HONG KONG SPECIAL ADMINISTRATIVE REGION

ORDINANCE NO. 21 OF 2007

L.S.

Donald TSANG
Chief Executive
29 November 2007

An Ordinance to amend the Patents Ordinance to implement the Protocol Amending the Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organisation in relation to patents and public health; and to provide for incidental and related matters.

[ ]

Enacted by the Legislative Council.

1. Short title

This Ordinance may be cited as the Patents (Amendment) Ordinance 2007.

2. Commencement

This Ordinance shall come into operation on a day to be appointed by the Secretary for Commerce and Economic Development by notice published in the Gazette.

3. Interpretation

Section 2(1) of the Patents Ordinance (Cap. 514) is amended by adding—

""Doha Declaration" (《多哈宣言》) means the Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 by the Fourth WTO Ministerial Conference at Doha, Qatar;

"eligible importing member" (合資格進口成員地) means—

(*a*) a WTO member country, territory or area recognized by the United Nations as being a least-developed country; or

(*b*) any other WTO member country, territory or area that has given notice in writing to the TRIPS Council that it intends to import pharmaceutical products in accordance with the General Council Decision or the Protocol;

"exporting member" (出口成員地) means a WTO member country, territory or area that makes a patented pharmaceutical product for export to an eligible importing member in accordance with the General Council Decision or the Protocol;

"General Council Decision" (《總理事會決定》) means the Decision adopted by the General Council of the WTO on 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration;

"patented pharmaceutical product" (專利藥劑製品) means—

(*a*) a pharmaceutical product which is an invention for which a standard patent or a short-term patent (as the case may be) has been granted;

(*b*) in relation to a process for which a standard patent or a short-term patent (as the case may be) has been granted, a pharmaceutical product obtained directly by means of the process or to which the process has been applied;

"pharmaceutical product" (藥劑製品) means—

(*a*) a pharmaceutical product within the meaning of section 2(1) of the Pharmacy and Poisons Ordinance (Cap. 138);

(*b*) an active ingredient that is needed for making of a pharmaceutical product mentioned in paragraph (*a*); or

(*c*) a diagnostic kit that is needed for the use of a pharmaceutical product mentioned in paragraph (*a*);

"Protocol" (《日內瓦議定書》) means the Protocol Amending the TRIPS Agreement adopted by the General Council of the WTO at Geneva on 6 December 2005, the Annex to the Protocol Amending the TRIPS Agreement, the Annex to the TRIPS Agreement and the Appendix to the Annex to the TRIPS Agreement;

"relevant instrument or legislation" (有關文書或法例) means—

(*a*) the General Council Decision;

(*b*) the Protocol; or

(*c*) legislation made by the exporting member or the eligible importing member, as the case may be, pursuant to or for the purpose of implementing—

(i) the General Council Decision; or

(ii) the Protocol;

"TRIPS Agreement" (《知識產權協議》) means the Agreement on Trade-Related Aspects of Intellectual Property Rights, being Annex 1C of the World Trade Organisation Agreement;

"TRIPS Council" (知識產權理事會) means the Council for Trade-Related Aspects of Intellectual Property Rights referred to in Article 68 of the TRIPS Agreement;

"WTO" (世界貿易組織) means the World Trade Organisation established in Geneva on 1 January 1995 under the World Trade Organisation Agreement;".

4. Special provision regarding invention covered by 2 or more patents

Section 9 is amended by repealing "or the provisions of Part IX relating to Government use" and substituting ", the provisions of Part IX relating to Government use, an import compulsory licence having effect under Part IXA or an export compulsory licence having effect under Part IXB".

5. Parts IXA and IXB added

The following are added immediately before Part X—

"PART IXA

IMPORT COMPULSORY LICENCES FOR PATENTED PHARMACEUTICAL PRODUCTS

72A. Interpretation of Part IXA

In this Part, unless the context otherwise requires—

"Director" (署長) means the Director of Health;

"import compulsory licence" (進口強制性特許) means a compulsory licence granted under section 72C;

"import compulsory licensee" (進口強制性特許持有人) means the holder of an import compulsory licence;

"proprietor" (所有人), in relation to a patent, means the proprietor of the patent that is granted in Hong Kong.

