

RESEARCH PAPERS

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POLICY SPACE FOR DOMESTIC PUBLIC INTEREST MEASURES UNDER TRIPS

Henning Grosse Ruse – Khan *

SOUTH CENTRE

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* Henning Grosse Ruse – Khan is a Research Fellow, Max Planck Institute for Intellectual Property-, Competition- and Tax Law, Munich (Germany); email henning-gr-khan@ip.mpg.de. An earlier version of this paper has been prepared in the framework of the Intellectual Property in Transition Project. The project was initiated in 2001 with the aim to investigate from a legal viewpoint how an effective and ethically acceptable IP system should be constructed in order to offer a balanced instrument for the 21st century. The earlier version can be accessed at <http://ssrn.com/abstract=1309526>. I wish to thank Susan Plattner and Ruth Claussen for their editorial assistance; and Xuan Li, Hans Ullrich, as well as Annette Kur, Marianne Levin and all other members of the IP in Transition project for their comments on earlier drafts. The views expressed in this paper are the personal views of the authors and do not necessarily represent the views of the South Centre or its Member States. Any mistake or omission in this study is the sole responsibility of the author.

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LIST OF ABBREVIATIONS

AA	(WTO) Agreement on Agriculture
Agenda 21	Environment and Development Agenda
Berne Convention	Revised Berne Convention on the Protection of Literary and Artistic Works
BIT	Bilateral Investment Treaty
Brundtland Report	United Nations Report of the World Commission on Environment and Development – Our Common Future
CARIFORUM	Caribbean Forum of African, Caribbean and Pacific States
CBD	Convention on Biological Diversity
CIPR	Commission on Intellectual Property Rights
CDIP	(WIPO) Committee on Development and Intellectual Property
DSF	Digital Solidarity Fund
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EC	European Community
EPA	EC - CARIFORUM Economic Partnership Agreement
EU	European Union
FAO	United Nations Food and Agriculture Organisation
GATT	(WTO) General Agreement on Tariffs and Trade (1994)
GATS	(WTO) General Agreement on Trade in Services
ICJ	International Court of Justice
ICESCR	International Covenant on Economic Social Cultural Rights
ILA	International Law Association
ILC	International Law Commission
ILO	International Labour Organisation
IP	Intellectual Property

MEA	Multilateral Environmental Agreement
Mercosur	Mercado Común del Sur (Common Market of the South)
NAFTA	North American Free Trade Agreement
PC	Paris Convention on the Protection of Industrial Property
PCDA	(WIPO) Provisional Committee on the Development Agenda
SPS	(WTO) Agreement on Sanitary and Phytosanitary Measures
SCM	(WTO) Agreement on Subsidies and Countervailing Measures
SCCR	(WIPO) Standing Committee on Copyright and Related Rights
TBT	(WTO) Agreement on Technical Barriers to Trade
TRIPS	(WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights
UNFCCC	United Nations Framework Convention on Climate Change
UCC	Universal Copyright Convention
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UDHR	Universal Declaration of Human Rights
UNEP	United Nations Environmental Programme
UNESCO	United Nations Educational Scientific and Cultural Organization
UNHRC	United Nations Human Rights Council
UNIDO	United Nations Industrial Development Organization
US	The United States of America
VCLT	Vienna Convention on the Law of Treaties
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WSIS	World Summit on the Information Society
WTO	World Trade Organization
WTO Agreement	Agreement Establishing the World Trade Organization

EXECUTIVE SUMMARY

This paper examines the scope of policy space available to integrate economic, social and environmental concerns under the World Trade Organization's (WTO) Agreement on Trade Related Aspects of Intellectual Property Protection (TRIPS). It does this by comparing the amount of discretion available for domestic public interest measures in two other core areas of WTO regulation: trade in goods and services. The paper concludes that the notion of general exceptions under the General Agreement on Tariffs and Trade (GATT) and under the General Agreement on Services (GATS) finds no equivalence in TRIPS. Still, an equivalent amount of policy space can be achieved by taking the TRIPS balancing objective and the WTO sustainable development objective seriously within the process of TRIPS interpretation and implementation. This opens significant room to integrate economic, social and environmental concerns in Intellectual Property (IP) regulation and decision-making. It is an approach which all WTO Members agreed to in para.4, 5 a) of the Doha Declaration on TRIPS and Public Health.

Against the background of a structural bias in international economic regulation in general, and WTO law in particular, there is a need for sufficient flexibility in international obligations protecting economic interests. This flexibility or policy space must allow room for domestic regulation of public interests relative to the increasing impact international regulation has on those interests at the domestic level. To the extent that TRIPS does not directly integrate 'external' interests and the application of *international* regimes on public interests remains limited and at best unclear in the WTO context, *domestic* measures remain the decisive elements for ensuring an overall balance between economic and public interests. This follows from the sustainable development objective in the preamble to the Agreement Establishing the WTO (WTO Agreement) and its application as a principle of integration by the WTO Appellate Body. It finds further support in international law and jurisprudence on sustainable development.

TRIPS, GATT and GATS can have an equally strong impact on interests such as public health, the environment, food security and nutrition, public order and morals as well as various other societal aspects. There is an equivalent need for deference to public interests in all three core areas of WTO regulation. Regarding trade in goods and services, the general exception in Art.XX GATT, as well as its counterpart Art.XIV GATS, manages surprisingly well to balance domestic policy space for the regulation of public interests with international trade obligations: in principle, they allow domestic measures which are implementing the recognised public policy objectives to override WTO obligations. The most common requirement is that WTO Members must choose the least trade restrictive measure which is reasonably available to them and equally effective in achieving the desired policy objective.

The concept of a general exception functions effectively as a 'disproportionality test' which leaves sufficient policy space in the hands of WTO Members. The WTO Appellate Body has repeatedly shown its willingness to ensure an overall balance of a WTO Members' rights (to regulate public interests domestically) and obligations (to adhere to the WTO rules on trade in goods and services). One important element utilised by the Appellate Body to achieve such a balance has been the objective of sustainable development in the preamble to the WTO Agreement. WTO jurisprudence nevertheless does not impose an internationally-set balance onto the domestic level. Instead it operates to delineate the scope of domestic policy space for regulating public interests from the international obligations to protect trade interests under WTO rules.

Is there an equivalent amount of policy space under TRIPS – an equal option for WTO Members to give preference to public interests such as education, public health, nutrition, access to knowledge, free speech and transfer of technology? The original developing countries' proposal for a public interest exception in TRIPS strongly resembles Art.XX GATT – but was severely curtailed by adding a TRIPS consistency test in the run-up to the Brussels Ministerial in 1990. The added language has effectively prevented Art.8:1 from functioning as an inherent right of WTO Members to override individual TRIPS obligations and so to serve as a comparable general public interest exception to the protection of IP. Such an exception is not obsolete due to the negative rights character of IP rights: several instances where public interests demand access to and dissemination of IP protected goods or services show that merely allowing the state to regulate and limit the commercial exploitation by the right holder is certainly not sufficient. Those individual TRIPS provisions

which concern the right of WTO Members to foresee exceptions and limitations to market exclusivity triggered by IP are written and (so far) interpreted as focussing predominantly on the economic interests of right holders. WTO jurisprudence until now has not utilised them in a way which allows WTO Members to give preference to public interests.

In para.4 and 5 (a) of the Doha Declaration on TRIPS and Public Health, WTO Members pointed to an alternative way of operationalising Art.8:1 TRIPS: by interpreting and implementing all individual TRIPS provisions in light of the balancing objective of Art.7 and the public interest principle in Art.8:1 TRIPS. Supported by the general principles of treaty interpretation in international law, all TRIPS provisions which embody broad and open language allow for an implementation which gives due respect to public interest considerations. This requires a clever reliance on the discretion and policy space that follows from the openness of individual provisions – combined with the use of general principles and objectives in the process of implementation. It implies a greater role and sophistication on the part of the interpreter/implementer. Individual provisions regulating exceptions and limitations are sufficiently open for this purpose – even though existing WTO Panel jurisprudence has certainly not realised this goal.

Beyond TRIPS, the WTO-overarching objective of sustainable development as a principle for reconciling economic, social and environmental interests further supports a balance in implementing individual TRIPS provisions. Relevant for all WTO Agreements, it links the rules on trade in goods, services and protection of IP and calls for coherence and WTO-internal consistency in allowing the recognition of public interests. The Appellate Body has shown its willingness to rely on this objective in cases dealing with conflicts between trade and public health or the environment. It is time to adopt the same approach for TRIPS. This is not only a matter of appropriate treaty interpretation and implementing of the WTO/TRIPS objectives as well as the Doha Declaration. It emanates from the need for internal consistency of the WTO as a legal system: allowing a proper balance in one area but denying it in another threatens legitimacy and acceptance of that area as well as the whole system and could easily be perceived as biased. Ensuring a comparable amount of policy space in TRIPS by means of interpretation and implementation helps domestic legal systems to provide a counter-balance to the structural bias towards right holders inherent in most TRIPS provisions.

In sum, TRIPS therefore *can* be interpreted and – more importantly – implemented in a manner which should offer a similar amount of policy space for domestic regulation of public interests. The scope of international obligations under the TRIPS regime is limited by its objective: we are not applying rigid rules – but rather flexible provisions with a relative amount of discretion to determine an appropriate balance of economic and public interests on the domestic level. Initially, this can be achieved by calling on national implementation legislation (as well as technical assistance provided in this regard) to make use of this policy space:

- Countries should adopt a tailored, integrative approach to IP protection both in international negotiations as well as national implementations.
- Limitations and exceptions to IP protection provide the most important tool for an integrative approach on the domestic level. In line with the Appellate Body jurisprudence on GATT and GATS exceptions, countries must not perceive the relevant TRIPS provisions as exceptions to the general rule of IP protection.
- Instead, an overall balance between all interests affected by IP protection should be achieved.
- The TRIPS provisions setting requirements for domestic exceptions and limitations offer sufficient open and broad treaty language to adopt an integrative approach. Countries should use this discretion when foreseeing exceptions and limitations in their national laws.

Finally, the policy space emanating from the WTO/TRIPS objectives and the Doha Declaration also places an obligation on WTO Panels and the Appellate Body to take the relevant treaty objectives seriously. Given the rather disappointing TRIPS jurisprudence of Panels so far, countries might consider demanding a comprehensive public interest exception integrated into TRIPS – for example by simply removing the consistency test in Art.8:1 TRIPS. Operating with a general exception in TRIPS however would call for a re-conceptualisation of a chapeau-like safeguard against the abuse of public interest exceptions in order to favour domestic industries. Several recent developments, initiatives or scholarly ideas further support the notion of a comprehensive general exception or other means to enlarge domestic policy space for public interests.

I. THE NEED FOR DOMESTIC POLICY SPACE WHEN IMPLEMENTING TRIPS

This section examines the relation between international IP protection and other societal interests or individual rights. In this regard, it identifies common notions in the three core areas of WTO regulation: trade in goods, services and the protection of IP. Against this background, different options for a regulative response to balance and integrate economic, social and environmental concerns are assessed. The main conclusion is that as long as no effective integration takes place on the international level, the concept of sustainable development embodied in the WTO preamble demands for sufficient policy space to balance the domestic level.

