Second Submission to the Australian Government's

Pharmaceutical Patents Review

by Novartis Pharmaceuticals Australia Pty Ltd
54 Waterloo Rd
North Ryde NSW 2113
Ph: 02 9805 3555
Fax: 61 2 9888 2452
About Novartis

Novartis was created in 1996 through the merger of Ciba-Geigy and Sandoz, and provides healthcare solutions that address the evolving needs of patients and societies.

Novartis is a diversified healthcare company and our uniquely broad business portfolio focuses on science-based healthcare sectors that are growing, reward innovation and enhance the lives of patients. In Australia the Novartis group of companies includes:
• Alcon (eye care)
• Novartis Animal Health
• Novartis Consumer Health
• Sandoz (generics)
• Novartis Pharmaceuticals
• Vaccines and Diagnostics

Novartis is the only company with leading positions in each of these areas.

Novartis operates in 140 countries employing over 120,000 people and with annual sales revenue around USD 55 billion. We have a significant commitment to ongoing research and development (R&D) and in 2012 we invested USD 9.1 billion in R&D globally. Novartis is the two company in the world across all industries in R&D spend, just behind Toyota. In Australia, Novartis employs over 1000 people earning annual revenues in excess of $1 billion. In addition to its focus on innovation to address unmet medical need Novartis, through its Sandoz division, is one of the leading suppliers of generics medicines globally.

More information about Novartis can be found at http://www.novartis.com/about-novartis/index.shtml

This submission is made by and on behalf of Novartis Pharmaceuticals Australia Pty Ltd, which is an Australian subsidiary of the Novartis group of companies, including Sandoz Australia Pty Ltd, which has been consulted in the preparation of this submission. For convenience Novartis Pharmaceuticals Australia Pty Ltd is simply referred to in the following responses as “Novartis”.

Contact details

Further enquiries about this submission should be directed in the first instance to Christine Black, Head of Government & Public Affairs by mail to P.O. Box 101, North Ryde, NSW 1670, email christine.black@novartis.com or by phone +61 2 9805 3555.
International Context

Draft Recommendation 3.1

Summary of the draft recommendation: The Government wants Australia to have strong IP laws that encourage innovation but retain the ability for local companies to manufacture for export. It wants to lead other countries in developing patent law along those lines.

Novartis Response: Neutral

It is important for pharmaceutical innovation that Australia has strong IP laws that protect innovative products. It is important for patients that such protection continues to enable innovator companies to invest in the research and development that brings new and better medicines and health-related outcomes to patients.

Local manufacture for export should not be in contravention of the IP rights that innovator companies have obtained for their innovations.

Draft Recommendation 3.2

Summary of the draft recommendation: The Government should analyse the impact of any changes to IP laws when involved in future trade negotiations and renegotiations, and avoid any retrospective changes that could prove to be costly to Australia or other countries.

Novartis Response: Neutral

Novartis agrees that a sound and strategic economic understanding of the costs and benefits to Australia and the world, and of the impacts of current and proposed IP provisions, both for Australia and other parties, should be included in future trade negotiations and renegotiations. However, the language used by the review panel suggests an underlying belief that revising the PTE system in 1998 was unexpectedly costly for the Government. We note that there is no evidence to support such a belief in the draft report.

Manufacturing for export and stockpiling

Draft Recommendation 4.1

Summary of the draft recommendation: Under existing law manufacturing a patented product for export or using a patented process solely for export to a country where there is no corresponding patent protection, without the authorisation of the patentee, constitutes patent infringement. However the Government requests the owners of Australian pharmaceutical patents to voluntarily agree not to enforce their patents in respect of such manufacturing for export.
Novartis Response: *Opposed*

The acts described – including the stockpiling of patented products for export during the 20-year TRIPS mandated patent term - would constitute an infringement of the patent rights that patentees have legally obtained in return for complying with the requirements of the Patents Act.

