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*Right to Health***The ‘Rule of Reason’ and the Right to Health:
Integrating Human Rights and Competition
Principles in the Context of TRIPS**

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In August 2001 the first public meeting of the American Society of International Law Project on Human Rights and International Trade (‘Project’) was held at the World Trade Institute in Berne, Switzerland. One session of that meeting was devoted to the relationship between human rights and the WTO Agreement in Trade-Related Aspects of Intellectual Property Rights (‘TRIPS Agreement’). As part of the follow-up to that meeting, the team leading the Project decided it would be useful to consider several ‘case studies’ that would seek more specifically to identify and analyse situations in which human rights and trade rules interact with each other. This study looks at the manner in which human rights may affect the application of competition rules and principles in the context of the TRIPS Agreement.

The analysis begins by observing that rights to life and health are well-recognized in human rights law, and that the right to health has been confirmed by the WTO Ministerial Conference in the Doha Declaration on the TRIPS Agreement and Public Health. It proceeds to demonstrate that the TRIPS Agreement rules governing competition provide substantial flexibility in terms of national policy, rule development, and application, and that this flexibility is sufficient to take into account human rights interests. The analysis turns to WTO Appellate Body jurisprudence for support for the proposition that Members are permitted to take into account non-trade interests in interpreting and applying TRIPS Agreement rules.

I. THE RIGHT TO HEALTH AND WTO LAW

A. Rights to life and health

The rights to life and health are established by treaty and customary international law. The human right to life prohibits governments from acting to deprive individuals of their right to exist.¹ While failure by a government to take adequate steps to address a threat to life (for example, in the circumstances of a disease outbreak) may constitute a deprivation of the right to life, commentary on the relationship between human rights and the TRIPS Agreement has focused attention on the right to health because this right is understood to impose a positive obligation on governments.²

The paper prepared for the first Project meeting analyses the complex relationship between human rights and WTO rules.³ It notes that some human rights are *jus cogens* norms that have a special character in international law, allowing for no derogation. In no case may a WTO rule, including a TRIPS Agreement rule, be allowed to conflict with a *jus cogens* human rights norm. On the other hand, treaties such as the WTO and TRIPS agreements may be inconsistent with other treaties or customary international law, including human rights treaties and norms. A conflict would need to be resolved by customary rules of treaty interpretation, including use of the principle of consistent interpretation.

B. 'Core' rights

In addition to norms of *jus cogens* and general treaty and customary rules, human rights law introduces the concept of 'core' rights. The concept of core rights is introduced because a number of human rights are subject to 'progressive realization'. Because governments are constrained in the availability of resources, it is not possible for each government promptly to provide adequate education, housing, and health care for all the people. Nonetheless, governments are obligated to take steps consistent with their means to realize these rights progressively.

Despite resource constraints, each human right begets an irreducible 'core' obligation that governments are obligated to fulfil. For example, in the case of housing, there is a core obligation not to evict residents without notice and an opportunity to make a challenge. The concept of 'core' human rights, which

¹ There is, of course, dispute regarding the content of the right to life, *inter alia*, concerning whether the death penalty can lawfully be imposed in criminal proceedings.

² See eg Report of the High Commissioner, The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights, Commission On Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, Fifty-second session, Item 4 of the provisional agenda, E/CN.4/Sub.2/2001/13 (27 June 2001).

³ F M Abbott, TRIPS and Human Rights: Preliminary Reflections, in (T Cottier/F Abbott/C Breining (eds), International Trade and Human Rights, Foundations and Conceptual Issues.

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might be thought of as the ‘core of the right’, raises the question whether there is an additional step in the hierarchy of international legal rules—including at the WTO—between absolute *jus cogens* obligations and general treaty and custom. If a TRIPS Agreement rule might ordinarily be inconsistent with a human rights rule established by treaty, might a ‘core’ human right have a special status that precludes such interference?

Neither the earlier paper nor this case study suggests a general answer to the question of what implications the concept of ‘core’ human rights may have for interpretation of the TRIPS Agreement. They suggest, however, that the relationship between WTO law and human rights law may be more nuanced than drawing a bright line between the treatment of *jus cogens* and general international law norms.

C. The content of the right to health

A human right to health is identified in a number of human rights instruments. Article 25 of the Universal Declaration of Human Rights refers to health, well-being, and medical care as the objectives of an adequate standard of living. Article 12(1) of the International Covenant on Economic, Social, and Cultural Rights (ICESCR) provides: ‘The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.’

The preamble to the Constitution of the World Health Organization states, *inter alia*:⁴

The States Parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples:

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

The WHO Constitution is of particular importance because of virtually universal state membership of the organization.⁵

Article XI of the American Declaration on the Rights and Duties of Man provides: ‘Every person has the right to the preservation of his health through sanitary and social measures relating to food, clothing, housing and medical care, to the extent permitted by public and community resources.’⁶

⁴ Available at <http://www.who.int>.

⁵ As of 2 September 2003, there were 192 states party to the WHO Constitution. *Ibid.*

⁶ See also art 26 of the American Convention on Human Rights providing for the progressive implementation of rights implicit in the Charter of the Organization of American States, including art 34 providing for the establishment of conditions for a ‘healthful’ life.

A number of other international agreements recognise a 'right to health'.⁷

The Committee on Economic, Social, and Cultural Rights has provided a detailed interpretation of the right to health established under Article 12, ICECSR in its General Comment No 14 (2000) on 'The right to the highest attainable standard of health'. The Committee elaborates on 'core' obligations:

Core obligations

43. In General Comment No. 3, the Committee confirms that States parties have a core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in the Covenant, including essential primary health care. Read in conjunction with more contemporary instruments, such as the Programme of Action of the International Conference on Population and Development, the Alma-Ata Declaration provides compelling guidance on the core obligations arising from article 12. Accordingly, in the Committee's view, these core obligations include at least the following obligations:

- (a) To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalised groups;
- (b) To ensure access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone;
- (c) To ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water;
- (d) To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs;
- (e) To ensure equitable distribution of all health facilities, goods and services;
- (f) To adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population; the strategy and plan of action shall be devised, and periodically reviewed, on the basis of a participatory and transparent process; they shall include methods, such as right to health indicators and benchmarks, by which progress can be closely monitored; the process by which the strategy and plan of action are devised, as well as their content, shall give particular attention to all vulnerable or marginalized groups.

⁷ General Comment No 14 (2000) to the ICESCR, following retrench to the Universal Declaration and the ICECSR, states:

Additionally, the right to health is recognized, inter alia, in article 5(e)(iv) of the International Convention on the Elimination of All Forms of Racial Discrimination of 1965, in articles 11.1(f) and 12 of the Convention on the Elimination of All Forms of Discrimination against Women of 1979 and in article 24 of the Convention on the Rights of the Child of 1989. Several regional human rights instruments also recognize the right to health, such as the European Social Charter of 1961 as revised (art. 11), the African Charter on Human and Peoples' Rights of 1981 (art. 16) and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988 (art. 10). Similarly, the right to health has been proclaimed by the Commission on Human Rights, as well as in the Vienna Declaration and Programme of Action of 1993 and other international instruments.

3. The right to health is closely related to and dependent upon the realization of other human rights, as contained in the International Bill of Rights, including the rights to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition against torture, privacy, access to information, and the freedoms of association, assembly and movement. These and other rights and freedoms address integral components of the right to health.

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44. The Committee also confirms that the following are obligations of comparable priority:

- (a) To ensure reproductive, maternal (pre-natal as well as post-natal) and child health care;
- (b) To provide immunization against the major infectious diseases occurring in the community;
- (c) To take measures to prevent, treat and control epidemic and endemic diseases;
- (d) To provide education and access to information concerning the main health problems in the community, including methods of preventing and controlling them;
- (e) To provide appropriate training for health personnel, including education on health and human rights.

In addition to the core obligations, the Committee interprets the right to health to incorporate an obligation on states, *inter alia*, to foster medical research.⁸ The obligation to pursue research is emphasized by the Report of the High Commissioner on Human Rights on the TRIPS Agreement.⁹

D. The TRIPS Agreement

A number of provisions of the TRIPS Agreement directly affect public health interests.¹⁰ Although a 'right to health' is not explicitly acknowledged in the agreement, the right of WTO Members to adopt measures necessary to protect public health is affirmed (conditioned on consistency with the agreement). The Doha Declaration on the TRIPS Agreement and Public Health was adopted in part to clarify that the right to health plays an essential role in interpretation of the agreement.

E. The Doha Declaration

The negotiating history and a more complete analysis of the Doha Declaration appear elsewhere.¹¹ It is important to emphasize here that the Doha Declaration is implicitly a human rights instrument, as well as a trade instrument. At paragraph 4, it states:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

The Members of the WTO have agreed by consensus that the TRIPS Agreement 'does not and should not' prevent them from taking measures to

⁸ *ibid* para 37. ⁹ Report of the High Commissioner (n 2) paras 37–41.

¹⁰ These are identified non-exhaustively in TRIPS and Human Rights (n 3).

¹¹ F M Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 *Journal of International Economic Law* (2002) 469 (emphasis added).

protect public health. The Agreement 'can and should be interpreted and implemented in a manner supportive of WTO Members' *right to protect public health*, and in particular, to promote access to medicines for all'.

The Declaration acknowledges the 'right to protect public health'. In any implementing action under the TRIPS Agreement and in any dispute settlement proceeding, this 'right to protect public health' must be acknowledged and given effect.

F. National law, human rights, and TRIPS

One of the principal conclusions of the general study of human rights and the TRIPS Agreement is that governments and courts are most likely to give effect to human rights in relation to intellectual property rights (IPRs) in the context of interpreting and applying the national constitution. Most countries give effect to human rights principles not by specifically incorporating or applying human rights treaties in national law, but rather by enshrining the rights of individuals in the national constitution.

Does the TRIPS Agreement limit the range of options available to introduce human rights and, more specifically, the right to health in national competition law? Does it encourage the introduction of human rights in national competition law?

II. THE TRIPS AGREEMENT AND COMPETITION¹²

A. Legal provisions

There are three provisions of the TRIPS Agreement expressly addressing competition. The first, Article 8.2, acknowledges the right of Members to act against abuse of IPRs, provided such action is consistent with the provisions of the Agreement.

Article 8, Principles

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

The second, Article 40, is a more detailed provision that, by its title and terms, is addressed to anti-competitive licensing practices or conditions.

¹² Parts of this discussion of the competition rules of the TRIPS Agreement are adapted from Report: Are the Competition Rules in the WTO Agreement on Trade-Related Intellectual Property Rights Adequate? in Preparing the Doha Development Round: Challenges to the Legitimacy and Efficiency of the World Trading System, E U Petersmann (ed), forthcoming 2003, European University Institute.

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Section 8: control of anti-competitive practices in contractual licences

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.¹³

Article 31(k), TRIPS Agreement, acknowledges that compulsory licensing is a remedy available to correct abuse of patents,¹⁴ providing:

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

Article 31(k) is the only part of the TRIPS compulsory licensing rules that incorporates a waiver of the condition that compulsory licences must be issued 'predominantly' for the supply of the domestic market.¹⁵

¹³ art 40, TRIPS Agreement, continues:

3. Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member to which the request for consultations has been addressed is undertaking practices in violation of the requesting Member's laws and regulations on the subject matter of this Section, and which wishes to secure compliance with such legislation, without prejudice to any action under the law and to the full freedom of an ultimate decision of either Member. The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.

A Member whose nationals or domiciliaries are subject to proceedings in another Member concerning alleged violation of that other Member's laws and regulations on the subject matter of this Section shall, upon request, be granted an opportunity for consultations by the other Member under the same conditions as those foreseen in paragraph 3.

¹⁴ art 31(l), TRIPS Agreement, addresses the problem of dependent patents whose exploitation might otherwise be blocked. This is also a competition-related provision.

¹⁵ Of course, compulsory licensing is not the only remedy available for anti-competitive abuse of IPRs, which may include, *inter alia*, injunction and fines.

At an indirect level, Article 6, TRIPS Agreement, as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health, authorizes each WTO Member to adopt its own policies and rules on the subject of exhaustion of rights.

Article 6

Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Doha Declaration

5(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.¹⁶

The exhaustion principle is fundamentally directed at maintaining competitive markets in trade.¹⁷

The general recognition of flexibility in implementing methods in Article 1.1, TRIPS Agreement, will of course apply in the competition context.

The first paragraph of the preamble to the agreement notes that IPRs should not themselves act to distort trade: '*Desiring* to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade'.

Part III, TRIPS Agreement, on the enforcement of IPRs is of course generally applicable to enforcement in the competition context as well requiring, for example, due process of law.

B. Interpretation

The TRIPS Agreement provides WTO Members with substantial discretion in the development and application of competition law to arrangements and conduct in the field of IPRs. The text of Article 8.2 requires that competition measures be 'consistent' with the TRIPS Agreement, and this suggests that competition law should not be used as a disguised mechanism for undermining the basic rights accorded under the Agreement. Measures may be taken to prevent abuse of IPRs, or resort to practices that 'unreasonably' restrain trade or that 'adversely affect' the 'international transfer of technology'. As discussed

¹⁶ WTO Ministerial Conference, Declaration on the Trips Agreement And Public Health (adopted 14 November 2001) Fourth Session, Doha, WT/MIN(01)/DEC/2 (20 Nov. 2001).

¹⁷ See eg F M Abbott, First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation, 1 *Journal of International Economic Law* (1998) 607.

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below, the question whether a particular practice ‘unreasonably’ restrains trade involves a classical balancing test taking into account the effects of conduct on consumers or industrial policy interests, and has been applied with significantly different results not only in different legal systems, but in the same legal systems over time. From the standpoint of competition rules customarily applied to IPRs-related practices in developed and developing Members, it is doubtful that such application in good faith will be limited by the text of Article 8.2.

Article 40.2 expressly envisions that Members may ‘specify’, in their legislation licensing, practices that ‘may in particular cases constitute an abuse’ of IPRs. This language encompasses the adoption of per se rules in respect to certain types of licensing practices, such as those applied by the EC in its technology transfer regulation.¹⁸ The ‘in particular cases’ language, which is acknowledged to represent less than ideal drafting, is intended to require that Members define such practices on the basis of their competitive merits, rather than in an overly abstract manner (and not to prevent the adoption of per se rules).¹⁹

While there might be ways to improve the drafting of Articles 8.2 or 40 so as to improve clarity, as a practical matter these provisions do not appear to impinge substantially upon Member discretion in the formulation and application of competition rules to IPRs, and it is doubtful that a new set of negotiations is needed to establish the presence of discretion from a legal standpoint. Moreover, the Doha Declaration on the TRIPS Agreement and Public Health, paragraph 5, has confirmed the flexibility inherent in parallel trade and compulsory licensing rules.

The TRIPS Agreement does not limit the remedial measures that may be imposed by competition authorities and courts. For example, it does not preclude the award of treble damages that may be imposed as a remedy in US antitrust proceedings. Remedies may include injunction, damages, fines and, as noted above, compulsory licensing.²⁰

III. THE RIGHT TO HEALTH AND CONSUMER PROTECTION

Antitrust or competition law is largely the product of the American experience of the late 1800s and early 1900s when the government and courts confronted the great railroad and oil trusts that dominated large parts of the US economy.²¹ The

¹⁸ See discussion of EC technology transfer regulation (n 19–24).

¹⁹ See Part 3, Intellectual Property Rights and Competition, in UNCTAD–ICTSD TRIPS Resource Book: An authoritative and practical guide to the TRIPS Agreement, available at <http://www.ictsd.org/iprsonline/unctadictsd/ResourceBookIndex.htm> (2003).

²⁰ There are certain conditions placed on compulsory licensing as antitrust remedy, but the main effect is to allow reduction of remuneration based on the remedial nature of the licence.

²¹ In its seminal decision in *Standard Oil Company of New Jersey v United States*, 221 U.S. 1 (1911) the U.S. Supreme Court said:

The debates show that doubt as to whether there was a common law of the United States which governed the subject in the absence of legislation was among the influences leading to the passage of the act. They conclusively show, however, that the main cause which led to the legislation was the thought that it was required by the economic condition of the times, that is, the vast accumulation

trusts were perceived as a threat from a variety of perspectives.²² The aggregation of power in the hands of a few commercial actors threatened the democratic roots of government. By controlling important economic gateways, the trusts threatened to retard general economic growth. The consumer was the ultimate victim of the trusts, paying higher prices than would be found in competitive markets.

