

International Trade in Pharmaceutical Products and the GATT 1994: The Case of Traditional Medicine

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WTO law has large implications for health policies in both industrialized and developing countries. This article provides an overview on the regulatory principles of the GATT 1994 on market access for pharmaceutical products in terms of tariffs and non-tariff barriers. These principles relevantly impact the international promotion and commercialisation of traditional medicine. The article critically assesses the legal state of the art and proposes interesting policy options.

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* Many thanks go to Dr. Marion Panizzon, World Trade Institute, Berne, for her critical comments and help.

I. Introduction

Over the last few years, the use of traditional medicine has been steadily growing around the globe. WHO statistics estimate that 80 per cent of the population in Africa rely on traditional medicine for their primary health-care needs.¹ Equally, traditional medicine – or, as often used interchangeably, complementary and alternative medicine – is becoming increasingly popular in developed countries.² In Switzerland, approximately half of the population occasionally uses some form of medical treatment which is not based on modern science but on traditional knowledge and wisdom, mainly homeopathy and acupuncture. Furthermore, traditional medicines, which are often based on traditional knowledge, are valuable for many other reasons. Traditional knowledge forms an integral part of the conservation and further development of the world's biological resources; it is of prime importance for the livelihood of indigenous and local communities as well as for a great number of people living in subsistence economies who depend on biodiversity for their day-to-day survival.³

Various international agreements constitute the relevant law concerning trade in pharmaceutical products in general and traditional medicines – as a relatively new field of interest – in particular.⁴ Amongst them is the WTO. Its regulatory principles on market access for goods in terms of tariffs and non-tariff barriers as well as its provisions for the protection of intellectual property rights have large implications for health policies in both developed and developing countries.⁵ Entangled in a complex web of international organizations and agreements, the WTO is one of the most influential agencies in this field – yet, its likely impact on the protection of, and the enhancement of market access for, traditional medicines has not been given much attention to date. In scholarly writings, it is generally the WTO's rules on the protection of intellectual property rights which are at the forefront of debate (and criticism).⁶ Pertinent questions about the safety and efficacy of traditional medicines

1 See for definitions World Health Organization, WHO Traditional Medicine Strategy 2002-2005, WHO, 2002, at 1. The first contribution in this book also provides a helpful overview on the various definitions.

2 World Health Organization (*supra* fn. 1), at 7.

3 SUSETTE BIBER-KLEMM/DANUTA SZYMURA BERGLAS, Problems and Goals, in: Susette Biber-Klemm/Thomas Cottier (eds.), *Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives*, Oxfordshire, CABI, 2006, 3-55, at 21.

4 See for an overview on the law on traditional knowledge SUSETTE BIBER-KLEMM/THOMAS COTTIER/PHILIPPE CULLET/DANUTA SZYMURA BERGLAS, in: Susette Biber-Klemm/Thomas Cottier (eds.) (*supra* fn. 3), 56-111.

5 See MIKE ROWSON, *World Trade Organisation: Implications for Health Policy*, Medact, 2000, at 2.

6 See Ingo Meitinger's contribution to this book.

and hence about their international commercialisation, however, reach beyond the scope of intellectual property protection. Main obstacles to their adequate promotion are likely to result from – often only *prima vista* legitimate and necessary – technical barriers to trade as questions of safety and efficacy are far from resolved. Moreover, a (too) restrictive interpretation of ‘like products’ prevents governments from privileging traditional medicines over their conventional counterparts by, e.g., subjecting them to different internal taxation and other regulatory measures.

This paper examines the GATT 1994 regulatory framework and its relevance for trade in pharmaceutical products. It does so with a special focus on traditional medicines, aiming at identifying the main problems and at providing inputs for further research. By way of introduction, Part II deals with market access in general and turns to tariffs, being the oldest and still most common instrument at the disposition of nation states to regulate the importation, and sometimes the exportation, of goods. Moreover, the potential of privileged market access for developing and least-developed countries’ products to developed countries’ markets is examined. Part III turns to the basic principle of non-discrimination. In particular the scope and contours of the term ‘like products’, finding itself at the heart of any discussion on non-discrimination, informs national policy-makers and shapes their freedom to treat traditional medicines more favourably than conventional products. The question arises whether preferential rules can be contemplated, in terms of domestic taxation and market regulations, for traditional medicines based upon a less conservative reading of the term ‘like products’ than that usually applied in WTO jurisprudence. Part IV addresses technical barriers to trade and sanitary and phytosanitary measures which represent, in addition to tariffs and quantitative restrictions, the two other classical instruments applied to the importation and exportation of goods at the border. The policy of tariff reduction has given rise to this new generation of trade restrictions which are more difficult to regulate and explain why defining market access has become truly complex. Lastly, Part V provides a short outlook.

Importantly, the object of WTO law is limited to governmental measures. Rights and obligations inherently do not extend to the conduct of non-state actors, in particular private firms. They are not directly entitled and obliged under the WTO. Even if governmental barriers to trade are removed for products, private conduct may still have the potential to offset the benefits of such actions, which aim at levelling the playing field, through private anti-competitive behaviour if the involved enterprises’ (combined) market power suffices to counteract governmental policies. Trade in pharmaceutical products is a prominent example in point as mergers between powerful global players or cartels (e.g., price fixing for vitamins) have frequently

demonstrated in the past.⁷ At this stage, WTO law does not address domestic competition policies affecting international trade such as cross-border mergers and acquisitions and export or import cartels. This is unsatisfactory. The introduction of regulatory guidelines for members' competition policies into the WTO is a necessity if the effectiveness of the regime is to be maintained.

II. Market Access and Tariffs

The multilateral trading regime of the WTO is founded on the theory of comparative advantage according to which open markets with low tariffs, coupled with the absence of subsidies and other non-tariff barriers, lead to increased trade across national borders and bring about prosperity, growth and poverty alleviation.⁸ This theory forms the conventional background against which the normative arguments for the case of liberal trade policies and the caveats of free trade are shaped. The Preamble to the WTO explicitly stipulates that its regulatory framework is based upon the idea of progressive liberalisation and the elimination of discriminatory treatment in international commerce. Hence, the GATT 1947/WTO provides a legal framework for gradually reducing tariffs and preventing or remedying circumvention of tariff cuts from indirect erosion and evasion, e.g. through the adoption of quantitative restrictions and discriminatory internal measures. Over the last fifty years, it has indeed been successful in achieving this goal.⁹

However, the WTO does not simply amount to a free trade agreement as such. It explicitly recognises the legitimacy of other policy goals and of the need to strike a proper balance between the interest of market access and that of domestic production.

7 See MITSUO MATSUSHITA/THOMAS J. SCHOENBAUM/PETROS C. MAVROIDIS, *The World Trade Organization: Law, Practice, and Policy*, Oxford, Oxford University Press, 2003, at 541-45.

