stopgap measure to ensure there was an interim solution whilst the Member States negotiated a final solution.[825]

III. The legal implications of the Decision

The Decision and the Chairman's Statement introduce a number of formal requirements for Member States, whether as exporter or importer, wishing to apply the solution. Member States will be required to determine when and what pharmaceutical products can be used, which countries are eligible, what safeguards are applicable and how technology transfer must be used to prevent the paragraph 6 problem. These legal implications are dealt with individually hereunder.

1. The pharmaceutical product

For the purposes of the Decision a pharmaceutical product is deemed to be 'patented product, or a product of a patented process, of the pharmaceutical sector'[826] that is needed to address a public health problem.[827] The definition of pharmaceutical product is qualified in numerous ways. Firstly, the product must be a patented product or result from a patented process. This qualification dispels any doubt that both patented products and patented processes can perpetuate the paragraph 6 dilemma. Secondly, the product must flow from the pharma-ceutical sector. This may seem self evident when dealing with pharmaceutical products, however in connection with the third qualification, those public health problems recognised in paragraph 1 of the Public Health Declaration, other sectors may have played a role in countering the public health problems. The nutritional sector for instance, may have patented products that help reduce certain health afflictions. An example hereof is the proposal to produce genetically engineered crops that can reduce allergic reactions or induce certain health effects.[828] Both the nutritional and agricultural sectors can play a significant part in reducing public health problems. In terms of the Decision these products will not fall under the definition 'pharmaceutical product'. This qualifica-

825 Decision para 11.

826 Decision para 1(a).

827 The Decision does not mirror the terminology used in the Public Health Declaration. Instead of referring solely to the pharmaceutical sector, the Decision limits the scope of the Decision to 'pharmaceutical products'. Although potentially viewed as a limitation of the Public Health Declaration its is in fact a better formulation for Member States as it resolves the problem of whether or not the Public Health Declaration scope includes certain medical devices. The choice of terms in the Decision also ensure a greater association with one of the core issues in the Public Health Declaration, the access to medicines set out in para 4 thereof. See Chapter 7(A)(IV) Pharmaceutical sector above.

828 Monsanto purports to have developed a soybean that can 'reduce or eliminate the amount of trans-fats in processed foods'. Cf. '*Monsanto*, (2006)'.

tion has a secondary consequence. Being a product 'of the pharmaceutical sector' implies that invention must have been patented by a person or company active in the pharmaceutical industry, or subsequently employed by the pharmaceutical sector. The result of this qualification is somewhat technical and unlikely to pose too much of a problem when the system is indeed implemented. Not-withstanding this, it may be relevant where a non-pharmaceutical company makes an invention that has secondary health improving consequences and/or where the patented invention is subsequently used in the pharmaceutical sector. In such situations, and where there is a genuine public health problem, the definition 'pharmaceutical product' will be flexible enough to incorporate such products.[829]

Thirdly, the pharmaceutical product itself must be *necessary* to address the public health problem.[830] The inclusion of the necessity test into the definition of the pharmaceutical product is both a logical extension of the *pacta sunt servanda* principle and a safeguard to ensure the system is not abused.[831] Here Member States will not be judged on the underlying policy decisions they make in respect to the pharmaceutical but as to whether the pharma-ceutical itself is the most appropriate medicine for treating the public health problem. Factors relevant in determining the most appropriate medication will include not only price, but also availability, usability, convenience and any other factor that would affect the usability of the pharmaceutical product.[832] In terms of the Decision this would include not only the finished product but also products used in the process of manufacturing the product and/or diagnostic kits used in the treatment of the public health problem.[833] This extension of the ordinary meaning of pharmaceutical product will have the consequence of extending beyond the term 'pharmaceutical' and apply to all products necessary to treat a public health problem. Whereas synthesised chemical products, microbicides, reagents and biologicals are likely to be readily accepted as falling within the definition of the Decision,[834] it is not clear whether this would be the case for medical machines or

829 A situation where this could apply set the prerequisites that there is no domestic industry able to (sufficiently) produce that product and it is used in good faith.

830 Paragraph 1(a) of the Decision limits the products to those '*needed to address* the public health problems' (emphasis added).

831 As mirrored by the good faith obligation in the Chairman's Statement.

832 Compare WTO *Korea – Beef* p. 49.

833 The Chairman's Statement states 'the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients.'

834 *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 10. Correa, at p. 11, argues that the definition of pharmaceutical product in the Decision is wide enough to include vaccines. Compare, *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 35. Contrast Cuba in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 9.

instruments.[835] However, as acknowledged by the Appellate Body, the 'more vital or important those common interests or values are, the easier it would be to accept as "necessary".'[836]

Fourthly, the Decision refers to the patented product and not to the individual patent. Although this is a minor issue, focussing the attention on the pharmaceutical implies that a compulsory license for that pharmaceutical can be granted and refer to all patents, both product and process related, used to protect it. Accordingly, the Decision indirectly acknowledges that a compulsory license may relate to all patents necessary to produce the product.[837]

Lastly, pharmaceutical products must be used to address the public health problems recognised in paragraph 1 of the Public Health Declaration.[838] This qualification addresses the scope of diseases capable of benefiting under the system and posed the greatest hurdle for negotiators of a final decision.[839] The attempts by the US to restrict the scope of diseases in the pre-Decision negotiations did not materialise.[840] The main reason for this was the common position by the majority of the developing Member States that they would not accept an erosion of the scope of the diseases mentioned in the Public Health Declaration.[841] All attempts to implement a list of diseases were rejected. A South African non-paper phrased the developing Member States position on lists best when it stated it is 'neither practicable nor desirable to predict the pharmaceutical product needs of Members desiring to protect

835 Art 2(2) of the SPS Agreement will assist in identifying which measures are justifiable. The standard imposed by Art 2(2) does not however require the 'best' means; instead it requires Member States to be able to scientifically justify the measures they take. This, in light of the fact that appropriate pharmaceutical products will generally bring a scientific benefit, should not pose a problem to Member States implementing the Decision in good faith. Further, the Appellate Body implements this requirement

836 WTO *Korea – Beef* p. 49

837 *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 28.

