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Supplementary Submission on Pharmaceuticals and Intellectual Property: Select Committee on the Free Trade Agreement Between Australia and the United States of America

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To: Mr Brenton Holmes
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Introduction

The following supplementary submission is designed to cover certain arguments on the issue of intellectual property and pharmaceutical raised before the Committee on 6 July 2004 chiefly by Mr Stephen Deady, DFAT the Lead Negotiator. Much of those discussions focused on the proposed changes to the TGA as part of the US Free Trade Agreement Implementation Bill 2004. Those changes are set out in Schedule 7 Clause 5 and 6 of the *US Free Trade Agreement Implementation Bill (2004 (Cth).* They attempt to add a new s26A(1A) and s26 B. These changes do not eliminate the "evergreening" problems implicit in 17.10.4. If they did, it would only be a matter of time till the US used its leverage under AUSFTA Ch21 (the dispute resolution and cross retaliation mechanism) to push for further amendments that better satisfied its intentions. These US intentions are unequivocally to ensure that drug prices rise in Australia, allegedly to offset the high research and development costs that US consumers are bearing.

This is a factually inaccurate pharmaceutical company argument for which no sound data has ever been put forward and much good data has been shown to contradict. Yet, our Government is considering making major policy changes to core social justice components of our health system under such US pressure. The Australian negotiators have not explained what we gained for this massive trade off. Perhaps the most disappointing aspect of the testimony by the Australian negotiators before the Senate Committee on 6 July is the absence of any reference by them to public health and social justice concerns. There testimony has made clear that these were never given priority status by the Australian negotiators. Surely then another reason for our Senators to delay

passing the implementing legislation for the AUSFTA is to create the opportunity for fairer negotiations in which our negotiating team is required and adequately trained to put some store by the first principle of our National Medicines Policy, universal access to affordable essential medicines and Australia's capacity to assist in rectifying public health problems in our neighbouring regions.

Relationship of the new s26B TGA and 17.10.4 AUSFTA to Drug Patent Evergreening

17.10.4 (a) requires Australia to "provide measures in its marketing approval process" to "prevent" generic manufacturers relying on original safety and efficacy information from marketing a product or use of such where either is claimed in patent. 17.10.4 (b) then requires notification of such attempt to the original patent holder.

Mr Deady submitted to the Senate that it was some type of success for the Australian negotiators that the TGA was not required to do the notification (6 July 98). It seems and important issue whether any of the Australian negotiators had read the US Federal Trade Commission July 2002 Report *Generic Drug Entry Prior to Patent Expiration: An FTC Study*.

An example of drug patent "evergreening" from the US is the *Buspirone Antitrust Litigation* in which Bristol Myers attempted to "evergreen" its buspirone patent hours before it was due to expire with the generic versions already aboard trucks ready to be marketed. Though found to be frivolous, the regulatory authorities had no option under the paragraph IV provisions of the Hatch-Waxman legislation but to issue an automatic injunction against generic market entry for 30 months. The FTC Report *Generic Drug Entry Prior to Patent Expiration: An FTC Study* details numerous similar instances.

In Canada, the *Patented Medicines (Notice of Compliance) Regulations* 1993, modelled on the Hatch-Waxman provisions are making it "virtually impossible" to bring out a generic equivalent of a drug in that country. An largely unsuccessful example from Australia is provided by the High Court decision over 17 "evergreening" patent claims over the anti-ulcer medication omeprazole in *Aktiebolaget Hassle v Alphapharm* [2002] HCA 59 (12 December 2002).

The FTC Report *Generic Drug Entry Prior to Patent Expiration: An FTC Study* under the Chairmanship of Timothy Muris made the following as its first and primary recommendation:

> ***Permit only one automatic 30-month stay per drug product per Abbreviated New Drug Application (ANDA) to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant's ANDA.***

This recommendation has been warmly received by the US administration. The FTC Report *Generic Drug Entry Prior to Patent Expiration: An FTC Study* details the 180 day exclusive marketing granted the first generic entrant as a compensation for notification. It also sets out statistics on how drug companies have been using these provisions to threaten and initiation that delays generic manufacturing entry. And these are US generic companies with much greater legal resources on tap to fight such battles that the struggling Australian generic industry. So the question raised here is: if these reforms and balances are part of the US scene, how is it that have been excluded from 17.10.4. Were our negotiators unaware of this issue and its importance to drug prices under the PBS (low PBS prices are crucially dependent on rapid entry of cheap generic drugs).