8 THOMAS COTTIER/MARION PANIZZON, *Enhancing Market Access*, in: Susette Biber-Klemm/Thomas Cottier (eds.) (supra fn. 3), 357-91, at 361; see for an overview on economic theories in international trade THOMAS COTTIER/MATTHIAS OESCH, *International Trade Regulation: Law and Policy in the WTO, the European Union and Switzerland*, Cases, Materials and Comments, London/Berne, Cameron May/Staempfli Publishers Ltd., 2005, at 33-43.

9 The average tariff rate in the industrial sector among developed GATT Contracting Parties amounted to 40% in 1947 and could be reduced, in several multilateral trade rounds, to 4% at the end of the *Uruguay Round* in 1995; see COTTIER/OESCH (supra fn. 8), at 74.

A. Functions of Tariffs

In pursuing policy goals other than trade liberalisation, tariffs remain, in principle, the basic trade policy instruments at the disposition of governments. Unlike quantitative restrictions, which are essentially banned under Article XI of the GATT 1994, tariffs are neither excluded nor abolished under WTO law. Nor are members barred from raising tariffs if they wish to do so, though not without offering compensation above the limits set forth in their schedules of commitments pursuant to Articles II and XXVIII of the GATT 1994. WTO law clearly favours tariffs over other trade-restrictive measures. The rationale for preferring tariff protection over all other types of trade barriers imposed at the border is well known: tariffs are the trade instrument, which is most closely related to the price of a product, and thus do not distort the international allocation of resources and the mechanisms of comparative advantage.¹⁰ Moreover, tariffs offer the advantages of legal security and predictability as potential traders can readily anticipate the costs of importation and exportation and thus of market access. Therefore, WTO law conceptually considers trade restrictions other than tariffs exceptional.

Beside of considerations of economic theory, tariffs have traditionally been relevant for another reason. For many centuries, they were and, for developing countries in particular, still are a main instrument of fiscal revenue (*fiscal tariffs*). Tariff collection at the border is simple and effective, compared to sophisticated domestic taxation. Article XXVIII^{bis}:3 of the GATT 1994 and a corresponding note explicitly recognise the needs of developing countries “to maintain tariffs for revenue purposes” and require the WTO membership to take into account their fiscal (as well as developmental, strategic and other) needs in tariff negotiations. As economies grow and domestic taxation develops, the fiscal importance of tariffs gradually diminishes and is replaced by their significance as instruments of economic policy (*protective tariffs*). In South Africa, for instance, customs and excise revenue still represented approximately 17 per cent of the total tax revenue at the end of the last decade, whereas such revenue is almost negligible for a country such as Switzerland.¹¹ At the same time, Switzerland strongly benefits of the protective function of tariffs as it still maintains

10 See BERNHARD HOEKMAN/CONSTANTINE MICHALOPOULOS/ALAN L. WINTERS, Special and Differential Treatment for Developing Countries: Towards a New Approach in the World Trade Organization, Worldbank Policy Research Working Paper No 3107, 1 August 2004, at 17; FRANCIS PERKINS, Africa's Agricultural Trade Reform and Development Options, The South African Institute of International Affairs, Trade Policy Briefing No 1, June 2003, at 3.

11 WTO Trade Policy Review: Republic of South Africa, Report by the Secretariat of 6 April 1998, WTO Doc. WT/TPR/S/34, at 38.

an average tariff of 36.2 per cent on imports of agricultural products (compared to 2.3 per cent on non-agricultural products).¹²

B. Tariffs on Pharmaceutical Products

Tariffs on pharmaceutical products are a special case. During the *Uruguay Round* negotiations, some 22 countries agreed to completely eliminate tariffs on pharmaceutical products and on certain derivatives and chemical intermediates used in the production of pharmaceutical products.¹³ The products concerned are items mainly classified in Chapter 29 (organic chemicals, tariff lines 2936, 2937, 2939 and 2941) and 30 (pharmaceutical products) of the Harmonized Commodity Description and Coding System of 1983 (HS). Moreover, the initiative applies to various 'international non-proprietary names' (INNs) which are classified in various chapters throughout the Harmonized System. At the time of writing, the EC member states, the United States, Canada, Japan, Norway, Switzerland and (at least partly) Australia participate in this sectoral initiative which has become known as the *Zero-for-Zero Initiative on Trade in Pharmaceutical Products*. It came into effect with the creation of the WTO in 1995 and effectively eliminated tariffs in the signatory countries on more than 7'000 pharmaceutical products, derivatives and chemical intermediates. Ever since, the signatories have been meeting once every three years to review the product coverage with a view to eliminating, by consensus, tariffs on additional and newly developed pharmaceutical and related products. In essence, this initiative was an efficient tool to bring about substantial tariff reductions among major trading players (prime supplying and importing countries) in the field of pharmaceutical products.¹⁴ Of course, this plurilateral negotiating package is subject to the principle of most-favoured-nation (MFN) treatment and thus benefits all WTO members alike, without requiring reciprocity.¹⁵ Therefore, developing countries' exports of pharmaceutical products to many developed countries do not face, with respect to tariff burdens, serious market access handicaps. As traditional medicines are in most cases considered to be pharmaceutical products under the Harmonized System, they equally profit from enhanced market access to the signatories of the plurilateral initiative. Some traditional medicines, however, might fall under HS tariff heading 2106 (food preparations), as they might be considered agricultural rather

12 WTO Trade Policy Review: Switzerland and Liechtenstein, Report by the Secretariat of 17 November 2004, WTO Doc. WT/TPR/S/141, at 46 (the maximum rate being 1'705 per cent for out-of-quota imports of edible bovine offal).

13 GATT Doc. L/7430; see ANWARUL HODA, *Tariff Negotiations and Renegotiations under the GATT and the WTO*, Cambridge, Cambridge University Press, 2001, at 81-2.

14 Besides pharmaceutical products, plurilateral negotiations during the Uruguay Round resulted in substantial reductions in tariffs on chemical products, medical equipment and information technology products.