838 Compare *Nolff*, 86 JPTOS 4 (2004) p. 295.

839 The scope of diseases was seen as the 'ultimate sticking point'. *WTO*, World Trade Report 2003 (WTO Geneva 2003) p. 168.

840 The scope of the diseases covered presented the greatest challenge to reaching a consensus and was the reason why the US blocked the acceptance of the Decision in December 2002. The US sought to limit the diseases and referred, *inter alia*, to those expressly mentioned in the Public Health Declaration, i.e. 'HIV/AIDS, malaria or tuberculosis or other infectious epidemics of comparable scale and gravity, including those that may arise in the future'. Cf. WTO Communication by the US 'Moratorium to Address Needs of Developing and Least-Developed Members with No or Insufficient Manufacturing Capacities in the Pharmaceutical Sector' (10.02.2003) IP/C/W/396/Corr.1 p. 2. Compare *Abbott*, 99 AJIL 2 (2005) p. 327-334, *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 10-11.

841 Neither the Public Health Declaration as a whole nor para 6 in particular contained *Abbott*, 99 AJIL 2 (2005) p. 328-330.

the public health by promoting access to medicines for all'.[842] The eventual acceptance by the US of the scope elicited in the Public Health Declaration has meant that each and every pharmaceutical product used to treat public health problems potentially falls within the ambit of paragraph 1(a) of the Decision.[843] In terms of this *any* pharmaceutical product has the potential to be licensed under the Decision, provided it is to treat a public health problem. In the *EC – Asbestos* case a risk can be 'evaluated either in quantitative or qualitative terms'.[844] This therefore allows Member States not only to classify health problems that affect thousands of persons as a problem but also isolated human *and* animal afflicted by a serious illness. This will generally be the case where the isolated disease has the potential to afflict significant amount of persons, such as the SARS and avian flu threats. The indiscriminate threat posed by the anthrax scare in the US in 2001 would also arguably fall within this definition of public health problem. Notwithstanding generally held views on what constitutes a public health problem, the final determination is and remains a domestic prerogative.[845]

2. Eligible countries

The factors determining which countries were eligible for the paragraph 6 solution was a major sticking point in the negotiations preceding the adoption of the Decision. Debates surrounded not only which Member States would be the beneficiaries of the system but also which Member States would qualify for exporting the pharmaceutical products. In what transpired to be the deal maker, a number of provisions, an explanatory annex and the Chairman's Statement were agreed upon to regulate and guide the determination of which Member States are eligible. Under the Decision eligibility is determined not only according to which countries can export and which can import but also when they may do either, i.e. compliance with both external and internal qualification requirements. This effectively forms the framework for applying the system.

a) The exporting Member State

The US sought early on in the paragraph 6 solution negotiations to limit the exporting countries to developing Member States with a sufficient pharmaceutical manufacturing capacity. The US's motivation was that in restricting the exporting Mem-

842 WTO Non-paper by South Africa 'Substantive and Procedural Elements of a Report to the General Council under Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health' (05.11.2002) JOB(02)/156

843 Compare *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 11.

844 WTO *EC – Asbestos* p. 65.

845 *Abbott*, 99 AJIL 2 (2005) p. 332.

ber States to de-veloping Member States this would insert more momentum for technology transfers, limit competition from countries with a developed pharmaceutical industry and would ensure that developing countries became more independent of developed Member States.[846] This pro-posal was however rejected by the developing Member States on the grounds that the Public Health Declaration did not limit the states entitled to supply the needy countries.[847]

The Decision, which contains no limitation, means that the Decision's waiver of Article 31(f) permits *any* Member State to assist needy Member States.[848] The Decision does however lay certain conditions for a Member States to qualify as an 'exporting Member'. It must comply with both the Decision's restrictions and formalities[849] and ensure that they are, to the extent necessary, incorporated into their domestic legal system.[850] Of primary importance for the exporting Member State will be the need to establish a mechanism that will ensure that the conditions imposed by the Decision are implemented in a good faith manner.[851] This will require Member States to ensure that both the relevant governmental agencies and the local compulsory license holder comply with the formal procedural requirements set out in the Decision. Paragraph 5 of the Decision also reiterates that the Member States are to ensure that those TRIPS obligations requiring legal tools to control the importation and sale of intellectual property protected items are effectively enforced. In particular, special attention must be given to ensuring that these measures will prevent the diversion of the pharmaceutical products to unintended destinations. In addition hereto, the exporting Member State should ensure that the paragraph 6 solution does not become an 'instrument to pursue industrial and commercial policy objectives'.[852]

The Decision obliges the exporting Member State to limit the scope and extent of the compulsory license to what is necessary for the importing countries needs. Paragraph 2(b) requires that the exporting Member State's license is limited in quantity, is exclusively for export, the products produced under the license are marked as being produced under such a license (i.e. by way of specific labelling or markings, provided it is feasible) and requires the publication of the quantities and identification characteristics on a website. The exporting country does not have to acquire prior authorisation to grant the compulsory license from either the TRIPS Council or

846 WTO Communication by the US 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (09.07.2002) IP/C/W/358 p. 3.

847 WTO Secretariat note 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation' (11.07.2002) IP/C/W/363 p. 8.

848 *Matthews*, 7 JIEL 1 (2004) p. 96, *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 104.

849 Para 2 of the Decision sets out the requirements for the exporting country to be waived of its obligations under Art 31(f) of the TRIPS Agreement. For example, para 2(c) of the Decision which requires that any compulsory license grants made under the system be 'notified' to the TRIPS Council. The wording of the para 2(c) indicates that the notification can be *ex post facto*.

850 *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 105.

851 In particular paras 1(c), 2b), 2(c) and 3 of the Decision.

852 General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 6.

any other international or foreign body or organisation. The granting of a compulsory license remains the exporting country's prerogative, subject to it abiding by the abovementioned requirements.