I.1 The Impact of International IP Regulation

One common denominator in all fields of economic rule-making is their significant potential impact on (non-economic) societal interests for the sake of a harmonised global economy. This certainly has its advantages for those able to utilise the system¹ and, at least in the area of classic trade liberalisation, allows countries to rely on their comparative advantage.² By the same token it can be detrimental for interests not sufficiently addressed and recognised within this increasingly comprehensive regulatory regime. *De jure* or *de facto*, the reach of the global trading system today extends to societies, groups and individuals everywhere. This also applies to international economic regulation beyond trade in goods or services – such as the international regime for the protection of IP.

In particular the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) not only affects the protection of interests of those who engage in the development and production of creative or innovative products and services. Its impact also extends to various economic, social, cultural or environmental policies which WTO Member States pursue. The debate on patent protection for pharmaceutical products under the WTO TRIPS Agreement as well as access to life-saving drugs is probably the most commonly known example of international intellectual property (IP) rules impacting on common societal interests (public health) as well as individual human rights (right to health).³ Beyond the TRIPS / Public Health paradigm, patent protection under TRIPS is argued to be in conflict with the Convention on Biological Diversity;⁴ digital copyright rules

¹ For example by reducing transaction costs in international commerce, providing security and foreseeability on a global level as well as reducing various types of barriers to enter national markets.

² A general explanation of the theory of comparative advantage and its origins in the work of Adam Smith and David Ricardo as well as the main argument for specialisation and (free) international trade and its current implications can be found in P Van der Bossche, *The Law and Policy of the World Trade Organization* (Cambridge, 2005) at 19-24; For an Economist's perspective see S Brakman, H Garretsen, C Van Marrewijk & A Van Witteloostuijn, *Nations and Firms in the Global Economy* (Cambridge, 2006) at 63-95.

³ On the TRIPS and public health debate see H Hestermeyer, *Human Rights and the WTO – The Case of Patents and Access to Medicines* (Oxford University Press, Oxford, 2007); M Varela, 'The WTO, Intellectual Property and Aids – Case Studies from Brazil and South Africa' (2004) *JWIP* 523; F Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) *JIEL* 469; D Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) *7 JIEL* 73; For the human rights perspective see 'UN Economic and Social Council, The Impact of the Agreement on Trade Related Aspects of Intellectual Property Rights on Human Rights', E/CN.4/Sub.2/2001/13 (27 June 2001); UNHCR Sub-Commission on Human Rights, Intellectual property rights and human rights, resolution 2000/7; On the WTO 'response' see *Ministerial Conference*, 'Doha Declaration on the TRIPS Agreement and Public Health' (WT/MIN(01)/DEC/2), 20 November 2001 as well as *General Council*, 'Decision of 30 August 2003', (WT/L/540 and Corr.1), 1 September 2003 and *General Council*, 'Decision of 6 December 2005', (WT/L/641) 8 December 2005.

⁴ *TRIPS Council Secretariat*, 'The relationship between the TRIPS Agreement and the Convention on Biological Diversity – Summary of Issues raised and points made', IP/C/W/368/Rev.1 (February 2006) available at http://www.wto.org/english/tratop_e/trips_e/ipcw368_e.pdf (accessed 7 July 2009); *Commission on Intellectual Property Rights* (CIPR), 'Integrating Intellectual Property and Development Policy' (London, 2002), Ch.4: Traditional Knowledge, Access and Benefit Sharing (available at http://www.iprcommission.org/papers/pdfs/final_report/Ch4final.pdf) Rojas /

potentially interfere with access to knowledge⁵ or the protection of personal data and privacy;⁶ trademarks can limit the freedom of expression;⁷ seizing goods by IP enforcement border measures may serve as a significant barrier to trade⁸ and certain exercises of IP rights, especially in licensing agreements, may be anti-competitive or inhibit the transfer of technology.⁹

Furthermore, some of the most relevant contemporary problems facing the global community today link or ‘intersect’ with IP protection. The current attempts to tackle climate change by strengthening a global regime for the reduction of carbon emissions under the United Nations Framework Convention on Climate Change (UNFCCC)¹⁰ *inter alia* focus on the transfer of carbon-reducing, ‘green’ technologies to developing countries. IP protection here can function as an incentive for research, development and production of such technologies, but it may also severely limit the transfer and dissemination of these technologies.¹¹ In the same vein, ensuring food security is an issue on which IP protection certainly has an impact. Patent and especially plant variety protection can ‘incentivise’ innovations in agricultural production and offer new technologies, tailored crops or other food-securing solutions to developing countries – while at the same time serving as a potential barrier for the re-use of harvested seeds, as well as the wide distribution of IP protected crops in general. Striking a balance between incentives for new innovations on the one hand and the dissemination of the resulting technology on the other is one of the objectives of TRIPS.¹²

In other fields of global trade regulation, similar impacts of trade rules on domestic public policies exist: WTO dispute settlement cases on the right to refuse imports of hormone-containing beef and imports of tuna or shrimp caught without a specific tool to protect dolphins or sea turtles indicate how WTO obligations on trade in goods can interfere with domestic measures on the protection of the

Mueller / Winkler (Ed), ‘Disclosure Requirements: Ensuring Mutual Supportiveness between the WTO TRIPS Agreement and the CBD’ (*IUCN, ICTSD*, Geneva 2005) – available at http://www.iprsonline.org/resources/docs/Disclosure_req_book.pdf; for a recent proposal to amend TRIPS in order to achieve coherence with the CBD see ‘India, Brazil, et al. - Communication on a Proposal to Amend TRIPS’ (WT/GC/W/564) 31 May 2006.

⁵ Dussollier, Poulet, Buydens, ‘Copyright and Access to Information in the Digital Environment’, (*UNESCO Study CII-2000/WS/5*, Paris, 17 July 2000); H Grosse Ruse – Khan, ‘Access to Knowledge under the International Copyright Regime, the WIPO Development Agenda and the European Communities’ new External Trade and IP Policy’, in E Derclaye (ed), *Research Handbook on the Future of EU Copyright* (Edward Elgar Publishing: forthcoming 2009).

⁶ On the issue of protecting personal data and enforcing IP rights see the European Court of Justice (ECJ) judgement of 29 January 2008 in the case of *Productores de Música de España Promusicae vs. Telefónica de España* (C275/06) considering that the European law “does not require member states to lay down an obligation to disclose personal data in the context of civil proceedings”. See also O Vincents, ‘When Rights Clash Online: The Tracking of P2P Copyright Infringements vs. the EC Personal Data Directive’, *International Journal of Law and Information Technology* Vol. 16 No. 3 (2007), 270-296.

⁷ A Rahmatian, ‘Trade Marks and Human Rights’, in P Torremanns (ed), *Intellectual Property and Human Rights* (Kluwer, London, 2008), 335-358.

⁸ See for example the ‘RoundUp Ready’ case on the legality of border measure imposed under EC Regulation 1383/2003 against processed soy bean products (soy flour) from Argentina (*Monsanto Technology v. Cefetra, Argentina et al*, Interim Decisions of the Hague District Court, 19 March and 24 September 2008). Monsanto holds a European patent on an isolated gene sequence encoding certain enzymes which improve the growth of soy beans and invoked its patent rights to prevent the importation of soy flour processed from soy beans containing the patented gene sequence. The soy flour had been processed and from soy beans grown in Argentina where Monsanto holds no patents. The actions brought by Monsanto against the importation of processed soy-flour indicate the potential trade restrictive effect of giving customs the power to act in cases of alleged patent infringements.

⁹ See Art.8:2, 40 TRIPS as well as the explicit link made in the first of the new EC – ACP regional trade agreements, Art.142:2 of the EC – CARIFORUM Economic Partnership Agreement (EPA).

¹⁰ United Nations Framework Convention on Climate Change, ILM 1992, Vol.XXXI, p.849 - UN Doc. FCCC/INFORMAL/84 GE.05-62220 (E) 200705 (1992), available at <http://unfccc.int/resource/docs/convkp/conveng.pdf> (accessed 14 January 2009). Sustainable development again appears as a key concept which is addressed in the Preamble (recognising the aim to “achieve sustainable social and economic development”) and in the Conventions’ objectives in Art.3, including the goal “to enable economic development to proceed in a sustainable manner” and further recognising that “the Parties have a right to, and should, promote sustainable development.”

¹¹ For some emerging work on the role of IP in the transfer of ‘green’ technologies see <http://ictsd.net/programmes/energy/technology/> (accessed 22 January 2009).

¹² See Art.7 TRIPS which provides that “the protection and enforcement of intellectual property rights should contribute to the *promotion of technological innovation* and to the *transfer and dissemination of technology*, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”

environment, natural conservation and human, animal or plant health.¹³ In the field of liberating trade in services, market access commitments can clash with national concepts on public morals and public order – as evidenced in the *US - Gambling* dispute over the right of foreign service providers to offer online gambling services in the US.¹⁴ The list of non-trade interests being affected by trade interests and vice versa is certainly not exhaustive. Liberalising trade in the WTO framework has in turn led to specific disputes over import restrictions for genetically modified organisms (GMOs)¹⁵ and (potentially health threatening) retreaded tyres¹⁶ as well as a general debate over the relationship between trade and the environment, climate change and more recently food security.¹⁷

I.2 The Need for Integration and Reconciliation

The intersections mentioned above may cause interference or even potential conflict between economic interests and their regulation on a global level, and non-economic, public interests or human rights, in turn providing the potential for *mutual supportiveness* or coherence of these distinct values or perspectives. As exemplified in the WTO Secretariat's Special Study on Trade and the Environment, trade liberalisation and economic growth actually generate the wealth necessary to promote the environment and the latter in turn can also facilitate economic development.¹⁸ IP protection equally aims "to promote the progress of science and useful arts"¹⁹ and this "to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."²⁰ Therefore, economic interests *can* (and should) promote technological, cultural and societal advancement – as much as any uncompromising pursuit of these interests can negatively affect public goods and individual human rights. The natural and by now default answer to this potential conflict is the call for a proportional *balancing* of the different interests at stake.²¹

13 See the respective GATT / WTO disputes: *United States – Restriction on Imports of Tuna*, Panel Report DS21/R - 39S/155 (not adopted, circulated on 3 September 1991); *European Communities – Measures Concerning Meat and Meat Products (EC – Hormones)*, Appellate Body Report WT/DS26/AB/R (16 January 1998); *United States – Import Prohibition of Certain Shrimp and Shrimp Products (US – Shrimp)*, Appellate Body Report WT/DS58/AB/R (12 October 1998).

14, *United States – Measures Affecting the Cross Border Supply of Gambling and Betting Services (US – Gambling)*, Appellate Body Report WT/DS285/AB/R (7 April 2005).

15 *European Communities – Measures Affecting the Approval and Marketing of Biotech Products (EC – GMOs)*, Panel Report WT/DS291/R, WT/DS/292/R, WT/DS/293/R (29 September 2006).

16 *Brazil – Measures Affecting Imports of Retreaded Tyres (Brazil – Tyres)*, Appellate Body Report WT/DS332/AR/R (17 December 2007).

17 From the vast amount of literature and internet resources available see for example the Energy and Climate Change as well as Environment and Natural Resources Programmes by the International Centre for Trade and Sustainable Development (ICTSD) at <http://ictsd.net/programmes/energy/> and <http://ictsd.net/programmes/environment/>; for the more recent food security debate see 'High-Level Conference on World Food Security: the Challenges of Climate Change and Bioenergy', *Declaration on World Food Security* (Rome, 3-5 June 2008) available at http://www.fao.org/fileadmin/user_upload/foodclimate/HLCdocs/declaration-E.pdf

18 H Nordström, S Vaughan, 'Trade and Environment, WTO Special Studies Series No.4' (1999), available at http://www.wto.org/english/tratop_e/envir_e/environment.pdf.

