

**BOOK REVIEW \****Trade and Human Health and Safety*

Edited by GEORGE A BERMANN AND PETROS C MAVROIDIS

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Mention the World Trade Organization ('WTO')<sup>1</sup> and 'human health' and many people will immediately think of concerns about drugs for HIV/AIDS and malaria being priced out of the reach of the world's poor. International campaigns by organisations like Oxfam and Médecins Sans Frontières have drawn world attention to the globalised protection mandated by WTO law for the intellectual property rights of 'big pharma'. The campaign has framed the conflict as a choice between protecting commercial interests or protecting the health of the world's most vulnerable. In the face of mounting deaths from preventable diseases in developing countries, many because sufferers 'are unable to afford basic medicines', campaigners have called for 'fundamental reform of the WTO intellectual property rules'.<sup>2</sup> A global union of developing countries, the United Nations, the World Health Organization ('WHO'), civil society groups and many others took up the campaign and pressured the WTO to amend its law<sup>3</sup> to permit the ongoing production of cheaper, generic versions of patented drugs. In August 2004 the union succeeded to some extent in achieving this.

In the three years since then little has changed, in large part because the challenge is more complex than a simple conflict between commercial gain and human health. Low-priced drugs alone will not ensure access where there are no medical clinics or refrigeration, where transport infrastructure barely exists and where corruption is rife. But the campaign neatly demonstrated the potential for trade measures to become tangled up in broader social objectives, such as human health, and posed the question of whether the pursuit of trade objectives should be allowed to constrain domestic health policy. In broad terms, this is the question which a dozen eminent scholars address in *Trade and Human Health and Safety*. The contributing authors are indeed 'without exception, outstanding

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1 Established pursuant to the *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995) ('WTO Agreement').

2 Kevin Watkins, 'A Harsh Campaign to Prevent Affordable AIDS Treatment', *International Herald Tribune* (Paris), 12 February 2001.

3 The patent rights of intellectual property owners are set out in: *WTO Agreement*, above n 1, annex 1C (*Agreement on Trade-Related Aspects of Intellectual Property Rights*) 1867 UNTS 299 ('TRIPS Agreement').

experts in their field of expertise, and they include economists, political scientists and lawyers, all specialising in the WTO'.<sup>4</sup>

Interestingly, however, the volume does not deal with the 'access to drugs' controversy at all. In part, this is probably because the intellectual property component of WTO law is anomalous; it imposes domestic standards of protection for private property rights, while the other WTO treaties influence trade law in an entirely different way. Eschewing the popular focus, the authors concentrate instead on the agreement which forms the bulk of WTO law, the *General Agreement on Tariffs and Trade* ('GATT').<sup>5</sup> They also put aside, initially, the question posed in the drugs campaigns – whether the pursuit of trade objectives should be allowed to constrain domestic health policy – in favour of the more fundamental and antecedent question of whether WTO law constrains domestic health policy in the first place. Evidence of the existence of constraint is sought from multiple angles, including the texts of the treaties, policy tensions revealed by disputes determined in the WTO's dispute settlement system, the influence of other bodies of international law (such as human rights law) on WTO law and what might be called the political science of balancing trade liberalisation and human health objectives.

International trade in goods has a profound impact on human health. In mass markets, imported foods processed to poor standards can kill or injure large numbers, as can unsafe products. Trade in agricultural goods can spread exotic pests which destroy local food sources, leading to poor nutrition. Pesticides and additives in goods can pose longer-term dangers to human health. Countries attempt to protect themselves from such threats by adopting standards, setting up procedures to enforce them and restricting trade in goods which do not meet the standards. International trade in goods is principally regulated by *GATT*, which came into force in 1947 with the objective of liberalising trade in most goods and which still forms the greatest part of WTO law, although many supplementary agreements have since improved its effectiveness. *GATT* does not prevent WTO Member countries from adopting domestic measures for the protection of human health, even where those measures restrain trade. It takes what is described by the editors of this volume as a 'negative integration' approach to trade liberalisation, allowing the treaty parties to 'unilaterally define their [human health] policies affecting trade', including, of course, in relation to unsafe or dangerous goods.<sup>6</sup> Instead of forcing countries to accept each others' goods exports at all times, *GATT* attempts to 'integrate' countries through outlawing preferential treatment of one country's products over similar or 'like' products from another country. Importantly, this includes preferential treatment of a country's own products over 'like', imported versions. The most common complaint under *GATT* is that a country is favouring its own products and there is no doubt that countries will do it if they can get away with it.

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4 George A Bermann and Petros C Mavroidis, 'Preface to the Series' in George A Bermann and Petros C Mavroidis (eds), *Trade and Human Health and Safety* (2007) vii.

5 *WTO Agreement*, above n 1, annex 1A (*General Agreement on Tariffs and Trade*) 1867 UNTS 190.

6 *Ibid* 2.

