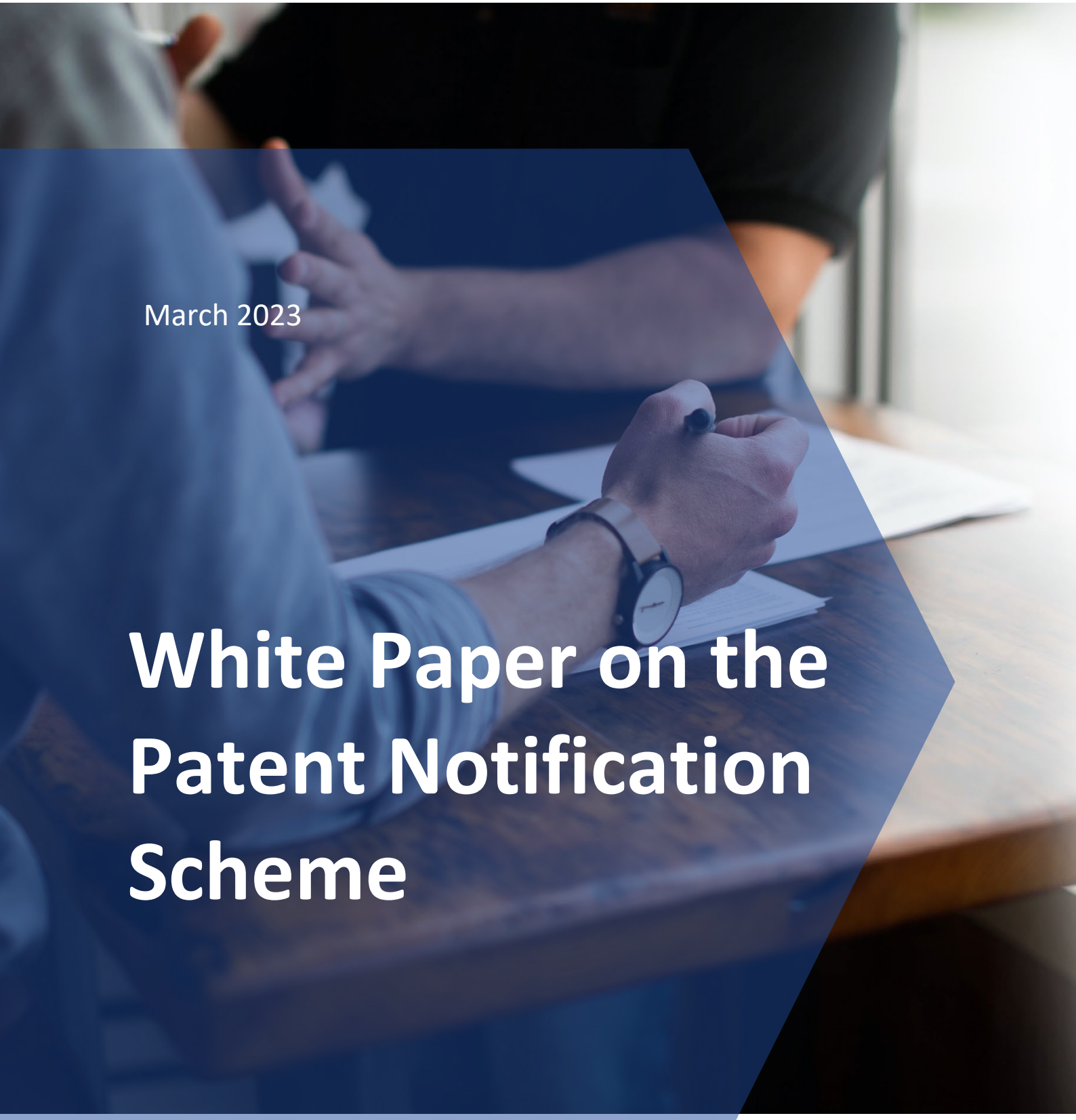

March 2023

White Paper on the Patent Notification Scheme

Medicines Australia

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Introduction

This whitepaper has been developed by Medicines Australia in conjunction with Bristol-Myers Squibb, Jones Day Lawyers and legal counsel from Medicines Australia's member companies.

