

**IPOS' GUIDE TO THE PATENTS
(AMENDMENT) ACT 2008**

Patents (Amendments) Act 2008



IPOS' GUIDE
Patents (Amendment) Act 2008

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What is in this Guide?

This round of amendments puts into place 2 groups of changes - the first group (hereinafter referred to as the “Doha amendments”) and the second group (hereinafter referred to as the “Competition amendments”).

Purpose of this Guide

The purpose of this Guide is to provide users with an overview of the 2008 amendments to the Patents Act.

Do take note that this Guide is neither exhaustive nor authoritative. Please refer to the Patents Act for details.

Feedback if any

This Guide is prepared by the Patent Quality Management Unit (PQMU).

If you have any suggestions or feedback in relation to this Guide, please drop us an e-mail (ipos_enquiry@ipos.gov.sg) and attention it to this Unit.

Patents Quality Management Unit (PQMU)
IPOS
3 Oct 08

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1. Introduction

Introduction to the Patents (Amendment) Act 2008

- 1.1 The Patents (Amendment) Bill 2008 was passed in Parliament on 25 Aug 2008 and through the Patents (Amendment) Act (Commencement) Notification 2008, the Patents (Amendment) Act 2008 (hereinafter referred to as the “2008 amendments”) shall come into operation on 1st December 2008.
- 1.2 The 2008 amendments can generally be classified into the “Doha Amendments” and the “Competition Amendments”.
- 1.3 The “Doha Amendments” relate to the implementation of certain measures under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as amended by the Protocol thereto concluded in Geneva on 6th December 2005 (The Protocol) as well as give effect to the Decision adopted by the General Council of the World Trade Organisation on 30th August 2003 (The Waiver) on the implementation of paragraph 6 of the Declaration on the TRIPS Agreement and Public Health adopted in Doha on 14th November 2001 (The Declaration).
- 1.4 The “Competition Amendments” restrict the application of Part X of the Patents Act to agreements made before the commencement of the new section 50A.

Agreements made thereafter will thus come entirely under the purview of the Competition Act.
- 1.5 This Guide aims to provide one with an understanding of the 2008 Amendments.

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2. "Doha amendments"

Getting Started

- 2.1 You are advised to have the following documents before you proceed to read the rest of this section in this Guide:-
- Patents Act
 - Patents (Amendments) Act 2008
 - TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights)

A table containing a list of relevant TRIPS website on this subject can be found at the end of this Guide.

Basic Concepts

Article 31
TRIPS

- 2.2 Under Article 31 (Other Use Without Authorization of the Right Holder) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), it states that where the law of a Member¹ allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, such use must respect the list of conditions found in the said Article.
- 2.3 One such condition is paragraph (f) to Article 31 which states “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”. This posed a concern particularly amongst developing member countries of the World Trade Organisation (WTO) which are not able to obtain sufficient supplies of a reasonably priced patented pharmaceutical product that addresses a public health problem from the patent owner and these countries have no or insufficient manufacturing capacity to produce the pharmaceutical product even if compulsory licences were issued.
- 2.4 On the other hand, there are WTO member countries which have such manufacturing capacities but even if compulsory licences were issued, the patented pharmaceutical products produced under them can only be predominantly for the supply of the market of the country issuing the license.

¹ TRIPS being a WTO agreement, applies to all WTO members and Singapore is a member thereof since 1 January 1995.

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Otherwise, the licenses would be in breach of Article 31(f) of the TRIPS Agreement.

What's new? –

2001: “The Declaration”

- 2.5 In a WTO Ministerial Conference held at Doha in November 2001, a Declaration on the TRIPS Agreement and Public Health (The Declaration) was made recognising 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. It acknowledged that intellectual property protection is important for the development of new medicines and agreed that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. As such, the Council for TRIPS was tasked to find an expeditious solution to this problem and to report to the General Council.

2003: “The Waiver”

- 2.6 On 30 Aug 2003, the WTO General Council adopted a proposal on the “Implementation of Paragraph 6 of the Doha Declaration on the TRIPS agreement and public health”. This decision which established a Waiver to the requirements of Article 31(f) of the TRIPS Agreement, would make it easier for member countries in need to import cheaper generic medicines made under compulsory licensing if they are unable to manufacture the medicines themselves.