19 Art.1 sec.8 of the Constitution of the United States of America; listing the legislative powers of the US Congress, *inter alia* to grant authors and inventors limited exclusive rights for the purpose mentioned above.

20 Art.7 TRIPS.

21 A general analysis of balancing and proportionality – also addressing trade and non-trade interests – in the law of the WTO can be found in M Hilf, S Puth, 'The Principle of Proportionality and its Way into WTO Law', in A v. Bogdandy, P Mavroidis, Y Meny (eds), *Studies in Honour of Claus Dieter Ehlermann* (Kluwer International Law, Den Haag, 2002); M Andenas, S Zleptnig, 'Proportionality and Balancing in WTO Law: a Comparative Perspective', *20 Cambridge Review of International Affairs (CRIA)*, Vol.20 No.1 (2007), 1 (7-18); M Hilf, 'Die Freiheit des Welthandels contra Umweltschutz', *NVWZ* 2000, p481-482; For an analysis on the WTO Appellate Body's approach to balancing economics and public interests see C Gerstetter, 'The Appellate Body's Response to the Tensions and Interdependencies between Transnational Trade Governance and Social Regulation', in C Joerges & E-U Petersmann, *Constitutionalism, Multilateral Trade Governance and Social Regulation*, (Hart Publishing, Oxford, 2006); see also the Appellate Body Reports *United States – Standards for Reformulated and Conventional Gasoline (US – Gasoline)*, Appellate Body Report WT/DS24/AB/R, page 16; *US – Shrimp*, as note 13 above, para.121; for balancing under TRIPS see Henning Grosse Ruse – Khan, 'Proportionality and Balancing within the Objectives of Intellectual Property Protection', in P Torremans (ed), *Intellectual Property and Human Rights* (Kluwer, London, 2008), 161-194.

In international law, the concept of sustainable development predominantly expresses this need in its main principle of integration and inter-relation of social and economic development and environmental protection.²² At the World Summit on Sustainable Development (WSSD),²³ held in Johannesburg (South Africa) all participating states assumed:

“a collective responsibility to advance and strengthen the interdependent and mutually reinforcing pillars of sustainable development — economic development, social development and environmental protection — at the local, national, regional and global levels.”²⁴

Further evidence of this need to integrate economic, social and environmental aspects follows from various international courts and tribunal decisions,²⁵ a Declaration by the International Law Association²⁶ and earlier UN Declarations and Reports such as the 1987 *Brundtland* Report on sustainable development.²⁷ For some, this principle of integration – understood as a procedural requirement to consider and balance all relevant economic, social and environmental concerns in the decision-making process – has developed into binding customary law.²⁸ In the context of various international treaties, including the WTO Agreements,²⁹ sustainable development is a recognised treaty objective. Within these treaty regimes, the call for reconciling interests should be put into

²² See *United Nations*, Report of the United Nations Conference on Environment and Development Annex I: Rio Declaration on Environment and Development, UN Doc. A/CONF.151/26 Vol. I, (12 August 1992), available at <http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm> (accessed 14 January 2009), Principle 4: “In order to achieve sustainable development, environmental protection shall constitute an integral part of the development process and cannot be considered in isolation from it” and Principle 25: “Peace, development and environmental protection are interdependent and indivisible.”

²³ The Conference brought together over 21.000 participants from 191 governments intergovernmental and non-governmental organisations, the private sector, civil society the scientific community and academia. Website including all documentation is available at <http://www.un.org/events/wssd/> (accessed 15 January 2009).

²⁴ Johannesburg Declaration on Sustainable Development, adopted at the 17th plenary meeting of the World Summit on Sustainable Development, on 4 September 2002, at 5 available at http://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/POI_PD.htm (accessed 15 January 2009).

²⁵ See the decision of the International Court of Justice (ICJ) in *GabCikovo-Nagymaros Project* (Hungary/Slovakia), Judgment, I. C. J. Reports 1997, p. 7. *Permanent Court of Arbitration*, In the Arbitration Regarding the Iron Rhine (“Ijzeren Rijn”) Railway, between the Kingdom of Belgium and the Kingdom of the Netherlands - Award of the Arbitral Tribunal (May 24, 2005) – available at http://www.pca-cpa.org/showpage.asp?pag_id=1155 (accessed 19 January 2009). In the WTO context, see in particular the Appellate Body’s decision in *US - Shrimp*, as note 13 above, at para.129 (fn. 107).

²⁶ *International Law Association*, Declaration of Principles of International Law Related to Sustainable Development, Resolution 3/2002 adopted at the 70th Conference of the International Law Association, held in New Delhi, India, 2-6 April 2002 (UN Doc. A/CONF.199/8, 9 August 2002), at 7.

²⁷ See *United Nations*, Our Common Future - Report of the World Commission on Environment and Development, UN Doc. A/42/427 – Annex (4 August 1987). The so called ‘Brundtland Report’ could build on the 1971 ‘Founex Report’ on the relationship between environment and development which was then recognised in the 1972 Stockholm Declaration of the United Nations Conference on the Human Environment, calling for the *integration* of environmental concerns in development decision-making (see in particular the principle 13 (“In order to achieve a more rational management of resources and thus to improve the environment, States should adopt an integrated and coordinated approach to their development planning so as to ensure that development is compatible with the need to protect and improve environment for the benefit of their population.”) and principle 14 (“Rational planning constitutes an essential tool for reconciling any conflict between the needs of development and the need to protect and improve the environment.”) as well as principles 2-5, 8, 9, 11, 12). The notion of re-conciliation and integration, in particular of environmental concerns within economic and social development was therefore already incorporated in the 1972 Stockholm Declaration. In the *Brundtland* Report, this key principle of “merging environment and economics in decision making” appears *inter alia* as one of seven “critical objectives” that follow from the principle of sustainable development: (see para.72 of the Report: “The common theme throughout this strategy for sustainable development is the need to integrate economic and ecological considerations in decision making”).

²⁸ See the Separate Opinion of Judge Weeramantry in the case *GabCikovo-Nagymaros Project* (Hungary vs. Slovakia), International Court of Justice (ICJ), Judgment, I. C. J. Reports 1997, p. 7 (25 September 1997) as well as the Award of the *Permanent Court of Arbitration*, as note 25 above, at para.5 (9).

²⁹ See the Preamble to Agreement Establishing the World Trade Organization (WTO Agreement), para.1 according to which the *Parties* concluded the WTO Agreements “(...) allowing for the optimal use of the world’s resources in accordance with the *objective of sustainable development*, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development (...)” (emphasis added).

operation in the provisions of the treaty and in particular in the process of treaty interpretation and implementation.³⁰

I.3 Fragmentation and Structural Bias of the WTO/TRIPS Regime

This process of weighing and balancing is quite a challenge – even in the purely domestic environment where the national legislator (in principle)³¹ has the authority to address and regulate all interests at stake. On the global level however, integrating and balancing diverging interests faces the challenge of a multitude of regimes, institutions and actors addressing individual bits and pieces of the whole puzzle – in short the ‘*fragmentation*’ of international law. A report of the International Law Commission (ILC) on this issue noted that the absence of a central authority in international relations, paired with the rapid normative development by different and uncoordinated legal regimes can lead to conflicts between rules or rule-systems and deviating institutional practices.³² In a pluralistic environment of specialised rules and rule-systems each focusing on solving specific problems, “answers to legal questions depend on whom you ask, what rule-system is your (sic) focus on”.³³

A brief look at the multitude of regimes, institutions and actors in international IP law provides ample evidence of fragmentation. The traditional domain of the multilateral GATT/WTO trading system is liberalising trade in goods. Since the Uruguay Round, it also includes services and intellectual property protection. International IP regulation however has its own traditional set of treaties, institutions and actors on the international level – most prominently the WIPO framework. However, IP is also addressed, although sometimes from a distinct perspective, in the UNESCO and FAO and more recently CBD and WHO context.³⁴ All these substantive areas, sometimes in combination with other ‘trade related’ issues such as competition policy, environmental and social standards, are increasingly also subject to regional (Mercosur, European Community, NAFTA) or bilateral agreements.³⁵ In the same way, investment protection, often encompassing ‘trade’ areas such as IP and the permanent establishment of service providers, is subject to a comprehensive net of bilateral and regional treaties.³⁶ Looking at the relevant pieces of international law from the environmental, public health, social or human rights perspective, one finds a very similar picture: various international institutions and treaties address overlapping subject matter on the international,

³⁰ For giving effect to sustainable development as a treaty objective in the WTO/TRIPS context see section VI. 1. of this paper.

³¹ In an environment of global trade, capital and investment flows, multilayered governance and increasing administrative interconnectedness between international, regional and national actors has however taken significant portions from the ‘sovereignty’ of the nation state to regulate all relevant public policy interests; compare C Godt, ‘The so called “Waiver Compromise” of Doha and Hong Kong – About contested concepts of the nature of the International Intellectual Property System, in I Govaere & H Ullrich (eds.), *Intellectual Property, Public Policy, and International Trade* (Peter Lang International, Brussels, 2007).

³² *International Law Commission*, Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law (U.N. Doc A/CN.4/L.682), 13 April 2006; on the issue of fragmentation see further M Koskienniemi & P Leino, ‘Fragmentation of International Law?’ 15 *LJIL* (2002) 553-579; G Teubner & A Fischer-Lescano, ‘Regime-Kollisionen: Zur Fragmentierung des Weltrechts’ (Frankfurt 2006) – an English version is available as ‘Regime Collisions: The Vain Search for Legal Unity in the Fragmentation of Global Law’ at <http://www.jura.uni-frankfurt.de/ifawz1/teubner/dokumente/regimecollisions.pdf> (visited 12/11/2007).

³³ *International Law Commission*, as note 32 above, para.483.

³⁴ See for example the Universal Copyright Convention (UCC) administered by the UN Educational Scientific and Cultural Organization (UNESCO); the International Treaty on Plant Genetic Resources for Food and Agriculture, administered by the UN Food and Agriculture Organisation (FAO); the Convention on Biological Diversity as well as the Bonn Guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization (Decision VI/24 of the VI. Conference of the Parties to the CBD); as well as the: World Health Organisation’s (WHO) Global strategy and plan of action on public health, innovation and intellectual property (adopted by the WHO Assembly, WHA 61.21, May 2008).

³⁵ See for example Part.III of the EC – CARIFORUM EPA (as note 9 above) with individual section on competition policy, environmental standards, social aspects and data protection.

³⁶ For a comprehensive database on the existing Bilateral Investment Treaties (BITs) see the UNCTAD website on investment instruments online, available at <http://www.unctadxi.org/templates/DocSearch.aspx?id=779>.

regional and bilateral plane.³⁷ In sum, each rule-system “has its experts and its ethos, its priorities and preferences and its structural bias” – each one is institutionally programmed to prioritise particular concerns over others.³⁸ This structural bias poses a significant challenge for reconciliation and balancing under the concept of sustainable development and its principle of integration.

