

14 Dec 2007

To all Patent Users,

**2007 CONSULTATION PAPER ON THE PROPOSED AMENDMENTS
TO THE PATENTS ACT (CAP. 221)**

A. Invitation

You are invited to submit written comments on the proposed amendments to the Patents Act, which are set out in Annex B. The background to the amendments is set out in Annex A.

B. Information for persons making submissions to this Paper

- a. Submissions on Annex B (Proposed amendments) should be sent by email to:-

IPOS_enquiry@ipos.gov.sg,
- b. The closing date for submissions is **14 January 2008**.
- c. In submitting a representation, you agree that unless representations are clearly marked “Confidential”, IPOS may disclose and make available the representation to the general public, in whole or in part, through its website or other means.

Thank you.

INTELLECTUAL PROPERTY OFFICE OF SINGAPORE
Plaza By The Park,
51 Bras Basah Road, #04-01
Singapore 189554

Encl. Annexes A (Background) & B (Proposed amendments)

ANNEX A

1. INTRODUCTION

1.1 Singapore had in September this year, accepted¹ a 2005 Protocol of the WTO General Council to amend the TRIPS² Agreement. The Protocol seals a decision on patents and public health originally adopted in 2003³, which provides a solution to WTO members who are unable, due to lack of manufacturing capacity in the pharmaceutical sector, to make effective use of compulsory licensing under the TRIPS Agreement.

¹ http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm

² Trade-Related Aspects of Intellectual Property Rights (TRIPS)

³ An overview of the discussions at World Trade Organisation (WTO) is as follows:-

2001 – The Doha Declaration (Paragraph 6)

http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

In a WTO Ministerial Conference held at Doha in November 2001, a Declaration on the TRIPS Agreement and Public Health (“the Doha Declaration”) was adopted, paving the way for the Council for TRIPS to find an expeditious solution to a potential problem of making effective use of compulsory licensing under Article 31 of the TRIPS Agreement. The potential problem arises when a developing country is not able to obtain sufficient supplies of a reasonably priced pharmaceutical product that addresses a public health problem from the patent owner and that country has no or insufficient manufacturing capacity to produce the pharmaceutical product even if compulsory licences are issued. On the other hand, there are countries which have such manufacturing capacities but even if compulsory licences were issued, the pharmaceutical products produced under them can only be predominantly for the supply of the market of the country issuing the license. Otherwise, the licenses would be in breach of Article 31(f) of the TRIPS Agreement.

2003 – waiver to the requirements of Article 31(f) of the TRIPS Agreement

http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm

http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

The Doha Declaration adopted in 2001 was implemented by a decision of the WTO General Council on 30 August 2003. In this decision, the requirements of Article 31(f) of the TRIPS Agreement were waived thus permitting WTO “exporting Members” to issue compulsory licenses for the production and export of patented pharmaceuticals to “eligible importing Members” subject to certain conditions.

2005 – Protocol amending the TRIPS Agreement

http://www.wto.org/english/news_e/news05_e/trips_319_e.htm

http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm

It was in December 2005 when the Protocol to amend the TRIPS agreement was agreed by the WTO General Council. This Protocol replaced the 2003 decision which established only a waiver to the requirements of Article 31(f) of the TRIPS Agreement.

³ At the Aug 03 Meeting of the WTO General Council, and reiterated at its Dec 05 Meeting.

http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm

http://www.wto.org/english/news_e/news05_e/trips_319_e.htm

- 1.2 In addition to supporting these WTO initiatives, Singapore announced⁴ that she would only use the system under the Protocol as importer in situations of national emergency or other circumstances of extreme urgency.
- 1.3 Internet links to the Protocol and its related documents are available at the following web-sites:
 - http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
 - http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm
 - http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm
 - http://www.wto.org/english/news_e/news05_e/trips_319_e.htm
 - http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm
 - http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm
- 1.4 The amendments attached to the Protocol contain a new Article 31“bis” and annex to the TRIPS Agreement, and are open for acceptance by members until 1 December 2007.
- 1.5 However, at the last WTO TRIPS Council meeting in late October 2007, this December deadline has been extended to 31 December 2009. Once two thirds of members formally accept it, the amendments will take effect in those members and will replace the 2003 waiver. For each of the remaining members, the waiver will continue to apply until that member accepts the amendment.⁵
- 1.6 Anticipating the acceptance of the TRIPS amendments attached to the Protocol, amendments to the Patents Act have been drafted for this public consultation. The proposed amendments aim to give effect to the TRIPS amendments attached to the Protocol, as well as reflect Singapore’s announcement before the WTO General Council.
- 1.7 The proposed amendments, when finalized, are scheduled to be introduced in Parliament in 2008.
- 1.8 However, in the event that the TRIPS amendments attached to the Protocol are not adopted, the 2003 waiver will continue to apply. The proposed amendments (See Annex B) will then be revised to reflect the spirit of the 2003 waiver instead. In any case, it is noted that the obligations under the 2003 waiver are very similar to those found in the TRIPS amendments to the Protocol. Hence, no further consultation will be sought in this event.

