

Measures for Compulsory License for Patent Exploitation (2012)[Effective]

专利实施强制许可办法(2012) [现行有效]

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The State Intellectual Property Office

Measures for Compulsory License for Patent Exploitation, as deliberated and adopted at the executive meeting of the State Intellectual Property Office promulgated and shall come into force on May 1, 2012.

General: Tian Lipu

, 2012

for Compulsory License for Patent Exploitation

General Provisions

To standardize the granting, royalty determination and termination procedures regarding compulsory license for the exploitation of invention patents and utility models (hereinafter referred to as "compulsory license"), these Measures are formulated in accordance with the [Patent Law of the People's Republic of China](#) (hereinafter referred to as the "[Patent Law](#)"), the [Detailed Rules for the Implementation of the Patent Law of the People's Republic China](#) and the relevant regulations.

The State Intellectual Property Office shall be responsible for the acceptance and examination of requests for compulsory license, requests for royalties for compulsory license, and requests for the termination of compulsory license, and making decisions thereon.

Requests for compulsory license, requests for royalty determinations for compulsory licenses, and requests for the termination of compulsory license shall be handled in written form and in Chinese.

If a certificate or certification document submitted in accordance with these Measures is in a foreign language, the State Intellectual Property Office deems necessary, require the party to submit a Chinese translation of the certificate or certification document within a specified time limit; where the party fails to submit within the specified time limit, the certificate or certification document shall be deemed to have not been submitted.

To handle compulsory licensing matters, a foreigner, a foreign enterprise or any other foreign organization that has no regular residence or place of business in China shall entrust a legally formed patent agency to handle the relevant matters.

A party that entrusts a patent agency to handle compulsory licensing matters shall submit a power of attorney, indicating the scope of the power entrusted. If there are two or more members and none of them has entrusted a patent agency, unless otherwise stated, the first member designated in the written documents shall be deemed as the representative of this party.

I Presentation and Acceptance of Requests for Compulsory License

Where it has been three years since the date the patent right was granted and four years since the date the patent application was submitted, and

without any justifiable reason, fails to have the patent exploited or fully exploited, an entity or individual that satisfies the conditions for patent exploitation may request a compulsory license in accordance with the provisions of [Article 48](#) (1) of the [Patent Law](#).

If the patentee's exercise of the patent right is confirmed as monopolistic behavior pursuant to law, for the purpose of eliminating or reducing the monopolistic negative impact on competition, an entity or individual satisfying the conditions for patent exploitation may request a compulsory license in accordance with the provisions of [Article 48](#) (2) of the [Patent Law](#).

Where a national emergency or any extraordinary affair occurs, or where the public interest so requires, the relevant competent department of the State, in accordance with the provisions of [Article 49](#) of the [Patent Law](#), recommend that the State Intellectual Property Office grant a compulsory license to an entity satisfying the conditions for patent exploitation.

For the purpose of public health, an entity satisfying the conditions for patent exploitation may, in accordance with the provisions of [Article 50](#) of the [Patent Law](#), request a compulsory license for the manufacture of a drug for which a patent right has been obtained, and which is exported to the following countries:

developed country or region; or

developing country that is a WTO member and that notifies the WTO and expresses its desire to be an importer in accordance with the relevant international treaty.

Where an invention or utility model for which a patent right has been obtained represents a major technological advance of remarkable economic significance as compared with an earlier invention or utility model for which a patent right has already been obtained, and the exploitation of the latter relies on that of the former, the patentee of the later invention or utility model may, in accordance with the provisions of [Article 51](#) of the [Patent Law](#), request a compulsory license for the exploitation of the earlier patent. Where the State Intellectual Property Office has granted to the earlier patentee a compulsory license for the exploitation of the earlier patent, the earlier patentee may also request a compulsory license for the exploitation of the later patent.

The petitioner who requests a compulsory license shall submit a written request for a compulsory license, which shall indicate the following items:

name or title, address, postal code, contact person and telephone number of the petitioner;

nationality of the petitioner or the petitioner's country or region of registration ;

name, patent number, filing date of the application, and date of authorized announcement of the invention patent or utility model patent for which a compulsory license is requested, and the name or title of the patentee;

the facts and term of the request for a compulsory license;

whether the petitioner has entrusted a patent agency, the name and organization code of the entrusted patent agency and the name, practice certification number and license number of the patent agent designated by the agency;

the nature or stamp of the petitioner, and, if there is an entrusted patent agency, the stamp of the agency is also required;

the attached documents; and

any other items that need to be indicated.

The written request and its attached documents shall be made in duplicate.

Where a request for a compulsory license involves two or more patentees, the petitioner shall submit the written request and the duplicates of the

documents based on the number of patentees.