Competition law is intended to prevent an excessive accumulation of economic power in the hands of a single actor (anti-monopoly).²³ In this sense, competition law is an instrument for protecting democracy. Competition law is intended to protect the integrity of the market and thus to preserve the ability of producers to enter and compete against each other.²⁴ In this sense, competition law has an

of wealth in the hands of corporations and individuals, the enormous development of corporate organization, the facility for combination which such organizations afforded, the fact that the facility was being used, and that combinations known as trusts were being multiplied, and the widespread impression that their power had been and would be exerted to oppress individuals and injure the public generally. Although debates may not be used as a means for interpreting a statute (*United States v Trans-Missouri Freight Association*, 166 U.S. 318, and cases cited) that rule in the nature of things is not violated by resorting to debates as a means of ascertaining the environment at the time of the enactment of a particular law, that is, the history of the period when it was adopted. 221 U.S., 50.

²² In his concurring and dissenting opinion in *Standard Oil*, *ibid*, Justice Harlan said:

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'All who recall the condition of the country in 1890 will remember that there was everywhere, among the people generally, a deep feeling of unrest. The Nation had been rid of human slavery—fortunately, as all now feel—but the conviction was universal that the country was in real danger from another kind of slavery sought to be fastened on the American people, namely, the slavery that would result from aggregations of capital in the hands of a few individuals and corporations controlling, for their own profit and advantage exclusively, the entire business of the country, including the production and sale of the necessities of life. Such a danger was thought to be then imminent, and all felt that it must be met firmly and by such statutory regulations as would adequately protect the people against oppression and wrong. Congress therefore took up the matter and gave the whole subject the fullest consideration. All agreed that the National Government could not, by legislation, regulate the domestic trade carried on wholly within the several States; for, power to regulate such trade remained with, because never surrendered by, the States. But, under authority expressly granted to it by the Constitution, Congress could regulate commerce among the several States and with foreign states. Its authority to regulate such commerce was and is paramount, due force being given to other provisions of the fundamental law devised by the fathers for the safety of the Government and for the protection and security of the essential rights inhering in life, liberty and property. Guided by these considerations, and to the end that the people, so far as interstate commerce was concerned, might not be dominated by vast combinations and monopolies, having power to advance their own selfish ends, regardless of the general interests and welfare, Congress passed the Anti-trust Act of 1890... 221 U.S., 83.'

²³ Under s 2 of the U.S. Sherman Act it is not enough that an actor achieves market dominance, but that it does so through anti-competitive means or exercises its position abusively. Conceptually, in U.S. law the good monopolist may exist. See eg *United States v Aluminum Co. of America*, 148 F.2d 416 92d Cir. (1945), opinion by Judge Learned Hand, cited favourably by the Supreme Court eg in *Eastman Kodak v Image Technical Services*, 504 U.S. 451 (1992). Art 82 of the EC Treaty proscribes 'abuse' of dominant position, not the holding of dominant position in itself.

S 1 of the U. S. Sherman Act (with proximate parallel in art 81 of the EC Treaty) makes unlawful combinations or conspiracies in restraint of trade. S 2 of that Act (with proximate art 82 of the EC Treaty) makes unlawful monopolization or attempt to monopolize.

²⁴ U.S. antitrust law gives close attention to industrial policy interests. See eg the Herfindahl-Hirschman Index (HHI) used in evaluating mergers and acquisitions that focuses on the structure of the producer market in the U.S. Department of Justice and Federal Trade Commission 1992 Horizontal Merger Guidelines (with Revisions to s 4 on Efficiencies (8 April 1997)), available at <http://www.ftc.gov/bc/docs/horizmer.htm>, and the market share analysis in the DOJ-FTC Antitrust Guidelines for the Licensing of Intellectual Property, discussed below.

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industrial policy foundation. The ultimate goal of competition law is to protect the interests of consumers in obtaining access to goods and services at 'market' prices. In this sense, the principal object of competition law is consumer protection.²⁵ There was and remains no single policy foundation for competition law.

Which of the objectives of competition law is paramount—the governance, industrial policy, or consumer protection objective—is one question that might be answered by informing competition law with the international human right to health. Since the right to health pertains to the individual, we could say that it would inform competition law to the extent of elevating consumer protection interests over industrial policy interests. Consider a hypothetical case:

The market for pharmaceuticals in Country Alpha is dominated by two pharmaceutical companies, X and Y. Company Z brings a claim against X and Y for conspiring to prevent the entrance of a new competitor by establishing exclusive marketing arrangements with wholesale pharmaceutical distributors. Companies X and Y defend their marketing practices on grounds that the exclusive arrangements are necessary to protect a 'reasonable' market share and to allow an adequate return to promote research and development.

If an industrial policy basis for competition law is accepted, the court may find that the restrictive conduct is justified by protection of reasonable industrial policy objectives. Conversely, if a consumer protection interest is accepted, the court might say that despite the industrial policy interest, the interest of the consumer in lower prices predominates, and the conduct is unreasonable.²⁶ In such a context, an interpretation of the right to health as a right to consumer protection might affect the application of competition rules.

One possible answer to how competition law and the right to health inform each other is to say that the right to health is a consumer interest protected by competition law. A WTO Member can certainly adopt a consumer protection-oriented approach to competition law without any change to TRIPS Agreement rules.

IV. COMPETITION LAW AS AN INSTRUMENT FOR THE PROGRESSIVE REALIZATION OF HUMAN RIGHTS

A. *Per se* rules

Potentially anti-competitive conduct is typically subject to one of two types of rules: *per se* rules, and those that involve application of a 'rule of reason'. Though this specific terminology initially arose in US antitrust law, the EC incorporates similar principles in more detailed basic prohibitions in the

²⁵ See eg S A Riesenfeld (Antitrust and Consumer Protection).

²⁶ Of course, X and Y would argue that promotion of R & D enhances consumer welfare as well.

EC Treaty,²⁷ and in regulatory acts of the Commission which proscribe certain types of conduct, and allow for regulatory analysis of other types of conduct.²⁸ The competition authorities of each WTO Member (including legislators, executive officials, and courts) will determine which acts fall into which category. In the formulation of rules it might be asked, for example, whether there is a 'right to health' interest that would mandate a per se approach to a type of conduct.²⁹ Might a particular type of conduct presumptively interfere with the progressive realization of the right to health such as to bar it as a matter of competition law?

Developing country regulators may of course benefit from the comparative approach, looking to the existing practices of developed and developing country competition authorities. Moreover, a comparative approach might be supplemented by a historical approach—that is, looking to how competition laws have evolved to address different phases of economic development. A highly advanced economy may be able to self-correct through the operation of market forces more readily than an economy in a less advanced stage of development. In the advanced post-industrial economies, there are typically a significant number of potential competitors willing and able to challenge an enterprise that attempts to extract super-competitive prices, including by anti-competitive means. Developing economies are often characterized by a smaller number of potential competitors, based in part on the lower availability of capital. Because these economies may be more vulnerable to anti-competitive behaviours, while at the same time be faced with a relative lack of regulatory and enforcement capacity, developing countries may find a greater benefit from per se rules than developed countries.

²⁷ art 81, EC Treaty, includes a list of prohibited practices, such as practices that 'directly or indirectly fix purchase or selling prices or any other trading conditions' (art 81(a)).

²⁸ See eg Doc 396R0240, Commission Regulation (EC) No 240/96 (31 January 1996) on the application of art 85(3) of the Treaty to certain categories of technology transfer agreements (Text with EEA relevance), Official journal no L 031, 09/02/1996 P. 0002–0013.

²⁹ The U.S. Supreme Court said in *Continental T. V. v GTE Sylvania*, 433 U.S. 36; 97 S. Ct. 2549; 53 L. Ed. 2d 568; 1977 U.S. LEXIS 134 (1977):

Per se rules of illegality are appropriate only when they relate to conduct that is manifestly anti-competitive. As the Court explained in *Northern Pac. R. Co. v. United States*, 356 U. S. 1, 5 (1958), 'there are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use.'

fn16: Per se rules thus require the Court to make broad generalizations about the social utility of particular commercial practices. The probability that anti-competitive consequences will result from a practice and the severity of those consequences must be balanced against its procompetitive consequences. Cases that do not fit the generalization may arise, but a per se rule reflects the judgment that such cases are not sufficiently common or important to justify the time and expense necessary to identify them. Once established, per se rules tend to provide guidance to the business community and to minimize the burdens on litigants and the judicial system of the more complex rule-of-reason trials, see *Northern Pac. R. Co. v. United States*, 356 U.S. 1, 5; *United States v. Topco Associates, Inc.*, 405 U.S. 596, 609–610 (1972), but those advantages are not sufficient in themselves to justify the creation of per se rules. If it were otherwise, all of antitrust law would be reduced to per se rules, thus introducing an unintended and undesirable rigidity in the law. 433 U.S. 49–50.

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What kinds of practices might be considered to constitute a per se unreasonable interference with the right to health? Practices that have traditionally been associated with abusive licensing, such as exclusive grant-backs and tying arrangements, are logical candidates. However, to the extent that licensing practices may affect the research and development side of the public health equation, it may be useful to broaden the horizon of competition law regulators to include practices related to sales and marketing of patented and trademarked medicines within the scope of per se rules. Thus, for example, a pharmaceutical producer that offers to sell its patented products to wholesalers only on condition that they also purchase its off-patent products may be engaged in an unlawful patent-tying arrangement.

The submission of false or misleading information to regulatory authorities regarding the patent status of medicines might constitute a per se violation of competition rules since such submissions would by definition be intended to block competitors from entering the market, and there would be no redeeming social benefit to such practices.³⁰ The threat of an automatic finding of a violation of competition rules and its associated injunction and/or penalties might act to discourage such conduct *ab initio*.

The categorization of a practice as anti-competitive per se has the substantial advantage of reducing the transaction costs (and delays) involved in the application of norms because the need to present and adjudicate complex issues of fact is minimized. This has a particular appeal for developing countries that may lack the financial and technical resources required to confront foreign-based enterprises that may have greater access to resources. The potential advantages of reducing the transaction costs involved in prosecuting cases are apparent. There is, of course, a risk that overaggressive application of competition law may cause suppliers to be hesitant to enter or continue doing business in a market, and might result in higher public health costs. As with all legal endeavours, the question is one of finding an appropriate balance. The balance that works best in the OECD may not, however, be the balance that works best in developing countries at different stages of development.

B. Rule of reason

Human rights may well be factored into the application of the 'rule of reason'. A court (or competition authority) will apply the rule of reason when a type of

³⁰ As an illustration, the U.S. Federal Trade Commission recently completed an in-depth study of so-called 'Orange Book' practices by certain pharmaceutical enterprises. This study found that patents had been grossly abused at the Food and Drug Administration to prevent the entry of generic drugs onto the U.S. market. A principal violator company has been the subject of consent injunction and has paid substantial fines. See U.S. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study (2002)* available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> and *States and FTC Settle with Bristol-Myers Squibb in Buspar Monopolization Suit*, 28 *Antitrust Multistate Review* no 2, p 3, National Association of Attorneys General Antitrust Report (February 2003) Lexis-Nexis.

conduct raises potential anti-competitive concerns, but is not so presumptively harmful as to demand remedial action in all cases. The court asks whether under the circumstances the conduct is such as will cause, or potentially cause, an unreasonable restraint on trade.³¹

To elaborate, the US Sherman Act, Section 1, precludes combinations (and conspiracies) in restraint of trade.³² It was noted early on that all contractual arrangements in some sense restrain trade.³³ A contract for the sale of goods from Party A to Party B excludes the sale of the same goods from Party A to Party C. In the vast preponderance of cases, a contractual restriction is reasonable. It is only in cases where Party A imposes conditions on Party B that prevent Party B from using the goods in certain ways, or when Party A and Party B enter into the contract with the intent to harm Party C through unfair business practices, that the conduct may be 'unreasonable'. Courts are constantly wrestling with the question, when does conduct cross the line between reasonable and

³¹ In *Standard Oil v United States* (n 21) the Supreme Court said:

And as the contracts or acts embraced in the provision were not expressly defined, since the enumeration addressed itself simply to classes of acts, those classes being broad enough to embrace every conceivable contract or combination which could be made concerning trade or commerce or the subjects of such commerce, and thus caused any act done by any of the enumerated methods anywhere in the whole field of human activity to be illegal if in restraint of trade, it inevitably follows that the provision necessarily called for the exercise of judgment which required that some standard should be resorted to for the purpose of determining whether the prohibitions contained in the statute had or had not in any given case been violated. Thus not specifying but indubitably contemplating and requiring a standard, it follows that it was intended that the standard of reason which had been applied at the common law and in this country in dealing with subjects of the character embraced by the statute, was intended to be the measure used for the purpose of determining whether in a given case a particular act had or had not brought about the wrong against which the statute provided. 221 U.S., 60.

In *GTE Sylvania* the Supreme Court referred to the formulation by Justice Brandeis:

One of the most frequently cited statements of the rule of reason is that of Mr. Justice Brandeis in *Chicago Bd. of Trade v United States*, 246 U.S. 231, 238 (1918):

The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences.

³² art 81, EC Treaty, proscribes 'all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market'.

³³ In the *Standard Oil v United States* decision (n 21) the Supreme Court explained that while the language of the Sherman Act did not explicitly provide a criterion of unreasonableness on restraints of trade, Congress had considered the common law practices of the United Kingdom in approaching the subject of monopolization, and that the common law of England had evolved in a way that distinguished between the common constraints freely and ordinarily entered into by contract, and the types of constraints that imposed unreasonable restraints on competition. See 221 U.S. 50–61.

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unreasonable? Administrative authorities have in some cases issued extensive guidance on this question, such as the US Department of Justice and Federal Trade Commission 'Antitrust Guidelines for the Licensing of Intellectual Property' (1995) and the EC Commission 'Regulation on the application of Article 85(3) of the Treaty to certain categories of technology transfer agreements' (1996).

Does the human right to health potentially inform the rule of reason in the competition law context? Is a form of conduct more or less reasonable because it affects the right to health?

It would certainly appear so. That is, the evaluation of potentially anti-competitive practices quite plausibly and persuasively should take into account the 'interests' that are impacted by the conduct. A practice among automobile producers that may or may not restrain the introduction of a new type of exterior paint may be differentiated from a practice among pharmaceutical producers that may increase the price of essential medicines. Whereas in the first case the courts might demand a higher probability of risk to the market before requiring remedial action, in the second case the courts may well employ a lower risk threshold because of the nature of the prospective harm.

The WTO Appellate Body has indirectly approached this question in *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*.³⁴ In that case Canada had claimed an inconsistency in French regulations banning the importation of asbestos containing products on public health and safety grounds. The panel held that similar cement products with and without asbestos were 'like products' from a national treatment standpoint, and that the French regulations must therefore be considered under an Article XX(b) exception to GATT Article III.³⁵ The Appellate Body rejected the approach of the panel, saying that it had analysed the question of 'like products' too narrowly. To put the matter colloquially, there is a difference between products that will kill you and those that won't, even if they are both used as structural support for buildings. Two functionally equivalent products, one with well-established carcinogens and one without, are not 'like products'.³⁶

The logic of differentiating functionally equivalent products under GATT Article III on the basis of whether they are harmful to health would appear to extend to differentiating between different forms of potentially anti-competitive conduct depending on the effect on public health. There is an obvious difference between protecting the market for automotive paint and that for pharmaceutical products. A practice that artificially restrains the introduction of a new automobile paint will have a redistributive effect within the automotive sector, and may at the margins affect consumer welfare. A practice that artificially increases the price of cancer or AIDS treatments will have a direct effect on patients. Many live at the economic margins and will be priced in and out of the

³⁴ AB-2000-11 WT/DS135/AB/R (12 March 2001).

³⁵ *ibid* para 4.

