

Ministry of **Economic
Development**



M a n a t ū Ō h a n g a

**Acceptance of the Protocol
Amending the TRIPS Agreement to
Implement the Doha Declaration on
TRIPS and Public Health**

A Discussion Document

October 2007

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Information for Persons Making Submissions

Submissions in relation to this discussion paper are invited from any person interested in the issues relating to the Doha Declaration on the TRIPS Agreement and Public Health, and the resulting Protocol to amend the TRIPS Agreement.

Submissions will be considered in the development of recommendations to the government on these issues, and any resulting legislative amendments.

To aid respondents in making submissions, questions for discussion appear at the end of this paper.

Submissions should be sent to:

Doha TRIPS Protocol Submissions
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PO Box 1473
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E-mailed submissions are also welcome (preferably in Word or PDF format) and should be sent to:

patentsbill@med.govt.nz

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Submissions may be subject to disclosure under the Official Information Act 1982. Persons making submissions that include commercially or otherwise sensitive material that they wish the Ministry to withhold under that Act should clearly identify the relevant information and the applicable grounds under which the Ministry could withhold the information.

The closing date for submissions is **14 December 2007**

1. Introduction

1. The purpose of this consultation document is to obtain the views of the public on whether New Zealand should accept a Protocol amending the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (“the TRIPS Agreement”)¹. This Protocol, which implements the Doha Declaration on the TRIPS Agreement and Public Health was agreed to in December 2005.

2. The Doha Declaration deals with the granting of compulsory licenses for the production of patented pharmaceuticals for export to countries which require such pharmaceuticals to deal with public health problems, but have insufficient or no capacity to produce them themselves.

3. This document sets out the issues and considers legislative amendments necessary to give effect to the Protocol if New Zealand accepts it, and seeks public input on these issues.

1.1 Background

1.1.1 Patents and the TRIPS Agreement

4. Members of the World Trade Organisation (WTO) must provide minimum standards of patent protection. These standards are set out in Articles 27 – 34 of the TRIPS Agreement. Among other requirements, the TRIPS Agreement requires all WTO Members to grant patents for any invention, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application². In particular, this requires WTO Members to grant patents for pharmaceuticals.

5. The grant of a patent for an invention gives the patent owner the exclusive right to exploit the invention, for a maximum period of twenty years. That is, the patent owner can prevent any other person from exploiting the invention without the patent owner’s permission.

1.1.2 Compulsory Licenses and the TRIPS Agreement

6. A compulsory license allows a party to exploit a patented invention without the permission of the patent owner. Parties seeking compulsory licenses must usually apply to a court or a government agency (depending on the country). Holders of compulsory licenses are required to pay the patent owner “adequate remuneration”, which may be decided by negotiation, or if this fails, it is decided by a court or other agency. New Zealand’s current legislation requires applications for compulsory licenses to be made to the High Court.

7. Compulsory licenses are usually granted for activities that are considered to be abuse of the patent right. These could include the following:

¹ The text of the TRIPS Agreement can be found here: http://www.wto.int/english/docs_e/legal_e/27-trips.pdf

² See Article 27.1.

- a refusal by the patent owner to supply or license the invention in reasonable quantities and at a reasonable price;
- refusal to supply the invention to the market at all;
- using the patent in a manner determined to be an anti-competitive practice.

8. Article 31 of the TRIPS agreement permits signatories to issue compulsory licenses over patents, and sets out the conditions under which compulsory licenses can be granted. One of the conditions, set out in Article 31(f), is that any use of the invention authorised by the compulsory license:

“shall be predominantly for the supply of the domestic market of the [WTO] Member authorising the use”.

The provisions of Article 31(f) can be waived if the license is issued to deal with a practice determined to be anti-competitive (see Article 31(k)).

9. The effect of Article 31(f) is that products produced under a compulsory license can only be produced for, and sold predominantly within the country that granted the license. The license cannot authorise production for export as this would breach Article 31(f).

