

EIP

EU Commission proposes EU-wide compulsory licences for the first time

Compulsory licences are a feature of patent law across Europe. They are a recognition that there are some circumstances in which the public interest can over-ride the rights of patentees. While the basic principle is not controversial, there is considerable disagreement over what circumstances warrant the issuance of compulsory licences, as well as what safeguards for the patentee's interests are required once it is decided to issue a compulsory licence.

Currently only national authorities in the EU can issue compulsory licences, even when the conditions for granting them are set in EU law, for example [Regulation 816/2006](#) which covers licences for the manufacture of pharmaceutical products for export to countries with public health problems. Other situations in which compulsory licences can be issued are somewhat harmonised by the [TRIPS agreement](#), which generally requires that the licensee has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time, but this requirement may be waived in the case of emergency.

The current [proposal](#) from the EU Commission relates to compulsory licences in such crisis or emergency situations. It gives the EU Commission power to grant an EU-wide compulsory licence in relation to patents, utility models, and supplementary protection certificates, but only where a crisis mode or an emergency mode according to specified EU Regulations has been declared. This includes health emergencies but is not limited to them. Consistent with the TRIPS rules, there is no requirement to seek a licence from the rights holder in advance. It can be appreciated that issuing such licences on an EU-wide basis rather than a national basis would facilitate an agile response to an emergency

situation.

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The Commission must consult the relevant advisory body, dependent upon the type of emergency, to advise on whether a compulsory licence is needed under those circumstances. Upon receiving the opinion from the advisory body, the Commission decides whether to issue a compulsory licence.

The licensee must pay adequate remuneration to the patentee (or equivalent rights holder). The level of remuneration is determined by the Commission and specified in the compulsory licence (or may be determined later if further investigation and consultation is required).

Under this proposed Regulation, any compulsory licence is for use in the EU only, and the export of products manufactured under the licence is prohibited. Note however that the above Regulation 816/2006 provides a system of compulsory licences for export and it is also proposed to amend that Regulation to allow the EU Commission to grant that type of compulsory licence as well.

The draft Regulation requires both the licensee and the licensor to cooperate in good faith and there are strict controls over the licenced products. There are proposed fine up to 6% of annual turnover for intentional or negligent breach of these obligations.

It is probably not to be expected that these provisions will need to be used very often. However, when an emergency situation does arise, the proposals should allow a more streamlined and flexible response on an EU-wide basis.

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