³⁶ Although the Appellate Body left room for Canada to reargue the like products question, this option for all practical purposes appeared to be foreclosed by the decision.

market for medicines based on comparatively small changes in price. The courts and the public may have a compelling interest in heightened scrutiny of practices affecting the medicines market. There is apparent good reason for an approach that would involve early intervention in the pharmaceuticals market, while potentially tolerating later intervention in the automotive paint market. Application of the 'rule of reason', that is, deciding whether conduct is an unreasonable restraint of trade, may well be performed differently when the human right to health is at stake.

It might be argued that the foregoing analysis is the same as elevating 'consumer protection' interests above 'industrial policy' interests in antitrust analysis. Yet the notion of protecting consumer interests in the competition law context might be 'softer' than importing the human right to health. That is, governments are basically free to choose the basis of their competition policy, and might elect to pursue an industrial policy approach over a consumer protection approach. However, because the right to health is established by international law, it may be argued that competition authorities are compelled to take it into account in rule of reason analysis. This might even be seen to limit the flexibility of WTO Members in deciding whether to address anti-competitive conduct in the field of TRIPS. If the right to health demands progressive realization, and if anti-competitive conduct interferes with that path, then Members may be obligated to act.

V. THE ISSUE OF CONCRETIZATION

One of the critiques of a human rights approach to trade is that human rights are often stated in terms too general to be useful in concrete cases. It is helpful to identify specific contexts in which the application of a human rights rule to an economic/trade context would affect a particular outcome. There is a case ongoing before the Commission on Competition in South Africa which makes various allegations of excessive pricing by certain pharmaceutical patent holders. Indeed, the Complaint brought by the Treatment Action Campaign (TAC), among others,³⁷ presents both consumer protection and right to life and health arguments. It is said, for example:

50. Because high prices result in lack of access to treatment, the high prices of ARVs result in many avoidable opportunistic infections, preventable deaths and the resultant social and financial implications accompanying high levels of morbidity and mortality. Having established this, there can be no doubt that the high prices that are currently being charged in the private sector for ARVs *are to the detriment of consumers*.

51. The detriment that is caused is particularly grave by virtue of its direct bearing on the ability of consumers *fully to enjoy their constitutionally protected rights and in*

³⁷ *Hazel Tau, et al. v GlaxoSmithkline South Africa (Pty) Ltd*, In The Competition Commission Of South Africa, Statement of Complaint in terms of Section 49b(2)(B) of the Competition Act 89 of 1998.

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particular the rights to life, dignity and equality, and access to health care services. The high prices also have the effect that the best interests of children cannot properly be served.³⁸

The Complaint refers to the rule in South Africa regarding excessive pricing:

58. Section 8(a) of the Act prohibits a dominant firm from charging ‘an excessive price to the detriment of consumers’. An ‘excessive price’ is defined in section 1 as ‘a price for a good or service which—

‘(aa) bears no reasonable relation to the economic value of that good or service; and

(bb) is higher than the value referred to in subparagraph (aa)’’.

Although this study does not include research into the applicable case law of South Africa, it appears that analysis of the claims of excessive pricing would involve a rule of reason. What is a price that is unreasonable ‘in relation to the economic value of that good’?

The question of a reasonable price may well be informed, if not controlled, by the right to health of HIV–AIDS patients in South Africa. The invocation of the right will not alone be sufficient to determine whether the respondents are charging excessive prices, which will depend on a variety of factors. The Complainants are not seeking to deny the respondents a fair rate of return on investment. However, the Constitutional Court has already observed in its holding against the government in response to a challenge by TAC for failure to implement a treatment program in respect to mother-to-child transmission of HIV, that ‘A programme that excludes a significant segment of society cannot be said to be reasonable.’³⁹ Though the private sector may not be under the same affirmative obligation as the government in respect to supporting the progressive realization of the right to health,⁴⁰ the authorities making the decision regarding reasonableness at the Competition Commission (investigatory) level (and subsequently at the Competition Tribunal level) are acting under

³⁸ (Emphasis added.) To similar effect later in the complaint:

60.4 The nature and extent of the detriment to consumers that results from the high price. Thus, the fact that high prices cause avoidable loss of life and unnecessary suffering must be taken into account. The fact that this affects so many people must also be taken into account as must the fact that HIV/AIDS is the leading cause of mortality in South Africa and is regarded as the greatest health threat confronting South Africa at present.

60.5 The adverse impact of the high prices on constitutionally protected and internationally recognised rights. The health consequences of lack of access to treatment deprive people of the enjoyment of their constitutionally protected rights to life, dignity and access to health care services. It also deprives children of their right to have their best interests treated as paramount. The right to dignity is foundational to our constitutional order and with the right to life is regarded as one of the most important rights. Access to health care services allows people to live dignified lives. These rights are firmly entrenched in the Constitution and are also recognised at international law.

³⁹ *Minister of Health v Treatment Action Campaign*, Constitutional Court of South Africa, Case CCT 8/02 (decided 5 July 2002).

⁴⁰ art 27(2) of the SA Constitution says that ‘The state must take reasonable legislative and other measures, within its available resources, to achieve progressive realization of these rights.’ See *Minister v TAC*, *ibid*, para 4.

a constitutional mandate to promote progressive realization of that right. This mandate should affect their determinations regarding conduct in the private sector.

Moreover, the state may not ignore that the Constitution provides its right to health guarantee to individuals (Article 27(1) 'Everyone has the right to have access to health care services . . .'). A balance must be struck between the rights of private corporate actors to a fair return on investment and the right of individuals to access to health care.

The obligation on the government to promote progressive realization, combined with the right of individuals to health care (each of which corresponds to an international legal rule), does not compel the setting of a specific reasonable price, but it strongly argues in favour of balancing principles that are not one-sided.

VI. THE INEFFICIENT NATURE OF THE COMPETITION LAW APPROACH TO TRIPS

It is not infrequently suggested that competition law is an answer to perceived imbalances in the TRIPS Agreement, including in achieving the progressive realization of the right to health. Of course, it is a potentially important tool. However, some notes of caution are important.

- a. The application of competition law typically requires a significant investment and level of development in legal and institutional infrastructure. Such investments are burdensome for many developing countries, and may be unduly burdensome in a large number of cases.
- b. Proceedings under competition law tend to be costly, complex, and time-consuming. They typically involve substantial evidence gathering. IPRs holders are more likely than consumer groups and individuals to be able to sustain the costs of such proceedings. Governments may face substantial threshold barriers to their initiation or continuance. Although certain aspects may be made easier or less costly by choosing, for example, per se regulatory rules over rule of reason analysis by courts, there are nevertheless likely to be significant transaction costs involved if the subjects of investigation employ litigation strategies designed to impede the progress of proceedings.
- c. Facts are constantly changing. For example, in the widely reported *Microsoft* case brought by the Department of Justice, the conduct complained of was largely irrelevant by the time the proceedings had concluded, so that remedial measures were in many respects inconsequential. As a strategic actor, Microsoft would almost certainly conclude that its gains from unlawful conduct (eg, effectively eliminating Netscape as a competitor in the browser and middle software markets) far exceeded its costs.

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In South Africa, one of the respondents before the Competition Commission recently announced a significant decrease in prices.⁴¹ On one hand, this to some extent probably reflects the pressure of the instant proceeding, and may demonstrate its beneficial effect. At the same time, it may make it more difficult for the Complainants to obtain a finding of excessive pricing.

The application of competition law principles is part of an overall arsenal of useful measures to rebalance aspects of the TRIPS Agreement in favour of the right to health, but it is not likely an adequate solution in itself.

VII. CANCÚN AND BEYOND

The TRIPS Agreement as currently drafted provides WTO Members with substantial flexibility in the adoption and application of competition law, and it seems doubtful that changes to the terms of the TRIPS Agreement are needed to allow Members to use human rights, including the right to health, as part of their analytic framework. Human rights principles are typically reflected in national constitutions. The WTO dispute settlement system would approach tinkering with rights prescribed in a constitution—or constitutionally based rights—with great circumspection. Since the Doha Declaration has already recognized that Members in the context of TRIPS have the right to protect public health and promote access to medicines for all, the necessary groundwork from a WTO standpoint appears to be laid.

The WTO Working Group on the Interaction Between Trade and Competition Policy⁴² has considered various proposals for negotiation of a new trade and competition agreement,⁴³ and efforts were made to launch such negotiations formally as part of the Doha Development Round. Those efforts were not successful, having been taken off the Work Program of the Doha Development Agenda following the Cancun Ministerial.⁴⁴

Developing country Members of the WTO have reacted with scepticism to proposals for negotiation regarding additional competition rules, which

⁴¹ See announcement by GlaxoSmithKline regarding ARV pricing of May 2003, eg Positive reaction to cheaper AIDS drugs, *Business Day*, South Africa (29 April 2003) 22.

⁴² Ministerial Declaration (adopted 14 November 2001) Ministerial Conference, Fourth Session, WT/MIN(01)/DEC/1 (20 November 2001). Relevant provisions reproduced at Annex 1 to this paper. It appears unlikely that a mandate to negotiate a Trade and Competition Agreement will be adopted at the Fifth Ministerial Conference in Cancun. However, it is possible that the Working Group will be directed to continue its deliberations on this subject.

⁴³ Negotiations on substantive rules so far have focused on national and MFN principles, transparency, and control of 'hard core cartels'. Discussion on the issue of hard core cartels illustrates the difficulties Members are likely to face in dealing with substantive competition law principles. There is lack of agreement on how such cartels should be defined, whether any prohibition should take the form of a per se rule or follow a rule of reason approach, and how exceptions might be justified.

⁴⁴ See Doha Work Programme, Decision Adopted by the General Council on 1 August 2004, WT/L/579 (2 August 2004) para 1(g).

may seem anomalous in light of the many years of effort spent at UNCTAD attempting to devise ways of addressing problems of developmental imbalance by application of competition rules. Yet the apparent anomaly is not so difficult to explain. Developing country experience with the TRIPS Agreement, in particular, but also with subjects such as agricultural subsidies, has created an embedded climate of scepticism concerning the motives of developed Members within the WTO framework.

One of the concerns of developing Members is that competition rules that impose a strict national treatment standard would work against efforts to promote domestic industries, including small and medium enterprises. The South African Competition Act was specifically referenced in the 2002 Working Group Report to illustrate how developing Members have acted to retain flexibility to implement differentiated industrial policies (eg, encouraging small enterprises and 'black empowerment'). The Report stated:

Thus, the guarantees of non-discrimination and procedural fairness embodied in the Constitution and the existence of a Competition Act respecting those guarantees had not prevented the Government of South Africa from pursuing industrial and social policies even though the application of such policies required the selective promotion of particular interest groups.⁴⁵

Yet the Report does not suggest just how the South African Competition Act's allowance of preferences to previously disadvantaged groups would be accommodated under a principle of national treatment within a prospective multilateral competition agreement.

WTO Members generally recognize that anti-competitive practices in developed countries are having an adverse impact on developing countries. Yet the United States, for example, expressly exempts from the application of domestic antitrust law anti-competitive practices that affect only foreign markets.⁴⁶ Practices that are illegal in the US market are permitted in foreign markets,

⁴⁵ Report (2002) of the Working Group on the Interaction Between Trade and Competition Policy to the General Council, WT/WGTCP/6 (9 December 2002) para 44.

⁴⁶ The Sherman Act provides, for example

15 USCS § 6a (2003)

§ 6a. Conduct involving trade or commerce with foreign nations

This Act [15 USCS §§ 1 et seq., commonly 'the Sherman Anti-Trust Act'] shall not apply to conduct involving trade or commerce (other than import trade or import commerce) with foreign nations unless—

- (1) such conduct has a direct, substantial, and reasonably foreseeable effect —
 - (A) on trade or commerce which is not trade or commerce with foreign nations, or on import trade or import commerce with foreign nations; or
 - (B) on export trade or export commerce with foreign nations, of a person engaged in such trade or commerce in the United States; and
- (2) such effect gives rise to a claim under the provisions of this Act (15 USCS §§ 1 et seq.), other than this section.

If this Act (15 USCS §§ 1 et seq.) applies to such conduct only because of the operation of paragraph (1)(B), then this Act (15 USCS §§ 1 et seq.) shall apply to such conduct only for injury to export business in the United States.

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unless the US market is directly and substantially affected by the conduct or an exporter in the United States is directed and substantially affected. This is tantamount to encouraging such practices in developing country markets.

If developed Members are interested in demonstrating their bona fide intent to adopt competition principles working in favour of developing countries, a down payment on such negotiations might be a commitment to eliminate this sort of legislation, that is, a commitment to refrain from discriminating against foreign markets in the promulgation and application of competition rules. In the TRIPS and competition context, this would mean, *inter alia*, that licensing practices that are not tolerated in the home market will not be tolerated in a foreign market, and the enterprise subject of the complaint will face penalties in the home market for engaging in prohibited conduct overseas.⁴⁷

Article 40.3, TRIPS Agreement, provides for consultations and furnishing of non-confidential information, and for furnishing other information subject to the national law of the requested Member.⁴⁸ It is difficult to know the extent to which the national law of a Member will permit (or not) the mandatory furnishing of business information to the authorities (or private complainants) in another Member. Developing Members pursuing competition cases may have great difficulty obtaining critical information from private enterprises in developed Members, and a stronger form of cooperation agreement relating to such information might usefully be negotiated. However, it must be recognized that such information rules would run in both directions, and developing Members would also need to consider the extent to which they would be willing to furnish information in equivalent settings.⁴⁹

Developing Members differ widely in their capacity to address competition issues. Some have relatively well developed legal and prosecutorial infrastructures. In others, such infrastructures are very weak. A hard commitment on financial contribution from the developed Members to training of competition law authorities and the furnishing of suitable investigatory facilities would be useful. Since the TRIPS Agreement has an essentially satisfactory set of competition rules at present, there is no need to change the TRIPS rules in order to establish training and infrastructure programs. A critical aspect is to ensure that training and infrastructure support be provided by persons whose interests

⁴⁷ This may raise difficult issues in the application of competition law. A rule of reason analysis will include such matters as a determination of the relevant market and the conditions of competition in that market. The fact that an analysis would be difficult does not mean it should be avoided. *Per se* rules might assist when applied to conduct abroad.

⁴⁸ 'The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.' Art 40.3, TRIPS Agreement.

⁴⁹ An argument might be made that developing Members are entitled to special and differential treatment in the field of evidence sharing because, for example, of the comparative lack of resources necessary to pursue extraterritorial investigations.

are on the side of developing Members. A logical choice might be the build-up of resources at UNCTAD, though the creation of an autonomous training and support centre along the lines of the Advisory Center for WTO Law might also be considered.

The TRIPS Agreement allows for substantial flexibility in the development and application of competition rules. The Doha Declaration has reinforced the right to protect public health in the TRIPS context. The Appellate Body has recognized that considerations relating to public health may play an important role in the application of WTO rules. For the time being at least, introducing human rights considerations does not appear to be constrained by the TRIPS Agreement and existing WTO jurisprudence. It is, in the first instance at least, a matter of national governments introducing such considerations in the application of competition rules. Balancing under the rule of reason should necessarily include the present and prospective impact on the human right to health.

The Right to Health, Intellectual Property, and Competition Principles

SISULE F MUSUNGU

Commentary on Frederick M Abott

I. INTRODUCTION

This comment relates to the role of competition law as a requisite legislative measure to obviate the limitations imposed by intellectual property rules on the enjoyment of the right to health. The main question addressed is whether the implementation of the patent rules of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) without enacting and enforcing competition rules constitutes an unjustifiable failure to regulate the activities of individuals or corporations so as to prevent them from violating the right to health of others.

To address this question, several issues need to be examined. These include whether patent laws and rules impose a limitation on the enjoyment of the right to health; whether the government has a legitimate interest in protecting intellectual property rights, and especially patents; and whether the introduction of competition law would ensure that the limitations imposed on the right to health by patent rules are reasonable and justifiable.

Section II of the comment provides a background to the normative framework, the obligations and prima facie cases of violation of the right to health in context of the International Covenant on Economic, Social, and Cultural Rights (ICESCR). Section III discusses how intellectual property laws, especially patent rights, may limit the enjoyment of the right to health. Section IV then considers how competition rules can be interpreted under human rights law as a requisite legislative measure to guard against overbroad application of intellectual property laws and thereby promote the progressive realization of the right to health.