One means for sneaking in protection of one's own products is through the use of health and safety standards, so trade law has had to devise mechanisms which allow genuine health measures to be given the deference they deserve while also allowing protectionism masquerading as health measures to be struck down. One mechanism is restricting *GATT*'s prohibition against discrimination to 'like products', thereby allowing discriminatory human health measures to stand where the products in question have a health-related difference which makes them genuinely 'unlike' each other. The WTO Appellate Body has held that otherwise similar products will not be 'like' if one contains, for example, carcinogenic asbestos and the other does not.<sup>7</sup>

A further mechanism, also in keeping with *GATT*'s strategy of deference to non-trade domestic policy, is the exception under Article XX(b) which permits human health measures that unlawfully discriminate between like products but which are 'necessary for the protection of human ... health'. For example, environmental legislation requiring that certain pollutants be removed from gasoline before it is sold might deliberately place more onerous (and therefore discriminatory) reporting requirements on foreign suppliers if it is difficult for the local authority to otherwise verify their compliance.<sup>8</sup> To make use of the Article XX(b) exception, human health measures must be no more trade-restrictive than necessary to achieve their legitimate purpose and they must not be arbitrary, unreasonable or a disguised restriction on international trade.<sup>9</sup> These are formidable tests which a domestic health measure must pass and, as such, may be said to act as a constraint on the availability of domestic health protection options. *GATT* seems to proceed from an assumption that a health measure which affects trade in a discriminatory manner is inherently suspect and needs to be tested for genuineness of purpose. The use, in Article XX, of such imprecise criteria as whether a measure is necessary, arbitrary, unreasonable, or a disguise, necessitates an evaluative judgment, known in WTO circles as the 'smell test'. David Palmenter refers to this as a sense of whether the country in question is behaving 'correctly or incorrectly',<sup>10</sup> although this rephrasing is of use only to emphasise the vagueness of the criteria.

Clearly it is not ideal to be making decisions about the validity of domestic health policy measures by use of a 'smell test'. In order to bring more clarity and objectivity to the testing of these measures, the *Agreement on Sanitary and Phytosanitary Measures* ('*SPS Agreement*')<sup>11</sup> was introduced in 1995.<sup>12</sup> In the

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7 *European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, WTO Doc WT/DS135/AB/R (2001) (Report of the Appellate Body) ('*EC – Asbestos*').

8 In *United States – Standards for Reformulated and Conventional Gasoline*, WTO Doc WT/DS2/AB/R (1996) (Report of the Appellate Body) the Appellate Body held that the gasoline legislation was a disguised restriction on international trade.

9 *GATT*, above n 5, art XX *chapeau*.

10 David Palmenter, 'The WTO Standard of Review in Health Safety' in Bermann and Mavroidis (eds), above n 4, 224, 234.

11 *WTO Agreement*, above n 1, annex 1A (*Agreement on the Application of Sanitary and Phytosanitary Measures*) 1867 UNTS 493.

*SPS Agreement*, scientific knowledge is used to assess whether a measure has a genuine purpose, regardless of whether it is discriminatory. The *SPS Agreement* deals with measures for controlling pests and diseases and requires that a country either adopt international standards or, if it wants to be more restrictive, that its standards are supported by scientific evidence of the existence of a risk. Once a country has objectively established that there is a risk to human health it is free to decide on the level of protection it wants to give to its population.

Does the package of tests of genuine purpose in *GATT* and the *SPS Agreement* place constraints on domestic health policy? Alan Sykes argues that the tests in the *SPS Agreement* dramatically constrain domestic policy autonomy in one particular instance, that is, they displace the precautionary principle as an element in formulating domestic health policy. The ‘precautionary principle’ has been drawn from the environmental context and is expressed in Article 15 of the *Rio Declaration on Environment and Development*<sup>13</sup> as follows:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The principle, or an approach similar to it, is now applied in many domestic policy contexts, including human health.

Gabrielle Marceau and Joel P Trachtman take a different view to Sykes, pointing out that the *SPS Agreement* contains ‘a very specific, and limited’ statement of the precautionary principle, as evidenced by Article 5.7 of the *Rio Declaration*.<sup>14</sup> In essence, it allows Members to introduce provisional measures, where scientific evidence is insufficient, as long as the Member is working to obtain the further information needed. They also argue that there are other ‘expressions’ of the precautionary principle in the *SPS Agreement*. It expressly confers on Members the right ‘to determine the level of [health] protection they want’ in the face of evidence of risk,<sup>15</sup> the right ‘to be prudent’<sup>16</sup> (so as to take a generous view of the *sufficiency* of evidence of risk where lives are at stake), and the right ‘to rely on minority [scientific] opinion’.<sup>17</sup> The WTO Panel report in *EC – Asbestos* was strongly of the same view, warning that the alternative – that

12 The *Agreement on Technical Barriers to Trade* (*TBT Agreement*) was introduced at the same time. However, the TBT Agreement does not test the genuineness of a country’s technical standards; rather, art 2.2 merely requires that they be no more trade-restrictive than necessary and encouraging the adoption of international standards: *WTO Agreement*, above n 1, annex 1A (*Agreement on Technical Barriers to Trade*) 1868 UNTS 120.

13 Annex 1, Report of the United Nations Conference on Environment and Development (3–14 June 1992) UN Doc A/CONF.151/5/Rev.1 (1992) (*Rio Declaration*).

