

The WHO pandemic instrument must address the sharing of know-how/trade secrets: a proposal for a new measure

The World Health Assembly has convened an Intergovernmental Negotiating Body (INB) whose remit is "...to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response...". Two pertinent texts have been published: the 'Zero' text (1 February 2023, A/INB/4/3) and the 'Bureau' text (2 June 2023, A/INB/5/6). An important aim stated in both is that:

"The Parties recognize that inequitable access to pandemic-related products (including but not limited to vaccines, therapeutics and diagnostics) should be addressed by increased manufacturing capacity that is more equitably, geographically and strategically distributed." (Art. 7.1, A/INB/4/3; Option 11.A, A/INB/5/6)

However, this aim could be frustrated through a critical problem arising in the absence of agreement with intellectual property owners. Although both texts could likely assist in enabling the 'scaled-up' third party manufacture of 'simple' privately-owned pharmaceutical products (such as small molecule drugs) in the event of a future pandemic, neither could fully enable the equivalent manufacture of 'complex' pharmaceutical products (such as monoclonal antibody therapies or mRNA-based vaccines). The key issue is that neither text contains language providing for the compulsory sharing of know-how/trade secrets ('undisclosed information' in the sense of Art. 39.2 TRIPS) in the likely case it is held by a private pharmaceutical company. (The provisions currently included under, for example, Arts. 4(c), A/INB/4/3 and 11.A.5(c), A/INB/5/6, relating to parties that have received public funding, and Art. 11.B.5(a), A/INB/5/6, relating to government-owned technologies, are insufficient.)

Building on previous ML&P publications, this note outlines the critical intellectual property problem (see Annex). To stimulate concrete discussion about possible solutions, it also proposes the following provision for consideration by those taking part in the INB process:

Where the Director-General of the World Health Organization has determined that: (i) a pandemic outbreak, or the threat of a pandemic outbreak, represents a public health emergency of international concern (PHEIC); (ii) the urgent manufacture by qualified third parties of a pharmaceutical product is necessary to respond to the pandemic outbreak, or the threat of the pandemic outbreak; and (iii) the manufacture is prevented or hindered through lack of access to undisclosed information as defined in Art. 39.2 TRIPS possessed by one or more entities located in one or more Parties, that or those Parties shall compel that or those entities to share the undisclosed information with the third parties.

In considering this provision, it is important to be appreciate that although know-how/trade secrets are commonly referred to as types of intellectual property, not least due to their treatment as protected forms of 'undisclosed information' in the TRIPS (Trade-Related

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Aspects of Intellectual Property Rights) Agreement, they are not treated there as property in an absolute sense. Rather, Art 39 TRIPS only protects them against unfair competition and, in particular, under Art 39.2 TRIPS, against disclosure, acquisition or use “in a manner contrary to honest commercial practices”. This contemplates situations such as an employee misappropriating know-how/trade secrets to take or sell to a competitor firm. However, this provision does not bar the disclosure of know-how/trade secrets in a range of other situations whether to the public or, in confidence, to third parties if it is necessary to do so (Gurgula & Hull 2021; Levine & Sarnoff 2023).

For example, the mandatory disclosure of know-how/trade secrets to third party competitors is used as a remedy in European competition law and American antitrust cases to restore fair competition (Levine & Sarnoff 2023). The disclosure of know-how/trade secrets can also be required during a national emergency. The American Defence Production Act of 1950 provides a range of emergency ‘war powers’ which reportedly forced collaboration between two rival firms during the Covid-19 pandemic such that vaccine manufacturing plants were able to be switched over to joint production (Levine & Sarnoff 2023). The recent European Commission proposal for an EU-wide crisis-related intellectual property compulsory licensing mechanism provides another, even more explicit example. The Commission envisages imposing a duty on intellectual property owners in such circumstances to collaborate with licensees to ensure that manufacture is effectively and efficiently enabled. This collaboration includes providing access, if necessary, via the intervention of the Commission, to any associated ‘indispensable information’ (know-how/trade secrets).

