rium, an Article 30 solution and an Article 6 solution. It was also generally recognised that any solution would have to incorporate safeguards to ensure that the solution is used to resolve the problem identified in paragraph 6 and not as an indirect means to circumvent the TRIPS Agreement provisions.

The discussions on a solution proceeded slowly with Member States playing tug-of-war with the issue and using it to leverage movement in other WTO negotiations.[779] It was only 8 months after the 2002 deadline had passed – the 30th of August 2003 – that the Member States were able to reach a solution. The decision and its effect are discussed below.

B. The 30 August 2003 decision

The decision of the General Council on the 30th of August 2003 (the 'Decision')[780] was hailed as being a 'historic agreement for the WTO'.[781] Although this statement represents more wishful thinking than the legal reality of the solution reached, the Decision represented a milestone in that it introduced a system whereby Member States were empowered to help those fellow Member States without the domestic ability to help themselves.[782] Notwithstanding the Decision being a 'solution', it was by no means meant to be a final decision. It was for the majority an *ad hoc* solution to apply until the Member States could agree on a final decision. Upon a final solution being adopted the Decision would lapse.

The Decision, a 'temporary solution', comprised of 11 clauses and an annex qualifying certain issues therein. Its adoption was made on the premise of certain

779 -- 'Access to Medicines: WTO Members May Snatch Defeat out of the Jaws of Victory' (2002) 6 Bridges 8 p. 1-2.

780 Decision of the General Council 'Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health' (30.08.2003) WT/L/540 ('Decision') (Annex II hereto).

781 Director General Panitchpakdi, WTO Press Release Press/350/Rev.1. The DG was also quoted a saying that the 'final piece of the jigsaw has fallen into place' and that the decision was a completion of the Public Health Declaration. This comment was unfortunately somewhat premature as the decision was an interim solution. Whereas some Member States reiterated the DG's statement, some Member States were not so forthcoming with their compliments. The Djiboutian representative stated that although he was pleased with the decision he was nonetheless 'not satisfied'. The representative from the Barbados 'felt obliged to register [their] disappointment and concern'. The Jamaican representative was 'dissatisfied' with certain elements of the text. These and other Member States felt that opposing the decision would do more harm than adopting it. See in this regard Cuba, Djibouti, Barbados and Jamaica in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 9, 11, 13.

782 *Abbott,* 99 AJIL 2 (2005) p. 327.

'shared understandings' incorporated in a statement made by the Chairman (the 'Chairman's Statement') preceding the adoption of the Decision.[783]

I. The legal effect of the Decision and the Chairman's Statement

1. The waivers in the Decision

Unlike the procedural 'irregularities' and uncertainty regarding the legal effect of the Public Health Declaration, there is no doubt that the Decision has taken the form of a waiver, at least parts thereof.[784] The procedures chosen to adopt the text correspond with those required by Article IX.1, 3 and 4 of the WTO Agreement for a waiver.[785] In addition, the Decision also expressly notes that there were sufficient 'exceptional circumstances' which justified the waiver of the obligations contained in Article 31(f and h) of the TRIPS agreement.[786] Further confirmation of its waiver format was the adoption of an annual review procedure, a waiver requirement.[787] These factors confirm that all requirements for a waiver in terms of the WTO Agreement were met. As waivers, the adoption of the Decision has the effect of temporarily suspending the identified provisions, i.e. Member States will not be re-

783 Contained in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 at 6-7. The Statement was read out prior to the adoption of the Decision on 30.08.2003. The Chairman's Statement was accompanied by a 'Best Practices' attachment.

784 *Correa*, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WHO Geneva 2004) p. 5, *Hermann*, 6 ZEuS 4 (2003) p. 601-602. The Decision actually incorporates three waivers: para 2 (the waiver of Art 31(f) for the importing Member States), para 3 (the waiver of Art 31(h), the waiver of the exporting countries obligation to provide adequate remuneration) and para 6(i) (the waiver of Art 31(f) with respect to custom unions and free trade areas). Contrast *Hestermeyer*, 37 GRURInt 3 (2004) p. 198-199. Despite *Hestermeyer's* contention that the Decision may constitute an amendment he concludes that the Decision should be seen as a waiver. *Kramer* also incorrectly views the Decision as an amendment. Viewing the Decision in its individual parts clearly indicates that the document is primarily comprised of a number of waivers. The structure and the contents thereof confirm this. Cf. *Kramer*, Patentschutz und Zugang zu Medikamenten (Carl Heymanns Verlag Cologne 2007) p. 143-144.

