KEI Comment on the Footnote in Article 11 Regarding Technology Transfer

February 17, 2025

Introduction

One topic that has divided negotiations is references in the text that suggest that technology transfer is defined to be on voluntary terms. Various versions of the text have referred to mutually agreed terms (MAP), voluntary and mutually agreed terms (VMAT), non coercive, shared consensually, etc.

The global reality is that governments sometimes require technology transfer through a variety of measures. KEI has described these measures in several documents, including:

- 2024:3 KEI Briefing Note: What measures do US competition authorities refer to in technology transfer mandates.
  https://www.keionline.org/wp-content/uploads/KEI-BN-2024-3.pdf

- 2024:2 KEI Briefing Note: Examples of US competition cases that mandate transfer of technology and know-how.
  https://www.keionline.org/wp-content/uploads/KEI-BN-2024-2.pdf

- 2024:2A KEI Briefing Note: Comment on proposal by several countries to add language clarifying references to MAT or VMAT on the transfer of technology or know-how is without prejudice to other measures.
  https://www.keionline.org/wp-content/uploads/kei-bn-2024-2A.pdf

Of particular relevance to this week's negotiation are paragraphs 1, 32, 32a, and 32b of this 2024 EU resolution. See relevant paragraphs included in Annex 1 of this Comment.

- European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) No 816/2006 (COM(2023)0224 – C9-0151/2023 – 2023/0129(COD)) https://www.europarl.europa.eu/doceo/document/TA-9-2024-0143_EN.html

Note that the EU resolution text states that compulsory measures should be used when voluntary measures are not available or adequate, and that the compulsory measures would extend to patents, but also to trade secrets and know-how.

In no way will the United States or the members of the EU agree to be bound by an international norm that would prejudice their ability to use compulsory measures to require the sharing of intellectual property rights, know-how, cell lines, or other materials or technology, when voluntary measures are not available or adequate.

The effort to include language in the pandemic agreement on MAT, VMAT, or similar terms is designed to provide a pretext for bullying weaker trading partners and to prejudice courts and legislative bodies in developing countries when mandatory measures are used.

KEI recommendation

If there is language in the agreement referring to MAT, VMAT, or words with similar meaning, it is essential the text or footnote state plainly that any reference to voluntary measures be "without prejudice" to other options a party may pursue.

The second sentence in the September 16, 2024 version of the footnote is a good version because it not only refers to "measures" but to "other measures that parties may take."[1]

> *This understanding is without prejudice to other measures that parties may take pursuant to their domestic and/or national legislation, provided that such measures are consistent with their relevant international obligations regarding intellectual property,*

[1] The word "other" disappeared from subsequent versions of the footnote.

ANNEX 1: Paragraphs 1, 32, 32a and 32b from European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) No 816/2006 (COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))

(1) Crises require the setting-up of exceptional, swift, adequate and proportionate measures able to provide means to address the consequences of the crisis, without unnecessarily and disproportionally affecting the rights of citizens or the protection of intellectual property rights of businesses. In this context, the use of patented products or processes could prove indispensable to address the consequences of a crisis. Voluntary licensing agreements usually suffice to licence the patent rights on these products and allow their supply in the Union territory. Voluntary agreements are the most adequate, quick, and efficient solution to allow the use of patented products, and to scale up production in crises. Nevertheless, voluntary agreements may not always be available or only under inadequate conditions such as lengthy delivery times. In such cases, compulsory licensing can provide a solution to allow access to patented products, in particular products necessary to tackle the consequences of a crisis. [Am. 1]

. . .

(32) The relation between the rights-holder and the licensee should be governed by the principle of good faith. The rights-holder and licensee should work towards the success of the Union compulsory licence and collaborate, where necessary, to ensure that the Union compulsory licence effectively and efficiently fulfils its objective. The Commission may act as an enabler in achieving the good-faith cooperation between the rights-holder and the licensee, taking into account interests of all parties. In that respect, the Commission should also be entitled to take additional measures in line with Union law to ensure that the compulsory licence meets its objective and ensure that necessary crisis-relevant goods can be made available in the Union. Such additional measures may include requesting further information which is deemed indispensable to achieve the objective of the compulsory licence. These measures should always include adequate safeguards to ensure the protection of the legitimate interests of all parties.

