Law Council
OF AUSTRALIA

Business Law Section

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Transparency, Reforms and Evaluation Support Section
Therapeutic Goods Administration
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Woden ACT 2606

By email: tgareforms@health.gov.au, info@tga.gov.au

Dear Sir/Madam

Prescription medicines transparency measures: Implementation of generic medicines early notification to innovators of an application and publication of innovator application

1. This submission is made by the Intellectual Property Committee of the Business Law Section of the Law Council of Australia (the **Committee**).

2. The Committee makes the following comments in relation to the consultation regarding 'Prescription medicines transparency measures: Implementation of generic medicines early notification to innovators of an application and publication of innovator application' (March 2020).

3. The members of the Committee comprise solicitors, barristers and academics practising in the field of intellectual property law, research and policy and include senior practitioners many of whom are actively involved in pharmaceutical patent disputes, including advising in relation to the operation of, and obligations under, the current patent certification regime in section 26B of the *Therapeutic Goods Act* 1989 (Cth) (the **Act**).

No rationale for differentiating between innovative and generic medicines

4. At the outset, the Committee notes that the stated rationale for adoption of either of the notification options proposed in relation to generic medicines is flawed. The consultation paper states that the proposed notification process in relation to generic medicines involves:

   - *"respecting the commercial value of information on generic medicines applications prior to registration by not making this information publically* [sic: publicly] *available; and*

   - *respecting the need for timeliness in resolution of issues with the innovator patent holder by providing the innovator company with confidential earlier*

notification of a generic application that has passed preliminary assessment."

5. This rationale fails to recognise that the principal commercial value to a generic company in keeping the fact of an application confidential is that it is not known to the innovator company. It is, of course, the innovator company (usually through a subsidiary or licensee) who is the key competitor of the generic company in relation to the product in question. If notice is to be given to the innovator company, there is no strong rationale for withholding the information from other industry participants and the public.

6. Indeed, a requirement to provide notice only to the innovator company places the innovator company at a commercial advantage compared to other competitor generic companies who may also have generic applications in train in respect of the same product. In these circumstances, the innovator company would gain useful market intelligence about a generic application but other generic companies seeking to compete in relation to the same product would not receive that market intelligence.

7. Although the consultation paper suggests the innovator company would receive the notice on a confidential basis, it would not prevent the innovator company from instigating appropriate market-facing initiatives in the expectation of generic competition in due course (in addition to initiating any appropriate patent dispute).

8. The Committee submits that a preferable course is simply to publish details of generic applications that have passed preliminary assessment, in the same way as is proposed in relation to new innovator medicines.

9. This approach reflects Option 2 from the initial consultation paper on "*Whether the TGA should publish that a prescription medicine is under evaluation*" (February 2019). The Committee notes that the overwhelming majority of publicly available submissions in response to that consultation supported Option 2 in preference to the other options.

10. Finally, this submission refers below to the considerable practical difficulties that arise from either of the proposed notification processes. These difficulties would be entirely avoided if details of applications for approval of generic medicines were simply published, as proposed above.

Proposed notification options

11. Under either of the proposed notification options, a notification would be required under which the applicant "would be required to inform the patent holder that the application for registration of the new medicine intends to rely (in whole or in part) on the patentee's evidence or information" and "would be required to inform the patentee that the applicant proposes the use of the evidence or information relying on the evidence or information for which there is a patent."

12. This approach improperly blends two distinct concepts – first, the information and evidence lodged by the sponsor for an innovative product and on which a subsequent application for a generic medication relies (and which is subject to a period of data exclusivity as "protected information" under the Act), and secondly, an invention that is the subject of protection by a patent (such as a novel

compound with therapeutic utility, or a new method of treatment using a known compound).

13. It is wrong to suggest that "evidence or information" is subject matter "for which there is a patent". Indeed, the very concept of data exclusivity granted through the period that such information is considered "protected information" under the Act is in recognition that such evidence or information is not the subject matter of patent protection.

14. In addition, the "evidence or information" may not be the patentee's. There may or may not be identity between the owner of a relevant patent, and the owner of the "evidence or information" submitted in support of an application for registration on the Australian Register of Therapeutic Goods.

