

Belgium

Legal basis

Arts. XI.37 to XI.46 of the Code of Economic Law (hereinafter “CEL”).

Art. XI.37 and Arts. XI.40-XI.46 CEL implement Art. 12 Biotech Directive.

Art. XI.39 implements EU Regulation 816/2006.

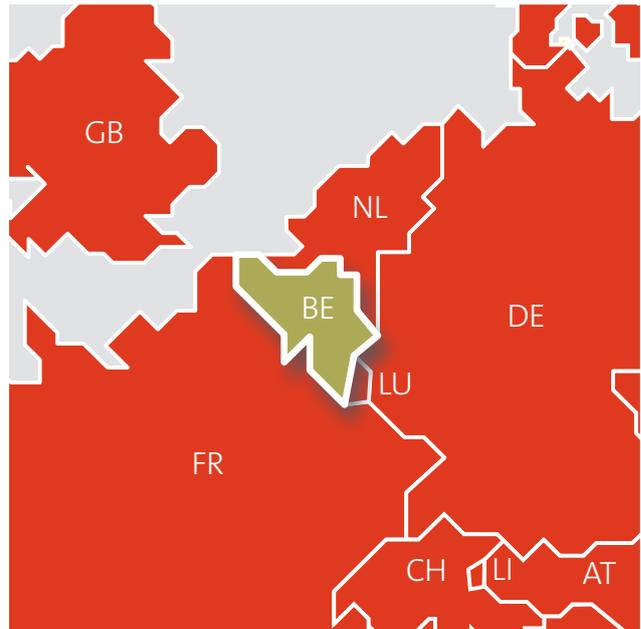
Grounds for applying for a licence

A compulsory licence may be applied for on the following grounds:

- lack of exploitation or dependency;
- export to countries with public health problems; and
- public health grounds.

There are six situations in which an application for a compulsory licence may be filed in Belgium:

- Lack of exploitation:** “when a period of four years from the filing date of the patent application or three years from the grant date of the patent, whichever period expires last, has elapsed without the patented invention having been exploited by means of importation or effective and continuous manufacture in Belgium and without the patentee being able to justify his inaction by legitimate reasons. In the case of a patent whose subject matter is a machine, effective and continuous manufacture in Belgium by the patentee of products obtained by means of that machine may be deemed to constitute exploitation of the patented invention in Belgium, when such manufacture appears more important for the economy of the country than the manufacture of the machine itself. A compulsory licence based on a lack of exploitation or insufficient exploitation shall only be granted on the condition that the licence is granted predominantly for the supply of the domestic market” (Art. XI.37, Sec. 1(1) CEL);
- Dependency (patent-patent):** “when an invention covered by a patent owned by the applicant for the licence cannot be exploited without infringing the rights deriving from a patent granted on an earlier filing, insofar as the dependent patent permits a significant technical progress of considerable economic interest compared to the invention claimed in the dominant patent, and on the condition that the licence is granted predominantly for the supply of the domestic market” (Art. XI.37, Sec. 1(2) CEL);
- Dependency (patent-plant variety):** “when a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, inasmuch as the licence is necessary for the exploitation of the plant variety to be protected and on the condition that the variety represents a significant technical progress of considerable economic interest compared to the invention claimed in the patent, and on the condition that this licence is granted predominantly for the supply of the domestic market” (Art. XI.37, Sec. 1(3) CEL);
- Cross-licensing (dependency patent-plant variety):** “to the holder of a plant variety right, when the holder of a patent concerning a biotechnological invention has obtained, based on the provisions of the law on the protection of plant varieties, a compulsory licence for the non-exclusive exploitation of the plant variety protected by that plant variety right because he cannot exploit the biotechnological invention without infringing said prior plant variety right, on the condition that this licence is granted predominantly for the supply of the domestic market” (Art. XI.37, Sec. 1(4) CEL);
- Export to countries with public health problems:** “for the manufacture of pharmaceutical products for export to countries with public health problems” in the meaning of Regulation (EC) No. 816/2006 (Art. XI.39 CEL);



- (vi) Public health grounds: “in the interest of public health” (Art. XI.38 CEL).