72B. Declaration of extreme urgency for public health problem

(1) The Chief Executive in Council may, for the purposes of applying sections 72C to 72J, by notice published in the Gazette declare a period of extreme urgency whenever the Chief Executive in Council considers it to be necessary or expedient in the public interest to do so to address any public health problem or threatened public health problem in Hong Kong.

(2) Where a period of extreme urgency has been declared under subsection (1), the Chief Executive in Council shall review from time to time, or cause to be reviewed from time to time, the public health problem or the threatened public health problem leading to the declaration.

(3) The period of extreme urgency declared under subsection (1) continues to run until such a date as may be specified by the Chief Executive in Council by notice published in the Gazette terminating the period of extreme urgency.

(4) A notice published under subsection (1) or (3) is subsidiary legislation.

72C. Grant of import compulsory licences for patented pharmaceutical products

During a period of extreme urgency declared under section 72B(1), where the Director considers that the pharmaceutical industry in Hong Kong has no or insufficient capacity to manufacture a patented pharmaceutical product to meet the needs for the product in Hong Kong, the Director may grant an import compulsory licence under the patent concerned, subject to such terms and conditions as he may impose, to a public officer or any other person to do in Hong Kong in relation to the product all or any of the following which appears to the Director to be necessary or expedient in connection with the extreme urgency giving rise to the declaration—

(*a*) importing, putting on the market, stocking or using the product;

(*b*) any other act which would, apart from this section, amount to an infringement of the patent concerned.

72D. Terms, conditions and nature of import compulsory licences

(1) The terms and conditions subject to which an import compulsory licence is granted under section 72C shall include—

(*a*) terms and conditions in respect of—

(i) the acts authorized to be done in relation to the patented pharmaceutical product under the licence;

(ii) the amount of the patented pharmaceutical product covered by the licence; and

(iii) the duration of the licence;

(*b*) terms and conditions providing that—

(i) the patented pharmaceutical product which is imported to Hong Kong under the licence shall not be exported out of Hong Kong;

(ii) the patented pharmaceutical product shall be—

(A) clearly identified as being imported under the licence through specific labelling or marking; and

(B) distinguished from the same product made by or under authorization of the proprietor of the patent concerned through special packaging, colouring or shaping; and

(iii) the licence is non-assignable except with that part of the enterprise or goodwill which enjoys the use of the patent under the licence; and

(*c*) any other terms or conditions as the Director thinks fit having regard to the public health needs in Hong Kong in the period of extreme urgency declared under section 72B(1).

(2) An import compulsory licence is non-exclusive.

72E. Payment of remuneration to proprietors of patents

(1) If remuneration has been paid to the proprietor of a patent granted in an exporting member for production and export of a patented pharmaceutical product to Hong Kong in accordance with the relevant instrument or legislation, no remuneration shall be paid to the proprietor of the patent concerned granted in Hong Kong for the import compulsory licence in relation to the product.

(2) If the proprietor of the patent concerned granted in Hong Kong establishes to the satisfaction of the Director that remuneration has not been paid to the proprietor of the patent granted in the exporting member for the production and export of the patented pharmaceutical product to Hong Kong in accordance with the relevant instrument or legislation and all legal remedies to recover payment of the remuneration in the exporting member have been exhausted, the Government shall pay to the proprietor of the patent concerned granted in Hong Kong such amount of remuneration—

(*a*) as may be agreed between the Director and the proprietor of the patent concerned granted in Hong Kong subject to any order made by the court on an application under section 72J(2); or

(*b*) as may be determined by the court on an application under section 72J(1) or (2),

for the import compulsory licence in relation to the product.

(3) Before reaching any agreement as to the amount of remuneration, the Director shall take into account any advice given by the Director of Intellectual Property as regards the remuneration.

(4) The total amount of remuneration agreed under subsection (2)(*a*) to be payable in respect of the patent or all the patents (if there is more than one patent in relation to the patented pharmaceutical product) shall not exceed 4% of the total purchase price for the product payable by the import compulsory licensee to the seller of the product in the exporting member.

(5) Where there is more than one patent in relation to the patented pharmaceutical product, the total amount of remuneration agreed under subsection (2)(*a*) shall be apportioned on an equal share basis among all the proprietors of the patents concerned.

