



Sent by email: patentsbill@med.govt.nz

13th December 2007

Doha TRIPs Protocol Submissions
Attention: Mr Warren Hassett
Competition, Trade and Investment Branch
Ministry of Economic Development
PO Box 1473
WELLINGTON

GlaxoSmithKline NZ Limited
8th Floor AMP Centre
Cnr Albert & Customs Streets
Private Bag 106600, Downtown
Auckland 1143
New Zealand

Tel. +64 9 367 2900
Fax. +64 9 367 2910

www.gsk.co.nz

Dear Mr Hassett,

SUBJECT: Consultation on Acceptance of the Protocol Amending the TRIPs Agreement to Implement the Doha Declaration on TRIPs and Public Health

Thank you for the opportunity to submit comments on this proposal. Specific answers to questions posed under Section 4 of the Consultation Document are covered in Attachment 1 of this letter. We would like to submit four additional comments that did not fit into the answers to the questions posed in the Document. The four additional comments are as follows:

1. As noted in paragraph 68, New Zealand's law should ensure that when the product is subject to patents in the country of importation, the importing country must have granted or must intend to grant a compulsory licence. In this regard, it should be noted that the importing country is required to notify the TRIPs Council that it has granted or intends to grant a compulsory licence to import. New Zealand's law could usefully refer to the need for such notification to have been made as a precondition to application for a compulsory licence to export. The Protocol also requires that the importing country must specify in its notification to the TRIPs Council the quantities of products it needs. Any compulsory licence to export should be limited to those specified quantities.
2. We agree with the recommendation in paragraph 75 that, in order to reduce the risk of diversion, there should be a requirement that products are distinguished – by packaging and/or colouring and/or shape – from any products distributed by the patent owner (or its licensees) unless this is not feasible or is likely to have a significant impact on price. The burden should be on the licensee to demonstrate in any particular case that such distinctions are not feasible or will have a significant impact on price. We also believe that the licence should contain a term requiring the licensee to provide evidence of delivery to the importing country.

- 3 Paragraph 76 refers to the need to consider what penalties should be provided for in violation of licence terms. We suggest that the rules to be applied should be the same as for any other compulsory licence, subject to an explicit rule that any violation of the terms as to differential packaging etc should give the patent owner a right to terminate.
- 4 We note that the consultation makes no reference to how the applicant for a compulsory license will demonstrate the safety and efficacy of the product. We suggest that rules are needed to ensure that any product to be exported is required to meet the same safety and efficacy standards as it would if it were to be marketed in New Zealand. However, any regulatory authorisation to export must explicitly ensure that it is not an authorisation to place the product on the market in New Zealand.

If you wish to discuss any parts of our submission please contact me.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'M. Bryant', written in a cursive style.

Michael Bryant
Director, Commercial Operations
GlaxoSmithKline New Zealand Ltd

ATTACHMENT 1

Consultation on Acceptance of the Protocol Amending the TRIPs Agreement to Implement the Doha Declaration on TRIPs and Public Health

Acceptance of the Protocol

Given the WTO membership's unanimous support for the Doha Declaration and New Zealand's role in drafting the waiver that later became the Protocol, there appears to be no reason why New Zealand should not accept the Protocol.

1. Do you agree with this proposition?

Yes.

2. If your answer to this question is no, what benefits would New Zealand gain (or what disadvantages would be avoided) by non-acceptance?

New Zealand as an Exporting Member

Acceptance of the Protocol by New Zealand without legislative amendment to become an Exporting Member would appear to render acceptance meaningless. Acceptance without such amendments does not seem a viable option.

1. Do you disagree with this proposition?

No, but note that the consultation document (paragraph 31) talks of use of the provisions of the Protocol potentially being of “commercial benefit to New Zealand pharmaceutical companies”. It is quite clear from the Chairman’s Statement made in 2003 and repeated at the time of the WTO General Council Decision to propose the TRIPs Amendment that the system is to be used to protect public health and “not be an instrument to pursue industrial or commercial objectives”. This principle should condition decisions that are made as to how to implement the amendment in New Zealand’s national law

2. If your answer to the preceding question is yes, why do you disagree?

Legislative Changes

If New Zealand accepts the Protocol and becomes an exporting Member, legislative changes will be required. The following questions deal with issues surrounding these changes. In answering these questions, submitters should consider the likely impact on applicants for compulsory licenses of the options suggested.

Purpose of the License

1. Should New Zealand's legislation specifically list the public health problems for which licenses can be granted under the Protocol?
2. If you think New Zealand's legislation should list the public health problems, which ones should be specified?
3. If you think that New Zealand's legislation should not list the public health problems, what broader definition of "public health problem" could be used?

Products for Which a License Should be Granted

1. The Protocol contains a definition of "pharmaceutical product". Should this definition be adopted "as is" by New Zealand?
2. If your answer to the preceding question is "no", and bearing in mind that any alternative definition may differ from, but must not be inconsistent with the definition in the Protocol, what alternative definition should be adopted?

Eligible Countries of Importation

1. Should non-WTO Members be included as eligible countries of importation?
2. If your answer to this question is "no", why should non-WTO Member countries be excluded?
3. Should any or all of the countries that have indicated that they will not use the Protocol as importing Members be excluded as eligible countries of importation?

Yes.

4. If your answer to this question is "yes", why?

If New Zealand's law does not contain these prohibitions, it is not clear whether or how exports to countries which have undertaken not to import could be prevented. New Zealand's laws should not facilitate the breach by other countries of their international commitments. Further, by inserting such a prohibition, New Zealand will be demonstrating its political support for the agreement that was reached at the WTO.

Voluntary Licenses

The requirement, in s46 of the Patents Act 1953, for applicants for compulsory licenses to take "all reasonable steps" to obtain a voluntary license may be stricter than the "make efforts" requirement of Article 31(b) of the TRIPS Agreement.

1. Should New Zealand amend its legislation to require applicants for compulsory licenses to "make efforts" to obtain a voluntary license?

No.

2. If your answer to this question is "no", why?

It is always preferable for issues such as these to be dealt with by agreement between the parties and to reduce the obligations to seek agreement is inherently undesirable. Further, the Article 31(b) TRIPS obligation refers to the need for the applicant for a licence to have offered reasonable terms and conditions and for the attempts to have been made over a reasonable period of time. These conditions are, in essence, a restatement of the existing requirement in New Zealand's law to take "all reasonable steps".