15 See for the principle of MFN treatment below III.A.

than pharmaceutical products, and thus face high levels of tariff protection still maintained by many developed countries in the field of agricultural products.¹⁶

Parallel to the successful plurilateral negotiations, tariffs are equally decreasing for pharmaceutical products among those WTO members which have not signed the *Zero-for-Zero-Initiative*.¹⁷ Average tariffs on pharmaceutical products are generally low or moderate in the developing world, with the exception of only a few (but economically attractive) countries such as India, Brazil and Tunisia (applied tariffs of approximately 12.5-15 per cent, 12-14 per cent and 20-43 per cent, respectively).¹⁸ The same holds true for active ingredients that go into the manufacture of pharmaceuticals, as some developing countries have average tariffs in the range of 20 to 30 per cent for such products (e.g., Burkina Faso, Pakistan, Tanzania, India, Kenya and Tunisia).¹⁹ At least some developing countries allow a limited number of essential drugs to enter duty free. Overall, there appears to be some scope for further lowering tariffs on health-related products. For instance, WHO statistics on barriers to trade in anti-malaria supplies show that tariffs on mosquito nets and insecticides in sub-Saharan African countries add 20 to 40 per cent to their prices.²⁰ South Africa has in practice eliminated almost all tariffs on pharmaceutical products and applies a zero tariff for most products falling under HS chapter 30, without having formally acceded to the *Zero-to-Zero Initiative*.²¹

C. S&D Treatment for Developing Countries

As traditional medicines are typically – although by no means exclusively – developed and used in developing countries, they might profit from WTO rules specifically drafted for their benefit. In fact, market access rights and tariff rates are not in all circumstances uniformly defined for developed and developing countries alike. Dispersed among the various agreements under the WTO umbrella are provisions providing for more favourable treatment to small and low-income countries. These provisions make up the concept known under the term of Special and Differential

16 The average EC tariff for agricultural products amounts to 16.5%, that of Switzerland to 36.2%.

17 See PIETRO FONTANA, *Ergebnisse der Uruguay Runde: Zollsenkungen, Zollbindungen und Tarifzierungen*, in: Daniel Thürer/Stephan Kux (eds.), *GATT 94 und die Welthandelsorganisation: Herausforderung für die Schweiz und Europa*, Zürich, Schulthess Polygraphischer Verlag AG, 1996, 227-253, at 249.

18 See online service at www.osec.ch/internet/zolltarife_weltweit; see also *WTO Agreements & Public Health, A Joint Study by the WHO and the WTO Secretariat*, 2002, para. 167.

19 *WTO Agreements & Public Health* (supra fn. 18), para. 167.

20 *WTO Agreements & Public Health* (supra fn. 18), para. 168. Uganda, for instance, eliminated taxes and import tariffs on mosquito nets and insecticides used to fight malaria in 2000 completely, thus responding to the pledge made by African Heads of State at the African Malaria Summit in April 2000.

21 See online service at www.osec.ch/internet/zolltarife_weltweit.

(S&D) Treatment. Originally set up in the *Tokyo Round* in 1979 and induced by the UN Conference on Trade and Development (UNCTAD), S&D rules have in the meantime become an integral “part of the WTO’s legal *acquis*”.²² S&D provisions are designed to accomplish mainly two objectives, namely to enhance market access conditions for the beneficiary countries and to exempt them from certain multilateral trade disciplines, thus giving them some flexibility in the use of trade and trade-related measures. Broadly speaking, they are intended to further the developing and least-developed countries’ integration into the multilateral trading system. In addition to granting more leniency in procedural matters (such as, for instance, longer transitional periods), some rules expressly provide for materially different treatment. With respect to traditional medicines, however, the GATT 1994 framework does not foresee specific provisions to this effect.²³

The *Generalised System of Preferences* (GSP), which permits to grant developing countries preferential market access, is one of the cornerstones of the concept of S&D treatment accorded to developing countries in the WTO. Since 1971, most OECD countries implemented GSP schemes according to a specifically drafted waiver. In the 1980ies, the waiver was superseded by the ‘Enabling Clause’ which is still valid today.²⁴ As of the date of writing, Australia, Canada, Japan, New Zealand, Norway, the United States, the European Communities and Switzerland accord preferences under the GSP to developing and least-developed countries. However, the effectiveness of current GSP schemes is increasingly doubted, as the privileges often remain without real practical impact and may be, from an economic viewpoint, even counterproductive. Four deficiencies are commonly identified. First, the WTO does not provide for a multilateral system of preferences. The current schemes are set up by each developed member on its own and do not follow common rules or guidelines. By arbitrarily granting and withholding preferences, developed countries can exert undue political leverage on developing countries. Second, rules of origin are often a prime suspect with regard to the under-utilisation of trade preferences. Beneficiaries under GSP schemes need to fulfil the requirements of the donor country’s own system of rules of origin. Third, some developed countries have

22 PETER SUTHERLAND et al., *The Future of the WTO: Addressing Institutional Challenges in the New Millennium*, Report by the Consultative Board to the Director General Supachai Panitchpakdi, WTO, 2005, para. 89; see for an overview on S&D treatment COTTIER/OESCH (supra fn. 8), at 552-74; PETER GALLAGHER, *Guide to the WTO and Developing Countries*, London, Kluwer, 2000; WILL MARTIN/ALAN L. WINTERS (eds.), *The Uruguay Round and the Developing Economies*, Cambridge, Cambridge University Press, 1995; with a particular view to traditional knowledge THOMAS COTTIER/MARION PANIZZON (supra fn. 8), at 364-74.

23 See with respect to Article 12 of the TBT Agreement below IV.A.

24 Decision of the Contracting Parties of 28 November 1979, GATT Doc. L/4903, BISD 26S/203 (1978-1979).

begun to link their GSP schemes to the furtherance of social and other policy goals and to make the availability of preferences conditional upon the fulfilment of policy goals such as environmental standards and labour rights. Fourth, it is argued that the GSP schemes in use do not adequately address those trade concerns which are most essential to developing countries such as agricultural products and textiles. With respect to pharmaceutical products (and hence also traditional medicines), the effect of tariff preferences is, in any way, reduced as tariffs are quite low in general and have been completely eliminated among the signatories to the *Zero-for-Zero Initiative*. Particular advantages and incentives to use tariff preferences are virtually lost, whereas the GSP might still provide an attractive platform to enhance market access for traditional knowledge-based products originating in developing countries as far as such products otherwise face high tariff burdens abroad.²⁵

Moreover, the GSP idea is not limited to North-South relations. The *Global System of Trade Preferences* (GSTP) permits developing and least-developed countries to maintain trade preferences with each other (South-to-South, so to speak). This scheme was, similarly to the GSP, introduced and authorised by the Enabling Clause. Upon intensive negotiations among the then-Group of 77 developing and least-developed countries, the Agreement on the Global System of Trade Preferences among Developing Countries entered into force in 1989. At the time of writing, however, only 44 countries have ratified the agreement which provides for most-favoured-nation (MFN) treatment among the signatories. With a view to the still rather high tariffs on pharmaceutical products in some parts of the developing world, the GSTP could potentially play a more significant role in granting trade preferences in this sector. Thus, the GSTP could also be an important port of entry for special rules relating to trade in traditional medicines among developing countries. In an effort to encourage trading activities, it might be possible to define traditional medicines either in terms of substance and quality or in terms of their process and production methods based upon the use of traditional knowledge or upon their impact on the conservation of biological diversity and environmental sustainability.²⁶

25 This applies, in particular, to agricultural products, see *supra* fn. 16.

26 Contrary to PPMs under the GATT 1994 in general (see below III.C.), the granting of trade preferences under the GSP/GSTP *conditional* upon the fulfilment of other policy goals not directly linked with the physical characteristics of a product is commonly considered to be consistent with WTO law, see *EC – Conditions for the Granting of Tariff Preferences to Developing Countries*, Report of the Appellate Body, 7 April 2004, WT/DS246/AB/R.