General procedure

For compulsory licences based on lack of exploitation or dependency (Art. XI.37 CEL), the competent authority to grant a compulsory licence is the Minister of Economy. For compulsory licences based on public health grounds (Art. XI.38 and XI.39 CEL) it is the Council of Ministers.

The specific procedure depends on the ground on which the application is based.

For compulsory licences based on lack of exploitation or dependency (situations (i) to (iv) above), the application must be submitted to the Minister of Economy and is then forwarded to the Commission for Compulsory Licences for the purpose of hearing the interested parties, reconciling them if possible and, if not, issuing a reasoned opinion on the merits of the application. Based on that opinion, the Minister then decides on the application and notifies the interested parties of his decision. Within four months of the notification of the decision, the patentee and the applicant must enter into a written licensing agreement determining their mutual rights and obligations. If an agreement cannot be found within that period, their reciprocal rights and obligations are determined by the court. The obligations of the applicant/licensee must in any case include the payment of an adequate remuneration to the patentee, taking the economic value of the licence into account. Once the terms of the licence have been negotiated or determined by the court, the Minister of Economy grants the licence by ministerial decree.

Applications for compulsory licences for the manufacture of pharmaceutical products for export to countries with public health problems (situation (v) above) follow the procedure provided by EU Regulation 816/2006. The authority having competence to grant compulsory licences under said Regulation in Belgium is the Council of Ministers.

For compulsory licences based on public health grounds (situation (vi) above), the applicant must submit his application to the Minister of Economy and send a copy of it to the Bioethics Advisory Committee. The Minister then forwards the request within ten days to the Bioethics Advisory Committee. During the same period, the Minister informs the patentee of the content of the application and invites him to take position concerning both the grant of the licence as such and the reasonable remuneration he would expect in the event the licence be granted. The patentee has one month to file his observations. The Bioethics Advisory

Committee then provides the Minister with a reasoned and non-binding opinion on the merits of the request. Within a period of three months after receiving said opinion, the Minister submits a draft motivated royal decree on the merits of the application as well as a proposal for remuneration of the patentee to the Council of Ministers, which then takes the decision. If the compulsory licence is granted, the royal decree must determine the duration, scope and other terms of exploitation, including the remuneration due to the patentee. In the event of a public health crisis, measures can be taken to accelerate the above procedure.

The above is without prejudice to the rules governing the powers of the Ministers of Economy and Defence to control the exploitation of inventions for national defence or national security reasons.

Contrary to some other countries, such as Germany, there is no possibility of obtaining a compulsory licence by way of preliminary relief in Belgium.

For compulsory licences granted for public health reasons, the terms of the licence are determined by the Council of Ministers. When exercising its discretion, the Council of Ministers has to take the observations of the patentee and the opinion of the Bioethics Advisory Committee into account.

For compulsory licences granted for lack of exploitation or dependency, the court has discretion in case the parties do not succeed in entering into a written licence agreement within four months of the notification of the decision of the Minister of Economy to grant the licence. When exercising its discretion, the court has to take the positions of the parties into account, as well as the opinion of the Commission for Compulsory Licences.

Appeal/review

An administrative appeal for annulment of the decision can be introduced before the Council of State.

The decision can also be revised under specific conditions:

First, the terms of compulsory licences based on lack of exploitation, dependency or public health grounds can be revised upon the request of one of the parties if new elements have arisen. The procedure is the same as for the grant of the licence.

Second, any interested party can request the authority who granted such licence to withdraw it if, after the expiry of the

period determined in the licence, the licensee did not exploit the invention by serious and continuous manufacture activities on Belgian territory. The opinion of the Commission for Compulsory Licences must be requested before the withdrawal of a compulsory licence granted for lack of exploitation or dependency.

Finally, compulsory licences granted for lack of exploitation or dependency can also be withdrawn upon the request of the patentee if it results from a final judgment that the licensee has committed an unlawful act towards the patentee or has violated his obligations.

Statistics and jurisprudence

None to date.