The whitepaper explores the need for reform in the registration of generic and biosimilar medicines on the Australian Register of Therapeutic Goods (ARTG) and an associated patent notification scheme. It looks at developments to date, problems with solutions proposed so far and posits its own evidence-based solution for effective, timely and transparent patent notification arrangements.

Why do we need this reform?

Timeframes

1. A Generic Sponsor is not, in practice, required to give notice of its application to a patentee. This enables the Generic Sponsor to obtain ARTG registration of the generic or biosimilar medicine without prior notice to a patentee. Under this course of action, the patentee only becomes aware of the application for registration of the medicine once the application has been considered, approved and the product the subject of the application entered on the ARTG; that is, at the same time as the general public.

2. Even if notice is provided by a Generic Sponsor (i.e., the Generic Sponsor notifies the patent holder of its application), the patentee may not be provided notification sufficiently well ahead of the marketing of the medicine for the patentee to be able test whether the Generic Sponsor's action constitutes infringement of patent. This is because the legislation provides only that the goods will not be included in the ARTG *unless and until* the applicant gives a certificate under section 26B of the *Therapeutic Goods Act 1989* (Cth) (or a notice that a certificate is not required)[1]. Therefore, the requirement to provide a section 26B certificate may be satisfied by a Generic Sponsor providing notification just prior to the medicine/biosimilar's entry on the ARTG (including the day before).

3. This feature of the current deficient patentee notification system permits a Generic Sponsor to solely control timing of the ARTG registration. This is because the Generic Sponsor can choose to complete all other steps for registration and obtain approval, but withhold the provision of the section 26B certificate to the TGA (which would trigger the ARTG entry) until such time as it is ready for launch. The Generic Sponsor is therefore able to plan with certainty for launch of its generic/biosimilar product and prepare for any infringement action by the patentee (and any revocation action) whilst the patentee remains unaware of the impending registration and launch and therefore potential infringement.

4. In contrast to the ability of the Generic Sponsor to prepare for launch and litigation according to its own timeframe, as the TGA itself has expressly noted,[2] the current notification requirements under section 26B may afford little time for the patentee to consider whether its patent is infringed and consequently to prepare for any infringement action. In fact, in cases of private market launch, no time at all is available, given the generic/biosimilar company is permitted to launch privately on and from ARTG entry.

[1] Section 25AB(3) of the TG Act.

[2] See TGA consultation paper at https://www.tga.gov.au/sites/default/files/prescription-medicines-transparency-measures.pdf, page 5.

5. Given these matters, under the current system, typically the first time that a patentee becomes aware of the potential for the launch of a generic / biosimilar medicine is upon its public entry on the ARTG. This may be followed immediately by a private launch, or by a PBS launch shortly thereafter.

6. In the case of PBS-listed pharmaceuticals, the commercial consequences of PBS listing of a generic or biosimilar can be significant and irreversible. The first PBS listing of a second brand of a pharmaceutical (i.e., the first generic or biosimilar) will cause the PBS price of the innovator pharmaceutical to be reduced by a mandatory minimum 25%. Once PBS listed, further significant price reductions may result, including from operation of the price disclosure regime.

7. Further, even where a patentee is in a position to commence proceedings for patent infringement following ARTG registration of the generic medicine, the usual timeframes for resolution of patent litigation proceedings are such that a first instance decision is likely to take at least 12 to 18 months to be delivered (at best, 8 to 12 months if the proceeding is expedited).

8. Given a generic/biosimilar pharmaceutical company can launch privately following ARTG registration, or within a short period thereafter on the PBS, there is insufficient time for even a first instance judgment to be handed down prior to generic/biosimilar entry (even if the Court grants expedition).

9. Given the matters set out above, the patentee often has no alternative but to attempt to prevent unauthorised generic/biosimilar launch prior to patent expiry by applying to the Court for an interlocutory injunction restraining launch on an urgent basis, pending final resolution of the matter (which may be up 1 to 2 years away).

10. However, preliminary injunctions are not granted as of right. Also, applications for preliminary injunction place significant stress on the court system, give rise to uncertainty for the patentee and the market and expose the patentee to the risk of further substantial financial detriment in payments of compensation under the cross-undertaking as to damages.