Permitting local generic manufacturers to manufacture patented medicines solely for export would constitute a derogation of IP rights for innovator companies. It could potentially undermine the purpose and value of the patent system for those that earn these rights.

Exportation to countries where Novartis has no IP protection for those medicines will nevertheless compete with Novartis products sold in those countries. Generic manufacturers will have only incurred a fraction of Novartis’ R&D costs.

The availability of generic copies of patented medicines requires Novartis to work with customs officials and local courts to attempt to enforce its IP rights in those countries where the patent rights have not yet expired. Novartis’ costs to enforce its IP rights add to the costs that Novartis already bears in order to bring innovative medicines to patients, and those costs are ultimately borne by patients and payers.

Innovator pharmaceutical companies, more than most other businesses, need to operate on a medium to long term and global basis so any agreement in Australia that might affect sales of Novartis products in Australia or elsewhere would need to be assessed and planned for.

In any event, the existing law provides the freedom for generic manufacturers to negotiate with patentees to avoid the infringement of patent or other IP rights. Such agreements, usually in the form of a patent or IP licence, would enable innovator companies to obtain some measure of return on their investments that made those medicines possible.

Novartis is opposed to any voluntary scheme, even if only an interim measure, on the basis that such a scheme will inherently lead to an inconsistent approach by originator companies. Should Novartis participate in any voluntary scheme, Novartis would be at a significant commercial disadvantage with respect to its competitors who market innovative medicines if any of those competitors does not voluntarily agree to waive its IP rights as requested. That disadvantage could be extreme as the term of any voluntary waiving of rights is potentially open-ended.

In the event that Australia did introduce such a scheme, it must be carefully thought out. Checks and balances will be required to ensure that such products are supplied only to those countries where there is no longer patent protection and do not find their way into protected countries or even back into Australia. There would also have to be fair compensation to patentees in Australia for the encroachment onto their legal rights.

It is worth noting that a scheme along these lines was introduced in France in recent years. As we understand this scheme, negotiations between the generic company who wishes to manufacture in France and the patentee are facilitated by the government, and the reward to the patentee for allowing the generic to manufacture in France prior to patent expiry may be a tax break. To our knowledge, this scheme has not been widely used since its introduction, perhaps suggesting that such a voluntary scheme is not effective in any event.
Extension of patent term – length of extension

Draft Recommendation 5 - Option 5.1

Summary of the draft recommendation: The Government proposes to replace the current PTE system in a favour of a direct subsidy system and use part of the associated savings to fund R&D directly. Some of this funding should be targeted to socially beneficial research for which patents provide inadequate incentives to conduct. Such areas include new antibiotics which, once developed, must be used as sparingly as possible to prevent the development of antibodies and pharmaceuticals to address rare diseases, paediatric illnesses and endemic health issues in low income countries. This option could also include an annual review of the savings delivered through any reduction in the length of extensions of term to be used in allocating funding to the replacement R&D subsidies.

Novartis Response: Opposed

Novartis, as a significant investor in socially beneficial research addressing areas such as rare diseases and paediatric conditions, supports maintaining the current system for extending the term of patents.

The current regime for granting patent term extensions (PTEs) in Australia was provided by the IP Law Amendment Act 1998. This was intended to provide limited but fair compensation to the owners of patents for approved pharmaceutical products who lose effective patent life whilst seeking the necessary regulatory approvals to market those products.

Since 1998, the standards that need to be met to obtain regulatory approval have risen, the investments that innovator companies need to make to secure to regulatory approval have increased, the average time taken to obtain regulatory approval is longer and the “bar” for achieving the grant of any patent is higher.

PTEs are available in most major industrialised countries. The cap at 5 years in Australia is in harmony with nearly every country that offers PTEs or SPCs (supplementary protection certificates).