(6) The Secretary for Commerce and Economic Development may by notice published in the Gazette vary the percentage specified in subsection (4).

72F. Notification of grant of import compulsory licences and remuneration agreed, etc.

(1) The Director shall as soon as practicable after the grant of an import compulsory licence under section 72C—

(*a*) give notice in writing to the proprietor of the patent concerned of the grant of the licence and its terms and conditions; and

(*b*) advertise in the official journal notice of the grant of the licence and its terms and conditions.

(2) The Director shall—

(*a*) as soon as practicable after any amount of remuneration has been agreed under section 72E(2)(*a*) between him and the proprietor of the patent concerned, advertise in the official journal a notice stating—

(i) the amount of remuneration so agreed with the proprietor of the patent concerned named in the notice and, where applicable, the apportionment of the amount of remuneration under section 72E(5); and

(ii) that any other person who is entitled to claim remuneration payable under section 72E(2) may make an application to the court under section 72J(2); or

(*b*) as soon as practicable after he is satisfied that he and the proprietor of the patent concerned have failed to agree on the amount of remuneration payable under section 72E(2), advertise in the official journal a notice stating—

(i) the fact of the failure to agree on the amount of remuneration with the proprietor of the patent concerned named in the notice; and

(ii) that any other person who is entitled to claim remuneration payable under that section may make an application to the court under section 72J(2).

72G. Termination of import compulsory licences

(1) The Director may terminate an import compulsory licence by giving notice in writing to the import compulsory licensee if he is satisfied that any term or condition of the licence imposed under section 72C has been contravened.

(2) The Director shall as soon as practicable after the termination of an import compulsory licence under subsection (1)—

(*a*) give notice in writing to the proprietor of the patent concerned of the termination; and

(*b*) advertise in the official journal notice of the termination.

72H. Disposal of patented pharmaceutical products after period of extreme urgency etc.

(1) On the termination of the period of extreme urgency by a notice under section 72B(3), the import compulsory licensee shall take reasonable steps to recall or cause to recall any patented pharmaceutical product which is imported under the import compulsory licence from any person (other than a person who is in possession of the product privately for non-commercial purposes) who is in possession of the product disposed of in accordance with the licence.

(2) An import compulsory licensee shall—

(*a*) surrender to the Director any patented pharmaceutical product which is in his possession or recalled under subsection (1); or

(*b*) dispose of the product in such a way as may be agreed with the proprietor of the patent concerned granted in Hong Kong.

(3) Where a patented pharmaceutical product is surrendered to the Director under subsection (2)(*a*)—

(*a*) the Government shall pay to the import compulsory licensee a sum equivalent to the purchase price for the product paid by the licensee to the seller of the product in the exporting member; and

(*b*) the Director shall—

(i) dispose of the product in such a way as may be agreed with the proprietor of the patent concerned granted in Hong Kong; or

(ii) in default of agreement, destroy the product as soon as practicable.

(4) For the avoidance of doubt, stocking of any patented pharmaceutical product which is imported under an import compulsory licence does not amount to an infringement of the patent concerned on the part of the import compulsory licensee or the Director from the termination of the period of extreme urgency by a notice under section 72B(3) until—

(*a*) the import compulsory licensee surrenders the product to the Director under subsection (2)(*a*) or disposes of the product under subsection (2)(*b*); or

(*b*) the Director disposes of the product under subsection (3)(*b*)(i) or destroys the product under subsection (3)(*b*)(ii),

as the case may be.

72I. No infringement of patents by persons to whom patented pharmaceutical products are disposed of in accordance with import compulsory licences

(1) A person to whom a patented pharmaceutical product is disposed of in accordance with an import compulsory licence may, without consent of the proprietor of the patent concerned, put on the market, stock or use the product, in Hong Kong, for the purposes in connection with the extreme urgency giving rise to the declaration under section 72B(1) as if he had been authorized by the licence to do so.

(2) A person to whom a patented pharmaceutical product is disposed of in accordance with an import compulsory licence shall not export or cause to export the product out of Hong Kong.