11. In order to obtain an interlocutory injunction, a patentee must make out a *prima facie* case of infringement and also that the 'balance of convenience' favours the grant of the injunction; that is, the loss the patentee will suffer if the injunction is not granted outweighs the harm that the alleged infringer will suffer if the injunction is granted. Several recent applications for interlocutory relief have been refused on various grounds including based on difficulty in calculating damages. Accordingly, there is a very real possibility that an interlocutory injunction will not be granted.

12. There are many potential disadvantages that arise from the application of the current system:

    (a) the patentee being required to prepare case evidence in a short period of time, in contrast with the generic / biosimilar company, which has been at liberty to prepare as it sees fit for a period of time prior to the ARTG listing;

    (b) the Court being required to adjudicate on the parties' rights on an urgent basis;

    (c) the patentee being exposed to the risk of payment of damages to generics/biosimilars (and potentially other third parties), and any other "person" including the Commonwealth under the 'usual undertakings as to damages' given by the patentee as the "price" of an interlocutory injunction. Notably the scope of recoverable damages under the undertaking is uncertain at law;

    (d) the Court having to hold a separate hearing to determine the rights of the parties on a final basis; and

    (e) the Court, potentially having to undertake a further complex hearing to assesses any claim(s) for damages under the undertaking as to damages.

Australia United States Free Trade Agreement (AUSFTA)

13. Article 17.10 : Measures Related To Certain Regulated Products, Subsection 4 of the AUSFTA provides for notification to the patent owner if another party submits a medicine for marketing approval during the term of an existing patent.

14. Under Section 26B of the *Therapeutic Goods Act 1989* (Cth) "the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market, the therapeutic goods in a manner, or in circumstances, that would infringe a valid claim of a patent" a certificate can be provided to the TGA to that effect. Notification is not required to be given to the patent holder.

15. The circumstances of paragraph 14 are in clear violation of the terms of the AUSFTA which does not draw such a distinction.

16. In order to adhere to the requirements of the AUSFTA, an effective, functioning patent notification regime should be implemented.

What has happened so far?

TGA consultation 1

17. In February 2019, the TGA published a consultation paper titled "Whether the TGA should publish that a prescription medicine is under evaluation – Transparency Reforms" (Consultation Paper). The Consultation Paper cited the TGA's commitment to "better health and wellbeing for all Australians through regulatory excellence" including being appropriately transparent about regulatory activities.

18. The Consultation Paper stated that the long-standing practice of the TGA is to treat the existence of a prescription medicine application as confidential until the medicine is approved and entered on the ARTG, or the existence of an application otherwise becomes publicly known (such as via a public announcement by the sponsor).

19. The Consultation Paper sought feedback on whether the TGA's existing practice should be continued or whether a range of transparency options, involving the publication of the fact that an evaluation of a prescription medicine is taking place, should be adopted.

20. In particular, the Consultation Paper identified four options for consideration by stakeholders on which submissions were invited:

- Option 1: Maintain the *status quo* i.e., no publication of information for new medicines under review.
- Option 2: Publication that a prescription medicine has been accepted for evaluation for all new chemical entities (including biological prescription medicines), extensions of indications, and all generic and biosimilar medicines.
- Option 3: Publication of all applications at two different time points depending on whether the medicine is a new medicine (on acceptance for evaluation) or a generic medicine or biosimilar (on approval but before registration on the ARTG).
- Option 4: Publication of applications for innovator medicines of highest public interest, but not generic or biosimilar medicines.

21. Relevantly, as noted above, 'Option 2' of the Consultation Paper envisaged that the TGA would publish the fact that a prescription medicine has been accepted for evaluation *inter alia* for all generic and biosimilar medicines.

22. Following the consultation process, the TGA announced that the Government had approved the implementation of transparency measures for prescription medicines, in respect of the:

- early publication of major innovator medicine applications; and
- earlier notification of generic/biosimilar medicine applications to the innovator.

TGA consultation 2

23. The TGA published a further consultation paper titled "*Prescription medicines transparency measures - Implementation of generic medicines early notification to innovators of an application and publication of innovator applications*" in March 2020 (March 2020 Consultation Paper).