Novartis is a major user of the PTE system in Australia and for the most part believes the Australian system and its operation is superior to those available in other jurisdictions, in that it is less burdensome than in many other countries to calculate what term of extended protection is likely to be granted, the application process is not onerous and the time needed to secure the extension is favourable. Novartis however suggests applying the PTE system to veterinary drug products too because the effective patent term lost while seeking regulatory approval by the Australian Pesticides and Veterinary Medicines Authority (APVMA) is often comparable to that lost while seeking regulatory approval by the TGA for human medicines.

Novartis, therefore, supports the status quo, but would ask the Australian government to consider extending the PTE system to veterinary medicines.

It is too soon to assess the success or failure of the current regime for granting PTEs as many active ingredients that were invented when the current regime came into existence have still to reach patients as approved medicines.
In the draft report, the review panel argues that the current system places an unacceptable and unsustainable burden on the funding of the PBS. The draft report does not provide any evidence that the PTE system is solely responsible for this. Novartis opposes the concept of reducing the term of patent term extensions - or worse, dismantling the PTE system entirely - in favour of providing a direct subsidy system.

By their very nature, subsidies tend to be offered to some favoured parties in order to artificially improve the prospects for success or competitiveness with respect to other less favoured parties. They are intended to interfere with the usual operation of the market. Although the intentions of such interferences may be laudable, the results can be or become unfair for unsubsidised parties, create dependencies for subsidised parties and lead to uncertainty for all parties.

It is not at all clear from the draft report who would be subsidised, who would not be subsidised, what types of investments would be subsidised, what types of investments would not be subsidised, what form the subsidy take, when and how would it be payable, how one would apply for a subsidy, who would decide the eligibility and terms of the subsidy, or whether decisions of that person or group of people would be appealable. These are critical questions for which the Review provides no detail or guidance.

Administering a subsidy system would not be a simple task. It would also create new costs and complexities.

As mentioned previously, the programme of significant investments that must be made by innovator companies to bring innovative medicines to patients requires those companies to make and deliver on strategic medium and long term plans. A subsidy system would be incompatible with that as it would mostly likely be prone to uncertainty and change.

In view of these serious concerns, Novartis supports maintaining the current PTE system as it is working efficiently, it is fair for all users, it does not discriminate between users, and it allows users to plan ahead.

The Australian Government’s agreement with Medicines Australia, via a Memorandum of Understanding, is working as intended to keep the PBS sustainable. It is important that reforms favour the more innovative products that meet previously unmet medical needs over less innovative, “me-too” products. Devaluing the PTE system for all products unfairly diminishes the incentive for innovator companies to develop the highly innovative products that often provide the first opportunities for patients to treat their disease or offer a step-change in existing care.

The Government could offer incentives available elsewhere to encourage innovator companies to invest in the research and development of new treatments for childhood diseases (e.g. paediatric patent extensions) and rare diseases (e.g. orphan drug exclusivities) and new indications where there is a public health need in Australia. If the review panel believes patents provide inadequate incentives for innovator companies to target “socially beneficial research”, then surely removing the possibility to extend the term of patents for pharmaceuticals that address those needs can only discourage that.

Novartis was the perhaps the first of an emerging group of innovator pharmaceutical companies that puts addressing the unmet medical needs of patients and understanding the cellular and molecular mechanisms that underlie those diseases ahead of chasing the next mass market blockbuster. Many of the medicines that have been launched in Australia in recent years address rare diseases such as multiple sclerosis (GILENYA®), wet age-related macular degeneration of the eye (LUCENTIS®) and cystic
fibrosis (TOBI PODHALER®). More such medicines are in the pipeline. Novartis has also responded to specific requests from the Australian Department of Health to help address the high rate of certain diseases that afflict Aboriginal Australians.

Devaluing the PTE system would unfairly target innovator companies whose significant investments in R&D have brought new and better medicines and unfairly favour local generic manufacturers (Australian-owned or otherwise) who wish to copy those medicines as soon as possible.