II. THE RIGHT TO HEALTH: NORMATIVE FRAMEWORK, STATE OBLIGATIONS, AND PRIMA FACIE CASES OF VIOLATION

The right to health is, today, solidly embedded in international, regional, and national human rights instruments. The right is recognized in various international and regional human rights instruments, in the Constitution of the World Health Organization (WHO) as well as in various national constitutions.¹

¹ See, for example, s 27 of the South African Constitution and art 13 of the Colombian Constitution.

At the international level, the starting point is article 25 of the Universal Declaration of Human Rights (UDHR).² It recognizes the right of 'everyone . . . to a standard of living adequate for the health of himself and his family, including food, clothing, housing and medical care and necessary social services'. The concept of health under the UDHR is further defined and given legal standing in international law by article 12 of the ICESCR.³ Article 12.1 of the Covenant recognizes 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.

Other international instruments that recognize the right to health on similar lines include the Convention on the Elimination of all Forms of Racial Discrimination (CERD),⁴ the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW),⁵ and the Convention on the Rights of the Child (CRC).⁶ The European Social Charter, the African Charter on Human and Peoples' Rights, and the San Salvador Protocol to the American Charter of Human Rights also recognize the right to health.

The right to health as conceptualized under article 12.1 of the ICESCR can be viewed as extending not only to timely and appropriate health care but also to the underlying determinants of health.⁷ Consequently, the provisions on the right to health in the ICESCR contemplates the enjoyment of a variety of essential facilities, goods, services, and conditions necessary for the realization of the highest attainable standard of health. The precise nature of the facilities, goods, and services to be provided in fulfilling the States' obligations will, however, vary from State to State and depend on a variety of factors, including the level of development.

The basic elements of the right are availability, accessibility, acceptability, and quality.⁸ According to the UN Committee on Economic, Social, and Cultural Rights (the CESCR), availability connotes functioning public health care facilities, goods, and services including relevant programs. The concept of accessibility, on the other hand, connotes a situation where there is equitable access and rational use of quality essential medicines.⁹ The concepts underpin the right to health making medicines essential products for basic human survival. It is within this context that essential medicines are considered as a critical component of any strategy for disease management.

The notion of the highest attainable standard of health in human rights instruments presupposes the progressive realization of the right and acknowledges

² Adopted by the UN General Assembly Resolution 217 (III) (10 December 1948).

³ Adopted by the UN General Assembly Resolution 2200 (XXI) (16 December 1966). The Covenant entered into force on 3 January 1976.

⁴ See art 5 (e).

⁵ See arts 11.1 (f) and 12.

⁶ See art 24.

⁷ S Musungu, *The Right to Health in the Global Economy: Reading Human Rights Obligations into the Patent Regime of the WTO-TRIPS Agreement*, in C Heyns (ed), *International Yearbook of the Regional Human Rights Masters Programmes 2001*, Centre for Human Rights, Pretoria, 194 (2003) 204.

⁸ For a discussion see CESCR General Comment 14, *The Right to the Highest Attainable Standard of Health*, (August 2000) para 12. Available at www.unhchr.ch.

⁹ M Scholtz, *WHO'S Role in Ensuring Access to Essential Drugs*, in *WHO Drug Information*, WHO, Geneva (1999) vol 13.

resource constraints. This does not, however, mean that the right is devoid of any real enforceable content. The broad definition of the right implies that the right does not merely require States to provide a comprehensive health care delivery and insurance system. The right also entails a duty to undertake measures to promote public health, prevent disease, and to eliminate other external causes of morbidity and mortality, reduce health inequalities, and improve the underlying conditions of health.¹⁰

The right to health can therefore be said to embrace two main parts, namely, elements related to health care and elements concerning the underlying preconditions of health, with the first being the core content of the right.¹¹ Guaranteeing the core content of the right to health and enhancing its overall realization imposes a number of clear obligations on States. In particular, article 12.2 (c) requires steps to be taken to prevent, treat, and control epidemic, endemic, occupational, and other diseases. The control of diseases refers to a State's obligation to make available technologies, using and improving epidemiological surveillance and data collection on a disaggregated basis, and the implementation or enhancement of immunization programs and other strategies to control infectious disease.¹² The obligation here is to ensure the provision of equal and timely access to basic preventive, rehabilitative health services and appropriate treatment for prevalent diseases, illnesses, injuries, and disabilities as well as the provision of essential drugs.¹³

The steps taken to fulfil the obligations imposed by the right to health should be deliberate and concrete.¹⁴ The obligations imposed by the right to health should be realized through all appropriate means, including legislative measures.¹⁵ The UN Committee on Economic, Social, and Cultural Rights (CESCR) has recognized that in many instances legislation is highly desirable and in some cases indispensable in fulfilling the State's obligations.¹⁶ In the case of patents and access to essential medicines, the competing international and national legal rights and obligations render legislative measures indispensable.

Understood from this perspective, violations of the right to health will include the failure to enact appropriate legislation; the formal repeal or suspension of legislation necessary for the continued enjoyment of the right; or the adoption of legislation that is manifestly incompatible with pre-existing domestic or international legal obligations in relation to the right to health.¹⁷ Violation of the right to health could also include failure to take measures necessary to safeguard persons within a State's jurisdiction from infringements of the right to health by third parties. The CESCR has concluded that this category of violations includes omissions such as failure to regulate the activities of

¹⁰ A Hendriks/B Toebes, *Towards a Universal Definition of the Right to Health*, 17 *Medicine and Law* (1998) 319, 325.

¹¹ S Musungu (n 7) 205.

¹² CESCR (n 8) para 16. ¹³ *ibid* para 17.

¹⁴ See General Comment 3, *The Nature of State Parties Obligations* (December 1990) para 2, available at www.unhchr.ch.

¹⁵ See art 2 of the Covenant.

¹⁶ See General Comment 3 (n 14) para 3.

¹⁷ CESCR (n 8) para 48.

individuals, groups, or corporations so as to prevent them from violating the right to health of others.¹⁸ The decision of the South African Constitutional Court (CCSA) in the 'Nevirapine case' provides a practical example of the issues that arise and the interests that have to be balanced in assessing violations of the right to health.

In this case, between the Treatment Action Campaign (TAC) and others and the Minister for Health and others, the Pretoria High Court had found that the government had not reasonably addressed the need to reduce the risk of HIV-positive mothers transmitting the virus to their babies at birth.¹⁹ In particular, the High Court found that the government had acted unreasonably in refusing to make Nevirapine available in the public health sector where the attending doctor considered it medically indicated and by not setting out a time frame for a national program to prevent mother-to-child transmission of HIV (MTCT).²⁰

The government appealed against the decision to the CCSA arguing that its restriction on the use of Nevirapine in public sector hospitals was justified and did not breach its obligations under sections 27 and 28 of the South African Constitution. The relevant sections provide that '[27(1)] Everyone has the right to have access to—(a) health care services, including reproductive health care'; and '[28(1)] Every child has the right—... (c) to basic nutrition, shelter, basic health care services and social services.'

While the CCSA varied the final order, it agreed with the High Court that the government had acted unreasonably in restricting access to Nevirapine in the public sector hospitals and had consequently breached its constitutional duty to take reasonable legislative and other measures to guarantee the right of pregnant women and their babies to have access to health care services. The CCSA concluded that the Constitution required the government to devise and implement within its available resources a comprehensive and coordinated program to realize progressively the rights of pregnant women and their newborn children to have access to health services to combat MTCT of HIV and ordered the government to remove the restrictions that prevented Nevirapine from being made available for the purpose of reducing the risk of MTCT of HIV at public hospitals and clinics.²¹

The two principal issues before the CCSA were whether the government was entitled to refuse to make Nevirapine, a registered drug, available to pregnant women who have HIV and who gave birth in public sector hospitals; and whether as a matter of law, the government was obliged to implement and set out clear time frames for a national programme to prevent MTCT of HIV,

¹⁸ CESCR (n 8) para 50.

¹⁹ *Minister of Health & Others v Treatment Action Campaign & Others* (2002) 10 BCLR 1033.

²⁰ Nevirapine was registered in 1998 by the South African Medical Council in terms of the country's Medicines and Related Substances Act 101 of 1965.

²¹ For additional analysis of the decision see G Annas, *The Right to Health and the Nevirapine Case in South Africa*, *The New England Journal of Medicine* (20 February 2003) 750.

including voluntary counselling and testing, antiretroviral therapy, and the option of using formula milk for feeding.

TAC argued that while it was aware of the desirability of a multiple strategy approach to MTCT of HIV it could not accept that the desirability of such a strategy provided a rational or lawful basis for depriving patients at non-research or training sites of the undoubted benefits of Nevirapine.²² Secondly, it argued that the conduct of the government was irrational, in breach of the Bill of Rights, and contrary to the values and principles prescribed for public administration under section 195 of the South African Constitution.²³

In arriving at its decision, the CCSA considered, among other issues, the enforcement of socio-economic rights, the government's policy of confining Nevirapine to research and training sites, the considerations to be made in determining the reasonableness of governmental action, and the powers of the court to grant injunctive or other non-declaratory relief in cases of this nature.

On the question of enforcement of socio-economic rights, the CCSA following its earlier decisions in *Grootboom*²⁴ and *Soobramoney*²⁵ categorically affirmed that the right to health or any of the other socio-economic rights contained in the Constitution were justiciable. The CCSA accepted the reasoning of Justice Yacoob in *Grootboom*:

I am conscious that it is an extremely difficult task for the State to meet these obligations in the conditions that prevail in our country. This is recognized by the Constitution which expressly provides that the State is not obliged to go beyond available resources or to realize the rights immediately. I stress however, that despite all these qualifications, these are rights, and the Constitution obliges the State to give effect to them. This is an obligation that Courts can, and in appropriate circumstances, must enforce.²⁶

Justice Yacoob went on to hold that although socio-economic rights under the Constitution could not be construed as entitling everyone to demand that the minimum core of the right be provided to them, the minimum core of the right was relevant in considering the reasonableness of State measures. On that basis, the CCSA concluded that the provisions on the right to health in the Bill of Rights placed a negative obligation upon the State and all other entities and

²² A summary of TAC's arguments are reproduced in the CCSA judgment at para 19.

²³ S 195(1) provides: 'Public administration must be governed by the democratic values and principles enshrined in the Constitution, including the following principles: High standard of professional ethics must be promoted and maintained; efficient, economic and effective use of resources must be promoted; public administration must be development-oriented; services must be provided impartially, fairly, equitably and without bias; people's needs must be responded to, and the public must be encouraged to participate in policy-making; public administration must be accountable; transparency must be fostered by providing the public with timely, accessible and accurate information; good human-resource management and career-development practices, to maximize human potential, must be cultivated; and public administration must be broadly representative of the South African people, with employment and personnel management practices based on ability, objectivity, fairness, and the need to redress the imbalances of the past to achieve broad representation.'

²⁴ *South Africa v Grootboom* (2000) 11 BCLR 1169.

²⁵ *Soobramoney v Minister for Health* (Kwazulu Natal), para 40. For the full judgment see (1997) 12 BCLR 1696.

²⁶ n 24 paras 93–94.

persons to desist from preventing or impairing the right to access to health care services, including reproductive health care.²⁷

With respect to the relevant considerations as to reasonableness, the Court again adopted its reasoning in *Grootboom* holding that, to be reasonable, governmental measures relating to socio-economic rights could not leave out of account the degree and extent of the denial of the right, and those whose needs are most urgent and whose ability to enjoy the rights is most in peril must not be ignored by the measures taken.²⁸ The Court further held that a programme for the realization of socio-economic rights must be balanced and flexible and should make appropriate provision for crises and short-, medium-, and long-term needs.²⁹

Regarding the Courts' power to grant the orders sought by TAC, the CCSA concluded that while matters of policy might be pre-eminently in the domain of the executive it did not mean that courts could not or should not make orders that have an impact on policy.³⁰ Where a State's policy is challenged as inconsistent with the Constitution, courts have to consider whether in formulating and implementing the policy in question the State gave effect to its constitutional obligations.³¹

III. PATENT LAWS AS A LIMITATION ON THE RIGHT TO HEALTH

The grant of a patent over processes for the manufacture of medicines or with respect to medicines themselves as products has the effect of giving the patent holder a monopoly over the use of the process and or the manufacture and sale of the medicines. Although various justifications are given for granting patents, one clear effect is that the cost for the covered technology is set at an artificially high level. For medicines, the high prices for new medicines resulting from the mandatory requirements for patent protection under TRIPS in developing countries have seriously compromised the ability of communities, governments, and other players in the health sector effectively to manage infectious and other diseases.

The cost disparity has virtually guaranteed that most of the sick in these regions of the world have little or no access to the best available treatments since in most of these countries up to ninety per cent of the costs of health care for the poor are out of pocket. High drug prices also mean that governments have to spend a disproportionate amount of money on medical supplies leaving very little for other critical health needs such as infrastructure development and training.

The ICESCR and other international and regional human rights instruments and constitutions, such as that of South Africa, contain a commitment and a legal duty to address these conditions and to transform society into one where

²⁷ n 24 para 46.

²⁸ *ibid* para 68.

²⁹ *ibid* para 68.

³⁰ *ibid* para 98.

³¹ *ibid* para 99.

life is based on human dignity. For as long as these conditions continue to exist for any reason including high prices resulting from patent protection, the aspiration to create societies based on human dignity will have a hollow ring.³²

It is therefore fair to say that the strengthening of patent protection for pharmaceutical processes and products under TRIPS has had the effect of limiting the enjoyment of the right to health as set out in article 12 of the ICESCR. The question then is whether the limitation imposed by TRIPS-based patent laws is reasonable and justifiable. The relevant considerations in an inquiry relating to limitations on rights include the nature of the right and the scope of the limitation; the purpose, importance, and effect of the limitation; and the availability of less restrictive means to achieve the legitimate government interest.³³ For our current purposes, the latter consideration is the most relevant.

Within the framework of human rights, the examination of the validity of governmental action must necessarily begin with the broad question what purpose is served by a particular law or policy? To do this, one needs to consider whether the law or policy serves a legitimate government interest. In essence, the patent system is justified on the basis that, since innovations and inventions are necessary to secure industrial progress and technological development, society has to provide incentives to inventors through the grant of time-bound monopoly rights. On this basis it is considered that patent laws in general serve a legitimate governmental interest. The case for patent protection as a legitimate government interest can also be made on the basis of human rights considerations or constitutional requirements. The implications of article 15 of the ICESCR are particularly important.

Article 15 of the ICESCR, which is modelled on article 27 of the UDHR,³⁴ recognizes 'the right of everyone to take part in the cultural life, to enjoy the benefits of scientific progress and its application as well as to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author'. The right 'to benefit from the Protection of the moral and material interests resulting from any scientific, literary or artistic production' is, however, distinct from intellectual property, and the scope of protection under article 15 does not necessarily coincide with what is termed intellectual property rights under national legislation and international agreements.

Consequently, while article 15 covers some aspects of the justification of the patent system, the right recognized therein is not a right to a patent, for example, but a right to the protection of the material interests in an invention. This means that there are various ways of fulfilling the obligations related to inventions,

³² *Soobramoney* (n 25) para 8.

³³ See, for example, the CCSA in *Prince v The President of the Law Society of the Cape of Good Hope*, Case CCT 36/00, para 45.

³⁴ art 27(1) provides that, 'Every one has the right to the material protection of the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author.'

patent protection being just one of those ways. Article 15 of the ICESCR does not therefore necessarily provide a *prima facie* justification for patent laws.

A case could, however, still be made for patent laws as a legitimate government interest based on article 15. While there remain differences as to what the optimum level and type of patent protection should be for developing countries, it can be argued that, tailored properly, patent protection may represent one of the ways of protecting the material interests of inventors in their inventions. The same analysis would suffice in cases where patent laws are justified as constituting a legitimate government interest on the basis of constitutional principles.³⁵ If these premises are accepted, the next question is whether the actual effect of the patent laws, purporting to serve a legitimate government interest, constitutes an overly broad legislation. This is where competition rules come in.