72J. References of disputes as to import compulsory licences

(1) If the Director and the proprietor of the patent concerned fail to agree on the amount of remuneration payable under section 72E(2), either party may, subject to subsection (5), apply to the court for an order to determine the amount of remuneration payable under that section.

(2) A person who is not a party to any agreement reached on the amount of remuneration under section 72E(2)(*a*) but is entitled to claim remuneration payable under section 72E(2) may, subject to subsection (5), apply to the court for an order for payment of remuneration under that section.

(3) In determining the appropriate amount of remuneration payable to the proprietor of the patent concerned, the court shall take into account all factors relevant to the circumstances, including—

(*a*) the economic value to Hong Kong of the use of the patented pharmaceutical product imported under the relevant import compulsory licence; and

(*b*) humanitarian or non-commercial factors relevant to the grant of the licence.

(4) The total amount of remuneration determined by the court under subsection (3) to be payable in respect of the patent or all the patents (if there is more than one patent in relation to the patented pharmaceutical product) may exceed the maximum amount of remuneration that may be agreed under section 72E(2)(*a*).

(5) No application may be made under subsection (1) or (2) after the expiry of the period of 28 days from the date of the advertisement of the notice under section 72F(2), unless the court determines otherwise.

(6) Any person aggrieved by—

(*a*) the grant of an import compulsory licence;

(*b*) any term or condition of an import compulsory licence imposed under section 72C;

(*c*) the apportionment of the amount of remuneration under section 72E(5); or

(*d*) the termination of an import compulsory licence under section 72G(1),

may, within 28 days after the date of the advertisement of the notice under section 72F(1)(*b*) or (2)(*a*)(i) or the date of the termination of the licence (as the case may be) or such further period as may be allowed by the court, apply to the court for a review of the grant of the licence, the terms or conditions of the licence, the apportionment of the amount of remuneration or the termination of the licence (as the case may be).

(7) In a review the court may—

(*a*) confirm, vary or cancel the import compulsory licence;

(*b*) confirm, vary or cancel a term or condition of the import compulsory licence imposed under section 72C;

(*c*) confirm or vary the apportionment of the amount of remuneration under section 72E(5);

(*d*) confirm or reverse the termination of the import compulsory licence under section 72G(1); or

(*e*) make any other order as the court thinks fit in the circumstances.

(8) The proprietor of the patent concerned may apply to the court for an order to terminate an import compulsory licence on the ground that any term or condition of the licence imposed under section 72C has been contravened.

(9) The court may, on an application under subsection (8)—

(*a*) make an order to terminate the import compulsory licence if the court is satisfied that any term or condition of the licence imposed under section 72C has been contravened; and

(*b*) make any other order as the court thinks fit in the circumstances.

PART IXB

EXPORT COMPULSORY LICENCES FOR PATENTED PHARMACEUTICAL PRODUCTS

72K. Interpretation of Part IXB

In this Part, unless the context otherwise requires—

"Director" (署長) means the Director of Health;

"export compulsory licence" (出口強制性特許) means a compulsory licence granted under section 72M;

"export compulsory licensee" (出口強制性特許持有人) means the holder of an export compulsory licence;

"Hong Kong patent number" (香港專利編號), in relation to a patent, means—

(*a*) a number assigned by the Registrar to a certificate issued in respect of the patent under section 27(1)(*b*);

(*b*) a number assigned by the Registrar to a certificate of grant issued in respect of the patent under section 118(2)(*b*); or

(*c*) a number assigned by the Registrar to a certificate of registration issued in respect of the patent under the Registration of Patents Ordinance (Cap. 42) which has been repealed under section 154(1);

"proprietor" (所有人), in relation to a patent, means the proprietor of the patent that is granted in Hong Kong.

72L. Application for export compulsory licences for patented pharmaceutical products

(1) At any time after the grant of a standard patent or a short-term patent in respect of a patented pharmaceutical product, any person may apply to the Director for the grant of an export compulsory licence under the patent concerned in relation to the product under section 72M.

