

**SUBMISSION TO THE ADVISORY COUNCIL ON  
INTELLECTUAL PROPERTY ON POST-GRANT  
ENFORCEMENT STRATEGIES**

**MEDICINES AUSTRALIA**

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Medicines Australia has considered ACIP's Issues Paper on Post-Grant Enforcement Strategies dated November 2006 ("Issues Paper") and responds to some of the questions in the Issues Paper below. Medicines Australia is aware that the Law Council of Australia: Business Law Section, Intellectual Property Committee ("IPC") has made submissions to ACIP dated 11 April 2007. Medicines Australia generally agrees with IPC's submissions and also makes the following observations:

**Question 5:** Would a post-grant opposition process offer greater benefits over the existing pre-grant opposition process?

**Question 6:** Would a post-grant opposition process assist patent owners to better enforce their patent rights?

1. Medicines Australia generally supports a post-grant opposition system enabling a patent owner to enforce their patent earlier. Medicines Australia submits that amendments to the Therapeutic Goods Act ("**TG Act**") adopted at the time of the US-Australia Free Trade Agreement as part of the so-called 'Latham Amendments', which introduced the risk of penalties of up to \$10 million for pharmaceutical patent holders attempting to enforce their patent rights, should be repealed. The certification requirement for innovator companies before bringing proceedings is unprecedented in its scope, is very onerous and subject to great uncertainty, and may deter their bringing of proper and genuine proceedings. The uncertainty created by these amendments discourages new investment in biotech and in pharmaceuticals. While the impact on the pharmaceutical industry is difficult to quantify, Medicines Australia submits that it is difficult to attract investments to Australia where there exists an uncertain investment environment and where environments in other jurisdictions are more attractive. See paragraphs 8 to 13 below.
2. An opponent would have the opportunity to oppose the grant within the prescribed post-grant opposition period.
3. Alternatively, an opponent could completely avoid post-grant opposition and commence revocation proceedings in a prescribed Court. As has been noted by IPC, revocation proceedings permit challenges on wider grounds of validity such as fraud, false suggestion or misrepresentation than are currently available under the opposition system. Medicines Australia would not support the making of opposition proceedings compulsory before revocation proceedings are commenced. This would only cause an unnecessary doubling up of opposition proceedings and court proceedings in which identical challenges to the validity of a patent may be made. It would also not relieve the current delay experienced under the pre-grant system. To avoid opposition proceedings and revocation proceedings being run concurrently on the same issues, Medicines Australia would support a stay of the opposition proceedings

to the extent that the same issues are dealt with in the revocation proceedings.

4. Any introduction of a post-grant opposition system of provisions that would allow outsiders to dispute the validity of a patent before a board of administrative judges is likely to increase, rather than reduce, delays and litigation.

**Question 7:** Would it be beneficial for a patent owner if, on request, IP Australia provided an opinion on the issue of patent validity or infringement?

5. Medicines Australia agrees with IPC's submissions that a patent owner currently receives an opinion on the validity of their patent during the examination process. Medicines Australia also agrees that IP Australia is not equipped to assess infringement which involves a consideration of expert and other evidence in accordance with the rules of evidence. Again, the requirement of any determination on these issues would require a patentee to incur costs on a non-binding administrative assessment, when those costs could be better spent on a final determination (by a court) on those issues.
6. Medicines Australia does not support the introduction of a Validity and Infringement Opinions Service similar to that implemented in the UK Patent Office. It is difficult to imagine that inviting the public at large to make submissions or observations commenting on the infringement or validity of a patent would reduce costs or delays to patentees. If anything, costs are likely to be increased if patentees are put to the expense of responding to submissions or observations of a number of third parties.

**Question 8:** Should it be mandatory to obtain a validity opinion from IP Australia prior to seeking legal action?

**Question 9:** Should the award of costs be linked whether a patent had been re-examined in terms of its validity by IP Australia before the question had been argued in Court proceedings?

