23 January 2013

Mr Tony Harris  
Chair  
Pharmaceutical Patents Review  
PO Box 200  
WODEN ACT 2606

Dear Mr Harris

Thank you for the opportunity to contribute to the Australian Government’s Pharmaceutical Patents Review.

Medicines Australia represents the research-based medicines industry in Australia, which brings new medicines, vaccines and health services to the Australian market. In 2011-12, our industry generated more than $4 billion in exports and for the third consecutive year, invested over $1 billion in research and development (R&D).

The process of bringing new medicines to the market involves a high degree of risk. Only a small portion of promising research yields safe and effective products, of which only a fraction are profitable enough to generate the necessary investment returns. On average, the cost of bringing new medicines to market is approximately $1.5 billion, including the cost of unsuccessful research projects, and it can take between 12 and 15 years to complete the process. Compared with other areas of technology, the time taken to develop new technologies in the medicines industry is significantly longer.

By guaranteeing a clearly defined period of market exclusivity, patents and other forms of intellectual property rights such as data exclusivity act to mitigate the commercial risks of bringing new medicines to market, making it significantly more likely for private enterprises to continue to invest in R&D for new medicines. Accordingly, there is a strong and enduring rationale for making sure that no new laws are implemented that would, in any way, undermine the ability of innovators to obtain patents or defend their legitimate interests. Patents allow companies to invest in R&D, with the expectation that they will have a fair opportunity to recoup this investment before others, who did not bear any of the initial risk or costs, are permitted to profit from both new as well as improved products.

A strong, stable and predictable intellectual property system is critical to Australia’s ability to attract investment in R&D and high-tech manufacturing. It is also critical to Australian patients being able to receive the latest treatments as quickly as possible.

The Australian medicines industry remains committed to constantly improving Australian patients’ access to new health technologies. It is important to understand that patents are not a barrier to access to medicines. Indeed, patents underpin the process of innovation in the pharmaceuticals industry and this process is what drives...
the invention and development of new medicines for previously incurable or unmanageable diseases.

In the following submission, Medicines Australia responds to the questions in the Review’s Discussion Paper released in November 2012. Medicines Australia looks forward to an ongoing engagement with the Review Panel and we will respond to future papers and draft reports in due course. Meanwhile, if you have any questions about this submission, please do not hesitate to contact me on 02 6122 8500.

Yours sincerely

Dr Brendan Shaw
Chief Executive
KEY FEATURES OF THE AUSTRALIAN MEDICINES INDUSTRY

- The Australian medicines industry is part of the global medicines industry which is currently worth around $900 billion, and which is expected to be worth over $1.5 trillion by 2016.¹

- The medicines industry is one of Australia’s largest exporters of manufactured goods. As figure 1 shows, the industry exports more by value than the Australian car and wine industries. Since 1990, exports of medicines have increased by more than 800%. In fact, Australia is now among the world’s leading exporters of medicinal products (see figure 2). Major markets for Australian pharmaceutical exports include Asia (40% of Australia’s medicines exports), southern Africa (20%) and Europe (16%).²

¹ IMS Health, 2011, IMAS Market Prognosis.
² Commonwealth Department of Foreign Affairs and Trade, 2011, STARS Database, based on ABS Cat No. 5368.0.
The medicines industry in Australia employs over 40,000\(^3\) exceptionally talented Australians, making it one of the largest employers of university graduates, especially science graduates in Australia. The industry creates high-quality jobs, which build high-value skills, help retain skilled professionals in Australia and attract outstanding talent from overseas. In the process, the industry is able to provide opportunities for career development in many professional areas, ranging from research and clinical sciences to marketing, information technology, manufacturing and health economics (see figure 3).

Since 2007, as figure 4 shows, the Australian medicines industry has invested over $4 billion in research and development (and nearly $7 billion since 2005), including on over 5,000 clinical trials\(^4\) in more than 30 therapeutic areas such as oncology and mental health.

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RESPONSES TO THE QUESTIONS IN THE DISCUSSION PAPER

1. Is the breadth of pharmaceutical patents eligible for an extension of term appropriate?

Yes.

Patent systems are core incentives needed to transform pharmaceutical innovations into therapeutic options for patients. Pharmaceutical innovation does not stop at discovery of the basic molecule but continues on for 10 to 12 years before product launch, and beyond. This is consistent with every other technology dependent industry, where improvements, upgrades and next generation products are the norm. New uses, new formulations and other modifications to an established product can have significant consequences for patient care, by providing superior therapy for a number of patients. Patient benefits occur when new diseases are addressed (i.e. additional indications), better safety profiles are provided (for example through fewer and less serious side effects) or greater efficacy or more convenient delivery for patients is provided which improves patient treatment adherence (for example where the number of tablets per day is reduced through the introduction of a slow release mechanism). Fostering these types of new, useful and non-obvious inventions that build on previous technologies also creates competition between products in a specific therapeutic class by offering alternatives for patients.

