

Measures on Compulsory Licensing for Patent Exploitation

Order No. 64 of the State Intellectual Property Office
(promulgated on 15 March 2012 and implemented on 1 May 2012)

Chapter I General Provisions

Article 1 The Measures are formulated in accordance with the Patent Law of the PRC (hereinafter as “the Patent Law”), the Implementing Regulations of the Patent Law of the PRC (hereinafter as “the Implementing Regulations”) and the relevant laws and regulations for the purposes of regulating the procedures relating to granting, royalty adjudication and termination of compulsory licensing for the exploitation of invention patents or utility model patents (hereinafter as “compulsory licensing”).

Article 2 The State Intellectual Property Office shall be responsible for accepting and examining the requests for granting, royalty adjudication and termination of compulsory licensing, as well as making decisions on the requests.

Article 3 The requests for granting, royalty adjudication and termination of compulsory licensing shall be executed in written form in Chinese.

Where any of the certificates or supporting documents submitted in compliance with the Measures is in a foreign language, the State Intellectual Property Office, if deems it necessary, may require the party concerned to submit a Chinese translation thereof within a specified time limit; failure to submit the translation thereof within the specified time limit shall be deemed as not having filed the certificate or supporting document.

Article 4 In handling compulsory licensing related matters, a foreigner or a foreign enterprise or any other foreign organization having no habitual residence or place of business in China shall entrust the matters to a legally established patent agency.

A party who entrusts a patent agency with compulsory licensing related matters shall submit a power of attorney that states clearly the scope of authority entrusted. Where one side of the party consists of two or more members and no patent agency is entrusted, the member of the party whose name appears first in the written documents submitted shall be deemed as representative of the party, unless otherwise stated.

Chapter II Submission and Acceptance of Requests for Compulsory Licensing

Article 5 Where a patentee, with no legitimate grounds, fails to exploit or adequately exploit its or his patent after the lapse of three years from the date on which the patent is granted and after the lapse of four years from the date on which the patent application is submitted, an entity or individual which is qualified to exploit the patent may file a request for the grant of compulsory licensing pursuant to Article 48 (1) of the Patent Law.

Where the act of exercising the patent right by a patentee is legally determined as monopolistic behavior, an entity or individual which is qualified to exploit the patent may file a request for the grant of compulsory licensing pursuant to Article 48 (2) of the Patent Law for the purpose of eliminating or reducing the adverse consequences of the act on competition.

Article 6 Where a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires, a competent department under the State Council may recommend to the State Intellectual Property Office the grant of compulsory licensing to a designated entity which is qualified to exploit the patent according to Article 49 of the Patent Law.

Article 7 For the purpose of public health, an entity which is qualified to exploit the patent may, pursuant to Article 50 of the Patent Law, file a request for compulsory licensing for manufacturing a patented pharmaceutical product and exporting the same to the following countries or regions:

- (1) The least developed countries or regions;
- (2) The developed or developing members of the World Trade Organization (WTO) that have expressed to the WTO their intention to be the importers according to the provisions of relevant international treaties.

Article 8 Where a patented invention or utility model brings important technical progress with obvious economic significance over a previously patented invention or utility model and the exploitation thereof depends on that of the earlier invention or utility model, the patentee may request for compulsory licensing for exploiting the earlier patent pursuant to Article 51 of the Patent Law. Where the State Intellectual Property Office has granted compulsory licensing for the exploitation of the earlier patent, the patentee of the earlier patent may request for compulsory licensing for the exploitation of the latter patent.

Article 9 In filing a request for compulsory licensing, a written request containing the following shall be submitted:

- (1) The name, address, and postal code of the requester, as well as the name and telephone number of the contact person;
- (2) The nationality of the requester or the country/region in which the requester is registered;
- (3) The name, patent number, application date, grant announcement date of the invention patent or utility model patent of which the compulsory licensing is requested, as well as the name of the patentee;

(4) The reasons and facts for the request for compulsory licensing, and the duration requested for the compulsory licensing;

(5) In case of entrusting a patent agency, the name and organization code of the entrusted patent agency as well as the name, practicing certificate number and contact telephone number of the agent designated by the patent agency;

(6) The signature or seal of the requester, and, in case of entrusting a patent agency, the seal of the entrusted agency as well;

(7) A list of the documents attached;

(8) Other items as required to be specified.