In facing intersections between economic, social and environmental issues, distinct rules and rule-systems are likely to lead to very different results. Decisive factors can be the norm and/or institution consulted and the perspective from which the conflict is perceived, the legal language by which it is addressed (or marginalised or even neglected) as well as the actors interpreting and applying the norm. All certainly have an impact on the outcome: how, if at all, the ‘other’ interests are taken into account as well as how (if at all) a balance is struck. The question is whether the regime is able and willing to integrate ‘other’ economic, social or environmental concerns outside its core subject matter. One example shall suffice here. Global rules on the protection of IP such as TRIPS focus on the interests of right holders and the scope of their exclusivity; on the other hand, the international health system under the WHO currently examines the role of IP in providing incentives for neglected diseases in developing countries and how IP protection affects access to drugs. International human rights bodies finally, are concerned with the impact IP protection has on the exercise of fundamental rights such as freedom of speech or the right to health; but also deal with the protection of human creations and inventions as a human right. It is not hard to imagine that the difference in focus, the individual structural bias, would lead to different and possibly conflicting results as for example, on the balance between protecting commercial interests to receive a return on an investment and the desire for cheap access to patented medication.

The example above reveals the structural bias of the law of the world trading system in general and TRIPS in particular: the pursuit of economic relations, and the interests of the main actors involved are at the forefront and *raison d’être* for its existence. The dominant discourse is about market liberalisation, investment protection and security and predictability of international trade. As pointed out in the introductory examples, non economic interests are significantly affected by these regulations. Another common denominator is that in the core areas of substantive WTO regulation, the density and comprehensiveness of international obligations owed by individual states has significantly increased during the process of economic globalisation which has directly affected the national autonomy to regulate: not only on the subject matter harmonised by international norms, but also areas where ‘other’ interests *de jure* or *de facto* intersect or interfere with harmonised rules.

In the wake of establishing the WTO, this increased density and comprehensiveness of international obligations has often been described using the metaphor of extending international rules ‘*behind the border*’³⁹ of the nation state, affecting various societal values, interests and lifestyles. Liberalising trade in goods has moved from reducing border tariffs⁴⁰ towards regulating ‘non-tariff barriers’ such as health-, safety- or technical standards as well as remedies against unfair trade.⁴¹

³⁷ For a UN database on Multilateral Environmental Agreements (MEAs) see <http://www.unep.org/dec/links/index.html>; for the various regional and international programmes of the World Health Organisation (WHO) see <http://www.who.int/entity/en/>; the various involvements of the International Labour Organisation (ILO) are listed online at http://www.ilo.org/global/Departments___Offices/lang--en/index.htm; human rights issues finally also interact with various other topics listed above and are addressed by various international and regional bodies (see <http://www.ohchr.org/EN/HRBodies/Pages/HumanRightsBodies.aspx>).

³⁸ *International Law Commission*, as note 32 above, para.488.

³⁹ See generally C Arup, *The New World Trade Organisation Agreements* (Cambridge, 2000), at 5-13: above all, this term has been used to paraphrase key developments in the transformation of the former GATT system mainly concerned with trade in goods towards the creation of the WTO with its comprehensive body of rules. Insofar, TRIPS itself is often perceived as a prominent illustration of this trend to impose obligations in areas which were traditionally regarded in the purview of domestic regulation – also referred to as ‘positive integration’: see B Hoekman & M Kostecki, *The Political Economy of the World Trading System* (Oxford, 2001) at 283 as well as the further discussion on the role of TRIPS in this context below.

⁴⁰ As it has been the ‘classic’ way of trade liberalisation during the first six Rounds of Negotiations under the GATT 1947 – see a detailed history in A Loewenfeld, *International Economic Law* (Oxford 2003), at 46-55; Matsushita, Schoenbaum, Mavroidis, *The World Trade Organization* (Oxford 2003), at 4-5; C Arup, as note 39 above, at 45.

⁴¹ See M Trebilcock & R Howse, *The Regulation of International Trade* (3rd Edn, London 2005), at 24

Areas so far untouched by global trade rules were considered as ‘*trade related*’⁴² – in this way including basically any subject matter, provided it has a potential impact on trade. Besides obvious candidates such as the regulation of services, government procurement- and subsidies, policies have become part of WTO rules.⁴³ Also IP protection, traditionally a special regime of its own which trade lawyers rather perceived as a (tolerated) barrier to trade,⁴⁴ became one, if not the key element of the new global trading system for most industrialised countries.⁴⁵ From their perspective, global IP standards are crucial to ensure markets for their IP protected goods and services abroad and to prevent competition based on imitation and copying in technologically advancing developing countries.⁴⁶ In order to achieve this, TRIPS as the WTO Agreement on *Trade Related Aspects of Intellectual Property Rights* had to overcome the perceived ‘shortcomings’ of international IP protection.⁴⁷ This necessitated a significant curtailment of the freedom to tailor IP protection – in economic terms – to suit the domestic comparative advantage⁴⁸ and further to address non-economic domestic interests and societal values without interference from trade rules. It so led to IP regulation under TRIPS reaching well beyond what had been known so far.⁴⁹ TRIPS therefore fits well into the overall trend to ‘reach behind the border’ in other areas of WTO law.

In sum, the overreaching and dominant notion in the process of economic globalisation has been to perceive the world from a trade perspective. Commentators observed after the birth of the WTO: this tendency is sure to subject many more matters – at the core of economics, politics, cultures and law – to the influence of trade norms and processes.⁵⁰ The origins of TRIPS and its wider context in particular indicate a structural bias towards economic interests and protection of right holders. At the same time, significant intersections to other economic, social (including human rights), environmental and cultural interests exist. The question arises whether TRIPS, embedded in the WTO system, contains mechanisms for integrating these ‘other’ concerns in line with the objective of sustainable development – as recognised in the WTO preamble.

I.4 Elements of Integration within TRIPS

The TRIPS Agreement does recognise and address some of its intersections with social, cultural, environmental, human rights or other societal interests. This section aims to provide a brief overview on the most prominent of these intersections and how TRIPS aims to achieve integration in the form of balance and reconciliation at the *international* level. A more detailed analysis of the tools for

⁴² Compare C Arup, as note 39 above, at 11.

⁴³ M Trebilcock & R Howse, as note 41 above, at 24.

⁴⁴ Due to their territorial nature IP rights allow the title holder to prevent imports of goods containing the protected subject matter (or the provision of services building on it), in this way erect artificial barriers between countries and thereby prevent free trade. Expression of this perception is Art.XX (d) GATT which allows GATT contracting parties to justify inconsistencies with other GATT provisions (and thereby to restrict free trade) if necessary to secure compliance with laws protecting patents, trademarks and copyrights; Compare C Correa, *Trade Related Aspects of Intellectual Property Rights* (Oxford, 2007), at 2-3; H Ullrich, ‘Technology protection According to TRIPS’, in Beier / Schricker, *From GATT to TRIPS – IIC Studies* Vol.18 (New York, 1996), at 376 and P Katzenberger & A Kur, ‘TRIPS and Intellectual Property’, in the same volume, at 5.

⁴⁵ A Kur, ‘A New Framework for Intellectual Property Rights – Horizontal Issues’, 35 IIC (1/2004) 4-7; C Arup, as note 39 above, at 11-13 and especially H Ullrich, as note 38 above, at 357 et seq; see further B Hoekman & M Kosteci, as note 39 above, at 283, C Correa, as note 44 above, at 10.

⁴⁶ For a more detailed discussion on the increased impact of IP protection on domestic autonomy see H Grosse Ruse – Khan, as note 21 above.

⁴⁷ These included the relative autonomy to foresee exceptions to the protected subject matter and limitations to the scope of protection as well as the lack of any system of effective enforcement of existing international IP obligations.

⁴⁸ Compare M Trebilcock & R Howse, as note 41 above, at 400-401: Whenever the *comparative advantage* (see note 32 above) of a WTO Member in a specific industry or field of technology lies more in production based on imitation than innovation, trade and economic theory suggest that such a country should adopt an IP regime which allows (some extent of) imitation.

⁴⁹ See J Watal, *Intellectual Property Rights in the WTO and Developing Countries* (The Hague, 2001) at 1-7; L Bently & B Sherman, *Intellectual Property* (2 Edn, Oxford, 2004), at 5-8.

⁵⁰ C Arup, as note 39 above, at 5.

achieving integration at the *domestic* level is at the core of this paper and follows in sections III to V below.

The most well-known issue concerns the relationship between IP protection under TRIPS and access to (essential) medication. It is sometimes perceived as a potential conflict between the human right to health⁵¹ (and the corresponding state duty to offer or at least facilitate access to medication)⁵² versus patent protection for drugs under TRIPS. The Doha Declaration on TRIPS and Public Health⁵³ as well as the 2003 and 2005 decisions⁵⁴ on a waiver of Art.31 f) TRIPS should be seen as the WTO response to the access to essential drugs issue. Regardless whether the Doha Declaration and the so called ‘paragraph 6 solution’ in the form of the proposed Art.31 *bis* TRIPS and the new Annex to TRIPS fully resolves any potential conflict with the right to health, it does amount to an attempt to explicitly integrate social concerns and reconcile these with the economic interests expressed in patent exclusivity.⁵⁵

Another example is the ongoing attempts to ensure coherence with the Convention on Biological Diversity (CBD)⁵⁶. In the framework of the Doha Development Round of Negotiations relating to outstanding implementation issues as well as the review mandated under Art.27:3 (b) TRIPS, the relationship between the TRIPS Agreement and the CBD has for some time now been subject to a controversial debate in the TRIPS Council. At issue are questions over the role of IP regarding access to- and exploitation of generic resources and related traditional knowledge in the wider context of sustainable use of biological diversity.⁵⁷ The current debate focuses on the introduction of a mandatory requirement for the disclosure of origin of biological resources and/or associated traditional knowledge used in inventions for which IP rights (especially patents) are applied for. In the summer of 2006, a proposal for an amendment of TRIPS by inserting a new Art.29*bis* TRIPS was presented by Brazil, China, Cuba, India, Pakistan, Peru, Thailand and Tanzania.⁵⁸ About two years later, more than two thirds of the WTO Members⁵⁹ support what can be perceived as

⁵¹ The right to health is expressed in Art.25 of the Universal Declaration of Human Rights (UDHR), adopted and proclaimed by the UN General Assembly in resolution 217 A (III) of 10 December 1948 at Paris. It is further incorporated in Art.12 of the International Covenant on Economic Social Cultural Rights (ICESCR) where states recognise the “right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”

⁵² The entitlements of *inter alia* availability, accessibility and affordability of essential medication flowing from the right to health as expressed in the ICESCR are further defined in *Committee on Economic, Social and Cultural Rights (CESCR)*, General Comment No. 14 (2000): The right to the highest attainable standard of health, Geneva, 25 April-12 May 2000. See also A Yamin, ‘Not just a Tragedy: Access to Medications as a Right under International Law’ (2003) 21 *Boston University International Law Journal* Vol.21 (2001) 101-145.

⁵³ *Ministerial Conference*, Doha Declaration on the TRIPS Agreement and Public Health, as note 3 above.

⁵⁴ *General Council*, Decision of 30 August 2003 and Decision of 6 December 2005, both as note 3 above.

⁵⁵ Critics point to the limited workability of the ‘paragraph six solution’ and the burdening, comprehensive requirements for using the system. In over five years existence, the system has only been used once so far (see the request by Rwanda for producing patented medicines under a compulsory license in Canada for export – see http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm (visited 20 October 2008)). For further literature on this issue, see note 3 above.