Draft Recommendation 5 - Option 5.2

Summary of the draft recommendation: To change the current PTE system so that the PTE for qualifying patents will be no longer than those of equivalent patents in major trading partners. This could be achieved by (a) Providing an extension expiring up to 5 years after the original patent term or upon the expiry of the equivalent patent extension in one of a list of other jurisdictions including the United States and European Union; or (b) Changing the method of calculating the length extensions of term to provide an incentive to submit applications for regulatory approval in Australia earlier than is currently the practice.

Novartis Response: Opposed

Novartis supports maintaining the current system for extending the term of patents for the reasons provided above in response to Draft Recommendation 5 - Option 5.1.

Devaluing the PTE system by cutting PTEs to the shortest expiry dates in certain reference countries is an approach taken in some countries - generally those that have no or very little local R&D to support – however, it encourages a “race to the bottom” as more countries follow that approach. This would undermine the central (and broadly accepted) tenet of the existing system which is designed to provide a benchmark of 15 years of effective patent life. As a result, it would create significant uncertainty for innovators in the critical R&D phases regarding the scope of the effective patent life they will receive if their research results in a patentable invention.

It would also mean the term of important IP rights in Australia would be determined by political decisions made elsewhere – far from Australia. Experiences with similar approaches in other countries have shown that a PTE-system that references expiry dates in a group of other countries can drastically increase the complexity of the system and lead to a largely undesired level of legal uncertainty.

Choosing US or certain EU countries as reference countries may lead to unfair situations because the conditions for obtaining PTEs or SPCs as well as the underlying patents may be different from Australia in those jurisdictions. The US has for instance a system wherein certain patents are already extended due to delays in prosecution proceedings at the USPTO (Patent Term Adjustment) whereas Australia has not introduced such a system. This results already in a disparity of the regular patent term between US and Australia which would make it even more difficult to align the duration of PTEs between the two countries.

Predicting the term of a PTE in Australia would be especially difficult should the list of reference countries be periodically reviewed and changed.
Some innovator companies might even make strategic decisions about whether to or when to seek marketing decisions in certain countries to improve the prospects for maximising PTEs in other countries.

Option (a) would disqualify any secondary patents from being extended and that can significantly restrict the options that are currently available to patentees. Sometimes the first or only patent will be a secondary patent. Some medicines that would normally qualify for an Australian PTE could be denied such protection solely because, for whatever reason, that medicine does not qualify for a PTE in a reference country. That could be especially true for medicines that contain multiple active ingredients, given in many instances PTEs are not available in the US.

Option (b) is not defined sufficiently to be able to provide a response. How would the PTE be calculated?

**Extension of patent term – scope incl. technical problems**

**Draft Recommendation 6.1**

**Summary of the draft recommendation:** To no longer allow the term of patents for methods of use or for manufacture to be extended.

**Novartis Response: Opposed**

New uses, presentations or formulations of previously known and approved products can bring huge advantages for patients. It therefore is essential that any pharmaceutical patent system ensures that innovator companies are rewarded for investigating all forms of medical innovation, not just new compounds. Novartis supports any changes that incentivise R&D in new uses of previously known medicines.

The proposed change will restrict the opportunities for innovator companies to extend the term of patents that protect new and innovative medicines. Most importantly, it may, unintentionally or otherwise, deprive innovator companies of the ability to obtain a PTE for certain medicines where, for whatever reason, there is no Australian patent for the active ingredient or a formulation of that active ingredient.

Although it has been common for many medicines to be protected by a compound/NCE patent, a formulation patent and sometimes one or more of salts patents, polymorph patents, process patents or use/method of use patents, that is not the case for other medicines. Sometimes the active ingredient of a medicine is not a new chemical entity (NCE) or there is no innovation involved in formulating the particular active ingredient, however a significant innovation that enables a new medicine to provide a meaningful benefit to the health outcome of a patient is protected by another type of patent.

The existing legislation already places some limitations on a qualifying patent for a PTE but at least it can sometimes still allow a critical secondary patent to be extended. That is important for innovator companies to obtain a fair return for the significant investments they made to bring that medicine to patients – not to mention those medicines that did not survive the R&D process.
Draft Recommendation 6.2

Summary of the draft recommendation: To delete Section 76A of the Patents Act that requires applicants for PTEs to provide information on the use of public and private research funds in pharmaceutical R&D.