The written request and the attached documents shall be submitted in duplicate.

Article 10 Where a request for compulsory licensing involves two or more patentees, the copy number of the written request and the attached documents shall correspond to the number of the patentees.

Article 11 Where a request for compulsory licensing is made pursuant to Articles 48 (1) or 51 of the Patent Law, the requester shall provide evidence to prove that it or he has requested for a license for patent exploitation from the patentee on reasonable terms but has not been able to obtain a license within a reasonable period of time.

Where a request for compulsory licensing is made pursuant to Article 48 (2) of the Patent Law, the requester shall submit the effective judgment or decision issued by a judicial organ or anti-monopoly law enforcement agency determining that the act of exercising the patent right by the patentee is monopolistic behavior.

Article 12 Where a competent department under the State Council recommends the grant of compulsory licensing in accordance with Article 49 of the Patent Law, it shall specify the following:

(1) The granting of compulsory licensing is required by the occurrence of a national emergency or any extraordinary state of affairs, or for the purpose of public interest;

(2) The name, patent number, application date, grant announcement date of the invention patent or utility model patent of which the granting of compulsory licensing is recommended, as well as the name of the patentee;

(3) The duration of compulsory licensing recommended to be granted;

(4) The name, address, postal code, contact person and telephone number of the designated entity which is qualified to exploit the patent;

(5) Other items as required to be specified.

Article 13 Where a request for compulsory licensing is made pursuant to Article 50 of the Patent Law, the requester shall provide the relevant information concerning the importer, the pharmaceutical product required by the importer and the granting of compulsory licensing.

Article 14 Under any of the following circumstances relating to a request for compulsory licensing, the request shall not be accepted and no notification will be sent to the requester:

(1) The patent number of the invention patent or utility model patent of which the granting of compulsory licensing is requested is unclear or hard to identify;

(2) The documents submitted for the request are not in Chinese;

(3) The request for compulsory licensing is obviously groundless;

(4) The patent of which the granting of compulsory licensing is requested has been terminated or has been declared invalid.

Article 15 Where the documents submitted for the request do not comply with the provisions of Articles 4, 9 or 10 of the Measures, the requester shall make rectification within 15 days upon receipt of the notification. In case of failure to make rectification within the time period, the request will be deemed as not having been submitted.

Article 16 If the State Intellectual Property Office accepts a request for compulsory licensing, it shall deliver a duplicate copy of the written request to the patentee. Except otherwise specified, the patentee may state its or his opinions within 15 days upon receipt of the notification. Failure to make a reply within the specified time limit will not influence the decision-making of the State Intellectual Property Office.

Chapter III Review of and Decision on Request for Compulsory Licensing

Article 17 The State Intellectual Property Office shall review the reasons, information and relevant supporting documents provided by the requester as well as the opinions stated by the patentee. Where on-site verification is required, the State Intellectual Property Office shall assign two or more staff members to conduct the verification.

Article 18 The State Intellectual Property Office may hold a hearing upon the request of the requester or the patentee.

The State Intellectual Property Office shall notify the requester, the patentee and any other interested parties 7 days before the hearing.

Except for involvement of state secret, trade secret or personal privacy in the proceeding, the hearing shall be held in open session.

During the hearing, the requester, the patentee and the interested parties have the right to make pleading and cross-examine.

A transcript of the hearing shall be made and passed to the participants for signing or sealing upon confirmation of no mistakes therein.

The hearing procedure is not applicable to cases in which the granting of compulsory licensing is recommended or requested pursuant to Articles 49 or 50 of the Patent Law.