III. Basic Principle of Non-Discrimination

The basic principle of non-discrimination amounts to a constitutional cornerstone in the WTO legal framework. It forms, together with the protection of other legitimate policy goals (traditionally but inadequately dealt with under the heading of exceptions), an indispensable and constitutive element of the treaty-based multilateral trading system – and is equally relevant for any discussion of the proper treatment of traditional medicines vis-à-vis their conventional counterparts.

A. Most-Favoured-Nation and National Treatment

The two prime non-discrimination principles are that of most-favoured-nation (MFN) treatment and of national treatment (NT). They are of paramount importance and apply, in principle, across the board in WTO law.²⁷ Article I of the GATT 1994 obliges a WTO member to accord unconditionally and immediately all privileges granted to a product originating in one member state to like products originating in any other member state. Article III of the GATT 1994 applies the principle in relation to the treatment of domestic products. Upon customs clearance, all foreign products are entitled to obtain treatment no less favourable than domestic like products. Both principles are expressions, and variations, of the idea of equality and equal treatment. Economically, they seek to bring about level playing fields and fair conditions of competition for products, which have different origins, and, to some extent, even for foreign people. They serve the purpose of reducing differential treatment and discrimination which are inherent to the system of nation states and their political economy, as the identity of states and its citizens, its producers and consumers is often defined in terms of according special rights and privileges which are not extended to foreigners and foreign products.

Under general international law, states are essentially free to treat others as they deem best and to enter into any agreement of any kind and content. The sovereignty and equality of nation states entails the power to choose one partner and to discriminate the other. There are only very few limitations beyond those found in the UN Charter. Norms relating to *ius cogens* hardly affect trade relations, except for the prohibition of slavery in its different forms or policies supporting racial segregation. The principle of *pacta tertiis nec nocent nec prosunt* (a treaty must neither benefit nor impair a third party) equally is of limited effect. Short of specific treaty provisions, it certainly

27 See for these principles THOMAS COTTIER/PETROS C. MAVROIDIS (eds.), *Regulatory Barriers and the Principle of Non-Discrimination in World Trade Law: Past, Present, and Future*, Ann Arbor, The University of Michigan Press, 2000; WTO Secretariat, *The Fundamental WTO Principles of National Treatment, Most-Favoured-Nation Treatment and Transparency*, 14 April 1999, WTO Doc. WT/WGTCP/W/114.

does not limit the conclusion of preferential and discriminatory trade agreements, having the potentially distorting effect of trade diversion. Non-existent in customary international law, non-discrimination principles therefore need to be positively agreed upon among trading partners. MFN and national treatment essentially stem from the traditions of bilateral trade agreements. They can be found in agreements as early as in the 12th century and throughout trade and investment agreements of the 19th and early 20th century.²⁸ In the GATT 1947 framework, these principles were multilateralised, putting an end to policies based on bilateral reciprocity.

B. 'Like Products'

Given the radical impact of equal treatment obligations on nation states, it is apparent that they are often not given full but merely limited effect. Such limitations are inherent to the different forms and variations of equality. It all boils down to the question as to which products need in fact be treated alike. The scope and practical relevance of Articles I and III of the GATT 1994 depend to a large extent on the reading of the term 'like products'. Its definition essentially sets the benchmark for national regulatory freedom to treat imported products differently from domestically produced as well as to differentiate between products of different foreign origin. Not astonishingly, the matter is at the heart of WTO law and policy, and much attention has been paid to it in jurisprudence and literature. In 1970, the Border Tax Adjustment Working Party provided the starting point for the analysis of likeness when it established the relevant criteria in order to define permissible internal tax adjustments applicable to like products crossing national borders.²⁹ Since then, the so-called Border Tax Adjustment criteria have consistently been used in determining likeness pursuant to Articles I and III of the GATT. In addition to the three criteria of i) physical characteristics; ii) consumers' tastes and habits; and iii) the product's end-uses in a given market, tariff classification has additionally been established as the fourth criterion over the years.³⁰ These criteria are relevant for determining likeness across the board in WTO law, as the term 'like products' appears in various provisions and agreements. Read in context, however, the term's exact meaning might slightly vary from one provision to the other – a phenomenon which has become known as

28 COTTIER/OESCH (supra fn. 8), at 346-47.

29 Border Tax Adjustments, Report of the Working Party, adopted 2 December 1970, BISD 18S/97 (1972), para. 18.

30 See for the relevant case law and scholarly reception COTTIER/OESCH (supra fn. 8), at 390-407.

the Appellate Body's 'accordion approach', widening and narrowing the scope of likeness as different provisions apply.³¹

With respect to pharmaceutical products, the classical Border Tax Adjustment approach means that traditional medicines and conventional, modern health-care products are basically considered 'like' as far as they share common physical characteristics. Granting privileges to traditional medicines vis-à-vis their conventional counterparts in terms of tariff and non-tariff treatment seems in particular possible if consumer preferences can be clearly distinguished.³² WTO jurisprudence to date indicates that health concerns can well translate into diverging consumer preferences.³³ Thus, they may allow different regulatory approaches to traditional and modern medicines. Furthermore, it might be conceivable that not only health but also other non-trade concerns such as the protection of biodiversity and the environment, sustainability in agriculture and the conservation of traditional knowledge result in different consumer preferences and decisively shape the determination of likeness under the Border Tax Adjustment criteria, thus opening a potential gap length for different regulatory approaches to traditional and conventional medicines.

Persistent reliance by WTO panels and the Appellate Body on the Border Tax Adjustment criteria for determining 'likeness' has not remained undisputed. Strict dependence on those criteria in general, and the physical characteristics of a product in particular, amounts to high levels of intrusiveness and considerably limits the scope of governments to undertake product differentiations, even domestically, in the pursuit of non-trade policy goals. As the objective of the GATT 1994 is to ban protectionism, and not to limit the pursuit of legitimate policy objectives, a school of thought has begun to question the Border Tax Adjustment criteria and to develop an alternative test seeking to target protectionist product distinctions more precisely and to leave governments more leeway in regulating legitimate non-trade concerns. Accordingly, a definition of 'likeness' should take into account whether a measure

31 *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body, 4 October 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, at 21: "The concept of 'likeness' is a relative one that evokes the image of an accordion. The accordion of 'likeness' stretches and squeezes in different places as different provisions of the WTO Agreement are applied. The width of the accordion in any one of those places must be determined by the particular provision in which the term 'like' is encountered as well as by the context and the circumstances that prevail in any given case to which that provision may apply."

32 *COTTIER/PANIZZON* (supra fn. 8), at 383, with respect to traditional knowledge.