Novartis Response: Supported

The introduction and implementation of Section 76A of the Patents Act added a burden on applicants for PTEs to provide certain financial information in the form of a return for a purpose that was unclear. It was unclear what if any were the consequences of not providing timely returns. Nevertheless Novartis devised and implemented a process to comply with this requirement, which for Novartis only served to increase local legal costs.

Draft Recommendation 6.3

Summary of the draft recommendation: To amend Section 70(3) of the Patents Act to clarify that the ARTG registration on which an extension of term is based is that of the relevant product, the use of which would infringe the claim.

Novartis Response: Neutral

Suggestions that the word “containing” in Section 70(3) could include products in which the patented substance might only be present as an impurity or a minor contaminant or racemate would appear to be unreasonable. The Merck decision referred to briefly in the draft report appears to be exceptionable and seemingly contrary to the intent of the legislation. It may, perhaps, be readily distinguishable on its facts.

That said, the proposal by the Law Council to amend the Section to clarify that the basis for an extension is the first inclusion on the ARTG of a therapeutic good the use of which would otherwise infringe the claims of the relevant patent is not objectionable.

Draft Recommendation 6.4

Summary of the draft recommendation: to amend Section 117 of the Patents Act to provide that the supply of a pharmaceutical product subject to a patent which is used for a non-patented indication will not amount to infringement where reasonable steps have been taken to ensure that the product will only be used in a non-infringing manner. And to further impose a presumption that “reasonable steps” have been taken where the product has been labelled with indications which do not include any infringing indications.

Novartis Response: Supported

Novartis supports such an amendment or at least the principle behind such an amendment.
Novartis submits that care must be taken to ensure that Australian law on contributory infringement does not disregard those circumstances where the supplier has taken all due care to ensure that the product is not put to an infringing use. If an indication is explicitly carved-out by a supplier, this should be accepted as *prima facie* evidence for the supplier having taken reasonable steps to ensure that the product is not put to an infringing use. Of course, as in *Sanofi–Aventis Australia Pty Ltd v Apotex Pty Ltd (No. 3) [2011] FAC 846*, this should not preclude the patentee from providing contrary evidence that, irrespective of any carve-out, as a matter of fact the product is being (or will be) put to or promoted for an infringing use. However, under normal circumstances the burden of proving such a case rests with the patentee.

**Evergreening and follow-on patents**

**Draft Recommendation 7.1**

*Summary of the draft recommendation:* The Government should ask the Productivity Commission to review the effectiveness of the Raising the Bar Act at the earliest opportunity and not later than three years from the commencement of the Act.

*Novartis Response: Supported*

It is useful to measure and analyse the impact of any significant change to a process. If the changes appear to create some unexpected or unintentional consequences it would be useful to identify that at an early stage. However, drawing conclusions after only a few years of the revised examination standards could be difficult beyond sheer numbers of application filed v patents granted.

**Draft Recommendation 7.2**

*Summary of the draft recommendation:* The Government should establish an external patent oversight committee that is tasked with reviewing grants and decisions issued by IP Australia and auditing the processes involved in making such decisions.

*Novartis Response: Opposed*

Industry in general, and in particular pharmaceutical companies, want IP Australia to grant good quality patents with a consistency in the standard of examination. Novartis would encourage IP Australia and its governing bodies to introduce processes to ensure a consistent high quality of the granting process. However, it is not necessary in Novartis’ view to create a totally new administrative body such as an external patent oversight committee. Experiences from other jurisdictions (e.g. European Patent Office and USPTO) have shown that a well working quality control system for patents is best situated within the patent offices.

**Additional comments**
The draft report appears to identify evergreening and follow-on patents as issues to be addressed but it is not clear from the draft report how an external patent oversight committee would address these issues.