The United States and the European Union thus already acknowledge and use TRIPS compatible powers to compel the sharing of know-how/trade secrets in their own jurisdictions when it is necessary to do so. It can be added that, in any case, Art. 73(b)(iii) TRIPS also permits countries to take any necessary action regarding intellectual property for the protection of their essential security interests during a “time of war or other emergency in international relations”, which justifiably includes the outbreak of a pandemic (Abbott 2020).

We suggest that it must be in the interests of all countries, High-Income Countries (HICs) and Low- and Middle- Income Countries (LMICs) alike, to consider extending this thinking about the sharing of know-how/trade secrets to address the broader international problem relating to pandemics identified here. Given the democratization and spread of technologies such as synthetic biology and machine learning, it is increasingly likely that future pandemic countermeasures and associated know-how/trade secrets could be developed in present day LMICs and that third-party manufacturers in HICs would be the ones seeking such sharing.

It is thus very important that any WHO instrument includes a provision ensuring access to know-how/trade secrets located in any country which will support the necessary distributed manufacturing and, thus, secure timely, widespread and equitable access to vital pandemic products.

References

Abbott, F., 2020. **The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic.** South Centre Research Paper 116.

Gurgula, O. and Hull, J., 2021. **Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer.** Journal Of Intellectual Property Law and Practice, 16(11), pp.1242-1261.

Levine, D.S. and Sarnoff, J.D., 2023. **Compelling Trade Secret Sharing.** Hastings LJ, 74, p.987.

Further reading

The European Commission's proposal on a new EU-wide compulsory licensing regime.

Olga Gurgula (guest, Medicines Law & Policy) 8 Sep 2023.

(<https://medicineslawandpolicy.org/2023/09/the-european-commissions-proposal-on-a-new-eu-wide-compulsory-licensing-regime/>)

Perehudoff K, 't Hoen E, Mara K, et al., 2022. **A pandemic treaty for equitable global access to medical countermeasures: seven recommendations for sharing intellectual property, know-how and technology.** BMJ Global Health, 7:e009709.

(<https://gh.bmj.com/content/bmjgh/7/7/e009709.full.pdf>)

Lessons for a pandemic preparedness treaty from previous successes and failures with treaty-based technology transfer. Christopher Garrison (Medicines Law & Policy) 19 Oct 2021.

(<https://medicineslawandpolicy.org/2021/10/lessons-for-a-pandemic-preparedness-treaty-from-previous-successes-and-failures-with-treaty-based-technology-transfer/>)

What is the 'know-how gap' problem and how might it impact scaling up production of Covid-19 related diagnostics, therapies and vaccines? Christopher Garrison (Medicines Law & Policy) 16 Dec 2020.

(<https://medicineslawandpolicy.org/2020/12/what-is-the-know-how-gap-problem-and-how-might-it-impact-scaling-up-production-of-covid-19-related-diagnostics-therapies-and-vaccines/>)

Annex

A1. Scenario 1: Simple pharmaceutical product

Consider the scenario shown in Figure 1 where private company X owns patents covering a pharmaceutical product in countries A and B and, in a pandemic emergency, it is urgently required that company Y manufactures the product in country B. In this scenario, although company X keeps secret some additional know-how/trade secrets relating to the manufacture of the product, the pharmaceutical product is a simple one and there is enough information provided in the published patent document alone to permit its manufacture. The patent in country B is therefore the only issue that needs to be dealt with.