“Incremental innovation” should not be confused with minor or obvious advances, and patenting incremental innovation should not be confused with efforts to extend patent protection on original inventions (i.e. so-called “evergreening”). Regardless of whether subsequent patents are applied for, no later granted patents can extend the term of an earlier one. It is just not possible. By definition, a second patent cannot be issued for the same invention. When patents on the original inventions expire, then imitators are free to copy the original from a patent system perspective. Subsequent patent applications will be for other innovations which build on the prior original invention and will usually be progressively narrower in scope. Importantly, subsequent patent applications should not stop the original patent for an older technology from expiring.

Incremental inventions, like the basic substance, must meet the core patentability criteria of novelty, inventiveness and utility to survive the expert scrutiny of the patent office examination process. The merit of the innovation can only be decided by patients and medical professionals after a product is available. Patients, physicians and also purchasers will choose between the added value offered by the improved product and the older off-patent version. If, on the other hand, a new product turns out not to be sufficiently desirable or needed by patients, then the innovator will have wasted time and millions of dollars in fees, trials and approvals in developing those innovations, as the generic version of the original product could be used rather than the subsequent version. Only when doctors and healthcare authorities are convinced of the advantages of the subsequent product over the original's generic version will the innovation be a success. If it is not then prescribers, buyers and users will prefer generic equivalents of the old product and newer versions will struggle to gain market share.

“Evergreening”, or the constant renewal of a patent through minor or obvious changes, is a misleading concept from the patent perspective. Referring to
incremental innovation or important inventions that build on prior technologies as “evergreening” is both factually inaccurate and contrary to the workings of the patent system and the workings of a highly competitive pharmaceutical industry. In fact, were originators capable of “evergreening”, the well-known and well-documented concept of a “patent cliff” – namely the unprecedented number of medicines that are losing patent protection over the next few years – would not exist. But it does exist and it is having an enormous adverse impact on the commercial operations of originator pharmaceutical companies. According to a leading U.K. market research firm, these companies stand to lose nearly $140 billion in global sales by 2016 as a result of patent expiries on major products such as Lipitor®, Plavix®, Nexium® and Glivec®. Already in Australia, patent expiries have led to hundreds of job losses, including around 300 jobs since October last year. The impact on the industry of these patent expiries, including job losses, corporate restructuring and curtailing of research, suggests that ‘evergreening’ is more a concept than a reality.

It is also important to be careful about jumping to the conclusion that an instance where there are complex intellectual property law issues involved is “evergreening”. It is often claimed by some that evidence of “evergreening” exists because of the costs involved in identifying the patent status of a medicine. The claim is that because these costs exist, this must be an unfair or adverse result. In fact, the costs of sorting through these issues is generally part of the normal operation of running a pharmaceutical business, be it an originator or a generic pharmaceutical company.

Whilst options to ensure greater efficiency should certainly be explored, it is worth considering that though some stakeholders might try to argue that patent protection needs to be weakened because it is an unfair barrier to trade or causes some other problem, the reason they are making such arguments is more likely to be the result of a desire to save costs by getting around rules that should more appropriately be thought of as part of the normal business operating costs. Complex patenting arrangements are not unfair “evergreening” strategies as claimed by some, rather they are part of the normal practice of running a high-tech business and should be recognised as such.

2. Is the length of the extension of term provided for appropriate?

Yes, but serious consideration should be given to further extending pharmaceutical patent terms in Australia to compensate companies for the increasingly inefficient and time-consuming working of the process to get new medicines listed on the Pharmaceutical Benefits Scheme (PBS), which accounts for almost three-quarters of the market for prescription medicines in Australia.

A system of patent term extensions was implemented in Australia, in part, to provide pharmaceutical inventions an effective patent life more in line with that available to inventions in other fields of technology. Despite this, however, Medicines Australia’s own analysis of publicly available data shows that the average effective patent life for pharmaceutical products in Australia is between 11 and 12 years, which is significantly less than the maximum effective patent life of 15 years intended through
patent term extension for pharmaceutical products in Australia, and far less than the 20 or 25 years of protection that Australian patents provide "on paper". It is also important to note that a considerable number of extended patents – nearly half of them – still do not achieve an effective patent life of 15 years (see table below for some examples\(^9\)), despite receiving the full five year patent extension permitted under the current legislation. If the time taken to list these medicines on the PBS were taken into account, the effective patent life for these products would be even less.

**Table 1: Selected Pharmaceutical Substances Which Have Received a Five Year Patent Term Extension, Showing That the Effective Patent Terms Were Less than 15 Years**

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Patent</th>
<th>Filing Date</th>
<th>Earliest First Regulatory Approval Date</th>
<th>Final Patent Expiry Date</th>
<th>PTE (years)</th>
<th>Technical Eligibility (years)</th>
<th>Effective Patent Term (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibritumomab</td>
<td>368276</td>
<td>7/7/1997</td>
<td>12/7/2000</td>
<td>7/7/2012</td>
<td>5</td>
<td>8</td>
<td>14</td>
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<tr>
<td>Clofazimine</td>
<td>736339</td>
<td>14/1/1998</td>
<td>30/7/2010</td>
<td>14/1/2023</td>
<td>5</td>
<td>7</td>
<td>13</td>
</tr>
<tr>
<td>Posaconazole</td>
<td>681753</td>
<td>20/12/1994</td>
<td>15/3/2006</td>
<td>20/12/2019</td>
<td>5</td>
<td>7</td>
<td>13</td>
</tr>
<tr>
<td>Olmesartan</td>
<td>647887</td>
<td>21/2/1992</td>
<td>6/9/2004</td>
<td>21/2/2017</td>
<td>5</td>
<td>7</td>
<td>13</td>
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</tr>
</tbody>
</table>

\(^9\) For a full list, please contact Medicines Australia. Data in this table has been extracted from publicly available sources, including the ARTG and AusPat.

