Dear Mr. Harris:

PHARMACEUTICAL PATENTS REVIEW
DRAFT REPORT

Eli Lilly and Company is a leading, global pharmaceutical company that develops medicines that help people live longer, healthier, more active lives. Although headquartered in the United States of America, Lilly has been present in Australia for over 50 years and provides medicines vital to the health of many hundreds of thousands of Australians, via the Pharmaceutical Benefits Scheme (PBS).

The draft Report
Lilly is extremely concerned about the direction, detail, analysis and conclusions contained in the draft Report. Lilly has seen the two previous submissions from Medicines Australia and are aware that Medicines Australia and the Pharmaceutical Research and Manufacturers of America (PhRMA) are submitting responses to the report. Lilly shares the concerns and comments expressed in both of these responses.

Before dealing with certain specific aspects of particular concern, Lilly would like to take this opportunity to challenge one underlying aspect of the draft Report that permeates throughout.

The Committee’s apparent view of global investment decision making
Lilly takes particular exception to comments made in the draft Report regarding the importance of intellectual property in global pharmaceutical investment decisions. In particular, the statements:

"... it is difficult to see why a pharmaceutical firm would choose to conduct R&D in Australia merely because the Government decided to offer an extension of term here. More fundamental issues such as the relative cost of R&D and skill availability should influence the location of R&D spending."

Answers That Matter.
"Both representatives considered that patent protection also played some part in attracting funding, because industry partners were more inclined to invest where there was patent protection. However, where the investor is an international company and the market is global, a patent portfolio that spans major markets such as the US and Europe is likely to be of far more importance than the relative strength or duration of patent protection in Australia. In particular, it is unlikely that the length of patent term extensions should be a key determinant in the decision whether or not to conduct research in Australia."

In reaching this position, what would appear to be the Committee’s conclusion, the Committee acknowledges the contrary argument from Medicines Australia but then appears to dismiss it in favour of an assertion made by the Generic Medicines Industry of Association. It is noteworthy that Medicines Australia represents the organisations that actually make the global investment decisions concerning research and development and that the Generic Medicines Industry of Association represents those who are the commercial beneficiaries of any weakening of Australia’s intellectual property regime.

Lilly also notes the quotation of Duckett, at page 89 of the draft Report, in this regard as well as the submission of the Grattan Institute which acknowledges limitations in making similar assessments:

"It is very hard for external analysts to determine how much protection is required to ensure adequate returns for pharmaceutical innovation."

Setting aside the broader contention, the quote in no way addresses the impact on investment in Australian research and development.

Lilly's investments in Australia

Lilly conducts a great deal of research and development in Australia, in its ideas and its potential medicines. Lilly:

- invests approximately $30 million annually in Australian clinical trials and related activities;
- successfully partnered with Melbourne firm, Acrux, to develop one of its products — ultimately taking that product to global markets. Acrux has subsequently become the first biotechnology start-up to enter the ASX 200;
- is a cornerstone investor in $US250 million Queensland-based investment fund targeting developing Australian biotechnology; and
- has entered into a range of partnerships and arrangements with other Australian companies, universities and research organisations to develop new Australian ideas into medicines.

Global investment decision making

Decisions to invest in research and development are complex, vary greatly between jurisdictions and are made taking into account a wide range of factors. There is no one, key factor that has a linear relationship with the decision to invest. That does not make any individual factor less important.

John Lechleiter, Chairman, President and Chief Executive Officer of Lilly, writing as the recent Chair of PhRMA, outlined the four key factors that, in his view, were vital to cultivate and maintain the right environment for innovation to flourish. The very first element was intellectual property protection, with Lechleiter calling it:
"... the lifeblood of any enterprise that derives value from ideas. It takes over a decade — and well over a billion dollars — to carry a new medicine from the drawing board to the pharmacy. The scientists who make medical discoveries — and investors who assume extraordinary risks to bring them to market — depend on retaining the rights to their inventions for a reasonable period of time. Without these protections, neither scientists nor investors could stay in the business of innovation."

The other factors cited are: open access to approved medicines, allowing clinicians to determine prescribing; appropriate levels of remuneration and consistent, transparent and rigorous registration. To this may be added the comparative strength and cost of a jurisdictions research and development capacity, as the Committee rightly recognises, as well as broader business issues.

