

Order of the Director of the State Intellectual Property Office No. 64

The Measures for Compulsory Licensing of Patent Implementation has passed the review of the directorate meeting, which are hereby promulgated and will come into force on as of May 1, 2012.

Director General: TIAN Lipu

March 15, 2012

Measures for Compulsory Licensing of Patent Implementation

Chapter I - General Provisions

Article 1

In order to standardize the implementation of granting, fees adjudication and termination procedures for compulsory licenses of patents of inventions or 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 Implementing Regulations of The Patent Law of The People’s Republic of China and the relevant laws and regulations.

Article 2

The State Intellectual Property Office shall be responsible for handling the acceptance and examination of petitions, and shall make decisions on granting the compulsory license, the adjudication of use fees of the compulsory license and the termination of the compulsory license.

Article 3

Petitions for granting a compulsory license, for adjudication of use fees of the compulsory license and for termination of the compulsory license shall be executed in Chinese in writing. If the certificates or certification documents submitted in compliance with these Measures are in a foreign language, the State Intellectual Property Office can, if deemed necessary, request the party concerned to provide the Chinese translation thereof within a specified period of time; failure to submit the Chinese translation within this period of time will be deemed as failure to provide the relevant certificates or certification documents.

Article 4

If a foreigner having no habitual residence or place of business in China, a foreign enterprise or other foreign organization applies for a compulsory license, the handling of the procedure should be entrusted to a legally established patent agency. If the party concerned entrusts a patent agency to handle the compulsory licensing procedures, they shall submit a power of attorney clearly indicating in writing the delegation of authority. If the party concerned consists of more than one member and authority is not entrusted to

a patent agency, then unless otherwise declared, the first member indicated in the submitted documents will be regarded as the representative.

Chapter II - Submission and Acceptance of Petitions for Compulsory Licensing

Article 5

If a patentee has without good reason not implemented or fully implemented their patent within three years from the date of grant of the patent right and within four years from the date of filing of the patent, then an entity or individual which is able to implement the patent can petition for a compulsory license based on the provisions of Article 48 paragraph 1 of the Patent Law.

If the actions of a patent right holder in exercising their patent right are legally deemed to be monopolistic actions, then in order to eliminate or reduce the negative effects of said actions on competition, an entity or individual which is able to implement the patent can petition for a compulsory license based on the provisions of Article 48 paragraph 2 of the Patent Law.

Article 6

In an emergency or irregular event of the state, or for the purposes of public interest, the competent department under the State Council is entitled to recommend the State Intellectual Property Office to grant a compulsory license for implementing the invention patent or utility model patent of the petition based on the provisions of Article 49 of the Patent Law.

Article 7

For purposes of public health, an entity which is able to implement the patent can petition for a compulsory license based on the provisions of Article 50 of the Patent Law for the manufacture of patented medicines and export of the same to the following countries or regions:

1. The most underdeveloped countries or regions.
2. Developed or developing members of the World Trade Organization that express via said organization that they wish to be importers based on the relevant international treaties.

Article 8

If a patented invention or utility model is an important technical advancement over a previously patented invention or utility model and has prominent economic significance, and if the implementation thereof depends on the implementation of the earlier invention or utility model, the patent holder can request that the compulsory license be issued for the previous patent based on the provisions of Article 51 of the Patent Law. If the

State Intellectual Property Office grants a compulsory license to implement the previous patent, the patent holder of the previous patent may request that the compulsory license be issued for a later patent.

Article 9

When petitioning for the grant of a compulsory license, an application for a compulsory license should be submitted to the State Intellectual Property Office, indicating the following items:

1. The name, address, postcode, contact telephone number of the petitioner;
2. The nationality of the petitioner or registered country or area;
3. The name, patent number, date of application and date of grant of the invention patent or utility model patent which is the subject of the petitioned compulsory license, and the name of the right holder of the invention patent;
4. The reasons for, facts relating to and term of the compulsory license;
5. If authorizing a patent agency, the name and ID thereof, and name, registration number and contact telephone number of the agent specified by the agency;
6. The signature or stamp of the petitioner and if there is an authorized agency the stamp of the agency;
7. A list of attached documents;
8. Any other items that must be stated.

The petition and attached documents should be executed in two copies.

Article 10

If a petition for a compulsory license relates to more than one patent right holder, the petitioner should submit copies of the petition and attached documents according to the number of patent right holders.

Article 11

If a petition for a compulsory license is made based on Article 48 paragraph 1 or Article 51 of the Chinese Patent Law, the petitioner should provide evidence proving that a reasonable request was made to the patent right holder to permit the petitioner to implement the patent, but within a reasonable period of time the petitioner was unable to obtain such permission.