(2) The application shall be made in writing and—

(*a*) shall specify the following information—

(i) the name and address of the applicant and of any agent or representative authorized by the applicant for the purpose of the application;

(ii) the name of the patented pharmaceutical product to be made and sold for export under an export compulsory licence the subject of the application;

(iii) the amount of the patented pharmaceutical product to be made and sold for export under the export compulsory licence;

(iv) the name of the eligible importing member to which the patented pharmaceutical product is to be exported under the export compulsory licence;

(v) the duration of the export compulsory licence applied for by the applicant;

(vi) the Hong Kong patent number or Hong Kong patent numbers in relation to the patented pharmaceutical product;

(vii) the proposed labelling, marking, packaging, colouring or shaping for the patented pharmaceutical product required by section 72N(1)(*b*)(ii);

(viii) the address of a website on which the applicant is required to post the information referred to in section 72N(1)(*b*)(iii);

(ix) any information obtained pursuant to subsection (3);

(x) any other information as the Director may reasonably require for the purposes of granting the export compulsory licence; and

(*b*) shall be accompanied by—

(i) a copy of the written request from the eligible importing member, any representative, non-governmental organization or international health organization authorized by the eligible importing member to the applicant for the patented pharmaceutical product and the amount of the product requested;

(ii) a copy of the notification made by the eligible importing member to the TRIPS Council stating—
(A) the name and the amount of the patented pharmaceutical product requested by the eligible importing member;
(B) where the eligible importing member is not a least-developed country recognized by the United Nations, that the eligible importing member has no or insufficient capacity to manufacture the patented pharmaceutical product; and
(C) where the pharmaceutical product is patented in the eligible importing member, that the eligible importing member has granted or intends to grant a compulsory licence to import the product in accordance with the relevant instrument or legislation;
(iii) where applicable, a copy of notice of the intended application given to the proprietor of the patent concerned under subsection (4)(*b*)(i) or (5)(*a*)(i);
(iv) where applicable, a declaration made by the applicant under the Oaths and Declarations Ordinance (Cap. 11) declaring that he has made reasonable efforts in accordance with subsection (4)(*a*) to obtain authorization from the proprietor of the patent concerned on reasonable commercial terms and conditions but the efforts have not been successful within 28 days after they had been made; and
(v) if the pharmaceutical product is patented in the eligible importing member, documentary evidence of any compulsory licence granted by the eligible importing member for importation of the product.

(3) A person who intends to make an application under subsection (1) shall, before he makes the application, take reasonable steps to obtain from the eligible importing member information on the amount of the patented pharmaceutical product to be made and exported to the eligible importing member by any exporting member other than Hong Kong under any compulsory licence granted elsewhere.

(4) Where a person intends to make an application under subsection (1) and the eligible importing member has not notified the TRIPS Council that it is faced with a national emergency or other circumstances of extreme urgency, the person shall—

(*a*) not later than 28 days before the date of the application, make reasonable efforts to obtain authorization from the proprietor of the patent concerned on reasonable commercial terms and conditions to make and sell for export the patented pharmaceutical product of such amount as requested by the eligible importing member; and

(*b*) not later than 14 days before the date of the application—

(i) give the proprietor of the patent concerned notice of the intended application containing the information required under subsection (2)(*a*) (except subparagraphs (viii) and (x) of that subsection); and

(ii) attach to the notice all the documents and documentary evidence required under subsection (2)(*b*) (except subparagraphs (iii) and (iv) of that subsection).

(5) Where a person intends to make an application under subsection (1) and the eligible importing member has notified the TRIPS Council that it is faced with a national emergency or other circumstances of extreme urgency, the person shall—

(*a*) (i) at any time before the application is made, give the proprietor of the patent concerned notice of the intended application containing the information required under subsection (2)(*a*) (except subparagraphs (viii) and (x) of that subsection); or

(ii) as soon as practicable after the application is made, give the proprietor of the patent concerned notice of the application containing the information required under subsection (2)(*a*);

(*b*) attach to the notice all the documents and documentary evidence required under subsection (2)(*b*) (except subparagraphs (iii) and (iv) of that subsection); and

(*c*) as soon as practicable after notice is given under paragraph (*a*), submit a copy of the notice to the Director.