\(^10\) "Technical Eligibility" = “Earliest First Regulatory Approval Date” minus “Filing Date”; see, Section 77 of the Patents Act 1990. This effectively shows the time taken to develop a medicine from the filing date of a patent application to the date it is approved by the regulatory authority.
<table>
<thead>
<tr>
<th>Medical Name</th>
<th>Date Filing</th>
<th>Date Pre-clinical</th>
<th>Date Clinical</th>
<th>Duration</th>
<th>FDA Approval</th>
<th>Patent Term</th>
<th>Previous Approval</th>
<th>Total Duration</th>
</tr>
</thead>
</table>

On average, it takes between 12 and 15 years to bring new medicines to market, including the time taken to complete basic, pre-clinical and clinical research. Some medicines take even longer; leflunomide, for example, which is mentioned in the Discussion Paper, took the manufacturer more than 16 years to develop and the table above shows that the period from patent filing to TGA approval was 15 years or greater for a number of products, including nearly 20 years for duloxetine. This means that typically up to two-thirds of the patent term is spent bringing a new medicine to market. In addition, companies routinely require several years to obtain reimbursement in Australia (through the Pharmaceutical Benefits Scheme) which further delays market entry for most medicines available in Australia.

In recognition of these sorts of lengthy delays, the Australian Government in 1999 granted pharmaceutical companies the right to seek “patent term restoration” – that is, the right to apply for up to five years of patent term extension, in order to achieve an effective patent life of up to 15 years from the date of first entry of the product on the Australian Register of Therapeutic Goods.

The reasons for granting this right are stated in the second reading of the Intellectual Property Laws Amendment Bill 1997:

On average, it takes between 12 and 15 years to bring new medicines to market, including the time taken to complete basic, pre-clinical and clinical research. Some medicines take even longer; leflunomide, for example, which is mentioned in the Discussion Paper, took the manufacturer more than 16 years to develop and the table above shows that the period from patent filing to TGA approval was 15 years or greater for a number of products, including nearly 20 years for duloxetine. This means that typically up to two-thirds of the patent term is spent bringing a new medicine to market. In addition, companies routinely require several years to obtain reimbursement in Australia (through the Pharmaceutical Benefits Scheme) which further delays market entry for most medicines available in Australia.

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The reasons for granting this right are stated in the second reading of the Intellectual Property Laws Amendment Bill 1997:

to compensate pharmaceutical patent holders for delays in obtaining regulatory approval for new products;
- to provide incentives for pharmaceutical companies to continue to invest in R&D in Australia;
- to provide an effective patent life more in line with that available to inventions in other fields of technology; and
- to create a patent regime for pharmaceuticals which is in line with Australia’s competitors.

Since the patent term extension provisions were introduced, the time taken to get a medicine through the regulatory and reimbursement evaluation processes in Australia has increased significantly. The situation is getting worse, not better, with such recent policy measures as “Cabinet deferrals” and additional post-Pharmaceutical Benefits Advisory Committee reviews.

The time taken for a new chemical entity to be approved by the TGA has increased from around 10 months in 1999 to more than 18 months in 2012. This has meant that the patent term extension period legislated in 1999 has become less effective over time and, in fact, effectively the patent term extension period in place since 1999 has been reduced.

Similarly, the assessment times for getting medicines on the PBS have increased since patent term extensions were introduced. The time taken to get a medicine approved on the government’s subsidy scheme which accounts for nearly three-quarters of the market for prescription medicines in Australia, has increased. A 2009 study found that since 1995 the median number of months from when a medicine was first launched on the market in the US to when it was subsidised on Australia’s PBS was between 20 and 30 months, or between 1.5 and 2.5 years (see figure below). Since 2006, however, this time had been increasing and by 2008 the median time between first launching a new medicines in the US and being finally subsidised in Australia was 43.9 months, or over 3.5 years.\(^\text{12}\)

If anything then, the Review should be looking at the option of increasing the term of patent extension.

Figure 5: Median Lag Between FDA Approval and PBS Listing, months, 1995-2008

\(^\text{12}\) Centre for Strategic Economic Studies, The Impact of PBS Reforms on PBS Expenditure and Savings, Victoria University, 2009.
It was clearly not the intent of the 1999 amendment to the patents legislation to limit or reduce the rights of patent holders in Australia. On the contrary, the intent was clearly to enhance these rights in order to provide an incentive for ongoing investment in R&D and the continued availability of innovative medicines in Australia. In this, the Australian Government followed the actions taken by governments of most other advanced economies around the world, including Japan, South Korea, Israel, the United States, the United Kingdom and most countries in Europe, which also provide extended patent terms for pharmaceuticals.

