contents of the Decision. Those developing Member States fearful of a restrictive interpretation of the scope of paragraph 11 sought to downplay the role and application of the Chairman's Statement.

One of the problems that led to the Decision being temporary and not final was the dispute over the legal form of the solution.[924] It is therefore surprising to read that paragraph 11 of the Decision expressly refers to a solution that will *amend* the TRIPS Agreement.[925] By referring to an amendment the Member States effectively ruled out solutions on the basis of authoritative interpretations of Article 30, waivers in terms of Article IX.3 of the WTO Agreement and moratoriums. The choice of the word amendment steered the course for future discussions.

C. Article 31bis of the TRIPS Agreement

The negotiations for a final solution to the paragraph 6 dilemma made little headway after the adoption of the temporary Decision. Member States were at logger heads over the scope of the final solution. Some Member States, mainly developing countries, sought to readdress and correct the shortcomings in the Decision in order to ensure that the final system become an effective solution to the paragraph 6 dilemma.[926] These plans were viewed sceptically by developed Member States who saw the Decision as being the raw form for the final amendment.[927]

The Member States' inability to resolve the final solution weighed on the other WTO negotiations. It was the pressure to remove this obstacle and the resignation that a better deal was unlikely to be struck that spurred the Member States to finalise the solution to the paragraph 6 dilemma.

The final solution, adopted on the 6th of December 2005 by the General Council, is a direct transformation of the Decision; merely its format was altered.[928] The decision of the General Council (the 'Amendment') provides for the insertion of a new provision into the TRIPS Agreement: Article 31*bis*.[929] Only upon the entry into ef-

924 *Oh*, 10 Bridges 1 (2006) p. 22.

925 The Decision notes that the final solution, the amendment, should be based on the Decision. As the Decision is a combination of waivers it seems apparent that 'based' refers not to form but rather to content.

926 Compare WTO Communication by Nigeria and others 'Implementation of Paragraph 11 of the 30 August Decision' (10.12.2004) IP/C/W/437, *Oh*, 10 Bridges 1 (2006) p. 22.

927 ICTSD 'TRIPS Council Considers Public Health, Biodiversity' *Bridges Weekly Trade News Digest* (08.12.2004) 1.

928 *Law*, 18 ELDB 3 (2006) p. 4.

929 The TRIPS Council submitted IP/C/41 to the General Council as a proposal for the amendment of the TRIPS Agreement. This proposal was considered and was adopted by consensus by the General Council on 06.12.2005 (Decision of the General Council 'Amendment to the TRIPS Agreement' (08.12.2005) WT/L/641 ('Amendment')). The Amendment contained an attachment titled 'Protocol Amending the TRIPS Agreement' (the 'Protocol'). Para 1 of the Protocol states that, upon its entry into force, Art 31*bis* will be inserted after Art 31 into the TRIPS Agreement. The Annex to the TRIPS Agreement will be inserted after Art 73. Para 4

fect of Article 31*bis* and the Annex will the provisions of the Decision be officially substituted. The reason for the delay in the operation of the Amendment is the fact that the Amendment constitutes an alteration to the TRIPS Agreement and as such needs the ratification of the Member States. Only once the Protocol Amending the TRIPS Agreement found in the Amendment (the 'Protocol') is validly ratified will Article 31*bis* come into operation. Until this occurs the system set out in the Decision will remain in effect.[930] Hence, the Amendment will only take effect when it is ratified by all the Member States, alternatively, the 1st of January 2007, whichever is the latest. If all the Member States have not ratified the Protocol prior to the 1st of January 2007, the Protocol will only come into operation when two-thirds of the Member States have ratified the Protocol and only apply to those Member States who have ratified the Protocol.[931] Thereafter the Protocol will apply to each Member State upon its ratification.[932]

The entry into force of the Protocol will formalise the rights and obligations contained in the Decision and will be equal in weight to the other rights and obligations found in the TRIPS Agreement. The scope of the obligations will mean that effect of the obligations and rights are limited to the paragraph 6 dilemma.[933] As with the Decision, any Member States wanting to exercise the exclusions mentioned in Article 31*bis* will be required to adopt the same into the national legal system.

