus and innovative spirit of biotech.

Our existing portfolio of biologics and other compounds addresses some of the world’s most complex, unmet medical needs. With a patient-centred approach we have been instrumental in changing the lives of thousands of patients here in Australia across multiple disease areas. Diseases in which AbbVie plays a crucial role in assisting patients include arthritis, psoriasis, Crohns disease, Parkinson’s, prostate cancer and HIV/AIDS.

Focused on developing advanced therapies that address complex and serious diseases, AbbVie has a strong portfolio of compounds currently in clinical development. Spanning Immunology, Virology, Neuroscience, Oncology and Women’s Health we are focused on delivering new solutions that truly make a difference for patients. Our expertise and spirit will advance discovery and allow us to harness these break-throughs to improve healthcare both on a global and local basis.

This focus is matched with a strong commitment to research and innovation both globally and here within Australia. Our commitment to innovation has already been recognised locally with AbbVie being named as number 10 in the Business Review Weekly Magazine’s Top 30 Most Innovative Companies in Australia. This award recognised our commitment to innovation both inside and outside the laboratory.

The ability for AbbVie to continue to innovate and bring new therapies to market is inextricably linked to the intellectual property framework that makes such research and development commercially viable. As a member of Medicines Australia, AbbVie has reviewed their submission to this inquiry and would like to formally record our support for the positions outlined within it.

In further support of Medicines Australia’s submission, AbbVie would like to address a number of specific areas highlighted in the Background and Suggested Issues Paper, released by IP Australia in November 2012.
2. Patent Standards

AbbVie is broadly supportive of the improvements made to the patent system through adoption of the Intellectual Property Laws Amendment (Raising the Bar) Act 2012.

By raising the threshold requirement to achieve patentability the Act better aligns Australia’s intellectual property system with patent standards elsewhere. Furthermore the provisions of the Act relating to the “research-use exemption” provide a workable framework that addresses concerns held by some stakeholders that patents have the potential to stifle scientific research.

AbbVie takes the view that these reforms should be allowed to operate without additional legislative or regulatory amendment. Given the nature of patents and the lead time required to assess any changes to the system, further amendments are premature at this time.

3. Follow-on patenting

A drug product often embodies multiple inventions, such as the compound itself, and the manufacturing process that efficiently makes the compound, and the formulation that renders the compound bioavailable. Innovation is a never ending process. A compound is rarely useful by itself. A compound must be properly formulated before it becomes useful as a drug. As a result, pharmaceutical companies often spent more time and resource on developing the right formulation(s) than discovering a new compound. Likewise, over the course of the product lifecycle other research and development are carried out. This work is undertaken in an effort to continue to identify new uses and indications, improved manufacturing processes or new formulations for medicines. These important, and often indispensable, innovations can have significant benefits for patients and represents considerable time, effort and monetary investment from industry.

It is important to reflect that in order to successfully achieve a follow-on patent, the innovator must meet the same requirements that apply to all inventions, including meeting novelty and inventiveness thresholds. It should also be noted that patenting incremental innovation does not extend the protection granted to the original product under the original patent.

When these two points are taken together it is clear that any patents granted, in this circumstance, obviously involve sufficient innovation in order to meet the criteria for patentability and leave the product in its original form open to generic competition upon expiry of the original patent. Rather than limiting innovation, this system encourages it by allowing
firms who successfully innovate to protect their intellectual property while opening up original products to competition.

Once a generic manufacturer commences production of an original product they are either free to compete in the marketplace based on the characteristics of that product or can attempt to identify their own innovation.

Both the innovator and generic pharmaceutical sectors are globally focused with companies operating in multiple jurisdictions. Any changes to this system would undermine the intent of Australia’s intellectual property system as a means of fostering innovation and would place Australia at a disadvantage in terms of the introduction to innovative products, particularly in light of the international environment in which firms operate.

Furthermore, to make changes to the patent system for pharmaceuticals in this instance would place the pharmaceutical industry at a distinct disadvantage when compared to other industries. Innovation and change is the mainstay of all technology dependent industries including electronics, telecommunications and the resource sector. To single out the pharmaceutical industry would be contrary to the long standing practice in this policy area of ensuring a common approach to these issues across all industries.

**Case study – critical follow-on innovation for Norvir® (Ritonavir)**

Norvir® is a product prescribed to patients with HIV and is used in combination with other medication to assist in the management of the disease. When first registered in Australia, Norvir was sold in capsule form and required constant refrigeration. For HIV patients, particularly those in the workforce, this requirement represented a significant barrier to being compliant with their medication. Many reported only taking their medication on an ad-hoc basis to avoid needing to refrigerate their medication in the workplace for fear of the stigma attached to HIV.

Various studies have shown that for patients with HIV, strict adherence to treatment regimens is vital to their ongoing health and wellbeing. Patients who do not maintain strict adherence have a high likelihood of developing resistance to their medication.