72M. Grant of export compulsory licences for patented pharmaceutical products

The Director may grant an export compulsory licence under the patent concerned, subject to such terms and conditions as he may impose, to an applicant to make a patented pharmaceutical product and sell the product for export to an eligible importing member if he is satisfied that—

(*a*) all the requirements of section 72L have been met;

(*b*) the amount of the product applied for by the applicant to be made and sold for export under the licence does not exceed the amount stated in the notification referred to in section 72L(2)(*b*)(ii)(A), after taking into account any information obtained pursuant to section 72L(3); and

(*c*) the application is made in response to the request from the eligible importing member referred to in section 72L(2)(*b*)(i).

72N. Terms, conditions and nature of export compulsory licences

(1) The terms and conditions subject to which an export compulsory licence is granted under section 72M shall include—

(*a*) terms and conditions in respect of—

(i) the acts authorized to be done in relation to the patented pharmaceutical product under the licence;

(ii) the amount of the patented pharmaceutical product authorized to be made and sold for export under the licence;

(iii) the eligible importing member to which the patented pharmaceutical product is to be exported under the licence; and

(iv) the duration of the licence;

(*b*) terms and conditions providing that—

(i) the licence is non-assignable except with that part of the enterprise or goodwill which enjoys the use of the patent under the licence;

(ii) the patented pharmaceutical product shall be—

(A) clearly identified as being made under the licence through specific labelling or marking; and

(B) distinguished from the same product made by or under authorization of the proprietor of the patent concerned through special packaging, colouring or shaping;

(iii) the export compulsory licensee shall, before shipment of the patented pharmaceutical product to the eligible importing member under the licence, post on the website maintained by or on behalf of the licensee or on the WTO website information in relation to—

(A) the amount of the patented pharmaceutical product that will be exported to the eligible importing member under the shipment; and

(B) the labelling, marking, packaging, colouring or shaping for the patented pharmaceutical product required by subparagraph (ii);

(iv) the export compulsory licensee shall pay to the proprietor of the patent concerned such amount of remuneration as determined by the Director under section 72P(1) for the export compulsory licence in relation to the product;

(v) where there is more than one patent in relation to the patented pharmaceutical product, the export compulsory licensee shall apportion on an equal share basis among all the proprietors of the patents concerned the total amount of remuneration determined by the Director under section 72P(1);

(vi) subject to subparagraph (vii), the patented pharmaceutical product made under the licence shall be exported only to the eligible importing member specified in the licence; and

(vii) if the patented pharmaceutical product is also patented in the eligible importing member, the product shall be exported to the eligible importing member after it has granted a compulsory licence for importation of the product; and

(*c*) any other terms or conditions as the Director thinks fit.

(2) An export compulsory licence is non-exclusive.

72O. Notification of grant of export compulsory licences

The Director shall as soon as practicable after the grant of an export compulsory licence under section 72M—

(*a*) give notice in writing to the proprietor of the patent concerned, as identified pursuant to the information specified in the application in accordance with section 72L(2)(*a*)(vi), of the grant of the licence and its terms and conditions; and

(*b*) advertise in the official journal notice of the grant of the licence and its terms and conditions.

72P. Determination of remuneration payable to proprietors of patents

(1) The Director shall determine the amount of remuneration payable to the proprietor of the patent concerned under section 72N(1)(*b*)(iv).

(2) In determining the amount of remuneration, the Director shall take into account any advice given by the Director of Intellectual Property as regards the remuneration.

(3) The total amount of remuneration determined by the Director under subsection (1) to be payable in respect of the patent or all the patents (if there is more than one patent in relation to the patented pharmaceutical product) shall not exceed 4% of the total purchase price for the product payable by the eligible importing member to the export compulsory licensee.

(4) The Secretary for Commerce and Economic Development may by notice published in the Gazette vary the percentage specified in subsection (3).

72Q. Termination of export compulsory licences

(1) The Director may terminate an export compulsory licence by giving notice in writing to the export compulsory licensee if he is satisfied that—

(*a*) any term or condition of the licence imposed under section 72M has been contravened; or

(*b*) any information, document or documentary evidence specified in or accompanying the application in accordance with section 72L(2) is false, incorrect or incomplete in any material particular.

(2) The Director shall as soon as practicable after the termination of an export compulsory licence under subsection (1)—

(*a*) give notice in writing to the proprietor of the patent concerned, as identified pursuant to the information specified in the application in accordance with section 72L(2)(*a*)(vi), of the termination; and

(*b*) advertise in the official journal notice of the termination.

