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WTO adopts compromise on the waiver of patent rights to address COVID-19 pandemic

On 17 June 2022, the Ministerial Conference, the topmost decision-making body of the World Trade Organization ("WTO"), adopted a Decision (Document WT/MIN(22)/W/15/Rev.2) related to the use of patent rights in the COVID-19 pandemic (the "Decision"). The Decision effectively enables "developing countries" (see below) to authorize the use of the subject matter of a patent without consent of the right holder and without fulfilling all conditions for the grant of a compulsory license as foreseen by the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement").

Publiziert: 21 Juni 2022

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Background

On 2 October 2020, the governments of India and South Africa submitted a Communication (Document IP/C/W/669; the "Communication") to the Council for TRIPS, the WTO body responsible for administering and monitoring the operation of the TRIPS Agreement. The Communication called for a sweeping "waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19". It proposed that the sections of the TRIPS Agreement related to copyright, related rights, designs, patents and trade secrets be waived in full and by all WTO members "in relation to prevention, containment or treatment of COVID-19" for an undetermined number of years. The stated objective of the Communication was to enable swift and effective distribution of medicines and vaccines against COVID-19 in the world, including in least-developed countries.

The original Communication received increased attention in May 2021 when the US government

announced that it would in principle support such a waiver of the TRIPS Agreement. Over the last months, the two original initiators, along with the United States and the European Union, worked out a compromise that was eventually submitted to the WTO Ministerial Conference and that served as a basis for the Decision that was finally adopted.

Content of the Decision

The Decision sets forth that the rights provided for in Article 28.1 of the TRIPS Agreement (that is, the exclusive rights conferred by a patent) can be limited by an "eligible Member" by authorizing the use of a patent required for the production and supply of COVID-19 vaccines in accordance with Article 31 of the TRIPS Agreement (the provision related to compulsory licensing), some conditions of which are explicitly waived. The conditions as set out in the Decision are summarized below:

a) Personal scope of application: "eligible Member"

The Decision defines "eligible Members" as "developing country Members" of the WTO. The WTO distinguishes "developed countries", "developing countries" and "least-developed countries". Whereas there is an exhaustive list of (currently 46) least-developed countries, "developing country" is not a term defined in the WTO treaties. Rather, WTO members can announce themselves whether they are "developed" or "developing" countries. Currently, the majority of WTO members consider themselves "developing countries".

Three comments follow from the restriction of the Decision to "developing countries":

- First, the Decision does not have any direct impact on the law of developed countries (among which Switzerland, the US and all EU member states). However, the Decision prevents developed countries from initiating proceedings for violation of the TRIPS Agreement against developing countries who make use of the flexibilities foreseen by the Decision before the WTO dispute settlement bodies.
- Second, footnote 1 of the Decision "encourages" those developing country members who have "existing capacity to manufacture COVID-19 vaccines" to make a binding commitment not to avail themselves of the Decision. This "encouragement" seems to contradict the general direction of the Decision. At the time of writing, it is unclear whether any developing country members will answer positively to this encouragement.
- Finally, the Decision does not change the current legal position of least-developed countries ("LDC"). Since the inception of the WTO, LDC have benefitted from an almost full waiver of the TRIPS Agreement (see Article 66 of the TRIPS Agreement and the decision of 29 November 2005 of the Council for TRIPS). Currently, LDC are not required to apply the TRIPS Agreement, with the exception of some of the basic non-discrimination rules. Hence, LDC are currently not required to protect or enforce any patents or trade secrets (whether or not related to COVID-19 vaccines), nor to have a legislation on patents or trade secrets in the first place.

b) Substantive scope of application: "a patent required for the production

and supply of COVID-19 vaccines"

The substantive scope of application of the Decision is potentially ambiguous. On the one hand, the Decision explicitly only refers to "patents" and Article 28.1 of the TRIPS Agreement (which only relates to patents). On the other hand, the Decision mentions in a footnote that it understands the term "subject matter of a patent" as including "ingredients and processes necessary for the manufacture of the COVID-19 vaccine".

It is not yet clear what this footnote means. On its face, the reference to "ingredients and processes" may simply be understood to clarify that the Decision relates to both compound and method patents. However, the term "necessary for the manufacture of" vaccines may also be understood to relate to all ingredients and processes that are indeed necessary to manufacture a vaccine, whether or not they are protected by a patent. This reading would enlarge the scope of the Decision to trade secrets and confidential information "necessary" for the manufacture of a vaccine.