A petitioner requesting a compulsory license in accordance with the provisions of [Article 48](#) (1) or [Article 51](#) of the [Patent Law](#) shall provide evidence such petitioner, under reasonable terms, requested the patentee's permission for the exploitation of the patent, but failed to obtain such permission within a reasonable period of time.

Where a petitioner requesting a compulsory license in accordance with the provisions of [Article 48](#) (2) of the [Patent Law](#) shall submit an effective judgment or decision of an administrative or anti-monopoly law enforcement institution that rules, pursuant to law, that the patentee's exercise of the patent right is monopolistic behavior.

Where the relevant competent department of the State Council recommends the grant of a compulsory license in accordance with [Article 49](#) of the [Law](#), it shall indicate the following items:

Compulsory license shall be granted where a national emergency or any extraordinary affair occurs, or where the public interest so requires;

the patent number, filing date of the application and date of authorized announcement of the invention patent or utility model patent for which the compulsory license is recommended, and the name or title of the patentee;

The recommended term of a compulsory license;

The address, postal code, contact person and telephone number of the designated entity satisfying the conditions for patent exploitation; and

Other items that need to be indicated.

Where a petitioner requests a compulsory license in accordance with the provisions of [Article 50](#) of the [Patent Law](#), the petitioner shall provide the following information on the importer, the required drugs and the grant of a compulsory license.

A request for a compulsory license shall not be accepted under any of the following circumstances, and the petitioner shall be notified:

The patent number of the invention patent or utility model patent for which a compulsory license is requested is not clear or is hard to identify;

The request documents are not written in Chinese;

Or that there are no grounds for requesting a compulsory license; or

The patent right for which a compulsory license is requested has been terminated or declared as invalid.

Where the request documents are not in conformity with the provisions of Article 4, 9 or 10 of these Measures, the petitioner shall make supplementary documents within 15 days of receiving notice; and if the petitioner fails to do so within the time limit, the request shall be deemed to have not been filed.

Where the State Intellectual Property Office accepts a request for a compulsory license, it shall send the duplicate of the written request to the patentee in a timely manner. Unless otherwise specified, the patentee shall make a statement of opinion within 15 days of receiving notice; a patentee's failure to make a statement of opinion within the time limit shall not affect the decision-making of the State Intellectual Property Office.

II Examination of Compulsory License Requests and Decision

The State Intellectual Property Office shall examine the reasons stated, the information provided and the relevant certification documents submitted by the petitioner 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 examiners to conduct the on-site verification.

Where a petitioner or patentee requests a hearing, the State Intellectual Property Office shall organize a hearing.

The Intellectual Property Office shall notify the petitioner, the patentee and other interested parties seven days before holding a hearing.

If there state secrets, trade secrets or personal privacy is involved, the hearing shall be open to the public.

If the hearing is held, the petitioner, patentee and other interested parties may offer arguments and conduct cross-examinations.

Transcripts shall be made when holding a hearing and be verified by and affixed with the signature or seal of the persons participating in the hearing to ensure that no error exists.

Procedures shall not be applicable to recommendations on the grant of, or requests for, a compulsory license in accordance with the provisions of the [Patent Law](#).

Where a petitioner withdraws a request before the State Intellectual Property Office makes a decision, the procedures for the examination of the compulsory license shall be terminated.

If the petitioner and the patentee conclude a licensing contract for exploitation of a patent before the State Intellectual Property Office makes a decision, the petitioner may apply to the State Intellectual Property Office in a timely manner and withdraw the request for a compulsory license.

Where, upon examination, it is deemed that the request for a compulsory license falls under any of the following circumstances, the State Intellectual Property Office shall make a decision on rejecting the request for a compulsory license:

The petitioner fails to comply with the provisions of Article 4, 5, 7 or 8 of these Measures;

The grounds for requesting a compulsory license are not in conformity with the provisions of [Articles 48, 50](#) or [51](#) of the [Patent Law](#);

The grounds are not in conformity with the provisions of [Article 52](#) of the [Patent Law](#) where the request for a compulsory license involves the invention-conductor technology;

The request for a compulsory license fails to comply with the provisions of Article 11 or 13 of these Measures; or

The information provided and the relevant certification documents submitted by the petitioner are insufficient or fake.

The Intellectual Property Office may, before making a decision on rejecting the request for a compulsory license, notify the petitioner of the decision and the reasons for the decision. Unless otherwise specified, the petitioner may make a statement of opinion within 15 days of receiving the notice.

