Notwithstanding the additional references to the flexibilities in the Public Health Declaration, neither the Decision nor Article 31*bis* limit or extend the scope and application of the flexibilities found in the TRIPS Agreement.

e) Conclusion

Undoubtedly the contents of the Public Health Declaration will have settled the uncertainty surrounding some of the unclear and/or uncertain means of interpretation and implementation of compulsory licenses. Notwithstanding the clarification of these issues, the Public Health Declaration was, in respect to compulsory licenses, a mere reaffirmation of the norms existing in the agreement from its inception, and as such do not permit legal scholars no interpret new direct legal rights or obligations into the TRIPS Agreement.[737] With the exception of system enabling certain Member States to satisfy their domestic compulsory licenses in other countries, the newly adopted Article 31*bis* does not alter the current reading or understanding of the obligations under the TRIPS Agreement. Instead Article 31*bis* serves to confirm the sovereignty of the concept of the flexible interpretation of the TRIPS provision. As such, and in connection with the Public Health Declaration, both have an important role for the future implementation of international intellectual property rights and their effect on national legal systems. Member States, especially those uncertain or subject to international intimidation, will now have more ammunition to defend their desires to make meaningful use of their compulsory license system.[738]

III. The extension of the transitional period for LDCs

1. Paragraph 7 of the Public Health Declaration

In addition to reaching an agreement on the clarification of certain TRIPS provisions, the parties to the Doha Ministerial Conference agreed that the complete implementation of the TRIPS Agreement by certain Member States, initially set for 2006, would not be required until 2016. Paragraph 7 of the Public Health Declaration states:

> 'We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council

737 *Correa* notes that the Public Health Declaration, or parts thereof, merely state the obvious. Cf. *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 15.

738 An amendment to the Belgium patent system has introduced a compulsory license to be granted on public health grounds. During the adopting thereof express reference was made to the Public Health Declaration. See *Van Overwalle*, 37 IIC 8 (2006) p. 908-909.

for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.'

The reason for the inclusion of the extension of implementation duty arose as a result of Article 66 of the TRIPS Agreement. Article 66.1 states that LDCs were not required to im-plement the TRIPS obligations until 2006.[739] As this date was fast approaching and clearly in the minds of the LDCs during the negotiations leading up to the Public Health Declaration, these Member States sought to have their obligations further extended.

The transitional period in Article 66.1 was initially seen as a significantly long period of time for LDC Member States to create and implement a comprehensive and functioning intellectual property rights system. However, as the expiry date of the transitional period approached, LDC Member States began to question whether this period was in fact long enough.[740] The difficulties lay not only in enacting a comprehensive intellectual property system but also in implementing such a system and being sufficiently well versed in the system to ensure it is implemented in a manner that is conducive to social and economic welfare. Developed Member States viewed the transition period as being one of the core flexibilities available in the TRIPS Agreement.[741] The diverging views came to a head in the negotiations preceding the Public Health Declaration. The LDC Member States feared that the expiry of the transitional periods would require an intellectual property rights system that would accentuate poverty and dependency, especially with the advent of diseases such as HIV/AIDS, tuberculosis and malaria. In the light of these difficulties the LDCs pushed to have the implementation of these obligations delayed.[742] The TRIPS Agreement makes provision for the extension of the transition periods in Article 66.1 of the TRIPS Agreement and requires each LDC Member State to apply for the extension individually. The LDCs did not use this approach but instead chose

739 Art 66 of the TRIPS Agreement does however note that LDCs are nonetheless required to implement Arts 3 (national treatment), 4 (most-favoured nation treatment) and 5 (multilateral agreements). The implementation period is calculated in terms of the general transitional period of one year in Art 65.1 plus the 10 year transitional period foreseen by Art 66.1. Cf. *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 716.

740 Tanzania made reference to the obligation developed Member States have in respect of providing incentives to enterprises and institutions to promote and encourage technology transfers. Cf. Tanzania in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 30.