785 Decision preamble. The procedural progress of the waiver proceeded as follows: on 28.08.2003 the TRIPS Council approved a draft decision (IP/C/W/405) and had forwarded it to the General Council for adoption. The General Council is empowered by Art IV to carry out the functions of the Ministerial Conference in the intervals between its meetings. The requirements set by Art IX.4 of the WTO Agreement, i.e. exceptional circumstances, the terms and conditions, the review thereof and the termination are all dealt with by the Decision. Cf. Decision preamble, paras 2, 8, 11. Cf. *Nolff*, 86 JPTOS 4 (2004) p. 303.

786 The text contained in the preamble referring to the existence of exceptional circumstances was inserted subsequent to the Motta draft proposal in December 2002. Cf. WTO Draft Decision (16.12.2002) JOB(02)/217 p. 2.

787 WTO Agreement Art IX.4. An additional review mechanism was included in para 8 of the Decision.

quired to comply with the waived obligations, provided they comply with the terms and conditions governing the application of the waiver.[788]

The Member States included three waivers in the Decision to implement their paragraph 6 solution. The first sets out the circumstances when a Member State will be entitled to grant a compulsory license solely for export without infringing Article 31(f).[789] The second waiver was adopted to ensure that the requirement of having compulsory licenses in both the exporting and the importing Member State does not lead to a double remuneration for the patent holder.[790] The third waiver makes provision for establishing economies of scale within the context of the dilemma set out in paragraph 6 of the Public Health Declaration. In terms of the Decision, the limitations imposed by Article 31(f) will not apply within the context of a regional trade agreement. This effectively allows, under certain conditions, one of the parties in the regional trade agreement to produce the pharmaceutical products for the benefit of a fellow partner country in the regional trade agreement.[791]

2. The Decision's moratorium

In addition to the waiver the Member States included a moratorium whereby they agreed to forgo dispute settlement claims concerning the implementation of the waivers in terms of Articles XXIII(1)(b and c) of the GATT Agreement.[792] Decisions taken by the General Council should, unless indicated otherwise elsewhere, be concluded by consensus. This was the case with the adoption of the moratorium in the Decision.[793] The effect of this moratorium is that Member States will be unable to challenge measures taken in terms of the waivers that have the effect of nullifying or impairing any direct or indirect benefit accruing to a Member State. In the WTO *India – Patent Protection II* case, where an analogous set of facts was considered, the Appellate Body stated that the 'meaning of this provision is clear: the *only* cause of action permitted under the *TRIPS Agreement* during the first five years after the entry into force of the *WTO Agreement* is a "violation" complaint under Article

788 WTO Agreement Art IX.3(b). Cf. *Correa*, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WHO Geneva 2004) p. 5.

789 Decision para 2.

790 Decision para 3.

791 Decision para 6. A potential beneficiary of this provision is SACU.

792 Dispute settlement moratoriums do not have a formal procedure that must be fulfilled in order to become applicable and as such the adoption of a moratorium is to rest with the General Council, during the interim periods, and the Ministerial Conference when it sits. The Appellate Body has held that the TRIPS Council was authorised to decide upon the moratorium set out in Arts 64.2 and 3 of the TRIPS Agreement (WTO *India – Patent Protection II* p. 14). This delegation of powers to the TRIPS Council derives from Art IV.5 of the WTO Agreement. All other decisions not delegate remain in the General Council in terms of Art IV.2 of the WTO Agreement

793 WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 8.

XXIII:1(a) of the GATT 1994.'[794] In other words the DSB will only be able to hear a case challenging the non-conformity of a Member State's actions under the Decision. Hence, the waivers do not permit Member States *carte blanche* when implementing the Decision. The principles of *pacta sunt servanda* remain applicable and the Member States are bound to ensure that actions comply with the Decision.

The validity of non-violation proceedings under the TRIPS Agreement has been a contentious issue since the expiry of the provision suspending non-violation and impairment actions based on the TRIPS Agreement in the 1st of January 2000. Within the five year suspension the Member States were required to determine how the non-violation proceedings should apply to the TRIPS Agreement. An agreement has however been difficult to come by. Whilst an agreement has been out of reach, the Member States have agreed to stay any non-violation actions until a decision has been reached.[795] The moratorium contained in the Decision guarantees that the lack of definitive clarity under Article 64 (and any subsequent changes) will not affect the waivers contained in the Decision. The necessity of this provision is unclear. The Appellate Body had made it clear that neither it nor a panel is authorised to decide on the application of non-violation complaints; this authority was exclusively left to the TRIPS Council, which can only be altered by the consensus of all Member States. It stated in no uncertain terms that Article 64.3 of the TRIPS Agreement is '*not* a matter to be resolved through interpretation by panels or by the Appellate Body'.[796] The Appellate Body's clear positioning on Article 64 should have removed any doubt or misconceptions Member States could have had.