If a petition for a compulsory license is made based on Article 48 paragraph 2 of the Chinese Patent Law, the petitioner should submit an in-force judgment or determination by a judicial authority or an anti-monopoly law enforcement agency that the actions of the patent right holder in exercising their patent right are deemed to be monopolistic actions according to the law.

Article 12

If a department under the State Council makes a recommendation to grant a compulsory license based on Article 49 of the Chinese Patent Law, it should indicate the following:

1. That it is necessary to grant a compulsory license because of an emergency or irregular event of the state, or for the purposes of public interest;

2. The name, patent number, date of application and date of grant of the invention patent or utility model patent which is the subject of the petitioned compulsory license, and the name of the right holder of the invention patent;
3. The term of the compulsory license;
4. The name, address, postcode, contact person and telephone number of the entity able to implement the patent;
5. Any other necessary information.

Article 13

If a request to grant a compulsory license is made based on Article 50 of the Chinese Patent Law, the petitioner should submit information related to the importer, the medicines they require and the granting of the compulsory license.

Article 14

In any of the following cases the petition for a compulsory license will not be accepted and the petitioner will be notified thereof:

1. The patent number of the invention patent or utility model patent relating to the petitioned compulsory license is not clear or is hard to identify;
2. The petition documents are not in Chinese;
3. It is clear that there is no reason for the petition for a compulsory license;
4. The patent right which is the subject of the petition has terminated or been invalidated.

Article 15

If the petitioning documents do not meet the provisions of Articles 4, 9 or 10 of these Measures, the petitioner shall within 15 days upon receipt of notification thereof rectify the documents. If the petitioner fails to rectify the documents, the petition will be deemed as not submitted.

Article 16

If the State Intellectual Property Office accepts a petition for a compulsory license, it shall timely forward a copy thereof to the patent right holder. Except where specified, the patent right holder should state their opinion within 15 days of receiving this notification; however, if no response is made, this will not negatively influence the decision of the State Intellectual Property Office.

Chapter III - Examination and Determination of Petitions for Compulsory Licensing

Article 17

The State Intellectual Property Office shall examine the reasons, information and related evidentiary documents submitted by the petitioner, and the opinion of the patent right holder. If an on-site examination is required, it shall dispatch at least two employees to perform the on-site examination.

Article 18

If the petitioner or patent right holder requests a hearing, the State Intellectual Property Office may organize a hearing.

The State Intellectual Property Office shall notify the petitioner, patent right holder and any other interested parties 7 days before the hearing.

Unless it relates to state secrets, company secrets or personal and private matters, the hearing shall be public.

In the hearing, each of the petitioner, the patent right holder and any other interested party may defend themselves and cross-examine the other party.

A written record will be made of the hearing and passed to all participants in the hearing who will sign or seal the same after confirming that there are no mistakes therein.

Procedures relating to a hearing do not apply if a petition for granting of a compulsory license is made based on the provisions of Article 49 or Article 50 of the Chinese Patent Law.

Article 19

The petitioner may withdraw their petition for a compulsory license prior to the decision by the State Intellectual Property Office, at which point the examination procedures relating to the petition for a compulsory license terminate. If the petitioner and patent right holder agree on a licensing contract for patent implementation prior to the decision by the State Intellectual Property Office, timely notice should be given to the State Intellectual Property Office and the petition for a compulsory license should be withdrawn directly.

Article 20

If during examination of the petition for compulsory license any of the following apply, the State Intellectual Property Office shall refuse the petition for a compulsory license:

1. The petition does not conform to the provisions of Articles 4, 5, 7 or 8 of these Measures;
2. The reasons for petitioning for the grant of the compulsory license do not conform to the provisions of Articles 48, 50 or 51 of the Patent Law;
3. If the petition for a compulsory license involves the invention and creation of semiconductor technologies, and the reasons thereof do not conform to the provisions of Article 52 of the Implementing Regulations of the Patent Law;
4. The petition for a compulsory license does not conform to the provisions of Articles 11 or 13 of these Measures;
5. The reasons, information or evidentiary documents submitted by the petitioner are insufficient or incorrect.

Before the State Intellectual Property Office issues a decision to reject a petition for a compulsory license, it shall notify the petitioner of the intended decision and state the reasons thereof. Except where specified, the petitioner can submit an opinion within 15 days of receiving said notification.

Article 21

If the Examiner has carried out examination and asserts that the reasons for granting the petition for a compulsory license are valid, the State Intellectual Property Office shall grant a compulsory license. Before making the decision to grant a compulsory license, it

shall notify the petitioner and patent right holder of the intended decision and the reasons thereof. Except where specified, both parties can submit an opinion within 15 days of receiving said notification.

