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Compulsory licensing in Europe

A country-by-country overview



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Thierry Calame, European Patent Lawyers Association (EPLAW)

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Introduction

Compulsory licensing of patents is not frequently used throughout Europe, but in certain situations it allows government or government-appointed authorities to override patent holders' exclusive right to exclude all others from using their inventions. From the patent holder's perspective, a compulsory licence may seem radical whilst from that of the public interest, it may be a necessity, for example where life-saving inventions are concerned. Compulsory licences are granted on limited grounds with significant judicial or administrative scrutiny.

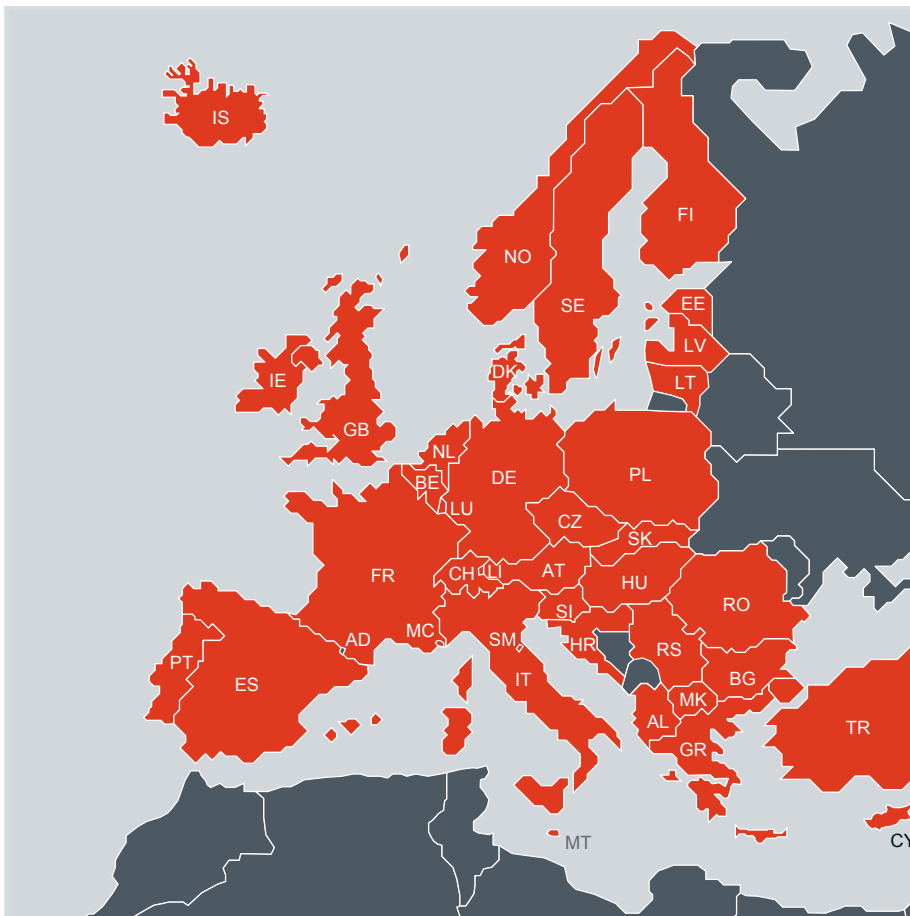
The various justifications and conditions for this measure are largely based on international agreements, and regional and national legislation. The Paris Convention recognises the countries' competence for providing compulsory licences to prevent abuses that may result from failure to work the invention or failure to work it on reasonable terms. Decades later, the WTO countries concluded the TRIPS Agreement, which lays down further rules applicable to compulsory licences, in particular grounds for their grant. On an EU level, legal bases for granting compulsory licences are provided for in the 1998 Biotech Directive regarding plant variety rights

and, in view of implementing Art. 31bis TRIPS, the EU Regulation No. 816/2006 with regard to the manufacture of pharmaceutical products for export to countries with public health problems.

Most European countries have integrated the regime of granting compulsory licences into their IP legislations, although possible grounds for grant may differ between them. The competent authorities vary as does the procedural framework leading to the grant of a compulsory licence as this depends on the national civil or administrative procedures.