3. The Chairman's Statement

Immediately prior to the Decision being adopted in the General Council, the General Council Chairman, Ambassador Carlos Pérez del Castillo, was asked to read out a statement approved by the TRIPS Council.[797] The statement became known as the 'Chairman's Statement'.[798] As the WTO procedural structures do not make formal provision for such statements, it is unclear what legal consequences the Chairman's

794 WTO India – Patent Protection II. Original italics.

795 TRIPS Agreement Arts 64.2 and 3. The Hong Kong Ministerial Conference was not able to bring about a final decision on whether or not non-violation disputes may be brought under the TRIPS Agreement. Cf. Hong Kong Ministerial Declaration p. 8.

796 WTO *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* Report of the Appellate Body (19.12.1997) WT/DS50/AB/R 14. Original italics.

797 The General Council Chairman notes that the Statement was forwarded to him 'on the approval of the TRIPS Council'. The General Council agreed however only 'taken note of' the Chairman's Statement.

798 The Statement was largely to appease US's demands that were not directly incorporated into the draft Decision. Cf. Third World Network, Comment on the Chair's Statement of Understanding of December 16, *Van den Bossche*, The Law and Policy of the World Trade Organisation (CUP Cambridge 2005) p. 149-150.

Statement is to be given.[799] As the WTO does not accord such statements any express legal standing, such a statement will bear any direct legal effect from the WTO rules. In the WTO arena, direct legal consequence will only flow from a decision made by the General Council or a Ministerial Conference and from a DSB decision. From a procedural perspective, the Chairman's Statement was not voted upon at the General Council meeting.[800] Instead the Chairman asked the General Council to 'take note' of the statement. The Chairman's Statement can therefore not be deemed to be a formal Council or Ministerial decision.[801] This lack of formal legitimacy does not imply that the Chairman's Statement is without any legal effect; by adopting the Decision 'in light of the Chairman's Statement' the Member States have acknowledged that the Chairman's Statement does have a limited relevance.[802] As an instrument of informal consensus, its role will serve to assist interested parties in determining the meaning of the Decision.[803] In terms of Article 31(2)(b) of the Vienna Convention, an instrument accepted in connection with an agreement by the parties to the agreement will set the context for determining the purpose of an agreement.[804] This role is justified when the Chairman's Statement is seen as a complementary act.[805] In the *US – Copyright Act* case the panel noted that 'uncontested interpretations given at a conference, e.g., by a chairman of a drafting committee, may consti-

799 The Decision, as set out in WTO Doc WT/L/540, contains a footnote wherein it refers to the Chairman's Statement. This footnote does not however form part of the original documentation and is instead an *ex post facto* editorial insertion by the WTO Secretariat. It has been expressly noted that the footnote 'was added without the consent or consensus of the Members'. Cf. WTO Communication by Rwanda and others 'The TRIPS Agreement and Public Health' (06.04.2005) IP/C/W/445 p. 2. Academics also diverge on the legal implications of the Decision. Cf. *Hestermeyer*, 37 GRURInt 3 (2004) p. 199-200, *Hermann*, 6 ZEuS 4 (2003) p. 604, *Oh*, 10 Bridges 1 (2006) p. 22.

800 The contents of the Chairman's Statement was largely due to the negotiations between the US, India, Brazil and South Africa. Cf. ICTSD 'WTO Members Expected to Agree on Health and TRIPS Pre-Cancun' *Bridges Weekly Trade News Digest* (28.08.2003) p. 2.

801 The approval of the Statement by the TRIPS Council confirms the intention of the Member States that the contents of the Statement be used for the interpretation of the Decision. However the Chairman's Statement was itself never the subject of a decision. The Chairman proposed at the 30.08.2003 General Council meeting that the 'General Council take note of the [individual Member State] statements and, in the light of the Chairman's Statement he had just read out, *adopt the draft Decision*' (emphasis added).

802 The General Council Chairman stated that 'in the earlier informal discussions and consultations no delegation had indicated any intention of preventing the adoption of the draft Decision of 16 December 2002 in the light of the proposed Statement by the General Council Chairman'. Cf. General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 at p. 4. Compare *Hermann*, 6 ZEuS 4 (2003) p. 604.