To look at one factor, such as intellectual property (IP) protection, in isolation and, arbitrarily, dismiss its importance is to fly in the face of what happens in the real world. The question that an investment committee or the board would face would be: does the substantial dilution of IP rights in Australia including for example removal of up to five years of patent term extension, reduce the desirability of Australia as an investment destination compared to one of Australia's (rapidly developing) competitors?

The answer is, yes.

Specific comments
The draft Report makes a large number of recommendations the majority of which serve to dilute IP rights in Australia vis-a-vis other developed world countries and, critically, a number of the more progressive developing world countries. Furthermore, as an overarching matter, a number of the recommendations contained in the draft Report show a lack of regard for Australia's existing international obligations and the spirit with which Australia has entered into current trade negotiations. Almost all of the recommendations in the draft Report are of concern to Lilly, including 3.1, 4.1, 5.1, 5.2, 6.3, 6.4, 8.1 and 8.2. As expressed above these are addressed in responses from others such as Medicines Australia and PhRMA, however the additive comments below are intended to focus on a selection of the most material aspects.

Patent term extensions
The draft Report appears to make a fundamental mischaracterisation as to the purpose of providing patent term extensions. Patent term extensions are not subsidies to the industry. Rather, they are intended to compensate the patent holder for the effective patent life lost during the delay in coming to market because of the regulatory approval process. These term shortening Government approval processes generally do not occur in other industries. The regulatory approval processes are specific to each country or, for the EU where simultaneous central approval occurs, to a region. As such, patent term extensions are necessarily unique to the circumstances within each country. This rationale is well acknowledged in the international community and for example is expressed clearly in the Recitals to the EU Regulation on Supplementary Protection Certificates (SPCs) EC Reg 469/2009:

"(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.

(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research."
4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

(5) This situation leads to a lack of protection which penalises pharmaceutical research.

(6) There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection.

(9) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community.

10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.”

In addition to stating the purpose of providing Patent term extensions through the provision of SPCs, these Recitals show the balance that needs to be struck between reward for innovation and public health and indeed that this has been taken into account in the EU system.

The same was also discussed in the US Supreme Court decision of Eli Lilly v. Medtronic, 496 U.S. 661 (1990) where the Supreme Court noted that:

“The parties agree that the 1984 Act was designed to respond to two unintended distortions of the 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval. First, the holder of a patent relating to such products would as a practical matter not be able to reap any financial rewards during the early years of the term. When an inventor makes a potentially useful discovery, he ordinarily protects it by applying for a patent at once. Thus, if the discovery relates to a product that cannot be marketed without substantial testing and regulatory approval, the “clock” on his patent term will be running even though he is not yet able to derive any profit from the invention.”

The second “unintended distortion” referred to by the Court in that case was the result of the Bolar decision which held that it was infringement of a patent to develop drugs, and Hatch-Waxman overruled that decision allowing generic drug development during the term of the patent for sale after the patent expired.

In addition, it is pointed out that there is no other developed country that has had patent term extensions and has proposed cutting them back. The global norm in the developed world countries is to introduce such measures to promote innovation and investment, not remove them.
The recommendation to reduce Patent term extensions will breach the AUSFTA.
Under the Article 17.9.8(b) of the AUSFTA, Australia must provide extensions of term for pharmaceutical patents. It is seemingly accepted by the Committee that scrapping patent term extensions altogether would not be an option. However, the draft Report notes that the AUSFTA does not specify a particular length for the extensions. In this regard Lilly notes with force that the absence of a duration is not persuasive to legitimise reducing the duration of Patent term extensions as currently available in Australia.

It is quite apparent that Art 17.9.8(b) was intended to require Australia to provide Patent term extensions to an equivalent standard as the USA. This is the only realistic meaning of this provision as there would be no point in agreeing that PTE would be included in the AUSFTA unless it was to harmonise the IP laws between the two countries. Indeed it is abundantly clear that this is the case when considered in historical context. The AUSFTA was concluded in 2004 and entered into force on 1 January 2005. The US had already had a Patent term extension system for pharmaceutical products for over 20 years. The context of the negotiations were always that the US would not ask a country to provide less protection for IP in the trading partner than the US provided. Lilly takes the view that the Australian Government concluded the AUSFTA in good faith and with a clear understanding of the meaning of Art 17.9.8(b).

