

MARCH 2008 Singapore: Proposed amendments to the Singapore Patents Act

01 Mar 2008

The General Council of the WTO agreed in 2003 to waive the requirements of Article 31(f) of the TRIPs Agreement, in order to facilitate the import of pharmaceutical drugs to countries with no or insufficient manufacturing capacity. Singapore has accepted the amendments to the TRIPs Agreement and amendments have been proposed to the Singapore Patents Act to conform the TRIPs Agreement.

Article 31(f) of TRIPs allows a WTO member to issue compulsory licences provided that the use of the compulsory licences is authorized predominantly for the supply of the domestic market of the member authorizing such use. This provision restricts the exportation of products manufactured under compulsory licensing to a large extent.

Article 31(f) was waived with respect to pharmaceutical products in the 2003 decision to address problems that have arisen when a developing country is unable to afford sufficient supplies of pharmaceutical products from the patent owner or when the country has no or insufficient manufacturing capacity to produce the pharmaceutical products even when compulsory licences are issued. The waiver of Article 31(f) means that WTO "exporting members" are permitted to issue compulsory licences for the production and exportation of patented pharmaceutical products to "eligible importing members" who are unable to manufacture pharmaceutical products themselves.

Singapore has announced that it will only use the system as importer in situations of national emergency or other circumstances of extreme urgency.

The WTO General Council has further implemented a protocol amending the TRIPs Agreement to ensure that the system is used in good faith to protect public health and not used as an instrument to pursue industrial or commercial policy objectives.

The proposed amendments to the Singapore Patents Act are intended to give effect to the amendments attached to the Protocol and to ensure that reasonable measures are taken so that patent protection is not being undermined in Singapore. For example, the proposed amendments to the Singapore Patents Act provide for the Singapore government to notify the TRIPs Council of its intention to use the system as an eligible importing member during situations of national emergency or other circumstances of extreme urgency. Furthermore, to ensure that patent protection is not undermined and to limit the rights to use the patented invention, other than for the purposes of public health under the system, it is proposed that the Singapore Patents Act be amended to restrict the re-exportation of the pharmaceutical products manufactured by compulsory licenses issued under the system. It is also proposed that the Singapore Patents Act will be further amended to impose a new ground of infringement if pharmaceutical products manufactured under the system that are not meant to be imported into Singapore have been wrongly diverted and exploited in Singapore.

The Protocol will take effect once two thirds of WTO members formally accept the amendments made to the TRIPs Agreement before December 31 2009. Accordingly, the proposed amendments to the Singapore Patents Act, when finalized, are scheduled to be introduced in Parliament in 2008.

The TRIPs Agreement provides guidelines on how each WTO member should determine what constitutes a national emergency or other circumstance of extreme urgency. For example, public health crises including HIV/AIDS, tuberculosis, malaria and other epidemics can be constituted as a national emergency or circumstance of extreme emergency. However, the proposed amendments to the Singapore Patents Act raise questions as to how circumstance of extreme urgency could be interpreted in Singapore. Furthermore, the TRIPs council would need to be satisfied that Singapore can be regarded as an "eligible importing member" provided that Singapore has established with the council that it has insufficient or no manufacturing capacities for manufacturing pharmaceutical products needed in situations of national emergency or circumstance of extreme urgency.

The implementation of the Protocol and the proposed amendments to the Singapore Patents Act may result in a series of procedural and institutional obligations to ensure that the system is used in good faith and that patent protection is not being undermined. However, such obligations may seem like an ineffective and impractical solution to protect public health since the implementation of the proposed amendments may restrict the flexibilities available to members of the WTO, particularly in developing countries.

Although Singapore is a pharmaceutical manufacturing research and production centre in south-east Asia, Singapore is still heavily dependant on imported medical products and is also a major re-export point to neighbouring countries in south-east Asia. The proposed amendments to the Patents Act will potentially restrict the re-exportation of pharmaceutical products imported into Singapore under this system, so that the system will not be used as an instrument to pursue industrial or commercial policy objectives in Singapore. However, the restriction on the re-exportation of pharmaceutical products to neighbouring developing countries may raise the issue of whether the proposed amendments to the Singapore Patents Act are implemented for the purpose of protecting public health under the TRIPs Agreement. This would apply to neighbouring developing countries, which may require certain

pharmaceutical products on an expedited basis.

In view of the fact that Singapore generally does not have sufficient manufacturing capacity for large-scale production of pharmaceutical drugs, it will be important to determine the nature and extent for interpreting the "circumstances of extreme urgency" in Singapore, so that the rights of patent owners are not compromised in light of the object and the purpose of the amendments made to the TRIPs Agreement.



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