1 ARTICLE 31

1.1 Text of Article 31

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[7] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(*footnote original*) [7] "Other use" refers to use other than that allowed under Article 30.

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

1.2 General

1. With respect to other use of the subject matter of a patent without the authorization of the right holder, paragraph 5(b) of the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, clarifies that:

> "(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."[1]

2. With respect to the term "law of a Member", paragraph 2 of the the Ministerial Decision on the TRIPS Agreement of 17 June 2022 clarifies that:

> "…an eligible Member may authorize the use of the subject matter of a patent under Article 31 without the right holder's consent through any instrument available in the law of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place. For the purpose of this Decision, the "law of a Member" referred to in Article 31 is not limited to legislative acts such as those laying down rules on compulsory licensing, but it also includes other acts, such as executive orders, emergency decrees, and judicial or administrative orders."[2]

1.3 Article 31(b)

3. With respect to what constitutes a national emergency or other circumstances of extreme urgency, paragraph 5(c) of the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, clarifies that:

> "(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health

[1] WT/MIN(01)/DEC/2.
[2] WT/L/1141, para. 2.

> crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."[3]

4. Paragraph 3(a) of the the Ministerial Decision on the TRIPS Agreement of 17 June 2022 clarifies that eligible Members having authorized the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder pursuant to paragraphs 1 and 2 of that Decision "need not require the proposed user of the subject matter of a patent to make efforts to obtain an authorization from the right holder as set out in Article 31(b)."[4]

1.4 Article 31(f)

5. Following the entry into force of the Protocol Amending the TRIPS Agreement[5], Members to which the amended TRIPS Agreement applies may derogate from the obligation set out in paragraph (f) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products pursuant to paragraphs 1 and 3 of Article 31*bis*, paragraph 2 of the Annex and the Appendix to the TRIPS Agreement.[6] For other Members that have yet to accept the Protocol, the waiver provisions established under the General Council decision of 30 August 2003 on the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" continue to apply.[7]

6. Eligible Members having authorized the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder, pursuant to paragraphs 1 and 2 of the Ministerial Decision on the TRIPS Agreement, adopted on 17 June 2022:

> "…may waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market and may allow any proportion of the products manufactured under the authorization in accordance with this Decision to be exported to eligible Members, including through international or regional joint initiatives that aim to ensure the equitable access of eligible Members to the COVID-19 vaccine covered by the authorization."[8]

1.5 Article 31(h)

7. Following the entry into force of the Protocol Amending the TRIPS Agreement[9], importing Members to which the amended TRIPS Agreement applies may derogate from the obligation set out in paragraph (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products pursuant to paragraph 2 of Article 31*bis,* provided that the right holder has been remunerated by the exporting Member. Exporting Members are required to pay adequate remuneration:

> "…taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member."[10]

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[3] WT/MIN(01)/DEC/2.
[4] WT/L/1141, para. 3(a).
[5] WT/L/641. The decision on an "Amendment of the TRIPS Agreement" to which the Protocol Amending the TRIPS Agreement was attached was adopted by the General Council on 6 December 2005 in the light of a statement read out by the Chairman as reflected in paragraphs 29-32 of the minutes of the General Council meeting in WT/GC/M/100. The Amendment Protocol entered into force on 23 January 2017 following acceptance by two thirds of WTO Members, as required pursuant to paragraph 3 of Article X of the WTO Agreement (WT/Let/1236).
[6] See the document on Article 31*bis* of the TRIPS Agreement (Practice).
[7] WT/L/540 and Corr.1. This waiver decision implements paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It was adopted by the General Council in the light of a statement read out by the Chairman as reflected in paragraphs 29-31 of the minutes of the General Council meeting in WT/GC/M/82.
[8] WT/L/1141, para. 3(b).
[9] WT/L/641. The decision on an "Amendment of the TRIPS Agreement" to which the Protocol Amending the TRIPS Agreement was attached was adopted by the General Council on 6 December 2005 in the light of a statement read out by the Chairman as reflected in paragraphs 29-32 of the minutes of the General Council meeting in WT/GC/M/100. The Amendment Protocol entered into force on 23 January 2017 following acceptance by two thirds of WTO Members, as required pursuant to paragraph 3 of Article X of the WTO Agreement (WT/Let/1236).
[10] See the document on Article 31*bis* of the TRIPS Agreement (Practice).

For Members that have yet to accept the Protocol, the waiver provisions established under the General Council decision of 30 August 2003 on the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" continue to apply.[11]

8. Paragraph 3(d) of the Ministerial Decision on the TRIPS Agreement of 17 June 2022 states:

> "(d) Determination of adequate remuneration under Article 31(h) may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines in order to support manufacturers in eligible Members to produce and supply these vaccines at affordable prices for eligible Members. In setting the adequate remuneration in these cases, eligible Members may take into consideration existing good practices in instances of national emergencies, pandemics, or similar circumstances.[4]
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> (*footnote original*) [4] This includes the remuneration aspects of the WHO-WIPO-WTO Study on Promoting Access to Medical Technologies and Innovation (2020), and the Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies published by the WHO (WHO/TCM/2005.1)."[12]

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[11] WT/L/540 and Corr.1. This waiver decision implements paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It was adopted by the General Council in the light of a statement read out by the Chairman as reflected in paragraphs 29-31 of the minutes of the General Council meeting in WT/GC/M/82.
[12] WT/L/1141, para. 3(d).