The authorisation of a compulsory license by an exporting country must, aside from the waiver of Articles 31(f and h), comply with the requirements of Article 31. This infers that in terms of Article 31(b) the requirement to enter into prior negotiations with the patent holder remains, unless the compulsory license is based on a 'national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'. However, as it is not the exporting Member State that suffers from the public health problem this may result in the exporting Member States requiring prior negotiations with the patent holder in the exporting country.[853] The territorial nature of patent rights on the one hand and Article 31(b) on the other give the impression that the urgency should be domestic in order to circumvent the prior negotiation requirement.[854] However, the extreme urgency mentioned in Article 31(b) is not limited to national emergencies and can, in theory, extend to urgencies beyond its border. As the TRIPS Agreement is silent on the origin of an extreme urgency and that there is, although indirectly, recognition that compulsory licenses can be used in limited circumstances for the benefit of foreign Member States, there does not appear to be any provision that would prevent a granting authority from fast-tracking the compulsory license process on the basis of a foreign extreme urgency. Mutual state respect would dictate that the use of an extreme urgency in one country in terms of Article 31(b) should be respected and where applicable applied where it is to that states benefit. This stance is supported by the Public Health Declaration's express statement that the TRIPS Agreement should be interpreted in a 'manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for *all*' (emphasis added).[855] As there is no reference to the recognition of foreign emergencies in terms of Article 31(b) in the Decision, the exporting Member States would be free to develop their own policies for reacting to a request under the system set out in the Decision.

853 *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 36.

854 Paris Convention Art 4bis. Art 31(b) of the TRIPS Agreement refers to 'national' emergencies. It is however to be noted that the territoriality of patents in Art 4bis of the Paris Convention refers to the *application, nullification or forfeiture* of the patent. It does not refer to their *limitation* under the compulsory licensing system. Further, emergencies in terms of Art 31(b) do not ground their licensing, they only form the basis for it fast-tracking the licensing process. Finally, the Paris Convention's concept of territoriality does not refer to the scope/territory of extreme urgencies.

855 Public Health Declaration para 6.

b) The importing Member State

Although every Member State is able to become an 'importing Member' under the Decision, the importing country may only import when two requirements are met. Firstly, it must be an 'eligible' country and secondly it must meet the requirements set for importation. As both are necessary to participate as a recipient in the system both requirements are discussed below.

Eligibility is easily met under the Decision. LDC Member States are regarded as automatically being eligible.[856] Other Member States are required to give notification to the TRIPS Council of their intention to use the system.[857] The notification by non-LDCs does not require the TRIPS Council's consent; it is simply a notice, there are no requirements regulating its contents and can be submitted at any time.[858] The notice does not oblige Member States to use the system. Accordingly, it can be made as a precautionary measure and need not be based on any existing or threatening emergency.

Although eligible, a Member State will only be able to import in a Decision-compliant manner when it has met the formal requirements set out in paragraph 2(a) of the Decision. Only when these requirements are fulfilled will there be compliance with the Article 31(f) waiver requirements. These requirements require all Member States (both LDCs and non-LDCs alike)[859] to notify the TRIPS Council of the following:

856 Decision para 1(b). Notwithstanding this Rwanda, a LDC, saw it necessary to notify the WTO of its intention to use the system. Cf. --, Rwanda Becomes the First Country to Try to Use WTO Procedure to Import Patented HIV/AIDS Drugs (2007) 11 Bridges 27 p. 4.

857 *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 17-18.

858 Decision fn. 2. The exporting Member State will however not be able to export the product until the notification has been made by the importing Member State. Cf. *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 17-18.

859 *Abbott* and *Correa* rightly note that the notification of the Member State's intention to use the system (para 1(b)) and the notification in respect to the scope of the use (para 2(a)) can be separate notifications. This would theoretically permit there to be two separate notifications: the one being a once-off notification in terms of para 1(b) and the other being a specific notification detailing what pharmaceutical product and how much thereof will be used. Practically, it is more likely that Member States will indicate their intention by way of a notification for the specific pharmaceutical, i.e. combining the two notifications into one. Cf. *Abbott*, 99 AJIL 2 (2005) p. 336, *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. 15.

- the names and expected quantity of the pharmaceutical products required
- confirmation that a compulsory license has been, or will be, granted in respect of the pharmaceutical product, if it is the subject of a patent right[860] and
- confirmation that it does not have any or sufficient production facilities for the requested products.[861]

Whereas the first notification's role is questionable,[862] the second notification's purpose is not. As indicated above, the eligible Member States are required to notify the TRIPS Council of the amount and identity the pharmaceuticals required and, where applicable, issue a domestic compulsory license for the importation and use of the pharmaceutical product.[863] Where the eligible Member State is not a LDC it must 'confirm' that it has insufficient or no domestic pharmaceutical production capacities to meet its needs. The non-application of the latter requirement frees LDC Member States from having to *prove* its inability to produce the relevant pharmaceutical product domestically in sufficient quantities as it is deemed not to have such capacities.[864]

In order to meet the latter requirement non-LDC Member States are required to confirm one of two situations: either that it has no production capacities at all or that it has some production capacities however these are, at the time in question, insufficient to meet the production needs.[865] The question of available capacities is taken as at the time when the need arises and is specific to the particular pharmaceutical.[866] The Chairman's Statement expands on the Decision's requirements and requires that

860 Importing Member States are therefore required to comply with Art 31 as a whole, i.e. binding that importing country into determining the scope, duration, the remuneration and other conditions of the compulsory license. Para 4 of the Decision waives the Art 31(h) requirement for the eligible importing Member State enabling it, should it chose to do so, to refrain from granting remuneration to the patent holder. *Correa* notes that the importing Member States is not obliged to limit the quantity of the needed pharmaceuticals in its domestic compulsory license grant. It will however be required to set out the quantity in the notification to the TRIPS Council. As this notification sets out what is 'needed' by the importing Member States, this figure will be in establishing the necessity by the exporting Member State. 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. 18.