⁵⁶ United Nations Convention on Biological Diversity, ILM 1992, Vol.XXXI, p.818, available at <http://www.cbd.int/doc/legal/cbd-un-en.pdf> (accessed 15 January 2009).

⁵⁷ Claims over the inconsistency of TRIPS with CBD principles evolve around the fact that TRIPS does not offer IP protection tailored to traditional knowledge recognised under the CBD and facilitates or at least does not prevent ‘bio-piracy’ in form of IP protected exploitation of innovations based on generic resources or related traditional knowledge, see the literature in note 4 above.

⁵⁸ *Brazil, et al* - Communication on a Proposal to Amend TRIPS (WT/GC/W/564), 31 May 2006. The proposed Art.29 *bis* *inter alia* provides: “(1) For the purposes of establishing a *mutually supportive relationship* between this Agreement and the Convention on Biological Diversity, in implementing their obligations, Members shall have regard to the objectives and principles of this Agreement and the objectives of the Convention on Biological Diversity. (2) Where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, *Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge*, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin. *Members shall also require that applicants provide information including evidence of compliance with the applicable legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing* arising from the commercial or other utilization of such resources and/or associated traditional knowledge. (Emphasis added).

⁵⁹ See K Mara, ‘Push Continues For TRIPS Biodiversity Amendment, Geographical Indications Extension’, *Intellectual Property Watch* (30 October 2008) available at <http://www.ip-watch.org/weblog/index.php?p=1294> (visited 5 November

another example for integration of social justice and biological diversity issues into the TRIPS Agreement.⁶⁰

Other more indirect forms of integrative approaches can be seen in the concept of special and differential treatment for developing countries, in TRIPS predominantly implemented in the form of extended transition periods for the implementation of TRIPS or certain sections of it.⁶¹ While these transition periods or their extensions do not directly guarantee or translate into balancing public interests or other concerns with IP protection, they are flexibilities which allow (least) developing countries to adjust to the TRIPS standards and take more time to determine the most appropriate implementation.⁶² This in turn is hoped to secure a national implementation which is mindful of- and able to take into account those interests potentially affected by strong IP protection. In this regard, transition periods can provide a form of policy space that allows for integration and reconciliation of all relevant economic, social and environmental interests.

Finally and in the wider context of international IP regimes, it is worth mentioning that the current WIPO Development Agenda⁶³ has an important role to play in adopting a comprehensive and inclusive approach to IP regulation. All of the six clusters⁶⁴ (encompassing the 45 agreed proposals) contain elements where the principle of integration is crucial for WIPO to:

- identify the role of IP in today's global challenges such as climate change, food security and access to drugs, knowledge and technology;
- provide meaningful technical assistance to developing countries mindful of the other interests affected by IP laws;
- and address its role as an institution that is part of the UN family and able to achieve coherence with the work of other UN bodies on the environment, health or human rights.

2008). In spring 2008, the proposal received further endorsement from e.g. the Group of African States, the Group of Least Developed Countries as well as the ACP Country Group. In the further negotiations aimed to finally conclude the Doha Round, a strategic alliance between the EC, Switzerland and most developing countries on the Doha TRIPS issues emerged: While the EC and Switzerland seem willing to support text based negotiations on disclosure mechanisms in patent applications, most developing countries support the extensions of protection for geographic indications (see the proposed modalities for text based negotiations in *Trade Negotiations Committee*, Draft Modalities for TRIPS Related Issues – Communication from Albania, Brazil, China, Colombia, Ecuador, the European Communities, Iceland, India, Indonesia, the Kyrgyz Republic, Liechtenstein, the Former Yugoslav Republic of Macedonia, Pakistan, Peru, Sri Lanka, Switzerland, Thailand, Turkey, the ACP Group and the African Group, TN/C/W/52 (19 July 2008) available at http://trade.ec.europa.eu/doclib/docs/2008/september/tradoc_140562.pdf.

⁶⁰ S Musungu & M Oliva, 'The TRIPS Agreement at the Crossroads: Intellectual Property and Sustainable Development in the Doha Round', in M.C. Cordonier Segger & M Gehring (eds), *Sustainable Development in World Trade Law*, (The Hague: Kluwer Law International, 2005), 273-297 (at 279-281, 288-291).

⁶¹ See the extension of the transition period for least developed countries from, originally, 1 January 2006 to July 2013 (Decision by the Council for TRIPS of 29 November 2005, IP/C/40). It is noteworthy in that context that the decision also contains a freeze-plus clause according to which it is forbidden to reverse current laws already granting a more favourable status to right holders. Countries will therefore not profit from the extension, if such laws were introduced in the framework of FTAs or in anticipation of the approaching lapse of the transition period. One must bear in mind in this regard that the decision by the Council for TRIPS was taken only about *one month* before the lapse of the transition period. Many countries will therefore already have tried – and possibly succeeded – to implement new, TRIPS-compliant laws, which must remain in force. Earlier on, by decision of 27 June 2002 (IP/C/25), the transition period for least developed countries in regard of the introduction of patent protection for pharmaceutical and agricultural products had already been extended to 2016.

⁶² Art.66:1 TRIPS explicitly recognises “the special needs and requirements of least-developed country Members” and “their need for flexibility” when establishing a basis for transition periods and their extension.

⁶³ On 28 September 2007, the WIPO General Assembly adopted the 45 proposals which the PCDA agreed upon during two key sessions in February and June that year. (See *WIPO General Assembly*, General Report – Forty-Third Series of Meetings, (A/43/16) 12 November 2007, at para.334 and Annex A). Of those proposals, 19 had been selected for immediate implementation (*Ibid*, Annex B). It further approved the establishment of a Committee on Development and Intellectual Property (CDIP) which had the tasks to develop a work-program for implementation of the adopted recommendations and to monitor, assess, discuss and report on the implementation process.

⁶⁴ The six clusters concern: (A) Technical assistance and capacity building; (B) Norm-setting, flexibilities, public policy and public domain; (C) Technology transfer, information and communication technologies (ICT) and access to knowledge; (D) Assessment, Evaluation and Impact Studies; (E) Institutional matters including mandate and governance; (F) other issues.

In particular proposals 22,⁶⁵ 24,⁶⁶ 35,⁶⁷ 37,⁶⁸ 40,⁶⁹ and 45⁷⁰ provide evidence of an integrated approach which aims to balance IP protection with other economic, social and environmental issues and aligns WIPO's work with that of other institutions in these areas.⁷¹ International IP regulation would lose much of its described structural bias if these proposals for actions are effectively implemented.

For the time being however, one must conclude that TRIPS in particular contains only few provisions that actively integrate 'other' interests on the international level. TRIPS nevertheless does contain other provisions which take a more passive role and *allow a balance of interests on the domestic level*. The most prominent ones will be introduced below.

I.5 Domestic Policy Space to Integrate

In the absence of an explicit competence and any comprehensive positive regulation on public interests in the WTO legal system, sufficient deference to domestic public policy measures is decisive. Especially where individual TRIPS provisions fail to achieve an effective integration of social, environmental concerns on the international level, also the concept of sustainable development demands a balance of interests at the national level.⁷² Even if one does not agree that this principle has developed into customary international law,⁷³ its objective in the WTO preamble appears to be sustainable development.⁷⁴ In the words of the WTO Appellate Body, "it must add colour, texture and shading to our interpretation of the Agreements annexed to the WTO Agreement".⁷⁵ This includes TRIPS. Integrating and balancing the economic interests expressed in TRIPS provisions with social and environmental concerns therefore must be performed in the process of (TRIPS) interpretation. This is not only relevant for the dispute settlement organs of the WTO – it primarily is a call for WTO

⁶⁵ Proposal 22 states that "WIPO's norm-setting activities should be supportive of the development goals agreed within the UN system, including those contained in the Millennium Declaration."

⁶⁶ Proposal 24 demands: "To request WIPO, within its mandate, to expand the scope of its activities aimed at bridging the digital divide, in accordance with the outcomes of the World Summit on the Information Society (WSIS) also taking into account the significance of the Digital Solidarity Fund (DSF)."

⁶⁷ Calling "WIPO to undertake, upon request of Member States, new studies to assess the economic, social and cultural impact of the use of intellectual property systems in these States".

⁶⁸ Stating that "Upon request and as directed by Member States, WIPO may conduct studies on the protection of intellectual property, to identify the possible links and impacts between IP and development." See also proposal 38 on integrated impact assessments.

⁶⁹ Proposal 40 requests "WIPO to intensify its cooperation on IP related issues with UN agencies, according to Member States' orientation, in particular UNCTAD, UNEP, WHO, UNIDO, UNESCO and other relevant international organizations, especially WTO in order to strengthen the coordination for maximum efficiency in undertaking development programs."

⁷⁰ Requiring WIPO "to approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns, with a view that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations", in accordance with Article 7 of the TRIPS Agreement."

⁷¹ See also proposals 15, 16, 19, 20 relating to the preservation of the public domain and access to knowledge in the norm-setting processes of WIPO.

⁷² See Ch.8 of Agenda 21 (Environment and Development Agenda), a Plan for Action on the Implementation for the achievement of sustainable development worldwide – agreed at the 1992 Rio Earth Summit (as note 23 above) – available online at <http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=52> (accessed 14 January 2009).; para.7.2-7.3 of the ILA Declaration (as note 26 above); further S Jodoin, 'The Principle of Integration and Interrelationship in Relation to Human Rights and Social, Economic and Environmental Objectives', *CISDL Legal Working Papers* (Montreal, 2005), at 4 – available at http://www.cisd.org/pdf/sdl/SDL_Integration.pdf (accessed 20 January 2009).

⁷³ For the debate on the formal legal status see A Marong, 'From Rio to Johannesburg: Reflections on the Role of International Legal Norms in Sustainable Development', *Georgetown Int'l Envtl. Law Review* Vol.16 (2003-2004), 21-76, at 45-64.

⁷⁴ According to the Appellate Body, the WTO treaties' objective of sustainable development calls for "integrating economic and social development and environmental protection" (*US – Shrimp*, as note 13 above, at para.129 (fn.107)). For a detailed discussion of the Appellate Body's reliance on the concept of sustainable development in *US – Shrimp* and other cases on trade and environment, see *G Marceau, A Call for Coherence in International Law*, *JWT* Vol.33 No.5 (1999), 87-152.

⁷⁵ *US – Shrimp*, as note 13 above, at para.152.

Members to *implement* TRIPS provisions in a manner which balances IP protection with the affected societal interests and policies.

Art.7 TRIPS underlines this with its own appeal for a balance: a balance between the promotion innovation and the transfer and dissemination of technology; between producers and users of technological knowledge; as well as rights and obligations – with the overall aim of social and economic welfare.⁷⁶ By virtue of Art.31 of the Vienna Convention on the Law of Treaties (VCLT)⁷⁷, those treaty objectives expressed in Art.7 as well as the WTO Preamble are one of three main elements for the interpretation of treaties. Besides ordinary meaning and context, Art.31:1 VCLT requires an interpretation in light of the object and purpose of the treaty.⁷⁸ Paragraphs 4 and 5 a) of the Doha Declaration have highlighted an interpretation of all TRIPS provisions in light of, *inter alia*, its objectives under Art.7 as a decisive flexibility which WTO Members are encouraged to use.⁷⁹

It follows that an interpretation of all TRIPS provisions must give due regard to the principle of integration and the notion of balance – as embodied in the WTO Preamble and Art.7 TRIPS. In the Doha Declaration all WTO Members consented that putting such an ‘integrative interpretation’ into practice is a crucial flexibility provided under TRIPS. Any implementation of TRIPS therefore allows and should be based on integrating economic, social and environmental aspects affected by IP protection. The ability and discretion to do this under the provisions of TRIPS then is a central factor defining the scope of an international obligation to comply with WTO rules. The analysis made in this paper therefore aims to explore the respective scope of international obligations in WTO law. Especially for the WTO/TRIPS regime, how much room for public interests exists at the national level? To be more specific: is the balance Art.7 TRIPS calls for already inherent and fully exhausted in the individual TRIPS provisions or are they sufficiently flexible to allow WTO Member States to find their own balance between IP rights and the public interests mentioned in Art.7 and 8?