IV. COMPETITION RULES AS A SAFEGUARD AGAINST OVERBROAD LIMITATION BY PATENT LAWS ON THE RIGHT TO HEALTH

The central question here is whether the application of the TRIPS standards tempered by competition principles and rules would constitute a less restrictive means of protecting inventions than applying the TRIPS standards without competition considerations. In other words, would the limitations placed on the right to health by the TRIPS standards be less onerous if competition rules were applied? The limitation analysis involves the weighing up of competing values and ultimately an assessment based on proportionality.³⁶ In this case, the proportionality assessment can be undertaken on the basis of the provisions of the TRIPS Agreement.

The TRIPS Agreement envisages a balance between the promotion of technological innovation and the transfer and dissemination of technology, and between the users and producers of technology. The balance can be gleaned from several provisions of the Agreement including provisions setting out the objectives and principles of the Agreement; the provisions relating to transfer of technology; the provisions relating to exceptions to exclusive rights; and the provisions relating to the control of anti-competitive practices in contractual licenses. The basic concept of balance under TRIPS is found in the objectives and principles of the Agreement.

The objective of the system under the Agreement set out in article 7 'is to promote technological innovation and the transfer and dissemination of

³⁵ See, for example, the US Constitution which provides in art 1, s 8 that the US Senate shall have power 'To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries'.

³⁶ *Prince v The President of the Law Society of the Cape of Good Hope*, case CCT 36/00 at para 45. Available at <http://www.concourt.gov.za/site/judgments/judgments.htm>.

technology to the mutual benefit of innovators and consumers and in a manner conducive to social and economic welfare, and to the balance of rights and obligations'. The principles upon which the balance is to be achieved are stated in article 8 of the Agreement. First, Members in formulating or amending their laws may adopt measures necessary for the protection of public health and nutrition and measures to promote public interests in sectors of vital importance to socio-economic and technological development.³⁷ Secondly, Members may adopt appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort by them to practices that unreasonably restrain trade or adversely affect the international transfer of technology.³⁸

The TRIPS Agreement therefore recognizes that there are underlying national public policy objectives that must be taken into account when implementing the Agreement at the national level. This obviously includes human rights objectives. Article 8.1 of the Agreement, in particular, should be read as an interpretive principle in favour of the adoption of internal measures deemed necessary for the protection of health including competition principles and rules.

Article 8 permits Members to take measures to protect public health and to take appropriate measures to prevent abuse of intellectual property or the resort by right holders to practices that unreasonable restrain trade or adversely affect international transfer of technology. The article therefore provides policy space to take measures for the protection of the right to health. The introduction of competition law could be one of these measures although the use of other TRIPS flexibilities would also suffice as measures that can be taken to reduce the limitation that the TRIPS standards place on the enjoyment of the right to health. Indeed, the preamble to the WTO Agreement, which establishes the entire framework of the WTO system, does not make free trade an end in itself.³⁹ Rather, it establishes the objectives of the system as related to the fulfilment of basic human values, including the improvement of living standards for all people and sustainable development.

The other article of TRIPS Agreement that is relevant for the proportionality assessment is article 40. Article 40 permits Members to specify and outlaw licensing practices or conditions that may have an adverse effect on competition in the relevant market. Article 40 underscores the importance that the TRIPS regime gives to competition as a factor in ensuring that the patent system serves the purpose for which it is intended.

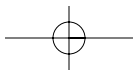
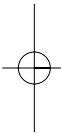
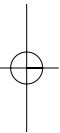
Overall, it can be concluded that the TRIPS Agreement, through article 8 and article 40, contemplates the use of competition policy as means of achieving

³⁷ art 8.1. ³⁸ art 8.2.

³⁹ R Howse/M Mutua, *Trading in Human Rights: The Human Rights Obligations of the WTO*, ICHRRD (April 2000).



the balance in the patent system. These provisions of the TRIPS Agreement therefore provide a prima facie basis to argue that the failure to implement and interpret TRIPS rules on patents in the context of competition principles results in limitations on the right to health that are more extensive than is necessary to achieve the governmental purpose of protecting innovation.



International Trade and Human Rights: Conflicting Obligations

PRABHASH RANJAN

Commentary on Frederick M Abbott

I. INTRODUCTION

Today, one of the challenging questions that confront the global community is that whether international trade¹ and human rights² impose conflicting obligations on nation states or not? If the answer to this question is no, then there is no need to have a debate. But if the answer to this question is in the affirmative, how do we resolve the conflict?

Some dismiss this debate of conflicting obligations as just another linkage of trade with a non-trade issue. Some take an extreme view that international trade and human rights are mutually exclusive and the obligations imposed by one can be pursued only at the cost of the other. There are still others who think that international trade and human rights, though they impose contradictory obligations on nation states, can be reconciled with the help of instruments of international law or by bringing human rights into the WTO.

At the outset, my answer to the above-posed question is yes. I subscribe to the view that international trade and human rights impose conflicting obligations. This study identifies three instances that demonstrate the conflict between international trade and human rights, and discusses measures to resolve the conflict.

Before I come to the conflict, I would like to dwell on the issue of obligations imposed by international trade. It has often been argued that the primary reason for conflict between international trade and human rights is the conflicting nature of obligations imposed by them on nation states. In other words, the conflict between international trade and human rights exists because the former imposes negative obligations and latter imposes positive obligations.

II. DOES INTERNATIONAL TRADE IMPOSE NEGATIVE OR POSITIVE OBLIGATIONS?: A FUTILE DEBATE

It has often been argued that international trade imposes negative obligations on nation states. It is important to understand what we mean by negative obligations. As a starting point, we need to understand what is meant by the

¹ The term 'international trade' is not limited just to the multilateral trading system under the aegis of the WTO, but also includes the numerous regional/bilateral-trading arrangements.

² According to Black's Law Dictionary, human rights are the freedom, immunities, and benefits that, according to modern values, all human beings should be able to claim as a matter of right. Also see Universal Declaration of Human Rights.

word 'obligation'. According to Black's Law Dictionary, an obligation is a legal or moral duty to do or not to do something. A positive obligation means that there is a legal or moral duty to do something, whereas a negative obligation imposes a legal or moral duty to refrain from doing something.

Applying these definitions to international trade, it can be said that international trade imposes a legal or moral duty to refrain from certain behaviours. In other words, international trade imposes a limitation on a country by asking it not to act on a certain issue or matter. For instance, international trade may require a country not to have any Quantitative Restrictions (QR) on the imports of a particular product entering its territory. In such a scenario a country is being restricted from adopting QR on a particular imported product.

However, international trade also imposes positive obligations. In other words, international trade can also impose a legal or moral duty to do something. For instance, international trade may require a country to grant patent protection according to the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) by enacting a patent law or by making its existing patent law compliant with TRIPS. If positive and negative obligations are understood in the manner in which it is discussed above, international trade imposes both positive and negative obligations.

The other common meaning assigned to the term 'negative obligation' is limitation on sovereignty. In other words, international trade imposes limitations on the sovereignty of a country. In order to understand limitations on the sovereignty of a country, one has first to understand the meaning of the word 'sovereign'. According to Black's Law Dictionary, the word 'sovereign' means a person, body, or state vested with independent and supreme authority. In other words, a country that is a sovereign state has no other authority dictating terms to the sovereign. But, is this a feasible description of a sovereign state? Accepting such a viewpoint would be tantamount to negation of the entire concept of 'international law', which imposes obligations on all countries.

If one defines sovereignty as decision-making ability, any shift or re-allocation of this decision-making ability could be described as an attack on the sovereign character of a country. This shift or re-allocation may take place in two ways. One could be a forcible shift, for instance one country invading another country and forcibly taking decision-making power. The other could be a shift by consent, where a state gives its consent to follow an international organization or an international treaty. For example, member countries agree to follow WTO rules on trade matters. However, because such a shift takes place by the consent of the country it cannot be described as an attack on the sovereign character of that country.³

My submission is that it is fruitless to debate whether the obligations imposed by international trade are positive or negative. The real issue is that

³ For more on this debate see J H Jackson (1997): 'The Great 1994 Sovereignty Debate: United States Acceptance and Implementation of the Uruguay Round Results', 36 *Columbia Journal of Transnational Law*, 157.

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international trade imposes obligations on countries, some of which are quite serious in nature. Similarly, human rights law also imposes obligations on nation states. Many of the obligations imposed by human rights law require changes in domestic legislation. This study addresses how these two sets of obligations sometimes come into conflict with each other.

III. THE CONFLICT

Obligations imposed by international trade often conflict with the obligations imposed by the two most fundamental human rights instruments: the International Covenant on Economic, Social, and Cultural Rights (ICESCR) and the International Covenant on Civil and Political Rights (ICCPR). These conventions are legally binding on the member countries. Apart from these internationally binding conventions, the constitutions and municipal legal systems of many countries also impose various human rights obligations on their respective governments.

Fulfilling obligations under international trade often conflicts with not just the obligations imposed by international conventions but also the obligations imposed by municipal legal systems. I will take three examples to demonstrate this conflict.

A. TRIPS and the right to health

Many developing countries do not provide product patents on pharmaceuticals and food products. For instance, the Indian patent law provides that in the case of inventions of substances intended for use, or capable of being used, as food or as medicine or drug no patent shall be granted in respect of claims for the substances themselves.⁴ This means that a medicine or a drug itself cannot be patented, although the process to manufacture that medicine or drug can be patented.

Granting product patents, though rewarding the inventor, always escalates the price of the product. India does not recognize product patents on medicines or drugs in order to keep their prices down and thus maintain their accessibility to the poor.

This policy will soon change.⁵ India, being a signatory to the WTO Agreement,⁶ has an obligation to ensure the conformity of its laws, regulations, and administrative procedures with its obligations as provided in the annexed Agreements.⁷ TRIPS is one of the annexed agreements of the WTO, and therefore India must comply with the provisions of the TRIPS agreement.

⁴ See s 5(1) of the Indian Patents Act (1970).

⁵ Some change in this position was made by the second patent amendment act, but the third patent amendment act (discussed in this paper) intends to bring about sweeping changes in the Indian patent law.

⁶ Marrakesh Agreement establishing the World Trade Organization.

⁷ See art XVI.4 of the Marrakesh Agreement establishing the World Trade Organization.

Article 27 of the TRIPS Agreement states that patents shall be available to all inventions, whether processes or products.⁸ In order to fulfil the obligation imposed by Article 27, the third patent amendment bill⁹ has been introduced in the Lok Sabha (House of the people) Indian Parliament.¹⁰ This bill seeks to omit section 5 of the Indian Patents Act 1970, which provides only for process patents for medicines, or drugs. If the Indian Parliament passes this amendment bill, beginning on 1 January 2005, Indian patent law would extend product patent protection to all products including food, medicines, and drugs. Adopting a product patent regime for pharmaceuticals would undoubtedly have an impact on the prices of the medicines and would restrict the accessibility of medicines to the poor sections of Indian society.

The right to live in good health free from disease is one of the foremost human rights. Article 12 of ICESR recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The right to health is also a fundamental right¹¹ under the Indian Constitution.¹² An integral component of right to health is to have accessibility to medicines. However, adoption of product patents for pharmaceuticals would restrict access to many of the medicines by India's poor. This will infringe the right to health of the people of India.

Critics may argue that, after the Doha Declaration on TRIPS and Public Health¹³ and the 30 August 2003 decision to implement paragraph 6 of this declaration,¹⁴ the apprehensions pertaining to conflict between TRIPS and health are not relevant anymore. This is not true, as the declaration and the decision suffer on two fronts.

First, this declaration and decision have only improved the accessibility to life saving medicines and drugs; not to all kinds of medicines. Moreover, the definition of 'eligible importing member' given in the 30 August decision¹⁵ states that developing countries may receive the benefit under this decision only in case of national emergency or extreme urgency. In other words, in situations other

⁸ See art 27.1 of the TRIPS Agreement.

⁹ See Bill No 92 of 2003, The Patents (Amendment) Bill (2003)—A bill to further amend the Patents Act 1970.

¹⁰ The third patent amendment bill was introduced in the last Lok Sabha. But the bill lapsed because of the dissolution of the house and new elections. The same patent amendment bill would be re introduced in the newly constituted Lok Sabha.

¹¹ Fundamental rights are justiciable rights guaranteed by the Indian Constitution to the people of India against the state. The Indian Constitution does not mention the word 'human rights'. However, it is now well settled that fundamental rights in the Indian Constitution are equivalent to human rights, as understood in international jurisprudence.

¹² Right to health is a fundamental right under right to life given in art 21 of the Indian Constitution.

¹³ See WT/MIN(01)/DEC/2 available at www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

¹⁴ See Implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health (WT/L/540) on www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

¹⁵ See para 1(b) of Implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health.

than national emergency or extreme urgency, the relevance of this decision for developing countries is of no value. The right to health includes accessibility to all kinds of medicines, at all times, whether national emergency or not, irrespective of whether they are life saving or are ordinary anti-allergic medicines.

Secondly, the accessibility to medicine under this declaration and decision even in cases of national emergency or extreme urgency is not without cost. The requirement to pay adequate remuneration to the patent holder as laid down in Article 31(h) of the TRIPS Agreement¹⁶ makes the business of exporting member to importing member a costly affair. Thus, the conflict between the obligations imposed by TRIPS and the obligations imposed by human rights are quite apparent.

B. RTAs and human rights

As I mentioned in the Introduction, the term international trade does not imply only multilateral trading regime under the WTO, but also includes a host of Regional Trade Agreements (RTA) and Bilateral Trade Agreements (BTA). Thus, when we talk of studying the obligations imposed by international trade, we cannot ignore the obligations imposed by the RTAs and BTAs. According to OECD estimates, in 2004, more than forty-three per cent of international trade took place through the regional trading agreements.¹⁷ This figure is expected to swell to fifty-five per cent by the end of 2005.¹⁸ Therefore, the significance of these regional and bilateral trading arrangements cannot be ignored.

One dimension of almost all RTAs and BTAs is that they impose obligations that are more stringent than those imposed by the WTO. The provisions of RTAs are popularly known as 'WTO plus' provisions. There are two ways in which some of the provisions that are given in RTAs could be described as 'WTO plus'. The first case is where RTAs contain those provisions that do not exist in the WTO in the form of agreements on, *inter alia*, competition, investment, labour standards, or environment. The second case is of those provisions that exist in the WTO in the form of an agreement, but are enshrined in the RTAs in a more stringent form, like those providing patent protection for a specified term, which is more than 20 years.¹⁹

These 'WTO plus' provisions impose obligations that are more strict than those imposed by the WTO. Here I would like to focus on the issue of providing protection to plant varieties, an obligation imposed both by the WTO and also by many RTAs. I have chosen this issue because it is directly and closely linked to the livelihood of millions of poor farmers across the South. My attempt here

¹⁶ See para 3 of Implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health.

¹⁷ See www.oecdobserver.org/news/printpage.php/aid/1094/All_for_one.html.

¹⁸ *ibid.*

¹⁹ The term of patent protection given in the TRIPS Agreement is 20 years. See art 33 of the TRIPS Agreement.

is to show that the obligation imposed by many of the RTAs for the protection of plant varieties on member countries is more strict than the obligation imposed by WTO in this regard. After this, I will explain how carrying out such an obligation will result in a human rights violation.

First, let us understand the obligation imposed by the TRIPS Agreement. Article 27.3(b) of TRIPS states that countries shall provide for protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. According to this obligation all member countries have to provide protection to plant varieties. However, this Article provides an option to extend protection either by patents or by an effective indigenous system.²⁰

It has been argued by many that extending protection to plant varieties by patents under Article 27.3(b) means providing protection under the International Convention for the Protection of New Varieties of Plants. This convention was adopted in Paris in 1961 and led to the establishment of the International Union for the Protection of New Varieties of Plants (UPOV), which is an intergovernmental organization with its headquarters in Geneva. TRIPS does not mention UPOV.

UPOV suits the interests of industrial plant breeders, located for the most part in industrialized nations.²¹ It does not recognize the rights of the farmers, such as the right to save, re-sow, or exchange seeds obtained from their yield. It neither provides for benefit sharing nor recognizes the rights to biodiversity of the indigenous people. The only aim of UPOV is to institutionalize and legalize 'open loot'.

It is interesting to note that unlike TRIPS, a majority of RTAs do not provide any option to member countries to extend other forms of protection to plant varieties. Several RTAs²² mandate UPOV as the apposite model to protect plant varieties. These RTAs do not give the *sui generis* option to the member countries. Hence, following the obligation imposed by RTAs would mean adopting UPOV to provide protection to plant varieties and thus negating the rights of the farmers.