The suggestion that the savings could be used to directly fund research is naive.
The draft Report does not quantify the amount of the subsidy to be paid, nor how the amount will be distributed. There would be no guarantee that any such savings would be used to subsidise research in the long term e.g. future Governments, and even if it did then to believe with any real conviction that this will lead to new medicines for the Australian or the world wide market is unrealistic given the cost and uncertainty of pharmaceutical research. While it would clearly be a good thing to have local companies seeking solutions for unmet medical needs in Australia, this is not effectively done through direct grants by Government. The majority of new medicines are created as a result of the incentives of the IP system. The development of new biopharmaceutical products requires over a decade of research and development (R&D) and a billion dollars on average. Companies are willing to make those kinds of investments when it is clear that they will have some market exclusivity at the end of the development period. Therefore, if a local innovator biopharmaceutical industry is desired, the last thing one would want to do would be to shorten the period of patent term.

It is not appropriate to link Patent term in Australia to regulatory approvals in other countries.
As discussed above, once the reason for PTE is understood it is clear that the PTE must have national character. Tying the PTE to the term granted in the United States or the EU would not necessarily compensate the patent holder for unreasonable curtailment of the patent term by the marketing approval processes in Australia. A PTE granted in the United States or Europe does not reflect whether the patent term was unreasonably curtailed by the marketing approval process in Australia. Further, other jurisdictions use different methods to calculate the appropriate patent term extension. As a result, tying the patent extension term in Australia to patent expiration in other jurisdictions would defeat the very purpose of granting a patent extension as well as violate Australia's international obligations under the AUSFTA (discussed above).

Contributory infringement
Contributory infringement (also sometimes called indirect infringement) is a valuable provision in the patent law that, as a matter of equity, prevents illegal use of a protected innovation through supply of the essential means to carry use when it is clear to a reasonable person that the means supplied...
are suitable for and will be used to put the invention into effect. In essence it prevents a cynical circumvention of the Patent right. To remove or weaken this provision would be detrimental to all technical innovators – foreign and domestic.

It is pointed out that the leading cases on indirect infringement, at least in Europe are not pharmaceutical cases. In the UK for example the two leading cases are on mechanical devices - a potato decodding machine (Grimme Maschinenfabrik GmbH &co KG v Derek Scott, UK Court of Appeal [2010]EWCA Civ 1110) and a negative pressure wound therapy device (KCI licensing Inc vs Smith and Nephew Plc and others - UK Court of Appeal [2010]EWCA Civ 1260). In Germany the leading case from the Federal Supreme court (Deckenheizing BGH X ZR 153/03) is on room ceilings.

It is further pointed out that any sector specific amendment to the Australian patent act could be seen as a violation of TRIPS Art 27 which demands equivalent patent protection be available in all fields of technology. Introduction of a two-tier system for a key effective provision governing the extent of patent protection would place Australia in breach of its international obligations.

However, there is no reason why a change is needed. There is no difference in equity between contributory infringement in a mechanical device setting and contributory infringement when applied to pharmaceutical cases. Method of use patents are frequently granted by the Australian patent office and have been confirmed as patentable by the courts. The so-called off label prescribing of a medicine labelled for a non-patented indication for the treatment of a patent indication when it would be known by any reasonable person operating in the pharmaceutical business that this will occur is clearly a patent violation — the manufacturer knows his medicine will be put to the infringing use. The law in Australia should not be modified provide a situational loophole to circumvent validly granted IP rights.

