1 Windsor Framework: compulsory licensing of patents to tackle an EU-wide crisis[1]

The proposed Regulation is legally and politically important because:

- it has implications for Northern Ireland under the Windsor Framework and may affect access to innovative patent-protected products or technologies needed to address a public health crisis or other emergencies affecting critical supply chains.

Action

- Write to the Minister.
- Draw to the attention of the Northern Ireland Affairs Committee.

Overview

1.1 In its Work Programme for 2023, the European Commission highlighted "a collision of crises"—Russia's illegal full-scale invasion of Ukraine, spiralling energy costs, geopolitical tensions, and disruption to supply chains during and after the Covid-19 pandemic—to underscore the need for the EU to strengthen its resilience to future challenges and its ability to respond more quickly to new crises. Intellectual property rights play an important strategic role in stimulating creativity and innovation. The Commission anticipates that the introduction of an EU Unitary Patent system in June 2023 providing patent protection across most EU Member States based on a single application will ensure a simpler, more cost-effective and predictable legal framework to encourage investment in new products and technologies. It considers that these incentives for innovation also need to be balanced against speed of access to critical products and technologies so that they can be used for public good in times of crisis and suggests that compulsory licensing, a recognised feature of patent law, offers a solution. It allows governments acting within the legal framework established by the World Trade Organisation in the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement') to authorise a third party to manufacture and distribute a patent-protected product without the consent of the patent holder.

1.2 There are no harmonised EU rules on compulsory licensing. The Commission considers that the current patchwork of 27 national compulsory licensing regimes is inefficient and hinders the EU's ability to respond at pace to a crisis, particularly for products which depend on cross-border supply chains. Member States can only grant a compulsory licence for their own territory, leading to fragmentation within the EU Single Market and an inability to guarantee supplies of critical products throughout the EU. The Commission has therefore put forward a proposed Regulation which would not replace

1 Proposal for a Regulation on compulsory licensing for crisis management and amending Regulation (EU) 816/2006; COM(23) 224; Articles 114 and 207 TFEU; ordinary legislative procedure; Department for Science, Innovation and Technology; Devolved Administrations consulted; 42210.

these national systems but establish an overarching EU framework for the compulsory licensing of intellectual property rights[2] to be used for crises within the EU that have a cross-border dimension. While recognising that voluntary agreements are likely to remain the most effective means to accelerate the manufacturing of patent-protected products, the Commission believes that an EU-wide framework for compulsory licensing would provide an essential safety net in an emergency if voluntary agreements cannot be reached.

1.3 Under the proposed Regulation, an EU-wide compulsory licence would only be granted once a crisis or emergency had been declared under one of five existing or planned EU instruments and the Commission considered it necessary to enable a patent-protected 'crisis relevant product'—one that is 'indispensable' to respond to the crisis—to be exploited. The instruments concern crises affecting the functioning of the EU Single Market and its supply chains,[3] public health emergencies,[4] and significant shortages affecting the supply of semiconductors[5] or the security of gas supply.[6] They are intended to provide the EU with a means of ensuring access to products needed to tackle a crisis, such as new vaccines or other critical products or components. The EU compulsory licence would cover all EU countries affected by the crisis and/or with relevant manufacturing capacity.

1.4 The proposed Regulation sets out the procedures and conditions for granting an EU compulsory licence. It would require the Commission to consult an advisory body before granting a licence, explore the possibility of reaching a voluntary licensing agreement, consider the rights and interests of the holder of the patent and the person (licensee) to whom the compulsory licence is to be granted, and ensure adequate remuneration for the holder of the patent.[7] Products manufactured under the compulsory licence would need to be clearly labelled as such and distributed exclusively within the EU. The Commission would have a power to impose fines or penalty payments on the patent holder or the licensee if it found either to be in breach of obligations relating to the compulsory licence.[8]

1.5 The proposed Regulation would ban the export of most products covered by an EU compulsory licence, but an exception is made for the export of medical products to eligible—mainly low income—countries outside the EU experiencing public health problems and lacking their own manufacturing capability.[9] This would avoid the need for these countries to seek separate national compulsory licences for a medical product in each EU country involved in the manufacturing process.

2 The EU compulsory licence would apply to the following intellectual property rights: patents and patent applications, utility models and supplementary protection certificates.

3 Proposal for a Regulation establishing a Single Market emergency instrument (COM(22) 459.

4 Regulation (EU) 2022/2371 on serious cross-border threats to health and Regulation (EU) 2022/2372 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

5 Proposal for a Regulation establishing a framework of measures for strengthening Europe's semiconductor ecosystem (Chips Act), COM(22) 46

6 Regulation (EU) 2017/1938 concerning measures to safeguard the security of gas supply.

7 Remuneration for the patent holder would be capped at 4% of the total gross revenue generated by the licensee under the compulsory licence.