In his oral testimony before the Committee on 6 July 2004 Ms Harmer admitted that this whole notification process under 17.10.4 and s 26B is entirely new (6 July 82). What the new process in s26B does is to create a situation where generics will be inhibited in making commercial decisions about whether to seek to enter a market near the expiry of a "blockbuster" (high sales volume) PBS listed drug. The inhibiting factors now will be:

1) the expense of doing an exhaustive search for both product and process patents, many of which may be complicated by spurious "evergreening" patents design to prolong monopoly rights at the expiry of the compound patent by "claims" to patent rights over method of delivery etc. Companies do this already of course, but if foreign trends are anything to go by patent offices in Australia will soon witness an inrush of complex patent "claims" making the task much more difficult.
2) The risk of filing a misleading certificate: this will expose the intended generic to a criminal penalty (under s26A) and invalidate its marketing approval. Effectively

this now prevents a generic manufacturer banking on a period of profit making while it held the patent until the spurious "evergreening" patent claims could be worked out in the Federal Court. The fact that s26 (1A) allows listing with the TGA inquiring into the correctness of the certificate, does not solve the problem that if the original patent holder subsequently challenges the certificate as misleading because it fails to mention a "claimed" patent then the generic manufacturer will have committed a crime and the marketing approval would be invalid.

3) By Article 4 of the Trade and Intellectual Property (TRIPS) Convention, the increased IPRs granted under a bilateral treaty such as the AUSFTA, must "immediately and unconditionally" be granted to all other members of the World Trade Organisation. Multinationals from the vast drug industries of Europe and Japan, as well as the US will have access to the process of threatened litigation stalling generic entry established under 17.10.4.

- Under Article 17.10.4 there are no stated restrictions on the number or duration of such patent "claims." The Australian Generic Medicines Industry Association (GMiA) submitted to the Senate AUSFTA hearings that the word "prevent" in Article 17.10.4 creates a presumption of patent validity in strict sense requiring permitting automatic injunctions on marketing approval for mere allegations of patent infringement. GMiA stated that if the US pushes for this interpretation of 17.10.4 this would make it increasingly impossible to bring out the cheap generic drugs that keep our PBS prices down.
- 17.10.4 breaches s 2102 (4) of the Trade Act 2002 (US) by denying respect for the flexibility to "use to the full" the public health exceptions of the TRIPs Doha Declaration on IPR's.

Specific Terms of s26B

26B Certificates required in relation to patents

Section 26 B(1) The certificate required by this subsection is either:

(a) a certificate to the effect that the applicant is not marketing, and does 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; or

(b) a certificate to the effect that:

(i) a patent has been granted in relation to the therapeutic goods; and

(ii) the applicant proposes to market the therapeutic goods before the end of the term of the patent; and

(iii) the applicant has given the patentee notice of the application for registration or listing of the therapeutic goods under section 23.

The certificate must be signed by, or on behalf of, the applicant and must be in a form approved by the Secretary.

(2) A person is guilty of an offence if:

(a) the person gives a certificate required under subsection (1); and

(b) the certificate is false or misleading in a material particular.

Maximum penalty: 1,000 penalty units.

(3) For the purposes of this section, a patent is taken to have been granted in relation to therapeutic goods if marketing the goods without the authority of the patentee would constitute an infringement of the patent.

(4) In this section:

patent has the same meaning as in the *Patents Act 1990*.

The key words here are "taken to have been." The difference between using these words rather than "is" highlights that the section is concerned with what the generic manufacturer can should presume. The standard is considerably less than would have been the case if "granted" was defined as "issued or even lodged" in the patent office.

Conclusion

The problems of 17.10.4 will never be solved by any combination of words in Australian domestic legislation. Any such domestic statutory construction will become a battleground for lawyers of the pharmaceutical companies with the ultimate reference point being conformity with the words of 17.10.4 on pain of trade sanctions.

We are entitled to ask the US to amend this section so it reflects standards recommended by its own Federal Trade Commission report *Generic Drug Entry Prior to Patent Expiration: An FTC Study*.

At page 69 of the Senate Committee hearings the Chair cites the Supplementary Note to Dr Dee's Report which notes that only with this AUSFTA in place will the drug companies be delivered the crucial means of ensuring cheaper generic drugs do not enter

the market. I agree with Dr Dee that the main threat to the PBS lies in the patent provision, particularly 17.10.4.

Mr Deady (6 July 70) repeatedly claims that all 17.10.4 does is prevent market approval and market entry while a patent is in force. It is as if he has never read the US Federal Trade Commission Report mentioned above. The issue Mr Deady fails to address is WHAT TYPE OF PATENTS prevent such market approval, HOW MANY PATENTS per drug and FOR HOW LONG they prevent market entry. Mr Deady never answers the question of why patents that might ultimately be found spurious and speculative by the Federal Court should now for the first time be allowed to interfere with approval under the TGA.