Intellectual property: A revised framework for compulsory licensing of patents


This briefing provides an initial analysis of the strengths and weaknesses of the European Commission’s impact assessment (IA) accompanying the above-mentioned proposal, submitted on 27 April 2023 and referred to the European Parliament’s Committee on Legal Affairs (JURI). The proposal was included in the Commission’s 2023 work programme and in the working document accompanying the joint declaration on EU legislative priorities for 2023 and 2024.

Compulsory licensing of patents allows a government to authorise the use of a patent by a third party, without the consent of the patent right holder, subject to conditions aimed at preserving the interests of the patent holder. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) sets out the international legal obligations as regards compulsory licensing. It explicitly allows compulsory licensing under certain conditions, such as limited duration and the payment of adequate remuneration. The first type of compulsory licensing scheme is for the domestic market, which applies to all types of products (Article 31 TRIPS). The second scheme is compulsory licensing for export, which only applies to pharmaceutical products (Article 31bis TRIPS). The EU implemented this second disposition through the adoption of Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health issues.1

Other EU legislation (on plant variety rights and biotechnical inventions) in the area of compulsory licensing of patents is limited.2 Compulsory licensing in the EU is therefore mainly regulated by national law, resulting in diverging national compulsory licensing schemes.

The proposal envisages a new EU-wide compulsory licensing instrument that would complement EU crisis response instruments. It aims to further enhance the EU’s resilience, by ensuring access to key patented products and technologies in a crisis, if voluntary agreements are not available or not adequate.

Problem definition

The IA starts by describing the political context of the initiative. During and after the COVID-19 pandemic, the conflicting interests of (affordable and sustainable) access to health products and promoting innovation incentives that are key for developing new health products (such as vaccines and therapeutics) was in the political spotlight. This included a discussion about the role of intellectual property rights and compulsory licensing in a crisis situation. The present initiative is included in the Commission’s intellectual property action plan from November 2020, in which the Commission expressed ‘the need to ensure that effective systems for issuing compulsory licenses are in place, to be used as a means of last resort and a safety net’.

In its resolution of 11 November 2021, the European Parliament calls on the Commission to analyse and explore possible options for ensuring effectiveness and better coordination of compulsory licensing in the EU (see paragraph 50). In its conclusions of 18 June 2021, the Council of the EU
considered that the EU – besides its active engagement in a comprehensive dialogue in the context of the World Trade Organization (WTO) and other international fora to explore how effective and pragmatic approaches, such as patent pooling, licensing initiatives and knowledge/vaccine sharing platforms can best support affordable and equitable access to COVID-19 medicinal products, diagnostics, vaccines and treatments – stands ready to discuss other tools, including the flexibilities provided for in Articles 31 and 31bis of the TRIPS Agreement (see paragraph 7 of the Council conclusions).

The IA defines the main problem to be tackled by the present initiative, namely the impossibility for the EU to rely on Member State-based compulsory licensing to address a cross-border crisis in a timely manner, should voluntary agreements fail due to territorial limitations and legal fragmentation (IA p. 9). The IA defines and explains the problem drivers: i) divergent national schemes on compulsory licensing; ii) inadequate territorial reach of compulsory licensing; iii) no dedicated forums to deal with compulsory licensing that could bolster EU resilience in times of crisis.

The IA substantiates its findings with references to several sources, in particular the Commission’s consultation activities in the preparation of the IA. The IA provides a well-structured analysis of the existing situation, examining the nature and scale of the problem, as well as who it would affect and how (IA, Annex 3). With the aid of a problem tree, the IA illustrates the drivers behind the problems and the consequences deriving from them (IA, p. 11). It comprehensively describes the views of stakeholders on the problem drivers.

**Subsidiarity/proportionality**

The proposal is based on Article 114 (approximation of laws in the single market)) and Article 207 (common commercial policy) of the Treaty on the Functioning of the European Union (TFEU). Since the envisaged initiative would have an impact on Regulation (EC) No 816/2006, and on the possibility to export goods manufactured in the EU, it should also include Article 207 TFEU as a legal basis. The IA includes a section on subsidiarity (IA, p. 21), where it describes the legal basis and explains the necessity and added value of EU action.

