

**1 ARTICLE 31BIS OF THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS.....1**

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**1 ARTICLE 31BIS OF THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS**

**1.1 Text of Article 31*bis***

***Article 31bis***

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.
2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.
3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries ([L/4903](#)), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.
4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.
5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health ([WT/MIN\(01\)/DEC/2](#)), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

## **1.2 Text of the Annex to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)**

### ***Annex to the TRIPS Agreement***

1. For the purposes of Article 31bis and this Annex:

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health ([WT/MIN\(01\)/DEC/2](#)). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included<sup>1</sup>;

*(footnote original)* <sup>1</sup> This subparagraph is without prejudice to subparagraph 1(b).

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification<sup>2</sup> to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members<sup>3</sup> and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

*(footnote original)* <sup>2</sup> It is understood that this notification does not need to be approved by a WTO body in order to use the system.

*(footnote original)* <sup>3</sup> Australia, Canada, the European Communities with, for the purposes of Article 31bis and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.

(c) "exporting Member" means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The terms referred to in paragraph 1 of Article 31bis are that:

(a) the eligible importing Member(s)<sup>4</sup> has made a notification<sup>2</sup> to the Council for TRIPS, that:

*(footnote original)* <sup>4</sup> Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 3 of Article 31bis on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

*(footnote original)* <sup>2</sup> It is understood that this notification does not need to be approved by a WTO body in order to use the system.

(i) specifies the names and expected quantities of the product(s) needed<sup>5</sup>;

*(footnote original)* <sup>5</sup> The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31bis of this Agreement and the provisions of this Annex<sup>6</sup>;

*(footnote original)* <sup>6</sup> This subparagraph is without prejudice to Article 66.1 of this Agreement.

(b) the compulsory licence issued by the exporting Member under the system shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website<sup>7</sup> the following information:

*(footnote original)* <sup>7</sup> The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to the system.

— the quantities being supplied to each destination as referred to in indent (i) above; and

— the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify<sup>8</sup> the Council for TRIPS of the grant of the licence, including the conditions attached to it.<sup>9</sup> The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

*(footnote original)* <sup>8</sup> It is understood that this notification does not need to be approved by a WTO body in order to use the system.

*(footnote original)* <sup>9</sup> The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31*bis* should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with

Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.

7. The Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council.

### **1.3 Text of the Appendix to the Annex to the TRIPS Agreement**

#### ***Appendix to the Annex to the TRIPS Agreement***

##### Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

- (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

or

- (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

### **1.4 General**

1. In paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, Ministers recognized the following:

"WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."<sup>1</sup>

2. Subsequently, the General Council adopted a Decision on the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" on 30 August 2003 (2003 Decision). It granted temporary waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products.<sup>2</sup>

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<sup>1</sup> [WT/MIN\(01\)/DEC/2](#).

<sup>2</sup> [WT/L/540](#) and [Corr.1](#). This waiver Decision 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](#).

3. On 6 December 2005, the General Council adopted a Decision on the "Amendment of the TRIPS Agreement" to which the Protocol Amending the TRIPS Agreement was attached.<sup>3</sup> The purpose was to make the waivers from paragraphs (f) and (h) of Article 31 of the TRIPS Agreement a permanent part of the TRIPS Agreement.

4. In accordance with Article X:3 of the Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement), the Protocol entered into force on 23 January 2017, upon acceptance by two-thirds of the WTO Members.<sup>4</sup> Consequently, the TRIPS Agreement was amended as set out in the Annex to the Protocol by inserting Article 31*bis* after Article 31 and by inserting an Annex to the TRIPS Agreement and an Appendix to the Annex to the TRIPS Agreement after Article 73. Article 31*bis*, the Annex, and the Appendix modify paragraphs (f) and (h) of Article 31 of the TRIPS Agreement for Members who have accepted the Amendment to the TRIPS Agreement.<sup>5</sup>

5. In accordance with Article X:3 of the WTO Agreement, for each other Member that accepts the Protocol after its entry into force, the Protocol takes effect upon acceptance by each such Member. In the meantime, the waivers granted under the General Council Decision of 30 August 2003 continue to apply to these Members.