Although the Amendment does not amount to a change to the provisions of the Decision, its format differs from that in the Decision. The reason is purely functional; whereas the Decision implemented waivers, Article 31*bis* creates exclusions.[934] Article 31*bis* consists of 5 sub-paragraphs, structured as follows:

- Article 31*bis*(1) excludes the operation of Article 31(f) for an exporting Member State exporting pharmaceutical products in accordance with the system[935]

states that the Protocol will come into force in terms of Art X.3 of the WTO Agreement, having the effect that the Art 31*bis* and the Annex will become operational on 01.20.2007 or as soon thereafter as two-thirds of the Member States have ratified the Protocol. Cf. WTO General Council 'Annual Report (2005)' (07.12.2005) WT/GC/101 p. 6-7.

930 Para 11 of the Decision states that the Decision 'shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member'.

931 The US notified the WTO on 10.12.2005 that it has accepted the Protocol. Cf. *USTR*, Special 301 Report (2006) p. 11.

932 Protocol para 3, WTO Agreement Art X.3.

933 Art 31*bis*(5) ensures that the rights, obligations and flexibilities in the TRIPS Agreement remain unaffected by the Amendment, save where expressly stated otherwise.

934 For example the Decision uses the wording 'shall be waived'; the Amendment states 'shall not apply'. Compare Decision paras 2, 3, 6 and Art 31*bis*(1-3) respectively.

935 Art 31*bis*(1) states: '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'.

- Article 31*bis*(2) excludes the operation of Article 31(h) preventing the double remuneration of patent holders in the exporting and importing Member States[936]
- Article 31*bis*(3) states that Article 31(f) shall not apply to Member States within a regional trade agreement made up of at least 50% LDC Member States[937]
- Article 31*bis*(4) constitutes an entrenched moratorium on non-violation complaints under Article XXIII of the GATT Agreement[938] and
- Article 31*bis*(5) serves to confirm that the Amendment shall not serve to restrict the flexibilities found in the provisions of the TRIPS Agreement (excluding Articles 31(f and h)).[939]

The contents of Article 31*bis* form the normative skeleton of the system. This legal foundation is augmented by the Annex to the TRIPS Agreement, a document essentially incorporating the bulk of the provisions that create the framework for the system. Together these documents constitute the entire text of the Amendment. Like the Decision before it, the interpretation of the system incorporated therein is subject to the contents of the Chairman's Statement. As was done prior to the adoption of

936 Art 31*bis*(2) states: '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'.

937 Art 31*bis*(3) states: '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'.

938 Art 31*bis*(4) states: '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.'

939 Art 31*bis*(5) states: '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)'.

Decision, the 'new' Chairman's Statement was taken 'note of' by the General Council and 'in the light of this statement' prior to the adoption of the Amendment.[940]

The uncertainty that surrounded the legal status of the Chairman's Statement will, as a result of the repeated approval by the TRIPS Council and the absence of any objections to the reading of the Chairman's Statement in light of the Amendment, be somewhat lessened. The repetition and the inclusion of the same material elements of the original Chairman's Statement support the view that the document forms part of the context of the Amendment.[941] As the TRIPS Council approved the contents of the Chairman's Statement for a second time it would be difficult for a Member State to deny that the statement exhibits qualities and characteristics of an agreement. From an interpretational perspective, the result is that the Chairman's Statement under the Article 31*bis* system may, upon its adoption, prove to be the 'main, if not sole, supplementary means of interpreting it'.[942] Notwithstanding this, the Chairman's Statement is not unencumbered. The General Council agreed to reaffirm the statements made by certain Member States after the adoption of the Decision.[943]

The new Chairman's Statement differs in one relevant point. It inserts a new sentence explaining that Article 31*bis*(4) is without prejudice to the question of whether the application of Articles XXIII(1)(b and c) of the GATT Agreement applies to the TRIPS Agreement as a whole.[944] The inclusion of this sentence seeks to ensure that Article 31*bis*(4) does not influence the ongoing discussion on, and to what extent, non-violation challenges will apply to the TRIPS Agreement.[945]