Finally, the current text of the Decision is explicitly limited to COVID-19 vaccines only. However, as per section 8 of the Decision, the WTO Members will decide "on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics". Hence, it will be known by the end of 2022 whether the waiver as set out in the Decision will be extended to these products.

c) Condition of application: "to the extent necessary to address the COVID-19 pandemic"

By stating that "eligible Members" shall only authorize the use of patent rights "to the extent necessary" to address the pandemic, the Decision makes it clear that the flexibilities provided for are subsidiary to other means of tackling the lack of vaccines. In particular, if voluntary licensing allows to fully address the needs for COVID-19 vaccines in a given Member state, the Member state does not have the freedom to authorize the use of patents without the consent of the right holder.

d) Procedural aspects and differences compared to Article 31 of the TRIPS Agreement

In strong contrast to the original Communication by India and South Africa, the Decision explicitly only authorizes the use of a patent "in accordance with the provisions of Article 31" of the TRIPS Agreement (the provision of the TRIPS Agreement on compulsory licensing of patents), some conditions of which are "clarified and waived" by the Decision. As a result, the process foreseen by Article 31 remains generally applicable, except for the conditions that are "clarified or waived" in sections 2 to 6 of the Decision.

The "clarifications and waivers" provided by the Decision are the following:

- The authorization to use a patent can be granted by any instrument available, including executive orders, emergency decrees, government use authorizations, and judicial or administrative orders;
- There is no need to make efforts to obtain a voluntary license from the patent holder first (waiver of Article 31(b) of the TRIPS Agreement);
- The authorization does not need to be restricted predominantly to supply the domestic market,

but can be granted to export to other eligible Members (waiver of Article 31(f) of the TRIPS Agreement), but eligible Members must ensure that no re-exportation of products manufactured under the Decision takes place;

The other general conditions of Article 31 of the TRIPS Agreement remain applicable: any authorization to use must be considered "on its individual merits" (Article 31(a)), the scope and duration must be limited to the authorized purpose (Article 31(c)), the authorization is non-exclusive and non-assignable (Article 31(d) and (e)), and the authorization must be subject to judicial review (Article 31(i) and (j)).

e) Possible waiver of regulatory data protection

The Decision states that Article 39.3 of the TRIPS Agreement, which obliges WTO members to protect regulatory data submitted in the process of a marketing authorization of pharmaceutical products, "does not prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccines produced under this Decision". This provision seems to allow eligible Members to suspend the protection of regulatory data filed by the manufacturer of a COVID-19 vaccine to allow generic manufacturers to supply the market with sufficient vaccines.

f) Remuneration of the right holder

The Decision confirms the principle set out in Article 31(h) of the TRIPS Agreement that the authorization to use a patent is contingent on the payment of adequate remuneration to the patentee. However, the Decision indicates that "adequate remuneration" shall in this case "take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines [...]".

g) Duration of the "waiver"

The provisions of the Decision can be applied for 5 years from the date of the Decision. The General Council may extend this period taking into account the pandemic situation.

Expected consequences of the Decision on licensing deals in Switzerland

Neither the TRIPS-Agreement nor the Decision are generally considered self-executing. In other words, executive or legislative action by national governments and/or legislatures is necessary to implement the Decision, whereby any authorization to use a patent can only be given in a specific case (Article 31(a) TRIPS). While the Decision does not have any impact on national Swiss law (Switzerland does not qualify as an "eligible Member"), it will have several consequences on licensing agreements involving Swiss entities and/or governed by Swiss law.

- If a license agreement governed by Swiss law encompasses an eligible Member that makes use of the Decision to authorize the use of one or more licensed patents on its territory, this may constitute a development unexpected by the parties and (depending on the agreement) a force majeure event. The consequences of such an event may reflect on the amount of the agreed remuneration and even lead to a possible termination of the agreement.

- If a Swiss licensor is unable to collect contractually agreed license fees from its licensee because an eligible Member makes use of the flexibilities foreseen in the Decision, this may constitute an insured event under the applicable export risk insurance rules. Whether a claim for payment exists must be ascertained in each case.

Please do not hesitate to contact us in case of any questions.

Legal Note: The information contained in this Smart Insight newsletter is of general nature and does not constitute legal advice.

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