The initiative aims to ensure that the compulsory licensing system is fit for purpose to guarantee a more efficient functioning of the single market during crises. In the current compulsory licensing system, Member States can only act nationally (compulsory licensing for their own territory); according to the IA, this is not sufficient to tackle a cross-border crisis which is ‘most probable due to the prevalence of cross-border supply chains’ in the EU (IA, p. 21). Action at EU level would create a single procedure to grant an EU-level compulsory licensing scheme with instruments to tackle a cross-border crisis. As recommended by the **Task Force on subsidiarity, proportionality and ‘doing less more efficiently’**, a separate **subsidiarity grid** accompanies the IA, which also covers **proportionality**. According to the IA, the initiative ‘does not go beyond what is necessary to achieve the identified objectives’ (subsidiarity grid, p. 5). The deadline for the **subsidiarity check** by national parliaments was 1 September 2023. No reasoned opinions had been submitted by that deadline.

**Objectives of the initiative**

The **general objective** is to enable the EU to respond to crisis situations, which are not defined in the IA, but build on other existing and upcoming emergency instruments and responses, in a timely manner and using the full potential of the single market. In times of crisis, critical products and components can be made available across EU Member States and supplied without delays to EU citizens and firms, or third countries. The IA defines three **specific objectives (SOs)**: i) to improve the key features of compulsory licensing (trigger, scope, conditions, coherence) (SO1); ii) to ensure that a compulsory licence can accommodate the reality of cross-border value chains operating in the single market (SO2); iii) to support the resilience of the EU by improving coordination, streamlining decision making and allowing compulsory licences to better complement EU action in times of crisis, including for export purposes to non-EU countries (SO3).
The objectives correspond to the problems and the problem drivers identified in the IA. The IA uses an 'objectives tree' to depict the relationship between the objectives (IA, p. 22); the specific objectives are distinct from the general one and appear to comply with the S.M.A.R.T. criteria (specific, measurable, achievable, relevant and time-bound), with the exception of the time-bound criterion (see the Better Regulation Toolbox, Tool #15).

Range of options considered

The IA explains, in an adequate manner, what would happen under the baseline scenario (‘no policy change’, IA, pp. 23-24), including the existing framework (e.g. existing national rules and Regulation (EC) No 816/2006) on the possibility to export goods manufactured in the EU and related initiatives, such as HERA and the SMEI. The IA examines four policy options (POs) to achieve the three specific objectives. It provides a broad range of options with recommendations on compulsory licensing for crisis management (PO1); harmonisation of national laws on compulsory licensing for crisis management (PO2), which would entail the adoption of a directive; harmonisation plus a binding EU-level measure on compulsory licensing for crisis management (PO3); and EU-level compulsory licensing to complement existing EU crisis instruments (PO4).

Table 1 – Overview of policy options

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<th>Option</th>
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<tr>
<td><strong>Baseline</strong></td>
<td>No policy change: The compulsory licensing system in the EU would continue to operate based on the existing national rules and Regulation (EC) No 816/2006. There would be no coordination between Member States and compulsory licensing would remain mainly applicable to national territories (and subject to possible restrictions such as embargos). This would result in maintaining an inefficient tool for addressing crises in the single market.</td>
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<td><strong>Option 1</strong></td>
<td>Non-legislative measures – Recommendation on compulsory licensing for crisis management: This would identify (i) good national practices on compulsory licensing for crisis management and (ii) good coordination practices, with a view to increasing their uptake in Member States. This would increase the efficiency and effectiveness of national compulsory licensing schemes, including for export purposes to non-EU countries.</td>
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<td><strong>Option 2</strong></td>
<td>Harmonisation of national laws on compulsory licensing for crisis management: The legislative initiative would align national laws on the grounds, scope, procedure and conditions for granting a compulsory licence for crisis management. The compulsory licence would remain within the remit of Member States and predominantly have a national effect.</td>
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<tr>
<td><strong>Option 3</strong></td>
<td>Harmonisation and EU-level binding measure to grant a compulsory licence for crisis management: Under this option, the compulsory licence could be triggered in two scenarios: (i) by an EU-level decision activating a crisis mode or declaring an emergency under an existing EU crisis instrument (e.g. activation of the emergency mode under the single market emergency instrument (SMEI)); or (ii) upon a request made to the Commission by more than one Member State in the event of a crisis affecting multiple countries (cross-border crisis). The Commission, assisted by the relevant advisory body, would adopt an activation measure requiring one or several Member States to issue a compulsory licence.</td>
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<tr>
<td><strong>Option 4</strong></td>
<td>EU-level compulsory licence to complement existing EU crisis instruments: The triggers would be the same as under Option 3. However, the Commission, assisted by the relevant advisory body (composed of Member State representatives), would adopt an activation measure granting a compulsory licence. This option would lead to the issuance, by the Commission, of one compulsory licence, with its own procedure and conditions and applicable to the territory of several EU countries or the whole EU. Option 4 would leave unchanged national legislation on compulsory licensing.</td>
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*Source: Compiled by the authors on the basis of the IA (IA, pp. 24-33 and executive summary of the IA, pp. 2-3).*
The IA provides information about options discarded following the analysis of the four policy options (IA, pp. 33-34). The IA describes why compulsory licensing has not been considered to cover other IP rights (e.g. plant variety rights, design rights or copyright), but not in sufficient depth and without additional details on the options discarded at an early stage. Furthermore, a third of the respondents, having participated in the context of an external study (see 'Stakeholder consultation' section below), are of the opinion that compulsory licences should also apply to other IP rights, but without defining which types of other IP rights.