The Member States that agreed to opt-out of the system under the Decision and Chairman's Statement confirmed that they would continue to either fully or partially opt-out of the system under the Protocol. This was achieved by 'choreographed' unilateral undertakings, either in writing or by way of a statement, made by the relevant Member States.[946]

940 WTO General Council 'Annual Report (2005)' (07.12.2005) WT/GC/101 at p. 7, WTO General Council Minutes (27.03.2006) WT/GC/M/100 p. 12. The TRIPS Council 'approved' the forwarding of the statements to the Chairman. It was read out in the General Council and the proposal to take note of the statements was formally adopted. The statements made by certain Member States after the adoption of the 30 August Decision were also formally reaffirmed.

941 ICTSD 'Members Strike Deal on TRIPS and Public Health; Civil Society Unimpressed' *Bridges Weekly Trade News Digest* (07.12.2005) p. 2.

942 ICTSD 'Members Strike Deal on TRIPS and Public Health; Civil Society Unimpressed' *Bridges Weekly Trade News Digest* (07.12.2005) p. 2-3.

943 WTO General Council Minutes (27.03.2006) WT/GC/M/100 p. 12.

944 The statement concerning Art 31*bis*(4) followed the identical procedure to the Chairman's Statement. Cf. WTO General Council Minutes (27.03.2006) WT/GC/M/100 p. 8-9.

945 The Hong Kong Ministerial Declaration mandated the continued 'examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 and make recommendations to our next Session. It is agreed that, in the meantime, Members will not initiate such complaints under the TRIPS Agreement'. Cf. WTO Ministerial Declaration (22.12.2005) WT/MIN(05)/DEC ('Hong Kong Ministerial Declaration') p. 8.

946 ICTSD 'Members Strike Deal on TRIPS and Public Health; Civil Society Unimpressed' *Bridges Weekly Trade News Digest* (07.12.2005) p. 2.

The first country to make a notification in terms of the paragraph 6/Article 31*bis* system was Rwanda.[947] On 19 July 2007 it notified the TRIPS Council that it would import TriAvir from a Canadian generic manufacturing company.[948]

An observation of the system put in place by the Decision could lead to the conclusion that the developed Member States prevailed in securing their interests. The system to be enforced by the Article 31*bis* is complex, bureaucratic and does not provide the easiest solution for Member States seeking access to medicines. Instead the developed countries were able to maintain a system that paid more attention to safeguards than to efficiency – the initial goal of paragraph 6 of the Public Health Declaration.

Despite the unattractiveness of the system as a whole, the spread of diseases and the limited supply of pharmaceuticals have multiplied the amount of countries unable to counter public health threats adequately with domestically produced pharmaceuticals. This has been highlighted in particular by the avian influenza threat where the producer of a medication identified as being the most effective, Roche, released a statement stating that despite concerted efforts to stockpile the medication Tamiflu in advance, orders made for the medication at the beginning of 2006 would only have been produced in 2008.[949]

947 WTO Notification from Rwanda 'Notification Under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (19.07.2007) IP/N/9/RWA/1.

948 WTO Notification from Canada 'Notification Under Paragraph 2(C) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (05.10.2007) IP/N/10/CAN/1. The Canadian counter notice accordingly fulfilled the formal requirements for the Article 31*bis* system by adding the pharmaceutical (a combination of lamivudine, nevirapine and zidoudine), the authorised manufacturer (Apotex Inc.), the website for information, the amount (15,600,000 tablets) and the duration (2 years).

949 --, Roche Completes Tamiflu Stockpile for WHO *Agence France-Presse* (19.04.2006). In the case of Tamiflu, Roche has granted 11 voluntary licenses to pharmaceutical producers around the globe in order to assist it in meeting the needs of society. Taiwan has however issued a compulsory license for the production of a generic version of Tamiflu. Cf. *Hille*, Taiwan employs compulsory license for Tamiflu Financial Times (25.11.2005).