Given the basic structure and methodology of regimes for the protection of IP,⁸⁰ the first and foremost area where national implementation is likely to integrate ‘other’ interests would be exceptions and limitations to IP protection.⁸¹ National laws often foresee exceptions for private, research, educational or other privileged uses of IP protected material or limit IP rights to the benefit of certain user groups (disabled people, students) or institutions (libraries, the press, the judiciary).⁸² In principle, states could utilise the concept of exceptions, including compulsory licenses to also address

⁷⁶ Art.7 states: “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” As further discussed below, this provision – along with the principles contained in Art.8:1 – arguably present the most important elements for an integrative approach. Distinct to examples such as Art.31 *bis* or the proposed Art.29 *bis*, Art.7 and 8 TRIPS do not exclusively operate on the international level. Their most important contribution to a balance of interest lies instead in widening the policy space for an integrative implementation of TRIPS at the *domestic* level.

⁷⁷ Vienna Convention on the Law of Treaties (VCLT) done at Vienna on 23 May 1969 (United Nations, Treaty Series, vol. 1155, 331).

⁷⁸ Art.31:1 VCLT provides: “A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.” For a detailed analysis on the balancing role of Art.7 in the process of TRIPS interpretation and implementation see H Grosse Ruse – Khan, as note 21 above.

⁷⁹ In para.5 a) of the Doha Declaration (as note 3 above) WTO Members recognise as one of the main flexibilities under TRIPS: “In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.” In para.4 they “reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for” social (in that case public health) purposes.

⁸⁰ IP protection is commonly structured in the following way: 1) subject matter of protection; 2) right holders; 3) rights granted / scope of protection; 4) transferability, licensing; 5) exceptions and limitations to protection; 6) duration of protection; and 7) enforcement – compare for example Part II and III of TRIPS.

⁸¹ Compare A Kur; ‘Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?’ in M Levin, A Kur (eds) *Intellectual Property in Transition*, forthcoming 2009 – available at <http://ssrn.com/abstract=1317707> (accessed 29 January 2009). Otherwise a country might choose to limit the scope of protectable subject matter (compare Art.9:2 which limits copyright protection to the expression of an idea and Art.27:2, 3 TRIPS which covers certain areas where Members may reject the patentability of certain inventions).

⁸² See in general S Ricketson, ‘WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment’ (SCCR/9/7), (Geneva, 2003).

other intersections of IP protection with areas such as the environment, climate change or food security. The crucial question then is whether the TRIPS provisions regulating exceptions to IP protection in national laws do allow sufficient policy space to integrate these concerns on the domestic level.

In the following sections, this paper therefore examines the flexibility of those TRIPS provisions to accommodate an integrative approach. It focuses on Art.8:1 TRIPS which is the only horizontal provision addressing “measures necessary to protect *public health and nutrition*, and to promote the *public interest in sectors of vital importance to their socio-economic and technological development*”.⁸³ In its structure and substance, Art.8:1 resembles the concept of a general exception which can be found in the two other core areas of WTO regulation, the trade in goods and services.⁸⁴ These provisions have so far frequently served to balance trade interests with other societal concerns⁸⁵ and are often described as a tool to implement integrative approaches under the concept of sustainable development.⁸⁶ The Appellate Body further relied on that concept and its incorporation in the WTO Preamble to justify a broad interpretation of the general exception under GATT.⁸⁷ The key question is whether Art.8:1 TRIPS – given the common overarching objective of sustainable development in the WTO Preamble – can perform an equivalent function. Section III. 1. below therefore examines the scope of policy space under Art.8:1 TRIPS. In Section IV this is compared with the notion of general exceptions under GATT and GATS and the relevant jurisprudence of the WTO Appellate Body on the right of WTO Members to balance trade obligation with societal concerns under these provisions.

Beyond the horizontal approach in Art.8:1 TRIPS, several provisions in TRIPS regulate and limit the right of WTO Members to impose exceptions and limitations on the protection of individual IP rights such as copyright, trademarks or patents. In this regard, Art.13, 17, 26:2 and 30 TRIPS take an approach which originates from Art.9:2 of the Berne Convention on the Protection of Literary and Artistic Works⁸⁸ and is commonly referred to as ‘three step test’.⁸⁹ The scope of flexibility to integrate and give effect to other societal interests under these provisions will be assessed further in section III. 2. Section V. then compares IP protection with trade in goods and services and contrasts the policy space under the respective regimes. Given that there is no convincing argument for having less policy space within TRIPS, alternatives to a general exception suggested in section VI should be employed to secure equivalent flexibility to integrate other societal interests. If taken seriously, in particular the WTO- and TRIPS objectives can play a decisive role in an integrative and balanced implementation of TRIPS. Backed further by the Doha Declaration, one can justify an equivalent amount of domestic policy space in all three areas of WTO law.

⁸³ Art.8:1 TRIPS, emphasis added.

⁸⁴ See Art.XX GATT and Art.XIV GATS and the comparative analysis on policy space under these norms in section IV, V below.

⁸⁵ See the WTO Appellate Body decisions in *US – Gasoline*, as note 21 above, at 16; *US – Shrimp*, as note 13 above, at para.121; compare also P Van der Bossche, as note 2 above, at 600; compare also C Godt, as note 31 above, at 251-252, and C Gerstetter, as note 21 above, at 120-124. For a further discussion see section IV below.

⁸⁶ M.C. Cordonier Segger, ‘Integrating Social and Economic Development and Environmental Protection in World Trade Law’, in M.C. Cordonier Segger & M Gehring (eds), *Sustainable Development in World Trade Law*, (The Hague: Kluwer Law International, 2005), at 152, 168.

⁸⁷ See *US – Shrimp*, as note 13 above, at para.152 and the further analysis in section VI 1. below.

⁸⁸ Revised Berne Convention on the Protection of Literary and Artistic Works (of 9 September 1886, completed at Paris May 4, 1896, last revised at Paris July 24, 1971, amended in 1979, WIPO Publication No.287 (E), WIPO 1992.

⁸⁹ Art.9 (2) addresses the general conditions for national copyright exceptions on the right to reproduction. It provides: It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in *certain special cases*, provided that such reproduction *does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author*. (Emphasis added).

II. TRIPS FLEXIBILITIES FOR IMPLEMENTING PUBLIC INTEREST MEASURES

This section examines the scope of policy space available under the TRIPS Agreement to integrate and give effect to public interests as they ‘intersect’ with IP protection. Any detailed analysis on this topic would most likely have to take the form of a commentary on the TRIPS Agreement and in any case go well beyond the scope of this paper. Nevertheless, with its Art.8:1, TRIPS contains one horizontal provision addressing wider societal concerns such as public health and nutrition; and public interest in sectors of vital importance to socio-economic and technological development in general. As section IV will show, the approach of Art.8:1 partly resembles the notion of general exceptions under GATT and GATS as well as the language used therein. At the same time, there are crucial differences which may prevent Art.8:1 from playing a relevant role. The other main provisions under TRIPS which further set out the policy space the agreement provides are those describing a right to foresee exceptions to specific IP rights addressed in TRIPS (Art.17, 26:2, 30 and further Art.31). Here the paper takes a birds-eye view and builds on other research findings⁹⁰ which have addressed this issue extensively.

II.1 Art.8:1 TRIPS – A General Exception to Override IP Protection?

Entitled ‘Principles’, Art.8:1 TRIPS is the only horizontal provision within TRIPS which addresses public interests affected by IP protection and their relation to interests and rights protected under individual TRIPS rules. In its final version, as embodied in the TRIPS Agreement, this provision reads:

Art.8 (Principles)

(1) *Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.*⁹¹

While an initial, brief look at Art.8:1 may leave the reader with the impression of a defence which could override TRIPS obligations, its language includes a clause which requires all measures adopted under Art.8:1 to be *consistent with all other TRIPS provisions*. The next section tracks the history of this provision.

a) The Negotiating History of Art.8:1 TRIPS

The idea to apply the concept of a general public policy exception to IP protection first appears in the form of treaty language⁹² in the original proposal by several developing countries on trade related

⁹⁰ See in particular the analysis on exceptions to exclusive rights under the different versions of the three step test by A Kur; as note 81 above.

⁹¹ Art.8:1 TRIPS (emphasis added).

⁹² An earlier submission of India already referred to the “primacy of public interest” under which “a state has the inherent right to take measures in public interest abridging the rights of holders of intellectual property rights”. Such measures may “in pursuance of vital concerns as security, public health, nutrition, agricultural development, poverty alleviation and the like”, see *Uruguay Round of Multilateral Trade Negotiations – Communication from India, Applicability of the Basic Principles of the GATT and of Relevant International Intellectual Property Conventions (MTN.GNG/NG11/W/39)*, 5 September 1989. For a discussion on related submissions (again from India) which discuss the need to balance IP and public interests see *ICTSD / UNCTAD, Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement* (Geneva, 2005), Part One, Chapter 6, section 2 – available at www.iprsonline.org/unctadictsd/ResourceBookIndex.htm.

aspects of IP within the GATT system.⁹³ Yusuf A. notes that the main intention was to preserve sufficient flexibility for regulating potentially conflicting public interests.⁹⁴ In Section (2) of Art.2 on ‘Principles’ this text provided that:

In formulating or amending their national laws and regulations on IPRs, *Parties have the right to adopt appropriate measures to protect public morality, national security, public health and nutrition, or to promote public interest* in sectors of vital importance to their socio-economic and technological development.⁹⁵

This text reappeared unchanged in the first official version of the ‘Chairman’s Draft’⁹⁶ (or ‘Compositive Draft Text’) prepared by the chairman, Lars Anell of the Negotiating Group on Trade-Related Aspects of Intellectual Property Rights in the summer of 1990 in order to identify conflicts and overlaps in main proposals made so far.⁹⁷

In the negotiations that followed, the delegations – with the active involvement of the chairman - tried to eliminate their differences in short, informal sessions with the main actors and reported back to the larger group of delegations involved. A commentator has since pointed out how time pressure to report results to higher authorities such as the Trade Negotiations Committee (TNC) lead to speeded progress and “frantic work” during the last few weeks before a Ministerial Meeting was scheduled in Brussels in December 1990.⁹⁸ It may have been this time pressure, coupled with the need to compromise, which led developing country delegations to accept the essential weakening of ‘their’ language on the right to implement public interest policies. While the so called ‘Brussels Draft’⁹⁹ which was submitted by the negotiating group on TRIPS retained most of the language from the initial developing countries’ proposal, it was subjected to a very decisive further condition. Art.8:1 now states:

*Provided that PARTIES do not derogate from the obligations arising under this agreement, they may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development.*¹⁰⁰

The Brussels Draft therefore represents the birth of the TRIPS consistency test in Art.8:1. In the further negotiations, this issue did not seem to play any major role.¹⁰¹ Even though its wording¹⁰² and

⁹³ See *Communication from Argentina, Brazil, Chile, China, Colombia Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay*, Applicability of the Basic Principles of the GATT and of Relevant International Intellectual Property Conventions (MTN.GNG/NG11/W/71), 14 May 1990. The text therein was later endorsed by two other developing countries, Pakistan and Zimbabwe. It became known as the “developing countries’ proposal” (see D Gervais, *The TRIPS Agreement – Drafting History and Analysis* (2nd Edn, London, 2003), at 1.18).