Where, upon examination, it is deemed that the grounds of the request for a compulsory license have been established, the State Intellectual Property Office shall make a decision on granting the compulsory license. The State Intellectual Property Office shall, before making a decision on granting a compulsory license, notify the petitioner and patentee of the decision to be made and the reasons for the decision. Unless otherwise specified, both parties may state their positions within 15 days of receiving the notice.

The Intellectual Property Office shall, before making a decision on granting a compulsory license in accordance with [Article 49](#) of the [Patent Law](#), notify the petitioner and patentee of the decision to be made and the reasons for the decision.

The decision on granting a compulsory license shall indicate the following items:

The name or title and address of the entity or individual that has obtained the compulsory license;

The name, patent number, filing date of the application and date of authorized announcement of the invention patent or utility model patent for which a compulsory license is granted;

The scope and term of the compulsory license granted;

s, factual and legal bases for the decision;

mp of the State Intellectual Property Office and the signature of the person in charge;

e of the decision; and

relevant matters.

Importer and the patentee shall be notified of the decision on granting a compulsory license within five days after the decision is made.

Where the State Intellectual Property Office makes a decision on granting a compulsory license in accordance with [Article 50 of the Patent Law](#), it shall include the following requirements in the decision:

The amount of drugs manufactured based on a compulsory license shall not exceed the amount needed by the importer, and all drugs must be exported in the same quantity.

The labels or marks shall be indicated on the drugs manufactured under a compulsory license clearly indicating that they are manufactured according to the terms of the compulsory license; and the drugs shall have specific colors or shapes, or be packed in a particular manner if it is feasible and the price of drugs will not be significantly affected; and

For each consignment of drugs being shipped, the entity that has obtained the compulsory license shall publish on its website or the relevant WTO website the amount of drugs to be shipped, the name and address of the importer and the drug identification features mentioned in Item 2 of this Article.

Where the State Intellectual Property Office makes a decision on granting a compulsory license in accordance with [Article 50 of the Patent Law](#), the competent department of the State Council shall notify the WTO of the following information:

The name and address of the entity that has obtained the compulsory license;

The name and quantity of exported drugs;

For each consignment of drugs:

The name and address of the entity that has obtained the compulsory license; and

The websites mentioned in Article 23 (3) of these Measures.

V Examination of Requests for Royalty Determinations for Compulsory License and Decision on Determinations

To request a determination of the royalty for a compulsory license, the petitioner shall submit a written request for a determination of the royalty for the compulsory license, which shall indicate the following items:

The name or title and address of the petitioner;

The nationality of the petitioner or the petitioner's country or region of registration;

The document number of the decision on granting a compulsory license;

The name or title and address of the respondent;

The reason for requesting the determination of the royalty for the compulsory license;

the petitioner has entrusted a patent agency, the name and organization code of the entrusted patent agency and the name, practice certification number of the patent agent designated by the agency;

nature or stamp of the petitioner, and if there is an entrusted agency, the stamp of the agency is also required;

the attached documents; and

ems that need to be indicated.

The request and its attached documents shall be made in duplicate.

The request for determination of the royalty for a compulsory license shall not be accepted under any of the following circumstances, and the pet
otified:

cision on granting a compulsory license has not been made;

itioner is not the patentee or the entity or individual that has obtained the compulsory license; or

des have not negotiated or have reached an agreement upon negotiation.

Where the State Intellectual Property Office accepts the request for the determination of the royalty for a compulsory license, it shall send the du
request to the opposing party in a timely manner. Unless otherwise specified, the opposing party shall make a statement of opinion within 15 da
the notice; and if the opposing party fails to make a reply within the time limit, it shall not affect the decision-making of the State Intellectual Propre

In the course of determining the royalty for a compulsory license, parties from both sides may submit written opinions. The State Intellectual Property O
to the oral opinions of both parties as required in light of the actual circumstances of the case.

Where a petitioner withdraws a request for determination before the State Intellectual Property Office makes a decision, the determination proce
minated.

The State Intellectual Property Office shall, within three months of receiving a written request, make a decision on determining the royalty for a
ry license.

A decision on the determination of the royalty for a compulsory license shall indicate the following items:

ne or title and address of the entity or individual that has obtained the compulsory license;

ne, patent number, filing date of the application and date of authorized announcement of the invention patent or utility model patent for which a
ry license has been granted;

t of and reasons for the determination;

mp of the State Intellectual Property Office and the signature of the person in charge;

e of the decision; and

relevant matters.

Both sides shall be notified of the decision on the determination of the royalty for a compulsory license within five days after the decision is made

' Examination on Requests for the Termination of Compulsory License and Decision

A compulsory license will terminate automatically under any of the following circumstances.

n of the compulsory license prescribed in the decision on granting the compulsory license expires; or

ention patent or utility model patent for which a compulsory license has been granted has been terminated or declared invalid.