It is not appropriate for the Government to try to claim under the undertaking as to damages. The premise of the first part of draft recommendation 8.1 is that the Government has a right to claim under the undertaking as to damages. It is not clear whether that is legally correct:

- Draft recommendation 8.1 ignores the specific legislative provisions that already exist in the TGA, namely, ss 26B, 26C and 26D. These provide for compensation to the Government in specific circumstances. If the Australian Government could claim under the undertaking, then that would render the s 26C certificate provisions nugatory.
- The Government does not automatically qualify as a "person" for the purposes of the usual undertaking and from a policy perspective, it is not appropriate for the Government to claim loss under the undertaking. The Government makes a policy decision to compensate pharmaceutical products through the PBS. It negotiates a price with the pharmaceutical supplier. It would hardly be proper for the Government to be allowed to turn around and ask for compensation for monies paid due to a deliberate policy decision.
- It is also entirely unacceptable for an originator company to, in effect, be required to set aside substantial sums of liquid funds to satisfy damages awards which may ultimately be made to Government while they are involved in patent litigation. The revenues received from successful existing products are crucial to the ongoing funding of the business operations and. The issue is compounded where a company has multiple products subject to patent litigation at the same time or close together in time – it would be a massive, uneconomic burden for any pharmaceuti-
It is not appropriate for Government to give incentives to generic companies in order to challenge innovator pharmaceutical patents

Firstly as a matter of principle the concept of the Australian Government encouraging patent litigation by generics and offering financial rewards to generic companies is wholly inappropriate given the Government's role in granting the patent.

Notwithstanding the above the suggestion is one-sided and ignores the fact that there is a balance to be struck here. It is highly unproductive for the innovative industry to constantly face frivolous challenges on perfectly good pharmaceutical patents, and the vast majority of pharmaceutical patents are just that. The experience in the US under the Hatch Waxman process shows this. Essentially all US pharmaceutical products face patent challenges on the first day possible (four years from regulatory approval). This is to take advantage of the incentives provided to the first generic challenger. This generally includes all of the patents covering the product. In the vast majority of cases, the compound patents challenged are found to be valid and infringed. Of course from the innovator perspective money spent defending frivolous challenges is effectively diverted away from R&D of new medicines and it must be clear that, for the innovator, every patent challenge must be seen as a business threat and defended to the full.

The generic industry on the other hand has no, or very low, R&D costs and so are, among others things, in the business of challenging patents as a core function. The generic challenger if successful will recoup most of its litigation costs under the existing system and any non-recovered costs will be minor and should be seen as a cost of doing business. This needs to be kept as it provides the checks and balances with frivolous litigation. Surely there is a better way for generic companies and the Australian Government to spend resources than in needless patent litigation spent in a low probability effort to challenge an innovator's IP rights.

In summary then there is no need to provide generic companies with additional Government incentives when the commercial incentives plainly already exist within the current business model and any such Government intervention or subsidy to the generics would be prejudicial to the innovative industry and would risk disturbing the balance between genuine litigation to attempt to remove an invalid patent and frivolous litigation.

What future do Australians want?

Having discussed how global investment decisions are made and just a few of the many issues within this draft Report that could serve to harm the innovative pharmaceutical industry and disrupt the business model that has successfully served to provide Australia and the world with new medicines, the more fundamental question for Australia is: What are Australians' priorities for the future? How do they want investments made? The Inquiry's terms of reference include:
2. The role of Australia’s patent system in fostering innovation and hence to bringing new pharmaceuticals and medical technologies to the market;

3. The role of the patent system in providing employment and investment in research and industry;

6. Australia’s position as a net importer of patents and medicines.”

These terms each beg the investigation of how best use is made of Australia’s extensive investigation and research of the causes of disease and disability. They ask: What can we do to help develop the very rapidly developing Australian biotechnology sector? One count identifies 100 Australian Stock Exchange listed innovative health technology companies and over 400 non-listed ones. Submission after submissions notes the quality and strength of Australia’s indigenous capacity for discovery. How do is this best supported? How does Australia reap the full benefits of its efforts, the return on its investment?

Unfortunately, based on the draft Report, the opportunity provided by the Inquiry appears largely to be missed with comparatively little content spent addressing these national issues. The recommendations of the draft Report offer little in support and much that is adverse to best answering these questions.

A real opportunity
It is open to the Committee to ensure the Final Report addresses the policies that will allow Australia to realise the promise of its highly regarded health science and research industry. The Committee can look at the strong weight of submissions regarding the robustness of our current intellectual property regime and provide policy solutions that support rather than hinder access to better medicines.

Australians — as researchers, investors, taxpayers and, above all, patients — stand to be the beneficiaries.

Yours sincerely,

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