741 Compare US in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 at 36-37. The US representative is quoted as saying: 'I would like to remind delegations that among the most significant flexibilities contained in the TRIPS Agreement are the transition periods provided to developing and least-developed country Members'.

742 Compare WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 at p. 4. In the latter proposal Brazil calls for an extension of *5 years* on patents affecting the public health in both developing and least-developing Member States.

to proceed as a unit, requiring a general extension to all LDCs. Not only did a united front spread the burden but the TRIPS forum, swayed by the political momentum flowing from the HIV/AIDS crisis, presented a more opportune vehicle to acquire a blanket extension.

Unlike the extensive debates on compulsory licenses, Member States found it relatively easy to reach an agreement on the extension of the patent obligations for LDCs. A reason for this ease stems from the fact that the extension was limited to LDCs, as opposed to both developing and developed Member States, and to pharmaceutical products. [743]

The limitation on the countries eligible for the extension derived from Article 66.1 which limits the initial transitional period to LDCs. This limitation however was the key to the quick adoption of the paragraph 7 instruction. It is the LDCs that are on the one hand most susceptible to public health problems and on the other hand least able to respond to these problems. Further, the lack of technical knowledge and infrastructure means that LDCs pose little of a threat to pharmaceutical industry, either the developing countries or elsewhere.[744] The reason why this was not extended to benefit all developing Member States was the fact that a large portion of these countries already had functioning intellectual property systems and that a large number of these countries had both an operational pharmaceutical industry, a large market and thus the ability to exploit any extension.[745]

What was precisely meant by a 'pharmaceutical product' was not set out in the Public Health Declaration. Clearly however the reference to the product and not the type of patent implies that the product can derive from a product patent or a process patent.[746] Viewed within the context of the Public Health Declaration, in particular

743 Thus excluding pharmaceutical process patents.

744 Most LDCs lack a domestic pharmaceutical industry and thus rely on imports for more developed countries which, by reason, already have a viable pharmaceutical patent protection system.

745 Developing countries had however called for an extension in terms of Art 65.4 of the TRIPS Agreement. Cf. WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 9.

746 A pharmaceutical product can be patented itself or be the product of a patented process. As the Public Health Declaration refers to pharmaceutical products and not to patents, it must be concluded that the pharmaceutical products, irrespective of how they are protected by patent rights, are excluded. Were the meaning to be limited to patented products alone it could lead to the situation where pharmaceutical manufacturers would patent the process only and in so doing 'fence-off' the pharmaceutical product. This would defeat the object of the Public Health Declaration. The reference in the second sentence of para 7 to 'rights' does not limit its application only to product rights in terms of Art 28.1(b). Hence it must be seen as a reference to the rights contained in Art 28 as a whole. *Correa* concurs and notes that the EC also agrees. He also notes that the US views this phrase as meaning all pharmaceutical patents. Cf. *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 38. The minutes of the TRIPS Council Meeting in which the Extension was granted do not reflect a dispute in this regard. The view taken by the LDC Member States – i.e. that it refers to both patented products and processes – was not contested by any

paragraph 6, it would appear that pharmaceutical products would refer to all products produced in the pharmaceutical sector. In the absence of any subsequent agreement by the Member States this approach will remain the most authoritative.[747] Although the extension is granted within the broader scope of public health problems the concept 'pharmaceutical product' will not be limited to pharmaceutical products necessary to protect the public health.[748] Paragraph 7 does not limit the products to those 'necessary'. The extension is absolute; any pharmaceutical product can be excluded from being patented in a LDC.[749]

Aside from the limitation to pharmaceutical products, paragraph 7 also limits the extension to the scope of patents and undisclosed information, Articles 27-34 and 39 respectively. This limitation corresponds to the demands made by the developing Member States in the negotiations prior to the Public Health Declaration. It was felt that not only could patents limit the access to affordable medicines but that also the expansive protection of undisclosed information could have a similar effect by limiting generic producers from relying on the original data supplied by the pharmaceutical producers in the process of obtaining market access for the pharmaceutical.[750]

of the other Member States at the TRIPS Council Meeting. Cf. TRIPS Council Minutes (18.07.2002) IP/C/M/36 p. 48-52.

