

compulsory licenses in these countries toothless and ineffective.⁶⁵⁰ This problem is amplified by the fact that Article 31(f) of the TRIPS Agreement prevents these predominantly poor or small countries from having their compulsory license worked in a third country.⁶⁵¹ Although being aware of this technical quandary in the negotiations preceding the Doha Ministerial Conference,⁶⁵² the Member States were unable to reach an agreement on how the problem should be solved.⁶⁵³ To rectify this, the Member States issued a formal instruction ‘to find an expeditious solution’ to the problem of local use of compulsory licenses within the context of pharmaceuticals.

III. The postponed implementation of certain TRIPS-obligations

Article 66.1 of the TRIPS Agreement acknowledged that LDCs would require additional transitional periods for the enforcement of all TRIPS obligations. Economic, financial and administrative constraints made the implementation of intellectual property rights problematic, especially where the lack of a viable technology base would render these countries more dependent on foreign products. Article 66.1 of the TRIPS Agreement permitted the 10 year transition period – expiring in 2006 – to be extended on making a ‘duly motivated’ request by individual countries. It was however clear in the negotiations preceding the Doha Ministerial Conference that the LDCs were not in the ‘economic, financial and administrative’ position to implement the remaining TRIPS obligation,⁶⁵⁴ especially when faced with the constraints they would impose on the access to pharmaceutical products.⁶⁵⁵ Despite initial opposition,⁶⁵⁶ the developed Member States concurred that LDCs should be afforded more time to implement the TRIPS Agreement. To this effect the Member States at the Doha Ministerial Conference agreed that a further 10 year extension be

650 The option to grant a compulsory license for the importation of pharmaceutical product remains a theoretically valid option. With the global scope of patent protection, especially after the transitional periods expired in 2001 and 2005, the availability of off patent versions of the sought products will progressively wane.

651 Compare Chapter 5(C)(III)(3)(h) above. Cf. *Gregg Bloche*, 5 JIEL 4 (2002) p. 840.

652 The EC submission was first to formally note that Art 31(f) may pose a problem for supplying foreign market without adequate domestic pharmaceutical production facilities. This was followed shortly thereafter by a submission from the developing countries group. Cf. 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 p. 3, WTO Submission by Brazil and others to the TRIPS Council ‘TRIPS and Public Health’ (29.6.2001) IP/C/W/296 p. 8.

653 *Straus*, Patentschutz durch TRIPS-Abkommen – Ausnahmeregelungen und –praktiken und ihre Bedeutung, insbesondere hinsichtlich pharmazeutische Produkte in Bitburger Gespräche Jahrbuch 2003 (CH Beck Munich 2003) p. 128-129.

654 WTO Submission by Brazil and others to the TRIPS Council ‘TRIPS and Public Health’ (29.6.2001) IP/C/W/296 p. 9.

655 Compare Zimbabwe in TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 46. Contrast *USTR*, Special 301 Report (2006) p. 11.

656 Compare Australia, EC in TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 56, 58.

given to LDCs with respect to pharmaceutical products. The Public Health Declaration instructed the TRIPS Council to give effect to this concession.

B. *The legal status of the Public Health Declaration*

The Public Health Declaration, like the Doha Ministerial Declaration,⁶⁵⁷ was adopted by the WTO Member States at the Doha Ministerial Conference in November 2001.⁶⁵⁸ Although separate documents, both Declarations were adopted by a consensus decision of the Ministerial Conference – the core decision making body at the WTO.⁶⁵⁹

The Public Health Declaration was hailed as a political success at the Doha Ministerial Conference. However, before the dust could settle, questions arose concerning the precise effect of the Public Health Declaration.⁶⁶⁰ In the years that followed much was written and said about the legal status of the Public Health Declaration – much of it sought to ignore the public law realities of the document and grant it an extraordinary legal status.⁶⁶¹ Viewed from a legal standpoint, the Public Health Declaration will only constitute an original source of WTO law if it was granted such.⁶⁶² As the WTO does not accord ministerial declarations any specific legal status⁶⁶³ it must be determined whether the consensus achieved at Doha has fulfilled any other requirements that afford binding consequences. Under the WTO Agreement and international treaty law the Ministerial Conference is empowered to make decisions

657 WTO Ministerial Declaration (20.11.2001) WT/MIN(01)/DEC/1 ('Doha Ministerial Declaration').

658 A similar course was used in both the Singapore and Geneva Ministerial Conferences. Cf. WTO Ministerial Declaration on Trade in Information Technology Products (13.12.1996) WT/MIN(96)/16, WTO Ministerial Declaration on Global Electronic Commerce (25.05.1998) WT/MIN(98)/DEC/2.

659 WTO Agreement Art IV, IX.

660 *Davey*, Institutional Framework in Macrory, Appleton and Plummer (eds) *The World Trade Organisation: Legal, Economic and Political Analysis* (Springer New York 2005) vol 1 p. 63, *Hestermeyer*, 37 GRURInt 3 (2004) p. 196. The EC and US view on the binding nature of the separate declaration was at times diametrically opposed. The then USTR Zoellick referred to the Public Health Declaration a 'landmark *political* declaration on the TRIPS Agreement and public health' (emphasis added). The EC on the other hand were initially unwilling to conclude a separate declaration on the grounds that an independent declaration might be assumed to have more weight than the principal Ministerial Declaration. Cf. EC in TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 58.

661 The political consequences of the Public Health Declaration are not doubt as important as the legal consequences. A political evaluation of the Public Health Declaration is however beyond the scope of this dissertation.

662 *Gregg Bloche*, 5 JIEL 4 (2002) p. 842, *Matsushita et al*, *The World Trade Organization: Law, Practice, and Policy* (2nd edn OUP Oxford 2006) p. 37.

663 *Correa*, *Implications of the Doha Declaration in the TRIPS Agreement and Public Health* (WHO Geneva 2002) p. 44.