7. Medicines Australia does not support the mandatory obtaining of a validity opinion from IP Australia before commencing proceedings when validity is already assessed at the examination stage and at opposition stage. Medicines Australia does not support additional approval steps that delay the grant of a patent due to the lengthy development time in pharmaceuticals.

8. Medicines Australia also submits that section 26B of the Therapeutic Goods Act already provides some (albeit limited) protection for pharmaceutical patent holders by:
  - requiring a person applying for registration or listing of therapeutic goods to certify either that they believe, on reasonable grounds, that they are not marketing, and do not propose to market, the therapeutic goods in a manner, or in circumstances, that would infringe a patent that has been granted in relation to the therapeutic goods. This process usually requires an independent opinion on validity to be obtained. or
  - requiring a person to certify that a patent has been granted in relation to the therapeutic goods, and if the person proposes to market the therapeutic goods before the patent term expires, they have given the patentee notice of their application for registration or listing of the therapeutic goods.
9. However, Medicines Australia proposes that further amendments be made in order that mechanisms are in place to ensure a balanced and sustainable outcome for the industry as a whole. Medicines Australia submits that the current process (under s. 26B) is flawed in a range of respects. It effectively denies a patent holder notice of, and the ability to assess the validity of, a generic company's non-infringement assertion. Likewise, it effectively denies a patent holder the opportunity to properly consider its position and discharge its obligations in relation to the "good faith" and "reasonable prospects of success" certificate it is compelled to give under s. 26C.
10. Under Article 17.10(4) of the Australia-United States Free Trade Agreement, Australia agreed to adopt or uphold measures to prevent marketing approval for pharmaceutical products that would infringe an existing patent unless the patent holder has provided consent. The Government of Australia implemented these obligations by requiring applicants for marketing approval to provide a certificate to the Therapeutic Goods Administration to the effect that they either are not infringing an existing patent or they have notified a relevant patent holder that they intend to infringe a patent. The provisions did not provide patent holders with a minimum period of notice of generic market entry.
11. This results in a huge onus on patentees to firstly constantly undertake competitor surveillance. Secondly, if a patentee wants to seek an interlocutory injunction, the onus under s. 26C is onerous not only insofar as the scope of the "good faith" and "reasonable grounds" is unclear, but the fact that it must, of necessity, require seeking and obtaining legal opinion on complex patent issues in a very short timeframe with the potential penalty of \$10 million if the s. 26C Certificate is found false or misleading in a material particular. Contrast this penalty to the \$110,000 for an individual or \$500,000 for a company, if the advice given in a s. 26B Certificate is false or misleading.

12. Further, no industry other than the pharmaceutical industry has such a complex set of certificates and a duty to obtain legal advice on complex matters as well as the threat of such onerous monetary penalties which must be considered before bringing an interlocutory or infringement action.
13. The above are major detriments, particularly for a patentee contemplating bringing an interlocutory injunction, coupled with the apparent reluctance of courts to grant injunctions in the area of pharmaceutical patents (see our comments under paragraph 18).

Medicines Australia believes that the Government should

- repeal the Labor Party amendments (known as the 'Latham Amendments'); or
  - require the TGA to provide the sponsor of an originator product with a copy of a certificate under section 26B(1)(a) that is provided in relation to an application for registration by the TGA of a generic brand of the originator product; and
  - publish brief details of all applications for PBS listing so that sponsors of originator products can monitor it to ascertain if threatened infringement of a patent is imminent.
14. Further the widening of the springboarding provisions as a result of the recent amendments to s. 119A of the Patents Act, means that a generic company is able to springboard at any time following the grant of a pharmaceutical patent (rather than from the date the extension period is granted) reducing the ability of the patent holder to enforce their rights. Under the data exclusivity provisions set out in s. 25A of the TG Act, a generic company is unable to obtain inclusion on the Australian Register of Therapeutic Goods based on safety and efficacy data submitted by an originator company during the time of data exclusivity (currently 5 years) except with the consent of the originator company. Data exclusivity provisions can be important where a complex submission for a new drug to gain registration and therefore access to the Australia market will require a long time to gain approval. The United States currently provides 5 years plus 3 years for an additional indication for the same molecule whereas the European Union provides a period of 10 years data exclusivity. Medicines Australia submits that an amendment to extend the data exclusivity provisions in the TG Act to make it consistent with the US or European Union is appropriate. In Medicines Australia's view, additional opportunities and benefits for generic manufacturers should be counterbalanced by additional opportunities and benefits for innovators. Such an approach would accord with the position in other countries.
  15. Medicines Australia does not support the linking of an award of costs to whether the patent has been re-examined. Medicines Australia also agrees that all the circumstances of a case must be considered when deciding how to award costs.

