

**Intervention at Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, 9th session (INB9), 18 March 2024.**

by Ellen 't Hoen, Director, Medicines Law & Policy

Thank you for the opportunity to speak.

Covid-19 exposed grave inequity in access to pandemic countermeasures and lack of access to manufacturing know-how. This is one of the important reasons why we are here.

My comments focus on article 11 transfer of technology and know-how. The draft before us contains some important improvements compared to the last version discussed at INB8.

1. We welcome the clearer language on commitments to technology and know-how sharing as well as to transparency.
2. The provisions related to intellectual property (IP) in the draft operationalise provisions in World Trade Organization (WTO) rules – and do not contradict them.
3. Also welcome is the recognition of Parties' rights to use the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities. Recognition of existing rights does of course not change the status quo. But an unambiguous commitment not to challenge the use of these rights, in Article 11, would.
4. A provision to guarantee access to undisclosed information or know-how is still missing. We have drafted a proposal for such a provision, which is in an annex to this statement.

I thank you for your attention.

## **Annex: How to solve the know-how problem in the WHO Pandemic Accord**

By Christopher Garrison

### Introduction

One of the most important Intellectual Property (IP) problems which the Pandemic Accord negotiators need to solve is now in danger of being completely ignored. This is the problem of guaranteeing access to 'undisclosed information', also known as 'know-how'. Such undisclosed information is typically held in secret by pharmaceutical companies but can often be necessary to enable the large-scale production of pandemic countermeasures such as medicines, vaccines and diagnostics. If access to such undisclosed information is not guaranteed then, even if all the patent-related barriers are overcome during a future pandemic by compulsory licensing or otherwise, there will still be no certainty that the large-scale production of particular pandemic countermeasures will be able to take place. This would surely represent a critical failure of the Pandemic Accord process.

In the apparent absence of any other attempts to solve this problem, we therefore propose the following provision for insertion as a separate sub-section in Article 11 of the draft Pandemic Accord:

#### **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.*

We have discussed an earlier version of this provision [here](#) and [here](#). A significantly weaker form of this provision was included in earlier drafts of the Pandemic Accord but now appears to have been removed entirely (latest draft 14.02.2024). We therefore urge the Pandemic Accord negotiators to introduce the above provision into the negotiating text so that it can form the basis for a robust solution to the know-how problem. It is not too late.

### The know-how problem

A patent application must include a description of how to carry out the invention it describes. For example, if the invention is a product, it must describe at least one workable way to make that product. If it fails to do that, for example, by being too vague or by leaving out a crucial feature, then even if the patent is granted, it will be invalid and can be revoked. This 'disclosure' requirement of patent law is included in Art. 29.1 of the WTO TRIPS Agreement. However, it is important to realise that this requirement only applies at the time when the application for the patent is made. For a pharmaceutical product, this is typically at a very early stage in its development. Over time, if the pharmaceutical product looks like it will be a successful (profitable) one, it is highly likely that the process for its manufacture will be developed from the very basic one described in the patent to a much more efficient one, suitable for making the product at large scale. There is no requirement, however, for the patent holder to go back and include the details of this more efficient process in the published patent specification or indeed to publish them anywhere else. Instead, these details are likely to be kept as a secret, commonly known as 'know-how' (or 'trade secrets'). This type of undisclosed information is given a limited degree of protection under Art. 39.2 of the WTO TRIPS Agreement.

This difference between the basic manufacturing process (made public in the published patent specification) and the much more efficient manufacturing process (kept as secret know-how) has a vital consequence for access to medicines. A pharmaceutical firm could enter into a voluntary agreement to licence its patent and share its know-how with another pharmaceutical firm, in which case that other firm will be able to produce the product at large scale too. However, in the absence of such a voluntary agreement, if other pharmaceutical firms cannot analyse the marketed pharmaceutical product to find out the details of this missing know-how ('reverse-engineering') or if they cannot re-develop the know-how themselves, then even when the patent expires, they will still be unable to make the product at large scale. This problem can occur during the lifetime of a patent too. Although granting a compulsory patent licence in theory permits firms to, for example, make a patented pharmaceutical product, the published patent specification will only explain how to do this in the basic way. Without the additional know-how, they will likely not be able to make the product at large scale.