861 Only where the Member States is not a LDC.

862 The purpose behind the two-stage notification system is unclear. Whereas the notification to be provided by the non-LDCs (paragraph 1(b)) will draw attention to their potential use of the system, the notice does not have any other practical value. As the second notification (paragraph 2(a)) also draws attention to the systems use – in this case in more detail and with substantiated contents –the first notification effectively becomes redundant.

863 Compare *Nolff*, 86 JPTOS 4 (2004) p. 300.

864 Compare *Nolff*, 86 JPTOS 4 (2004) p. 300.

865 Annex to the Decision.

866 *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 26. The Authors state that sufficiency will also be dependent on whether the costs to start production of the product are 'material' or not, the time frame for production of sufficient quantities meeting sufficient standards.

the notification also include information as to how the Member State reached its conclusion that it has no or insufficient production facilities.[867] It appears that the Chairman's Statement further allows other Member States to seek clarification about the conclusion through the Director-General or Chair of the TRIPS Council.[868] Despite this review mechanism it is clear that the establishment of insufficient or no production facilities remains a national prerogative.[869] This, together with the fact that the notification does not require the assent of the TRIPS Council, will mean that any challenge to the importing Member State's assessment of its domestic production capacities will not have a suspensive effect on the use of the system.[870]

Should the domestic production capacities improve sufficiently to allow domestic production, then the system will cease to apply, i.e. the waiver will no longer excuse the obligation under Article 31(f). This is somewhat of an unsatisfactory formulation because as soon as the 'capacity has become sufficient … the system shall no longer apply'.[871] If a compulsory license has been granted in terms of the paragraph 6 system, and it transpires that that country subsequently has a sufficient production capacity (e.g. due to a new production plant), then the Decision will require that the compulsory license be terminated. The termination of the compulsory license on the grounds of subsequent production capacities must be 'established'. What and when a production sufficiency is established should be determined either on the same grounds upon which the insufficiency was initially determined or by way of fulfilment of a set of pre-determined statutory, administrative or judicial conditions. Despite the apparent immediacy of the termination provision in the Decision, it does not pre-empt or waive the termination provisions set out in Article 31(g). As the Decision does not waive or suspend the application of Article 31(g) the termination of the compulsory license must also give due regard to the legitimate interests of the

867 General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 at p. 7. The information to be provided was clarified in the discussion following the adoption of the Decision. It noted that it 'had been clarified during the consultations that this did not involve provision of a great deal of technical or other information but only the brief and concise indication of the methodology for determination of insufficient capacity and the conclusions that were drawn on the basis of available data'. Cf. India in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 at 13. Compare *Abbott*, 99 AJIL 2 (2005) p. 336.

868 General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 at p. 7, *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 17-18. In this regards, the Chairman's Statement does not expand on the Decision and thus cannot be used as a means of interpretation. The statement may however be viewed as a preferred manner to resolve disputes in an informal way.

869 *Abbott*, 99 AJIL 2 (2005) p. 336, *Oh*, 10 Bridges 1 (2006) p. 22.

870 A DSU challenge to the 'eligibility' of a Member State, including the assessment of its domestic production facilities, will not be made against the importing Member States but against the exporting Member States as it is the eligibility that entitles the exporting Member States to use the waiver of Art 31(f) of the TRIPS Agreement. Accordingly, this circumstance may lead to a situation where the exporting Member State is found liable under the DSB for actions committed by the importing Member State.

871 Annex to the Decision para (ii).

licensee. This would enable the licensee the opportunity to recoup the investments made in connection with the compulsory license.[872]

A problem with certain paragraph 6 solutions proposed prior to the Decision was that they only concerned situations where there was a valid patent, and therefore a patent system, in the importing Member State. As a number of LDCs have no patent system they were not able to obtain the benefits considered under certain paragraph 6 proposals.[873] The Decision succeeded on averting this problem by regarding all Member States, regardless of whether it has a valid patent on the pharmaceutical product or not, as potential beneficiaries of the solution. In terms of the Decision the only difference between a Member State without a valid patent on the product and one with a patent is that the latter will be required to grant a compulsory license in its own territory for the importation of the licensed product. [874]

The definition of the eligible importing Member State in paragraph 1(b) of the Decision states that certain Member States had elected not to use the system as an importer either completely or in limited circumstances. This opt-out by certain Member States played a central role in bringing about a solution to the paragraph 6 problem. It gave the US the much needed 'security' it required to withdraw their blocking stance to the proposal made by Ambassador Motta. The 'note' in paragraph 1(b) of the Decision states:

> 'It is noted that some Members will not use the system set out in this Decision as importing Members 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 circumstance of extreme urgency'[875]

The significance of this opt-out is, legally speaking, complex.[876] The text in the Decision acknowledges that some Member States do not intend to use the system. The unwillingness to use a system indicates a voluntary[877] and unilateral act; it does not constitute an agreement. Instead the opt-out assumes the form of a 'renunciation' of rights, in this instance of substantive rights. The renunciation combined with the absence of any objection by the relevant Member States indicates that it is their in-

872 The lack of any financial security for parties exercising compulsory license will negate the desire on behalf of the pharmaceutical industry to exercise and apply for compulsory licenses. The lack of any willing participants would render the compulsory license system ineffective and permit anti-competitive behaviour on behalf of the patent holders.

873 A number of proposals made during the para. 6 solution negotiations acknowledged the eligibility of certain Member States without patent protection but who still had the need for a system that would permit the exportation of pharmaceutical products under a compulsory license. Cf. WTO Secretariat note 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation' (11.07.2002) IP/C/W/363 p. 6.

874 Decision para. 2(a)(iii).

875 Footnote omitted.

876 Compare *Fiedler,* Unilateral Acts in International Law in: *Bernhardt et al* (eds) Encyclopaedia of Public International Law (Elsevier Amsterdam 1981) vol 4 p. 1018-1023.