Article 19 Where the requester withdraws its or his request before the State Intellectual Property Office arrives at a decision, the review of the request for compulsory licensing shall terminate.

Where the requester and the patentee reach a licensing agreement on patent exploitation before the State Intellectual Property Office arrives at a decision, the requester shall inform the State Intellectual Property Office in a timely manner and withdraw the request for compulsory licensing.

Article 20 If after review the request for compulsory licensing is found to fall under any of the following circumstances, the State Intellectual Property Office shall make a decision of dismissing the request:

- (1) The requester does not satisfy the provisions of Articles 4, 5, 7 or 8 of the Measures;
- (2) The reasons for the request for compulsory licensing do not comply with the provisions of Articles 48, 50 or 51 of the Patent Law;
- (3) The invention-creation involved in a request for compulsory licensing is a semiconductor technology and the reasons for the request do not comply with the provisions of Article 52 of the Patent Law;
- (4) The request for compulsory licensing does not comply with the provisions of Articles 11 or 13 of the Measures;

(5) The reasons, information or the relevant supporting documents provided by the requester are inadequate or untrue.

Before making the decision to dismiss the request for compulsory licensing, the State Intellectual Property Office shall notify the requester of its intention to make the decision and the grounds for it. Except otherwise specified, the requester may state its or his opinions within 15 days upon receipt of the notification.

Article 21 If after review the reasons for the request for compulsory licensing are found to be tenable, the State Intellectual Property Office shall make a decision of granting compulsory licensing. Before making the decision, the State Intellectual Property Office shall notify the requester and the patentee of its intention to grant the compulsory licensing and the grounds for it. Except otherwise specified, the requester and the patentee may state their opinions within 15 days upon receipt of the notification.

In granting compulsory licensing pursuant to Article 49 of the Patent Law, the State Intellectual Property Office shall notify the patentee in advance of its intention to make the decision and the grounds for it.

Article 22 The decision on the grant of compulsory licensing shall contain the following:

- (1) The name and address of the individual or entity to which the compulsory licensing is granted;
- (2) The name, patent number, application date and grant announcement date of the invention patent or utility model patent relating to the compulsory licensing granted;
- (3) The scope and duration of the compulsory licensing granted;
- (4) The reasons, facts and legal basis for the decision;
- (5) The seal of the State Intellectual Property Office and the signature of the responsible person;
- (6) The date of issuing the decision; and
- (7) Other relevant matters.

The decision of granting the compulsory licensing shall be notified to the requester and the patentee within 5 days upon issuance of the decision.

Article 23 In granting compulsory licensing in accordance with Article 50 of the Patent Law, the State Intellectual Property Office shall specify the following requirements in the decision:

- (1) The quantity of the pharmaceutical product manufactured under compulsory licensing shall not exceed the quantity required by the importer and all of the pharmaceutical product shall be exported to such importer;

(2) The pharmaceutical product manufactured under compulsory licensing shall use specific label or tag to indicate clearly that it is manufactured under compulsory licensing. Given no significant impact on its price, the pharmaceutical product, where feasible, shall be in special color, shape or package; and

(3) Prior to shipping of the pharmaceutical product, the entity that has been granted the compulsory licensing shall publish on its web page or relevant web page of World Trade Organisation the information including quantity of the pharmaceutical product shipped to the importer and features identifying the pharmaceutical product as specified in item (2) of this Article.

Article 24 Where the State Intellectual Property Office grants compulsory licensing in accordance with Article 50 of the Patent Law, the competent department under the State Council shall inform the World Trade Organisation of the following:

(1) The name and address of the entity to which the compulsory licensing is granted;

(2) The name and quantity of the exported pharmaceutical product;

(3) The importer;

(4) The duration of the compulsory licensing; and

(5) The web page referred to in Article 23 (3) of the Measures.