6. The original deadline for acceptance of the Protocol was 1 December 2007. On 13 December 2023, the General Council approved the Ninth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement. Under this extension, the Members concerned have until 31 December 2025 to accept the Protocol.<sup>6</sup>

7. Paragraph 7 of the Annex to the TRIPS Agreement, as amended by the Protocol Amending the TRIPS Agreement, and paragraph 8 of the 2003 Decision of 30 August 2003 respectively provide that the Council for Trade-Related Aspects of Intellectual Property Rights (Council for TRIPS) shall review annually the functioning of the Special Compulsory Licensing System established under Article 31*bis* of the amended TRIPS Agreement and the 2003 Decision with a view to ensuring its effective operation. The Council shall report annually on its operation to the General Council.<sup>7</sup>

8. In order to use the special compulsory licensing mechanism established under Article 31*bis* of the TRIPS Agreement, both the importing and the exporting Member(s) are required to make a notification to the TRIPS Council in accordance with paragraphs 2(a) and 2(c) of the Annex to the TRIPS Agreement.<sup>8</sup> Members may use the e-TRIPS Submission System to submit notifications under Article 31*bis*, and the e-TRIPS Gateway to access notifications by Members.<sup>9</sup> As clarified by footnotes 2 and 8 to the Annex to the TRIPS Agreement, these notifications do not need to be approved by a WTO body.

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<sup>3</sup> [WT/L/641](#). This Decision was adopted by the General Council 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](#). Before the adoption of the Decision, the Chairman also made a statement relating to paragraph 4 of Article 31*bis* in the proposed amendment. This statement is recorded in paragraph 28 of the minutes of the General Council meeting in [WT/GC/M/100](#).

<sup>4</sup> [WT/Let/1236](#).

<sup>5</sup> A regularly updated list of acceptances since the adoption of the Protocol on 6 December 2005 is available online at [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm).

<sup>6</sup> [WT/L/1180](#). Earlier General Council decisions to extend the period for acceptance can be found in documents: [WT/L/1122](#); [WT/L/1081](#); [WT/L/711](#); [WT/L/785](#); [WT/L/829](#); [WT/L/899](#); [WT/L/965](#); and [WT/L/1024](#).

<sup>7</sup> For the TRIPS Council Report of 2023 on the Annual Review of the Special Compulsory Licensing System see [IP/C/97](#). Earlier reports can be found in documents: [IP/C/94](#); [IP/C/90](#); [IP/C/86](#) and [Corr.1](#); [IP/C/84](#); [IP/C/82](#); [IP/C/79](#); [IP/C/76](#); [IP/C/72](#); [IP/C/69](#); [IP/C/66](#); [IP/C/63](#); [IP/C/61](#); [IP/C/57](#); [IP/C/53](#); [IP/C/49](#); [IP/C/46](#); [IP/C/42](#); [IP/C/37](#); and [IP/C/33](#).

<sup>8</sup> Notifications by eligible importing Members can be found in document series [IP/N/9/\\*](#). Notifications by exporting Members are circulated in document series [IP/N/10/\\*](#).

<sup>9</sup> The e-TRIPS Submission System and e-TRIPS Gateway are available at: [https://www.wto.org/english/tratop\\_e/trips\\_e/etrips\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/etrips_e.htm).

9. Many Members with manufacturing and export capacities in the pharmaceutical sector have implemented the derogations permitted under Article 31*bis* of the TRIPS Agreement in domestic or regional law.<sup>10</sup>

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Current as of: June 2024

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<sup>10</sup> A regularly updated list of implementing measures that WTO Members have notified to the TRIPS Council is available at: [https://www.wto.org/english/tratop\\_e/trips\\_e/par6laws\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm).