

## Italy

### Legal basis

Intellectual Property Code (Codice della proprietà industriale 2005, hereinafter IP Code or IPC).

The Biotech Directive (including its Art. 12) has been implemented into the IP Code.

EU Regulation 816/2006 is directly applicable.

### Grounds for applying for a licence

There are two possibilities to obtain a compulsory licence, all regulated by the IP Code:

- due to lack of exploitation (Art. 70 IPC);
- due to dependent patent (Art. 71 IPC, and Art. 81 octies IPC regarding biotech and plant varieties pursuant to the implementation of the Biotech Directive).

### General procedure

The Italian Patent and Trademark Office (*Ufficio Italiano Brevetti e Marchi*, hereinafter UIBM) is competent to grant a compulsory licence. An IP civil court may issue an order equivalent to a compulsory licence but there is no precedent for this. Such an order may be also applied via a preliminary measure in order to skip the length of the UIBM procedure.

By way of example, recently in 2017 the Antitrust Authority issued a FRAND licence in the copyright sector by order within an administrative proceeding.

According to Art. 199 IP Code:

- (a) Whoever wishes to obtain a compulsory licence must submit a grounded request to the UIBM, indicating the amount and method of payment of the compensation offered.
- (b) The UIBM shall promptly give notice of the request, by way of a registered mail letter, return receipt requested, to the owner of the patent and to those who purchased rights to the patent based on legal documents that have been registered or noted.
- (c) Within sixty (60) days of the date of receipt of the registered mail letter, the owner of the patent and all



those who have rights based on the registered or noted legal documents may oppose the granting of the request or state that they do not accept the amount and method of payment of the compensation. Grounds must be stated for any oppositions.

- (d) In the case of oppositions, within forty-five (45) days of the expiration date of the term for the submission of the same, the UIBM shall convene the opponent, the owner of the patent and all those who have rights based on registered or noted legal documents, for an attempt at conciliation. The notice of call is sent to the parties by registered mail letter, return receipt requested, or by other methods, including by computer, provided that those methods guarantee sufficient certainty of receipt of the communication.
- (e) In the notice of call, the UIBM must communicate and transmit a copy of the oppositions filed to the opponent.
- (f) The opponent (patent owner) may submit written counter-arguments to the UIBM by the fifth day prior to the date that the meeting is to be held.
- (g) In the forty-five (45) days subsequent to the date of the meeting for the attempt at conciliation, the Ministry of Productive Activities either grants the licence or rejects the request.
- (h) The term for the conclusion of the proceeding is one hundred eighty (180) days, starting from the date the application is filed.

A compulsory licence shall not be granted if it is found that the requesting party has infringed the patent, unless the party can demonstrate its good faith.

In order to decide whether to grant the compulsory licence, the UIBM shall evaluate the specific issues and evidence relating to the two grounds upon which compulsory licences may be based.

### Compulsory licences on the grounds of lack of effective exploitation

The procedure begins with a request submitted by any interested person. UIBM will consider:

- Evidence that the applicant has contacted the owner of the patent first and has been unable to obtain a contractual licence from him at fair conditions;
- Evidence of lack of effective exploitation by the owner:
  - once three years have passed from the date of issue of a patent or four years from the date of filing of an application, whichever comes last;
  - directly or through one or more licensees,
  - producing in the territory of the country or importing objects produced in a member state of the EU or the European Economic Area or a member state of the WTO;
  - has not implemented the patented invention or has implemented it to an extent that is gravely disproportionate to the country's needs; or
  - has been suspended or reduced in such a manner as to be gravely disproportionate to the country's needs, for more than three years.

Where there is evidence of possible causes outside the patent owner's control or that of his successor in title, a compulsory licence cannot be granted. Such (exempting) causes shall not include the lack of financial means, and if the same product is circulated abroad, the lack of demand in the internal market for the product patented or obtained with a patented procedure. The grant of compulsory licence does not release the owner of the patent or his successor in title from the obligation to implement the invention.

The licence shall be revoked if the invention has not been implemented within two years of the date of granting of the first compulsory licence or if it has been implemented to an extent that is gravely disproportionate to the country's needs.

### Compulsory licences for dependent patents

The procedure begins with a request submitted by any interested person. UIBM shall consider the following:

- Evidence that the applicant has contacted the owner of the first patent and has been unable to obtain a contractual licence from him at fair conditions.
- Evidence that the invention protected by the second patent cannot be used without harm to the rights relating to the first patent granted based on a previous application.
- Evidence that with respect to the object of the first patent, the second patent represents an important technical advance of considerable economic importance.

If the compulsory licence is granted, the owner of the first patent shall have the right to be granted a compulsory licence at reasonable conditions on the second patent, in a "grant back" option, on a non-exclusive basis.

According to Art. 72(7) IPC, the UIBM has discretion as to the terms of the compulsory licence:

*"In the order granting the licence, the following shall be determined: the scope and duration, the methods of implementation, the terms and other conditions on which the granting of the licence is based in relation to its purpose, and the amount and method of payment of the compensation. In the event of opposition, the amount and method of payment of the compensation are determined in accordance with Art. 80."*

### Appeal/review

The decision is taken by the UIBM, which is a branch of the Ministry of Productive Activities. Hence, it can be appealed as an administrative procedure before the Lazio Regional Administrative Court (T.A.R. Lazio).

### Statistics and jurisprudence

None to date.