

## Lithuania

### Legal basis

Patent Law of the Republic of Lithuania of 18 January 1994, No. I-372; new edition of the Patent Law of the Republic of Lithuania in force since 3 February 2012 (hereinafter PL). The PL also implements Art. 12 Biotech Directive.

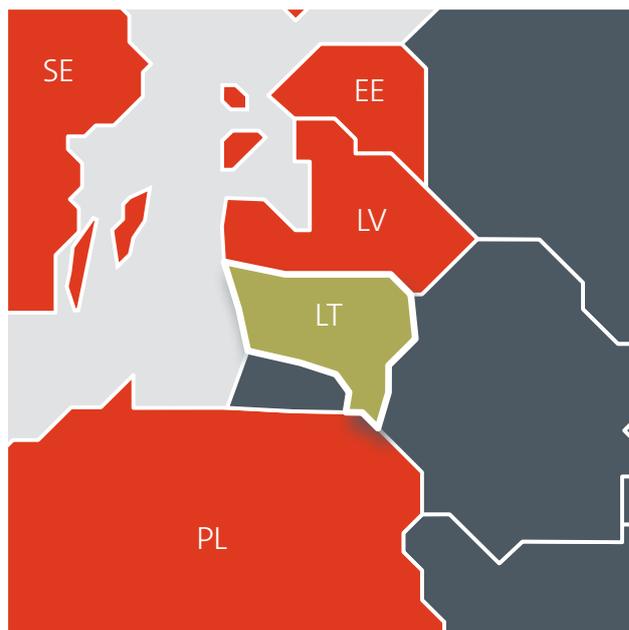
### Grounds for applying for a licence

There are three different legal grounds on which a compulsory licence may be applied for and granted in the Republic of Lithuania:

- (i) When a patented invention is related to a protected plant variety or vice versa, namely:
  - (a) Where a plant breeder cannot acquire or exploit a plant variety right without infringing the exclusive rights protected by a prior patent.
  - (b) Where the owner of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right.
- (ii) In cases indicated in the EU Regulation 816/2006.
- (iii) With authorisation of the Government of the Republic of Lithuania, if a patented invention is related to public needs (if the patent proprietor does not provide reasonable terms to license the product and it is required for general public welfare), national security and public health protection, development of economically important sectors, or if a competent court determines that a method of the exploitation of a patented invention by its owner or licensee is anti-competitive.

### General procedure

The procedures and competent authorities differ depending on which grounds the compulsory licence is granted. In all cases, compulsory licences may only be remunerable, non-exclusive and non-transferrable. The competent court or authority, while deciding on granting of the compulsory licence, may further elaborate on these conditions, but does not have discretion to essentially change them, e.g. to grant a non-remunerable, exclusive and/or transferrable compulsory licence. Art. 35(1) PL foresees that importation of



a patented product qualifies as use/exploitation of that invention.

### For plant varieties

The compulsory licence may be granted by a decision of the Vilnius Regional Court. However, if the legal ground indicated in (i)(b) involves a Community plant variety (i.e. a plant variety protected on a pan-European scale), such compulsory licence may be granted by the Community Plant Variety Office (CPVO) under the Council Regulation (EC) No. 2100/94 of 27 July 1994 on Community plant variety rights.

The applicant shall make a claim to the Vilnius Regional Court against the owner of the claimed patented invention or protected plant variety for the grant of a compulsory licence. The applicant (claimant) must prove the existence of the legal ground indicated in (i) above, as well as two additional cumulative conditions:

- (1) that the applicant has unsuccessfully applied to the owner of the patented biotechnological invention or the holder of the plant variety right to obtain a contractual licence; and
- (2) that the plant variety or the patented biotechnological invention constitutes significant technical progress of considerable economic interest compared with the claimed patented invention or the protected plant variety. The court shall examine the claim, and issue a decision on either: (a) granting the compulsory licence,

if the legal ground exists and the indicated additional conditions are met, or, if otherwise, (b) the rejection of the applicant's claim. Such compulsory licence may only be remunerable, non-exclusive, non-transferrable, and the owner of the claimed patented biotechnological invention or the protected plant variety shall be entitled to a cross-licence to use the second patented invention or plant variety (i.e. authorisation to each owner to use both patented inventions).

## For pharmaceutical products

A compulsory licence may be granted by a decision of the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania.

In this case, the applicant shall address the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania with a standard application form provided in the Rules on Implementation of the Regulation. The application must include: (i) the notice to the WTO under Art. 8(1) of the Regulation; and (ii) documentation confirming the "Prior negotiation" condition under Art. 9 EU Regulation 816/2006. The State Medicines Control Agency shall initially examine the application together with its documentation, and address the owner of the claimed patented invention relating to the manufacture of pharmaceutical products, informing him about his right to submit explanations and additional information with regard to application (if any), as well as to the State Patent Bureau of the Republic of Lithuania for corresponding additional clarifications. The State Medicines Control Agency may also address the applicant for submission of additional information on whether the conditions indicated in Arts. 8 to 10 EU Regulation 816/2006 are met. Upon execution of the above-indicated procedural steps, the State Medicines Control Agency shall issue a positive or negative decision, together with, *inter alia*, the motives of such decision. Such compulsory licence may only be remunerable, non-exclusive and non-transferrable.

The compulsory licence may be revoked or amended in cases set forth in Art. 5(c) and/or 16 EU Regulation 816/2006.

## For the public interest

Compulsory licences on these grounds may be granted by a resolution of the Government of the Republic of Lithuania.

The applicant shall address the Government of the Republic of Lithuania with a request to permit the exploitation of a patented invention, together with documentation

confirming that the person seeking authorisation has requested but not received authorisation from the owner of a patent to use the patented invention. The Government of the Republic of Lithuania shall examine the request, together with consideration of whether the legal ground indicated (for public interest) exists, and, in the case of a positive decision, adopt a resolution authorising the use of the claimed patented invention, i.e. on granting of a compulsory licence.

In cases when authorisation to use a patented invention may be issued to the owner of a patent that improves a previously patented invention (second invention), and that may infringe the exclusive rights of the owner of the first patent, the Government of the Republic of Lithuania, before adoption of such resolution, shall also take into consideration whether the claimed invention in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent.

Such compulsory licence may only be remunerable, non-exclusive and non-transferrable, and the owner of the first patent shall be entitled to a cross-licence to use the invention claimed in the second patent (i.e. authorisation to each owner to use both patented inventions).

Furthermore, with regard to compulsory licences granted under the legal ground (i) above, the court that has granted the licence may, at the request of the owner of the claimed patented invention or protected plant variety, revoke the compulsory licence or change its conditions, if the legal basis constituting the granting of the licence has changed or disappeared.

The same may be applied *mutatis mutandis* to compulsory licences granted on public interest grounds ((iii) above). Such a compulsory licence may also be revoked when it is being used for a different purpose than the one for which the compulsory licence was granted in the first place.

## Appeal/review

All final decisions of a competent court or authority described in the above may be appealed to a Court of Appeal of Lithuania.

## Statistics and jurisprudence

None to date.