**Question 10:** Would mediation be of benefit in patent disputes?

**Question 11:** Should IP Australia provide a similar mediation service to that provided in the United Kingdom?

**Question 12:** Should mandatory mediation occur prior to an enforcement action being pursued in the courts?

**Question 13:** Would it be of benefit if mediation efforts were considered when legal costs are awarded?

16. A voluntary mediation service may assist opposing parties to discuss problems causing a dispute with help of an independent person without resorting to a court hearing. However, each matter will turn on its own particular circumstances.
17. Medicines Australia considers that mediation is often not successful in pharmaceutical patent litigation due to the complicated nature of the issues which arise and the lack of power given to a mediator to make binding orders on the parties.
18. While litigation costs may be avoided if genuine efforts towards mediation are made prior to the dispute entering the full trial stage, there are times, as is noted in the Issues Paper, when mediation may not be appropriate. These include where an urgent injunction is required, in cases involving complicated issues that need detailed analysis, where a party requires full disclosure and/or an examination of evidence to understand their position or where a neutral opinion is required on the question of genuine difference. Medicines Australia considers that mandatory mediation should not be required before an enforcement action is pursued in court. Medicines Australia also opposes the linking of a decision by one party not to mediate to an award for costs as this would assume some bad faith conduct on the part of that party or an attempt to impede a prompt resolution of the matter, when this may not be the case.
19. As is noted in footnote 14 of the Issues Paper, mediation is a dispute resolution process which is already part of the current procedures of the Federal Court. The Federal Court may refer the whole or any part of a proceeding to mediation, with or without the consent of the parties. The Courts should be entitled to take into account all the circumstances of a case, including any mediation efforts, in making an award for costs.

**Question 14:** Would an independent decision-making body, such as a patent tribunal, assist patent owners to effectively enforce their patents?

**Question 15:** Before seeking a hearing from the Federal or State Supreme Court should it be mandatory for patent owners to first seek judgment in a patents tribunal on questions of patent validity and/or infringement?

**Question 16:** Is it likely that a patent tribunal would add another layer of expense and complexity to the current process of patent enforcement?

**Question 17:** Are the other quasi judicial models that would be more effective?

**Question 18:** Would it be beneficial for a patent tribunal to hear post-grant opposition proceedings?

20. Medicines Australia has considered the pros and cons of establishing a patent tribunal. We consider that the establishment of a patent tribunal may add a further layer of costs and complexity to a dispute. Technical matters on validity and infringement require the preparation of expert evidence together with an appropriate forum and procedures for cross-examination of witnesses to test and assess that evidence. The Issues Paper suggests that much of the expense and time involved in determining patent validity or infringement before the Federal Court is spent on informing a (non-technical) court of highly technical concepts.
21. On the other hand, while it would still be necessary to prepare and present evidence of a highly technical nature to a presiding member of a tribunal, it is likely that these efforts and time would be significantly reduced because the matter would be heard by a person with background expertise in the subject matter. Further, a patent tribunal could be useful in the pharmaceutical patent area, as it is so specialised with industry specific issues. The tribunal could be educated in the complex TGA and PBS schemes which invariably arise in injunction hearings and this may result in a more balanced and educated approach to hearing interlocutory injunctions or pharmaceutical patents.
22. However, it is also conceivable that the setting up of a patent tribunal (even if the tribunal took over IP Australia's function of hearing post-grant oppositions) would not reduce the risk that the tribunal proceedings would be used by one or more of the parties as a dry run of their case with the principal intention of seeing what evidence the other side has prior to appealing to the Federal Court.