The IA refers to the factors that would continue to affect stakeholders involved in a compulsory licensing procedure under the status quo (baseline scenario). The options that were retained are linked to the specific objectives and the problem drivers. Each option considered the subsequent results, in line with the specific objectives of the initiative. In addition, the IA analyses the impacts of each policy option on stakeholders in the event of a cross-border crisis (IA, pp. 35, 37, 39 and 41-42) while also presenting a figure on task division between the different options, as compared to the baseline, in relation to the costs and benefits specific to compulsory licensing procedures (IA, p. 45).

Overall, the IA provides a sufficient and balanced description of the options, including detailed schemes describing the procedural steps envisaged under each option and taking into consideration the diverging views and concerns of stakeholders (for example, concerning the grounds on which a compulsory licence can be granted). The report also provides a summary presenting how the preferred option would achieve the specific objectives and its impact on different stakeholder groups.

Assessment of impacts

The IA analyses qualitatively and quantitatively the social, environmental, and economic impacts of the options and provides a summary of costs and benefits specific to the compulsory licensing procedures (IA, pp. 34-47; a more detailed analysis of costs and benefits is provided in Annex 3). It also refers to stakeholders’ views (when it comes to the specific objectives to be pursued), while indicating how representative they are (by providing the respective percentages and/or number of respondents), and presents how the different policy options would affect each stakeholder group, particularly patent owners, manufacturers, potential licensees, EU countries, the general public (EU citizens) and non-EU countries (IA, pp. 35, 37, 39, 41-42).

With regard to social impacts, the initiative brings positive results, as ‘it could help limit various disruptions to everyday societal processes by curbing the crisis or eliminating it altogether’ (IA, p. 43). According to the IA (IA, p.43), the exact amount of potential indirect socio-economic impacts that can be avoided is impossible to quantify, whereas the cost of a major crisis can be ‘paramount to any economy’ (see example on COVID-19 here). The environmental impacts will depend on the type of crisis that the EU may face in the future – for example, if the crisis concerns environmental threats, the positive impacts of the initiative could be decisive in increasing access to products and technologies able to tackle the crisis. However, no significant harm to the environment is expected under any of the policy options presented.

The IA dedicates a lot of space to assessing the economic impacts of key policy measures identified under all policy options, and presents a summary of costs and benefits (one-off and recurrent) specific to compulsory licensing procedures. The assessment of impacts is substantiated by several comparative tables and annexes. It also presents the recurrent costs/benefits if a cross-border crisis hits the EU by dividing them into: (i) direct compliance and enforcement costs/benefits for authorities; (ii) direct compliance cost/benefits for firms; (iii) indirect wider socio-economic benefits.