15. The consultation paper refers variously to giving notice to "the patent holder", "the patentee" and "the innovator" (which we assume is intended also to be a reference to the owner of a patent) as if it is always plain who that is. It fails to grapple with the complexities involved in identifying the relevant patents and to whom notice should be given. Taken at its broadest, the consultation paper may be taken as suggesting that notice should be given to any person who is the owner of a patent that is in any way relevant to the composition, manufacture or use of pharmaceutical product in question, irrespective of whether the patent may be infringed by marketing the generic product. Under option 2, this would extend to notifications in relation to expired patents. Such a course is plainly unworkable.

16. First, it is clear that there may be more than one person who owns patents that are relevant to a particular therapeutic good. For instance, it is common for persons other than the company that originally developed the product for its approved indication to hold relevant patents. By way of example, a third company may discover a second medical use for the product, or may develop a superior method for manufacturing the product at scale, or may develop a new delivery method. Each of these may be the subject of separate patent protection.

17. The Committee is aware that there are examples internationally of competing biosimilar companies engaging in patent litigation over the marketing of a biosimilar product so it is clear that not all relevant patent litigation is brought by the sponsor (or companies related to the sponsor) of the reference product.

18. Secondly, it is clear that a patent may exist that in the broadest sense could be said to be relevant to a particular therapeutic good even though there is no prospect of it being infringed (even if valid) by marketing the generic product. An example may be a patent for production of an intermediate compound that is useful in the commercial production of the therapeutic product in question, but which is not used in production of the generic product.

19. Taking these two concerns together, it is unclear under either of the options proposed in the consultation paper whether a generic applicant would be required to give notice to another generic company who happens to be the owner of a patent relating to a method of manufacture of the relevant product at industrial scale but whose patent will not be infringed by the first generic applicant. The Committee submits that such a regime would be unwieldy and subject to considerable uncertainty in the generic applicant determining which patents should

be considered relevant to the product in question, hence giving rise to a notification obligation.

20. The Committee proposes two alternative approaches.

21. Preferably, as submitted above, the fact that the generic application has passed preliminary assessment is simply published by the Therapeutic Goods Administration (**TGA**). This would allow any interested patent owner to monitor publications and raise its concerns as to the potential for patent infringement with the generic applicant. The Committee notes that Medsafe (New Zealand) has a regime under which details of all new applications are made available on a publicly accessible database.

22. Alternatively, a practical approach may be to require the generic applicant to give notice to the sponsor of the reference product. The notice regime would then need to permit the sponsor to disclose the generic applicant's notice to any person it considers owns a patent relevant to the product (such as its parent company, or a licensor).

23. However, a drawback of this approach is that no notice would be given to the owner of a patent who has no relationship with the sponsor and, accordingly, one of the objects of the proposed changes to bring forward in time any relevant patent disputes, may not be achieved.

24. Turning to the particular options proposed in the consultation paper, the Committee makes the following observations.

Option 1

25. For the reasons given above, it is unclear under Option 1 to whom a notice should be given and how the generic applicant is to identify which patents may be relevant for notification purposes if notification is required irrespective of whether a patent would be infringed by marketing of the generic product.

26. In relation to the proposed notification being on a confidential basis – it is unclear what confidence is intended to be protected here since, as noted above, if notice is to be given to the innovator company, there is no strong rationale for withholding the information from other industry participants and the public.

27. Moreover, since the object of the notification regime is to permit any necessary patent disputes to be commenced earlier in time, a confidential disclosure regime would create significant practical difficulties in meeting that object since it may require the patentee to take steps in any proceedings to preserve the confidentiality of that disclosure. Having regard to the high burden of demonstrating to a Court that a non-publication order or suppression order is appropriate (see, for instance, section 37AE and section 37AG of the *Federal Court of Australia Act* 1976 (Cth)), the Committee submits that to impose a confidentiality burden in relation to any notification would lead to unnecessary complication of subsequent Court action and provide little, if any, benefit to the generic applicant.

28. Additionally, it is unclear why it is proposed to preserve the requirement to provide a further, seemingly identical, certification prior to registration. This duplicates the

process for no apparent benefit (certainly any advantage of this approach is not articulated in the consultation paper).