1.1.3 Patented Pharmaceuticals and the TRIPS Agreement

10. As noted earlier, the TRIPS Agreement requires all WTO Members to grant patents for, *inter alia*, pharmaceuticals. This, together with the provisions of Article 31(f) (see above), has been identified as a potential problem for developing countries facing public health problems, such as, for example an epidemic of a serious disease such as AIDS, where:

- one or more patented pharmaceuticals are required to deal with the problem; and
- the country is unable to obtain sufficient supplies of the pharmaceutical, at a reasonable price, from the patent owner; and
- the country has no or insufficient manufacturing capacity for the pharmaceutical concerned.

11. In these circumstances, a developing country could issue a compulsory license to produce the pharmaceutical. But such a license would, by itself, have little effect, as no-one within the country would be in a position to exploit it. Since patent rights are granted on a national basis, a compulsory licence issued by one country has no effect in another.

12. One way around this would be for another country which does possess sufficient manufacturing capacity to issue a compulsory license. However, since the pharmaceuticals produced under the license would not be predominantly for the supply of the market of the country issuing the license, such a license would be in breach of Article 31(f).

1.2 The Doha Declaration

13. In an effort to deal with the problem mentioned above, the fourth WTO Ministerial Conference held at Doha in November 2001 adopted a Declaration on the TRIPS Agreement and Public Health (“the Doha Declaration”). The text of this declaration can be found at http://www.wto.int/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

14. This declaration (in paragraph 6) recognised that:

“WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement [and instructed] the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”

15. The Declaration, in particular the instruction in paragraph 6, was implemented by a decision of the WTO General Council on 30 August 2003. The text of this decision can be found at: http://www.wto.int/english/tratop_e/trips_e/implem_para6_e.htm. As a result of this decision, the requirements of Article 31(f) of the TRIPS Agreement were waived, to the extent WTO Members could issue compulsory licenses for the production and export of patented pharmaceuticals to “eligible importing Members” (defined in paragraph 2 of the decision). The 2003 decision also set out a number of other conditions that would need to be satisfied by Members making use of the system that it had established.

16. Eligible “importing Members” include any least developed country, and any other country that has notified the TRIPS Council of its intention to use the waiver as an importing Member. A number of developed countries, including New Zealand, have indicated that they will not use the waiver as an importing Member³. This indication has been recorded in the Protocol and will become part of an annex to the TRIPS Agreement.

17. The 2003 decision was an interim measure that did not amend the TRIPS Agreement. It merely established a waiver from the requirements of Article 31(f) of the Agreement. It was further agreed (in paragraph 10 of the 2003 decision) that Members would not challenge any measures taken by another WTO Member in conformance with the waiver established by the decision. The General Council also agreed to begin work on a Protocol amending the TRIPS Agreement to replace the waiver.

18. This Protocol was agreed to by a decision of the General Council on 6 December 2005. The Protocol adds an additional Article, 31*bis*, to the TRIPS Agreement which creates an exception to Article 31(f). This exception allows Members to issue compulsory licenses for the production and export of pharmaceuticals to an eligible importing Member. The text of the decision, including the text of the protocol and new Article 31*bis* can be found at: http://www.wto.int/english/tratop_e/trips_e/wtl641_e.htm.

19. The proposed Protocol to the TRIPS Agreement is open for acceptance by WTO Members until 1 December 2007 or any later date that may be agreed upon by the WTO,

³ The other countries are: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

and will take effect when two thirds of Members have accepted it. In the meantime the waiver established by the 2003 decision will remain in effect.

20. As of October 2007, ten WTO Members have accepted the Protocol. These Members are: the United States, Switzerland, El Salvador, the Republic of Korea, Norway, India the Philippines and Israel, Japan and Australia. A number of other Members, including Canada, Kenya and the EU have begun their domestic processes for formal acceptance. Most of these countries have decided to amend their patents legislation prior to accepting the protocol. Legislative amendments will be required if a country is to be able to use the provisions of the Protocol as an importing or exporting Member.

