

The European Parliament has now explicitly acknowledged the know-how problem too: time to include a workable solution in the draft Pandemic Accord.

By Christopher Garrison

We have been calling attention to the problem of sharing know-how necessary for the widespread production of pandemic countermeasures since the end of 2020 ([here](#), [here](#), [here](#) and [here](#)). Although it may be possible to manufacture 'simple' pandemic countermeasures, such as small-molecule medicines, on the basis of the information provided in published patent applications, this will not be true for all pandemic countermeasures. The manufacture of more complex ones, such as monoclonal antibody therapies or mRNA vaccines, is likely to require access to additional 'know-how' ('trade-secrets') developed after the relevant patent applications have been filed. Even if a compulsory licence has been granted to overcome a patent barrier, without access to that additional know-how, manufacture still won't be able to take place. The negotiating text of the Pandemic Accord does not presently include any provision which could solve this problem. We have warned that, if this situation persists, the effectiveness of any Pandemic Accord which does result from the INB process will be significantly reduced from the outset.

We therefore welcome the fact that the European Parliament has now explicitly acknowledged this problem too. Based on a draft of a European Commission Regulation intended to provide the framework for the use of compulsory patent licensing during a crisis in Europe, the European Parliament has added, for example, the following text (Amendment 17, Recital 32(b)):

"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."

We agree. Also acknowledging that a prompt and effective voluntary agreement to share know-how cannot always be concluded in a crisis, the European Parliament's version of the draft Regulation therefore proposes the following as a 'failsafe' or 'backup' solution (Amendment 66, Article 13(a)(2)):

"Where strictly necessary, the [European] Commission shall request the disclosure of the rights-holder's trade secrets to the licensee to the extent required to provide him with the necessary know-how to achieve the objective for which the Union compulsory licence is granted under this Regulation..."

Again, we agree, although with some reservations. The use of the term 'request' appears misleading as the draft Regulation contemplates that the rights-holder can be fined for a failure to comply (Amendment 71, Article 15(1)(c)). It can be questioned whether this is sufficiently robust to guarantee that the necessary know-how will be shared. The provision can nevertheless certainly be viewed as effectively authorising the compulsory sharing of know-how. Independent of this particular approach, though, the sharing of necessary know-how can be compelled in the appropriate circumstances in a TRIPS-compatible way as we have explained before (for example, [here](#)).

One potentially critical limitation of the proposal, however, is that it will only work if the European Commission is able to enforce its 'request'. There may be no problem if it is a French or German company which holds the necessary know-how but what if it is, for example, a Chilean or Indonesian company which does so, with insufficient legal or economic ties to the European Union? Any 'request' from the European Commission to share necessary know-how in these circumstances might be ignored. To this extent, it appears that the European institutions are effectively gambling that it will be their firms that have access to the necessary know-how. However, given technological progress in several fields, including Artificial Intelligence and Synthetic Biology, such know-how could be generated much more widely than before. The same will therefore be true for every other country: how can any country be sure that it would have access to the necessary know-how?

That is why we have proposed a simple extension to this type of provision to 'internationalise' the solution. We have suggested adding a new obligation for WHO Parties in the draft Pandemic Accord. Each Party would agree that if they happen to be the country in which the necessary know-how is located then, in the absence of an adequate voluntary agreement, they will take the necessary steps to compel the requisite sharing of that know-how. Thus ([here](#)):

"Article 11: Transfer of Technology

X. In addition to the undertakings in paragraph 1 of this Article, where the urgent manufacture by qualified third parties of a pandemic countermeasure is necessary to respond to a pandemic or the threat of a pandemic but the manufacture is prevented or hindered through lack of access to undisclosed information possessed by one or more private rights holders located in one or more Parties, that or those Parties shall compel that or those rights holders to share the undisclosed information with the third parties."

Each WHO Party could therefore have a higher degree of confidence that, where-ever the necessary know-how was located, it would be shared.

It is, of course, to be expected that the implementation of such a provision will need to address a number of relevant additional issues including as to the protection of the rights holders legitimate interests and the practicalities of the sharing. (We have touched on a few of these issues [here](#)). For the time being, however, we suggest that this provision should provide the basis of a workable solution. If it is rejected by INB negotiators for inclusion in

the draft Pandemic Accord, we will have to ask them to point out which other provision is going to be able to solve this problem. If they reject it whilst also agreeing that there is no other such provision, then they must recognise that this will represent a regrettable failure and that the effectiveness of any Pandemic Accord which does result from the INB process will indeed be significantly reduced from the outset. In order to avoid such a failure, we urge INB negotiators instead to take a close look at the European Parliament's explicit acknowledgment of this problem, consistent with our own earlier discussions of the problem, and to recognise that our proposed solution, or a similar equivalent, should be included in the text of the draft Pandemic Accord to form the basis of a workable solution.

Annex

Relevant extracts from draft European Commission Regulation

**Compulsory licensing for crisis management and amending Regulation (EC) 816/2006
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) 816/2006 (COM(2023)0224 –
C9-0151/2023 – 2023/0129(COD))**

Amendment 16

Proposal for a regulation

Recital 32 a (new)

Amendment

(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.

Amendment 17
Proposal for a regulation
Recital 32 b (new)

(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.

Amendment 66
Proposal for a regulation
Article 13 a (new)

Article 13a

Additional measures complementing the Union compulsory licence

1. Where necessary, the Commission shall decide, upon a reasoned request from the rights-holder or the licensee, or on its own initiative, on additional measures complementing the Union compulsory licence to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between the rights-holder and the licensee.
2. Where strictly necessary, the Commission shall request the disclosure of the rights-holder's trade secrets to the licensee to the extent required to provide him with the necessary know-how to achieve the objective for which the Union compulsory licence is granted under this Regulation. The lawful uses of the trade secrets by the licensee shall be strictly limited to the manufacturing of the crisis-relevant products in view of fulfilling the objective for which the Union compulsory licence has been granted.
3. Where the rights-holder is requested to disclose his trade secrets in accordance with paragraph 3, the Commission shall, prior to the disclosure of trade secrets, order the licensee to put in place all appropriate technical and organisational measures that the rights-holder reasonably identifies as necessary to preserve the confidentiality of trade secrets, in particular in relation to third parties, including, as appropriate, the use of model contractual terms, confidentiality agreements, strict access protocols, technical standards or the application of codes of conduct. If the licensee fails to implement the necessary measures required by the Commission, the Commission may withhold or, as the case may be, suspend the disclosure of trade secrets until the situation is corrected by the licensee.
4. Appropriate remuneration to the rights-holders in compensation for the disclosure of their trade secrets shall be granted in accordance with Directive (EU) 2016/943.
5. Where the Commission considers adopting additional measures as referred to in paragraphs 1 and 2, it shall consult the advisory body referred to in Article 6.

6. The implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the rules referred to in Article 7(6), points (a) and (b), and Article 7(7) and (8).