This book has been developed by the European Patent Academy together with the European Patent Lawyers Association (EPLAW) and other patent practitioners to provide a comprehensive overview of the different compulsory licensing regimes in all 38 EPC contracting states.

European Patent Academy



EPC contracting states
(1 December 2018)

List of abbreviations

Biotech Directive	Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ L 213, 30.7.1998, p. 13-21).
ECHR	European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14, 4 November 1950.
EPC	Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.
EU Regulation 816/2006	Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1-7).
Paris Convention	Paris Convention for the Protection of Industrial Property of March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and as amended on September 28, 1979.
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).
WTO	World Trade Organization

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Cyprus

Legal basis

The legal basis for compulsory licences in Cyprus is the Patents Law, Law 16(I) of 1998, as amended (1998 to 2006) (hereinafter PL), Part IX Arts. 49 to 56, which incorporates the European Patent Convention and the Patent Cooperation Treaty.

The Biotech Directive was implemented with Cypriot law in 2002 in relation to the protection of biotechnical inventions; relevant are Arts. 2, 5A, 15A, 27A, 49A PL.

TRIPS was implemented into Cypriot law in 2002.

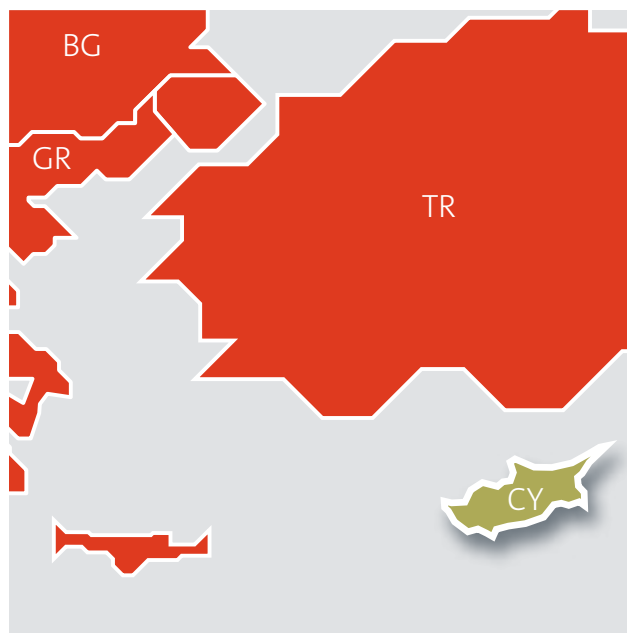
There is no specific reference to EU Regulation 816/2006 in Cypriot patent law on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

Grounds for applying for a licence

Application under Art. 49 of the Patents Law

Art. 49 provides that at any time after the expiration of four years from the date of the grant of a patent (or any other period as may be prescribed), any person may apply to the Registrar to obtain a compulsory licence under a patent on any of the grounds specified below:

- where the patented invention is capable of being commercially exploited in Cyprus, but it is not being exploited or is not being exploited as fully as is reasonable or practicable;
- where the patented invention is a product for which there is demand in Cyprus which:
 - is not being met; or
 - is not being met on reasonable terms; or
 - in respect of which, by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms:
 - a market for the export of any patented product made in Cyprus is not being supplied; or
 - the working or efficient working in Cyprus of any other patented invention which makes a substantial contribution to the art is prevented or hindered; or
 - the establishment or development of commercial or industrial activities in Cyprus is unfairly prejudiced;



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- in respect of which, by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in Cyprus is unfairly prejudiced.

If the Registrar of Companies, Patents and Trade Marks and Official Receiver (hereinafter Registrar) is satisfied that any of the above grounds are established, he may order the grant of a licence on such terms he thinks fit. Alternatively, the Registrar may by order adjourn the application for such period as will, in his opinion, give sufficient time for the invention to be used if the application is made on the ground that the patented invention is not being commercially used in Cyprus and it appears to the Registrar that the time which has elapsed since the grant of the patent has been insufficient to enable the invention to be used.

An application may be made in respect of a patent notwithstanding that the applicant is already the holder of a licence under the patent. In that event, the Registrar may, if he orders the grant of a licence to the applicant, order the existing licence to be cancelled or, instead of ordering the grant of a licence to the applicant, order the existing licence to be amended.