21. This protocol amending TRIPS Agreement will make it easier for countries with insufficient or no manufacturing capacity for pharmaceuticals to gain access to essential pharmaceuticals at a price they can afford. It will be of particular value to least developed and developing countries facing significant public health problems. Under the TRIPS Agreement as originally drafted, such countries might encounter difficulties in obtaining sufficient quantities of the pharmaceuticals they need at prices they can afford. As of August 2007 one country, Rwanda, has notified its intent to use the waiver established by the Doha Declaration to import pharmaceuticals produced under a compulsory license.

2. The Issues

22. This section briefly sets out the issues surrounding acceptance by New Zealand of the Protocol amending the TRIPS Agreement so as to implement the Doha Declaration. This discussion will focus on the following points:

- The effect of accepting the Protocol on New Zealand's TRIPS Obligations;
- Potential benefits and costs to New Zealand in accepting the Protocol;
- Potential benefits and costs to New Zealand of not accepting the Protocol.

2.1 TRIPS Obligations Under the Protocol

23. Under the Protocol Members are required to take reasonable measures to prevent the importation and sale of products produced under the provisions of the protocol, where these products were not produced for sale in the Member. This is to ensure that products are not "diverted" from the markets they were originally produced for. If diversion was not prevented, the owner of the patent over the products in the Member concerned could be unfairly disadvantaged.

24. The protocol makes it clear that Members can achieve this obligation using measures already required to be available under other parts of the TRIPS Agreement. As New Zealand's legislation already contains such measures, it is expected that no further legislation will be required. Measures currently available include the border protection provisions in the Copyright and Trade Marks Acts. In addition, patent owners can use the infringement provisions in the Patents Act to take action against any products "diverted" from their proper markets.

25. Importing Members are also obliged to prevent the re-export of any products imported under the Protocol. However, like all other developed Members, New Zealand has indicated to the WTO that it will not use the Protocol as an importing Member.

26. The Protocol recognises that eligible importing Members who are also developing countries may have difficulty in implementing the provisions relating to the prevention of diversion. In such cases there is an obligation on developed country Members to provide technical and financial assistance to facilitate implementation in the developing country, but only on request and under mutually agreed terms and conditions.

27. Technically, acceptance of the Protocol would not, of itself, require New Zealand to make any legislative amendments. As described below, however, acceptance without making any legislative amendments would render acceptance meaningless, and is not considered a viable option.

2.2 Benefits and Costs of Acceptance

28. The advantages of acceptance are likely to include the following:

- acceptance would show that New Zealand is a "good international citizen";
 - acceptance would allow New Zealand to use the provisions of the amendment as an exporting Member.
-

29. The intention of the Protocol is to allow WTO Members to issue compulsory licenses for the production for export of pharmaceuticals to developing countries which are suffering public health problems, and have no or insufficient pharmaceutical manufacturing capacity. It is important that WTO Members, particularly poorer countries, have access to the pharmaceuticals they need to deal with public health issues, at prices they can afford, and that they can make full use of the flexibilities available under the TRIPS Agreement. By accepting the amendment to the TRIPS Agreement, New Zealand would be affirming its commitment to this principle and confirming New Zealand as a “good international citizen”.

30. Following the 2005 Decision, the then Trade Negotiations Minister, Hon Jim Sutton, applauded the decision. In his press statement, the Minister observed that “New Zealand has strongly supported efforts to reach a permanent solution” and described the decision as sending “a strong message of commitment to the development objectives of this trade round.” Welcoming the legal certainty this decision offered following the August 2003 political decision, Mr Sutton commented that “a consensus decision carries special moral force.”

31. For the Protocol to achieve its purpose of assisting developing countries to get access to medicines necessary for public health purposes, countries that can produce pharmaceuticals at affordable prices need to be able to export them. This provides New Zealand with an opportunity to use the provisions of the Protocol as an exporting country. This could be of commercial benefit to New Zealand pharmaceutical manufacturers. They would be in a position to offer to produce pharmaceuticals under compulsory licenses issued in accordance with the Protocol.