Agriculture is the mainstay of the majority of developing countries. A very large section of population in these countries depends on agriculture for their livelihood. UPOV would severely impinge the rights of the farmers by affecting their livelihood. Affecting livelihood means infringing the right to adequate standard of living, which is a violation of Article 11 of ICESCR. It would deny them means to basic subsistence; deny their right to life, and thus violate Article 6 of ICCPR.²³

²⁰ India explored the *sui generis* option given in TRIPS and enacted the Protection of Plant Varieties and Farmer's Rights Act.

²¹ The new UPOV 1991 Act has in fact strengthened the breeder's rights that existed in UPOV 1978.

²² Some of the RTAs that provide for the UPOV model are NAFTA, EU-Mexico, and US-Jordan.

²³ Right to life is not limited to protection from any act, which damages or injures or interferes with the use of any limb or faculty of a person. Right to life also includes the right to bare necessities of life such as adequate nutrition, clothing, and shelter.

Thus, the conflict is apparent. Fulfilling the obligations under RTAs, in this particular case, would result in failure to fulfil the human rights obligations as enshrined under the two UN treaties, which are legally binding.

C. Trade facilitation and human rights

The third example I take to demonstrate the conflict between international trade and human rights pertains to a proposed agreement on trade facilitation. Trade facilitation is one of the four Singapore issues²⁴ and is billed as something that will benefit every country. It is being argued by many, both in developed and developing countries, that an agreement on trade facilitation under the WTO would bring substantial gains to all the member countries. The fundamental aim of trade facilitation is to cut the losses that businesses suffer at the borders so as to ensure a smooth movement of goods in international trade. The proponents of trade facilitation argue that it can save more than \$150 billion a year.

The July 2004 decision of the WTO has established modalities for negotiations on trade facilitation.²⁵ The decision states that concerns of developing and least developed countries related to cost implications of the proposed measures shall be addressed.²⁶

The proponents of trade facilitation are arguing that this particular provision would take care of the cost concerns of poorer countries in implementing the trade facilitation measures. It is important to understand that these are just modalities and not the final agreement. Whether the final agreement would take care of the cost concerns or not is a moot issue. Developing countries and LDCs have a very genuine concern related to cost implications of imposition of trade facilitation measures.

A binding commitment under trade facilitation would require countries to invest massive financial and human resources to build a comprehensive customs infrastructure. According to some estimates, small developing countries may have to spend more than \$100 million in order to create a customs clearance infrastructure that would be as efficient as that of other countries, like Singapore.²⁷ For many developing countries this figure is more than they spend on education.²⁸

My aim here is not to demonstrate the demerits or merits of trade facilitation. My intention is to highlight the concern related to the huge financial burden

²⁴ The other three Singapore issues are competition, investment, and transparency in Government procurement.

²⁵ See Annexure D (Modalities for negotiations on trade facilitation) of the Doha Work Programme: Draft General Council Decision, WT/GC/W/535 (31 July 2004).

²⁶ *Ibid* para 4.

²⁷ According to an estimate by Finger and Schuler (2000), the minimum costs of customs reforms alone will be about US \$40 million in most developing countries.

²⁸ See N Nanda (2003), WTO & Trade Facilitation, *Economic and Political Weekly*, vol XXXVIII no 26.

that an agreement on trade facilitation would impose on developing countries. Most developing countries operate on a tight budget constraint and a binding commitment on trade facilitation would only lead to diversion of resources from social sectors like health and education.

This diversion of resources from priority sectors has the potential to trigger human rights violation. Article 2 of ICESCR states that each party to the covenant undertakes, 'to take steps . . . to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized'.²⁹ In this Article, the phrase 'to the maximum of its available resources' is important. An obligation such as trade facilitation, as mentioned above, would eat into the already scarce resources of developing countries. Such an obligation would reduce the 'available resources' for member countries and thus prove a major impediment to fulfilling the obligation of progressive realization of the rights recognized in the covenant.

Article 12 of ICESCR recognizes the right of everyone to the attainment of the highest attainable standard of health, and similarly Article 13 of this covenant recognizes the right of everyone to education. Both of these articles require member countries to take certain steps to achieve these rights.³⁰ The obligation to achieve these rights requires huge financial resources. But, if developing countries have to spend large amounts on building customs clearance infrastructure, the resources that they could commit for sectors like health and education would be limited.

Critics may respond that this argument can be given for any obligation because all obligations impose financial burden. Undoubtedly, all obligations impose financial burden. But, what needs to be appreciated is that the degree of financial burden imposed is different for different obligations. Trade facilitation is one such obligation, which would impose enormous financial burden on all countries. The exorbitant costs of compliance with trade facilitation obligations creates apprehension that trade facilitation might come at the expense of human rights violations. Moreover, countries are already struggling to reconcile their human rights obligations with the trade obligations that they undertook during the Uruguay Round (UR). It would not be plausible to impose any new obligations, which have the potential to trigger human rights violation.

The conflict is apparent. An obligation in the form of trade facilitation would cripple the ability of the countries to fulfil their human right obligations by eating into their resource base.

IV. RESOLUTION OF CONFLICT

Different people have suggested different approaches to resolve the conflict between obligations imposed by international trade and human rights. One

²⁹ See art 2 of ICESCR.

³⁰ See arts 12 and 13 of ICESCR.

common method of reconciliation of the conflict, which is often prescribed, is to interpret the provisions of international economic law in light of the existing human rights obligations of the parties involved.

This argument stems from the fact that WTO law is a branch of public international law and therefore cannot be interpreted in isolation. Moreover, Article 3.2 of the Dispute Settlement Understanding states that provisions of the WTO agreements should be clarified in accordance with the customary rules of interpretation of public international law.³¹ Article 31 of the Vienna Convention on Law of Treaties (VCLT) gives the general rule of interpretation of treaties. In other words, the provisions of the WTO agreements should be interpreted in accordance with the general rule of interpretation given in Article 31 of VCLT. The Appellate Body (AB) has stated this position in a number of disputes. Article 31(3)(c) of VCLT states that while interpreting a treaty any relevant rules of international law applicable in the relations between parties should be taken into account. On the basis of this Article, many have argued that obligations imposed by human rights conventions or agreements should be used to clarify or interpret the provisions of WTO law.

But, the question to be asked is how far can one go? Possibilities of such an interpretation leading to ambiguous or manifestly absurd results cannot be ignored. If trade sanctions are imposed against a country for violating human rights obligations, there is every possibility that such trade sanctions would hurt the common people of that country. Will such trade sanctions not violate many of the provisions given in the WTO preamble, like raising standards of living and ensuring full employment?

Imagine another situation where a country like India refuses to recognize product patents on pharmaceuticals in its patent law arguing that it wants to fulfil its obligation on the right to health. Would developed countries, the greatest beneficiaries of product patent regime, not challenge India's patent law in the DSB? In such a case, how strong would India's defence be, that it wants to fulfil its obligation on right to health and therefore does not recognize product patents on pharmaceuticals?

Article XX, particularly Article XX (b),³² of the General Agreement on Tariffs and Trade (GATT) is also often mentioned as one provision that could justify the violation of GATT on the basis of principles like human rights. The interpretation of Article XX (b) given by the Appellate Body (AB) in *EC—Asbestos*³³ has opened the scope of justifying violation of GATT on the basis

³¹ See art 3.2 of the Understanding on Rules and Procedures Governing the Settlement of Disputes.

³² art XX (b) of GATT states that countries can adopt measures necessary to protect human, animal, or plant life or health provided the conditions given in the chapeau of art XX are satisfied.

³³ *European Communities —Measures Affecting Asbestos and Asbestos-Containing Products*, Report of the Appellate Body, WT/DS135/AB/R.

of human rights. In *EC—Asbestos*, the WTO referred to the conventions of the International Labour Conventions (ILO) for the first time and stated that Article XX (b) is open to dynamic interpretation.

The biggest apprehension of developing countries is that such arguments would lead to political and protectionist use of human rights. Given the experience of developing countries, such a fear is not unfounded.

In my view this conflict can be resolved in two ways:

(a) *Make rules fair*

One very important reason for conflict between international trade and human rights is that rules of international trade are not fair. They benefit one part of the globe at the expense of the other. Therefore rules of the game have to be fair. Rules should be such that they do not impose any undue obligation on the countries. Examples of making rules fair could be to reduce the term of patent protection from twenty years to ten years or have a mild rule on the question of product patent for pharmaceuticals. Similarly, the RTAs should not impose 'WTO plus' provisions on developing countries for reasons discussed above. Making rules fair also includes the new rules that would be negotiated in the future. Member countries should not allow any new rule to come in the ambit of WTO that would impose stringent obligations on them. Trade facilitation would fall into this category.

(b) *Honest implementation*

Another very important reason for human rights violation is the faulty and dishonest implementation of the rules. Countries misinterpret the rules of the game to their advantage. An example of dishonest implementation is that of agricultural subsidies. The EU and US have been providing trade-distorting subsidies to major agricultural commodities like rice, wheat, sugar, cotton, and so on. The rulings by the Panel on the cotton dispute case³⁴ and the sugar dispute case³⁵ have demonstrated the illegality of the agricultural subsidies being provided by developed countries. The huge agricultural subsidies by developed countries have enabled the agricultural producers of these countries to dump their agricultural produce³⁶ in developing countries. For instance, the dumping of cotton by the US in Africa has resulted in human rights violations of a very serious nature. The dumping of cotton by US has infringed the right to livelihood and right to life of millions of cotton farmers in West and Central Africa.³⁷

³⁴ *United States—Subsidies on Upland Cotton*, Report of the Panel, WT/DS267/R.

³⁵ *European Communities—Export subsidies on sugar*, Report of the Panel, WT/DS266/R.

³⁶ Agricultural dumping takes place when products are exported at a price less than their cost of production.

³⁷ For more on this see US and EU cotton production and export policies and their impact on West and Central Africa: Coming to Grips with International Human Rights Obligations available at <http://www.eginitiative.org/documents/cotton.pdf>.

V. CONCLUSION

Public international trade imposes onerous obligations on member countries. These obligations are often difficult to implement and come in the way of other obligations imposed by other international conventions like human rights conventions. We have seen that the conflict between the obligations imposed by international trade and human rights is quite apparent. However, international trade and human rights are not mutually exclusive concepts. Both can be respected at the same time. Differences persist on how to do this. In my view, if the rules of the game are made fair and if countries honestly implement these fair rules, human rights concerns can be addressed. But, for this, a strong international political will is needed.

Trade, Human Rights, and the WHO Framework Convention Tobacco Control: Just What the Doctor Ordered?

ALLYN L TAYLOR

I. INTRODUCTION

One of the most noteworthy recent developments in the domain of international health law is the World Health Organization's Framework Convention on Tobacco Control (FCTC or 'Convention').¹ In May 2003 the 192 Member States of the World Health Organization (WHO) adopted by consensus the FCTC, the Organization's first treaty, in order to promote national action and global cooperation to curb the growth of the tobacco pandemic.

Notwithstanding its significant limitations, the Convention is undoubtedly a pioneering initiative for the field of international health law and for WHO. Although health has traditionally been a limited area of international legal cooperation, there is growing awareness that contemporary globalization has led to the proliferation of cross border determinants of health status and is undermining the capacity of states to protect public health through domestic action alone. Consequently, globalization is creating a heightened need for new mechanisms to promote coordinated inter-governmental health action. This growing need for new mechanisms and models for collective health action is a key force behind recent developments in the expanding realm of international health law including, significantly, the WHO FCTC.² As WHO's first Convention, the FCTC also poses an important test case for future organizational involvement in international health lawmaking.

While the FCTC and the FCTC process raise a host of interesting questions, here I will focus primarily on the relationship of the FCTC to trade and human rights issues. Section II will provide a brief overview of the global tobacco epidemic and the historical origins of the FCTC. Section III and Section IV will examine how international trade and human rights issues were resolved in the FCTC negotiation process. Finally, Section IV will briefly address the significance of the FCTC for global tobacco control and future international health lawmaking under WHO auspices.

¹ WHO Framework Convention on Tobacco Control, available at http://fctc.org/about_FCTC/treaty_pdfs.shtml.

² A L Taylor Governing the Globalization of Public Health, *Journal of Law, Medicine & Ethics* 32 (2004) 500-508.

II. GLOBALIZATION OF THE TOBACCO EPIDEMIC AND THE WHO FCTC

Although it is generally known that tobacco is harmful to health, the sheer size and rapid global spread of this epidemic is not generally appreciated. Global tobacco consumption is one of the leading causes of preventable death worldwide. According to WHO, cigarette smoking and other forms of tobacco use currently kill 4.9 million people per year, with the majority of deaths occurring in industrialized countries. However, the epidemic is rapidly shifting to developing and transitional market economies and today the majority of smokers live in developing states. It is expected that by 2020 tobacco will kill up to 10 million people per year with 70 per cent of deaths occurring in developing states, if the epidemic is left unchecked.

A significant contributor to the increased risk of tobacco-related diseases worldwide is the globalization of the tobacco epidemic through the successful efforts of the tobacco industry to expand global tobacco trade and to achieve market penetration in developing countries and transitional market economies. Major transnational tobacco companies have effectively targeted growing markets in Latin America in the 1960s, the newly industrializing markets of Asia in the 1980s, and in the 1990s, and have moved into Eastern Europe, Africa, and China, and are increasingly targeting young persons and women.

As will be described in further detail, numerous econometric studies have shown that the global reach of the tobacco industry has been significantly enhanced by the relatively recent wave of international trade liberalization, particularly the Uruguay round of trade negotiations that included, for the first time, the liberalization of unmanufactured tobacco.

The globalization of the tobacco epidemic is not limited to international trade, of course. The epidemic is being spread and reinforced through a complex mix of factors that transcend national borders, including foreign direct investment, global marketing and communications, among other factors. Processes and practices that transcend national borders are fueling numerous aspects of the epidemic. For example, it is estimated that over one-third the cigarettes in international trade, over 355 billion cigarettes, simply disappear each year and that this number is increasing. Smuggled cigarettes pose a significant challenge to government treasuries as well as to public health because illicit cigarettes are sold at below-market price, making top international brands available to children in developing countries at cheap prices. This increases consumption and undermines efforts to keep children from smoking.

The WHO FCTC was primarily envisioned as a mechanism to promote national public health action and multilateral cooperation on aspects of tobacco control that transcend national boundaries. Early writings on the treaty emphasized that substantive tobacco control obligations should focus principally on expanding international cooperation to implement empirically

established demand reduction strategies for tobacco products.³ Hence, contrary to later claims by the tobacco industry, the treaty was neither envisioned nor designed to ban or prohibit tobacco consumption or production.

Taylor and Roemer first proposed the idea of this WHO framework convention/protocol approach to tobacco treaty in the early 1990s and in 1995 formally advanced the idea to the WHO Executive Board in a feasibility study.⁴ However, despite early work on the idea of a WHO framework convention, the proposed instrument did not receive significant political support from the WHO Secretariat or most WHO Member States until the election of Dr Gro Harlem Brundtland as Director-General of WHO in 1998.⁵

With a strong push from the WHO Secretariat in the late 1990s, the idea of a WHO framework convention on tobacco control began to gather political momentum. Formally negotiated by over 160 WHO Member States over a period of 4 years in 6 negotiation rounds and 2 working group meetings between 1999 and 2003, the text of the treaty was finalized by the WHO Intergovernmental Negotiating Body (INB) in March 2003 and adopted by the World Health Assembly in May 2003. The final text of the Convention cuts across a wide range of tobacco control topics, including advertising and promotion, smuggling and counterfeit cigarettes, warning labels, clear indoor air policies, and health education. At the time of this writing, 189 countries have signed the FCTC and 42 states have ratified it. Pursuant to the ratification requirements established by the Convention, the FCTC will enter into force for state parties on 27 February 2005.

III. INTERNATIONAL TRADE LAW AND TOBACCO CONTROL: THE DYNAMICS OF THE FCTC TRADE VERSUS HEALTH NEGOTIATIONS

The relationship of the FCTC to international trade law was one of the most divisive and hotly contested issues throughout the FCTC negotiations. As described above, the rapid spread of the tobacco epidemic to developing countries has been accelerated and compounded by various factors, including, in particular, international trade liberalization.