24. In particular, in relation to the system for early publication of major innovator medicine applications, the TGA noted that the submissions it received "*showed that the majority of stakeholders continue to support the earlier publication of major innovator medicine applications that are under evaluation by the TGA*". The outcome of this was the implementation of such a system with effect from January 2021.[3] As a result, information regarding three types of innovator medicine applications is now published by the TGA on its website, namely:

- Application type A: applications for a 'new medicine' containing a new active substance (new chemical entity or new biological entity) not currently approved in Australia;
- Application type B: applications for a 'new combination', where two or more already approved medicines are combined into a single product; and
- Application type C: applications for a 'new indication', or additional therapeutic use, for an already approved medicine.

25. However, no reforms which would have resulted in publication of the fact that evaluation of an application for ARTG registration of generic/biosimilar medicine was underway were implemented. This is despite widespread resistance to maintaining the status quo and support in favour of publication of details all generic / biosimilar medicine applications in accordance with Option 2 of the Consultation Paper identified above. For instance, the submissions by Medicines Australia dated 29 March 2019 described Option 2 above as the only option that fully supports transparency and advocated against any option which treated publication of innovator and generic applications differently.[4]

26. Rather, the outcome was that the TGA instead proposed a far more limited patent notification system, to address universally accepted failings in the current patentee notification regime under section 26 of the Therapeutic Goods Act (as described above). Notably this was different to Options 1 - 4 set out in the Consultation Paper.

Genesis of current TGA proposal for early patentee notification

27. Following several rounds of consultation, on 9 October 2020 the TGA announced that it had received a variety of opinions on the options that were set out in its Consultation Paper for the implementation

[3] The TGA announced that it would publish a description of major innovator medicine applications that are under evaluation by the TGA from January 2021 in a media release dated 9 October 2020, available at https://www.tga.gov.au/media-release/new-transparency-measures-prescription-medicines.

[4] Accessible at https://www.tga.gov.au/submissions-received-whether-tga-should-publish-prescription-medicine-under-evaluation#received.

of an early patentee notification system for generic and biosimilar medicine applications, none of which received consensus support.

28. Accordingly, the TGA introduced a new proposal which it described in the announcement, as providing a better balance between innovator and generic/biosimilar interests (the **TGA's Early Patentee Notification Proposal**).

29. The TGA's Early Patentee Notification Proposal, as set out in the TGA's announcement referred to above, is as follows:

"Applicants for first generic and first biosimilar medicines, subject to proposed changes to the Therapeutic Goods Act 1989, will be required to notify the patent holder when their application is accepted for evaluation by the TGA, before the TGA commences the evaluation.

The notification would be based on the existing arrangements under section 26B of the Act, but:

1. *will occur earlier in the process, following preliminary assessment*
2. *will be required to be to be given to the patent holder and to the TGA*
3. *will be required where the applicant does not market or propose to market the medicine before the end of the term of the patent, AND*
4. *where the applicant proposes to market the medicine before the end of the patent term*

The existing notification scheme under section 26B of the Act, will continue to apply to all other applications for generic and biosimilar medicines, prior to registration of a generic or biosimilar medicine on the ARTG."

30. However, even this more limited patentee notification system has been delayed, it appears due to the ACCC's concerns regarding the perceived potential that early notification may to lead to anti-competitive conduct in the form of 'pay-for-delay' agreements between patentees and generic/biosimilar pharmaceutical companies.

Problems with the TGA's notification proposal

31. The TGA's Early Patentee Notification Proposal is narrow in its operation and falls far short of the original transparency measures set out in the Consultation Paper.

32. Further, much of the detail of the TGA's patent notification proposal remains undefined and unclear pending the publication of further details, including draft legislation to give effect to the proposal.

33. However, based on the information currently available it appears the TGA's proposal will fall short in a number of respects, including due to:

(f) the intended application of the proposal only to 'applicants for first generic and first biosimilar medicines';

(g) the requirement that notification be given to 'the patent holder'; and

(h) the absence of details as to what information will be required to be provided to the patentee under the notification.

These issues are explored below.

A. Limitation to 'applicants for first generic and first biosimilar medicines'

34. As noted above, the TGA's proposal contemplates that only 'applicants for first generic and first biosimilar medicines' would be required to provide early notification to the patentee. All other applicants would only be required to provide notification in the usual manner pursuant to the existing notification scheme under section 26B.