23. Medicines Australia agrees with the doubts expressed in the Issues Paper that the tribunal would ultimately be performing an administrative function, so the possibility of placing restrictions on the Court hearing *de novo* appeals from the patent tribunal would be doubtful.
24. Presumably, the costs of implementing and administering a patent tribunal would also lead to increased fees to patent examination and administration, a cost which would be met by patentees.
25. On balance, Medicines Australia does not support the establishment of a patents tribunal.

**Question 21:** What can be done to ensure private enterprises provide a commercially viable patent insurance?

**Question 22:** Would patent holders benefit by a type of enforcement fund?

**Question 23:** How could an enforcement fund be administered and financed?

**Question 24:** Should an enforcement fund be established that is funded by patent examination and registration fees?

26. The Issues Paper contemplates that while all patent owners would be required to contribute to an enforcement fund through the payment of (presumably increased) patent fees (application, grant and renewal), only those patent owners who could show that they do not have access to financial resources would be entitled to access the fund. This may mean that some patent owners would be contributing to a fund which is used to finance litigation against them, which is unsatisfactory.
27. Medicines Australia also questions whether the costs of implementing and administering a fund (including the enactment of appropriate legislation) from increased patent fees would outweigh the benefit to a perhaps very limited number of persons who would be entitled to access the fund.

**Question 25:** Would patent owners be better able to pursue enforcement actions if there were high rates of the tax deductions for patent litigation expenses?

**Question 26:** Would more people be encouraged to use ADR measures if there were restrictions on tax deductions for litigation expenses?

**Question 27:** Could other tax incentives assist individuals and businesses to better enforce their patents?

28. As has been noted by Medicines Australia in paragraph 18 above, in some cases, litigation may be the only option for particular circumstances. A restriction on tax deductions for litigation expenses effectively penalises a party who may need to litigate.

**Question 28:** Should criminal penalties be available for patent infringement?

**Question 29:** Should criminal sanctions be available only in the event of wilful patent infringement?

29. While criminal proceedings may appear to have certain advantages, a major disadvantage of the State conducting infringement proceedings on behalf of a patent owner is the risk that limited resources would be committed by the State to an attack on a patent's validity, which may result in the revocation of the patent. However, Medicines Australia would agree to an amendment to the Patents Act permitting the imposition of criminal sanctions in civil proceedings.

**Question 30:** In addition to current efforts in international fora, what other strategies could Australia pursue internationally to assist patent owners enforce their patent rights in overseas jurisdictions?

**Question 31:** What kind of domestic changes, programs or strategies are more likely to assist patent owners with enforcement overseas?

**Question 32:** Would a publication or online information site dedicated to assist patent owners enforce or defend their rights in countries' specific jurisdictions be advantageous?

**Question 33:** Are there other strategies that could make overseas patent enforcement easier and less costly?

30. Generally, Medicines Australia cannot see any downside to IP Australia developing a set of guidelines for particular countries relating to enforcement and procedures in specific countries.

**Question 34:** Should there be legislative provisions relating to custom seizure of imported goods which infringe patents?

31. Medicines Australia agrees that provisions relating to customs seizure of imported goods which infringe patents, similar to those found in the *Trade Marks Act 1995* relating to trade mark infringements, would be a positive development for patentees.

**Contingency fees**

32. Contingency fee arrangements may benefit certain litigants in some circumstances. Generally, patent litigation is too complex for contingency fee proposals to be realistic.