877 *Abbott*, 99 AJIL 2 (2005) p. 336.

tention to be bound by the renunciation.[878] The binding nature of the opt-out will, at the very least, be sufficient to create an estoppel and will prevent those Member States having declared their renunciation of the benefits under paragraph 1(b) of the Decision from acting contrary to their declared intention.[879] The opt-out, as a unilateral act, may however constitute binding public international law.[880] Having regard to the requirements for establishing the binding nature of the act, it seems highly likely that this will indeed be the case with respect to the countries mentioned in the Decision.[881] The binding nature of the opt-out may extend to those countries listed in the Chairman's Statement. The reason for this is that those countries 'acquiesced' to the limited opt-out by refraining from objecting to their inclusion. The passivity of those Member States and their involvement in the TRIPS Council and its negotiations all confirm the presence of their intention to refrain from the full use of the system.[882] The binding nature of unilateral acts is based, to a large degree, on the principles of good faith and *jus aequum*.[883] It follows therefore that those Member States who opted out of the system will only be able to withdraw their renunciation (without infringing another Member States interests) when they does so in good faith. In this regard, those listed Member States will be able to use the system where

878 The lack of an objection by the Member States opting out may constitute evidence of the unilateral act by way of acquiescence. Cf. *Schwarzenberger*, International Law (Stevens & Sons London 1957) vol 1 p. 552.

879 *Fiedler*, Unilateral Acts in International Law in: *Bernhardt et al* (eds) Encyclopaedia of Public International Law (Elsevier Amsterdam 1981) vol 4 p. 1020.

880 Unilateral acts have been afforded binding legal nature by the Permanent Court of International Justice. Cf. *Certain German Interests in Polish Upper Silesia (Germany v Poland) (Merits)* PCIJ Rep Series A No 7 at 13. Also *Matsushita et al*, The World Trade Organization: Law, Practice, and Policy (2nd edn OUP Oxford 2006) p. 21.

881 *Fiedler* notes that the country making the act must act in free will, the person/body performing the act must be competent to represent that country and the country must legally and factually be able to act in accordance with the act. Further factors include the intention to be bound and that the undertakings be unconditional and definitive. *Fiedler* also remarks that as 'notification is the most common from employed in international relations, it also seems as a rule most appropriate one for unilateral acts'. Cf. *Fiedler*, Unilateral Acts in International Law in: *Bernhardt et al* (eds) Encyclopaedia of Public International Law (Elsevier Amsterdam 1981) vol 4 p. 1021-1022.

882 Compare *Schwarzenberger*, International Law (Stevens & Sons London 1957) vol 1 p. 552. The list of Member States partially opting out of the system thus acquires more legal weight in relation to the rest of the Chairman's Statement (the remainder having an interpretive function). This conclusion reflects the reference made to these countries in para 1(b) of the Decision.

883 Compare *Fiedler*, Unilateral Acts in International Law in: *Bernhardt et al* (eds) Encyclopaedia of Public International Law (Elsevier Amsterdam 1981) vol 4 p. 1020-1021, *Schwarzenberger*, International Law (Stevens & Sons London 1957) vol 1 p. 551. To the extent that the opt-outs were agreed to between those opting out, i.e. by way of an informal bilateral or restricted multilateral agreement, the DSU has taken such agreements into account when done so within the framework of a WTO Agreement. The DSU has also made reference to 'tacit' agreements. Cf. Also *Matsushita et al*, The World Trade Organization: Law, Practice, and Policy (2nd edn OUP Oxford 2006) p. 41-42.

they are no longer able to counter a public health problem with domestically produced pharmaceuticals. Only where a genuine paragraph 6 problem is experienced by that country will it be able to revoke its renunciation.[884]

Whereas the definitive legal classification of the opt-out is not entirely clear, the effect is. An exporting Member State would not be able to rely on the waiver of Article 31(f) if it were to export pharmaceuticals to a country that had opted out of the system. In other words its exportation under the system would only comply with the Decision if it were to obey the opt-outs by those Member States concerned. An exporting Member State will however be required to distinguish between two types of Member States that opted out of the system. In terms of paragraph 1(b) of the Decision there are two opt-out categories of countries: those who will not use the system and those who will only use it in certain circumstances. The first group was initially made up of 23 Member States.[885] As of the 1st of May 2004 a further 10 Member States were added.[886] By opting out of the waiver, these Member States acknowledge that the legal restrictions referred to in paragraph 6 of the Public Health Declaration do not, and will not, negatively limit its domestic treatment of public health problems. The opt-out thus implies that those Member States subscribing thereto either have sufficient pharmaceutical production facilities and/or the prices of the importation of the products would not unduly constrain the domestic health care system. It is therefore understandable that those countries that have opted out are either OECD or EC members or are classified as high income countries.[887] Further, this group of countries not only constitutes the developed Member States at the WTO[888] but they also house the major pharmaceutical high-profit markets. This pledge by these states reassured the US and its pharmaceutical industry that it would not lose existing valuable markets to generic manufacturers producing under compulsory licensed rights.

The second group of Member States took a similar position to the first group; it acknowledged that their compulsory license system is effective. However, unlike the first group these Member States were unable to say categorically that their compulsory license system will remain 'effective' in *all* circumstances. The qualification of the general opt-out by these Member States sought to reserve the opportunity to use the system in situations that were exceptional. To this extent this group of Member States agreed only to use the system 'circumstances of extreme urgency [and] in

884 Contrast *Abbott,* 99 AJIL 2 (2005) fn. 130 p. 336.

885 They are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

886 They are the countries that joined the EU on 01.05.2005 (Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia).

887 Of the Member States who have either completely or partially opted out, only three have no domestic pharmaceutical production capability – Iceland, Luxembourg and Qatar. Cf. WTO Secretariat note 'Available Information on Manufacturing Capacity for Medicines' (24.05.2002) IP/C/W/345 p. 13.

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

cases of public non-commercial use'.[889] This group of countries is made up of 11 Member States;[890] 9 of which are regarded by the World Bank as being 'high income' countries and two upper middle income countries.[891]

c) Conclusion

Determining eligibility goes to the core of the implementation of the policy issues identified in the Public Health Declaration. Not only does it seek to establish who the beneficiary of the system is but also which country, when and on what conditions, will be able to provide the assistance. The eligibility also ensures that the beneficiaries will be those countries unable to exercise the TRIPS Agreement in a manner that enables them to take full advantage of the tools provided within the patent system.