Chapter IV Review of and Ruling on Requests for Adjudication on Compulsory Licensing Royalties

Article 25 In requesting for adjudication on the royalties for compulsory licensing, a written request containing the following shall be submitted:

- (1) The name and address of the requester;
- (2) The nationality of the requester or the country/region in which the requester is registered;
- (3) The document number of the decision on the grant of the compulsory licensing;
- (4) The name and address of the requestee;
- (5) The reasons for the request for adjudication on royalties of compulsory licensing;
- (6) In case of entrusting a patent agency, the name and organisation code of the entrusted patent agency as well as the name, practicing certificate number and contact telephone number of the agent designated by the patent agency;
- (7) The signature or seal of the requester, and, in case of entrusting a patent agency, the seal of the entrusted agency as well;
- (8) A list of the documents attached;
- (9) Other matters as required to be specified.

The written request and the attached documents shall be submitted in duplicate.

Article 26 Under any of the following circumstances relating to a request for the adjudication of royalties on compulsory licensing, the request shall not be accepted and no notification will be sent to the requester:

- (1) A decision of granting compulsory licensing has not been made;
- (2) The requester is not the patentee or the entity or individual that has been granted the compulsory licensing;
- (3) The two parties have not conducted any negotiation or they have not reached an agreement through negotiation.

Article 27 If the State Intellectual Property Office accepts the request for adjudication of royalties on compulsory licensing, it shall promptly deliver a duplicate copy of the request to the other party. Except otherwise specified, the other party may state its or his opinions within 15 days upon receipt of the notification. Failure to make a reply within the specified time limit will not influence the decision-making of the State Intellectual Property Office.

In the course of adjudicating the royalties for compulsory licensing, both parties concerned may submit written opinions. The State Intellectual Property Office, if deems it necessary, may hear oral arguments of both parties.

Article 28 Where the requester withdraws its or his request for adjudication before the State Intellectual Property Office arrives at a decision, the adjudication procedures shall terminate.

Article 29 The State Intellectual Property Office shall within 3 months upon receipt of the written request make a decision on the adjudication of royalties for compulsory licensing.

Article 30 The decision on the adjudication of royalties for compulsory licensing shall contain the following:

- (1) The name and address of the individual or entity to which the compulsory licensing is granted;
- (2) The name, patent number, application date and grant announcement date of the invention patent or utility model patent relating to the compulsory licensing granted;
- (3) The contents of and reasons for the adjudication;
- (4) The seal of the State Intellectual Property Office and the signature of the responsible person;
- (5) The date of issuing the decision; and
- (6) Other relevant matters.

Both parties shall be notified of the decision of the adjudication of royalties for compulsory licensing within 5 days upon issuance of the decision.

Chapter V Review of and Decision on Request for Termination of Compulsory Licensing

Article 31 The compulsory licensing may be terminated automatically under any of the following circumstances:

- (1) The expiry of the term of the compulsory licensing as specified in the decision on the grant of the compulsory licensing;
- (2) The termination or invalidation of the invention patent or utility model patent of which the compulsory licensing is granted.

Article 32 Where the reasons for compulsory licensing are eliminated with no recurrence prior to the expiry of the term of the compulsory licensing as specified in the decision on the grant of the compulsory licensing, the patentee may request the State Intellectual Property Office to terminate the compulsory licensing.

In requesting for termination of the compulsory licensing, a written request containing the following shall be submitted:

- (1) The name and address of the patentee;
- (2) The nationality of the patentee or the country/region in which the patentee is registered;
- (3) The document number of the decision on the grant of the compulsory licensing requested to be terminated;
- (4) The reasons for requesting the termination of the compulsory licensing;
- (5) In case of entrusting a patent agency, the name, organisation code of the entrusted patent agency as well as the name, practising certificate number and contact telephone number of the agent designated by the patent agency;
- (6) The signature or seal of the patentee, and, in case of entrusting a patent agency, the seal of the agency as well;
- (7) A list of the documents attached;
- (8) Other matters as required to be specified.