It was also not the intent of the amendment to limit the scope of the rights which are conferred on patent owners during the terms of an extension. For example, Medicines Australia is aware of past (and possibly present) proposals to allow generic companies to manufacture patented medicines for export during the period of patent extension. Implementing this proposal would, as successive Australian Governments have already determined, contravene Australia’s international obligations under:

- Article 28 of TRIPS (reflected in section 13 of the Patents Act) which gives patentees the exclusive right to make, use and offer for sale (including for export or import) any product related to the patented invention for the entire term of the patent;
- Article 33 of TRIPS (reflected in section 67 of the Patents Act) which requires WTO members to grant patentees at least 20 years of [effective] patent protection; and
- Article 17.9.8(b) of the AUS-FTA, which reinforces the concept of patent term restoration and expressly refers to an adjustment of patent term, while making no suggestion that the rights conferred during the adjusted patent term should be less than the full patent rights as defined in TRIPS.

3. Are the recent amendments to increase the thresholds for the grant of an Australian patent appropriate in the context of pharmaceuticals? If not, why not and what further changes are necessary?

Yes, the amendments are appropriate.


Once fully implemented, this legislation will enhance Australia's patent system, which is already among the strongest in the world. Among its other achievements, the Bill introduced an explicit research use exemption, which directly addresses concerns among certain stakeholders that patents have the potential to stifle scientific research. An explicit research-use exemption makes it absolutely clear that scientists are free to conduct research on patented inventions, so long as it is for the purpose of investigating the patented invention and not their intention to infringe valid patents by selling or inappropriately using these inventions without the inventors' permission.

This legislation also included changes to harmonise Australian patent law with U.S. and European patent laws. In doing so, the legislation’s aim was to raise the standards of patentability in Australia to match those in other comparable jurisdictions. Medicines Australia supported this aim since it is in Australia’s best
interest to grant patents which can stand up to scrutiny in any jurisdiction around the world. More importantly, however, raising the standards of patentability directly addresses the concerns among certain stakeholders that IP Australia may have granted “weak patents” in the past.

These recent reforms were the result of extensive reviews of the patent system by bodies such as the Australian Law Reform Commission, the Advisory Council on Intellectual Property, the Productivity Commission and various Parliamentary inquiries. The changes introduced in the *Raising the Bar* bill are the outcome of the reviews, consultations and evaluations of the patent system by all these bodies over the last decade. Medicines Australia engaged in these reviews constructively and in good faith to identify reforms to the Australian patent system that would strike the appropriate balance between availability of technology and suitable incentive and reward for innovation.

It is vital that the **technology-neutral** reforms contained in the *Raising the Bar* bill are allowed to operate for a significant period of time before further changes to the patentability standards in Australia are even considered, especially as a stable and predictable environment is necessary for the long-term investments needed to develop new medicines.

It is important that the *Patents Act 1990* remains technology neutral, as required under the terms of the WTO Agreement of Trade-Related Aspects of Intellectual Property Rights. Medicines Australia strongly believes that Australia’s patent law should be interpreted and applied consistently, regardless of technology. Proposed amendments that seek to “carve out” certain technologies for different regulatory treatment will result in the continuing necessity to make changes to cover new technologies as they emerge and evolve over time.

Medicines Australia and its member companies are not opposed to the evolution and reform of the intellectual property system in Australia. In fact, there have been a number of significant reforms in this area that the industry has recognised as important changes and therefore supported. In addition to our support for the *Raising the Bar* bill, for example, Medicines Australia also supported the removal of copyright protection for Product Information sheets and the expansion of the so-called “springboarding provisions” in 2006. We also continue to support the implementation of the “TRIPS Protocol” in Australia and raising the standards for innovation patents.

The fact Medicines Australia recognised these changes and actively supported a number of them demonstrates that the originator pharmaceutical industry has a long track record of working constructively with governments and stakeholders to find the right balance in the intellectual property system.

4. **Do the systems for opposing and re-examination provide appropriate avenues for challenging the granting and validity of a pharmaceutical patent?**

Yes, the existing systems for challenging patents in Australia are appropriate.

As outlined in the Discussion Paper, there are already sufficient opportunities for third parties to challenge the validity of patent applications or granted patents and these processes are comparable, if not more extensive, than those found in other
comparable jurisdictions such as the United States and the European Union. Additionally, the scope of review available in opposition and re-examination proceedings will be broadened by the amendments introduced by the *Raising the Bar* bill. It would be premature to assess the efficiency of the avenues for challenging patents prior to observing the effects of these amendments.

Medicines Australia would not support the implementation of additional methods of challenging patent rights in Australia since these would impose additional costs and administrative burdens, with no obvious gains for the large majority of relevant stakeholders.

For example, several past reviews, such as the Advisory Council on Intellectual Property’s review of post-grant enforcement strategies, have recommended the establishment of independent tribunals to issue non-binding decisions in patent-related disputes. Medicines Australia believes that there is no basis upon which pharmaceutical patents should be treated differently from any other patents in terms of avenues for reviewing the validity of patent applications or granted patents. These additional methods of resolving patent-related disputes would not negate the need for court action, and would therefore create additional steps in patent enforcement without any significant benefit.

5. **Do interlocutory injunctions, as the law is currently applied, provide appropriate relief in cases involving pharmaceuticals?**

Yes. Medicines Australia does not believe that there is any basis for interlocutory injunctions in pharmaceutical patent cases to be treated differently from other interlocutory injunctions.