The EU institutions can also carry certain direct costs linked with this initiative, including those related to good governance of the overall process (in case of a cross-border crisis) and the existence of such additional costs (in EU-level compulsory licensing) if none of the existing emergency bodies or instruments (e.g. the SMEI or HERA coordination committees) can assume this role (IA, pp. 46-47). In relation to this matter, the IA explains (IA, p. 47) that the positive outcomes (direct and indirect benefits) of the new compulsory licensing system for crisis management would counterbalance any
minor direct compliance and enforcement costs, and would lead to indirect wider socio-economic impacts. A short chapter on the issue of fair compensation and adequate remuneration of rights holders is provided in Annex 6 (p. 129) of the IA. The IA also provides information on the estimated impact on costs and benefits of the preferred option in separate tables (IA, Annex 3, pp. 68-69).

The IA highlights that the initiative will have a clear impact on fundamental rights. In particular, through the increased probability of supply of critical goods and services, the most fundamental needs and rights of EU citizens, such as safety and health, would be more swiftly and efficiently catered to in a crisis setting. Hence, the initiative may have a positive impact on the right to health and on the right to environmental protection (Articles 35 and 37 of the Charter of Fundamental Rights of the European Union, CFEU). On the down side, compulsory licensing partially deprives patent owners of control of their rights, affecting the right to intellectual property of patent owners (Article 17(2) CFEU). The IA dedicates a specific section to the Sustainable Development Goals (SDGs) in Annex 3 (IA, pp. 70-71), where it mentions the SDGs relevant to the preferred option (PO4) and the expected progress towards the Goals, depending on the exact type of crisis (e.g. health-related, environmental, energy, etc.).

The IA further compares the options in terms of their effectiveness, efficiency and coherence. It presents all options in a summary table showing how they score (IA, p. 48) and how they would affect (costs and benefits) each stakeholder group (IA, p. 50). After comparing the options, Option 4 appears to score best and has been selected as the preferred option: according to the IA, it provides clarity on the features of the compulsory licence, as well as coherence, since there would be a single EU-level compulsory licence, while it also provides for an EU-wide effect on the compulsory licenses (e.g. by guaranteeing a territorial scope that fits cross-border crises). Option 4 can support other EU crisis instruments by embedding compulsory licences within them, and it would strengthen the EU’s bargaining position, as 27 countries would run negotiations together and at once. Option 4 also scores highly in terms of transparency in decision making concerning exports.

Stakeholders favour the option of allowing a compulsory licence to be granted at EU level in the event of an EU-wide crisis compared to nationally granted compulsory licences for EU-wide crises (IA, Annex 2, p. 65). However, there is a stark contrast between stakeholders: all NGOs consider that such a measure would have a positive effect on the ability to tackle crises and on access to critical goods, whereas a majority (around 50%) of companies and business associations consider that the impact would be negative. A larger majority of companies and business associations consider that it would have a negative effect on EU businesses (87%) and IP owners (90%).

According to the IA, all options comply with the proportionality principle and do not go beyond what is necessary to achieve the objectives of the initiative. Their respective scope is limited to aspects that Member States cannot achieve satisfactorily on their own and where Union action can produce better results or is necessary. PO4 introduces a new layer through an EU regulation establishing an EU-level compulsory licence. The initiative is limited to compulsory licensing to tackle cross-border crises, while Member States retain their full competence as regards compulsory licensing on other grounds.

SMEs/Competitiveness

The initiative is considered relevant for small and medium-sized enterprises (SMEs) and has been listed by the SME envoys network in the SME filter. It targets patented products that are needed for crisis management, regardless of the patent owner (be it a large company or a SME). In line with the Better Regulation Guidelines (see also the Better Regulation Toolbox, Tool #23), a SME test has been carried out, the main findings of which are described in detail in a separate annex (IA, Annex 8), although it appears that no targeted SME consultation was conducted. Evidence was gathered through an open public consultation (OPC) where SMEs contributed. However, the IA stresses that they did not constitute the majority of respondents (74 in total, out of which 18 were companies/business organisations). Regarding possible negative impacts, the IA states that contributions received in the call for evidence and in the OPC have not pointed towards potential
negative consequences for SMEs. Since SMEs own patents, even if this applies to them to a small extent, it cannot be ruled out that a SME-owned patent will be subject to a compulsory licence. Nevertheless, as the initiative focuses on patents, very few of the SMEs could possibly be affected directly by compulsory licencing. With regard to the possible impacts on competitiveness and innovation, including investments in innovative products in case of a crisis, the IA refers to the steps taken to ensure that the incentives for innovation through IP protection are retained, while also ensuring access to critical products in cross-border crisis situations (IA, pp. 44-45).