The patentee shall submit the written request and the attached documents in duplicate.

Article 33 Under any of the following circumstances relating to a request for terminating the compulsory licensing, the request shall not be accepted and no notification will be sent to the requester:

- (1) The requester is not the patentee of the invention patent or utility model patent of which the compulsory licensing is granted;

(2) The document number of the decision on the grant of the compulsory licensing requested to be terminated is not specified;

(3) The documents submitted for the request are not in Chinese;

(4) The request for terminating the compulsory licensing is obviously groundless.

Article 34 Where the documents submitted for the request do not comply with the provisions of Article 32 of the Measures, the requester shall make rectification within 15 days upon receipt of the notification. In case of failure to make rectification within the time period, the request will be deemed as not having been submitted.

Article 35 If the State Intellectual Property Office accepts the request for terminating the compulsory licensing, it shall deliver a duplicate copy of the request to the entity or individual that has been granted the compulsory licensing. Except otherwise specified, the entity or individual that has been granted the compulsory licensing may state its or his opinions within 15 days upon receipt of the notification. Failure to make a reply within the specified time limit will not influence the decision-making of the State Intellectual Property Office.

Article 36 The State Intellectual Property Office shall review the reasons and relevant supporting documents provided by the patentee, as well as the opinions stated by the entity or individual that has been granted the compulsory licensing. Where on-site verification is required, the State Intellectual Property Office shall assign two or more staff members to conduct the verification.

Article 37 In case the patentee withdraws its or his request before the State Intellectual Property Office arrives at a decision, the corresponding procedures shall terminate.

Article 38 If after review the reasons for the request for terminating the compulsory licensing are found to be untenable, the State Intellectual Property Office shall make a decision of dismissing the request for terminating the compulsory licensing. Before making the decision, the State Intellectual Property Office shall notify the patentee of its intention to dismiss the request for terminating the compulsory licensing and the grounds for it. Except otherwise specified, the patentee may state its or his opinions within 15 days upon receipt of the notification.

Article 39 If after review the reasons for the request for terminating the compulsory licensing are found to be tenable, the State Intellectual Property Office shall make a decision of terminating the compulsory licensing. Before making the decision, the State Intellectual Property Office shall notify the patentee of its intention to terminate the compulsory licensing and the grounds for it. Except otherwise specified, the individual or entity that has been granted the compulsory licensing may state its or his opinions within 15 days upon receipt of the notification.

The decision on the termination of the compulsory licensing shall contain the following:

(1) The name and address of the patentee;

(2) The name and address of the individual or entity to which the compulsory licensing has been granted;

(3) The name, patent number, application date and grant announcement date of the invention patent or utility model patent relating to the granted compulsory licensing;

(4) The document number of the decision on the grant of the compulsory licensing;

(5) The facts and legal basis for the decision;

(6) The seal of the State Intellectual Property Office and the signature of the responsible person;

(7) The date of issuing the decision;

(8) Other relevant matters.

The decision of terminating the compulsory licensing shall be notified to the patentee and the entity or individual to which the compulsory licensing has been granted within 5 days upon issuance of the decision.

Supplementary Provisions

Article 40 The decision that has come into force regarding the granting or termination of compulsory licensing as well as the automatic termination of compulsory licensing shall be registered on the patent register and published in the patent gazette.

Article 41 Where a party concerned is dissatisfied with the decision by the State Intellectual Property Office on compulsory licensing, it may apply for an administrative review or initiate an administrative litigation.

Article 42 The interpretation of the Measures is vested with the State Intellectual Property Office.

Article 43 The Measures shall come into force on 1 May 2012, upon which the Measures on Compulsory Licensing for Patent Exploitation promulgated as Order No.31 of the State Intellectual Property Office on 13 June 2003 and the Measures on Compulsory Licensing for Patent Exploitation Relating to Public Health Issues promulgated as Order No.37 of the State Intellectual Property Office on 29 November 2005 shall be repealed.