35. Pending the publication of further details, it is unclear how the concept of applications for 'first generic and first biosimilar medicines' is to be defined, although it is apparent any such definition will need to have regard to a number of complexities in the pharmaceutical patent landscape including those discussed at section B. below. Similarly, it is also unclear how a Generic Sponsor is to know whether or not it is the first applicant.

36. However, regardless of how the concept is to be defined, any limitation to a 'first' applicant would render the proposal ineffective to meet the needs of patentees and the public and the intended purpose of early notification.

37. This is because the relevant detriment which early patent notification is intended to protect against is, as discussed above, the commercial detriment to a patentee arising from unauthorised launch of a generic or biosimilar medicine, rather than simply the first application or registration for such medicine on the ARTG (although these are also relevant matters).

38. Early notification to patentees of ARTG applications by Generic Sponsors is intended to provide additional time in which patentees can act (including through instituting proceedings against Generic Sponsors) to protect against the commercial harm of an unauthorised launch of a generic or biosimilar medicine prior to patent expiry.

39. Where the launch takes the form of the PBS listing of a first generic / biosimilar product, this includes significant harm in the form of a mandatory minimum 25% price reduction on such listing, as noted above. However, in many instances, second and subsequent applicants for ARTG registration of generic/biosimilar medicines may also present the threat of commercial harm to an innovator pharmaceutical company.

40. For instance, the first ARTG applicant for a generic/biosimilar product may not be the first to PBS list. Further, entry into the market by second and subsequent PBS listed products have the potential to cause further commercial harm to the innovator by reason of price reductions which may occur by operation of the statutory price disclosure regime.

41. Limiting early notification to only the first applicant could therefore result in second and subsequent applicants achieving ARTG registration with no notice to the patentee until ARTG registration is achieved, resulting in the same deficiencies as seen in respect of the current section 26B regime. That is, patentees may be afforded no time (in the case of private launch) or potentially very limited time (in the case of PBS launch) in which to take action to prevent harm arising from any unauthorised launch.

B. Notification to 'the patent holder'

42. The TGA's Early Patentee Notification Proposal refers to notification being required to be given to 'the patent holder'.

43. Pending the publication of further details, it is unclear what the concept of 'the patent holder' is to encapsulate and whether it will take into account a number of complexities which exist in the pharmaceutical patent landscape, some of which are discussed below.

44. For instance, it is not uncommon for there to be multiple patents that are relevant to a particular medicine on the basis that certain patents may cover the composition of the product whilst others may cover the manufacture and/or method of use of the product.

45. It therefore also follows that there may be more than one patentee that ought to be notified.

46. Further, in the case of biosimilars, patents of relevance may extend not just to those held by the innovator pharmaceutical company, but potentially also those that are held by competing biosimilar pharmaceutical companies.[5]

47. It is unclear whether under the TGA's Early Patentee Notification Proposal notification would be required to be given in respect of all such patents and patentees. However, the use of the phrase ''*the* patent holder" (emphasis added) suggests perhaps these complexities are yet to be explored.

48. Further, it is unclear as to how the patent holder is to be determined, although it is presumably through information made publicly available on the IP Australia AusPat database, the accuracy of which will be dependent upon patentees ensuring any assignment of rights are duly recorded.

49. It is also unclear to what extent assessment of matters as to infringement and validity of the relevant patents (however they may be identified) will be of relevance to the identification of the patentees to whom notification must be given, and if so, how those assessments will be made and by whom.

50. In light of the above, and in the absence of additional information from the TGA, it appears that these uncertainties may, as is the case with the current section 26B regime, be left to be resolved at the discretion of the Generic Sponsor.

51. If that is the case, whether or not early notification is received by patentees will be a matter that is ultimately decided by the Generic Sponsor, such that, as is the case under the current regime, a patentee may not receive any early notification and be afforded the opportunity to avoid the detriments against which early notification is intended to protect.

52. Accordingly, this aspect of the TGA's proposal would also fail to overcome the deficiencies of the current regime.

C. Manner and content of notification

53. The manner of the required notification is also unclear based on the information currently available.

54. Further, specific details as to the content of the required notification under the TGA's proposal has yet to be clarified. For instance, although the notification is required to be given to the patentee, it is unclear whether confidentiality restrictions would apply to the information disclosed through the notification, and whether the TGA itself will re-publish any part of the notification on its website.

