

F. Related measures taken to reflect the Public Health Declaration

The reaction to the Public Health Declaration and the subsequent TRIPS decisions has been multifarious. National governments have taken steps to alter their domestic policies and legislation, countries interacting with one another have reflected the policies of the Public Health Declaration either expressly or tacitly and international bodies have recognised the contents in one way or the other. A brief sampling of the measures taken is dealt with below.

I. International and multilateral policies and measures

International bodies such as the WHO Assembly and the UN Commission on Human Rights have been vocal on propagating the use of the TRIPS flexibilities.¹⁰⁶² In the May of 2004 the WHO Assembly, whilst taking into account the Public Health Declaration and the Decision, urged countries as ‘a matter of high priority’:

‘to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights;

...

to encourage that bilateral trade agreements take into account the flexibilities contained in the WTO TRIPS Agreement and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health’.¹⁰⁶³

International bodies have also taken the view that the Public Health Declaration has clarified the use of compulsory licenses and that Member States can take compulsory license measures without fear of threats or reprisals from industry or foreign governments.¹⁰⁶⁴

II. Bilateral policies and measures

The move towards more comprehensive bilateral trade relationships has resulted in the negotiating parties often including obligations on intellectual property rights. This has especially been evident in bilateral free trade agreements involving the

1062 WHO World Health Assembly Resolution ‘Global Health-sector Strategy for HIV/AIDS’ (28.05.2003) WHA56.30 at 2, UNCHR Res 2004/26 ‘Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria’ (16.04.2004) UN Doc E/CN.4/2004/L.11/Add.3 p. 58.

1063 WHO World Health Assembly ‘Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS’ (22.04.2004) WHA57.14 p. 3-4.

1064 *WHO/WTO, WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat* (WTO Secretariat Geneva 2002) p. 16.

US.¹⁰⁶⁵ The US has progressively sought to negotiate commitments from the other parties that exceed the obligations found in the TRIPS Agreement.¹⁰⁶⁶ These so-called 'TRIPS-plus' obligations were criticised as a tactic by the US to achieve its goal of higher intellectual property protection through direct pressure.¹⁰⁶⁷ Critics, including the UN special human rights Rapporteur Paul Hunt, warned that the conclusion of such TRIPS-plus agreements would 'water-down internationally agreed health safeguards'.¹⁰⁶⁸ In some cases activists campaigning for access to health felt that the TRIPS-plus FTAs could dissolve current HIV/AIDS medication programmes.¹⁰⁶⁹ The opposition to the TRIPS-plus commitments reached such a level that some countries negotiating FTAs with developed countries have suspended or refused to conclude such trade agreements containing intellectual property obligations in excess of the TRIPS Agreement.¹⁰⁷⁰ To allay these concerns, the US has agreed to enter into a 'side letter' or 'understanding' with the relevant FTA partner wherein the parties recognise their commitment to the Public Health Declaration and the Article 31*bis* provisions.¹⁰⁷¹ The agreements note that the FTA chapter on intellectual property rights 'do not affect a Party's ability to take necessary measures to protect public health by promoting access to medicines for all'.¹⁰⁷² Further, the FTAs expressly state that they will not prevent a party to the FTA to make effective utilisation of the Decision.¹⁰⁷³ The supplementary agreements do not however mean that the FTA intellectual property provisions are subservient to the provisions and poli-

1065 Compare *Correa*, GRAIN (2004) p. 3-9.

1066 For example the application of the utility requirement as addressed in the US-Australian FTA. Cf. *Straus*, TRIPS, TRIPS-plus oder TRIPS-minus – Zur Zukunft des internationalen Schutzes des Geistigen Eigentums in: *Ohly et al* (eds) *Perspektiven des Geistigen Eigentums und Wettbewerbsrechts* (CH Beck Munich 2005) p. 206-207.

1067 ICTSD 'IP Standards in US-Peru FTA to Affect Talks with Columbia and Ecuador?' *Bridges Weekly Trade News Digest* (25.01.2006) p. 4.