32. There appear to be no obvious disadvantages of acceptance. If it were decided that New Zealand should accept the Protocol as an exporting country, some legislative amendment would be required, but no other government action would be needed.

33. There would be no obligation on New Zealand to manufacture pharmaceuticals for export under a compulsory license granted under the Protocol. Any decision to manufacture pharmaceuticals in New Zealand under such a license would be a commercial decision made by the manufacturers concerned.

2.3 Non-Acceptance

34. There would appear to be no particular advantages to New Zealand in not accepting the Protocol.

35. There are, however, possible disadvantages to New Zealand should we not accept the Protocol. In December 2005 the WTO unanimously endorsed the Protocol and New Zealand played an active role in negotiating the waiver which forms the basis of the Protocol. In light of this, non-acceptance might suggest that New Zealand had negotiated in bad faith. In addition, non-acceptance would prevent local generic pharmaceutical firms from using the regime established by the Protocol as an opportunity to produce pharmaceuticals for export.

3. New Zealand as an Exporting Member

3.1 Possible Legislative Amendments

36. As mentioned earlier, New Zealand could, technically, accept the Protocol without making any amendments to its existing legislation. Such amendments would be necessary if New Zealand is to be able to use the Protocol as an exporting member.

37. There does not seem to be any advantage to New Zealand in accepting the Protocol without legislative amendment to enable New Zealand to become an exporting Member. New Zealand has some pharmaceutical manufacturing capacity, and so could export under the Protocol. There does not seem to be any advantage to New Zealand in accepting the Protocol without legislative amendment to enable New Zealand to become an exporting Member.

38. On the other hand, acceptance without legislative amendment could have the same disadvantages as not accepting the Protocol, as set out in paragraph 35 and might suggest a lack of commitment to the principles behind the Protocol by New Zealand. Further, New Zealand has a general policy that, prior to taking on any international commitments, our legislation is amended to give effect to those commitments, even where the commitments do not oblige New Zealand to change its legislation. On this basis, acceptance of the Protocol without legislative amendment is not considered to be a viable option.

39. If New Zealand is to use the Protocol as an exporting Member, it will be necessary to amend New Zealand's patent legislation, the Patents Act 1953. This Act has recently been reviewed, and a draft Patents Bill to replace the Patents Act 1953 is expected to be introduced to Parliament before the end of 2007.

40. The following discussion is directed towards the nature of amendments required if New Zealand is to export under the Protocol. Since New Zealand has indicated that it does not intend to use the Protocol as an importing Member legislative amendments to enable this will not be considered.

3.2 Current Compulsory License Provisions

41. Section 46 of the Patents Act 1953 sets out the conditions for granting a compulsory license in New Zealand. Section 46(4)(c) states that a compulsory license issued under s46 is to be limited to the supply of the patented invention "predominantly in New Zealand". This would not allow the production, primarily for export, of any patented product for which a compulsory license was issued. The proposed Patents Bill does not make any changes to the compulsory license provisions contained in the Patents Act 1953.

42. The Protocol also sets out (in the annex to the Amendment to the TRIPS Agreement) the terms under which an exporting Member may grant a compulsory license in accordance with Article 31 *bis*. Section 46 does not contain these terms. Suitable amendments to the compulsory license provisions will be needed if New Zealand is to be able to use the Protocol as an exporting Member.

43. This raises the question of the nature of the amendments that might be required or desirable. In particular, consideration will need to be given to the level of prescription and

detail that might be required. In other countries that have amended their compulsory license provisions to accord with the Protocol, the level of detail and prescriptiveness varies considerably. This paper considers what level would be appropriate for New Zealand.

3.3 What Amendments would be Required?

3.3.1 Other Countries

44. A number of other countries have amended their legislation to meet the requirements of the Protocol as an exporting Member (although some have yet to formally accept the Protocol). The level of prescriptiveness and detail of the amendments varies from country to country, and appears to be influenced by the state of the local pharmaceutical manufacturing industry.

