Submission to the Australian Government’s

Pharmaceutical Patents Review

by

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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 60 billion. We have a significant commitment to ongoing research and development (R&D) and in 2011 we invested USD 9.2 billion in R&D globally. 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

Contact details

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Medicines Australia

Novartis is a member of Medicines Australia (MA) and accordingly, in general supports the submission lodged by MA on behalf of the innovative pharmaceutical industry generally.

This submission highlights some additional specific points that reflect both Novartis’ global perspective and its broad range of business operations. To the extent of any inconsistency between this submission and the MA submission this submission should be taken as reflecting the Novartis view.
Responses to questions raised in Background and Suggested Issues Paper

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

Reply
It is difficult to understand why Australia has excluded veterinary medicines from the eligibility of patent term extension. Veterinary medicines are subject to similarly strict and lengthy regulatory proceedings as human medicines. In addition to efficacy and safety data, applicants for marketing authorization of veterinary drugs, in particular for the treatment of food producing animals, often have to provide additional data to show that residual levels of the drug or its metabolites create no harm to consumers. Tests to produce those data take considerable additional time during which the patent cannot be effectively exploited. Moreover, the review time by the Australian Pesticides and Veterinary Medicines Authority for a veterinary drug can take easily 30 months according to our observation. Considering those factors and considering that Australia is the only country excluding veterinary drugs from patent term extension within the group of OECD-countries which offer patent term extension to compensate for regulatory delays, Novartis would suggest that Patent Term Extensions (PTE) be made available for veterinary drugs under similar conditions as they are available for human drugs.

The current legislation in Australia excludes process and indication/method of use patents, other than those related to recombinant DNA-technology, from the eligibility for a PTE. The reasons for discriminating those types of patents cannot be seen. There may be cases wherein the active ingredient of a new drug is well known for non-pharmaceutical purposes and therefore a pharmaceutical product would just be protected by a patent directed on the first or second/further medical indication. The same logic as for compound or composition of matters patents would apply under those circumstances, i.e. there would be a considerable loss of effective patent term due to the generation of the necessary data to obtain regulatory approval. Novartis would thus suggest extending the possibility of obtaining a PTE to all types of patents including process patents, but at least to method-of-use/indication patents.

Question 2:
Is the length of the extension of term provided for appropriate?

Reply
Novartis submits that the length of the patent term extensions in Australia is in line with similar provisions in other developed countries having patent term extensions and this appears to be sufficient. The need for such an additional protection period for patented products that cannot be commercially exploited immediately but require regulatory approval is outlined clearly in the Background and Suggested Issues Paper on pages 4 and 5. Differences in the expiry of the extension of a patent compared to other countries would result from the different periods required for registration and thus approval dates, e.g. the EU (where the term is calculated the
same way as in Australia) may sometimes have an earlier regulatory approval than Australia, but the actual total period of protection from the approval date till expiry when the product can be marketed is the same as in the EU - or may be indeed shorter if the approval is so late that the cut-off of a maximum of 5 years of extension comes into play.

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

**Reply**
Novartis supports generally initiatives to harmonize patent standards worldwide and changes to ensure that after a detailed substantive examination quality patents are granted that are likely to stand up in litigation. As such, the recent amendments to Australian patent law seem an appropriate measure since they appear to introduce provisions similar as e.g. in the EP patent practice. At present we cannot have any experience how it will play out in practice because the law will only come into force this year.

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

**Reply**
Novartis notes that a number of amendments introduced by the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* are intended to address some of the current inefficiencies of the pre-grant opposition system. We refer, in particular, to the new deadlines introduced by the Act for the filing of divisional patents and the amendments to s.223 of the Patents Act 1990 regarding extensions of time.

Whilst Novartis would prefer to see a post-grant opposition system introduced with strict (but manageable) timeframes to ensure that oppositions are dealt with efficiently, Novartis acknowledges that it would be premature to advance such reform without first assessing the effects of the amendments introduced by the Raising the Bar Act on the time taken to resolve oppositions and the costs of either mounting or defending an opposition.

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

**Reply**
Novartis submits that in terms of providing ‘appropriate relief’, the law as currently applied, is achieving a balance between the interests of the patentee and those of the challenger/defendant in the context of interlocutory injunctions. A significant development in this respect has been the
introduction of Federal Court Practice Note CM14, which explicitly states that the usual
undertaking as to damages applies to any person, whether or not a party to the litigation.