The reality of pharmaceutical product development is innovation does not end with the invention of an active ingredient. Often many technical challenges will need to be solved to provide a product to patients that is safe, effective and convenient to use. Some alternatives might be explored if they are needed at a later date. Some of those solutions will be novel and inventive and merit patent protection. Some options are investigated and protected to attempt to obtain freedom-to-operate with the knowledge that competitors may investigate and protect innovations including intermediates and alternative salts and/or crystal forms of active ingredients.

IP Australia and later third parties are able to challenge the patentability of those solutions. Australia having recently “raised the bar” when examining patent applications should enable IP Australia to ensure that innovations that are not worthy of patent protection are not patented. Further initiatives within IP Australia and the courts to streamline procedures to resolve patent disputes would be welcome to generic manufacturers and innovator companies alike.

Sometimes further research and development can lead to innovative ways of reaching new patient populations and technical challenges that are addressed in doing that can be novel and inventive and merit separate and additional patent protection. This does not prevent generic competitors lawfully copying the earlier medicines for the previous purposes when any patent protection has expired.

Andrew Christie et al of the University of Melbourne recently published an article (Open Access, Vol 8. No.4 April 2013) that reports on a study analysing patenting associated with some of the most expensive drugs in Australia. The authors note although there have been longstanding concerns that pharmaceutical companies are “evergreening” and creating “patent thickets” for that purpose, “there is virtually no empirical information identifying this behaviour, estimating its frequency, or revealing its nature”.

The study reported that high-cost drugs tended to have a large number of patents associated with them but most of those patents were in the name of a company other than the originator. In fact “among 736 patents connected to high-cost drugs in Australia, 3 in every 4 were owned by entities other than the drug’s originator”. Many of the non-originator patents were for combinations with other active ingredients, alternative formulations, however many were for intermediates of different forms of the active ingredients that the authors concluded could be sought by non-originator companies to obtain bargaining power with respect to the originator companies.

The authors concluded that “non-originator companies are investing substantial resources in follow-on innovations related to “blockbuster” drugs”. The study identified originators tended to protect, in addition to the active ingredient, delivery mechanisms and formulations for the active ingredient, or processes for making of formulating the active ingredient, whereas non-originators tended to protect delivery mechanisms and formulations for the active ingredient.

Nowadays, regulatory authorities are increasingly not approving and payers are increasingly not paying for new medicines that do not demonstrate clear benefits over existing medicines. Innovator companies that offer “mere line extensions” will not survive for long in the market.

In many jurisdictions, attempts to abuse the patent system can be addressed by anti-competition legislation.
So-called “patent thickets” require patents to be granted to provide a truly effective barrier. The patent attorneys who advise generic manufacturers are skilled in assessing the relevance, the strengths and the weaknesses of multiple patents and in most cases have plenty of time to challenge any patents of doubtful validity. The patent attorneys who advise innovator companies also need to assess the relevance, the strengths and the weaknesses of third party patents to be able to satisfy their clients that they have freedom-to-operate. This can involve challenging third patents or entering licence agreements so the way forward for innovator companies is not always free from obstructions. An inexpensive and timely way of challenging such patents is therefore one of the best ways to ensure high quality patents.

Challenges to patent grants and validity

Draft Recommendation 8.1

Summary of the draft recommendation: the Government should take a more active role in challenges to patents that relate to a PBS-listed pharmaceutical. This could involve the Government recouping certain costs to the PBS arising from delayed generic entry. It should also include implementing measures to reduce disincentives for generic manufacturers to challenge patents by providing negotiated incentives for a party who successfully challenges a patent.

Novartis Response: Opposed

The manner in which the Government could seek to interfere in the process by which innovator companies and generic competitors resolve disputes concerning patents is not clear from the Review and therefore cannot at present be supported by Novartis.