2005: “The Protocol”

- 2.7 In December 2005, a Protocol to amend the TRIPS agreement was approved by the WTO General Council. This Protocol replaced the Waiver and made permanent the decision on patents and public health originally adopted in 2003.
- Annexed to the Protocol amending the TRIPS agreement is Article 31bis. This Article allows for patented pharmaceutical products made under compulsory licences to be exported to WTO members lacking production capacity. It also deals with the avoidance of double remuneration to the patent-owner.

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

Implementation of Amendments to TRIPS

- 2.8 The new Article 31bis, the annex and its appendix of the TRIPS Agreement are attached to the Protocol. These in turn are attached to a decision of the General Council, which adopted the Protocol. The Protocol was open for members to accept it by 1 December 2007.

At the last TRIPS Council meeting in late October 2007, this December 2007 deadline was extended until 31 December 2009. Once two thirds of members formally accept it, the amendment will take effect in those members and will replace the Waiver. For each of the remaining members, the Waiver will continue to apply until that member accepts the amendment.

Singapore's announcement

- 2.9 Some WTO Members have declared that they will not use the system set out in the TRIPS changes as importing Members. 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. In this regard, Singapore announced that she would only use the system as importer in situations of national emergency or other circumstances of extreme urgency.

Singapore had also proceeded to accept the TRIPS amendments on 28 September 2007.

The Patents (Amendment) Act 2008 in Singapore

- Section 2 2.10 The 2008 amendments to section 2 of the Patents Act provide definitions for the following terms:
- “Council for TRIPS”
 - “Doha Declaration Implementation Decision”
 - “relevant health product”
 - “TRIPS Agreement”
 - “WTO Agreement”

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- 2.11 These set the stage of the 2008 amendments in Singapore as they cover both the requirements under the TRIPS Amendment in 2005 (The Protocol) as well as the decision in 2003 (The Waiver) which will apply to all WTO members in the event that the Protocol is not accepted. The text found in both the Protocol and the Waiver is essentially the same. Hence, for ease of reference in this Guide, the term “TRIPS changes” will be used.
- 2.12 It is also to be noted that the 2008 amendments only provide for the case where Singapore is acting as an “eligible importing member” under the TRIPS changes, for or during a national emergency or other circumstances of extreme urgency.
- 2.13 Key features of the TRIPS changes with regard to “eligible importing member” are as follows:-
- a) The need to notify the Council for TRIPS of its intention to use the system set out in the TRIPS changes as an importer as well as to inform the said Council of the following:
 - (i) Specification of the names and expected quantities of the product(s) needed;
 - (ii) Confirmation that the “eligible importing member” has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question; and
 - (iii) Confirmation that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with the TRIPS changes.
 - b) Definition of a “Pharmaceutical Product”
 - c) Obligation to remunerate the patent owner for the use of the patented pharmaceutical product if he has not been remunerated in the exporting member
 - d) Reasonable measures taken to prevent re-exportation
 - e) Effective legal means to prevent importation and sale of wrongly diverted products made under the TRIPS changes

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2.14 The 2008 amendments correspondingly reflect the key features of the TRIPS changes as follows:

- Section 56 a) Amendment to Section 56 inserts a new subsection (1A) to provide for the required notification to the Council for TRIPS giving effect to the TRIPS changes.
- Section 2 b) Introduction of a definition of a “relevant health product” under section 2 of the Patents Act which refers to a “Pharmaceutical Product” under the TRIPS changes. It is noted that the term “relevant health product” is not to be confused with the term “pharmaceutical product” under the Patents Act. The former specifically refers to products under the TRIPS changes.
- Section 62 c) Amendment to Section 62 inserts a new subsection (2) to say that no remuneration shall be payable in respect of the import or subsequent use under section 56(1A) of any relevant health product, if the patentee has received or will receive any other remuneration in respect of that relevant health product.
- Section 60 d) Amendment to Section 60 states that 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 and where the court has terminated the right under section 56 to use a patented invention, the court may make such consequential orders as it thinks necessary.
- Section 66 e) Amendment to Section 66 restricts the parallel importation and specific patent defence provisions such that the defences do 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.