Interlocutory injunctions are a vital means of protecting patent owners from unpredictable and irreversible effects of patent infringement while the validity of a patent is being tested in court. In Australia, the first listing of a generic medicine on the Pharmaceutical Benefits Scheme automatically triggers a 16% statutory price reduction for a comparator (originator) product. There is no evidence to suggest that the Australian Government would reverse this price reduction in the case where an originator company successfully defends its patents. This issue, among others, has been repeatedly cited by the Federal Court of Australia as a key rationale for granting at least 20 interlocutory injunctions since 2007. Such injunctions are only granted where a patent owner can demonstrate to the Court that it has a prima facie case of infringement and that, on the balance of convenience, the circumstances favour the grant of an injunction. That two of these 20 injunctions were granted in cases where patents were subsequently revoked does not in any way undermine the necessity of interlocutory injunctions as a means of preventing third parties from causing irreparable harm to patent owners in the vast majority of cases where patents are in fact upheld.

The scope of review available in opposition and re-examination proceedings will be broadened by the amendments introduced by the *Raising the Bar* bill. These

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13 Medicines Australia is aware of at least one example in the last 10 years where the Australian Government categorically refused to restate the original PBS price or provide the originator company compensation when a generic brand illegally entered the market and triggered a statutory price reduction. While the generic brand was subsequently withdrawn after court proceedings, leaving only the original brand on the PBS, the Government did not provide any restitution or compensation to the originator company. So previous experience would suggest that these interlocutory injunctions are important in ensuring the rights of the patent holder are appropriately protected.
changes will further ensure that interlocutory injunctions are not granted with respect to patents of questionable validity. It would be premature to make any changes to the current regime prior to observing the effect of these amendments.

As discussed above, in many cases, the primary basis upon which an injunction is granted are large statutory price reductions upon the entry of new generic products and the irreversibility of such price reductions. It would be inappropriate to deprive originator pharmaceutical companies of the ability to prevent the marketing of generic products which infringe a valid granted patent and, at the same time, maintain a regime which would prevent restoration of the status quo upon success at final hearing.

However, undertakings as to damages should be reviewed to avoid misapplication of the broad language common to them, and such undertakings should be limited to those persons who are party to the proceedings. If an injunction is ultimately found to have improperly prevented the launch of a generic product, the generic pharmaceutical company so enjoined has an avenue to recover their loss pursuant to the undertaking as to damages. The generic pharmaceutical company is ultimately protected.

The Australian Government ought not be seeking to recover its damages under an undertaking as to damages in cases to which it was not a party. Putting aside legal arguments about the ability of the Australian Government to claim damages pursuant to the usual undertaking as to damages, on one view, such recovery is bad public policy. To the extent that the Australian Government is able to recover damages pursuant to the usual undertaking as to damages, the quantum of such claims will act as a significant deterrent to patentees enforcing their rights in Australia and will, therefore, result in fewer pharmaceutical products coming to market in Australia.

6. Is Australian law on contributory infringement appropriate in relation to pharmaceuticals?

While there is little case law by which to assess the efficacy of the law on contributory infringement, Medicines Australia believes that Section 117(1) of the Patents Act should be redrafted to clarify that the contributory infringement regime applies to both method of production and method of use claims.

It is clear that s117 was introduced to be applied in circumstances where end-users of a product, the use of which would infringe a patent, were supplied the product by a third party. Restricting the provision to method of production claims reflects poor drafting and not the intention of the Australian Government. There is no basis upon which to distinguish the availability of contributory infringement for method of production claims and the unavailability of contributory infringement for method of use claims. Indeed, if a supplier has infringed a method of production claim, they would be liable for direct infringement and no resort to contributory infringement provisions would be necessary. This is particularly important with respect to pharmaceutical patents where methods of medical treatment are commonplace.

The contributory infringement provisions are otherwise appropriate. There is no need for any further changes in this area of the law. The contributory infringement provisions apply to all patents and provide an appropriate avenue of redress against suppliers of patent infringing pharmaceuticals. Without these provisions, the only
avenue of enforcement available would be to enforce patents against individual
doctors, other healthcare professionals and/or patients. Clearly, this should be
avoided at all costs. Accordingly, the contributory infringement provisions are
particularly important in relation to patents for pharmaceuticals.

7. Are the current timeframes in which infringement proceedings must
commence appropriate for pharmaceutical patents?

Yes, current timeframes are appropriate. As far as Medicines Australia is aware, in
every case since 2007, patent owners have initiated interlocutory and/or infringement
proceedings within, on average, 2 to 3 weeks of learning about a generic company’s
intention to enter the market whilst there is still a valid patent in place.

8. Are follow-on patents being used to inappropriately extend patent
protection for pharmaceuticals?

Reference to patents as “follow-on”, “secondary”, “incremental” or “evergreening” is
not appropriate, particularly in the context of an objective review of pharmaceutical
patents. The use of such terms is pejorative, particularly in the case of
“evergreening”, and has been recognised as such by the High Court of Australia.14
The use of such terms suggests, without evidence, that the applicants of such
patents have made an application motivated by improper and anti-competitive
objectives.