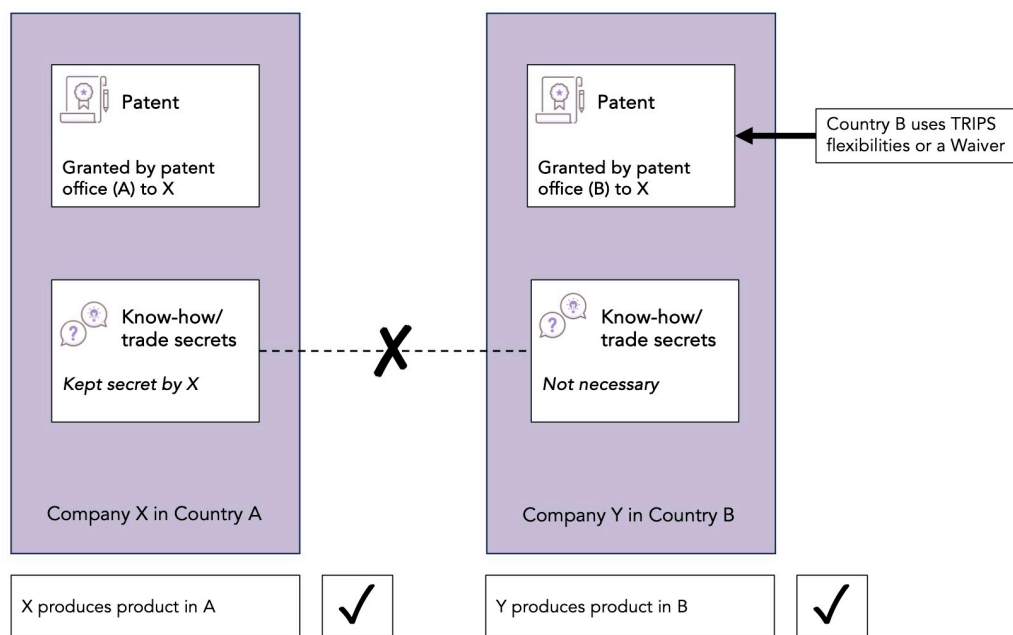


Figure 1. Simple pharmaceutical product.

A voluntary patent licence agreement between companies X and Y would enable company Y to manufacture in country B.

In the absence of an agreement, the patent rights of company X in country B could instead be 'overcome' either by a compulsory licence implemented in national law (as provided for under the TRIPS Agreement) or by an appropriate Waiver implemented in national law (for example, as agreed under a new WHO pandemic instrument) in country B.

In this scenario, country B would therefore have the appropriate jurisdiction and powers to enable manufacture of the pharmaceutical product by company Y (Fig. 1).

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A2. Scenario 2: Complex pharmaceutical product

Consider the alternative scenario shown in Figure 2. In this case, the additional know-how/trade secrets relating to the manufacture of the product kept secret by company X in country A is necessary for the manufacture of the pharmaceutical product. The patent in country B and lack of the know-how/trade secrets in country B are therefore both issues that need to be dealt with.

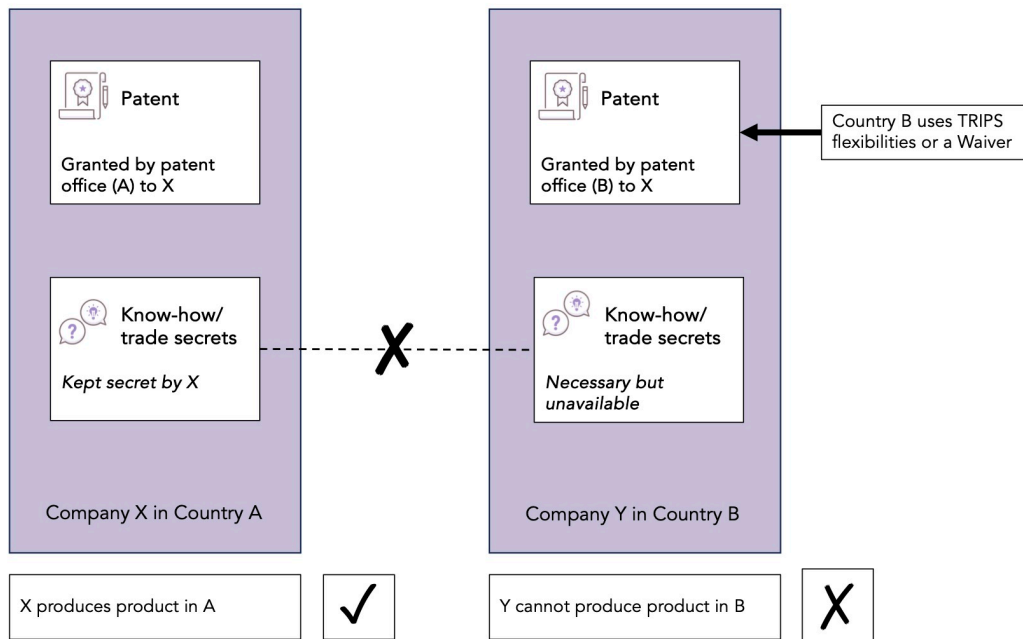


Figure 2. Complex pharmaceutical product.