Option 2

29. Option 2 suffers the same difficulties as Option 1 in determining to whom a notice should be given.

30. In addition, it raises the further problem of requiring a notice to be given irrespective of whether a patent remains in force or has expired. Such an approach is entirely unworkable. It would, for instance, require notice to be given to all former owners of patents even where the patents have long since expired and the relevant product has been genericised for many years. By way of example, an application for a generic thalidomide would trigger an obligation to give a notice to the patentee of the original thalidomide molecule, developed in the 1950s, notwithstanding that the compound patent covering thalidomide expired almost 60 years ago.

31. It is clear that any notification requirement should be in respect only of patents currently in force.

32. This concern would also be ameliorated either by the Committee's proposal of publication, or the alternative of requiring notice only to the sponsor of the reference product.

33. The Committee answers the particular questions on which consultation has been sought as follows.

Question1: What is your preferred notification option?

34. As outlined above, both options are highly problematic.

35. If the options were limited to giving notice to the sponsor of the reference product, the Committee prefers Option 2 since this avoids the generic applicant making the sole determination of which patents are relevant (i.e., which have expired).

Question 2: What is the predicted impact, financial and otherwise?

36. The impact of the options as originally proposed would be considerable since they both involve much uncertainty for the generic applicant in ascertaining which patents are relevant and, hence, trigger notification obligations.

37. If the options were limited to giving notice to the sponsor of the reference product, the predicted impact would be to assist in ensuring that any necessary patent litigation brought by the sponsor (or related entities or its licensor) is commenced earlier, with the hope that the cost and uncertainty associated with seeking interlocutory injunctive relief can be avoided.

Question 3: What changes would you propose to minimise burden on industry?

38. As outlined above, the government's objective of ensuring that patent owners of relevant patents are provided with earlier notice of generic applications could be better achieved simply by the TGA publishing those details, as is intended in

respect of innovative medicines. This approach would minimise the burden on industry.

Question 4: What other requirements for information should the notification include?

39. The proposed form of notification, adapted from the existing form for the patent certificates under section 26B of the Act, is entirely inadequate and highlights the problems of the present patent certification regime.

40. In practice, certificates under section 26B(1)(b), which were the intended way in which notice would be given to a patentee, are rarely given because they effectively require the applicant to certify positively that their product will infringe. Accordingly, certificates under section 26B(1)(a) are routinely given. They are common and properly given on the basis of a reasonable belief formed notwithstanding that the question of validity and/or infringement will be subject to serious dispute and is likely to be contested by the patentee.

41. Under either of the options proposed, these same concerns will result in generic applicants almost always giving a notification that "the applicant does not propose to market their medicine in a manner, or in circumstances, that would infringe a valid claim of a patent…".

42. This form of notification would not provide the patentee with any useful information.

43. Under the current certification regime, although it is an offence to give a certificate that is false or misleading in a material particular, as far as the Committee is aware, no one has ever been prosecuted for this offence. It is difficult to see how it could be since it would require, first, the determination of a patent dispute and then proof to the criminal standard that a certificate stated to be given in good faith and belief on reasonable grounds, was false or misleading in a material particular. This burden is simply too high to serve any useful purpose.

44. The Committee considers these proposed amendments to be an opportunity to remove from the legislation a burdensome patent certification regime that has not worked well to date.

45. The information that would in fact be useful is product sponsor, product name, active ingredient(s) and proposed indications.

46. Again, the Committee considers that the preferable course is simply for this information to be published by the TGA upon generic applications passing preliminary assessment.

Transitional arrangements

47. The consultation paper does not address whether the proposed new notice (or, if the Committee's proposal is adopted, publication) regime would apply only in relation to generic applications lodged after commencement of the amending legislation, or would apply in relation to all generic applications that have passed preliminary assessment but have not yet been approved.

48. The Committee submits that the fairer approach is the first – notice (or publication) only in relation to new generic applications that have passed preliminary assessment after the amending legislation commences. Notification obligations (or publication) in relation to new generic applications may influence a generic company's strategy and timing for lodging a generic application with the TGA. Imposing notification obligations (or publication arrangements) retrospectively in relation to applications under evaluation would unfairly take those applicants by surprise, imposing a new regime not in force at the time of lodging the application.

Conclusion and further contact

49. The Committee would be pleased to discuss any aspect of this submission.

50. Please contact the chair of the Committee, Matthew Swinn on +61 3 9643 4389, if you would like to do so.

Yours faithfully

Greg Rodgers
Chair, Business Law Section