Before the State Intellectual Property Office makes the decision to grant a compulsory license based on Article 49 of the Chinese Patent Law, it shall notify the patent right holder of the intended decision and the reasons thereof.

Article 22

The decision to grant a compulsory license should clearly indicate the following:

1. The name and address of the individual or entity obtaining the compulsory license;
2. The name, patent number, date of application and date of grant of the invention patent or utility model patent which is the subject of the petitioned compulsory license, and the name of the right holder of the invention patent;
3. The scope and term of the granted compulsory license;
4. The reasons for, facts relating to, and legal basis for the decision;
5. The stamp of the State Intellectual Property Office and the signature of the responsible persons;
6. The date of the decision;
7. Any other relevant matters.

The petitioner and the patent right holders should be notified of the decision to grant the compulsory license within 5 days of making the decision.

Article 23

If the State Intellectual Property Office grants a compulsory license based on Article 50 of the Chinese Patent Law, it should clearly state the following in the decision:

1. The amount of medical products produced under the compulsory license should not exceed the amount needed by the importer; moreover, all of it must be exported to the importer;
2. The medical products produced under the compulsory license should bear a special tag or mark clearly indicating that they are produced under the compulsory license; when feasible, and provided that it does not obviously negatively influence the price of the medical products, the medical products themselves should adopt a special color or shape, or special packaging should be used for the medical products.
3. Prior to shipping the medical products, the entity that has obtained the compulsory license should publish the amount of medical products being sent to the importer and information relating to the distinguishing features of the medical product according to (2) above, on its web page or on the related web page of the WTO.

Article 24

If the State Intellectual Property Office grants a compulsory license based on Article 50 of the Chinese Patent Law, the competent department under the State Council shall provide the following information to the WTO:

1. The name and address of the entity that has obtained the compulsory license;
2. The name and amount of the exported medical products;
3. The importer;
4. The term of the compulsory license;

5. The web page according to Article 23 Item 3 of these Measures.

Chapter IV - Examination and Adjudication of Fee Adjudication Requests of a Compulsory License

Article 25

Upon requesting adjudication of use fees for a compulsory license, the party concerned should submit a Request for Adjudication of Compulsory License Use Fees, therein clearly indicating the following:

1. The name and address of the petitioner;
2. The nationality of the petitioner or registered country or area;
3. The document number of the decision to grant the compulsory license;
4. The name and address of the petitioned;
5. The reasons for requesting adjudication of the use fees of the compulsory license;
6. If authorizing a patent agency, the name and ID thereof, and name, registration number and contact telephone number of the agent specified by the agency;
7. The signature or stamp of the petitioner; and if there is an authorized agency, the stamp of the agency;
8. A list of the attached documents;
9. Any other items that must be stated.

The Request and attached documents should be executed in two copies.

Article 26

In any of the following cases relating to the request for adjudication of the use fees of the compulsory license, the State Intellectual Property Office will not accept the request and notify the petitioner:

1. The decision to grant a compulsory license has not yet been made;
2. The petitioner is not the patent right holder or an entity or individual holding a compulsory license;
3. The two parties have not held negotiations or have already reached an agreement as a result of negotiations.

Article 27

If the State Intellectual Property Office receives a Request for Adjudication of Compulsory License Use Fees, it shall timely send a copy of the Request to the other party. Except where specified, the other party should state their opinion within 15 days of receiving this notification; however, if no response is made, this will not negatively influence the decision of the State Intellectual Property Office. In the process of adjudicating use fees of the compulsory license, both parties can submit written opinions. The State Intellectual Property Office may, if necessary, hear the oral opinions of both parties concerned.

Article 28

If the petitioner withdraws their petition for adjudication prior to the decision by the State Intellectual Property Office, the adjudication procedure terminates.

Article 29

The State Intellectual Property Office shall within three months upon receipt of the petition make a decision on adjudication of the use fees of the compulsory license.

Article 30

The decision on the adjudication of the use fees of the compulsory license shall indicate the following items:

1. The name and address of the individual or entity obtaining the compulsory license;
2. The name, patent number, date of application and date of grant of the invention patent or utility model patent which is the subject of the granted compulsory license;
3. The reasons for the adjudication;
4. The stamp of the State Intellectual Property Office and the signature of the responsible persons;
5. The date of the decision; and
6. Any other relevant matters.

Both parties shall be notified of the decision on adjudication of the use fees of the compulsory license within 5 days of the decision being made.

Chapter V - Examination and Decision regarding Terminating the Compulsory License

Article 31

The compulsory license automatically terminates under any of the following conditions:

1. The term of the compulsory license as specified in the decision to grant the compulsory license has expired;
2. The invention patent or utility model patent which is the subject of the compulsory license expires or is invalidated.