Australia has a sophisticated and effective legal system to challenge and enforce IP rights. However, on the world stage, it is one of the most expensive jurisdictions to litigate. Any initiatives to streamline procedures to resolve patent disputes would be welcome to generic manufacturers and innovator companies alike. Introducing some sort of Governmental penalty for the unsuccessful party would be most unwelcome as it would increase complexity, legal costs and commercial uncertainties for both parties.

Draft Recommendation 8.2

Summary of the draft recommendation: To introduce a transparency register linking therapeutic goods registered with the TGA with related patents.

Novartis Response: Opposed

The manner in which the Government could introduce an Australian “Orange Book” is not clear from the draft report and therefore cannot at present be supported by Novartis.
Non-patent TGA-related issues

Draft Recommendation 9.1

Summary of the draft recommendation: The Government should actively contribute to the development of an internationally coordinated and harmonised system where data protection is provided in exchange for the publication of clinical trial data.

Novartis Response: Supported

A significant portion of the investments that innovator companies need to make in order to bring new and innovative medicines to patients are made in generating the technical and clinical data that shows the medicine is safe and effective. Innovator companies provide that information to regulatory authorities on a confidential basis and in most countries regulatory data protection (RDP, aka data exclusivity) laws set a period during which time this very valuable information will remain confidential. Generic competitors have the option of generating their own technical and clinical data for a generic copy of the medicine but they very seldom wish to make the investments needed to do that. Instead they reference the innovator’s data when it is no longer protected by RDP.

Innovator companies and generic companies usually operate on an international, often global, basis. Harmonisation between the RDP laws in various countries would increase clarity and certainty for both types of businesses and so it would be welcome for that purpose.

It should be noted that regulatory data protection (RDP) is shorter in Australia than many other major industrialised countries. The eligibility for RDP is more restrictive than in many countries in that it is only available if the active ingredient has not been previously approved for medicinal use in Australia. This means innovator companies will have no RDP even when the product involves heavy investments to generate pre-clinical and clinical data for an innovative use or a formulation compared to the previously approved drug product. This can be disadvantageous for patients relying on future new treatment options of known drug products. In such situations the patent system often fails to provide sufficient protection although patients may greatly benefit from the innovation.

The current 5 years of data exclusivity for new molecular entities is an absolute minimum in order to protect the considerable investment originators make into generating the data to show effectiveness and safety of a new drug. A longer term (e.g. 8-10 years as in the EU or Japan) would be a more adequate measure to encourage investment into new medical research and development and so ensure the funding for future research into unmet medical needs.

Integrated approach to the pharmaceutical system

Draft Recommendation 10.1
Summary of the draft recommendation: The Government should establish a non-statutory Pharmaceutical System Coordinating Committee (PSCC) that reports to Parliament on an annual basis on the success and effectiveness of the patent, marketing approval and PBS systems, particularly where these interface. The PSCC should ensure there is sufficient engagement and coordination between the relevant agencies and take account of costs to government, efficiency of registration and approval processes and respond to issues raised by industry. The PSCC should comprise senior officials from at least DIICCSRTE, IP Australia, DoHA (Pharmaceutical Benefits Division and TGA), DFAT, Finance and Treasury (as chair).

Novartis Response: Neutral

This is more a statement of intent than a recommendation for a specific change in Australian law or practice in connection with the protection of pharmaceuticals.

Draft Recommendation 10.2

Summary of the draft recommendation: To amend the objects clause of the Patents Act to stipulate the Act should (a) further Australia’s national interest and enhance the well-being of Australians, including by providing reasonable access to healthcare; and (b) provide strong, targeted IP protection - but only up to the point at which the costs (to consumers and the impediment of ‘follow on innovation’) are no greater than the benefits of incentivising innovation that would otherwise not occur.

Novartis Response: Opposed

No objection to (a).

Object to (b) as it implies local politics and budgeting should affect how the legal rules set out in the Patents Act could or should be applied by IP Australia, other parts of the Australian Government and/or the Australian courts. Legal predictability and certainty is an absolutely essential element for innovative businesses to invest and bring new products to the Australian market.