

## Our position

# Regulation on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

Proposed amendments

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €3.7 trillion in 2022, directly supports more than 4.9 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

**Key proposed amendments based on AmCham position paper**

**bold:** addition  
 strikethrough: deletion

Provision	Proposal text	AmCham EU suggestion	Comment/justification
Recital (31)	<i>The legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing act, should be subject to judicial review.</i>	<i><b>The present Regulation provides the legal basis for a Union compulsory licence which permits potentially serious interferences with intellectual property rights within the meaning of Article 17(2) of the Charter of Fundamental Rights of the European Union. Therefore, in accordance with Article 52 of the Charter and the case-law of the Court of Justice, the present Regulation must itself define the scope of the limitations on the exercise of those fundamental rights, and must also provide for minimum safeguards so that rights-holders have sufficient guarantees to protect their rights effectively against the risk of interferences that are disproportionate or otherwise non-compliant with Union law, and to ensure that the essence of their rights is protected. Therefore, as a minimum guarantee, the legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing act, should be subject to judicial review. In order to be effective in</b></i>	<i>The “standstill periods” proposed in Recital (31) and in Articles 8(i) and 8a ensure that a prima facie review by the General Court of the European Union of an implementing act granting a Union compulsory license can take place before that act can have irreversible consequences, and after the rights-holder has been provided with all relevant information, see amended Recital (20). The possibility of effective review forms an important part of the overall measures taken to comply with the requirements of Article 52 of the Charter of Fundamental Rights of the European Union, and to ensure that interferences with the right to property enshrined in Article 17(2) of the Charter are not disproportionate, and comply with the requirements of the present Regulation.</i>

	<p><b><i>practice, judicial review must be possible at a time when potentially non-compliant interferences can still be prevented or rectified. To that end, a specific mechanism to prevent unwarranted irreversible consequences shall be put in place. An implementing act granting a Union compulsory licence shall not enter into force immediately, but shall be subject to an initial standstill period of no less than 10 calendar days<sup>1</sup> within which the rights-holder can lodge an application for annulment and an application to suspend the implementing act before the General Court of the European Union. That initial standstill period shall not commence until the rights-holder has been given the relevant information which is essential for them to seek effective review.<sup>2</sup> A further standstill period shall commence on the day when such applications for annulment and interim measures are lodged</i></b></p>	
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<sup>1</sup> A precedent for such a mechanism exists in EU public procurement law, which aims to ensure that a review of contract award decisions can take place when impending infringements of EU law can still be rectified, and to prevent situations where the consequences of a disputed award decision are made irreversible. See Recitals (3), (4), (6) and (12), and Article 1, of Directive 2007/66/EC of the European Parliament and of the Council of 11 December 2007 amending Council Directives 89/665/EEC and 92/13/EEC with regard to improving the effectiveness of review procedures concerning the award of public contracts, OJ L335 of 20.12.2007, pages 31-46. Directive 2007/66/EC introduced a minimum standstill period of 10 calendar days during which rejected tenderers can submit an application for interim measures against an award decision. If such an application is submitted, the contracting authority must not conclude the contract before the competent review body has made a decision on the application either for interim measures or for review of the award decision. In this respect, Directive 2007/66/EC codifies the judgment of 28 October 1999 in *Alcatel Austria AG and others*, Case C-81/98, EU:C:1999:534. The institutions of the EU are subject to a similar standstill period when they award certain contracts subject to the EU Financial Regulation. See Articles 170(2), 175(2) and 178(1) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, OJ L193 of 30.07.2018, pages 1-222, as amended.

<sup>2</sup> See Recital (3) of Directive 2007/66/EC, which provides that tenders should be given such relevant information.

		<p><i>with the General Court, and shall end when the General Court has taken a decision on the application for interim measures and/or a decision on the application for annulment.</i></p>	
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<p><b>Art 8a Standstill periods</b></p>	<p><b>NEW</b></p>	<p><b>1. An implementing act granting a Union compulsory licence shall not take effect before the end of an initial standstill period which shall be no less than 10 calendar days from the day following the day of publication of the Union compulsory licence in the Official Journal of the European Union.</b></p> <p><b>2. Where a rights-holder affected by an implementing act granting a Union compulsory licence has not been provided with the information referred to in Article 7(3) prior to the day of publication of the Union compulsory licence in the Official Journal of the European Union, the standstill period referred to in paragraph 1 shall commence on the day following the day on which the rights-holder has been provided with such relevant information.</b></p> <p><b>3. If a rights-holder, before the expiry of the initial standstill period, lodges an application for annulment of the implementing act and an application to suspend the implementing act before</b></p>	<p>The “standstill periods” proposed in Recital (31) and in Articles 8(a) and 8(i) ensure that a prima facie review by the General Court of the European Union of an implementing act granting a Union compulsory license can take place before that act can have irreversible consequences. The possibility of effective review forms an important part of the overall measures taken to comply with the requirements of Article 52 of the Charter of Fundamental Rights of the European Union, and to ensure that interferences with the right to property enshrined in Article 17(2) of the Charter are not disproportionate and comply with the requirements of the present Regulation.</p> <p>Paragraph 2 of Article 8a ensures that rights-holders can exercise their rights of access to the file.</p> <p>Compulsory licensing should remain as a <b>last resort to be considered in well-defined EU-wide crisis situations where a voluntary agreement cannot be reached in a reasonable timeframe.</b> Moreover, it should feature necessary guardrails for it to be exercised within the right policy and judicial framework.</p> <p>To safeguard the robustness of the EU IP protection system, any CL should be granted within the right legal framework with <b>adequate judicial oversight.</b> Priority and sufficient time should be given to finding a voluntary agreement with the rights-holder. Currently, <b>the proposals are vague on process and lack independent judicial oversight through all stages of CL</b> (pre, during and post grant).</p>
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<p><b>Art 22 Jurisdiction of national courts and remedies according to national law</b></p>	<p><b>NEW</b></p>	<p><b>1. The rights of the rights-holder to initiate legal proceedings against the licensee for infringement of the respective intellectual property right before national courts, including the Unified Patent Court, remains unaffected.</b></p> <p><b>2. If the licensee does not comply with the restrictions specified by Union compulsory licence with respect to exploitation, the rights-holder shall all available remedies according to the applicable national laws against the licensee.</b></p>	<p>While the Commission has proposed that the rights-holder has a right to be heard before the granting of a CL, <b>the proposed Regulation should include a distinct, clear and accelerated process for right-holders to request independent merits and judicial reviews of the CL granted.</b></p> <p>In the extraordinary situation where a CL is granted, the Commission would be immediately and irrevocably depriving a company of their IP rights, which this EU institution did not grant in the first place. Therefore, <b>more independent judicial protection through all stages of the CL (pre, during and post grant) would be required than in the ordinary circumstances to respect fundamental principles of EU law.</b></p>