45. Countries with significant pharmaceutical manufacturing industries, such as the EU and Canada, have enacted quite prescriptive regimes. Other countries, such as Norway, with more modest pharmaceutical industries have enacted relatively simple regimes. New Zealand has a relatively small pharmaceutical industry mainly involved in producing “generic” pharmaceuticals (that is, pharmaceuticals for which the patents have expired). In light of this, a relatively simple regime may be the most appropriate for New Zealand, rather than a more detailed framework as adopted by countries with large pharmaceutical industries.

3.3.2 Issues to be considered

46. Any amendments to New Zealand’s patent legislation will need to address at least the following issues:

- The purpose of any compulsory license issued;
- Products for which a license may be granted;
- The conditions under which a license may be granted;

3.3.2.1 Purpose of the License

47. This issue deals with the circumstances under which a license may be issued. The Protocol, in its definition of “pharmaceutical product” refers to public health problems as recognised in paragraph 1 of the 2001 Doha Declaration on the TRIPS Agreement and Public Health. Paragraph 1 states:

“We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”

Comment

48. This definition might be considered a little restrictive. If New Zealand were to adopt it, there may be a risk that New Zealand may not be able to apply it to assist with access to medicines for a public health issue that may arise in the future and does not fall within the

list of health issues in listed in paragraph 1 of the Doha Declaration⁴. A less prescriptive definition may avoid this problem. For example, Norway's legislation refers to a "State's current need for the product for health purposes, as described in the notification" (The "notification" refers to the importing Member's notification to the TRIPS Council to import pharmaceuticals that have been produced under compulsory licence for a particular public health reason).

3.3.2.2 Products for which a license may be granted

49. The Protocol contains (in the annex to new Article 31*bis*) a definition of "pharmaceutical product":

' "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included'

50. The Norwegian legislation adopts this definition⁵. Canada does not have a single definition of "pharmaceutical product", instead an annex to its legislation lists particular products or processes that may be subject to the compulsory licensing scheme. The Swiss legislation does not have a specific definition, but an explanatory note states:

"Any medicine, active ingredient, diagnostic kit or vaccine which is patented or produced on the basis of a patented process and which is necessary to remedy public health problems such as HIV/AIDS, tuberculosis, malaria or other epidemics in the country of importation may be the object of a compulsory license. As far as all preconditions for a compulsory licence are met, it is important that such licenses are also available for vaccines, since they allow pandemics to be effectively prevented and combated. Therefore, it is suggested to interpret the Decision of 30 August 2003 broadly and explicitly include vaccines in the scope of the compulsory licensing regime of Article 40d of the draft Patent Act."

Comment

51. The Canadian approach requires regular updating and maintenance as products on the market change and are updated. This approach may not be appropriate for New Zealand given the small size of our pharmaceutical industry. There would be an additional problem of deciding what products or processes to place on the list. This is likely to take time and expend considerable resources.

52. Merely adopting the definition in the Protocol may, however, be restrictive. Switzerland's reference to vaccines may suggest some doubt as to whether the Protocol's definition includes vaccines. It would seem desirable to include vaccines as they can be used to prevent or combat pandemics. On this basis, a definition along the lines of that suggested for Switzerland may be more appropriate for New Zealand, rather than simply adopting the Protocol definition.

⁴ HIV/AIDS, tuberculosis, malaria and other epidemics.

⁵ See Section 101 of Norway's Patents Act.

3.3.2.3 Eligible Importing Countries

53. The Protocol defines an eligible importing Member as:

“eligible importing Member” means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex (“system”) as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

54. The following questions arise in deciding how New Zealand should define an “eligible importing Member”:

- Should any countries be specifically excluded?
- Should eligible importing countries be required to meet any conditions additional to those set out in the protocol?
- How should non-WTO Members be dealt with?

55. Some countries, for example, Switzerland, have, in their domestic legislation, chosen to exclude those countries that have indicated to the TRIPS Council that they will not use the provisions of the Protocol as an importing nation. This exclusion is not required by the Protocol.