747 The *India – Patent Protection* cases I and II the DSB was required to deal with pharmaceutical chemical products under Art 70 of he TRIPS Agreement. Both the panel and the Appellate Body avoided discussing the scope of the term. Cf. WTO *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* Report of the Panel (05.09.1997) WT/DS50/R, WTO *India – Patent Protection II*.

748 The contrary argument that the only those pharmaceutical products can be excluded that are used to treat public health problems contains some merit. Firstly, Art 66.1 of the TRIPS Agreement is an exception to the material obligations contained in section 5 of the TRIPS Agreement and as such should be interpreted restrictively. Secondly, the context of the Public Health Declaration is generally limited public health problems. However these two points cannot rebut the ordinary meaning of the words in para 7 of the Public Health Declaration. It is plainly evident from para 7 as a whole that the exception of pharmaceutical products is not coupled to public health problems. With the exception of the limitation to patents, undisclosed information and pharmaceutical products, the phraseology used in para 7 is absolute.

749 It would make little difference if the products were limited to public health problems as the term public health itself is unlimited; hence the products used to treat them could not be limited.

750 Compare India in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 24, EC and Senegal in the TRIPS Council Minutes (18.07.2002) IP/C/M/36 p. 50-51.

2. The TRIPS Council decision extending the transition period

Paragraph 7 was formally adopted by the TRIPS Council on the 27th of June 2002 (the 'Extension').[751] The Extension is an opt-in system, in other words LDC Member States are not required to take advantage of the Extension but may do so. LDC Member States opting for the extension are only excluded from enforcing Sections 5 and 7 of the TRIPS Agreement, i.e. patents and undisclosed information respectively. The scope of the exemption extends to pharmaceutical products and will last until the end of 2015.

The Extension of the transitional period under Article 66.1 included a number of procedural irregularities that have brought certain issues into question. In the third preamble paragraph of the Extension it states that paragraph 7 of the Public Health Declaration 'constitutes a duly motivated request' for the extension of the transitional period.[752] This statement is factually unfounded as paragraph 7 contains no express statements explaining or justifying the need for an extension. No reference is made in the preamble to prior discussions or negotiations and as such do not form part of the request. Within the context of the Public Health Declaration as a whole, no mention is made to the LDCs' difficulties in implementing the TRIPS agreement or the problems that would arise in implementing the TRIPS Agreement. Thus, it must be concluded that paragraph 7 fails to establish a ground for the extension of the transitional period. Although a formal motivation is absent in both paragraph 7 and the Extension, it must be assumed that the Member States would not have consented to the extension of the transitional period unless they were convinced – in one way or the other – that the Extension was justified. An additional procedural inconsistency is the extensions decisions reference to paragraph 7 constituting a 'request'. Paragraph 7 however makes no reference to it being a request. It instead 'instructs' the TRIPS Council to give effect to the extension. No evidence has been found that a formal request was ever made.[753] Despite the procedural limbo in which the Extension stands, the Member States do not contest the validity of the legal instrument.

Paragraph 7 and the Extension, implementing a *de jure* relief for LDCs, constitute little more than a consolation prize in the ambit of the Public Health Declaration. The delay in implementation has little effect on the majority of the LDCs. In a study of thirty African Member States, only two have no pharmaceutical product protec-

751 Decision of the TRIPS Council 'Extension of the transition period under Article 66.1 of the TRIPS Agreement for least-developed countries for certain obligations with respect to pharmaceutical products' (27.06.2002) IP/C/25 ('Extension').