8 The licensee or patent holder would have a right to be heard before the Commission acts and to appeal to the EU Court of Justice.

9 This would be implemented through an amendment to Regulation (EU) 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

1.6 The Commission anticipates that a compulsory EU licence would only be granted "during major crises affecting the EU, as a measure of last resort" and that the frequency of use is likely to be "very low".[10] To ensure that it has an overview of measures being taken across the EU and determine whether a compulsory licence at EU level is justified, EU Member States would have to notify the Commission of any national compulsory licences they grant to address national crises or emergencies.

The Government's position

1.7 In his Explanatory Memorandum dated 14 June 2023, the Minister for AI and Intellectual Property (Viscount Camrose) says that the introduction of a new EU-wide compulsory licensing system for crisis management within the EU *would not* apply in Northern Ireland. By contrast, the provisions on the grant of a compulsory EU licence for the manufacture within the EU of medical products for export to countries with public health problems *would* apply in Northern Ireland as the proposed Regulation would amend an existing EU law (Regulation (EU) 816/2006) which continues to apply in Northern Ireland under the Windsor Framework.[11] The Minister suggests that an EU-wide compulsory licence granted for these limited purposes "may" apply in Northern Ireland unless the 'Stormont Brake' (discussed below) is used, but he expects the impact on the Northern Ireland market to be "minimal" because compulsory licensing is "a last resort and rarely used mechanism". He says the WTO website records only two notifications of requests for compulsory licences in relation to the manufacture of pharmaceutical products for export to countries with public health problems.

1.8 The Minister notes that the UK Government "has not had any substantive engagement with the EU in relation to the development of the proposal", nor has it prepared its own impact assessment. The Government will continue to analyse "potential practical implications" as the proposed Regulation progresses through the EU's legislative process, but he does not expect there will be any impact on Northern Ireland's participation in UK Free Trade Agreements or in UK-wide Common Frameworks. He adds that the UK Government has no plans to amend the compulsory licensing provisions which form part of UK domestic patent law.

Our analysis

1.9 We note the lack of any substantive engagement with the EU on the development of the proposed Regulation, even though it may have implications for Northern Ireland because it includes provisions amending an EU law which continues to apply in Northern Ireland. The amended law would apply in Northern Ireland under a process of dynamic alignment provided for in Article 13(3) of the original Protocol on Ireland/Northern Ireland. The Windsor Framework has introduced a new emergency brake mechanism (the Stormont Brake) which will only become operational once the Northern Ireland Executive and Assembly have been restored. The Stormont Brake could be used in relation to those parts of the proposed Regulation which would amend EU law already applicable in Northern Ireland, provided sufficient Members of the Assembly (a minimum of 30 'MLAs' from at least two parties) wish to oppose the application of the amended EU law (assuming it

10 See page 8 of the Commission's explanatory memorandum accompanying the proposed Regulation.

11 The Windsor Framework in this context refers to the UK/EU Withdrawal Agreement Protocol on Ireland/Northern Ireland as amended by Joint Committee Decision 1/2023.

is adopted by the EU) and the UK Government is satisfied that the stringent criteria for applying the Brake have been met.[12] These criteria are that the amended EU law differs significantly in content or scope from the law it would replace and that it would have a sustained and significant impact specific to the everyday life of communities in Northern Ireland. The UK's Unilateral Declaration relating to the operation of the Stormont Brake also makes clear that MLAs should only seek to apply the Brake "in the most exceptional circumstances and as a last resort".[13] The Minister does not indicate whether he considers that the amending provisions in the proposed Regulation might satisfy these criteria. Nor does he tell us whether the proposal has been discussed in the Joint Consultative Working Group, an official-led body established amongst other things as a forum for the EU to inform the UK of planned EU laws that would apply in Northern Ireland.

1.10 Under the proposed Regulation an EU compulsory licence could only be granted by the Commission to tackle a crisis or emergency within the EU which has been declared under one of five existing or planned EU instruments listed in the Annex. The Minister does not explain which, if any, of these instruments apply (or might apply) in Northern Ireland and whether this would affect his assessment that those parts of the proposed Regulation which are entirely 'new' (rather than amend already applicable law in Northern Ireland) are not within the scope of the Windsor Framework. We note, for example, that one of the planned EU laws—a proposal for a Single Market Emergency Instrument to ensure vital supply chains can continue to function in a crisis affecting the EU Single Market—could affect laws that do apply in Northern Ireland under the Windsor Framework.