Where the reasons justifying a compulsory license cease to exist and are unlikely to recur prior to the expiration of the valid term of compulsory li
ed in the decision on granting the compulsory license, the patentee may request the State Intellectual Property Office to make a decision on termi
ulsory license.

At the termination of a compulsory license, the patentee shall submit a written request for terminating the compulsory license, which shall indicate items:

ne or title and address of the patentee;

ionality of the patentee or the patentee's country or region of registration ;

document number of the decision on granting a compulsory license for which a request is filed for its termination;

s and facts regarding the request for terminating the compulsory license;

the patentee has entrusted a patent agency, the name and organization code of the entrusted patent agency and the name, practice certification i
none number of the patent agent designated by the agency;

nature or stamp of the patentee, and, if there is an entrusted agency, the stamp of the agency is also required;

the attached documents; and

ems that need to be indicated.

en request and its attached documents shall be made in duplicate.

The request for terminating a compulsory license shall not be accepted under any of the following circumstances, and the applicant shall be notif

itioner is not the patentee of the invention patent or utility model patent for which a compulsory license has been granted;

document number of the decision on granting a compulsory license for which a request for its termination is not clearly stated;

uest documents are not written in Chinese; or

ar that there are no ground for terminating the compulsory license.

Where the request documents are not in conformity with the provisions of Article 32 of these Measures, the petitioner shall make supplement an
i within 15 days of receiving the notice; and if the petitioner fails to do so within the time limit, the request shall be deemed to have not been filed.

Where the State Intellectual Property Office accepts the request for terminating a compulsory license, it shall send, in a timely manner, the dupli
request to the entity or individual that has obtained the compulsory license. Unless otherwise specified, the entity or individual that has obtained
y license shall make a statement of opinion within 15 days of receiving the notice; and if the entity or individual fails to make a reply within the tim

affect the decision-making of the State Intellectual Property Office.

The State Intellectual Property Office shall examine the reasons stated and the relevant certification documents submitted by the patentee as well as those stated by the entity or individual that has obtained the compulsory license. Where on-site verification is required, the State Intellectual Property Office may send one or more staff members to conduct the on-site verification.

Where a patentee withdraws a petition before the State Intellectual Property Office makes a decision, the relevant procedures shall be terminated.

Where, upon examination, it is deemed that the grounds of the request for terminating a compulsory license have not been established, the State Intellectual Property Office shall make a decision on rejecting the request for terminating the compulsory license. The State Intellectual Property Office shall, before making a decision on rejecting the request for terminating the compulsory license, notify the patentee of the decision to be made and the reasons for the decision. Unless otherwise specified, the patentee may make a statement of opinion within 15 days of receiving the notice.

Where, upon examination, it is deemed that the grounds of the request for terminating the compulsory license have been established, the State Intellectual Property Office shall make a decision on terminating the compulsory license. The State Intellectual Property Office shall, before making a decision on terminating the compulsory license, notify the entity or individual that has obtained the compulsory license of the decision to be made and the reasons for the decision. Unless otherwise specified, the entity or individual that has obtained the compulsory license may make a statement of opinion within 15 days of receiving the notice on terminating the compulsory license. The statement of opinion on terminating the compulsory license shall indicate the following items:

name or title and address of the patentee;

name or title and address of the entity or individual that has obtained the compulsory license;

name, patent number, filing date of the application and date of authorized announcement of the invention patent or utility model patent for which the compulsory license has been granted;

document number of the decision on granting a compulsory license;

and legal bases regarding the decision;

stamp of the State Intellectual Property Office and the signature of the person in charge;

date of the decision; and

any other relevant matters.

The patentee and the entity or individual that has obtained the compulsory license shall be notified of the decision on terminating the compulsory license within 15 days of the decision being made.

IV Supplementary Provisions

Where a decision on granting or terminating a compulsory license has come into force, or a compulsory license automatically terminates, it shall be published on the patent register and published in the patent gazette.

Any party may, pursuant to law, file an application for administrative reconsideration or file an administrative lawsuit against the decision made by the State Intellectual Property Office on compulsory licensing.

These Measures shall be subject to the interpretation of the State Intellectual Property Office.

These Measures shall come into force on May 1, 2012. The [Measures for Compulsory License for Patent Exploitation](#) issued by Order No. 31 of the State Intellectual Property Office on June 13, 2003 and the [Measures for Compulsory License for Patent Exploitation concerning Public Health Problems](#) issued by Order No. 37 of the State Intellectual Property Office on November 29, 2005 shall be abolished concurrently.

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database@chinalawinfo.com