803 The body of law justifying the Chairman's Statement as an interpretational tool is disputed. Having regard to the informal nature of acceptance of the Chairman's Statement, only Art 31(2)(b) of the Vienna Convention is able to divest the statement of any legal relevance. Compare *Hestermeyer*, 37 GRURInt 3 (2004) p. 200.

804 *Aust*, Modern Treaty Law and Practice (CUP Cambridge 2000) p. 190.

805 *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 104. The authors also note that Chairman's Statement was 'a common understanding of all WTO Members'.

tute an "agreement" forming part of the "context"'.[806] Viewing the Chairman's Statement as an uncontested interpretation, and therefore as an agreement, would mean that its role as an interpretation tool would be guaranteed by Article 31(2)(a) of the Vienna Convention.[807] Similar acts have also recognised under public international law as constituting an agreement under Article 31(2)(a).[808] Whether classified under Article 31(2)(a) or 31(2)(b) of the Vienna Convention, the Chairman's Statement will qualify as a source of information when interpreting the Decision.[809] This is supported by the phraseology of the Chairman's Statement.[810] This therefore means that the Chairman's Statement will serve as an aid in interpreting the Decision.[811] The extent of their role as an interpretational tool will however be tempered

806 WTO *United Stated – Section 110(5) of the US Copyright Act* Report of the Panel (15.06.2000) WT/DS160/R 18.

807 *Ortino* critically notes that the Appellate Body in the WTO *United States – Gambling* case took a limited approach to determining which instruments served to establish the 'context' of a text (Art 31)and which served as a 'supplementary' means of interpretation (Art 32). Cf. *Ortino*, 9 JIEL 1 (2006) p. 127-132.

808 *Aust*, Modern Treaty Law and Practice (CUP Cambridge 2000) p. 189-191. *Aust* remarks that instruments, such as the 'Chairman's Statement' and 'Understandings' (both present in the context of the Decision), operate as a political tool in treaty making. He notes that a separate document read by the chairman may indeed form part of the treaty but was structures separately in order to make it more politically digestible. Compare EC in the TRIPS Council Minutes (31.01.2006) IP/C/M/49 at 37 where it states 'the Chairman's Statement constituted a shared agreement accepted by all Members and context for the interpretation of the Decision, it should continue to represent context for the interpretation of the amendment'. The EC, at p. 39, also viewed the Chairman's Statement as falling within the scope of Art 31(2)(a) of the Vienna Convention. The Chairman's Statement was 'noted' prior to the adoption of the Decision. The timing of the Chairman's Statement will not affect present any material doubt as to its status as Art 31(2)(a) of the Vienna Convention merely refers to agreements made 'in connection with the conclusion of the treaty'. As the Chairman's Statement clearly fits this description, the timing of its appearance is immaterial.

809 The role of the Chairman's Statement may further be justified under Arts 31(3)(b) and 32 of the Vienna Convention. Cf. India in the TRIPS Council Minutes (31.01.2006) IP/C/M/49 p. 40. Also a combination of the acquiescence and estoppel principles could potentially prevent a Member State from denying the role of the Chairman's Decision on the grounds that it did not protest or counter the validity or role of the statement at the time when it was presented. Cf. *Müller and Cottier*, Acquiescence in: *Bernhardt* (ed) Encyclopaedia of Public International Law (North-Holland Amsterdam 1992) vol 1 p. 14-16. This rule of public international law will apply should any of those Member States listed in the Chairman's Statement not consider itself bound by the opt-out.

810 The Chairman notes that the statement 'represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented'. Cf. General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 6.

811 The role of the Chairman's Statement to the Decision plays a similar, yet less, important role in the Public Health Declaration does to the TRIPS Agreement. The distinction between the two is that the Public Health Declaration was formally adopted by the Member States as a Ministerial Declaration. Contrast *USTR*, Special 301 Report (2006) p. 11, where the USTR views the Decision and Chairman's Statement as a single solution to be 'interpreted and applied' as such.

by the remarks made by the Member States after the adoption of the Decision.[812] In these remarks, a number of Member States voiced their understanding of the Chairman's Statement. These remarks, to the extent that they qualify certain issues in the Chairman's Statement, will serve to counter or confirm that there was consensus or a consensual understanding of an issue. Accordingly, the actual 'key understandings' in the Chairman's Statement can be inferred to as referring only to those issues that were not rebutted in the remarks made by the Member States after the adoption of the Decision.[813]