Simplification and other regulatory implications

In light of the 'one-in, one-out' (OIOO) approach (Better Regulation Toolbox, #Tool 59), the IA stresses that the estimated savings for patent holders and manufacturers (potential licensees) could be lower by roughly 75% to 80% when compared to the status quo scenario (i.e. based on a hypothetical situation where a single compulsory licensing procedure would replace 4-5 procedures in each jurisdiction). When it comes to Member States, the expected compliance and enforcement costs might not be affected or might even be improved, if national compulsory licensing negotiations were to be replaced by EU-level negotiations, as the same effort would be shared among several countries. The IA further explains that it is not possible to quantify the exact monetary value of cost savings for stakeholders due to the scarcity of such events, and also because the type of future potential crisis and its scale is unknown. However, given the envisaged role of the new instrument (to be used only during major crises affecting the EU and as the last resort measure), it is not expected to be used frequently. According to the IA, the initiative is fully coherent with other EU initiatives, especially those aiming at improving the EU’s resilience to crises (e.g. HERA, the Health Union package, the SMEI). Annex 3 of the IA provides a summary of costs and benefits (pp. 68-70), including OIOO-related costs.

Monitoring and evaluation

The IA suggests the inclusion of a provision requiring an evaluation report five years after the granting of the first EU-level compulsory licence (IA, p. 53). To this end, it provides a list of relevant monitoring indicators to evaluate whether the three specific objectives have been achieved, including information on the origin and provision of the data to be collected (IA, p. 54). It is further highlighted that recourse to compulsory licensing is expected to be rare, as it will be triggered by exceptional circumstances, acting as a last-resort mechanism. Subsequently, the monitoring of the basic descriptive indicators would not require the setting up of additional systems for data collection and monitoring (the collection and processing of information can be done manually).

Stakeholder consultation

The Commission carried out various stakeholder consultation activities, a description of which can be found in a separate annex, as required in the Better Regulation Guidelines (IA, Annex 2), including a call for evidence from 1 to 29 April 2022 (57 contributions were submitted). An OPC was launched from 7 July to 29 September 2022 and received 74 replies. More than half of the answers came from business associations (30%) and company/business organisations (24%), mostly from the health sector (34%). In March 2022, the Commission launched an external study on ‘Compulsory licensing of intellectual property rights’ that aimed to collect data through desk research, case studies and interviews with stakeholders, as well as organising two workshops. The workshops focused on collecting information on specific compulsory licence cases and exchanging views on policy options for compulsory licensing in Europe in case of a crisis.

The IA (IA, Annex 2) includes an analysis of the responses provided by the different groups of stakeholders on the relevance of compulsory licensing as a crisis management instrument and their views on compulsory licensing for exports. Various consultation activities examined experiences of stakeholders and national experts with compulsory licensing at Member State level, particularly regarding possible policy options to ensure an effective compulsory licensing system for crisis management. In addition, as part of the OPC, stakeholders’ views were collected on the impact of
possible options, with a particular focus on the impacts on EU businesses and IP owners, the ability of the EU to tackle crises and access to critical goods during crises.

The IA provides the views of the different stakeholder groups on the problems and the options, and on the expected impacts of the preferred option. It further describes the expected impacts of the preferred option on the stakeholder groups identified as being most affected, particularly current patent holders and any company that may take the role of a future manufacturer (licensee) (IA, Annex 3). The IA presents in a transparent way the diverging views of the different stakeholder groups, and it appears that the views of stakeholders and their support for the preferred option were broadly taken into account. However, the feedback from this consultation strategy could have been better reflected in the IA, particularly regarding the potential impact on competitiveness and innovation of compulsory licensing, by better presenting the diverging views of affected stakeholders.