However, seeking and defending an interlocutory injunction in Australia is disproportionately
expensive, in relation to the size of the country’s pharmaceutical market. Legal costs often run
into several hundred thousand dollars, with the hearing of the interlocutory injunction often
becoming a mini-trial in itself. Furthermore, beyond the interlocutory injunction stage it remains
the case that Australia is a comparatively slow jurisdiction, in terms of the time taken from
initiating proceedings to receipt of a judgment (2 years+) and that patent litigation in
disproportionately expensive (with legal costs ranging typically from $750,000 to $2million+ for
each party to the proceedings).

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

Reply
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 steps to
ensure that the product is not put to an infringing use.

For example, if an indication is explicitly carved-out by a supplier, this should be accepted *prima facie* as 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 arguing that, irrespective of any carve-out,
as a matter of fact the product is being put to an infringing use.

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

Reply
The periods for claims from patent infringement as laid down in section 120(4) of the current
Australian Patent Act (3 years from grant or 6 years from act of infringement) are not particularly
relevant in the classical originator/generic disputes of the pharmaceutical industry, because
normally the patentee is very much interested in immediate relief in the form of an injunction and
therefore initiates proceedings soon after he becomes aware of infringing activities or even
threats of infringing activities. The current 6 year statutory period of limitation for claims from
patent infringement in Australia appears therefore not to pose any issue for the pharmaceutical
industry. It would be desirable, especially for patents in industry sectors where infringement is
not directly evident from the sold products, to keep the 6 years period provided for in Sec. 120(4)
of the Patents Act, because in particular smaller and medium enterprises may have delays in
finding out about a potential infringement of their patents in Australia.
Question 8:
Are follow-on patents being used to inappropriately extend protection for pharmaceuticals? If so, how? And, if they are, is this sound policy and what changes, if any, are needed?

Reply
Often follow-on patents protect valuable further improvements of known pharmaceutical products, e.g. new formulations that facilitate patient compliance. Patentees need certainty in being able to protect such improvement inventions by solid patents in order to have an incentive to invest in such valuable improvements. On the other hand, generic companies should be able to compete with the original version of the product after expiry of the earlier filed patents. Thus, the scope of those improvement patents must always be narrower than the earlier filed patents so that third parties are normally in a situation to use the older technology after expiry of the earlier filed patents without infringing the follow-on patents. Should there be attempts by patentees to cover with the follow-on patents something that is not novel or not inventive anymore in view of the earlier filed patents (sometimes referred to as “evergreening”) the present patent system has the means and is well situated to prevent such inappropriate extensions. A streamlined post-grant opposition procedure may further simplify and promote such goal (see response to Question 4).

Question 9:
Is the law on data exclusivity appropriate?

Reply
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. To put it into perspective, the enormous data set to demonstrate efficacy and safety of a drug is generated at the authorities’ request and requires large investments in time and money on behalf of the innovator. Such commercial data is highly valuable and proprietary. In other industries such data is usually kept confidential as product know-how. Therefore, the statement that data exclusivity keeps information out of the public domain is looking at the issue from the wrong perspective. The limited period of data exclusivity ensures that generic competitors will be able to benefit from these data and approve their products without having to undergo the same process and investments to generate their own data independently. If the data exclusivity period is short, e.g. 5 years, it is more likely that it will not be sufficient to recoup the investments made in order to show efficacy and safety for regulatory approval. Without sufficiently long data exclusivity, there is reduced incentive for an innovator to apply for marketing authorizations for new medicinal products in a country. An attractive market for new product launches will lead to investment in building a skilled local workforce, in patient care programs, in physician and healthcare worker education programs, etc. Most of those activities are not and cannot be funded by generic companies.
Question 10:
Are the laws on patent certificates appropriate?

Reply
Novartis submits that the current laws on patent certificates under sections 26B, 26C or 26D of the Therapeutic Goods Act are appropriate, but should not be made more burdensome on the parties providing such certificates.

Question 11:
Are the laws on copyright of product information appropriate?

Reply
In Novartis’ view copyright law should not hinder a generic applicant from including the necessary safety and dosage information into the product leaflet in connection with indications for which there is no other intellectual property right, e.g. patent protection. For that reason the recently introduced Sec. 44BA of the Australian copyright law is regarded as sufficient and appropriate.