3. Safeguards

In any compulsory license system potential abuse may arise from both state and individual practices. The abuse potential is however amplified in a system that encompasses multiple parties in at a minimum two jurisdictions with countries. To prevent the abuse and misuse of the Decision's system the developed Member States demanded that comprehensive safeguard measures be created to ensure that, on the one hand, the benefits reach the needy country and, on the other, that the pecuniary loss felt by the patent holder is limited to the importing country's market. These safeguards, eventually adopted by the Member States, function on two levels. On the one level – that of the system itself – the safeguards ensure that the system is designed solely to benefit the needy country. To this effect safeguards were inserted to ensure the system remains transparent and accountable. The second level – general ancillary safeguards – require the exporting and importing countries to ensure that their general patent protection measures provide a sound legal basis for enforcing the system. The two approaches adopted are dealt with separately below.

889 Decision para 1(b).

890 These Member States are Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and the United Arab Emirates. 7 of these Member States (Hong Kong China, Israel, Korea, Mexico, Singapore, Chinese Taipei and Turkey) further verbally opted out of the public non-commercial use of the system. Not included in this number are the 10 EC accession states, who also opted out of the public non-commercial use during prior to their accession. Cf. WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 5-6.

891 Mexico and Turkey are classified by the World Bank as being 'upper middle income' countries. They are, together with Korea, also OECD members. Cf. *World Bank*, Country Classification (2005).

a) Safeguards inherent to the system

The Decision ensures that only when certain conditions, i.e. safeguards, are met will the waiver of Article 31(f) be effective. The safeguards in the Decision are therefore mandatory and require positive compliance. Phrased differently, the safeguards create the system. In order for the system to operate both importing and exporting Member States must abide and enforce certain protective measures.

The importing Member State must identify the needed pharmaceutical and the quantity it requires. This safeguard establishes and consequently limits the 'need'. Whereas the quantity is expressed and safeguarded in the notification, there is no express obligation compelling the importing Member State's compulsory license to quantify its license requirements – this is neither a mandatory nor regular requirement of standard compulsory licenses. Standard com-pulsory licenses are seldom limited in quantity as the consumed quantity is dictated by market demands. The Decision's compulsory license system does not create a standard compulsory license. The Decision states that the exporting state cannot grant a license that exceeds the actual needs of the importing country.[892] It is clear that this limitation seeks to safeguard against uncontrollable and unaccountable production amounts. This safeguard does not however require that there need not be a direct correlation between what is the *expected* need (i.e. what is set out in the notification) and what is the *actual* need (the limit that must be imposed by the exporting country), it is likely that the exporting Member States will draw this conclusion; thus making no distinction between what is expected and what is actually needed. As the Decision does not require an absolute quantity, Member States are entitled to qualify the quantity by making it dependent on variables.[893] The use of these safeguards in a flexible manner is essential to ensuring effective use of the system.[894] Both accountability and common sense understanding on what is understood under an 'expected quantity' will ensure that the system is effective for both the needy country and the patent holder.

As discussed above, the inability to provide self-help must also be established. This safeguard ensures that the system retains its legitimacy. The final system-bound

892 Para. 2(b)(i) of the Decision.

893 The quantification of the amount of pharmaceuticals 'needed' need not automatically be in absolute terms. Instead of just referring to a specified number of units it may also be possible to base the need on the number of patients or hospitals over a period of time. Cf. *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 112, *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 24. *Abbott* and *Van Puymbroeck* suggest that the importing country reserve a right to revise the quantity where it transpires that the expected needs no longer suffice.

894 In Rwanda's notification it reserved the right to alter the amounts it required as 'it is not possible to predict with certainty the extent of the country's health needs'. Cf. --, Rwanda Becomes the First Country to Try to Use WTO Procedure to Import Patented HIV/AIDS Drugs (2007) 11 Bridges 27 p. 4.

safeguard for the importing Member State is the 'reminder' that the existing non-waived compulsory license requirements in Article 31 must, to the extent applicable, be complied with. The documentation of compliance with these safeguards via the notification requirements ensures the system will remain accountable.

Not only do the majority of safeguards rest on the exporting Member State's shoulders but the Member State is also the party in the system that carries the liability for any non-compliance with the waiver and its conditions. As the exporting Member State is both the gatekeeper and the party carrying the liability for the system, it will be more engaged in ensuring that the system is used in a legitimate and compliant manner.

The overriding safeguard provision is the obligation to only grant a compulsory license 'to the extent necessary'.[895] This will imply in practice that the compulsory license in the exporting country will have to mirror the pharmaceutical and its quantity set out in the importing Member State's notification.[896] It does not however imply that the exporting Member State will have to validate the correctness or reasonableness of the importing country's notification.[897]

In addition to the general safeguards, the Decision sets specific domestic law conditions for the use of the system. These domestic safeguards require definitive action on behalf of the exporting Member States. To this effect the grant of the compulsory license must limit the compulsory license to the amount necessary to supply the needs of the importing country;[898] the pharmaceutical products must bear certain marks identifying them, either by labelling or marking, as being produced under the system; and the licensee must be required to inform, via a website, the quantities produced under the system, the destination of the products and the distinguishing features of the product.