There is no basis upon which patents to product improvements should be treated
differently to any other patents. Patents to cover product improvements must meet
the requirements of the Patents Act, in the same manner as patents on original
inventions upon which they are based. If a product improvement meets the
requirements of patentability under the Patents Act, the patentee is entitled to
exercise its rights under the resulting patent.

The practice of bringing new and improved products, new pharmaceutical products
or new formulations of pharmaceutical products, benefits the community. To the
extent that a new product has been listed on the PBS, this indicates that the
Australian Government has decided that it is clinically effective and cost-effective
when compared to similar available treatments. Similarly, to the extent that a new
product is the subject of a patent, it has been found to be a new invention that is
useful to the public.

See response to question 1 for further details.

9. Is the law on data exclusivity appropriate?

No.

The data required by the TGA before it registers a new medicine for sale in Australia
is extensive. It is derived from years of basic and pre-clinical research, followed by
numerous clinical trials involving thousands of volunteers and patients from around
the world. Clinical trials alone cost on average $700 million per medicine and can
take up to 10 years to complete. Without the protection of data exclusivity, generic

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14 Merck v Arrow Pharmaceuticals Ltd [2006] HCA Trans 616 per Gummow J.
companies could begin relying on original data, which they played no part in generating, to bring competing products to market as soon as an innovative medicine is approved for sale, thus depriving originators of the opportunity to recoup their investment. This would be especially harmful in cases where:

- an originator product is approved for sale just before it is about to lose patent protection;
- patent protection is, for whatever reason, unreliable or insufficient, as may be the case with biological medicines; or
- a product is approved for sale after it loses patent protection.

The current term of data exclusivity in Australia is five years, beginning from the date of a new medicine's first inclusion on the ARTG. It was first introduced in 1998, and its provisions are administered under section 25A of the *Therapeutic Goods Act 1989* by the TGA.

Australia's data exclusivity system is one of the weakest in the developed world. In fact, among OECD countries, Australia's data exclusivity system is firmly the weakest, with most member countries offering between eight and 12 years of data exclusivity. This places Australia at a considerable disadvantage.

Extending the term of data exclusivity in Australia is important because:

1) There is a demonstrable link between extending data exclusivity and achieving better health outcomes for Australian patients. For instance, in a recent survey of pharmaceutical companies operating in Australia, eight companies answered “yes” when asked “In the past ten years, has your company ever considered the term of data exclusivity in Australia to be an important factor when making a decision on whether to sell a product in Australia?”. Six of the eight noted that data exclusivity was "very important" or "extremely important" in the decision making process. These eight companies provided a total of 13 examples of medicines which they chose not to sell in Australia or whose sale was delayed or otherwise affected in Australia over the last 10 years due to what they perceived as an insufficient period of data exclusivity. The 13 medicines covered several therapeutic areas, including those on the Australian Government's Health Priority List such as mental health, neurology, oncology and infectious diseases. Seven of the eight companies gave "insufficient patent protection" as the reason for why (a longer term of) data exclusivity would have influenced their companies' decision to sell these products in Australia. In short then, extending the term of data exclusivity will encourage companies to bring new medicines to Australia, and in doing so ensure that Australian patients continue to have access to as many treatment options as possible. Moreover, Medicines Australia is aware of at least two current examples where companies are delaying the introduction of new therapies because of Australia’s lax data exclusivity provisions.

2) Extending the term of data exclusivity will help bring the Australian intellectual property system in line with leading OECD nations. This will improve Australia's attractiveness as a destination for foreign investment by global biopharmaceutical companies. It will also support the local biotechnology sector, which has only recently begun entering the international market with its own products such as Gardasil®, Relenza®, Axiron®, and a suite of ground-breaking products based on stem cell technology being developed by Victorian company Mesoblast. Moreover, as industry leaders note, extending the term of data exclusivity would
send a powerful signal to the international business community that Australia values innovation as much as any developed country in the world, and that it is prepared to take the necessary steps to attract its fair share of the global investment pie.

3) Conventional patent protection is likely to prove insufficient in preventing the premature market entry of “biosimilars”, or generic copies of innovative biological medicines, whose manufacturers may be able to design-around existing patents on innovative biological medicines while still taking advantage of an abbreviated regulatory approval pathway. In this case, data exclusivity would serve as an alternative form of protection against premature competition. With these emerging developments in medical technology, patents run the risk of becoming less effective in protecting intellectual property and data exclusivity provides the opportunity to provide complementary protection that operates alongside patent protection.

4) Quality research programs on new medicines may be stopped because of uncertainties around patent protection. Extending data exclusivity encourages researchers here and overseas to develop new medicines that benefit patients regardless of the patent status or concerns about future patent challenges.

5) Extending the term of data exclusivity would mean that proprietary data is given the same level of protection in Australia as it is in other comparable parts of the world. The concept and importance of data exclusivity is already recognised by Australia in awarding five years, and internationally the importance of protecting the intellectual property in regulatory data is recognised as well. The problem is just that Australia’s standards are falling behind those of world’s best practice. The TGA, for example, adopts the same standards for registration of medicines as the European Medicines Agency in most cases, meaning that the data submitted in the two jurisdictions is very similar (if not identical). Yet data pertaining to new medicines receives only half the protection in Australia as it does in the European Union. European markets are also similar to Australia in that they are large single payer markets where it may take many years to obtain reimbursement.