752 Art 66.1 of the TRIPS Agreement requires any extension request to be 'duly motivated'.

753 Other interesting results of para 7 are fact that there is no certainty as to which countries are deemed LDCs. The WTO does not contain a category or standards in terms of which states are formally determined to be either LDCs or not. It is however not a requirement of the waiver process that each Member State must individually apply for a waiver. Cf. WTO Secretariat note 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Information on Waivers' (24.10.2002) IP/C/W/387 p. 3.

tion and thus the only two immediately able to take advantage of the Extension.[754] As Article 66 of the TRIPS Agreement is not constrained by the 'freezing clause' contained in Article 65.5,[755] LDCs with patent protection for pharmaceutical products are entitled to amend their intellectual property system so as to exclude such pharmaceutical products from being patented.

The extent to which the Extension will be exercised is yet to be seen. A prime candidate for the use would have been Mozambique. In attempts to come to grips with its public health problems Mozambique, a LDC and a country struggling with HIV/AIDS, has decided not to exclude pharmaceutical inventions from being patented but have instead proceeded to grant a compulsory license, a choice that marks the easiest method to obtain medication currently.

Paragraph 7 of the Public Health Declaration and subsequently paragraph 2 of the Extension explicitly note that in addition to the agreed extension, LDC Member States are still permitted to apply for an extension to the transitional arrangements above and beyond those contained in paragraph 7 of the Public Health Declaration. The inclusion of this provision is to reaffirm that Member States are not prohibited from applying for additional extensions beyond the scope of the Public Health Declaration. Accordingly, LDCs are still able to apply for extensions to the implementation of other obligations arising out of the TRIPS agreement.[756]

3. The General Council waiver of Article 70.9

The lack of a reference in paragraph 7 of the Public Health Declaration to the exclusive marketing rights that accrue under Article 70's mailbox system posed a problem for LDCs negotiating the paragraph 7 extension.[757] The LDCs' problem with the mailbox system stemmed from the obligation on those Member States not granting pharmaceutical and agricultural chemical inventions patents to grant such inventions exclusive marketing rights for a period of 5 years after obtaining marketing approval. This restriction was interpreted as applying to those Member States wanting to exercise the paragraph 7 Extension. Were this obligation to apply it to LDCs this would effectively mean that the concessions obtained in the Public Health Declara-

754 The countries are Angola and Eritrea. Cf. *Thorpe*, CIPR Study Paper 7 (2002) p. 11. Other LDCs from other continents that might be able to take advantage of the Extension include Afghanistan, Cape Verde, Comoros, Lao PDR, Maldives and Sao Tome and Principle.

755 Art 1.1 of the TRIPS Agreement states that Member States are not required to implement an intellectual property rights system that is more extensive than is required by the TRIPS Agreement.

756 *Baker*, Process and Issues for Improving Access to Medicines: Willingness and Ability to use TRIPS Flexibilities in Non-Procuring Countries (Fretwells London 2004) p. 14.

757 TRIPS Agreement Arts 70.8 and 9. Cf. *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 41.

tion could be 'effectively blocked' by the inventors exercising a quasi-patent right and a 5 year market monopoly.[758]

The momentum that carried the adoption of the Public Health Declaration and the Extension was used to adopt a waiver of Article 70.9. The Article 70.9 waiver was formulated in a manner that would ensure it corresponded to the Extension. To this effect, the Article 70.9 will be waived until the 1st of January 2016. [759]