The marking and labelling requirement in paragraph 2(b)(ii) of the Decision derives from practical experiences pharmaceutical exporters have had in attempting to control the diversion of their products to unintended destinations.[899] To avoid a situation whereby this safeguard would make the licensed products unaffordable or unfeasible to produce, a proviso was included which stated that this obligation would not apply where such a 'distinction is feasible and does not have a significant

895 Decision para 2.

896 It also goes without saying that the entire production manufactured under this system must be for export purposes.

897 Compare *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. 17.

898 See Chapter 7(B)(III)(2)(b) above.

899 To this effect the 'Best Practices' referred to in the Chairman's Statement serve as an illustration. The Chairman's Statement notes that the 'Best Practices' will assist in preventing the diversion of the pharmaceutical product.

impact on price'.[900] This proviso was not to the liking of the US who called for the Chairman's Statement to acknowledge that it 'is the understanding of Members that, in general, special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals'.[901] This subsequent 'understanding' has effectively reduced the flexibility found in paragraph 2(b)(ii) of the Decision by affirming that packaging and shape changes will be necessary, unless there is clear evidence that the changes would lead to a significant increase in the price. It is unlikely that this requirement will pose an unreasonable restriction on the actual exercise of a license under this system. The reason for this is that this requirement could be met simply by confirming on the packaging that the product is under compulsory license. This alteration in the packaging would in most cases be necessary simply because the names given to most modern medications are subject to trademark protection and such names could not, without the right holder's authorisation, be used on the licensed product.[902] The distinguishing characteristic may however be unfeasible where the changes mean that the pharmaceutical must undergo new bioequivalence studies and/or marketing approval.[903]

The Decision also requires that notification must be given of the granting of a compulsory license under the system. In the notification to the TRIPS Council the exporting Member State must set out the conditions imposed on the grant of the compulsory license, include details pertaining to the identity and location of the licensee, the licensed product, the quantities to be produced, the destination of the products, the internet address of the notification and the duration of the license.[904]

A final safeguard that applies to and affects both the exporting and the importing Member States is that of remuneration. The Decision's system requires two compulsory licenses to be granted, one in the exporting country and one in the importing country.[905] This therefore leads to a potential situation where, in terms of Article 31(h), the patent holder is entitled to compensation in both countries.[906] As the notion of double remuneration ran against the spirit of the Public Health Declaration and the access to affordable medicines, the Member States were able to agree that payment of the remuneration should only be due in either the importing or exporting country.[907] A waiver of the Article 31(h) obligation presented little debate – the formulation however did. The problem that arose was: what standard is to be used to

900 Decision para 2(b)(ii). It is uncertain how active ingredients, usually sold in their basic form, will be changed to comply with this requirement. Also problematic are the alterations required for diagnostic kits. In this regard only superficial changes will be feasible.

901 General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 6.

902 Compulsory licenses are not permitted for trademarks. Cf. TRIPS Agreement Art 21.

903 Compare *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 113.

904 Decision para 2(c).

905 No requirement for a compulsory license in the importing country will exist where there is no valid patent in that country. Cf. Decision para 2(a)(iii).

906 *Nolff*, 86 JPTOS 4 (2004) p. 301-302.

907 This is effectively a safeguard against an abusive exploitation of the patent holder's rights.

determine the level of remuneration? This was eventually solved by waiving the importing Member State's remuneration obligation and requiring that the remuneration be paid in the exporting Member State. This remuneration is to be 'adequate' and is to 'take into account the economic value' of the use of the product in the importing Member State. By requiring the exporting Member State to provide for the remuneration of the patent holder the Member States have safeguarded the patent holder's right to remuneration. By shifting the onus of paying the remuneration to the exporting country, the system has ensured that the level of remuneration, although most likely lower than a 'standard' compulsory license in the exporting country, will be more likely and higher in value than in the importing countries jurisdiction.[908] Before a Member State can take advantage of the waiver of Article 31(h) the importing Member States will be required to amend their domestic laws to this effect. As the waiver may only be used within the context of the Decision, such Member States will be required to make a distinction in their domestic law between compulsory licenses granted within the scope of the Decision and compulsory licenses granted under other circumstances. Whether or not a Member State would be entitled to make a zero remuneration award instead of adopting the waiver is not certain. As the system effectively couples the license granted in the importing country with the license granted in the exporting country it, can be said that they form one 'case'.[909] Further, as the Decision already requires *adequate* remuneration to be paid in the exporting country the adequacy requirement in the importing country could be said to have been met. The Decision reinforces this by requiring the exporting country to base the adequacy of the remuneration on factors prevailing in the importing country.

b) General safeguards

Leading up to the adoption of the Decision, developed Member States expressed their fear that a potential solution could easily be used to divert those pharmaceutical products produced under the system. To avoid this, the developed Member States

908 *Nolff* states that when the export Member State does not grant any remuneration the importing country will be required to grant adequate remuneration. This view does not arise from the wording of the Decision. Neither the Decision nor Art 31(h) require that remuneration be given in every instance. Both require *adequate* remuneration. If the exporting Member State finds zero remuneration sufficient this does not oblige the importing Member State to once again re-evaluate the issue. Even if it does, and this may indeed be the case where there is no domestic rule waiving Art 31(h), it may also come to the conclusion that a zero remuneration rate is adequate. Cf. *Nolff*, 86 JPTOS 4 (2004) p. 302 fn. 26. Compare *Abbott and Van Puymbroeck,* Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Washington 2005) p. 38.

909 Article 31(h) states that remuneration should be 'paid in the circumstances of each case'. This is supported by the fact that both share the same object and purpose, i.e. alleviating a particular public health problem.

sought anti-diversionary safeguards to be included into the Member States' domestic laws, instituting a positive obligation to act. Whereas the developing Member States did not oppose anti-diversionary obligations, they were cautious to commit to requirements that would prove too burdensome for their limited resources. The problem was resolved by requiring anti-diversionary measures to be taken subject to the Member State's means. In other words, an importing Member State must take measures that would prevent the imported licensed products from being re-exported. However, where the importing Member State has limited resources, such measures need only be 'within their means [and] proportionate to their administrative capacities'.[910] The developed Member States for their part committed themselves to providing assistance (both technical and financial) to the importing Member State to facilitate their compliance with this requirement.[911] The assistance is to be provided upon request by the importing Member State, on terms and conditions acceptable to both parties. The principal assistance is likely to come in the form of an improved national customs system. Incorporated within this system may be specific procedures whereby the customs authorities (or other government officials) are able to monitor both the importation and distribution of the pharmaceutical products.