Extending the term of data exclusivity in Australia will have many benefits. It will, for example:

- bring the Australian intellectual property system in line with leading OECD nations;
- improve Australia’s attractiveness as a destination for foreign investment by global bio-pharmaceutical companies;
- support the Australian biotechnology sector, which has only recently begun entering the international market with its own products;
- encourage companies to bring new medicines to Australia, and in doing so ensure that Australian patients continue to have access to as many treatment options as possible; and
- reduce reliance on patent protection, which involves expensive litigation and which, in any event, may become increasingly unreliable in preventing the premature market entry of biosimilars.
10. Are the laws on patent certificates appropriate?

In Australia, generic companies may apply to the TGA and be granted marketing approval for a generic medicine at any time during the patent term of the originator medicine containing the same active ingredient. This is commonly referred to as the “spring boarding” provision in the Patents Act 1990 (section 119 A). Currently, the originator company (the patent holder) is not directly notified when a generic company has applied for registration, or has been granted registration for the generic product, or has applied for PBS listing. There are examples where the first notice the originator company received of generic market entry was receipt of a letter from the Department of Health and Ageing advising of a pending price cut on the PBS, to be triggered by the listing of the generic product.\(^\text{15}\)

In order to be registered, a generic company almost always relies on data submitted by an originator company on the safety and efficacy of a medicine. The generic company must demonstrate “bioequivalence” to the relevant originator product registered in Australia. Thus, the generic company identifies the originator product upon which it is relying for safety and efficacy data relevant to the generic product. In practice, the generic company cannot obtain registration of its product until the data exclusivity period has expired, which is currently five years from the date of registration (or listing) of the first product containing the active ingredient.

In order to be listed on the PBS, sponsors of products must comply with a number of administrative requirements. This documentation must be submitted three months prior to the date of PBS listing. One document required is the Certificate of Medicine Registration, issued by the TGA, which the sponsor may provide up to 15 days after the deadline for other documentation. For example, to achieve August 1 listing on the PBS, a company must provide most documents by 15 May, but would have until 31 May to provide the Certificate of Registration. This provides a minimum of two months between the date of TGA registration and the date of PBS listing. These administrative arrangements came into effect in early 2009.

Currently, originator pharmaceutical companies in Australia do not receive any notice of a third party’s intention to enter the market with a product that may infringe a valid and enforceable patent prior to its listing on the ARTG. Originator companies are only able to access this information once the generic brand has already been registered on the ARTG, and even then the originator company itself has to actively go and find that information on the ARTG website. It is not directly notified by the TGA. As a result, originator pharmaceutical companies are unaware of a potential infringement until after the generic product has received marketing approval (and has been listed on the Australian Register of Therapeutic Goods), or after the generic product has been considered for PBS listing. While in recent years the Australian Government has introduced quicker publication of new brand names on the ARTG website, this still does satisfy what was envisaged in the AUSFTA.

According to the terms of AUSFTA, “if the Party [Australia] permits a third person to request marketing approval to enter the market with a product during the term of a patent identified as claiming the product....the Party [Australia] shall provide for the patent owner to be notified of such request and the identity of any such other person”.\(^\text{16}\) However, under the current system, a generic company must certify only

\(^{15}\) See for example, Merck & Co v. GenRx [2006] FCA 1407.

\(^{16}\) See Article 17.10.4 of the AUSFTA, available here.
to the TGA (and not to the company whose data it is relying on to gain marketing approval) either that:

a) acting in good faith, it believes, on reasonable grounds, that it is not marketing and does not propose to market a therapeutic good in a manner, or circumstance, that would infringe a valid claim of a patent that has been granted in relation to the therapeutic good (known as a Section 26B(1)(a) certificate); or

b) a patent has been granted in relation to a therapeutic good and it proposes to market that good before the relevant patent term has expired and it has given the patentee notice of its application for registration or listing of the therapeutic good (known as a Section 26B(1)(b) certificate).

There is currently no mechanism that requires either the TGA or the generic company in this instance to notify the patent holder that the latter is intending to market a product which it believes, in good faith, would not infringe a valid patent. Nor, as far as Medicines Australia is aware, is there any system employed by the TGA to verify the claims made by a generics company in its certification. In fact, it is not even clear to Medicines Australia what the TGA does with those certificates or even if the TGA checks whether those certificates have been provided in the first place.

There is a serious impact on originator companies from generic medicines entering the market prior to the expected expiry of the originator patent, in part through mandatory and irreversible price cuts for innovator products listed on the PBS and through market share erosion whether the product is listed on the PBS or available through private prescription. Notification through the published listing of a generic brand on the PBS is not sufficient notification of a generic brand receiving marketing approval, because the PBS is not concerned with approval for sale in the Australian market; this is the TGA’s role. As highlighted earlier, the approach adopted by the Australian Government over the years in its unpreparedness to provide price restitution and/or compensation for originator companies wrongly affected by the entry of a generic brand adds to the damage this lack of notification entails. Moreover, there is a subset of medicines on the Australian market that will not be listed on the PBS and therefore patent holders of these medicines will not receive the marketing approval notification envisaged in AUSFTA.