56. Canada’s legislation divides WTO Members into different categories and specifies conditions according to the category the importing country belongs to. These are set out in “country schedules” which would need to be amended as circumstances change. Other countries have not followed this approach, and it is not required by the Protocol.

57. The Protocol makes no provision for non-WTO Members, but does not prohibit its application to non-Members. To date all countries that have amended their legislation to accord with the Protocol have provided for non-WTO Members to be considered as eligible importing states.

Comment

58. In accepting the Protocol, New Zealand would be bound to accept the requirements for eligible importing countries. There seems to be no compelling reason for going beyond these requirements, either by excluding some countries or by setting additional conditions. By simply adopting the Protocol’s definition, New Zealand would retain the flexibility to decide a country’s eligibility, as circumstances demand.

59. There also appears to be no reason to exclude non-WTO Members, particularly as such Members are likely to be poorer countries with little or no pharmaceutical manufacturing capacity. Since the purpose of the Protocol is to promote better access to medicines, it would seem unjust to exclude some poorer countries from its benefits merely because they are not Members of the WTO. Most Pacific Island nations are not Members of the WTO, and given New Zealand’s responsibilities to the Pacific region, and its close

relationships with some Pacific Island countries, it would seem preferable to include non-WTO Members in any New Zealand legislation implementing the Protocol.

3.3.2.4 Conditions for granting a license

60. The Protocol only amends Article 31(f) of the TRIPS Agreement, and does not change the other requirements for granting a compulsory license. It does, however, introduce a number of additional requirements.

Voluntary license to be sought from patent owner

61. TRIPS Article 31(b) requires that, before a compulsory license is sought, efforts must be made to obtain authorisation from the patent owner to use the patented invention on reasonable terms and conditions and that such efforts have not been successful within a reasonable period of time.

62. Section 46(7) of the Patents Act 1953 requires the person applying for a compulsory license to first have taken “all reasonable steps” to obtain a license or a license from the patent owner. While this is compliant with TRIPS, however, the “all reasonable steps” requirement may be rather more onerous than the “make efforts” requirement of TRIPS. Further, section 46 does not make any reference to “a reasonable time”.

63. Article 31(b) of TRIPS allows Members to waive the requirement to seek a voluntary license “in the case of a national emergency or other circumstances of extreme urgency”. This waiver is not present in s46, although provisions along these lines appear in s58, which deals with Crown use of a patented invention during an emergency. If this waiver is invoked, the patent owner must be informed as soon as reasonably possible.

Comment

64. The requirement in s46, for an applicant for a compulsory license to have taken “all reasonable steps” to obtain a voluntary license may be a higher standard than the “make efforts” requirement of TRIPS. Given the humanitarian objectives of the Protocol, it may be appropriate to adopt the TRIPS standard, at least for compulsory licenses granted under the terms of the Protocol.

65. There is also the question of what constitutes a “reasonable period of time”. This, like “reasonable terms and conditions” is likely to depend on the circumstances of each particular case and it would seem appropriate for the authority issuing the license to determine.

66. New Zealand’s current compulsory license provisions (excluding those for “Crown Use”) do not contain a waiver of the requirement to seek voluntary licenses in cases of national emergency or other similar circumstances. Countries seeking compulsory licenses under the Protocol may well do so to deal with an emergency situation such as an epidemic or natural disaster in the importing country. Under such circumstances it would seem unreasonable, and at odds with the humanitarian objectives of the Protocol, not to waive the requirement to seek a voluntary license. On this basis, New Zealand should consider introducing such a waiver.

Importing country must grant or intend to grant a compulsory license

67. The Protocol requires that if the products for which a compulsory license is sought are protected by a patent in the country of importation, the importing country, must, of course have granted or intend to grant a compulsory license. The TRIPS Council must be notified of this.

Comment

68. It would be in keeping with the Protocol for New Zealand's legislation to require that, before a compulsory license was granted under the Protocol, the importing country must have granted or intend to grant a compulsory license. This would, of course, only apply if the pharmaceutical concerned was protected by a patent in the importing country. In the event that a pharmaceutical is not protected in the importing country, only the exporting Member would be required to issue a compulsory licence.

