GMiA

Generic Medicines Industry Association Pty Ltd

ABN 19 096 009 540

PO Box 222
Pymble BC
NSW 2073

12 October 2012

Ms Alison McClelland
Commissioner
Productivity Commission
Locked Bag 2, Collins Street East
MELBOURNE VIC 8003

Dear Commissioner,

The Generic Medicines Industry Association (GMiA) welcomes this opportunity to contribute to the Commission's review of compulsory licensing of patents in Australia and thanks the Commission for granting it an extension of the time in which to do so.

While acknowledging the important role played by patents in our community, getting newly-developed medicines, and subsequently more cost-effective generic versions, into the hands of patients as quickly and in the most affordable way possible is clearly in the national interest. As a matter of principle, our members support any measure which might promote the deployment of such medicines in Australia more quickly than would otherwise be the case. On that basis, the GMIA supports the objective of the compulsory licensing of patents. However if reforms cannot be implemented to lighten the burden on applicants for compulsory licences they will continue to have no impact on public access to medicines.

Our members have not found it feasible to rely upon those provisions in order to provide more cost-effective generic medicines to the public. Moreover, though they face barriers to market access which are higher than necessary to protect the legitimate interests of patentees, compulsory licensing is a relatively indirect, inefficient and ineffective means of overcoming those barriers. The same can be said in relation to addressing the "specific concerns" raised in the Commission's terms of reference – particularly in relation to genetic technologies.

The remainder of this submission is divided into two parts. The first discusses potential reforms to the provisions for the compulsory licensing of patents. However, in GMiA's view the scope for reform is limited. The second refers to more direct, efficient and effective means of improving public access to generic medicines in particular.

1 Limited opportunity for reform of the compulsory licensing provisions

Two aspects in particular of the provisions in their current form fail to promote the objective of getting newly-developed medicines and cost-effective generic medicines into the hands of patients as quickly and in the most affordable way possible as possible.

i. First, s 133(1) of the Patents Act 1990 (Cth) provides that an application for compulsory licensing cannot be initiated until the expiry of the prescribed period (currently three years after the sealing of the relevant patent). It is difficult to see what purpose is served by such a

delay – which adds little to the public interest test and detracts from the competition test. The justification for this delay should be reviewed.

ii. Secondly, the provisions impose an unfeasibly heavy burden on an applicant for compulsory licensing – acting as a disincentive to such an application. Specifically, both the public interest and competition tests impose significant evidentiary burdens.

In the case of the public interest test, that burden is exacerbated by the vagueness of the guidance as to the reasonable requirements of the public. GMiA notes that this test appears directed to the interests of local industry, rather than consumers. Vesting the power to order compulsory licensing in an administrative body might lighten that burden by removing the need for strict proof in accordance with the law of evidence, however scope for judicial appeal would most likely negate this.

Further, any attempt to prove a contravention of Part IV of the Competition and Consumer Act (for whatever purpose) is invariably the subject of lengthy (and costly) litigation, relying to a large extent on expert evidence. As a regulator, the Australian Competition and Consumer Commission is not in the same position as IP Australia: it cannot be asked to assess, to some lesser standard, whether a patentee has contravened Part IV of the Competition and Consumer Act. Similarly in respect of concerns about the price at which access to patented genetic technologies is granted, this is also something which should be the subject of a legal judgement, and is properly a matter for consideration under Part IV of the Competition and Consumer Act. In those circumstances, compulsory licensing can only provide, at best, a secondary means of enforcement.

The disincentive referred to above may be reflected in the fact there have been so few applications to date (none successful). Whether or not that is so, the very lack of successful applications means that the compulsory licensing provisions in their current form provide little, if any, comfort that they can be relied upon to influence patent owners' conduct.

2 More efficient and effective means of promoting patient access to generic medicines

We note that the Commission itself has said that it, "*will consider whether it is more efficient and effective to use alternatives to compulsory licensing*" (Issues Paper, page 29). There are real impediments to getting generic medicines into the hands of patients as quickly and in the most affordable way possible, which impediments are not necessary for the purposes of the statutory monopoly held by patentees. However, compulsory licensing is an indirect, inefficient and ineffective means of addressing those impediments – as well as the specific concerns raised in the Commission's terms of reference in relation to genetic technologies. In the case of entities engaging in research into new genetic therapies, which is not within the scope of the research exemption in s119C of the Patents Act, the hurdles to establish a technology- or licensee-specific compulsory licence in respect of gene sequence patents may not ease the administrative burden on those entities.

Reforms to address evergreening and improve public access to cost-effective generics

Evergreening involves the extension of the patentee's statutory monopoly by way of further patents, obtained for purely strategic purposes, in respect of product features other than the new chemical entity the subject of the original patent and often of questionable validity. It defeats the objective of getting cost effective generic medicines into the hands of patients as quickly and in the most affordable way possible. In our members' experience, it is one of the main impediments to developing, manufacturing, marketing and selling more affordable generic versions of medicines which ought to no longer be subject to a statutory monopoly.

Compulsory licensing is simply not at all concerned with the practice of evergreening. The GMIA is developing a series of proposals for reform to Australian law to address the practice. These proposals are directed to the following issues in particular:

- The lack of incentives for generic companies to challenge the validity of pharmaceutical patents, given the high cost of litigation relative to market size
- The need to increase the threshold for the grant of interlocutory injunctions in respect of pharmaceutical patents
- The need for increased patent transparency for the purposes of the patent certification process under s26A and 26B of the Therapeutic Goods Act 1989 (Cth)
- The stifling effect of method of treatment patents and potential liability under s117 of the Patents Act on the marketing of generic products for non-patented uses
- The grant of extensions of term under Part 3 of the Patents Act in respect of formulation patents
- Omissions in s44BA of the Copyright Act 1968 (Cth) exempting product information and related documents from copyright infringement

No collecting agency

The relatively high expense involved in establishing and maintaining a collecting agency cannot be justified. The GMIA does not support it as an alternative to any of the suggestions made above.

The GMIA looks forward to the Commission's draft report.

Kind regards,

Kate Lynch
Chief Executive Officer
Generic Medicines Industry Association Pty Ltd