Patent holders have a right to protect and defend their intellectual property rights. Under current Australian law, if an originator company wishes to initiate action against a potential infringer, the originator company must meet its own certification requirements under section 26C of the *Therapeutic Goods Act 1989* before commencing court proceedings. The patent holder is liable to pay a pecuniary penalty to the Commonwealth of up to $10 million if the presiding court finds the certification to be false or misleading in a material particular or an undertaking given in the certificate has been breached. An originator company, the patent holder, must be afforded sufficient time, through notification in advance of generic market entry, to enable it to undertake due diligence to ensure the accuracy of the section 26C certificate. The corresponding penalty for potential infringements by generic companies for filing a false or misleading section 26B certificate is up to $550,000 or (up to) only 5.5 per cent of a patent holder’s potential liability. Clearly there is a gross imbalance in the preventative deterrents for originator and generic medicine companies filling false or misleading claims in patent cases in Australia.
Medicines Australia believes that section 26B of the Therapeutic Goods Act should be redrafted to ensure that patent disputes in relation to therapeutic goods are resolved prior to the goods being available to the public.

Medicines Australia believes that the lack of notification and the unduly prejudicial penalties that can be imposed on patent holders for seeking to defend their intellectual property significantly weakens an otherwise robust and equitable intellectual property system in Australia. The Australian Government should, therefore, implement an effective notification system so that patent holders are able to defend their intellectual property in a timely manner and without causing unnecessary delays in generic market entry. Ironically, introducing the measures envisaged in the AUSFTA is likely to resolve many of these issues earlier than is otherwise the case in the Australian system and is therefore likely to lead to more efficient outcomes for originators, generics, the Government and ultimately patients.

11. Are the laws on copyright of product information appropriate?

On 24 February 2011, the Government introduced legislation to prevent companies from asserting copyright on Product Information documents, arguing that companies could inappropriately assert copyright protection as a means of delaying generic market entry in the off-patent market.

Medicines Australia has no objection to the use of Product Information to support the entry of prescription medicines in the off-patent market; indeed, this supports the use of medicines in an appropriate way. Accordingly, Medicines Australia did not oppose the implementation of the Therapeutic Goods Legislation Amendment (Copyright) Bill 2011. It should be noted, however, that biosimilars, unlike small-molecule generics, are not identical to originator biological medicines. This important difference must be carefully considered in the context of preparing product information sheets. While biosimilars may be deemed by the regulator as similar, all the science to date shows that they are often not the same, and therefore there may well be a need to ensure differences in product information are maintained.

INACCURACIES AND OMISSIONS IN THE DISCUSSION PAPER

Medicines Australia would like to note the following inaccuracies and omissions in Review’s Discussion Paper in relation to data exclusivity:

- The U.S., in relation to “small-molecule drugs”, provides a three-year additional term of data exclusivity for a new indication or a new dosage form of a previously approved product. There is no limit on the number of extensions allowed, but an extension only protects new data used to get an additional indication/dosage form approved.17

- Japan’s re-examination period varies from four to 10 years and not four to six years. The exact duration depends on the type of pharmaceutical product: orphan drugs (10 years); drugs containing new active ingredients (8 years); and drugs with efficacy and effects different from those of previously approved versions of the drugs (4 years).18

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18 Pharmaceutical and Food Safety Bureau (PFSB), Re-examination Period of Medicinal Products with New Active Ingredients, Notification No. 0401001, 1st April 2007.)
EU countries have an “8+2+1” system, not an “8+2” system; the “8+2+1” system applies to both new chemical and biological entities.19 “+1” allows an additional year of data exclusivity, on top of the standard “8+2” years, if the medicine is registered for an additional indication.20

Medicines Australia believes that it is also important to compare Australia’s data exclusivity system with other OECD and G20 countries against which it competes for foreign investment. For example, Turkey and China offer six years of data exclusivity, South Korea and Canada up to eight years, and Switzerland offers 10 years of data exclusivity.21 Russia also recently introduced a six year of data exclusivity as part of its WTO obligations. These countries are omitted in the Review’s Discussion Paper.

It should also be noted that both the European Union and the United States provide:

- additional paediatric exclusivity period of six months to provide an incentive for the development of paediatric medicines;22,23 and
- additional intellectual protections for “orphan drugs” to provide an incentive for the development of such medicines.

No such intellectual property-related incentives are available in Australia, albeit fee waivers for initial TGA registration and PBS listing are available for orphan drug registration and PBS listing.

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20 The first registrant may obtain the additional one year extension (“+1”) for a new indication only once, having already received marketing approval for this new indication. The one year extension does not apply to new strengths, new dosage forms or new routes of administration of existing (originator) medicinal products. Furthermore, the marketing approval for the new indication must be obtained during the first eight years of exclusivity.
23 In the United States, this exclusivity is applied by the FDA to the end of all existing market exclusivity or patent terms for all products containing the active moiety granted a paediatric extension. See: Food and Drug Administration, Qualifying for Paediatric Exclusivity Under Section 505A of the Federal Food, Drug and Cosmetic Act, as amended by the Food and Drug Administration Modernisation Act of 1997.