1068 ICTSD 'Concerns Raised Over Access to Medicines Under Trade Treaties' *Bridges Weekly Trade News Digest* (14.07.2004) p. 4.

1069 Human Rights Watch, (2002).

1070 For example South Africa who refused incorporate TRIPS-plus obligations in a FTA with the EFTA. A group of minister representing 10 South American countries issued a joint declaration in which they committed themselves to avoid TRIPS-plus commitments in bilateral and regional trade agreements. They were Argentina, Bolivia, Brazil, Chile Columbia, Ecuador, Paraguay, Peru, Uruguay and Venezuela. Cf. *Khor*, South American Ministers Vow to Protect Access to Medicines IRC Americas Program Report (15.06.2005).

1071 The US has concluded 7 FTA s since 2002; those with Singapore and Australia do not contain any references to the Public Health Declaration. The remaining 5 do; either as a side letter or understanding or references are made within the body of the FTA. They are Bahrain, Chile, the CAFTA states (Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras and Nicaragua), Morocco and the Oman. The side letters and understanding are almost identical in content. Only the US/Chile FTA refers to the Public Health Declaration in the preamble of the chapter on intellectual property rights. This FTA was signed in 2003 and predates the Decision. Compare *Roffe*, 8 *Bridges* 7 (2004) p. 17-18.

1072 CAFTA Understanding Regarding Certain Public Health Measures (05.08.2004).

1073 The US/Chile FTA also expressly permits Bolar-type exceptions. Cf. *UNCTAD/ICTSD*, Resource Book on TRIPS and Development (CUP New York 2005) p. 444-445.

cies of the Public Health Declaration and Article 31*bis*. The FTAs instead contains limits that restrict the application of the TRIPS Agreement and the Public Health Declaration.¹⁰⁷⁴ As an example, the title of the US/central American FTA understanding on public health clearly states that it only applies to ‘certain public health measures’.¹⁰⁷⁵ Further, the FTAs refer to the Decision/Article 31*bis* and the Chairman’s Statement as being ‘the TRIPS/health solution’.¹⁰⁷⁶ The US’s desire to afford the Chairman’s Statement as being an integral part of the Decision is evident in its FTAs. In addition to the specific references to the Public Health Declaration in supplementary agreements, the US has also sought to reduce the flexibilities permitted in the TRIPS Agreement. To this extent the US has sought, *inter alia*, better/TRIPS-plus protection for undisclosed data,¹⁰⁷⁷ fewer patentability exclusions, patent protection for new uses of known patents, patent term extensions, the exclusion of parallel imports and limited grounds for compulsory license.¹⁰⁷⁸ Commenting on the US’s use of these provisions, *Abbott* stated that:

‘the provisions relating to patents and regulatory approvals with respect to medicines ... are intended to restrict the flexibilities inherent in the TRIPS Agreement, Doha Declaration and Decision on Implementation of Paragraph 6... They appear designed to negate the effective use of compulsory licensing by blocking the marketing of third party medicines during the term of patents’.¹⁰⁷⁹

Not all states in negotiations for a FTA with the US have succumbed to the pressure and appeal of the FTA. In some cases they have stalled the negotiations, as is the case with SACU. SACU officials doubted whether the high-level US intellectual property standards they were ‘appropriate’ for developing countries.¹⁰⁸⁰

1074 *Abbott*, 99 AJIL 2 (2005) p. 352.

1075 The USTR Special 301 Report notes that although the US supports the flexible interpretation of the TRIPS Agreement they should only be used to ‘address *serious* public health problems’ (emphasis added). Cf. USTR, Special 301 Report (2006) p. 10.

1076 Compare USTR, Special 301 Report (2006) p. 11.

1077 Not all data exclusivity provisions in the US FTAs are subject to public health understandings. Cf. ICTSD ‘IP Standards in US-Peru FTA to Affect Talks with Columbia and Ecuador?’ *Bridges Weekly Trade News Digest* (25.01.2006) 5.