In recent years, there has been significant econometric work concluding that tobacco trade liberalization has had a negative impact on public health in low-income countries. For example, analysis conducted for a World Bank report in the late 1990s found that trade liberalization and market penetration

³ A L Taylor, *An International Regulatory Strategy for Global Tobacco Control*, *Yale Journal of International Law* 21 (1996) 257–304.

⁴ A L Taylor/R Roemer, *An International Strategy for Tobacco Control*, Geneva, World Health Organization (1996), WHO Document WHO/PSA/96.6. See also R Roemer/A L Taylor/J Lariviere, *The Origins of the WHO Framework Convention on Tobacco Control*, forthcoming in the *American Journal of Public Health* 2005; 95: 936–938.

⁵ For background on the historical development of the WHO FCTC, see generally R Roemer et al (n 4). See also P Szasz, *WHO Tackles the Tobacco Pandemic*, *Translex* (23 December 1999).

has been linked to a greater risk of increased tobacco consumption, particularly in low- and middle-income countries.⁶ There are a variety of reasons why trade liberalization has led to an increase in tobacco consumption in poor states. Among other things, reductions in barriers to tobacco trade lead to greater competition, reduction in prices for tobacco products, and increased advertising and promotion.

Economists argue that the implementation of the WTO multilateral agreements has had a unique impact in accelerating global tobacco consumption by mandating sizable reductions in tariff and non-tariff barriers to trade in tobacco and tobacco products. Of particular importance is GATT (1994). For example, GATT (1994) called upon the EU to reduce its tariff on cigars by 50 per cent, on cigarettes and other manufactured tobacco products by 36 per cent, and on unmanufactured tobacco by 20 per cent. Article XX of the text of the Agreement provides a critical and highly limited exception to its trade liberalization provisions for national measures to protect public health that would otherwise violate GATT (1994). GATT has elaborated on the implications of Article XX in the context of national tobacco control regulations in a 1990 case involving Thailand's ban on cigarette imports and advertising. In this case, American tobacco companies challenged Thailand's ban on advertising and imports, prompting an investigation by the USTR who referred the matter to GATT. As is well known, the panel ruled that Thailand's practice of permitting the sale of domestic cigarettes while banning the importation of foreign cigarettes was not 'necessary' and, therefore, not justifiable under Article XX(b) since alternatives to banning imports were available to protect public health. The panel further found, however, that requiring foreign tobacco companies to abide by tobacco control regulations that applied equally to domestic and foreign tobacco products was appropriate and consistent with GATT obligations.

The WTO Secretariat has also indicated that a number of other WTO multilateral agreements also have important implications for global tobacco trade and tobacco control efforts. Such agreements include the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Agreement on Technical Barriers to Trade, the Agreement on Agriculture, and the Agreement on Subsidies and Countervailing Measures.⁷

Regional and bilateral agreements have also had a significant influence on the transnationalization of the tobacco epidemic by reducing tariff and non-tariff barriers to tobacco trade. Among the most notable of the tobacco-related bilateral treaties are the agreements between the United States and Japan, South Korea, and Taiwan negotiated during the Reagan and first Bush administrations.

⁶ See A L Taylor et al, *The Impact of Trade Liberalization on Tobacco Consumption* in P Jha/F Chaloupka (eds), *Tobacco Control in Developing Countries*, Oxford University Press (2000) 343–364. See also *Confronting the Tobacco Epidemic in an Era of Trade Liberalization*. WHO Doc WHO/NMH/TFI/01.4 (2001) available at www.wpro.who.int/pdf/rcm53/rd/10_TFI.pdf.

⁷ See generally *Confronting Tobacco in an Era of Trade Liberalization* (n 6).

As a consequence of the widely recognized linkage between trade liberalization and tobacco consumption, the relationship between trade law and the FCTC was a keenly contested issue throughout the six rounds of negotiations conducted by the WHO Intergovernmental Negotiating Body (INB). For example, during the fifth session of the INB, informal negotiating meetings, open to all WHO Member States, were organized to hammer out the nexus between international trade law and the FCTC. In addition, ad hoc restricted membership working groups sought to resolve the issue. None of these meetings or working groups produced meaningful results. As described further herein, the key issues in this realm were finally resolved on the final day of the final negotiating session.

The global public health impact of tobacco trade was a premier concern for the majority of the developing countries and newly industrializing states from WHO's regions in Africa, Asia, the South Pacific, and Latin America, who made up the lion's share of the 160 or more delegations participating in the treaty negotiations. These state delegations were primarily led by representatives of national health ministries and often included either junior lawyers or no representative at all from foreign affairs ministries. The positions advocated by these state delegations were strongly supported by the many non-governmental organizations that also had an important influence on the treaty negotiations. Among the NGOs, perhaps the most significant and influential was the Framework Convention Alliance, a group of over 150 NGOs from around the world. Like their state delegation counterparts, the majority of the NGOs active in the FCTC negotiations came from national public health backgrounds and not prior treaty codification efforts. A few anti-corporate globalization NGOs were also involved in the process and appeared to view the FCTC as an opportunity to codify a 'corporate accountability' treaty.

These state delegates and activists participating in the FCTC negotiations generally expressed three key types of concerns about the relationship between global tobacco consumption and international trade liberalization and, consequently, how trade issues should be addressed by the FCTC. First, it was repeatedly argued that national tobacco control regulations designed to advance public health could be vulnerable potentially to challenges in the WTO, whether such regulations were implemented by states unilaterally as national public health measures or pursuant to future obligations established by the FCTC. For example, some developing states and activists argued that plain black and white tobacco product packaging standards implemented by countries could be deemed as a violation of trademark protections contained in the WTO TRIPS agreement. Secondly, activists as well as delegates from many developing states expressed concern about the harmful consequences of market liberalizing measures and, at times, argued that the FCTC should reverse the results of the GATT Thai decision and allow states to apply restrictions on foreign brands, including closing markets to foreign tobacco. As the American NGO, the Campaign for Tobacco Free Kids, has written, 'health advocates

have asserted that tobacco monopolies are just what the doctor ordered.⁸ Thirdly, at least some of the states participating in the negotiations viewed the issues involved on a broader scale than the tobacco context. Fresh from a prolonged, continuing, and not completely satisfactory debate on access to medicines, particularly HIV–AIDS anti-retrovirals, during the same period of time at the WTO, some states appeared to see the WHO FCTC as an alternative forum or platform to take a stand on the sovereign right to prioritize public health over international trade obligations.

While a variety of states expressed such concerns during the course of the negotiations, South Africa and India led discussions in the health and trade area on behalf of the developing countries, particularly toward the close of the negotiations. Recurring themes expressed by those states concerned with addressing the impact of international trade liberalization on tobacco consumption in the FCTC included the following:

- Liberalization of tobacco trade stimulates global tobacco consumption and harms public health, particularly in poor countries.
- Existing trade agreements do not adequately protect tobacco control measures from trade-based challenges.
- The FCTC should not be “subordinate” or “subject to” existing international trade law. Rather, the FCTC should take “precedence” over existing international trade law.
- The FCTC should include a clear and explicit provision that in the event of conflict between provisions of the FCTC and obligations established by international trade agreements, the FCTC should control.
- The FCTC should include a clear and explicit provision that public health should take precedence over commercial interests and that measures taken by states to advance public health should not be deemed a violation of international trade law. Notably, the argument in support of this position was not based on the human right to health. Rather, parties repeatedly argued for this position on the basis of the sovereign right to protect public health.

In sharp contrast to the position taken by many of the developing countries and newly industrializing states, some industrialized states, particularly the major tobacco product exporters, joined by other states argued that the

⁸ Campaign for Tobacco Free Kids, Public Health, International Trade and the Framework Convention on Tobacco Control 2001, available at http://fctc.org/about_FCTC/topics.shtml#trade. The claim that closed markets and national tobacco monopolies are ‘just what the doctor ordered’ is based on the proposition that closed markets allow states to maintain control over the tobacco industry, to prevent marketing and price competition that accompany tobacco trade liberalization and to keep out brands with demonstrated appeal to traditionally nonsmoking women and children. In contrast to the tobacco transnationals, national tobacco monopolies are noted for being bureaucratic, inefficient, and poor marketers of low quality products. It should be noted, however, that China which, until recently, maintained a closed market and national tobacco monopoly has extremely high prevalence rates for smoking among adult males, with over 68% of Chinese men smoking.

FCTC should be developed and applied in a manner consistent with existing international trade law. States actively joining this general position included Australia, New Zealand, Canada, China, Cuba, Argentina, the United States, Japan, and the European Union. Some of these states repeatedly advocated the following themes on the nexus between trade, public health, and the FCTC:

- States are committed to the protection of public health. However, both health and trade are of national interest and should not be subject to prioritization. Rather, standards on health and trade should be “mutually supportive”.
- Measures taken to protect public health should not discriminate against international trade: states should treat domestic and foreign tobacco and tobacco products on the same footing.
- The FCTC should include a clear and explicit provision that measures taken to protect public health should be implemented in a manner consistent with other international obligations and should not be applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade.

While positions on the trade and health issue remained diametrically opposed throughout most of the negotiations, near the end of the fifth negotiating session in November of 2002 the EU proposed an alternative text that, ultimately, by satisfying none of the parties involved, became the basis for compromise. In particular, the EU proposed that instead of clear and explicit provisions on the relationship of the FCTC to other international agreements and the rights of parties to take public health measures that discriminate against international trade, that the treaty remain silent and allow the provisions of Article 30 of the Vienna Convention to apply in the event of conflict between the FCTC and any of the WTO agreements. This proposal was incorporated in the Brazilian Chair’s final revised text prepared for the sixth and final session of the INB in March 2003.

Indeed, neither side of this contentious trade–health debate was satisfied with the Chair’s final revised textual proposal. Developing state delegates, particularly those hoping to establish the FCTC as a stand on the trade versus health issue, viewed the Chair’s text as almost a betrayal. Some of the delegates from industrialized countries involved also expressed keen disappointment. While satisfied that the revised text did not include an explicit provision advancing national public health measures over existing international obligations, most of these states had emphasized the need for a clear provision in the text that the treaty should be interpreted and applied in a manner consistent with existing international obligations. On the final day of negotiations the Chair’s compromise text was accepted with the addition of a new preambular provision placed as the first clause of the agreement that reads, ‘[d]etermined to give priority to their right to protect public health’.

IV. HEALTH AND HUMAN RIGHTS IN THE FCTC NEGOTIATION PROCESS

In contrast to the extensive consideration given to the trade issues, there was virtually no discussion of human rights during the course of treaty negotiations and the states did not incorporate a human rights framework in the final text of the Convention. This absence of a rights framework in the final text of the Convention and, moreover, any meaningful discourse on the intersection between human rights and public health during the course of negotiations comes as a surprise to many Convention observers.

Other than vague references in the preamble to Article 12 of the Covenant on Economic, Social, and Cultural Rights as well as the Convention on the Rights of the Child and CEDAW, the final text of the Convention contains virtually no references to human rights. During the course of negotiations, individual states would, on rare occasion, propose the inclusion of ill-defined general principles that seemed to have some connection to the language of rights, such as the ‘right to clean indoor air’ or the ‘right to full disclosure of the contents of tobacco products’, but such proposals gathered no attention. Further, as described above, repeated arguments made during the negotiations that public health should be prioritized over international trade were based upon the sovereign right to protect public health, not the human right to health.

The widespread influence of the public health community in the negotiation process may partially explain the absence of any meaningful consideration of human rights in the FCTC treaty discussions and final text. As described earlier, representatives of national public health ministries typically led the state delegations from developing and transitional market economies. Public health experts also dominated the makeup of non-state actors who had an important influence on the treaty negotiations, including NGOs and the WHO Secretariat. Notably, human rights NGOs did not participate in the FCTC negotiation process.

Over the past ten to fifteen years, the field of health and human rights has become a significant area of scholarly research and international legal concern. Contemporary health scholars recognize that human rights and protection of public health are intertwined and interdependent. Evolving approaches to public health, arising principally from approaches to the global HIV–AIDS epidemic, emphasize that protection of human rights is a vital component of protecting public health. At the same time, the domain of human rights in relation to health has expanded in the last decade with bodies of the United Nations system with responsibility for human rights paying increasing attention to the interrelation between health and human rights, and a variety of tailored instruments now address the rights of particular populations.

Despite these developments, the evidence that national health ministries participating in the FCTC negotiations did not meaningfully consider rights-based approaches suggests that human rights may not yet be widely embraced

or, perhaps, appreciated by the global public health community outside such areas as HIV–AIDS, particularly within developing countries and transitional market economies.

Indeed, the FCTC negotiations illustrate that there remain important distinctions between the practice and the principles of human rights and public health and that the critical interconnections between the two realms, such as the role of personal autonomy in advancing the collective good, may remain underappreciated by at least some large segments of the global public health community. For example, during the course of the FCTC negotiations textual proposals that were potentially highly burdensome on personal autonomy were made by state delegations and, on occasion, by senior WHO officials, on the grounds of protecting public health without consideration of their human rights impact. For example, on several occasions it was suggested that the treaty incorporate provisions calling upon states to protect the foetus from involuntary tobacco smoke. As a further example, it was suggested that the treaty incorporate provisions prohibiting smoking in private places, including the home. While such provisions were not included in the final text of the Convention, it is notable that there was no discourse during the INB sessions on the impact of such measures on human rights or how impinging on human rights could undermine efforts to advance public health.

Human rights approaches may also have been neglected in the FCTC negotiations because the tobacco control community may be highly suspicious of the language of rights in general. The tobacco industry has long captured and used rights language to advance its agenda. Particularly noteworthy is the industry's effective marketing of the concept of the 'right to smoke'.

V. THE FCTC AND THE FUTURE OF INTERNATIONAL HEALTH LAWMAKING AT WHO

There are a number of fascinating questions raised by the FCTC negotiations and the final text of the Convention itself. As this is the first convention ever negotiated at WHO in its more than fifty-year history, one of the most interesting questions raised concerns the implications of this process for future health law negotiations, particularly under WHO auspices.

WHO is unique among United Nations specialized agencies in that the Organization has traditionally neglected the use of international legal instruments to advance its global public health goals. A decade ago I attributed WHO's traditional conservatism about the use of international legal instruments largely to its cultural predispositions—its organizational culture.⁹ WHO's unprecedented consideration of the role of international law and institutions in promoting public

⁹ A L Taylor, *Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions for Health*, *American Journal of Law & Medicine* 18 (1992) 301–346.

health policies in tobacco control as well as in other realms of international health law concern suggests a rethinking, reformulation, and expansion of the organization's traditional scientific, technical approaches to public health. As I have described elsewhere, these legal developments may herald a turning-point: a new era in international health cooperation and, perhaps, an important step towards a new international health law leadership role for WHO.¹⁰ A question that remains is whether the organizational changes in support of international legal approaches initiated under the tenure of Dr Gro Harlem Brundtland, a unique WHO head because of her unconventional background in international lawmaking and diplomacy as well as public health, reflect merely limited and inconsequential deviations from established procedures, or are key steps towards genuine adaptation or evolution of WHO's conservative culture that will be sustained and fostered under WHO's new Director-General, Dr Jong-wook Lee, and beyond.

The final text of the Convention also raises important issues. Much has been written about the significance of the FCTC negotiation process in promoting national and international tobacco control. However, viewed as an international instrument, the FCTC has number of aspects that raise concern about the potential effectiveness of the agreement in promoting national implementation of tobacco control norms. The FCTC is modelled upon the framework convention-protocol approach, an approach to international lawmaking made popular in the realm of international environmental law. Although there is no single definition of a framework convention, such treaties tend to establish broad obligations and concrete institutions of global governance that provide a platform to promote negotiation and codification of detailed obligations in future protocol agreements. While the FCTC tends to establish broad obligations found in many framework conventions, the text is quite expansive and, in some respects, establishes quite concrete substantive obligations. In fact, the FCTC establishes an entire catalogue of substantive obligations constituting about seventeen articles.