Through ongoing investment in research and development AbbVie developed a new melt-extrusion technology that has allowed, for the first time, a solid dose formulation of the product allowing Norvir® to be produced in tablet form.
Case study – critical follow-on innovation for Norvir® (Ritonavir) (cont)

This removed the requirement for the product to be refrigerated. This innovation has had a direct and beneficial impact on the lives of HIV patients who are reliant on Norvir®. By removing the requirement to refrigerate their medication they can avoid privacy concerns in the work environment and can improve compliance.

In order to fund the research and development required and to ensure a commercial return on this investment, AbbVie has been successful in applying for a new patent to cover this innovation. Without this protection this investment, for the benefit of patients, would not have been possible.

4. Data Exclusivity

Data exclusivity is an important component of intellectual property that recognises the cost, time and risk involved in generating the data that is relied upon for registration of medicines by the Therapeutic Goods Administration. When reviewing the data exclusivity regimes in other OECD countries, it is clear that Australia significantly lags behind the protections provided in comparable jurisdictions elsewhere. Whilst most of these nations provide data exclusivity of between 8 and 12 years, Australia’s system only allows for 5 years post a medicines first entry on the Australian Register of Therapeutic Goods.

There are a number of issues raised by the limited data exclusivity provisions provided in Australia. In particular these issues heavily impact on products that are first approved for sale towards the end of their patent protection. Given the time taken to develop a medicine for market, post securing the first patent, and achieving regulatory and reimbursement approval this dramatically reduces the time available for companies to recoup their investment in the development process. An extension of this issue is when a product is approved for sale after it has lost patent protection. In this circumstance data exclusivity provides the only protection available for these products. Finally data exclusivity plays an important role in circumstances where, for some reason, patent protection is insufficient.

Issues arising from the shortened timeframe available in Australia are compounded when the delay between registration on the Australian Register of Therapeutic Goods and listing on the Pharmaceutical Benefits Scheme is taken into account. On average a new medicine takes 3 years from registration to being reimbursed on the Pharmaceutical Benefits Scheme and reaching the market. This, dependant on the patent circumstances of the individual product,
leaves a company with potentially only 2 years of data exclusivity in order to recoup their significant investment in generating the data required for registration.

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**Case Study – Lucrin® (Leuprorelin acetate) and Central Precocious Puberty**

Lucrin® is a product that is registered in Australia for use in the treatment of prostate cancer. Clinical data shows that it may have application in the treatment of Central Precocious Puberty (CPP).

CPP is a very rare and devastating childhood disease, which can affect children as young as two. Children suffering from the condition enter puberty far earlier than normal and suffer from rapid growth of bones and muscle, changes in body shape and size, and development of the body’s ability to reproduce. The prevalence of CPP in Australia means that the condition is considered to have orphan status and there is a very high unmet need for effective treatments.

Following initial discussions, the Therapeutic Goods Administration have requested Pharmacokinetic studies to be performed.

Lucrin® has lost patent protection and has been listed on the Australian Register of Therapeutic Goods since the year 2000. Should AbbVie invest in the required study and seek registration there would be no protection of the intellectual property generated as data exclusivity has lapsed and no patent protection exists.

In order to bring this treatment to an exceptionally vulnerable patient population, AbbVie now faces the prospect of being required to invest in additional studies while not being afforded protection for any data generated.

This case study encapsulates a number of the issues outlined above with Australia’s data exclusivity arrangements. AbbVie strongly supports Medicines Australia’s call for an extension to data exclusivity. AbbVie would also advocate investigation of the Japanese system which allows for data exclusivity to attach to each indication. The introduction of such a system in Australia would address the commercial issues outlined in the case study above and would greatly enhance Australian patients access to medicines.
5. Conclusion

Intellectual property rights provide the foundation for all technology dependant industries to continue to innovate and to bring new and exciting products to market. In no other industry is this as important as the Pharmaceutical Industry. Ongoing technological advancements, that meet areas of high unmet medical need, rely upon the protections and rights provided by intellectual property systems both locally and globally.

As a new biopharmaceutical company, AbbVie is at the forefront of innovation with a strong focus of turning science into caring for our patients. With a significant commitment to research and development, AbbVie focuses on developing advanced therapies that address complex and serious diseases.

AbbVie understands that a balance between the commercial rights of companies and the communities they serve is required. For this reason AbbVie was broadly supportive of the improvements made to the patent system through the adoption of the Intellectual Property Laws Amendment (Raising the Bar) Act 2012.

In the case of follow-on patenting, AbbVie strongly holds the view that incremental innovation should be encouraged and it a vital part of the medicine development process that greatly benefits patients. AbbVie believes that the current system strikes the right balance between rewarding this innovation while still allowing generic competition to occur.

Finally, AbbVie believes that Australia’s data exclusivity regime requires extension in order to bring our system in line with other, similar jurisdictions. In addition AbbVie recommends that amendments be made to our data exclusivity provisions to allow new data, generated for new indications to be provided protection. This is particularly important in orphan diseases with significant unmet need.