33 *EC – Measures Affecting Asbestos and Asbestos-Containing Products*, Report of the Appellate Body, 12 March 2001, WT/DS135/AB/R; see MATTHIAS OESCH, *Commentary on EC – Asbestos*, *International Trade Law Reports*, London, Cameron May, 2003, 441-65, at 459-60.

has the aim and/or effect of protecting domestic production.³⁴ The Appellate Body, however, appeared to reject such an 'aims-and-effect' test in its report on *Japan – Alcoholic Beverages*.³⁵ At least, the current state of law and practice recognises implicitly what the 'aims-and-effect' test seeks to achieve expressly, namely to enlarge the governments' leeway of manoeuvre in the pursuit of legitimate, non-protectionist policy goals.

C. Process and Production Methods

Moreover, products might not only be defined by their physical properties, their end-uses in a given market and consumers' tastes and habits. They can also be characterised and distinguished by way of how they have been produced, i.e., on the basis of process and production methods (PPMs). In such a case, an isolated comparison of the end-products does not reveal any (physical) differences; it is the 'history' of the product that distinguishes it from other (physically similar) products. The recognition of PPMs implies that it is explicitly allowed to pursue non-trade policy concerns and, based on their legitimacy, to accordingly differentiate between physically similar products. PPMs are particularly important, and discussed in academic writings, in relation to environmental concerns and human or labour rights. However, they might be of equal relevance in the field of pharmaceutical products. Granting privileges to traditional medicines vis-à-vis modern types of medical treatment might be legitimate with a view to the policy goals of, *inter alia*, protecting biodiversity by conserving the sources of herbal medicines in a sufficient quantity, of furthering local, 'decentralized' and low-cost health systems and of supporting the continual passing down of necessary traditional knowledge on which traditional medicines are based.³⁶

The issue as to whether Articles I and III of the GATT 1994 allow different regulatory approaches to products, which are physically similar but processed or produced

34 The 'aims-and-effect' test was first applied in *US – Measures Affecting Alcoholic and Malt Beverages*, Report of the Panel, adopted 19 June 1992, DS23/R, BISD 39S/206 (1993), and further developed in *US – Taxes on Automobiles*, Report of the Panel, 11 October 1994 (not adopted), DS31/R, 33 I.L.M. 1397 (1994); see for an account WILLIAM J. DAVEY/JOOST PAUWELYN, *MFN-Unconditionality: A Legal Analysis of the Concept in View of its Evolution in the GATT/WTO Jurisprudence with Particular Reference to the Issue of 'Like Product'*, in: Thomas Cottier/Petros C. Mavroidis (eds.) (supra fn. 27), 13-50, at 38-40.

35 *Japan – Alcoholic Beverages* (supra fn. 31), at 19-21.

36 See for such elements of basic health care and traditional medicines SUSETTE BIBER-KLEMM/DANUTA SZYMURA BERGLAS (supra fn. 3), at 50.

differently, is highly controversial.³⁷ A very early GATT 1947 panel report, *Belgium Family Allowances*, is often interpreted, and cited as an important precedence, to the effect that discrimination on the basis of how (physically similar) products are produced or processed is prohibited under the GATT.³⁸ The subsequent case law is inconsistent; mostly, PPMs have been rejected.³⁹ In particular, they are commonly opposed by developing countries which consider PPMs a (too) forceful tool in the hands of developed countries to impair developing countries' market access rights (e.g., in the form of high environmental or labour standards). Moreover, the debate on PPMs is closely related to the systemic value and relevance of the exceptions provided for in Article XX of the GATT 1994 and to the issue of extraterritorial application of trade-related measures by WTO members.⁴⁰ It is argued that admitting measures under the GATT 1994 on the basis of extraterritorial criteria would mean that economically powerful WTO members could try to impose their own perceptions of appropriate environmental policies or other non-trade concerns upon other members.

The current state of the art appears to be that PPMs are not permitted under the GATT 1994. A different regulatory approach to traditional medicines vis-à-vis conventional pharmaceutical products solely based upon the different product and production methods would most likely be considered unjustifiably protectionist. At this stage, PPMs would not meet the classical Border Tax Adjustment test of likeness which renders considerations of equity and ecological policy goals, of course, more difficult. Still, the near future might bring a change of attitude towards PPMs. Two reasons stand in favour of such optimism: First, the matter is at the heart of interfacing trade regulation with other policy concerns, in particular the environment, biodiversity, human rights and culture. Thomas Cottier and Marion Panizzon convincingly

37 See COTTIER/OESCH (supra fn. 8), at 412-18; ROBERT HOWSE/DONALD REGAN, *The Product/Process Distinction – An Illusory Basis for Disciplining 'Unilateralism' in Trade Policy*, in: *European Journal of International Law* 2000, 249-89; MATSUSHITA/SCHOENBAUM/MAVROIDIS (supra fn. 7), at 461-69; RONALD STEENBLIK, *Liberalising Trade in 'Environmental Goods': Some Practical Considerations*, OECD Trade and Environment Working Paper No 2005-05, 16 December 2005, at 11-2; with respect to traditional knowledge COTTIER/PANIZZON (supra fn. 8), at 385-86.

38 *Belgian Family Allowances (Allocations Familiales)*, Report of the Panel, adopted on 7 November 1952, BISD 1S/59 (1955).

39 An important precedent being *US – Restrictions on Imports of Tuna (Tuna I)*, Report of the Panel, 16 August 1991 (not adopted), DS21/R, BISD 39S/27 (1993).

40 See for extraterritorial application *US – Import Prohibition of Certain Shrimp and Shrimp Products*, Report of the Appellate Body, 12 October 1998, WT/DS58/AB/R, paras. 133; for an analysis MATTHIAS OESCH, *US – Shrimp Case*, in: Rüdiger Wolfrum (ed.), *Max Planck Encyclopedia of Public International Law*, Oxford, Oxford University Press, forthcoming 2007, para. 9; LORAND BARTELS, *Article XX of GATT and the Problem of Extraterritorial Jurisdiction: The Case of Trade Measures for the Protection of Human Rights*, in: *Journal of World Trade* 2002(2), 353-403.

argue that product differentiation on the basis of PPMs will become a necessity in bringing about more coherence in treaty interpretation as many existing multilateral agreements already recognise the environmental, social and cultural implications of the process and production methods leading to a finished product.⁴¹ This holds true, in particular, for international conventions aiming at the protection of the environment (multilateral environmental agreements, MEAs).⁴² These agreements indicate that there has been an evolution in public international law towards an appropriate consideration of environmental, social and cultural concerns in the course of the production of a product. Thomas Cottier and Marion Panizzon conclude that the “PPMs in MEAs” discussion functions as a strong reasoning for why the WTO should allow to integrate PPMs in the like product definition for purposes of non-discrimination within Articles I and III of the GATT 1994.⁴³ Second, developing countries might begin critically to review their systemic rejection of PPMs. With respect to products such as traditional medicines and others based on traditional knowledge, developing countries might well be interested in legitimately protecting their own traditionally made products and in gaining enhanced market access for such products abroad.⁴⁴ Hence, developing countries might actively support the inclusion of PPMs into the GATT 1994 acquis. Under the current legal framework *de lege lata*, it will be up to the WTO dispute settlement organs to reassess the current state of law and practice and to bring PPMs back in. At the moment, it is not realistic to expect too much from the deadlocked *Doha round* negotiations in this respect. This is regrettable. Eventually, only multilateral negotiations would allow placing the issue of PPMs in the broader context of technology transfer and financial support in bringing about state of the art process and production methods, as developing countries would, from an economic viewpoint, still be disadvantaged by many PPMs in the field of environmental and labour standards.