55. It is also not clear whether the notification will simply inform patentees of the fact of an application having been made, or whether additional details of the application, including for instance the proposed indications would also be notified.

Proposed Solution

Option 1:

56. Many of the problems identified with the TGA's Early Patentee Notification Proposal can be resolved by the TGA making publicly available details of all applications for generic and biosimilar medicines which it has accepted for evaluation. This is in accordance with 'Option 2' originally put forward in the Consultation Paper insofar as it concerns generic and biosimilar medicines.

[5] As observed in the submissions by the Law Council of Australia dated 4 Juned 2020 https://www.lawcouncil.asn.au/publicassets/1a7fdbda-e8a6-ea11-9434-005056be13b5/3825%20--%20Prescription%20medicines%20transparency%20measures.pdf.

57. As the TGA itself has noted[6] a similar practice is adopted by regulatory authorities in a number of jurisdictions including by Medsafe, Health Canada, the European Medicines Agency and Swissmedic, each to varying degrees. For instance, in respect of New Zealand, Medsafe publishes details *inter alia* of all generic / biosimilar applications on a publicly searchable database once an application has been received and an invoice issued, such details including the type of application, its status, the product, active ingredient, and sponsor.

58. Such a practice would avoid selective application of the early notification scheme, remove burdens on Generic Sponsors, and provide patentees with the information they need to determine whether or not further action is warranted at their discretion.

59. There is also a significant public interest in adopting this approach as set out in the submissions to the TGA For example, the submissions of Painaustralia Ltd dated 25 March 2019 and NPS MedicineWise dated 30 March 2019 support the proposition that public access to information regarding generic/biosimilar applications is important including as it permits the public to make decisions regarding participation in a clinical trial, deciding whether to self-fund a treatment and/or await cheaper alternative.

60. As the submissions by GlaxoSmithKline noted, public disclosure provides *"clarity on when generic medicines may join the market and help logistical planning to maintain robust supply of medicines as they approach the end data exclusivity periods"*.

61. Further, consistency with New Zealand should be encouraged. As the submissions lodged by Johnson & Johnson noted, "*many products in Australia have shared packs with New Zealand and often align in timings for filings in both countries*".

62. In addition, 'Option 2' may go a long way to addressing the ACCC's concerns with the adoption of an early patentee notification scheme. That is, public disclosure of all applications on the TGA's website, as opposed to private disclosure by generic/biosimilar companies to innovator companies of selected applications may allay the ACCC's concerns that such patentee notification would result in anti-competitive conduct in the form of 'pay-for-delay' agreements between patentees and generic/biosimilar pharmaceutical companies behind the scenes.

Option 2:

63. Option 2 involves accepting the patent notification proposal at a high level and proposing matters that need to be addressed in any amending legislation (including having regard to the operation of the entirety of section 26B including regarding innovator obligations).

64. Regardless of the option selected, reforms to the early patentee notification regime are much needed and should not be further delayed.

Conclusion

65. An effective and timely patent notification regime would deliver a number of benefits to patients, sponsors and the system. It would deliver a fairer, more transparent and more equitable system than the prevailing approach.

66. It would provide patients with earlier notification of possible treatment options, allowing them to make more informed decisions regarding their care.

67. It would ensure Australia aligns with its AUSFTA obligations.

[6] See consultation paper

68. Early notification to the patentee affords an opportunity for patentees to consider the issues at hand and negotiate with the generic/biosimilar to resolve or narrow any dispute. For instance, the patentee would be afforded additional time in which to request information from the generic or biosimilar applicant, to better assess the likelihood of patent infringement, and if the requested information is not provided, to seek preliminary discovery prior to market entry.

69. If the dispute cannot be resolved, a patent notification scheme would lead to the more orderly resolution of disputes. Patentees are able to prepare and institute litigation well ahead of time and may be able to receive a first instance decision before launch, thereby, avoiding the difficulties and costs associated with interlocutory injunctions set out above.

Next steps

70. The Department of Health and Aged Care should develop patent notification exposure draft legislation to be released to departments and agencies, as well as to impacted stakeholders, for comment.

71. Subject to comment throughout the exposure draft process, the government should aim to implement an effective patent notification scheme within this term of government.

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