AUSFTA.

Submission No: 83

GMiA

Generic Medicines Industry Association Pty Ltd
ABN 19 096 009 540

PO BOX 12 Balmain NSW 2041
Telephone 02 9818 8033
Facsimile 02 9818 8565

RECEIVED
15 APR 2004
BY:.....

8 April 2004

Secretary
Joint Standing Committee on Treaties
Parliament House
CANBERRA ACT 2600

Dear Secretary

The Generic Medicines Industry Association (GMiA) is pleased to have this opportunity to comment on the Free Trade Agreement (FTA) between Australia and the United States of America.

For the information of Committee members, the members of the GMiA are Alphapharm, Arrow Pharmaceuticals, Douglas Pharmaceuticals Australia Ltd, Hexal Australia, Mayne and Sandoz Pty Ltd. Members employ around 3000 people, invest in research and development in the top tier of pharmaceutical companies in this country and export prescription medicines to about 50 countries.

The GMiA regards the proposed FTA as beneficial to the national economy with a range of benefits accruing over time.

However, in line with the comments by a number of sectors likely to be affected in some measure, the GMiA has some reservations about aspects of the proposed changes to intellectual property laws as they relate to the pharmaceutical industry.

Please note that we have made these reservations clear to Government and have been assured that there will be no delay to the entry of generics as a result of the FTA.

Our main focus is in relation to Article 17.10.5 . The essence of this paragraph is:

- The prevention responsibility – 17.10.5(a) and
- The notification requirement – 17.10.5(b)

The advent of the generic equivalents of branded pharmaceuticals has reduced the costs to both consumers and governments by introducing competition in a field where the large pharmaceutical companies rely on their patents to maintain their market share and prices of their products.

Article 17.10.5, if not implemented carefully, would enable these companies to further protect and in some cases extend patent life by various legal stratagems. As it is, Australian consumers and the PBS are disadvantaged by the extension of up to five years of existing 20 year patents.

Implementation of this Article, we understand, will be by way of amendment to the *Therapeutic Goods Administration Act 1989.*

Article 17.10.5(a)

The current wording of this paragraph requires that marketing of a generic equivalent must be prevented where the product or use is "claimed" in a patent.

As it stands today the courts decide if the patent is valid or infringed.

The GMiA perceives a number of practical problems with the proposed changes. First and foremost, it is not clear whether the Therapeutic Goods Administration (TGA) or other relevant authority, by this provision, is supposed to determine whether a product or use is *claimed* in a patent. Whether a product or use is claimed in a patent is not always clear from the terms of the patent itself and it is certainly not possible to identify in every case, whether such a claim is made. Currently a relevant court has been the body to determine whether a product, or its use, is in fact claimed in a patent. The Association's view is that a court should remain the body that determines matters of patent law.

Secondly, courts have sometimes overturned patents on the basis that they are wholly or partially invalid. Pharmaceutical patent disputes invariably involve questions of both infringement and validity and more often than not, the issue of validity (or lack thereof) determines the dispute. Therefore, the GMiA believes that to refuse the marketing of a product, simply because something is "claimed" in a patent, imposes a presumption of validity which is beyond anything found in the *Patents Act 1990* or applied by the courts.

Therefore, if generic manufacturers are forced to wait for otherwise invalid patents to lapse or are compelled to challenge for invalidity first, it is likely to delay rapid generic entry on to the PBS and drive up its cost to the taxpayers.

A literal interpretation of Article 17.10.5(a)(ii) would suggest that abuse of the system through the "evergreening" of patents will be further encouraged. Evergreening is the name that has been given to the process whereby patent holders, in order to extend their monopoly, are waiting until near the end of the life of the basic composition patent to progressively file a series of use patents.

Under this paragraph, if the product is claimed in a use patent, then marketing of a generic equivalent is prevented. This could lead to long delays or generic equivalents not reaching the market. It is vital that the current presumption allowing the marketing of generics is preserved because if it is not, it will undoubtedly lead to abuse of the system by the branded companies, as is the case in Canada.

I attach for your information a submission made by the Canadian Generic Pharmaceutical Association (CGPA) to the Canadian House of Commons Standing Committee on Industry, Science and Technology in June 2003 which was looking into the effect of the *Patented Medicines (Notice of Compliance) Regulations* in that country. As the CGPA states in the Executive Summary to its submission, "it is becoming virtually impossible to bring out a generic version of a drug in Canada, because recent case law in Canada has removed all effective limits on evergreening...Innovation is being replaced by litigation...".

Currently in Australia, once a Certificate of Registration has been issued by the TGA, it takes a minimum of ten weeks for a generic equivalent to be listed on the PBS - quite different from what could be if the FTA is not implemented carefully.

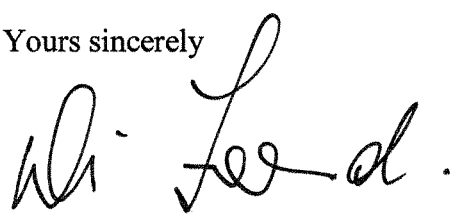
Article 17.10.5(b)

This paragraph provides for notification to the patent owner of the request for marketing approval. The GMiA is uncertain about this provision especially when should the patent owner be notified and by whom? Furthermore, we are unclear as to the rationale of the notification procedure, given that the marketing of a product during the patent term is not allowed unless the patent owner has consented or acquiesced to the approval.

In conclusion, the GMiA members fully respect the laws governing intellectual property however, they are concerned to ensure that "unfair" obstacles are not introduced into the current regulatory regime that will result in outcomes that will have an adverse effect on the PBS and the generic sector in Australia.

The GMiA believes that it is in the national interest for this Senate Select Committee, when reporting to the Parliament, to recommend that Article 17.10.5 is implemented in such a way that does not impact on the sustainability of the PBS or the viability of the generic pharmaceutical industry in Australia.

Yours sincerely



Di Ford
Executive Director