**Supporting data and analytical methods used**

With regard to supporting data, the IA lists key sources such as available literature; publicly available and referenced supporting studies and publications; stakeholder consultations; and data collected from desk research, as well as the PatentSight® database (IA, Annex 1, p. 56). The Commission acknowledges that the calculations of costs and benefits were limited by the lack of data: ‘In view of the absence of granular data on the subject, this assessment discusses the plausible magnitude of potential impacts of each policy option, rather than its exact quantification in monetary terms. As a consequence, the cost/benefit analysis is not developed to the level that otherwise is expected in an impact assessment’ (IA, Annex 4, p. 72). The IA is transparent about the evidence and analytical methods used, including the underlying assumptions (IA, p. 9 and Annex 6, pp. 87 and 134). The IA is also frank about limitations, notably challenges with regard to quantitative data (IA, p. 23).

Annex 4 of the IA on analytical methods contains geographical coverage of European patents and the list of international patent classification codes as provided by the PatentScope COVID-19 Index. Annex 6 provides supplementary evidence, including an illustration of the need for several national compulsory licences in case of an EU cross-border crisis; an overview of different national grounds for compulsory licensing applicable in crises; a detailed mapping of existing and upcoming emergency instruments and responses; selected examples of the definition of ‘crisis’ in other existing and upcoming emergency instruments and responses; and examples of compulsory licences and identified case law.

**Follow-up to the opinion of the Commission Regulatory Scrutiny Board**

The Commission’s Regulatory Scrutiny Board (RSB) issued a positive opinion with reservations on the draft IA report on 3 February 2023. The RSB criticised shortcomings that concern the following aspects: the problem definition; the description of the content and functioning of the EU-level option, including the intended safeguards, as well as the efficiency and effectiveness of an EU-level compulsory licence; and the impact on competitiveness and innovation, including investments in innovative products in case of a crisis. The Commission services describe in Annex 1 to the IA how the RSB’s recommendations were addressed, and it appears that the RSB’s comments have been taken into account in the IA. However, as already flagged, the IA still falls short of providing sufficient analysis of the competitive dimension to assess the impact of the initiative on the competitiveness of SMEs. In addition, although the views of stakeholders were broadly taken into account, there is room for improvement concerning diverging feedback on the potential impact on competitiveness and innovation of compulsory licensing.

**Coherence between the Commission’s legislative proposal and IA**

The IA supports the fact that the Commission proposal corresponds to the IA’s preferred option. The IA report suggests including a provision requiring an evaluation report five years after the granting of the first EU-level compulsory licence (IA, p. 53), while the Commission proposal (Article 25) envisages that the Commission shall present an evaluation report by the last day of the third year.
following the granting of the Union compulsory licence, in accordance with Article 7 of the proposal.

The monitoring indicators would be considered for evaluating progress.

The IA substantiates its findings with references to several sources, in particular the Commission’s consultation activities to prepare the IA. The specific objectives presented correspond to the problems and the problem drivers identified in the IA. Overall, the IA provides a sufficient and balanced description of the options, including detailed schemes describing the procedural steps envisaged under each option and taking into consideration the views and concerns of stakeholders. The assessment of the options’ impacts (social, environmental and economic, as well as impacts on fundamental rights) is qualitative and quantitative. A dedicated chapter with a cost-benefit analysis has been included. The IA appears to be based on sound research and analysis, and is transparent about the evidence and analytical methods used, with a clear acknowledgement that available data is limited when it comes to calculating costs and benefits. It describes comprehensively stakeholder groups’ views on the problems and the options, and provides views on the expected impacts of the preferred option. An SME test was carried out in line with the Better Regulation Guidelines; its main findings are described in detail in a separate annex. It appears that no targeted SME consultation was conducted, however. Competitiveness could have been discussed in more detail in the IA, particularly in terms of the impacts on SMEs.

ENDNOTES

1 Regulation (EC) No 816/2006 is intended to be part of wider European and international action to address public health problems faced by least developed countries and other developing countries, and particularly to improve access to affordable medicines that are safe and effective, including fixed-dose combinations, and whose quality is guaranteed.

2 Council Regulation (EC) No 2100/94 on Community plant variety rights provides for the possibility for the Community plant variety office to grant a compulsory licence for a Community plant variety right, on application by a Member State, by the Commission or by an organisation set up at EU level. Directive 98/44/EC provides for the possibility to apply for a compulsory licence, where a plant breeder cannot use a plant variety without infringing a patent or where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right.
