

Compulsory Licensing

Recommendations and explanations on the importance of independent judicial review and oversight in Compulsory Licensing Decisions.

Paragraph	Commission's proposal	Text suggestion	Rationale
<p><u>Introduction of a New Article 8 bis – Standstill Period</u></p>	<p>N/A</p>	<p style="text-align: center;">Article 8 bis - Standstill Period</p> <p>1. An implementing act granting a Union compulsory license shall not take effect before the end of an initial standstill period of no less than 10 calendar days from the day following the day of publication of the Union compulsory license in the Official Journal of the European Union. During this standstill period, the rights-holder has the right to lodge a request for annulment of the implementing act, and an application to suspend the implementing act before the General Court of the European Union.</p> <p>2. 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 the General Court of the European Union, the implementing act shall not take effect during a subsequent standstill period which shall commence on the day of lodgment of the application for annulment and the application to suspend the implementing act and/or the application for interim measures and shall end on the day after the day on which the General Court has taken a decision on the application to suspend the implementing act and/or on the application for interim measures.</p> <p>3. Where a rights-holder affected by an implementing act granting a Union compulsory license has not been provided with the information referred to in Article 7(3) prior to the day of publication of the Union compulsory license 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.</p>	<p>The “standstill period” proposed ensures 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 3 of Article 8 bis ensures that rights-holders can exercise their rights of access to the file.</p>

<p>Article 21 - Review by the Court of Justice of the European Union</p>	<p>In accordance with Article 261 TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.</p>	<p>1. In accordance with Article 261 TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission:</p> <p>(a) has granted a compulsory licence. It may cancel the licence, or amend any and all of its terms and conditions;</p> <p>(b) has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.</p> <p>2. Any rights-holder who is the subject of a Union compulsory license shall be automatically deemed to have standing to bring matters before the Court of Justice.</p> <p>3. Any review of a decision by the Commission under Article 21(1) shall be subject to an accelerated resolution procedure, with a maximum period of 18 months from filing to a first instance decision.</p> <p>4. If the rights-holder seeks a review by the Court of Justice of the European Union, the rights-holder may request the Union compulsory licence to be suspended with immediate effect. The Court of Justice of the European Union shall without any delay suspend the Union compulsory licence, unless the applicants of the Union compulsory licence provide sufficient evidence that the maintenance of the compulsory license does not cause any damage to the rights-holder which is out of proportion in respect to the crisis or emergency mode.</p> <p>5. Should the Court of Justice of the European Union find, upon review, that a given Union compulsory licence was improperly granted, the rights-holder shall be entitled to damages and compensation at full fair market value, to restore the position of the rights-holder <i>ex ante</i>.</p>	<p>The oversight of an independent judicial body since the beginning of the process is key. A CL is an exceptional circumstance, and a decision on it is directly applicable with direct impact on parties involved (unlike other legislation in normal circumstances), hence the standard appeal possibility post grant is not enough and does not guarantee the rule of law in such an exceptional circumstance. The possibility of effective review forms an important part of the 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>The provision of clear and substantive rights of appeal is critical to any fair process, yet beyond a reference to an appeal to the CJEU in relation to financial penalties, there is very little substance in the proposal. This is unreasonable and the rights-holder must be given express rights of appeal to the General Court and/or the CJEU</p>
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including a full review of the facts on which the decision to issue a CL is based, not limited to points of law, together with adequate rights of injunctive relief and compensation, throughout the CL procedure.

WTO TRIPS Agreement - Articles 31(h) and Art 31(i) requires Members to provide judicial review for decisions relating to the issuance of CLs and remuneration to the patent holder. Under the EU CL framework, the 'advisory body' will take several procedural steps, unlikely to be reviewable by the EU courts. And when the Commission issues a CL, it would do so in the form of an "implementing decision" – in the same way that a marketing authorisation, or an orphan designation, is granted by the Commission. Although a Commission decision granting an EU CL will be reviewable by the General Court, it is not clear that there would be a full review of the factors leading to that decision. To the extent that the review fails to deal with such substantive issues, the Court's practice would deny right holders' effective legal remedies. In addition, the EU CL framework does not

			<p>assess or even mention the need for protection in the form of injunctive relief against CL decisions that are incompatible with EU law.</p> <p>The right to request such relief appears all the more necessary if the EU CL permits the forced transfer of secret know-how and trade secrets, which are extinguished the moment they are disclosed or transferred.</p> <p>These text proposals would ensure a fair and workable system compared to the current situation in the proposal with no judicial oversight and no right to defense for the patent holder at the beginning of the process.</p>
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Explanation:

The lack of meaningful right to defense of the right holder is a critical shortcoming of the EU compulsory licensing framework. Without a formal review of a CL grant, with interim measures and injunctive relief available, there are insufficient checks and balances to rein in the EC's power in issuing CLs. The innovative pharmaceutical industry believes that a standstill period (in practice the right to defense) is one of the options that enables swift judicial review of any CL decision by the EC before the damage is already done. There are precedents where the Court has acted very fast on those types of decisions, as we are conscious that it would be during crisis situations, hence it should go fast.

The oversight of an independent judicial body (like the General Court) is key. A CL is an exceptional circumstance, and a decision on it is directly applicable with direct impact on parties involved (unlike other legislation in normal circumstances), hence the standard appeal possibility post grant is not enough and does not guarantee the rule of law in such an exceptional circumstance. The possibility of effective review forms an important part of the 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.