Input for draft reference document on the exception regarding the exhaustion of patent rights.

Pursuant to the decision of the thirty-third session of the Standing Committee on the Law of Patents ("SCP"), which was held in Geneva in a hybrid format from December 6 to 9, 2021, Member States and Regional Patent Offices were invited to send to the Secretariat any additional input for the preparation of a draft reference document on the exception regarding the exhaustion of patent rights.

Accordingly, Singapore has prepared the following input.

The relevant provisions may be found in section 66 of the Patents Act 1994 ("SPA") (see **Annex**). In particular, section 66(2)(*g*) and (*i*) of the SPA state as follows:

> **Meaning of infringement**
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> **66.— (1) …**
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> (2) An act which, apart from this subsection, would constitute an infringement of a patent for an invention is not an infringement of a patent if —
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> …
>
> (g) subject to subsections (3) and (6), it consists of the import, use or disposal of, or the offer to dispose of, any patented product or any product obtained by means of a patented process or to which a patented process has been applied, which is produced by or with the consent (conditional or otherwise) of the proprietor of the patent or any person licensed by the proprietor, and for this purpose "patent" includes a patent granted in any country outside Singapore in respect of the same or substantially the same invention as that for which a patent is granted under this Act and "patented product", "patented process" and "licensed" are to be construed accordingly;
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> …
>
> (i) subject to subsection (6), it consists of the import, disposal or offer to dispose of a patented pharmaceutical product for use by or on a specific patient in Singapore, or the use of that product by or on that patient, where —
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> (i) that product is required for use by or on that patient;
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> (ii) the relevant authority has granted approval specifically for the import of that product for use by or on that patient; and
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> (iii) that product was produced by or with the consent (conditional or otherwise) of the proprietor of the patent or any person licensed by the proprietor (and for this purpose "patent" includes a patent granted in any country outside Singapore in respect of the same or substantially the same product and "licensed" is to be construed accordingly).

Section 66(3) of the SPA further provides for exceptions to exhaustion of patent rights for the import of any patented pharmaceutical product. This states: -

> …
>
> (3) Subsection (2)(g) does not apply to the import of any patented pharmaceutical product by any person (called in this subsection and subsection (4) the importer) if —
>
> (a) the product has not previously been sold or distributed in Singapore by or with the consent (conditional or otherwise) of the proprietor of the patent or any person licensed by the proprietor of the patent to sell or distribute the product in Singapore;

(b) the import of the product by the importer would result in the product being distributed in breach of a contract between —

(i) the proprietor of the patent; and

(ii) any person licensed by the proprietor of the patent to distribute the product outside Singapore; and

(c) the importer has actual or constructive knowledge of the matters referred to in paragraph (b).

Section 66(6) of the SPA prohibits patented pharmaceutical products produced under compulsory licence for another country from being diverted into Singapore through parallel import. Aligned to the principles set out in TRIPS Agreement Article 31***bis***, this was put in place as a safeguard to ensure that the rights to import patented pharmaceutical products manufactured under compulsory licence are not abused for commercial profits and that patent holders are remunerated according to the use of their patents. Section 66(6) states that -

Subsection (2)(g) and (i) does 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.

Annex

Meaning of infringement

66.—(1) Subject to the provisions of this Act, a person infringes a patent for an invention if, but only if, while the patent is in force, the person does any of the following things in Singapore in relation to the invention without the consent of the proprietor of the patent:

(*a*) where the invention is a product, the person makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;

(*b*) where the invention is a process, the person uses the process or the person offers it for use in Singapore when the person knows, or it is obvious to a reasonable person in the circumstances, that its use without the consent of the proprietor would be an infringement of the patent;

(*c*) where the invention is a process, the person disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

(2) An act which, apart from this subsection, would constitute an infringement of a patent for an invention is not an infringement of a patent if —

(*a*) it is done privately and for purposes which are not commercial;

(*b*) it is done for experimental purposes relating to the subject matter of the invention;

(*c*) it consists of the extemporaneous preparation of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared;

(*d*) it consists of the use of a product or process in the body or operation of a relevant aircraft, hovercraft or vehicle which has temporarily or accidentally entered or is crossing Singapore (including the airspace above it and its territorial waters) or the use of accessories for such a relevant aircraft, hovercraft or vehicle;

(*e*) it consists of the use, exclusively for the needs of a relevant ship, of a product or process in the body of the ship or in its machinery, tackle, apparatus or other accessories, in a case where the ship has temporarily or accidentally entered the territorial waters of Singapore;

(*f*) it consists of the use of an exempted aircraft which has lawfully entered or is lawfully crossing Singapore as mentioned in paragraph (*d*) or of the importation into Singapore, or the use or storage, of any part or accessory for that aircraft;

(*g*) subject to subsections (3) and (6), it consists of the import, use or disposal of, or the offer to dispose of, any patented product or any product obtained by means of a patented process or to which a patented process has been applied, which is produced by or with the consent (conditional or otherwise) of the proprietor of the patent or any person licensed by the proprietor, and for this purpose "patent" includes a patent granted in any country outside Singapore in respect of the same or substantially the same invention as that for which a patent is granted under this Act and "patented product", "patented process" and "licensed" are to be construed accordingly;

(*h*) it consists of the doing of any thing set out in subsection (1) in relation to the subject matter of the patent to support any application for marketing approval for a pharmaceutical product, provided that any thing produced to support the application is not —

(i) made, used or sold in Singapore; or

(ii) exported outside Singapore,

other than for purposes related to meeting the requirements for marketing approval for that pharmaceutical product; or

(*i*) subject to subsection (6), it consists of the import, disposal or offer to dispose of a patented pharmaceutical product for use by or on a specific patient in Singapore, or the use of that product by or on that patient, where —

(i) that product is required for use by or on that patient;

(ii) the relevant authority has granted approval specifically for the import of that product for use by or on that patient; and

(iii) that product was produced by or with the consent (conditional or otherwise) of the proprietor of the patent or any person licensed by the proprietor (and for this purpose "patent" includes a patent granted in any country outside Singapore in respect of the same or substantially the same product and "licensed" is to be construed accordingly).

(3) Subsection (2)(*g*) does not apply to the import of any patented pharmaceutical product by any person (called in this subsection and subsection (4) the importer) if —

(*a*) the product has not previously been sold or distributed in Singapore by or with the consent (conditional or otherwise) of the proprietor of the patent or any person licensed by the proprietor of the patent to sell or distribute the product in Singapore;

(*b*) the import of the product by the importer would result in the product being distributed in breach of a contract between —

(i) the proprietor of the patent; and

(ii) any person licensed by the proprietor of the patent to distribute the product outside Singapore; and

(*c*) the importer has actual or constructive knowledge of the matters referred to in paragraph (*b*).

(4) For the purposes of subsection (3), where the importer has received a written notice containing the prescribed particulars, the importer is deemed to have constructive knowledge of the matters referred to in subsection (3)(*b*).

(5) To avoid doubt, in subsection (3), "patent" does not include a patent granted in any country outside Singapore in respect of the same or substantially the same product and "licensed" is to be construed accordingly.

(6) Subsection (2)(*g*) and (*i*) does 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.

(7) 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 —

(i) paragraph 1(*b*) of the Doha Declaration Implementation Decision; or

(ii) paragraph 1(*b*) of the Annex to the TRIPS Agreement;

"exempted aircraft" means an aircraft to which section 30 of the Air Navigation Act 1966 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.