D. General Exceptions

Irrespective of whether a conservative or progressive interpretation of ‘likeness’ is applied, the GATT 1994 might offer an additional justification for a different treatment between traditional and conventional medicines, thus promoting the sustainable use and adequate commercialisation of the former over the latter. The basic principle of

41 COTTIER/PANIZZON (supra fn. 8), at 386-87.

42 See for an illustrative list of MEAs potentially influencing international trade under the auspices of the WTO online at www.wto.org (click the link to environment/MEA database: Matrix on Trade Measures Pursuant to Selected MEAs).

43 COTTIER/PANIZZON (supra fn. 8), at 386; see also ROBERT HOWSE, *Adjudicative Legitimacy and Treaty Interpretation in International Trade Law: The Early Years of WTO Jurisprudence*, in: J.H.H. Weiler (ed.), *The EU, the WTO, and the NAFTA: Towards a Common Law of International Trade?*, Oxford, Oxford University Press, 2000, 35-69, at 56.

44 See COTTIER/PANIZZON (supra fn. 8), at 387.

non-discrimination is further balanced by a number of important exceptions for the protection of non-economic goals and ends of states. The principles of MFN and national treatment need to be read in conjunction with such non-trade concerns contained in key provisions of the GATT 1994. What the principles essentially seek to avoid is *illegitimate* protectionism and rent-seeking, based on privileges accorded in national law and policies. Validating traditional medicines demonstrates that the furtherance of policy concerns other than pure short-term, economically-driven motivations does not necessarily result in unsolvable tensions with the principle of non-discrimination.

In the context of trade in pharmaceutical products, Article XX of the GATT 1994 is of prime interest (termed 'General Exceptions'). It stipulates the relevant guidelines for the delicate balancing act between equal treatment, trade liberalisation and the pursuit of other legitimate policy goals. This provision justifies deviations from other rules, in particular, but not exclusively, from the principles of MFN and national treatment and from the prohibition of quantitative restrictions. It is composed of two distinct parts: First, Article XX of the GATT 1994 consists of an enumeration of specific motives and conditions for restricting trade, listed in paragraphs (a) through (j). Not all of them are of equal practical importance. The critical provisions which are frequently invoked in practice – as WTO members have become increasingly concerned with environmental and human health issues as well as with the protection of intellectual property rights – refer to measures necessary to protect human, animal or plant life and health (paragraph b), to measures necessary to secure compliance with laws relating to the protection of patents, trademarks and copyrights and to the prevention of deceptive practices (paragraph d), and to measures relating to the conservation of exhaustible natural resources (paragraph g). Paragraph (d) was, in the GATT 1947-years, the only provision explicitly dealing with intellectual property rights – hence being relevant for trade in pharmaceutical products – and was several times invoked in dispute settlement proceedings.⁴⁵ It has kept its relevance also after the coming into force of the WTO and its third pillar, the TRIPs Agreement. For instance, paragraph (d) provides, under the GATT 1994, the basis for combating the counterfeiting of drugs and for restricting parallel imports of essential drugs made available to developing countries.⁴⁶ Paragraph (g) might be invoked, for instance, if a WTO member applies specific measures to protect traditional medicines which

45 See for an overview COTTIER/OESCH (supra fn. 8), at 447-51; MICHAEL J. TREBILCOCK/ROBERT HOWSE, *The Regulation of International Trade*, London, Routledge, 3rd ed. 2005, at 402; panels confirmed several times that Article XX(d) is to be interpreted *narrowly*, placing the burden of justifying its use on the party invoking the exception, see *US – Section 337 of the Tariff Act*, Report of the Panel, adopted 7 November 1989, L/6439, 36S/345 (1990); *US – Measures Affecting Alcoholic and Malt Beverages*, Report of the Panel, adopted on 19 June 1992, DS23/R.

46 COTTIER/OESCH (supra fn. 8), at 448.

are considered to constitute non-renewable resources. Based on such rationale, it is conceivable that a WTO member adopts a system of differential taxation for traditional medicines and conventional pharmaceutical products, provided that the privileges do not amount to disguised protectionism.⁴⁷ The Appellate Body's rather generous interpretation of Article XX(g) in the *US – Shrimp* case seems to support such a reading.⁴⁸

Second, all exceptions listed in the paragraphs of Article XX are further qualified by the so-called *chapeau*. It applies in addition to the specific motives and is intended to prevent the abuse of the limited and conditional exceptions under which a contested measure might be preliminarily justified. The *chapeau* is a balancing principle to mediate between the right of a member to invoke an exception and its obligation to respect the rights of other members. It is, as the Appellate Body famously held, "but one expression of the principle of good faith."⁴⁹ As the exceptions set forth in the respective paragraphs have been consistently interpreted generously since the dawn of the WTO, the *chapeau* has gained in operational importance. The fulfilment of its requirements has in many cases become a difficult task to be accomplished by the members invoking Article XX of the GATT 1994.

IV. Technical Barriers to Trade

WTO rules which govern technical barriers to trade applied for the protection of human health and other policy goals are covered either by the Agreement on Technical Barriers to Trade (TBT Agreement) or by the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Under both agreements, various policy concerns other than trade liberalisation are considered perfectly legitimate objectives for restricting trade.

A. TBT Agreement

The TBT Agreement was first developed in the *Tokyo Round* (then also called 'Standards Code') and was further improved in the *Uruguay Round*, with a view to strengthening the basic disciplines enshrined in Article XX of the GATT 1994.⁵⁰ The TBT Agreement was largely inspired by the work undertaken within the EC

47 Cf. COTTIER/PANIZZON (supra fn. 8), at 385.

48 *US – Shrimp* (supra fn. 40), paras. 128-30; see OESCH (supra fn. 40), para. 5.

49 *US – Shrimp* (supra fn. 40), para. 158.