(32a) Where appropriate, the Commission should oblige the rights-holder to disclose the trade secrets which are strictly necessary in order to achieve the purpose of the Union compulsory licence. In such cases, rights-holders should receive an adequate remuneration. It is possible that a detailed description of how to carry out the invention might not be sufficient and complete enough to enable the licensee to efficiently use that invention. This could encompass, without being exhaustively limited to, the comprehensive transfer of necessary technology, expertise, data, samples, and reference products essential for production and obtaining market authorisation in collaboration with the licensee, taking into account both the rights-holder and the licensee’s interests. In cases where that additional information and know-how is necessary, some of which is an undisclosed trade secret, the disclosure of that necessary trade secret, with a view to only achieving the purpose of exercising the Union compulsory licence pursuant to this Regulation, should be considered to be lawful within the meaning of Article 3(2) and Article 5 of Directive (EU) 2016/943 of the European Parliament and the Council. While this Regulation requires the disclosure of trade secrets only when they are strictly necessary in

order to achieve the purpose of the Union compulsory licence, it should be interpreted in such a manner as to preserve the protection afforded to trade secrets under Directive (EU) 2016/943. The Commission should require the licensee(s) to put in place all appropriate measures reasonably identified by the rights-holder, including contractual, technical and organisational measures, to ensure the confidentiality of trade secrets, in particular vis-à-vis third parties and the protection of the legitimate interests of all parties. To that end, right holders should identify trade secrets prior to the disclosure. Those appropriate measures may consist of model contractual terms, confidentiality agreements, strict access protocols, technical standards and the application of codes of conduct. Where the licensee fails to implement the measures required for preserving the confidentiality of the trade secrets, the Commission should be able to withhold or suspend the disclosure of trade secrets until the situation is corrected by the licensee. Any use, acquisition or disclosure of trade secrets which would not be necessary to fulfil the objective of the Union compulsory licence or which would go beyond the duration of the Union compulsory licence should be considered to be unlawful within the meaning of that Directive. [Am. 16]

(32b) This Regulation should guarantee that the Commission has the authority to oblige rights-holders to provide all necessary information to facilitate the rapid and efficient production of critical crisis-related products, such as pharmaceuticals and other health-related items. This information should encompass details about know-how, particularly when it is essential for the effective implementation of compulsory licensing. While patent licensing alone might suffice to enable other manufacturers to quickly produce simple pharmaceuticals, in case of more intricate pharmaceutical products, such as vaccines during a pandemic, it is often insufficient. Where it is essential for the implementation of the compulsory licence, an alternative producer will also require access to know-how. [Am. 17]

ANNEX, previous versions of the Footnote on technology transfer

February 6, 2025

Proposed New 1(j) footnote under Article 11 for INB13:

For the purposes of this Agreement, Transfer of Technology is understood to be on fair and most favourable terms, including on concessional and preferential terms, and in accordance with mutually agreed terms and conditions. In the case of technology subject to patents, such transfer shall be provided on terms which recognize and respect protection of intellectual property rights.

December 5, 2024

Proposed New 1(j) footnote under Article 11 for INB12:

For the purposes of this Agreement, Transfer of Technology refers to a mutually agreed process where technology is shared consensually. This understanding is without prejudice to measures that Parties may take in accordance with their domestic or national legislation and

does not affect any rights they may exercise under it, provided that these measures are in line with their relevant international obligations regarding intellectual property rights.

Dec 4, 2024

Proposed New 1(j) footnote under Article 11 for INB12:

For the purposes of this Agreement, Transfer of Technology refers to a mutually agreed process where technology is shared consensually. This understanding is without prejudice to measures that Parties may take in accordance with their domestic or national legislation and does not affect any rights they may exercise under it, provided that these measures are in line with their relevant international obligations regarding intellectual property rights.

November 14, 2024

Proposed New 1(j) footnote under Article 11 for INB12:

For the purposes of this Agreement, Transfer of Technology refers to a mutually agreed process where technology is shared consensually. This understanding is without prejudice to measures that Parties may take in accordance with their domestic or national legislation and does not affect any rights they may exercise under it, provided that these measures are in line with their relevant international obligations regarding intellectual property rights.

September 16, 2024

New 1(j) Alt / footnote under Article 11:

Transfer of Technology is understood to mean non-coercive transfer and on mutually agreed terms. This understanding is without prejudice to other measures that parties may take pursuant to their domestic and/or national legislation, provided that such measures are consistent with their relevant international obligations regarding intellectual property,

And a New 1(k) Alt on know-how:
Know-how refers to knowledge and skills required to manufacture products.