The Decision goes one step further in paragraph 5. It requires, in addition to measures preventing the re-exportation, measures to prevent the importation of those products licensed under the system to markets to which they were not intended. This secondary safeguard seeks to protect the interests of both the importing country as well as the patent holder by ensuring that the products reach the needy and do not harm the patent holder in other markets. The safeguard requires from all Member States the 'availability of effective legal means to prevent the [unlawful] importation into, and sale in, their territories of products produced under the system'. This obligation does not specifically require new protection measures, rather it requires that those measures already required by the TRIPS Agreement are implemented and, more importantly, effectively enforced. The proper enforcement implies that Member States will have to permit civil actions (providing for injunctions[912] and damages[913]) by the patent holder. The enforcement of patent protection under the TRIPS Agreement is, unlike copyright and trademarks, principally a civil law matter and the enforcement of patent remains a duty of the patent holder.[914] Accordingly and as provided for in Articles 41 to 50 of the TRIPS Agreement, Member States are to ensure that national courts and/or administrative officials are able to enforce the patent holder's rights contained in Article 28 of the TRIPS Agreement.

910 Decision para 4 first sentence.
911 Decision para 4 second sentence.
912 TRIPS Agreement Art 44.
913 TRIPS Agreement Art 45.
914 Arts 51-60 of the TRIPS Agreement provide for specific procedures for inspection, seizure and destruction of goods that infringe copyrights and trademarks. Art 60 of the TRIPS Agreement requires that Member States enforce criminal sanctions for trademark counterfeits and copyright pirates.

The Public Health Declaration provided Member States with the confirmation that those flexibilities available within the TRIPS Agreement could be used, to the full, to address public health issues.[915] Concerns had arisen that the provisions in the Decision could extend beyond Articles 31(f and h) of the TRIPS Agreement and limit the application of the use of these flexibilities. To safeguard against the spilling over of the Decision, the Member States confirmed that the contents of the Decision should not be used beyond its scope, i.e. the paragraph 6 problem.[916]

4. Transfer of technology

In its attempt to resolve the paragraph 6 problem, the solution indirectly perpetuates the state of affairs that led to the problem by increasing the importing Member State's reliance on foreign producers. Aware of this paradox the Member States sought to specifically encourage the transfer of technical know-how and capacity building in the pharmaceutical sector.[917] This was specifically to be realised by and between the exporting and importing Member States.[918] The manner in which this objective will be realised is somewhat unclear. It appears from the contents of paragraph 7 of the Decision that the exporting country should promote the transfer of technology to the importing country. If this is indeed the case importing Member States would only acquire limited know-how which, in the scope of pharmaceutical production, would bring about little tangible and sustainable technology transfer. Further, if the licensee in the exporting Member State is itself burdened by this obligation it would dissuade many producers from providing assistance. In terms of the Decision the international obligation to provide technology transfers within the ambit of the system will rest with the exporting Member State itself.[919] Leaving the obligation with the Member State itself – and not the actual producer – would make for a more effective and less burdensome system.

The obligation to promote the transfer of technology and capacity building under paragraph 7 of the Decision makes an important break from the TRIPS Agreement obligations in Article 66.2: it requires that the assistance extend to all importing Member States, regardless of their status. This does not substitute the Article 66.2

915 Public Health Declaration para 4.

916 Decision para 9. The Decision relates only to one issue mentioned in the Public Health Declaration (para 6). It would be amiss to allow the *lex specialis* (i.e. the Decision) to limit those elements of the *lex generalis* (i.e. the Public Health Declaration) to which it does not relate.

917 The Public Health Declaration also recognised the importance of technical transfers. Para 7 states: 'We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2'.

918 Decision para 7.

919 Par 6(ii) of the Decision obliges developed Member States to provide technical cooperation to those developing Member States wishing to adopt a regional patent system.

obligation nor does it indirectly extend Article 66.2 to all Member States. The assistance is limited to those who actually require it.

The Decision also draws the attention to the direct obligations found in Article 66.2. It requires the Member States, in performing their obligations under Article 66.2, to pay 'special attention to … the pharmaceutical sector'.

IV. Procedure for the adoption of a final solution

The interim nature of the Decision, confirmed in paragraph 11 of the Decision, instructs the TRIPS Council to negotiate and adopt an amendment that would replace the Decision's solution. Until such time, the provisions of the Decision would apply.[920]

The process of finding a final solution should be 'based, where applicable, on this Decision'.[921] This infers that the final solution should derive from the Decision and not paragraph 6 of the Public Health Declaration. This limitation meant that the scope of the entire solution was already incorporated into the Decision. Hence, issues not found in the Decision would not fall within the scope of the final solution mandate. As such the Decision effectively limited the scope of the final solution to how the Decision could – in form and structure – be transposed into an amendment. The Member States did however recognise that there may be other extraneous issues that would have to be included in the final solution. The contents of paragraph 11 did however indicate that there would be an onus on proving that the 'new' issues would be necessary. This view was not shared by all Member States. Rwanda, for instance, stated on behalf of the African Group that:

> 'The ordinary meaning of the sentence "the amendment will be based, where appropriate, on this Decision" indicates that it was never the intention of the Members to use the entire August Decision as the amendment. Only the parts of the 30 August 2003 Decision that are appropriate are to be used'[922]

For these and other Member States, the final solution was supposed to constitute a more comprehensive and thought-out decision that made for an effective and operational solution to the paragraph 6 dilemma. They rejected any assertion that the Decision and the Chairman's Statement should be incorporated in their entirety into the final solution.[923] These Member States sought a solution based upon the Public Health Declaration and paragraph 6 thereof. In addition, emphasis was put on the system itself as being unable to achieve its intended goals. This dispute was aggravated by the potential role the Chairman's Statement might play in interpreting the

920 Para 11 serves as a resolutory condition: upon the occurrence/adoption of an amendment the obligations under the Decision will terminate.

921 Decision para 11.

922 WTO Communication by Rwanda and others 'The TRIPS Agreement and Public Health' (06.04.2005) IP/C/W/445 p. 2.

923 Contrast US in the TRIPS Council Minutes (31.01.2006) IP/C/M/49 p. 36.