50 See for an overview on the TBT Agreement CARLOS M. CORREA, Implementing National Public Health Policies in the Framework of WTO Agreements, in: *Journal of World Trade* 2000(5), 89-121, at 103-5; COTTIER/OESCH (supra fn. 8), at 750-64; MATSUSHITA/SCHOENBAUM/MAVROIDIS (supra fn. 7), at 510-13; *WTO Agreements & Public Health* (supra fn. 18), paras. 26-33.

and the EFTA and responds to two broad policy considerations. On the one hand, (mandatory) technical regulations and (voluntary) product standards, including packaging, marketing and labelling requirements, as well as procedures for testing and certifying compliance with these regulations and standards potentially serve the purpose of limiting market access for competing products. Since regulations and standards largely vary among different countries, they may be excessively strict and may be upheld artificially. Therefore, the TBT Agreement provides that technical regulations and standards shall not create unnecessary obstacles to international trade. On the other hand, members should be able to adequately pursue legitimate policy objectives such as the protection of national security, the prevention of deceptive practices and the protection of human, animal and plant life and health. Equally, labelling requirements are commonly considered legitimate in order to achieve adequate consumer information. The agreement is designed according to these two underpinnings which are explicitly referred to in the preamble. In order to do so, Article 2:4 of the TBT Agreement encourages members to base TBT measures on international standards where they exist (such as the *International Organization for Standardization* [ISO] and the *Codex Alimentarius Commission*, a joint body of the WHO and the FAO, focusing mainly on food safety). In the case of pharmaceutical products, the WHO is assigned a leading role in the area of standard setting for their quality, efficacy and safety through, *inter alia*, the *International Pharmacopoeia* and the *WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce*.⁵¹ Systemically, international standards are becoming a decisive benchmark for determining the WTO-consistency of national technical regulations, and the legitimacy of the standard setting organisation's decision-making process is watched with increasing attention and concern. In the absence of international standards (or in the case of deliberate deviation therefrom), members are obliged to prove the legitimacy and proportionality of regulations and standards.⁵²

With respect to traditional medicines, the major difficulty of adopting adequate technical regulations and standards is twofold: First, the quantity and quality of safety and efficacy data on traditional medicines are often insufficient and do not meet common criteria in order to support its use worldwide.⁵³ Scientific evidence from randomised clinical trials is only strong for some uses of acupuncture, some herbal medicines and manual therapies.⁵⁴ The lack of adequate research data results,

51 See COLETTE KINNON, *WTO: What's in it for WHO?*, WHO Task Force on Health Economics, Geneva, 1995.

52 COTTIER/OESCH (*supra* fn. 8), at 760-61.

53 World Health Organization (*supra* fn. 1), at 21.

54 World Health Organisation, *Traditional Medicine: Fact Sheet No. 134*, May 2003, online at www.who.int/mediacentre (click the link to fact sheets).

according to the WHO, not only from inadequate health care policies but also from a shortage of adequate or accepted research methodology for evaluating traditional medicines.⁵⁵ Therefore, it is highly recommended that further research in safety and efficacy be promoted, not only for health reasons as such but also for ensuring market access of traditional medicines under the TBT Agreement. Furthermore, the failure to undertake serious research in this area has not allowed the international community to develop international standards on safety, efficacy and quality control of traditional medicines.⁵⁶ Second, developing countries' products may simply not satisfy safety regulations and standards as commonly defined with production in industrialised countries in mind.⁵⁷ The TBT Agreement does not expressly address regulations and standards with a particular view to the needs and capabilities of developing countries. Their products have, in principle, to comply with the general substantive rights and obligations set out in the TBT Agreement. Special and differential (S&D) treatment only exists with respect to regulations and standards adopted by developing countries taking effect in their own jurisdiction. Traditional technology may be exempted from international standards pursuant to Article 12:4 of the TBT Agreement which permits developing country members to "adopt certain technical regulations, standards or conformity assessment procedures aimed at preserving indigenous technology and production methods and processes compatible with their development needs." While this regulatory approach clearly promotes the use by developing countries of indigenous technical barriers to trade, it does not require industrialised countries to open up their own markets for such products.⁵⁸ Therefore, this provision is not drafted in a way to facilitate the international commercialisation of products such as traditional medicines which do not *per se* meet safety standards acknowledged in the developed world.

Moreover, the debate on the legality of PPMs for regulatory purposes is also relevant in the context of the TBT Agreement. They have been dealt with *supra* under Articles I and III of the GATT 1994.⁵⁹ The TBT Agreement adds an additional perspective to the controversial issue. Its Annex 1 defines "technical regulation" as a "document which lays down product characteristics or their related processes and production methods ..." This definition is not entirely clear. On the one hand, it indicates that the TBT Agreement applies not to all PPMs but only to those which are in some

55 See World Health Organization, *General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine*, Geneva, 2000.

56 See World Health Organization (*supra* fn. 1), at 22, in particular referring to herbal medicines.

57 COTTIER/PANIZZON (*supra* fn. 8), at 375.

58 COTTIER/PANIZZON (*supra* fn. 8), at 375; they conclude that developing countries should aim at amending the TBT Agreement accordingly; see also CORREA (*supra* fn. 50), at 104.

59 See *supra* III.C.

way or other connected with the characteristics of the end product. They need to have a distinguishable effect on the product characteristics such as its quality or performance. If PPMs do not translate into the product, they should not be able to justify trade restrictions under the TBT Agreement.⁶⁰ On the other hand, it is difficult to see why the TBT Agreement should not extend to disciplining all existing PPMs and hence rendering them subject to the principle of proportionality.⁶¹ In fact, various members have notified to the WTO Committee on Technical Barriers to Trade (TBT Committee) regulations and standards which are based upon PPMs and thus affect the way in which the product at issue is processed and produced abroad.⁶² Again, this issue will most likely be raised, at some point or other, in formal dispute resolution proceedings, and the Appellate Body will have to clarify it.

B. SPS Agreement

The SPS Agreement was negotiated during the *Uruguay Round* as the disciplines of the GATT 1947 and the TBT Agreement were considered to be too general and lenient for assessing food standards. The SPS Agreement, being *lex specialis* to Article XX(b) of the GATT 1994 and to the TBT Agreement, contains detailed rules on the enactment of measures intended to protect human, animal and plant life or health from risks arising from additives, pests, contaminants or other disease-causing organisms.⁶³ According to Articles 3 and 5 of the SPS Agreement, trade-restrictive measures strictly need to be scientifically justified. The requirement to conducting a proper risk assessment in all SPS matters is central to the functioning of the Agreement. Article 2:2 of the TBT Agreement, in contrast, only requires that available scientific information may be one of the relevant elements of consideration in assessing risk, besides the motivation to standardise products, to ensure quality or to avoid consumer deception.⁶⁴ While the new SPS Agreement did not attract much attention during the negotiations, it quickly moved to the centre of major trade

60 See COTTIER/PANIZZON (supra fn. 8), at 377.

61 COTTIER/OESCH (supra fn. 8), at 762.

62 The Netherlands, for instance, made a notification with respect to "animals and plants belonging to protected indigenous and non-indigenous animal and plant species and products of these animals and plants", see Notification to the TBT Committee, 7 August 2000, WTO Doc. G/TBT/Notif.00/344.