1078 *Straus*, TRIPS, TRIPS-plus oder TRIPS-minus – Zur Zukunft des internationalen Schutzes des Geistigen Eigentums in: *Ohly et al* (eds) *Perspektiven des Geistigen Eigentums und Wettbewerbsrechts* (CH Beck Munich 2005) p. 206, *Abbott*, 99 AJIL 2 (2005) p. 350.

1079 *Abbott*, Quaker Paper 14 (2004) p. 12.

1080 ICTSD ‘Southern African Countries Reject ‘TRIPS-Plus’ Demands in FTA Negotiation’ *Bridges Weekly Trade News Digest* (09.03.2005) 5. *Abbott* notes that there is growing concern about the US’s approach to including intellectual property rights in bilateral FTAs. Cf. *Abbott*, 99 AJIL 2 (2005) p. 349. *Abbott* also remarks that whilst the US FTA standards reflect US legal standards, they fail to include the safeguard provisions found in US law. Cf. *Abbott*, UNCTAD-ICTSD Issue 12 (2005) p. 20. The EC has also called upon the US to refrain from impinging on the Public Health Declaration’s provisions in bilateral agreements. Cf. -- ‘EU criticizes USA TRIPS+ drive’ *E-Drug* (15.07.2004).

III. National policies and measures

The first developed Member State to adopt measures that reflect the Public Health Declaration was Belgium. In 2004 the Belgium legislature introduced for the first time a compulsory license to remedy possible access problems in the field of health care. The public health compulsory license made express reference to the TRIPS Agreement and the Public Health Declaration.¹⁰⁸¹ Its scope reflects a liberal reading of the TRIPS Agreement and makes use of the flexibilities found therein. The compulsory license does not however extend to compulsory licenses for export to countries without their own production facilities.

An example of the consequences the TRIPS Agreement and the Public Health Declaration has had on developing countries can be seen in the case of Ghana. With the expiry of the transitional periods in the TRIPS Agreement Ghana brought its patent system in line with the TRIPS standards.¹⁰⁸² Simultaneously, Ghana took advantage of the flexibilities mentioned in the Public Health Declaration to ensure the patent system would not ultimately stand in the way of its public health measures. Measures legislated include:

- The parallel importation of pharmaceuticals put onto any market with the patent holder's consent (i.e. international exhaustion system)¹⁰⁸³
- Compulsory licenses to remedy abusive patent practices and excessive prices¹⁰⁸⁴
- Compulsory licenses for insufficient local working of the patent¹⁰⁸⁵
- Administrative guidelines for determining 'adequate remuneration' for compulsory licensed patents¹⁰⁸⁶ and
- Shortened the compulsory license process by entitling licenses to be granted by ministerial authorisation.¹⁰⁸⁷

Other Member States have taken more direct measures to gain access to compulsory licensed pharmaceuticals. Zimbabwe, for example, declared a state of emergency allowing the state or its authorised agent to domestically 'make or use any patent ... used in the treatment of persons suffering from HIV/AIDS'.¹⁰⁸⁸ The state of emergency further permits the importation of any generic drug for these pur-

1081 *Van Overwalle*, 37 IIC 8 (2006) p. 908-909.

1082 Ghanaian Patent amendment act no. 657 of 2003. Ghana, for example, did away with the powers to temporarily exclude the patenting of pharmaceuticals (formally sec 8) and licenses of right (formally sec 54).

1083 *Cohen et al*, 1 Globalization and Health 17 (2005) p. 5-6.

1084 *Cohen et al*, 1 Globalization and Health 17 (2005) p. 5.

1085 Adequate importation will also fulfil the local working requirement. Cf. *Cohen et al*, 1 Globalization and Health 17 (2005) p. 5.

1086 *Cohen et al*, 1 Globalization and Health 17 (2005) p. 4.

1087 *Cohen et al*, 1 Globalization and Health 17 (2005) p. 5.

1088 Declaration of Period of Emergency (HIV/AIDS) Notice 2002 (24.05.2002) sec 2(a). The emergency was declared for a period of 6 months.