72R. References of disputes as to export compulsory licences

(1) Any person aggrieved by—

(*a*) the grant of an export compulsory licence;
(*b*) any term or condition of an export compulsory licence imposed under section 72M; or
(*c*) the termination of an export compulsory licence under section 72Q(1),

may, within 28 days after the date of the advertisement of the notice under section 72O(*b*) or the date of the termination of the licence (as the case may be) or such further period as may be allowed by the court, apply to the court for a review of the grant of the licence, the terms or conditions of the licence or the termination of the licence (as the case may be).

(2) In a review the court may—
(*a*) confirm, vary or cancel the export compulsory licence;
(*b*) confirm, vary or cancel a term or condition of the export compulsory licence imposed under section 72M;
(*c*) confirm or vary the determination of the amount of remuneration under section 72P(1);
(*d*) confirm or reverse the termination of the export compulsory licence under section 72Q(1); or
(*e*) make any other order as the court thinks fit in the circumstances.

(3) In determining the appropriate amount of remuneration payable to the proprietor of the patent concerned, the court shall take into account all factors relevant to the circumstances, including—
(*a*) the economic value to the eligible importing member of the use of the patented pharmaceutical product exported to it under the relevant export compulsory licence; and
(*b*) humanitarian or non-commercial factors relevant to the grant of the licence.

(4) The total amount of remuneration determined by the court under subsection (3) to be payable in respect of the patent or all the patents (if there is more than one patent in relation to the patented pharmaceutical product) may exceed the maximum amount of remuneration that may be determined by the Director under section 72P(1).

(5) The proprietor of the patent concerned may apply to the court for an order to terminate an export compulsory licence on the ground that—
(*a*) any term or condition of the licence imposed under section 72M has been contravened; or
(*b*) any information, document or documentary evidence specified in or accompanying the application in accordance with section 72L(2) is false, incorrect or incomplete in any material particular.

(6) The court may, on an application under subsection (5)—

(*a*) make an order to terminate the export compulsory licence if the court is satisfied that—

(i) any term or condition of the licence imposed under section 72M has been contravened; or

(ii) any information, document or documentary evidence specified in or accompanying the application in accordance with section 72L(2) is false, incorrect or incomplete in any material particular; and

(*b*) make any other order as the court thinks fit in the circumstances.

72S. Signature of documents by partnerships, companies and associations

For the purposes of this Part—

(*a*) a document signed for or on behalf of a firm shall be signed by all of its partners, by any partner stating that he signs on behalf of the firm or by any other person who satisfies the Director that he is authorized by the firm to sign the document;

(*b*) a document signed for or on behalf of a body corporate shall be signed by a director or the secretary or other principal officer of the body corporate or by any other person who satisfies the Director that he is authorized by the body corporate to sign the document; and

(*c*) a document signed for or on behalf of an unincorporated body or association of persons other than a firm shall be signed by any person who satisfies the Director that he is authorized by the unincorporated body or association of persons (as the case may be) to sign the document.".

6. Licences granted by order of the court or Registrar

(1) The heading of section 138 is amended by adding "**or by Director of Health**" after "**Registrar**".

(2) Section 138 is amended—

(*a*) by renumbering it as section 138(1);

(*b*) by adding—

"(2) Without prejudice to any other method of enforcement, any import compulsory licence or export compulsory licence granted under section 72C or 72M (as the case may be) has effect as if it were a deed, executed by the proprietor of the standard patent or the short-term patent (as the case may be) and all other necessary parties.".

7. Section added

The following is added—

"**139A. Protection of Government and public officers**

(1) No liability shall rest on the Government or any public officer by reason of the fact that—

(*a*) any authority is given under section 69; or

(*b*) any import compulsory licence or export compulsory licence is granted under section 72C or 72M (as the case may be).

(2) A public officer is not personally liable in respect of any act or omission of his if it was done or made by him in the honest belief that it was required or authorized in the exercise of any function, duty or power of his under Part IX, IXA or IXB (as the case may be).

(3) The protection conferred on public officers by subsection (2) in respect of any act or omission does not affect any liability of the Government in tort for that act or omission.".