The combination of a voluntary patent licence agreement and voluntary sharing of undisclosed information (know-how/trade secrets) between companies X and Y would enable company Y to manufacture in country B.

In the absence of an agreement, although the patent rights of company X in country B could again be 'overcome' by a compulsory licence implemented in national law (as provided for under the TRIPS Agreement) or by an appropriate Waiver implemented in national law (for example, as agreed under a new WHO pandemic instrument), there is currently no provision in either the TRIPS Agreement or the proposed drafts of a new WHO pandemic instrument accord which would compel a private company in country A to share the necessary undisclosed information (know-how/trade secrets) with company Y in country B in this situation. It is possible that company Y could undertake sufficient research to generate the missing know-how/trade secrets itself but, even if it were possible, it is unlikely to be successful on a time-scale which is useful in the circumstances of a pandemic.

In this scenario, under the proposed drafts of a new WHO pandemic instrument, country B would not therefore have the appropriate jurisdiction and powers to enable manufacture of the pharmaceutical product by company Y (Fig. 2).

A3. Scenario 3: Complex pharmaceutical product with new provision

Consider the scenario shown in Figure 3, showing a modification of scenario 2 where a newly agreed WHO pandemic instrument includes the following (or similar) provision:

Where the Director-General of the World Health Organization has determined that: (i) a pandemic outbreak, or the threat of a pandemic outbreak, represents a public health emergency of international concern (PHEIC); (ii) the urgent manufacture by qualified third parties of a pharmaceutical product is necessary to respond to the pandemic outbreak, or the threat of the pandemic outbreak; and (iii) the manufacture is prevented or hindered through lack of access to undisclosed information as defined in Art. 39.2 TRIPS possessed by one or more entities located in one or more Parties, that or those Parties shall compel that or those entities to share the undisclosed information with the third parties.

and where country A has appropriately implemented it in national law.

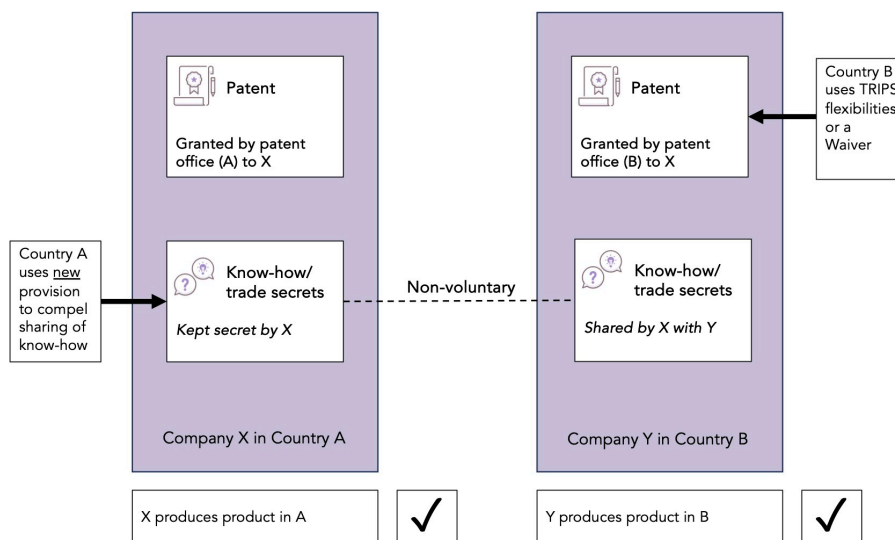


Figure 3. Complex pharmaceutical product with new provision.

In the absence of an agreement, the same action could be taken in country B to ‘overcome’ the patent rights of company X as in scenario 2 but, so long as the requirements specified in the provision were met, country A would additionally be required to compel private company X to share the necessary know-how/trade secrets with company Y. Sharing could occur directly or, for example, via the WHO Covid-19 Technology Access Pool (C-TAP), the Medicines Patent Pool (MPP) or an equivalent mechanism.

In this scenario, where a newly agreed WHO pandemic instrument included such a provision and its requirements were met, the combination of countries A and B would therefore have the appropriate jurisdiction and powers to enable manufacture of the pharmaceutical product by company Y in country B (Fig. 3).