⁹⁴ A Yusuf, ‘TRIPS: Background, Principles and General Provisions’, in C Correa and A Yusuf (Eds), *Intellectual Property and International Trade* (Kluwer Law International: London, 1998), (3-20) at 12-13.

⁹⁵ *Communication from Argentina, Brazil, Chile, China, Colombia Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay*, as note 93 above, Art.2 (2) (emphasis added).

⁹⁶ *Chairman’s Report to the Group of Negotiation on Goods*, Status of Work in the Negotiating Group, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/W/76, 23 July 1990, Article 8 (Principles), section B.2 (the B indicating that the text originates from and represents the interests of developing countries – as opposed to A which indicated proposals from industrialised countries).

⁹⁷ The draft was first circulated on 12 June 1990 under the chair’s sole responsibility; its official version (see note 108 above) then appeared in July 1990. On this and the overall TRIPS negotiating history and the pivotal role of this draft see D Gervais, as note 93 above, at 1.20-1.30.

⁹⁸ *Ibid.*, at 1.25.

⁹⁹ *Trade Negotiations Committee*, Draft of final act embodying the results of the Uruguay Round of Multilateral Trade Negotiations (MTN.TNC/W/35/REV.1), 3 December 1990.

¹⁰⁰ *Trade Negotiations Committee*, as note 99 above, Agreement on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Art.8:1 (Principles); at page 200 (emphasis added).

¹⁰¹ See D Gervais, as note 93 above, at 1.27-1.32.

position¹⁰³ within Art.8:1 still differs slightly from the final version, its substance has remained from hereon unchanged.¹⁰⁴ The table below demonstrates the key similarities and differences between Art.8B.2 in the early W/76 ‘Chairman’s Draft’¹⁰⁵ – juxtaposed against the final version of Art.8:1 in TRIPS.¹⁰⁶

Art.8B (W/76 Draft)	Art.8 TRIPS
<p>Principles (2) <u>In formulating or amending their national laws and regulations on IPRs, PARTIES have the right to adopt appropriate measures to protect public morality, national security, public health and nutrition, or</u> <u>to promote public interest in sectors of vital importance to their socio-economic and technological development</u></p>	<p>Principles (1) <u>Members may, in formulating or amending their laws and regulations, adopt measures</u> <u>necessary to protect public health and nutrition, and</u> <u>to promote the public interest in sectors of vital importance to their socio-economic and technological development,</u> <i>provided that such measures are consistent with the provisions of this Agreement.</i></p>

b) Diverging Views on Scope and Application of Art.8:1 in Light of the TRIPS Consistency Test

The final version of Art.8:1 TRIPS addresses a rather broad range of measures which potentially fall under its scope: WTO Members may not only adopt measures “necessary to protect public health and nutrition”. In very general terms, the areas of policy goals pursued by the national measures are extended to cover anything which can “promote the public interest in sectors of vital importance to their socio-economic and technological development”. This places substantial discretion in the hands of WTO Members. What promotes the public interest and what is of vital importance will vary depending on regional, national or even local circumstances.¹⁰⁷ The reference points of socio-economic or alternatively technological development thus do not impose any real restriction on the type of policies and aims WTO Members may pursue under Art.8:1.

The broad range of measures therefore covered under Art.8:1 are then qualified in two aspects. First, measures must be “necessary” to achieve the desired policy objective.¹⁰⁸ Applying the more recent jurisprudence of the Appellate Body, measures are necessary when they represent the least (IP) restrictive, reasonably available measure which is equally effective to achieve the desired policy objective.¹⁰⁹ As section IV will show, the scope for domestic policy space is significant.¹¹⁰ Furthermore, WTO Members’ wide discretion to define their policy goals under Art.8:1 TRIPS also enlarges the discretion as to which measures “necessary” to achieve them. Determining the policy

¹⁰² The Brussels Draft states “Provided that PARTIES *do not derogate from the obligations arising under this agreement*” instead of “provided that such measures *are consistent with the provisions of this Agreement*” used in all later versions as well as the final text of TRIPS.

¹⁰³ In the Brussels Draft it is the opening phrase of Art.8:1 (which might give it somewhat more weight or emphasis and resembles the chapeau of Art.XX GATT), whereas in the latter versions as well as the final text it appears as a qualification of the ‘right’ to adopt measures at the end of Art.8:1.

¹⁰⁴ Both the so called ‘Dunkel Draft’ of 20 December 1991 (MTN.TNC/W/FA) as well as the Final Act embodying the results of the Uruguay Round of Multilateral Trade Negotiations, Marrakech, 15 April 1994 (i.e. the current version of TRIPS) retains the TRIPS consistency test.

¹⁰⁵ *Chairman’s Report to the Group of Negotiation on Goods*, as note 96 above.

¹⁰⁶ The underlined text marks key similarities, whereas the *cursive text* indicates the main differences.

¹⁰⁷ Compare C Correa, as note 44 above, at 105-107; *ICTSD/UNCTAD*, as note 92 above, Part I, Chapter 6, section 3.

¹⁰⁸ This applies not only to the protection of public health or nutrition; but equally to the promotion of other vital public interests addressed in Art.8:1. The wording of Art.8:1 would support such an understanding where all the elements applicable to both set of measures are named once. See also A Yusuf, as note 94 above, at 13.

¹⁰⁹ For details see section IV 2) below.

¹¹⁰ Given the more recent decisions of the Appellate Body, the fear of transporting a narrow understanding of necessity (see C Correa, as note 44 above, at 107) into TRIPS seems unwarranted.

objective (e.g. easy and cheap access to medication) and setting a specific threshold to which it should be achieved (e.g. a percentage of the population which should be provided with essential drugs at an affordable rate) certainly has great impact on whether implementing measures (e.g. price controls, compulsory licenses) are necessary; i.e. whether less (IP-) restrictive alternative measures are equally effective and reasonably available.¹¹¹ In sum, the necessity test in Art.8:1 TRIPS leaves sufficient policy space and discretion to effectively pursue public interests outside IP rights on the domestic level.

Secondly, any measure which a WTO Member wishes to enact in pursuit of its vital public interests must be *consistent with the provisions of TRIPS*. On its face, Art.8:1 therefore does not allow any measures which would conflict with other obligations in TRIPS. One then wonders what the scope of application and rationale of this provision is. Several commentators have grappled with the TRIPS consistency requirement and offered ways to give it (and thereby Art.8:1) a proper meaning. It would go beyond the scope of this paper to discuss all these proposals in detail, so this section looks at a selection indicative of the range of options discussed. For some, Art.8:1 is “essentially a policy statement” that explains the rationale for measures taken under the specific exceptions and limitations foreseen in, *inter alia*, Art.30, 31 and 40.¹¹² In light of the consistency test, it “would be difficult to justify an exception not foreseen under the Agreement”.¹¹³ One might however ask whether such an understanding really gives any effect to Art.8:1 TRIPS. This could be achieved only if the specific exceptions and limitations to IP rights recognised under TRIPS are interpreted and implemented in light of the broad language supporting domestic public interests policies in Art.8:1 TRIPS.¹¹⁴

The *ICTSD / UNCTAD Resource Book on TRIPS* takes a similar starting point when it explains the role of Art.8 TRIPS “as a statement of TRIPS’ interpretative principle”.¹¹⁵ WTO Members are argued to have discretion to adopt internal measures which fall under the privileged policy objectives addressed in Art.8. Although not made explicit, this reasoning hints towards an interpretation and implementation of TRIPS which gives WTO Members some leeway to balance IP rights with public interests and thereby indirectly affects the scope of obligations under TRIPS in general.¹¹⁶ In an attempt to give effect both to the TRIPS consistency test as well as the right to adopt public interest measures, the authors advocate a presumption of TRIPS-consistency for any measures falling under Art.8:1. Challengers should bear the burden of establishing that the discretion built into Art.8:1 has been abused.¹¹⁷

This amounts to reversing the burden of proof whenever the consistency of domestic measures with a specific limitation and exception such as Art.13, 17, 26:2, 27:3, 30, 31 or 40 TRIPS is at stake. National measures, even if in conflict with an obligation to protect IP rights, would be presumed to be consistent with a specific exception in TRIPS and it would be for the complainant to show that the conditions e.g. of the three step test in Art.13 relating to copyright are not met.¹¹⁸ However operating

¹¹¹ C Correa (as note 44 above, at 107) comes to a similar conclusion when he points to WTO Members’ “significant room to define domestically the content and scope of the measures they can adopt.

¹¹² D Gervais, as note 93 above, at 2.84. M Blakeney understands Art.8 in the same way when he points specific exceptions (such as Art.27:3 TRIPS on patentable subject matter) which ‘implement’ the right to adopt health-related measures in consistency with other TRIPS provisions; see M Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement*, (Sweet & Maxwell: London, 1996), at 3.09

¹¹³ D Gervais, as note 93 above, at 2.84.

¹¹⁴ Section VI 1. comes back to this interpretative role.

¹¹⁵ *ICTSD / UNCTAD*, as note 92 above, Part I chapter 6 section 3.2.

¹¹⁶ On this linkage between objective-based treaty interpretation and the scope of international obligations see also section I above and IV below. On the matter of implementation policy space for balancing different interests based on the TRIPS objectives see H Grosse Ruse – Khan, as note 20 above, at 175-176.

¹¹⁷ *ICTSD / UNCTAD*, as note 92 above, Part I chapter 6 section 3.2.