However, like the Extension, a LDC Member State is not obliged to exercise the Article 70.9 Waiver. Its use is voluntary and does not require a notification of its use to the TRIPS Council or any other WTO body. It is also noteworthy that the Article 70.9 Waiver is only for the obligations contained in Article 70.9 and not for Articles 70.8 and 70.9, as initially proposed by LDC Member States in the consultations undertaken prior to its adoption.[760] The Swiss representative questioned whether a waiver of both Article 70.8 and 70.9 were necessary. Switzerland took the view that whereas exclusive marketing rights (Article 70.9) might restrict the implementation of the Extension, the mailbox system itself would not limit a LDC Member State's ability to acquire, manufacture and/or sell pharmaceutical products.[761] In the 'spirit of compromise and cooperation' and the fear that the issue would drag on otherwise, LDC Member States settled on a waiver of Article 70.9 alone.[762] Therefore, the exclusion of Article 70.8 from the waiver requires all Member States not granting pharmaceutical product inventors patents to implement a system that would enable these inventors to acquire a filing date for their inventions. Aside from the administrative obligations that flow from the implementation of Article 70.8, LDC Member States are likely to profit from the mailbox system for a number of reasons: Firstly, the Member States could require registration fees. Secondly, the implementation of the mailbox will permit such states time and experience in a 'patent-like' system. This would likely assist such states to have a put into place a functioning registration system in place prior to 2016 and which can be used subsequently for patent applications. Lastly, such Member States will have access to the information disclosed at the time of the mailbox application. This information would automatically serve to enrich domestic know-how.

758 Compare *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 41.

759 The waiver was finally adopted by the WTO General Council on 8.7.2002. Cf. Decision of the WTO General Council 'Least-developed country Members – Obligations under Article 70.9 of the TRIPS Agreement with respect to pharmaceutical products' (08.07.2002) WT/L/478 ('Article 70.9 Waiver').

760 The Chairman and Senegal, on behalf of the LDC Member States, in the TRIPS Council Minutes (18.07.2002) IP/C/M/36 p. 48, 49.

761 Switzerland in the TRIPS Council Minutes (18.07.2002) IP/C/M/36 p. 48-49. This standpoint was also mirrored by the EC and the US, p. 50.

762 Uganda, on behalf of the LDC Member States, in the TRIPS Council Minutes (18.07.2002) IP/C/M/36 at 53. Cf. ICTSD 'TRIPS Council Agrees on Extension for LDCs on Pharmaceutical Patents' *Bridges Weekly Trade News Digest* (03.07.2002) p. 1.

IV. Member States without domestic pharmaceutical production facilities

There was a general willingness amongst the WTO Member States to find a solution to the inability some Member States had in exercising compulsory licenses where they had no domestic production facilities to exercise the compulsory license. This willingness to find a solution stalled at the question of how the solution should be structured. Despite numerous suggestions[763] no solution could be reached at the Doha Ministerial Conference. To ensure that the matter did not fall from the negotiating table the Member States agreed that the negotiations should proceed in order to 'find an expeditious solution to this problem and to report to the General Council before the end of 2002'.[764]

Although there are numerous grounds that can be attributed to why Member States were not able to reach a solution at the Doha Ministerial Conference, the reality of the matter was that the negotiations on the issue raised its head relatively late in the pre-Doha negotiations and, despite the complexity of the issue, were only superficially discussed.[765] This length of time was insufficient to enable the Member States to find a solution that would address what some Member States saw as a shortcoming of the TRIPS Agreement and what others saw as a potential dissolution of certain fundamental intellectual property issues.[766] The Member States were however able to agree that the dilemma, then set out in paragraph 6 of the Public Health Declaration,[767] required further negotiations.

763 WTO Communication from the EC 'The Relationship between the Provisions of the TRIPS Agreement and Access to Medicines' (12.06.2001) IP/C/W/280 at 3-4, Malaysia, Tanzania (on behalf of the LDCs), Hungary in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 18, 29, 56, respectively WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 8.

764 Public Health Declaration para 6.

765 Norway stated in the pre-Doha negotiations that Art 31(f) 'raises many important questions, most of which cannot be dealt with in-depth at this stage'. Cf. Norway in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 at p. 17. The minutes of the TRIPS Council in September of 2001 also reflect the infancy of the discussions on the Art 31(f) dilemma.

766 The issues of territoriality, independence of patents (Art 4bis of the Paris Convention), exhaustion and safeguards all played a role in negotiating a solution to the para 6 dilemma.

767 Paragraph 6 of the Public Health Declaration states: 'We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.'