14 Gabrielle Marceau and Joel P Trachtman, ‘A Map of the WTO Law of Domestic Regulation of Goods’ in Bermann and Mavroidis (eds), above n 4, 9, 46.

15 *Ibid* 46–8. See also *SPS Agreement*, above n 11, art 3.3. See further, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WTO Doc WT/DS26/AB/R, AB-1997-4 (1998) [124] (Report of the Appellate Body).

16 Marceau and Trachtman, above n 14, 48.

17 *Ibid*. See also *EC – Asbestos*, above n 7 [178].

evidence of risk must always be established ‘with certainty’ – ‘would have the effect of preventing any possibility of legislating in the field of public health’.<sup>18</sup>

Sykes’ more ‘pessimistic view’<sup>19</sup> is that, by demanding that domestic health protection which is not based on international standards must be justifiable under science, the *SPS Agreement* restricts domestic health policy to that which can be justified with certainty according to today’s level of scientific knowledge. It appears to rule out a precautionary approach which, by definition, is based on wariness rather than hard evidence. A country might legitimately seek to ban the importation of food containing a particular additive in anticipation, for example, that longitudinal studies will demonstrate a risk to human health. Sykes agrees that, where the science is reasonably clear, WTO law does *not* constrain domestic measures which have a genuine health policy purpose, even those health measures which may fairly be described as precautionary in nature. Where he departs sharply is where the science is uncertain; he suggests that this will frequently be the case. In formulating public health policy, he explains, scientific evidence may well be inconclusive, highly tentative or preliminary; low levels of risk may be virtually impossible to prove scientifically; and scientists may disagree about the existence of risk.<sup>20</sup> In order not to ‘eviscerate’ its own requirements, Sykes argues, ‘in all cases of serious scientific uncertainty’ WTO law will overrule ‘the capacity of national regulators to choose the level of risk they will tolerate’. Herein, he concludes, lies a ‘fundamental conflict’ between the two and a powerful constraint on domestic health policy.<sup>21</sup>

This brings us back to the question of whether the pursuit of trade objectives *should* be allowed to constrain domestic health policy. Jeffrey L Dunoff has written extensively elsewhere about the underlying objectives of the international trade regime, asking in particular what benefits nations seek to secure from it.<sup>22</sup> In this volume he expresses agreement with Professor John Jackson that the dominant purpose of the *GATT/WTO* system in liberalising trade that crosses national boundaries is ‘to pursue the benefits described in economic theory as “comparative advantage”’. He explains that

[u]nder this theory, trade restrictions are inefficient intrusions into otherwise autonomously functioning markets ... The *SPS Agreement* ... provides a vehicle for challenging food ‘safety’ measures that are, in fact, simply disguised protectionism ... [thus helping to] eliminate barriers to trade and, hence, enlarge aggregate welfare.<sup>23</sup>

A problem with this approach, as Dunoff points out, is that in many instances, such as avoiding pest infestation, *SPS Agreement* measures may increase

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18 *EC – Asbestos*, above n 7 [8.221].

19 Alan O Sykes, ‘Domestic Regulation, Sovereignty and Scientific Evidence Requirements: A Pessimistic View’ in Bermann and Mavroidis (eds), above n 4, 257, 257.

20 *Ibid* 258.

21 *Ibid*.

22 Dunoff has identified two other responses: the ‘collective action model’ and the ‘embedded liberalism model’. All three responses are explained more fully in Jeffrey L Dunoff, ‘The Death of the Trade Regime’ (1999) 10(4) *European Journal of International Law* 733.

23 Jeffrey L Dunoff, ‘Lotus Eaters: Reflections on the *Varietals* Dispute, the *SPS Agreement* and WTO Dispute Resolution’ in Bermann and Mavroidis (eds), above n 4, 153, 163.

aggregate welfare through the very act of providing barriers to trade. This observation suggests that there may also be a theoretical conflict between the two sets of objectives. He also points out that, curiously, the term 'science' is left almost entirely undefined in the *SPS Agreement* and he cautions that it is by no means clear that reliance on science and risk assessment 'will [necessarily] lead to a reduction in protectionism'.<sup>24</sup>

Trade and human health and safety is a large topic, in both legal and public policy terms. The law regulating and affecting the capacity of nations to create and implement domestic health policy is complex and scattered over a number of agreements, with some uncertainty as to the effect of later treaties on the operative provisions of *GATT*. The contributors to this book are indeed, as the editors assert, amongst the most knowledgeable in what is frequently called the 'trade and ... field' – trade and environment, and development, and labour rights and (in this case) human health. Many themes other than precaution run through the various chapters, themes which share a position in the larger health policy context and, arguably, a profound significance for the ability of WTO Member nations to meet their health obligations under other international law.

The essays contained in *Trade and Human Health and Safety*, including those by authors not mentioned above, reveal the range of views which may be found on this topic and provide a sound basis for their assessment and evaluation. This eminently readable collection is an invaluable reference point for those working, studying or teaching in the area. It serves the essential function of promoting exchanges between those from disparate disciplines. Its publication is most welcome.

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24 Ibid 164.