1.11 Northern Ireland is not included in the Commission's Impact Assessment on the proposed Regulation and the Government has not prepared its own impact assessment. The Minister says that any impact on Northern Ireland would be limited because compulsory licensing is "a last resort and rarely used mechanism". He nonetheless recognises that the possibility of obtaining an EU compulsory licence through a centralised procedure might make its use more attractive in a crisis where speed and ease may be of the essence. Given recent experience of vaccine procurement during the COVID-19 pandemic, the Commission's aborted attempt to apply safeguard measures to exclude Northern Ireland from the EU Single Market's COVID-19 vaccine supply chain, and the strain it placed on UK/EU relations, we consider that a deeper analysis of the potential impact of the proposed Regulation on Northern Ireland in the event of a similar pandemic is warranted. We note, for example, that Article 5 of the proposed Regulation provides that an EU compulsory licence "shall be limited to the territory of the [European] Union", that Article 11 prohibits the export of products manufactured under an EU compulsory licence (other than the limited exception for certain pharmaceutical products), and that Article 22 requires Member States to notify the Commission when they grant a national compulsory licence to address a national crisis. It is unclear how these provisions would affect Northern Ireland given that it remains part of the UK's customs territory but is treated as if it were an EU Member State in areas where EU law continues to apply.

1.12 The Minister indicates that the Government does not intend to make any changes to the compulsory licensing provisions contained in the UK's domestic patent laws. This domestic law, it seems, would continue to apply in Northern Ireland to address a crisis affecting only the UK. As the Covid-19 pandemic has demonstrated, the globalisation

12 See Article 13(3a) of the Windsor Framework. In this context, the Windsor Framework refers to the Protocol on Ireland/Northern Ireland as amended by Decision 1/2023 of the UK/EU Withdrawal Agreement Joint Committee.

13 See Annex 1 to Decision 1/2023 of the UK/EU Withdrawal Agreement Joint Committee.

of supply chains means that crises are difficult to contain within national borders. This suggests at least the potential for confusion or conflict if two different compulsory licencing systems may apply in Northern Ireland but not elsewhere in the UK.

Action

1.13 We have written to the Minister requesting further information on the potential implications of the proposed Regulation for Northern Ireland. We have drawn this chapter to the attention of the Northern Ireland Affairs Committee.

Letter to the Parliamentary Under-Secretary of State (Viscount Camrose), Department for Science, Innovation and Technology

We have considered this proposal, which would allow the European Commission to grant an EU compulsory licence of intellectual property rights if necessary to respond to a crisis or emergency affecting the EU, as well as your accompanying Explanatory Memorandum. You state that the proposed Regulation would not as such apply in Northern Ireland under the Windsor Framework but that the amendments it makes to another EU law (Regulation (EC) 816/2006) on compulsory licensing of patents relating to the manufacture of medicines for export would apply unless the Windsor Framework 'Stormont Brake' is invoked. We welcome your response to the following questions to aid our scrutiny of the proposal.

- Noting that the EU is required to inform the UK of planned EU acts within the scope of the Windsor Framework so that the UK can comply fully with its obligations, has the proposed Regulation been discussed in the Joint Consultative Working Group and, if not, do you intend to raise it? What difference would the enhanced engagement with Northern Ireland stakeholders announced by the European Commission as part of the Windsor Framework agreement have made to your understanding of the proposal?

- Have you considered which, if any, of the existing or planned EU instruments listed in the Annex to the proposed Regulation that could prompt the grant of an EU compulsory licence, might apply in Northern Ireland? If any might apply, would this affect your assessment that those parts of the proposed Regulation which are entirely 'new' are not within the scope of the Windsor Framework?

- Given recent experience of vaccine procurement during the Covid-19 pandemic, the Commission's aborted attempt to apply safeguard measures to exclude Northern Ireland from the EU Single Market's Covid-19 vaccine supply chain, and the strain it placed on UK/EU relations, how do you anticipate that the proposed Regulation (if agreed by the EU) would affect Northern Ireland in the event of a similar pandemic (or crisis of a similar magnitude) in the future? We note, for example, that Article 5 of the proposal provides that an EU compulsory licence "shall be limited to the territory of the [European] Union", that Article 11 prohibits the export of products manufactured under an EU compulsory licence (other than the limited exception for certain pharmaceutical products), and that Article 22 requires Member States to notify the Commission when they grant a national compulsory licence to address a national crisis. How would

these provisions affect Northern Ireland given that it remains part of the UK's customs territory but is treated as if it were an EU Member State in areas where EU law continues to apply?

- The globalisation of supply chains means that crises are difficult to contain within national borders. We understand that the compulsory licensing provisions contained in the UK's domestic patent laws will continue to apply in Northern Ireland to address a crisis affecting only the UK. Is it possible that two different compulsory licencing systems—a domestic and an EU one—could apply in Northern Ireland if the EU is affected by the same crisis, and how would you address the risk of potential confusion or conflict?

We look forward to receiving your response by 4 September 2023.