Article 32

If, prior to the expiry of the term of the compulsory license specified in the decision to grant the compulsory license, the reasons for granting the compulsory license are eliminated and will not reoccur, the patent right holder may request the State Intellectual Property Office to terminate the compulsory license.

Upon requesting the termination of a compulsory license, an application for termination of a compulsory license should be submitted, indicating the following items:

1. The name and address of the patent right holder;
2. The nationality of the patent right holder or the registered country or region thereof
3. The document number of the granted compulsory license that is the subject of the termination request;
4. The reason for requesting the termination of the compulsory license;
5. If authorizing a patent agency, the name and ID thereof, and name, registration number and contact telephone number of the agent specified by the agency;
6. The signature or stamp of the patent right holder; if there is an authorized agency, the stamp of the agency;
7. A list of the attached documents;

8. Any other items that must be stated.

The patent right holder shall execute the request and attached documents in two copies.

Article 33

If any of the following cases relating to the request for terminating the compulsory license applies, the request will not be accepted and the petitioner will be notified:

1. The petitioner is not the right holder of the invention patent or utility model patent which is the subject of the compulsory license;
2. The document number of the decision to grant the compulsory license is unclear;
3. The request documents are not in Chinese;
4. It is clear that there is no reason for terminating the compulsory license.

Article 34

If the request documents do not conform to the provisions of Article 32 of these Measures, the petitioner should rectify the documents within 15 days of notification thereof. If rectified documents are not submitted within this period, the request will be deemed as not submitted.

Article 35

If the State Intellectual Property Office accepts a Request for Termination of Compulsory License, it shall send a copy of the Request to the individual or entity who has obtained the compulsory license. Except where specified, the individual or entity who has obtained the compulsory license should state their opinion within 15 days of receiving this notification; however, if no response is made, this will not negatively influence the decision of the State Intellectual Property Office

Article 36

The State Intellectual Property Office shall examine the stated reasons and related evidence submitted by the patent right holder, and the opinion of the individual or entity who has obtained the compulsory license. If an on-site examination is required, it shall dispatch at least two employees to perform the on-site examination.

Article 37

If the patent right holder withdraws their request prior to the decision by the State Intellectual Property Office, the related procedure terminates.

Article 38

If the Examiner has carried out examination and asserts that the reasons for the request to terminate the compulsory license are not valid, the State Intellectual Property Office shall reject the request to terminate the compulsory license. Before the State Intellectual Property Office issues the decision to reject the request for termination of the compulsory license, it shall notify the patent right holder of the intended decision and state the reasons thereof. Except where specified, the patent right holder can submit an opinion within 15 days of receiving said notification.

Article 39

If the Examiner has carried out examination and asserts that the reasons for the request to terminate the compulsory license are valid, the State Intellectual Property Office shall issue a decision to terminate the compulsory license. Before the State Intellectual Property Office issues the decision to terminate the compulsory license, it shall notify the entity or individual who has obtained the compulsory license of the intended decision and state the reasons thereof. Except where specified, the entity or individual who has obtained the compulsory license can submit an opinion within 15 days of receiving said notification.

The decision to terminate a compulsory license should clearly indicate the following:

1. The name and address of the patent right holder;
2. The name and address of the individual or entity who has obtained the compulsory license;
3. The name, patent number, date of application and date of grant of the invention patent or utility model patent which is the subject of the granted compulsory license;
4. The document number of the decision to grant the compulsory license;
5. The facts and legal basis for the decision;
6. The stamp of the State Intellectual Property Office and the signature of the responsible persons;
7. The date of the decision;
8. Any other relevant matters.

The patent right holder and the entity or individual who has obtained the compulsory license shall be notified of the termination of the compulsory license within 5 days of the decision being made.

Supplementary Provisions

Article 40

Decisions to grant or terminate a compulsory license, or automatic termination thereof, that have come into effect should be registered on the patent register and published in the patent gazette.

Article 41

If a party concerned objects to a decision of the State Intellectual Property Office regarding compulsory licensing, they can file for an administrative review or proceed with administrative litigation in accordance with the law.

Article 42

The responsibility for interpretation of these Measures is vested with the State Intellectual Property Office.

Article 43

These Measures take effect from May 1, 2012. Simultaneously, the “Measures for Implementing Compulsory Licensing” (No. 31) promulgated by the State Intellectual Property Office on June 13, 2003 and the “Measures for Implementing Compulsory Licensing of Patents Relating to Public Health Issues” (No. 37) promulgated by the State Intellectual Property Office on November 29, 2005, each expire.

Note:

This is an unofficial translation and is provided for your reference. Please refer to the Chinese original should you have any uncertainties on the law/regulations (http://www.sipo.gov.cn/zwgs/ling/201203/t20120319_654876.html).