Moreover, the FCTC lacks many of the core institutional arrangements found at times in framework conventions that can serve as the bedrock for an ongoing international legislative enterprise. For example, it is widely recognized that meetings of the contracting parties are the most important institution established by framework conventions. Most framework conventions establish bi-annual or annual meetings of the Conference of the Parties in order to keep governmental and media attention focused on a problem. In contrast, the FCTC only provides that there should be 'regular sessions'. As a further example, in contrast to many framework conventions, the FCTC does not establish any subsidiary institutions to assist the Conference of the Parties to monitor implementation of the agreement or to keep it abreast of scientific developments that may affect the development and implementation of the treaty. In addition, the text of the treaty also establishes strong impediments to the eventual

¹⁰ A L Taylor (n 2).

evolution of the treaty regime. In particular, the FCTC establishes a relatively high level of state participation to amend the framework convention and to adopt protocols—in both cases an affirmative vote of three-quarters of state parties present and voting is required in the absence of consensus.

These limited procedural requirements and institutional provisions coupled with the broad substantive obligations established by the treaty raise important concerns about the next stages of the FCTC process, the implementation of the framework convention, and the negotiation of protocols. Despite the important achievements of the FCTC and the FCTC process, overall WHO Member States appear to have negotiated an agreement that may be marked by important challenges of implementation and participation.

VI. CONCLUSION

The foregoing analysis can only begin to touch on the complex and fascinating issues surrounding the negotiations of the WHO's FCTC. As suggested above, since this is the first convention ever negotiated at WHO in its more than fifty-year history, one of the most interesting questions raised concerns the implications of this process for future health law negotiations under WHO auspices.

It has been widely observed that where lawmaking happens makes an important difference to the outcome of treaty negotiations. The character of treaty negotiations differs widely from the 3rd Committee of the United Nations to the 6th Committee and across the specialized agencies, including such agencies as the ILO, the IAEA, the FAO and, now, WHO. This article has illustrated that, in the case of WHO FCTC, the distinctive nature of the Convention can largely, but not exclusively, be attributed to the dominant role played by the global public health community at the treaty negotiations at WHO.

As described herein, the public health community was a dominant force in the FCTC negotiations: the majority of state delegates from developing and transitional market economies as well as the non-state actors involved in the process and senior WHO Tobacco Free Initiative Secretariat officials came from national and international public health backgrounds and not prior treaty codification efforts. Issues surrounding the character of the WHO treaty negotiation process and the role of the public health community in the FCTC negotiation process and potentially future negotiations at WHO are likely to be a continuing source of debate. Much has been written in the field of international environmental law as well as in other realms about the prominent role of scientific advisors in international treaty negotiations. Indeed, it is axiomatic that knowledgeable experts should play a critical role in contemporary treaty negotiations—in problem definition, fact-finding, and standard-setting as well as in building global public support. This is particularly the case with respect to highly technical instruments developed under the auspices of specialized

agencies, including WHO. At the same time, it is widely recognized that in the highly politicized context of treaty negotiations, there are important limitations with scientific experts leading the negotiation process. In the case of the WHO FCTC, this challenge played itself out in several areas, including, most clearly, the development of limited institutional and procedural mechanisms for the treaty regime. To this end, the FCTC process holds important lessons for future international public health law negotiations at WHO and, potentially, other forums. Participating states should carefully evaluate the FCTC negotiations and their outcome in order to devise a more appropriate and effective strategic balance between public health, political, and legal expertise collectively to advance global public health in future international health law negotiations.

Conflicting Rules in the WHO FCTC and Their Impact

WERNER MENG

Commentary on Allyn L Taylor

The report about the efforts of the World Health Organization to elaborate the Framework Convention on Tobacco Control¹ by Allyn Taylor is an interesting insight into the conditions under which the FCTC was negotiated. It is a study of the coordination of the Convention and WTO Law (including its deficiencies) and as such it is part of a much larger and increasingly urgent topic: fragmentation of public international law in general² and rules affecting international trade in particular. It also is a case study within our broad topic 'Human Rights and Trade'. At first sight this may seem amazing, since human rights are not even mentioned as such in this convention that is the framework for measures of states to improve public health and to contain—as this is formulated—the ever-growing 'tobacco epidemic'.

Of course, it would have been possible to declare the convention as an effort designed to realize the states' duty to provide 'the highest attainable standard of physical and mental health' according to article 12 paragraph 1 of the United Nations Covenant on Economic, Social, and Cultural Rights. States could also rely on their domestic human rights provisions. It would be appropriate to think that the prevention of smoking in public spaces could be an effort to guarantee the right of non-smokers not to be affected by breathing in a possibly cancerogeneous environment. The same is true of the prevention of further addiction to tobacco, particularly, but not only, of young people.

Human rights were also considered in the discussion during the negotiations. The final complete silence about this aspect may be due to the background and

¹ See also A L Taylor, Global governance, international health law and WHO looking towards the future, 80 *Bulletin of the World Health Organization* (2002) 975–980; A L Taylor/D W Bettcher, WHO Framework Convention on Tobacco Control: a 'Global Good' for Public Health (2000); C P Bump, Close but not Cigar: the WHO Framework Convention on Tobacco Control's Futile Ban on Tobacco Advertising, 17 *Emory International Law Review* (2003) 1251–1309; J N Eckhardt, Balancing interests in free trade and health. How the WHO's Framework Convention on Tobacco Control can withstand WTO scrutiny, 12 *Duke Journal of Comparative & International Law* (2002) 197–229; S D Murphy, Liability and the WHO Framework Convention on Tobacco Control, 5 *International Law Forum* (2003) 62–71; A Woo, Health versus trade. The future of the WHO's Framework Convention on Tobacco Control, *Vanderbilt Journal of Transnational Law* 35 (2002) 1731–1767.

² This subject is at present part of the working programme by the International Law Commission.

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expertise of the negotiators, who were mainly health and health law specialists. Or are the pertinent human rights positions perhaps too unclear or disputed to have been invoked instead of readily stated 'sovereign rights'? So the real problem is the coordination between FCTC and International Trade Law. But many features of this problem are also relevant and important for the relation between Trade Law and Human Rights law.

The relationship between the Framework Convention and WTO law was disputed throughout the negotiations. In the year before the end of the negotiations, the draft still contained two provisions that would have confirmed the priority of WTO law over the Convention.³ Now, in the final text,⁴ these provisions have disappeared and the sweeping statement at the beginning was added, that the contracting parties are 'determined to give priority to the right to protect public health'. While the omission of the two former clauses would have simply produced a convention that is later in time and more specific in content, that would, consequently, have to be considered under the pertinent rules of the Vienna Convention on the Law of Treaties, the last-minute addition in the preamble may even seem to confirm the prevalence of the Framework Convention at least as *lex specialis* that would not allow a later modification among less than all parties.⁵

Although the rules of general public international law on validity, application, and validity of treaties are not rules of interpretation that are mentioned as applicable in art 3.2 DSU, I share the opinion, that has so thoroughly been outlined recently by Joost Pauwelyn,⁶ that these rules apply to WTO law, at least as long as there are no special rules agreed among WTO members, because it is rooted in public international law.

The consequences of these rules, however, remain uncertain. If all the WTO members would also be members of the Framework Convention and its subsequent treaties, the situation would be as simple as stated in art 30.3 VCLT: in case of conflict the new rules would prevail. But the situation will most probably be more complicated. Until now 168 States have signed the FCTC, so far 25 have ratified it. It might take a rather long time until all the WTO members will be bound by it. Until then, the rules of art 30.4 VCLT will apply. Between the members of both systems, the FCTC applies in conflicts as the more recent set of rules. Between WTO members that are bound by FCTC and those who are not bound, WTO law will be applied exclusively.⁷

However this is only the mechanism. The substance is governed by art 41.1 b) VCLT, since the WTO law does not authorize modifications between less

³ According to art 30.2 Vienna Convention on the Law of Treaties (VCLT). For the development of the drafts see J Pauwelyn, WTO compassion or superiority complex?, Michigan Journal of International Law 24 (2003) 1177–1207, 1201.

⁴ http://www.who.int/tobacco/fctc/text/en/fctc_en.pdf (visited August 2004).

⁵ According to art 41.1 b) ii) VCLT.

⁶ J Pauwelyn, Conflict of norms in public international law (2003).

⁷ This might be done, if possible, and that means: if rights of the latter members are not defeated—interpreted in a way harmonizing both sets of obligations.

than all its partners—even the consensual solutions of disputes have to be in conformity with WTO law.⁸ So the FCTC can lawfully modify WTO rules between WTO members bound by both treaty systems only if other WTO partners are not affected in their treaty rights or obligations and if the rules were allowed to be modified at all considering the aim and purpose of WTO law.

It seems that there is no conflict—at least at present—between the Framework Convention and WTO Law. This was also confirmed by a joint study of the secretariats of WTO and WHO⁹ considering possible conflicts of GATT with health measures in general; of the Technical Barriers to Trade (TBT) Agreement in relation to product requirements such as packaging and labelling; of the Agreement on Agriculture in relation to government support for tobacco production; of the General Agreement on Trade in Services (GATS) in relation to restrictions on cigarette advertising; and of the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) in relation to trademark protection and the disclosure of product information considered by producers to be confidential.

They conclude¹⁰ that the draft text proposes as a guiding principle that ‘Tobacco-control measures should not constitute a means of arbitrary or unjustifiable discrimination in international trade. None of the provisions of the FCTC are inherently WTO-inconsistent, and many of the restrictions called for by some of its provisions may well be determined to be “necessary” for health protection under WTO rules.’ This refers to the seminal GATT panel decision in the case *Thailand—Restrictions on importation of and internal taxes on cigarettes*¹¹ that emphasized the non-discrimination and the necessity test concerning health measures according to art XX b) GATT 1947. Any new rules added to the framework in the future will be measured by these standards, at least among WTO members who are not part of both treaty systems. WTO dispute settlement organs will be the institutional entity that passes judgment on these matters. The double standard that may then possibly result would have to be examined under art 41.1(b)(ii), for whether it is consistent with the aim and purpose of WTO law.

However, the tools of conflict resolution provided by the VCLT do not seem appropriate for matters of international concern, outside the WTO, that incidentally involve trade. The WTO itself has accepted and espoused this point of view in the areas of labour rights.¹² The VCLT rules are not sufficient for coordination of different fragmented sub-systems of public international law,

⁸ See arts 3.5 and 22.1 DSU and also art 11 Safeguards Agreement, the prohibition of grey area agreements in the future.

⁹ WHO/WTO, WTO agreements and public health. A joint study by the WHO and the WTO secretariat (2002), 73–77.

¹⁰ *ibid* no 138.

¹¹ BISD 37S/200.

¹² W Meng, International Labor Standards and International Trade Law in E Benvenisti/G Nolte (eds), *The Welfare State, Globalization, and International Law* (2003) 371–394. Y Moorman, Integration of ILO core rights labor standards into the WTO, 39 *Columbia Journal of Transnational Law* (2001) 555.

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as they cannot avoid frictions. The rules resolve conflicts technically instead of substantially reconciling them. It is therefore necessary to provide coordination within the different systems that should work together. In order to coordinate various international systems of law, something more than the VCLT rules are needed.

Within the existing WTO law, such a possibility would be given by a waiver according to arts IX.3 WTO Agreement and XXV GATT. This solution was used in the case of the 'conflict diamonds'.¹³ A waiver requires a two-thirds majority of the members. In the case of the FCTC, this would probably require the consent of many members who are not yet bound by the FCTC, or perhaps, the consent of all WTO members—given the consensus practice found in art IX.1 WTO Agreement. It might be possible to argue that all the WTO members who have signed the tobacco treaty are under an obligation not to defeat the object and purpose of it (art 18 VCLT), and therefore would have to accept such a waiver. However even if a waiver might further the FCTC, it is difficult to assert that, without the waiver, the object and purpose of the tobacco treaty system are defeated by WTO law.

Moreover, the content of such a waiver remains a crucial problem. It could exempt tobacco trade entirely from the WTO discipline. But first of all it remains to be seen whether states with vested interests in tobacco production and trade would be willing to go that far. Furthermore such a broad waiver would remove the subject of concealed protectionism that the *Thailand cigarettes* panel was confronted with from the control of WTO law. However, there is no equivalent control in the FCTC system thus far, neither in terms of substantial nor of procedural law.

If the WTO members would not be willing to accept a blanket waiver of the entire tobacco industry, a waiver would have to be crafted in more restrictive terms—and/or FCTC law would have to be augmented by equivalent rules.¹⁴ Such a waiver would have to be elaborated in close cooperation between the WHO and the FCTC 'open-ended' negotiating mechanism on the one hand and the WTO and its members on the other. The problems to be considered will be manifold. Institutionally they would have to deal in greater details with the intertwining of both systems during the negotiations, but also for the solution of day-to-day conflicts arising from their parallel operation. They would also have to address the question of dispute settlement on both sides, the possibility of drawing on the expert knowledge of the other side, and the jurisdiction in particular cases (provided that the FCTC would develop any kind of meaningful dispute settlement at all). It would also have to be considered how parallel dispute settlement systems could cooperate, for example, by a reference procedure.¹⁵

¹³ WT/GC/W/498 (13 May 2003). See eg J Pauwelyn, *WTO compassion or superiority complex?*, 24 *Michigan Journal of International Law* (2003) 1177–1207.

¹⁴ So far, the 'sovereign rights' language of FCTC does not point in this direction.

¹⁵ As this is known from the cooperation between national courts and the European Court of Justice in the EU.

Concerning the substance matter, it would have to be decided how disputes about the abuse of 'sovereign rights to protect health' for concealed protectionist purposes would be dealt with, equivalent to the rule of the 'chapeau of art XX GATT. This is necessary between the WTO members that are bound by the two systems, but it should be regulated for all participants in these systems in a coherent and equivalent way. The rules about the standard of risk assessment should be coordinated and the rules for the protection of health should be balanced with property concerns in order to coordinate the regulations with human rights concerns. Finally, there should also be rules about the future modifications of WTO as well as FCTC law and their relation to each other in order to avoid unwanted consequences of a mechanical 'later in time rule'.

This catalogue of requirements may still have to be enlarged. It is a list of legal concerns that should be considered. The political will to cover this list comprehensively or only in part is a different question. However it is submitted that partial solutions will not remove the dangers of counterproductive conflicts between the two systems. The question is, whether a waiver is really the right tool to cover all these problems. Probably not, for it requires a complicated conditionality if it would be subject only to a WTO waiver and if the members would not be willing completely to release tobacco trading from the WTO discipline. However a waiver is perhaps the 'second-best solution' if a political will to resolve the problem by positively coordinated treaty rules is not available.

If a waiver is conditioned, or coupled with a 'sunset clause', this would mean that the tobacco regime remains under constant scrutiny of the WTO. This might not only create legal frictions as set out above, but also increase political reservations against the WTO for purportedly superseding all other public regulatory concerns like labour, culture, health, and human rights with trade liberalization. This political conflict potential should be considered before negotiating parties too easily leave conflict rules to general public international law.

The intricacies of the problem of coordination just mentioned raise another important aspect hinted at by Ms Taylor's report. If negotiations are held among specialists in medicine and health law, this might end in a result that is too narrowly confined to health concerns and does not sufficiently value the potential overlaps and mutual obstacles of the fragmented sub-systems of public international law. It requires the close cooperation of representatives and specialists of all the sub-systems involved in order to craft a regulation that is carefully designed in order to assure the coordination of all these systems. The WTO will participate as an observer in the open-ended working process for the elaboration of future rules within the Tobacco Convention's framework.¹⁶ This might be a favourable aspect of these negotiations.

¹⁶ WHO and WTO, WTO agreements and public health. A joint study by the WHO and the WTO secretariat (2002) no 139, 140.

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There is one general conclusion from this: our case study shows that in the law-making process, the background of the negotiators matters. If they are not carefully chosen from persons with different complementary expertise, the law-making process inherently contributes to the incoherence or lack of relation of the different sub-sets of regimes in general public international law. Whether the negotiators are specialists with a narrower expertise, or—on the other hand—diplomats, that are generalists and insufficiently counselled by their specialists back home: the specific focus of such uncoordinated negotiations and their results lead to an insufficient embedding of the new sub-system of law in public international law order as a whole. Fragmentation can only be overcome by careful cooperation and coordination.