⁴ At the Aug 03 Meeting of the WTO General Council, and reiterated at its Dec 05 Meeting.
http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm
http://www.wto.org/english/news_e/news05_e/trips_319_e.htm

⁵ http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm

2. KEY FEATURES UNDER THE PROTOCOL

2.1 WTO⁶ explains the TRIPS amendment as follows –

ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT

- a. Article 31“bis” allows pharmaceutical products made under compulsory licences to be exported to countries lacking production capacity. It also deals with the avoidance of double remuneration to the patent-owner.

ANNEX TO THE TRIPS AGREEMENT

- b. An annex to the TRIPS Agreement sets out terms for using the system, and covers matters such as definitions, notification and avoidance of pharmaceuticals being diverted to the wrong markets.

APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT

- c. An “appendix” to the annex deals with assessing lack of manufacturing capability in the importing country.

3. REFERENCE TABLE

For ease of reference, IPOS has prepared the following table highlighting provisions extracted from the TRIPS amendments attached to the Protocol to which eligible importing members would have to meet as well as the corresponding proposed amendments (See Annex B) that have been drafted.

TRIPS AMENDMENTS ATTACHED TO THE PROTOCOL THAT ELIGIBLE IMPORTING MEMBERS HAVE TO MEET	PROPOSED AMENDMENTS IN SINGAPORE
<p>NOTIFICATION TO THE TRIPS COUNCIL OF INTENTION TO USE</p>	<p>Article 31bis of TRIPS – Para 1(b) of the Annex</p> <p>1. For the purposes of Article 31bis and this Annex:</p> <p>(b) “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</p>
	<p>See proposed amendment section 56(1A) which provides for the Singapore Government to notify the TRIPS council of its intention to use the system under the Protocol, as an eligible importing member.</p> <p>Proposed amendment section 56(4) revises the existing provision to take into account the terminology under the Protocol.</p>

⁶ http://www.wto.org/english/news_e/pres05_e/pr426_e.htm

TRIPS AMENDMENTS ATTACHED TO THE PROTOCOL THAT ELIGIBLE IMPORTING MEMBERS HAVE TO MEET		PROPOSED AMENDMENTS IN SINGAPORE
	<p>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</p>	
<p>DETAILS OF THE NOTIFICATION TO THE TRIPS COUNCIL OF INTENTION TO USE</p>	<p>Article 31bis of TRIPS – Para 2 of the Annex</p> <p>2. The terms referred to in paragraph 1 of Article 31bis are that:</p> <p>(a) the eligible importing Member(s) has made a notification to the Council for TRIPS, that:</p> <p>(i) specifies the names and expected quantities of the product(s) needed;</p> <p>(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and</p> <p>(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a</p>	<p>See “relevant notification” referred to in proposed amendment section 56(1A)</p>

TRIPS AMENDMENTS ATTACHED TO THE PROTOCOL THAT ELIGIBLE IMPORTING MEMBERS HAVE TO MEET	PROPOSED AMENDMENTS IN SINGAPORE
	<p>compulsory licence in accordance with Articles 31 and 31bis of this Agreement and the provisions of this Annex;</p>
<p>REMUNERATION OBLIGATION</p>	<p>Para 2 of Article 31bis of TRIPS</p> <p>2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.</p>
<p>REASONABLE MEASURES TAKEN TO PREVENT RE-EXPORTATION</p>	<p>Article 31bis of TRIPS – Para 3 of the Annex</p> <p>3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country</p>
<p>See proposed amendment section 62 which identifies the remuneration obligation of the Government as an importing Member.</p>	<p>See proposed section 60(1A) which limits the rights to use the patented invention accordingly.</p>

TRIPS AMENDMENTS ATTACHED TO THE PROTOCOL THAT ELIGIBLE IMPORTING MEMBERS HAVE TO MEET		PROPOSED AMENDMENTS IN SINGAPORE
	<p>Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.</p>	
<p>EFFECTIVE LEGAL MEANS TO PREVENT IMPORTATION AND SALE OF WRONGLY DIVERTED PRODUCTS MADE UNDER THE PROTOCOL</p>	<p>Article 31bis of TRIPS – Para 4 of the Annex</p> <p>4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.</p>	<p>The proposed amendment to section 66 prevents the importer (distributor) from relying on the parallel import defence in section 66(2)(g) in the case where a Protocol Pharmaceutical Product (PPP) is wrongly diverted and imported into SINGAPORE.</p>

ANNEX B

The proposed amendments to the Patents Act are intended to (i) give effect to the TRIPS amendments attached to the 2005 Protocol; and (ii) set out the conditions and circumstances under which Singapore will make use of “flexibilities” permitted under the said Protocol.