Under Art. 50 PL, if the Registrar is satisfied, on an application made under Art. 49, that the manufacture, use or disposal of materials not protected by the patent is unfairly

prejudiced by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or the use of the patented process, he may order the grant of licences under the patent to such customers of the applicant as he thinks fit as well as to the applicant.

If the Registrar orders the grant of a licence under Art. 49 PL, he may direct that the licence should revoke all existing licences granted under the patent or deprive the proprietor of the patent of any right to work the invention concerned or to grant licences under the patent.

Art. 51 PL sets out the principles to be followed by the Registrar when deciding the outcome of applications under Art. 49 for compulsory licences. They are:

- inventions that can be exploited on a commercial scale in Cyprus and that it is in the public interest to exploit should be exploited there without undue delay and to the fullest extent that is reasonably practicable;
- the inventor or other person beneficially entitled to a patent should receive reasonable remuneration having regard to the nature of the invention;
- the interests of any person working or developing an invention in Cyprus under the protection of a patent at the time should not be unfairly prejudiced.

The Registrar is required to take the following matters into account:

- (i) the nature of the invention, the time that has elapsed since the publication in the Official Gazette of the Republic of a notice of the grant of the patent and the measures already taken by the proprietor of the patent or any licensee to make full use of the invention;
- (ii) the ability of any person to whom a licence would be granted under the order concerned to work the invention to the public advantage; and
- (iii) the risks to be undertaken by that person in providing capital and working the invention if the application for an order is granted.

The Registrar is not required to take account of matters occurring after the making of the application.

Grant of a compulsory licence by the Council of Ministers

In the interests of national security or public safety, the Council of Ministers may authorise the grant of a licence to a

government agency or a specified person to make, use or sell an invention to which a patent or an application for a patent relates, subject to payment of equitable remuneration to the proprietor of the patent or the patent application. The decision of the Council of Ministers with regard to remuneration may be the subject of recourse to the Supreme Court.

General procedure

The authority with jurisdiction to grant a compulsory licence is the Registrar. The Council of Ministers may also authorise the grant of a licence, where national security or public safety so requires.

Art. 56 PL provides that the following principles should be respected with regard to compulsory licences:

- each case must be considered on its individual merits;
- a licence should be permitted only if the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and has not succeeded in doing so within a reasonable period of time. This requirement does not apply in the case of a national emergency or other circumstance of extreme urgency or in cases of public non-commercial use. Even so, the right holder must be notified as soon as reasonably practicable;
- the scope and duration of use of the right should be limited to the purpose for which it was authorised, and in the case of semiconductor technology should only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- the use of the right should be non-exclusive and non-assignable, except with the enterprise or business to which it is granted, and predominantly for the purposes of supplying the domestic market;
- subject to adequate protection of the legitimate interests of the person to whom it is granted, the licence should be terminable if and when the circumstances which led to it cease to exist and are unlikely to recur; and
- the right holder should be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation.

Under Art. 52 PL the proprietor of the patent concerned or any other person wishing to oppose an application may submit a notice of opposition to the Registrar, which the Registrar must consider when deciding whether to grant the application. In the event of opposition, the Registrar may order the whole proceedings, or any question or issue of fact arising in them, to be referred to an arbitrator or mediator,

whose findings the Registrar will accept. If the parties cannot agree on a suitable appointee, the Registrar will decide on the appointment.

Art. 49 PL gives the Registrar discretion to grant a licence on such terms as he thinks fit, but this is subject to the court's jurisdiction to review the legal validity of any decision regarding a compulsory licence contained in Art. 56 PL.

Appeal/review

The Registrar's decision may be referred to the Administrative Court for review and the decision of the Administrative Court may be appealed before the Supreme Court panel of three Supreme Court judges.

The legal validity of any decision regarding a compulsory licence is subject to review by the Supreme Court.

Statistics and jurisprudence

There has been only one case in recent years, which related to licensing of a medication for a genetic condition ordered by the Council of Ministers under Art. 55 PL, but there is no reported decision as the issue was not contested.

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