Limits on production

69. The Protocol (in paragraph 2(b)(i) of the Annex) states that:

“only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;”

The Protocol does not specify how the “amount necessary” should be determined. This is left up to individual Members to decide.

Comment

70. There would seem to be no reason for New Zealand's legislation to prescribe how the “amount necessary” is to be determined. There will be a number of factors that will need to be taken into account, such as the nature and scope of the health problem being addressed, or the amount of product being manufactured under other compulsory licenses in New Zealand or other countries. These factors are probably best left to the license granting authority to decide, as this will enable the circumstances of individual cases to be taken into account.

3.3.2.5 Remuneration

71. There is a requirement in Article 31(h) that, if a compulsory license is granted, “adequate remuneration” be paid to the patent owner, taking into account the circumstances of the case and the economic value of the license. Article 31(h) does not define what is meant by “adequate”.

72. Section 46(6) of the Patents Act 1953 requires a compulsory licensee to pay the patent owner such remuneration as may be agreed between them. In the event that agreement cannot be reached, the remuneration is set by the Court.

Comment

73. New Zealand's current legislation is compliant with Article 31(h) and there should be no need to go further.

3.3.2.6 Identification of products produced under the license

74. The Protocol specifies that products to be produced under the license must be clearly identified as such through appropriate labelling or marking. There is a recommendation that the products “should” be distinguished by special packaging and/or special colouring or shaping provided that this does not have a major impact on the price. The purpose of this requirement is to make it easier to identify products that have been diverted from the markets they were produced for, so as to protect the legitimate interests of patent owners.

Comment

75. At the very least, the mandatory requirement to clearly identify such products through labelling or marking should be contained in New Zealand’s legislation. The recommendation regarding packaging, colouring or shaping is not mandatory, but it may be worthwhile for New Zealand to implement this as a legislative requirement. Norway and Switzerland follow this approach in their legislation.

3.3.2.7 Penalties for Violations of License Conditions

76. Another issue that will need to be considered is what (if any) penalties should be provided for violations of these (and other) conditions of the compulsory license.

3.3.3 Notifications

77. The Protocol has the following requirements regarding notifications:

- The person to whom the compulsory license (“licensee”) has been granted must post on a website (either the licensee’s website or the WTO website) the following information:
 - i. the quantities of product being supplied; and
 - ii. the nature of the special marking, labelling or packaging used to identify product produced under the license.
- The exporting Member is required to notify the TRIPS Council of the grant of the licence, the notification including the conditions attached to it, information about the licensee, the products concerned, the quantities to be supplied and the country(ies) being supplied.

Comment

As the notification requirements described above are mandatory, they will need to be in New Zealand’s legislation. The main issue to be decided is which government agency should be responsible for notifying the WTO of the grant of the license. In this respect, there may be a need to ensure that the agency concerned is notified of the grant, as the grant will be made by a court. The most likely candidates as responsible agencies would be IPONZ as it administers the Patents Act, through the Ministry of Foreign Affairs and Trade, as it has responsibility for New Zealand’s relationship with the WTO.

4. Questions for Consideration

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?
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.

3. Do you disagree with this proposition?
4. 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

5. Should New Zealand's legislation specifically list the public health problems for which licenses can be granted under the Protocol?
6. If you think New Zealand's legislation should list the public health problems, which ones should be specified?
7. 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

8. The Protocol contains a definition of "pharmaceutical product". Should this definition be adopted "as is" by New Zealand?
 9. 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?
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Eligible Countries of Importation

10. Should non-WTO Members be included as eligible countries of importation?
11. If your answer to this question is “no”, why should non-WTO Member countries be excluded?
12. 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?
13. If your answer to this question is “yes”, why?

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.

14. Should New Zealand amend its legislation to require applicants for compulsory licenses to “make efforts” to obtain a voluntary license?
 15. If your answer to this question is “no”, why?
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