We welcome your comments on the proposed amendments.

PROPOSED AMENDMENTS TO THE PATENTS ACT FOR CONSULTATION

Amendment of section 2

A. Section 2(1) of the Patents Act is amended —

(a) by inserting, immediately after the definition of “corresponding patent”, the following definition:

““Council for TRIPS” means the Council for Trade-Related Aspects of Intellectual Property Rights established under the TRIPS Agreement;”;

(b) by inserting, immediately after the definition of “relevant authority”, the following definition:

““relevant health product” means a patented invention which is a product referred to in paragraph 1(a) of the Annex to the TRIPS Agreement;”;

(c) by deleting the full-stop at the end of the definition of “scientific adviser” and substituting a semi-colon, and by inserting immediately thereafter the following definitions:

““TRIPS Agreement” means the Agreement on Trade-Related Aspects of Intellectual Property Rights, set out in Annex 1C to the WTO Agreement, as revised or amended from time to time;

“WTO Agreement” means the World Trade Organisation Agreement signed in Marrakesh in 1994 as revised or amended from time to time.”.

Amendment of section 56

B. Section 56 of the Patents Act is amended —

(a) by deleting the word “provision” in subsection (1) and substituting the word “section”;

(b) by inserting, immediately after subsection (1), the following subsection:

“(1A) Without prejudice to the generality of subsection (1), subject to sections 60, 61 and 62, but notwithstanding any other section of this Act, the Government and any party authorised in writing by the Government may import any relevant health product, and do anything in relation to any relevant health product so imported, for or during a national emergency or other circumstances of extreme urgency, if the Government has given the Council for TRIPS a relevant notification in relation to the relevant health product.”; and

(c) by deleting subsection (4) and substituting the following subsection:

“(4) In this section —

“integrated circuit” means a product, in its final or an intermediate form, in which the elements, at least one of which is an active element, and some or all of the interconnections are integrally formed in and on, or in or on, a piece of material and which is intended to perform an electronic function;

“relevant notification” means a notification that satisfies the requirements of paragraph 2(a) of the Annex to the TRIPS Agreement.”.

Amendment of section 60

C. Section 60 of the Patents Act is amended by inserting, immediately after subsection (1), the following subsection:

“(1A) The right under section 56 to use a relevant health product which is imported under section 56(1A) does not include a right to export the relevant health product.”.

Repeal and re-enactment of section 62

D. Section 62 of the Patents Act is repealed and the following section substituted therefor:

“Patentee entitled to remuneration

62.—(1) Subject to subsection (2), where an act is done under section 56, the Government shall pay such remuneration to the patentee as may be agreed, or as may be determined by a method agreed, between the Government and the patentee having regard to the economic value of the patented invention or as may, in default of agreement, be determined by the court under section 58.

(2) Subsection (1) shall not apply to the import or subsequent use under section 56(1A) of any relevant health product, if the patentee has received remuneration in respect of that relevant health product.”.

Amendment of section 66

E. Section 66 of the Patents Act is amended —

(a) by deleting the words “subsection (3)” in the 1st line of subsection (2)(g) and substituting the words “subsections (3) and (5A)”;

(b) by inserting, immediately after subsection (5), the following subsection:

“(5A) Subsection (2)(g) shall not apply to the import or sale of, or the offer to sell, any relevant health product produced for export to any country, other than Singapore, which is an eligible importing member of the World Trade Organisation.”; and

(c) by deleting subsection (6) and substituting the following subsection:

“(6) In this section —

“eligible importing member”, in relation to the World Trade Organisation, means a member of the World Trade Organisation which —

(a) is a least-developed country; or

(b) has given the Council for TRIPS the notification referred to in paragraph 1(b) of the Annex to the TRIPS Agreement;

“exempted aircraft” means an aircraft to which section 5 of the Air Navigation Act (Cap. 6) applies;

“relevant ship” and “relevant aircraft, hovercraft or vehicle” mean, respectively, a ship and an aircraft, a hovercraft or a vehicle registered in, or belonging to, any country, other than Singapore, which is —

(a) a party to the Paris Convention; or

(b) a member of the World Trade Organisation.”.

END