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3. "Competition amendments"

Getting Started

3.1 You are advised to have the following documents before you proceed to read the rest of this section in this Guide:-

- Patents Act
- Patents (Amendments) Act 2008
- TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights)

A table containing a list of relevant TRIPS website on this subject can be found at the end of this Guide.

Basic Concepts

3.2 Prior to the 2008 amendments, certain types of agreements involving patented inventions were presumed under the Patents Act to be inherently anti-competitive.

3.3 Section 51 deems void clauses in agreements that require or tie the licensee to procure something else in addition to the patented product from the patent holder, thus allowing a patent holder to unfairly extend his monopoly rights to an unrelated product.

3.4 Section 52 provides that one may determine agreements that require a patent licensee to continue to pay patent royalties after expiry of the patent, thereby effectively extending the life of the patent, to the extent (and only to the extent) that the contract or licence relates to the product or invention, by either party on giving 3 months' notice in writing to the other party.

3.5 In reality however, these agreements may not always be anti-competitive. For example, 'tying' arrangements may not be anti-competitive if there are alternative products on the market that serve the same purpose as the patented product. Also, agreements that require a patent licensee to pay royalties after the expiry of the patent may not amount to an abuse of monopoly rights by the patent owner since licensees may, for commercial reasons, prefer to distribute the royalties payable over a longer time period.

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- 3.6 Separately, the Competition Act was introduced in Singapore and was implemented at the following phases so as to allow time for the Competition Commission and for businesses to prepare for the implementation of the Competition Act.

Phase 1: On 1 January 2005, only the provisions establishing the Commission came into force.

Phase 2: On 1 January 2006, the provisions on anti-competitive agreements, decisions and practices; abuse of dominance; enforcement; appeal processes; and other miscellaneous areas came into force.

Phase 3: The remaining provisions pertaining to mergers and acquisitions came into force on 1 July 2007.

What's new? –

Section
50A

- 3.7 With the enactment of the Competition Act, agreements as set out in sections 51 and 52 of the Patents Act are more appropriately dealt with under competition law.
- 3.8 As there could be agreements that have been entered into on the basis of the law prior to the 2008 amendment, a new section 50A in the Patents Act is introduced to restrict the application of sections 51 and 52 to those agreements made before the commencement of the new section 50A. Agreements made after that will thus come entirely under the purview of the Competition Act.
- 3.9 This amendment will give businesses greater flexibility in structuring new commercial agreements where such agreements are regulated by competition law.

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REFERENCE
RELEVANT INTERNET LINKS

The Patents Act
http://www.ipos.gov.sg/topNav/leg/
TRIPS Agreement
http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm
Ministerial Conference: 14 Nov 2001
Declaration on the TRIPS agreement and public health
http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
Decision of General Council: 30 Aug 2003
Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health
http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm
General Council Chairperson's statement: 13 Nov 2003
http://www.wto.org/english/tratop_e/trips_e/gc_stat_30aug03_e.htm
Decision of General Council: 6 Dec 2005
Amendment of the TRIPS Agreement
http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm
General Council Chairperson's statement, 6 December 2005
http://www.wto.org/english/news_e/news05_e/trips_319_e.htm
Decision of General Council: 18 Dec 2007
Extension of the period for the acceptance by members of the protocol amending the TRIPS Agreement
http://docsonline.wto.org/DDFDocuments/t/WT/L/711.doc
Members accepting amendment of the TRIPS Agreement
http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm
Notifications by importing WTO Members
http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm
Notifications by exporting WTO Members
http://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm
Competition Act (Chapter 50B)
http://www.ccs.gov.sg/Legislation/CompetitionAct/index.html
Regulations made pursuant to the powers conferred under the Competition Act
http://www.ccs.gov.sg/Legislation/Regulations/index.html
Competition Commission of Singapore (CCS) Guidelines
http://www.ccs.gov.sg/Guidelines/index.html

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