63 See for an overview on the SPS Agreement CORREA (supra fn. 50), at 97-103; COTTIER/OESCH (supra fn. 8), at 778-99; HENRIK HORN/PETROS C. MAVROIDIS, National Health Regulations and the SPS Agreement: The WTO Case Law of the Early Years, in: Thomas Cottier/Petros C. Mavroidis (eds.), *The Role of the Judge in International Trade Regulation: Experience and Lessons for the WTO*, Ann Arbor, The University of Michigan Press, 2003, 255-84; MATSUSHITA/SCHOENBAUM/MAVROIDIS (supra fn. 7), at 494-510; WTO Agreements & Public Health (supra fn. 18), paras. 34-43; with respect to traditional knowledge COTTIER/PANIZZON (supra fn. 8), at 377-79.

64 See WTO Agreements & Public Health (supra fn. 18), para. 39; CORREA (supra fn. 50), at 104.

disputes after its coming into force at the end of the *Uruguay Round*. Questions regarding risk assessment and risk management, the proper balance of government discretion and adequate judicial review of member state determinations have extensively been tried and debated in this context. Moreover, the SPS Agreement finds itself at the heart of the debate on market access and trade restrictions for biotech products.⁶⁵

Technical regulations and standards on pharmaceutical products such as measures relating to the quality and other conditions for their approval and commercialisation usually do not constitute SPS measures (even though they are motivated, in essence, by health considerations).⁶⁶ They fall under the GATT 1994 and the TBT Agreement and need to satisfy the (more relaxed) disciplines set forth in those agreements.

V. Epilogue

This paper demonstrates that the GATT 1994 relevantly impacts the promotion and protection of traditional medicines. Whereas many developed countries have, by virtue of the *Zero-for-Zero Initiative*, eliminated their tariffs on pharmaceutical products (and hence also on traditional medicines), there is still some scope for further lowering tariffs on health-related products in developing countries. In those cases in which traditional medicines are considered agricultural products under the Harmonized System, they still face, however, high levels of tariff protection maintained by many developed countries. Furthermore, a change of paradigm with respect to the interpretation of 'likeness' under Articles I and III of the GATT 1994 would allow to differentiate between traditional medicines and their conventional counterparts and to adopt different internal taxation and other regulatory measures in order to foster traditional medicines. Such an approach would offer interesting policy options in both developing and developed countries. Yet, WTO panels and the Appellate Body have not acknowledged such a reading of 'likeness' to date.

Besides, the main obstacles to traditional medicines are likely to result from TBT measures. While the protection of human health by requiring adequate safety standards is imperative, enhanced involvement of developing countries and co-

65 See *EC – Measures Affecting the Approval and Marketing of Biotech Products*, Report of the Panel, adopted on 21 November 2006, WT/DS291/R, WT/DS292/R, WT/DS293/R; for an analysis MATTHIAS OESCH, *The Jurisprudence of WTO Dispute Resolution (2006)*, in: *Schweizerische Zeitschrift für Internationales und Europäisches Recht* 2006, 501-23, at 514-23.

66 CORREA (*supra* fn. 50), at 98; HANS-GEORG KAMANN, *Übereinkommen über die Anwendung gesundheitspolizeilicher und pflanzenschutzrechtlicher Massnahmen*, in: Hans-Joachim Priess/Georg M. Berrisch (eds.), *WTO-Handbuch*, München, Verlag C.H. Beck, 2003, para. 29.

operation between all stakeholders in standard-setting operations may relevantly assist in avoiding overly protectionist standards and in adequately acknowledging the various non-trade policy concerns for traditional medicines.⁶⁷ Such concerns are obvious, and their legitimacy is confirmed in a growing number of international agreements and conventions. Therefore, the pledge to better interface WTO law and other areas of public international law stands at the forefront. Two levels need to be distinguished. First, it is a matter of seeking coherence in a number of international negotiations, taking place in different and often quite isolated fora. Countries all over the globe, being developed or less developed, need to realise that they have, in essence, a mutual interest in finding sustainable and efficacious solutions as to the protection and promotion of traditional medicines. It essentially boils down to the process of defining standards for their quality, efficacy and safety. Such standards have not yet been satisfactorily defined, as standardising activities with respect to traditional medicines within, and outside of, the WHO are only in their infancies. The WTO needs to acknowledge that the WHO is assigned the leading role in this process. An important – but only first – step to this effect is the participation of the WHO as an observer in the WTO Committee on Technical Barriers to Trade (TBT Committee). In the current *Doha Round*, the quest for coherence and interactivity between the WTO and the WHO is not officially acknowledged. At least, the need to further clarify the relationship between the rules of the WTO and of other international legal sources has been affirmed for multilateral environmental agreements (MEAs). In the Doha Ministerial Declaration, it is explicitly agreed to negotiate rules “with a view to enhancing mutual supportiveness of trade and environment.”⁶⁸ The Convention on Biological Diversity with its policy goal of protecting and promoting biodiversity and equity comes to mind; it represents an example in point of the unresolved and (at least partly) controversial relationship of the WTO legal framework to the wider body of public international law. Only well-balanced and mutually acceptable procedures of co-operation and interaction ultimately assist in overcoming traditional rivalries between different international organisations as well as domestic government agencies.⁶⁹ Second, the relationship is equally addressed in WTO dispute settlement. The interfacing of different international regimes and agreements can in many cases readily be achieved under the rules of the Vienna Convention on the Law of Treaties, in particular its Article 31:3(c).⁷⁰ Pursuant to this provision, international legal instruments other than the WTO agreements can

67 See COTTIER/PANIZZON (supra fn. 8), at 387, with respect to traditional knowledge in general.

68 WTO Doc. WT/MIN(01)/DEC/1, adopted on 14 November 2001, para. 31.

69 See COTTIER/PANIZZON (supra fn. 8), at 380.

70 Article 31 sets out the general methods of interpretation; its paragraph 3(c) reads as follows: “There shall be taken into account, together with the context: (...) any relevant rules of international law applicable in the relations between the parties.”

relevantly inform the correct interpretation of WTO rules. This holds also true for trade in pharmaceutical products and the special case of traditional medicines. Most likely, WTO panels and the Appellate Body will be called upon, in some case or other, to give adequate consideration to the WHO and its active delivery of scientific and other evidence where public health concerns and access to traditional medicines are at issue.⁷¹ By doing so, panels and the Appellate Body could help to develop a 'traditional medicine perspective' through their daily dispute resolution work.

71 See for a precedent in which the WHO, upon the request of the panel, delivered factual evidence as to health effects of cigarette consumption *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes*, Report of the Panel of 7 November 1990, DS10/R, 37S/200; CORREA (supra fn. 50), at 113.