### A national solution to the know-how problem

There is a solution to this problem. In fact, WTO Members can compel the sharing of know-how in the appropriate circumstances in a TRIPS-compatible way (see [here](#)). This can effectively be thought of as a compulsory know-how licence. Article 39 of the TRIPS Agreement deals with the protection of undisclosed information, which includes know-how as defined under Art. 39.2 TRIPS. However, this protection is limited to forbidding dishonest or unfair commercial use. It is therefore permissible for WTO Members to require the disclosure of undisclosed information in circumstances which do not represent dishonest or unfair commercial use. It can be required, for example, in Antitrust / Competition law cases, where disclosure to other firms is necessary to restore fair commercial competition. More pertinently, though, it can also be required where disclosure is necessary in the public interest. For example, if a compulsory patent licence were granted during a pandemic to enable urgent production of a pharmaceutical product at large scale, it would be permissible for the patent holder to be also required to share any additional know-how necessary to enable that production.

The recent European Commission proposal on compulsory licensing for crisis management (2023) appears to provide a nice example (see [here](#), [here](#), and an event recording [here](#)). In order to adequately protect European Union citizens during a crisis, this proposal provides that:

*“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 the 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.”*

Notably, patent holders may be fined for failure to cooperate in good faith. In fact, though, this proposal may unfortunately not be as effective in protecting European citizens during a crisis as the European Commission would like to think. The European Commission may be able to effectively compel a European pharmaceutical firm holding undisclosed information in secret in Europe to cooperate and share it with compulsory patent licence holders. However, it is not obvious that it could do the same with, for example, an Asian firm which holds undisclosed information in secret in Asia but which lacks a legal or commercial presence in Europe. The European Commission would effectively appear to be

gambling that, for example, European pharmaceutical firms would just happen to be the ones which develop the vital pandemic countermeasure technology. This would seem to us an unreasonable gamble. An equivalent solution would be available to any WTO Member but, again, it would seem to us an unreasonable gamble that it would just happen to be its own firms which develop the vital pandemic countermeasure technology. Given the stakes involved in any future pandemic, we would prefer a more predictable and internationally effective solution.

### Our 'internationalised' solution to the know-how problem

We therefore suggest a simple new obligation for WHO Parties. Consider that there is a pharmaceutical firm (private rights holder) located in a WHO Party which possesses undisclosed information vital for the manufacture of pandemic countermeasures by other qualified manufacturers around the world. The WHO Parties would thus agree that, when it was necessary in the circumstances of a pandemic or the threat of a pandemic, whichever WHO Party in which the pharmaceutical firm was located would be obliged to compel the necessary sharing with the other qualified manufacturers around the world. Prior to the compelled sharing, it would of course be desirable that the pharmaceutical firm be given a chance to enter into voluntary sharing agreements. Given the urgency likely involved, however, if the voluntary negotiations were taking too long or had failed, i.e. when it was necessary, there would have to be a transition to compelled sharing. All WHO Parties could therefore be assured that the necessary sharing would take place, whether by voluntary or compelled means, so long as the relevant pharmaceutical firm was located in any WHO Party. The undisclosed information could either be associated with one or more patents or it could be independent.

The undisclosed information would likely be 'know-how' (Art. 39.2 TRIPS) but could also include otherwise undisclosed test or other data (Art. 39.3 TRIPS). We think that that our suggested provision reproduced above suitably describes an 'internationalised' solution of this type. Again, therefore, we urge the Pandemic Accord negotiators to introduce it into the negotiating text so that it can form the basis for a robust solution to the know-how problem.