In order for an interpretational tool within the ambit of the law of treaties to function it must embellish or elaborate on the contents of the treaty it is being used to interpret. Applying this rule to the Chairman's Statement it is evident that certain provisions of the Chairman's Statement cannot be applied unreservedly. The reason is that certain provisions in the Chairman's Statement set out more detailed 'obligations' than the Decision itself.[814] The inclusion of 'new' provisions means that these provisions are unable to apply in interpreting the Decision. As the new provisions do not have an interpretational role the only other role they could potentially assume would be an amendment.[815] As the Chairman's Statement does not meet the formal requirement for an amendment and the Chairman himself is not authorised to act in such a manner, they will not have any legal value and/or be *ultra vires*. It does however seem evident that the negotiating parties did not intend the Chairman's Statement to alter the Decision.[816] Accordingly, the Chairman's Statement will present a limited means for interpreting the Decision but will not and cannot be used to implement rights and/or duties not contained in the Decision.[817] In addition to the Chairman's Statement playing a role in the interpretation of the Decision, the Public Health Declaration too will play an important role.[818]

812 The Chairman's Statement refers to 'shared understanding of Members'. This does not imply that *all* Member States agreed. The negotiating history of the Chairman's Statement reflects that the wording was negotiated almost exclusively between Brazil, India, South Africa and the US. Cf. *ICTSD* 'WTO Members Expected to Agree on Health and TRIPS Pre-Cancun' *Bridges Weekly Trade News Digest* (28.08.2003) p. 2.

813 *Vandoren* and *Van Eeckhaute* state: the Chairman's Statement 'confirms the common understanding of all WTO Members that the primary objective of the [Decision] is to protect public health and that it should be used in good faith'. Cf. *Vandoren and Van Eeckhaute*, 6 JWIP 6 (2003) p. 781.

814 *Slonina*, Durchbruch im Spannungsverhältnis TRIPS and Health: Die WTO-Entscheidung zu Exporten unter Zwangslizenzen in: *Tietje, Kraft and Sethe* (eds) Beiträge zum Transnationalem Wirtschaftsrecht (MLU Halle 2003) Heft 20 p. 14.

815 The new provisions could not be considered 'subsequent practice' in terms of Art 31(3)(b) of the Vienna Convention will not apply as the provisions are neither subsequent nor do they interpret provisions of the Decision – they introduce new provisions that are neither included in the TRIPS Agreement nor in the Decision.

816 *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 104.

817 *Vandoren and Van Eeckhaute*, 6 JWIP 6 (2003) p. 781.

818 Which will have more sway in interpreting the Decision is unclear. Whereas the Chairman's Statement is the more current document, the Public Health Declaration represents an unequivocal agreement between the Member States. Cf. *Hermann*, 6 ZEuS 4 (2003) p. 602.

By adopting the waivers and moratorium the Member States have created a skeleton for a system based on exceptions to international trade obligations. In order for this skeleton to function, Member State will be required to add the muscle, i.e. to implement the system – and its conditions – into domestic law.[819]

II. The scope of the Decision

The adoption of the Decision came as a direct response to the dilemma set out in paragraph 6 of the Public Health Declaration. The Decision's preamble clearly confirms this. Accordingly, the Decision must be seen within the scope of providing those affected Member States with a means to effectively make use of their compulsory license system when their domestic pharmaceutical sector prevents or inhibits this.

The scope of the Decision also makes it clear that the central feature of the Decision, the system resolving the paragraph 6 dilemma, is not unlimited but is instead a 'drug-by-drug, country-by-country, case-by-case system'.[820] The qualifications to this system play a key role and seek to limit the scope by ensuring the system is only used to benefit the needy countries and not to the advantage of other Member States. The barrage of safeguards confirms this.[821] In addition to the system and the safeguards, the scope of the Decision is characterised by issues not initially foreseen in the Public Health Declaration. Although not mandated, the Member States agreed that the issues were sufficiently connected and important to justify their inclusion.[822] These issues sought to further the transfer of technology[823] and to prevent dispute proceedings[824] in respect to the system. Despite the introduction of a system to resolve the paragraph 6 problem, the Member States did at no time prior to the adoption of the Decision intend the Decision to be the final system; its role was merely a

819 This is a prerequisite for the exporting country. Cf. *Correa*, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WHO Geneva 2004) p. 6, *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 105.

820 *Oh*, 10 Bridges 1 (2006) p. 22-23.

821 Compare Chairman's Statement which states that 'Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives'. Cf. General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 6. Further, the remaining Art 31 provisions will continue to apply. Cf. *Law*, 18 ELDB 3 (2006) p. 6.

822 General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 7.

823 Decision para 7.

824 Decision para 10, General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 7.