¹¹⁸ Simply assuming a consistency with TRIPS obligations in general would not really add anything to the burden of proof status quo under which the complainant needs to establish the facts which indicate that the defendant has violated a TRIPS obligation. A real meaning becomes this presumption only if applied to consistency of national measures with a specific exception that allows deviating from specific TRIPS obligations.

this concept in practice might be difficult¹¹⁹ and WTO jurisprudence on TRIPS so far has not taken this approach.¹²⁰

Yet another understanding of Art.8:1 and the consistency requirement leans on the original idea for a public interest exception forwarded by developing countries in the Uruguay Round,¹²¹ and views Art.8:1 as *qualifying the scope of harmonisation required by TRIPS*. Despite its limitation via the consistency test, “the public interest principle offers a considerable degree of legislative flexibility to member states”.¹²² From this follows a narrow interpretation of the consistency test requiring only consistency with “the provisions of the agreement *as a whole*, including its preamble, objectives and principles.”¹²³ This approach in effect allows offsetting some inconsistency with specific obligations (such as copyright exceptions beyond the three step test requirements in Art.13) with, for example, adherence to the balancing objectives of Art.7 TRIPS. While it might be a desirable result in some instances, it does not correspond with the wording and ordinary meaning of the consistency test which refers to “the *provisions*” (plural) of TRIPS. Furthermore, judging overall or general TRIPS consistency appears a rather unclear and ambiguous test to operate.¹²⁴

Finally, Art.8:1 is also understood as a right to override individual TRIPS provisions where “the ‘consistency’ requirement may not be deemed to outlaw any governmental action necessary to protect the interests mentioned in Art.8:1” – even “if such action required the adoption of TRIPS-inconsistent measures”.¹²⁵ This is justified by a comparison to other areas of WTO law which foresee a general safeguard clause to give, if necessary, preference to public interest concerns over obligations on trade in goods and services.¹²⁶ Therefore, the TRIPS consistency requirement *should not* remove this basic balance in case of WTO IP regulation. While this certainly is a valid normative claim, it cannot argue away the existence of the consistency test and the general need to give effect to the meaning of the all the terms of a treaty.¹²⁷ It may just be the case that the political reality of negotiation tactics, reciprocal concessions and pressure by the key stakeholders in the Uruguay Round has led to a not justifiable (and thus ‘unjust’) discriminatory treatment of public interests in TRIPS as opposed to the other key areas of WTO regulation. This would call for amending TRIPS, but does as such not allow modifying the rights and obligations set out in the WTO agreements.¹²⁸

Before reaching this or similar conclusions, one must however exhaust all available ‘remedies’ and tools of treaty interpretation – in this case focussed on identifying the most appropriate meaning of

¹¹⁹ In order to trigger the reversed burden of proof, the defendant WTO Member would still have to show that its measure fall under Art.8:1 – i.e. is necessary to protect public health, nutrition or to promote vital public interests. Whether this in the end would provide any real benefits to the defendant may be doubted; in particular if the claimant can present facts indicating that specific TRIPS exceptions are not complied with.

¹²⁰ See in particular the Panel decision in *Canada – Patent Protection of Pharmaceutical Products (Canada – Patents)* WT/DS114/R, Panel Report (17 March 2000) where the Panel discussed the role of Art.8 (and Art.7) in relation to Art.30 TRIPS; on this issue compare A Kur as note 81 above; H Grosse Ruse – Khan, as note 21 above, at 187 – 191.

¹²¹ On the history of Art.8:1 see section a) above.

¹²² A Yusuf, as note 94 above, at 13. This approach resembles to some extent the one expressed in the *ICTSD / UNCTAD Resource Book* (see note 92 above) as both affect the scope of TRIPS obligations and the discretion or policy space left to WTO Members in their implementation.

¹²³ *Ibid* (emphasis added).

¹²⁴ How much and/or how many specific inconsistencies may be offset? Is there a quantitative and/or a qualitative measurement? And who decides – with what amount of discretion? Given all these ambiguities, it is unlikely that this test would actually achieve its purpose of providing a safe haven for enacting public interest measures.

¹²⁵ C Correa, as note 44 above, at 108.

¹²⁶ *Ibid*: “If that were the case, IPRs would assume an overriding preponderance in national policies, far beyond what is actually possible under GATT, which allows for the derogation of Members’ obligation.”

¹²⁷ See *US – Gasoline*, as note 21 above, at 21: “(...) interpretation must give effect to all the terms of the treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility.” This follows from the principle of effectiveness in treaty interpretation (as embodied in good faith element in Art.31 of the Vienna Convention on the Law of Treaties; compare *Yearbook of the International Law Commission*, The International Law Commission’s Commentary on Art. 27 to 29 of its Final Draft Articles on the Law of Treaties, Vol. II (1966), 219).

¹²⁸ See Art.3.2 DSU which limits the role of treaty interpretation (by WTO adjudicative bodies) “to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law” while it “cannot add to or diminish the rights and obligations provided in the covered agreements.”

the TRIPS consistency test. While several of the interpretations above do contain important elements for developing this understanding, the next section takes an approach which aligns with that adopted in WTO Dispute Settlement. By following “the customary rules of interpretation of public international law” which Art.3.2 of the WTO Dispute Settlement Understanding (DSU) calls on to guide WTO treaty interpretation, a pragmatic and realistic understanding of Art.8:1 TRIPS can be achieved.

c) Assessing Policy Space under Art.8 - Guidance from the Rules of Treaty Interpretation and the Doha Declaration

WTO judicial bodies and various scholars agree that the reference in Art.3.2 DSU to “the customary rules of interpretation of public international law” mainly calls for application of the Vienna Convention on the Law of Treaties¹²⁹ (VCLT).¹³⁰ The provisions of WTO Agreements, including TRIPS, thus are to be clarified by relying foremost on the Art.31 and 32 VCLT.¹³¹ Starting point for the interpretative exercise on the consistency requirement in Art.8:1 TRIPS is the ordinary meaning of the relevant treaty terms in their context.¹³² The relevant wording of Art.8:1 is “provided that such measures are *consistent with* the provisions of this agreement”. In its dictionary meaning, consistent is understood as 1) conforming to a regular pattern; unchanging; and 2) in agreement (when used as ‘consistent with’).¹³³ Measures taken under Art.8:1 need to conform, to be in agreement with the provisions of TRIPS. The ordinary meaning does not allow for a breach of individual obligations under TRIPS.

Secondly, the context of the consistency requirement must be examined. This includes not only the whole text of TRIPS and its Annexes; but also the agreement of all WTO Members expressed in the Doha Declaration on the TRIPS Agreement and Public Health.¹³⁴ In paragraph 4 Members declare:

“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. In this connection, we

¹²⁹ Vienna Convention on the Law of Treaties (VCLT), as note 77 above.

¹³⁰ M Lennard, ‘Navigating by the Stars: Interpreting WTO Agreements’, *JIEL* Vol.5 No.1 (2002), 17-89 (18). In the WTO context, Art.3.2 DSU requires the dispute settlement organs to clarify WTO treaty provisions accordingly; see *US – Gasoline*, (as note 21 above), at 16; *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, (India – Patents)* WT/DS50/AB/R, Appellate Body Report (19 December 1997), at para.46; *United States – Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany* (WT/DS213/AB/R) Appellate Body Report (28 November 2002), paras 61-62.

¹³¹ See *India – Patents*, as note 130 above, at para. 46. Due to the numerous references to the VCLT in WTO jurisprudence the latter has been called the ‘gospel for interpretation’; see A Qureshi, *Interpreting WTO Agreements* (Cambridge: CUP, 2006), at 3. Art.31 VCLT incorporates the general rule of treaty interpretation whereas Article 32 addresses supplementary means of interpretation and Article 33 deals with treaties drafted in different languages. According to Art.31 (1), “a treaty shall be interpreted in *good faith* in accordance with the *ordinary meaning* to be given to the terms of the treaty in their *context* and in the light of its *object and purpose*”. Section two then defines what constitutes context and section three mainly lists those subsequent agreements and practice that are as relevant as the agreements and instruments under section two. According to the drafters of the Vienna Convention, all elements mentioned in Article 31 must be read as one general rule of interpretation with no legal hierarchy of norms among the elements in section one and those in the further sections. See *Yearbook of the International Law Commission*, as note 127 above, at 220.

¹³² See I Sinclair, ‘The Vienna Convention on the Law of Treaties’ (2nd Edn, Manchester, 1984), at 121; *Yearbook of the International Law Commission*, as note 143 above, at 220.

¹³³ *Compact Oxford English Dictionary of Current English*, available at http://www.askoxford.com/dictionaries/compact_oed/?view=uk (accessed August 2008).

¹³⁴ The Doha Declaration constitutes relevant interpretative context as an agreement under Art.31 (3) (a) VCLT; Confirmed by F Abbot, as note 3 above, at 491-492; *ICTSD / UNCTAD*, as note 92 above, Part One, Chapter 6 (6.2.1) H Grosse Ruse – Khan, as note 21 above at 184; See also See S Charnovitz, ‘The Legal Status of the Doha Declarations’, 5 *JIEL* (2/2002), 211.

reaffirm the *right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.*¹³⁵

The first sentence of para.4 could be understood as a broad mandate for WTO Members to adopt public health related measures – irrespective of their obligations to protect IP under TRIPS. Members seem to agree that TRIPS does not and should not stand in their way to take “whatever step they consider appropriate to addressing public health concerns.”¹³⁶ The latter therefore can override TRIPS obligations. However, this broad understanding conflicts with the explicit requirement for TRIPS consistency. The Doha Declaration, even though adopted by consensus and clearly stating an ‘agreement’ of WTO Members,¹³⁷ is not part of the WTO Agreements.¹³⁸ It therefore can clarify the rights and obligations set out in WTO treaty law, but it cannot add or diminish any rights or obligations.¹³⁹ Accordingly, it cannot reduce or nullify the clearly expressed obligation to act in consistence with the TRIPS Agreement.¹⁴⁰

This result finds strong support in the second and third sentences of para.4 of the Doha Declaration qualifying the broad mandate of the opening sentence.¹⁴¹ These sentences indicate *how* the right to protect public health and access to medication is to be given effect within TRIPS. By means of interpretation and implementation which avoids conflicts with these public interests (2nd sentence). This in turn should be achieved by the full use of TRIPS flexibilities – especially those listed in para.5 (a) – (d) of the Doha Declaration (3rd sentence).¹⁴² In other words: TRIPS does not and should not interfere with public health concerns – *because* it can and should be interpreted and implemented (by using its flexibilities) in a manner supportive to these concerns. In this understanding, no conflict exists as long as the recipe of proper interpretation and implementation is followed. It further underlines the notion of domestic policy space to integrate economic, social and environmental concerns which flows from the objective of sustainable development. On this basis, no right to override TRIPS obligations is necessary.

In sum, the Doha Declaration’s para.4 testifies against a right to act in a manner inconsistent with specific TRIPS obligations. Instead, it indicates how pursuing the public interests mentioned in Art.8:1 can be aligned with the TRIPS consistency requirement. This in turn points to the main role Art.8:1 can play for public interest considerations within TRIPS: ensuring an interpretation and especially implementation which gives effect to these interests whenever necessary and as much as possible under the individual TRIPS obligation at stake. Para.5 a) of the Doha Declaration confirms this by listing as the first major TRIPS flexibility the right to interpret and implement each TRIPS provision in light of the TRIPS objectives in Art.7 and principles of Art.8.¹⁴³ The public interest principle of Art.8:1 therefore guides TRIPS interpretation and implementation. Especially in cases of ambiguity, of broad and open treaty language where more than interpretation is possible, TRIPS

¹³⁵ Doha Declaration on TRIPS and Public Health, as note 3 above, (emphasis added).

¹³⁶ *ICTSD / UNCTAD*, as note 92 above, Part I chapter 6 section 6.

¹³⁷ See para.4 of the Doha Declaration which opens with the phrase “*We agree (...)*” (emphasis added).

¹³⁸ Even though one could classify it as a ‘decision’ under Art.IV:1 and Art.IX:1 of the WTO Agreement (compare F Abbot, as note 2 above, at 491, S Charnovitz, as note 134 above, at 210; *ICTSD / UNCTAD*, as note 104 above, Part One, Chapter 6 section 6). One should note that this qualification is cumulative (not alternative) to the Declaration’s formal status in the *interpretation process* which follows from the rules of the VCLT.

¹³⁹ Considering the formal hierarchy of the relevant norms, any form of interpretation of WTO law is subject to the general requirement expressed in Art.3.2 DSU that it “cannot add to or diminish the rights and obligations provided in the covered agreements”.

¹⁴⁰ A similar argument follows from the last sentence in Art.IX:2 of the WTO Agreement relating to so called authoritative interpretations adopted by and binding upon WTO Members: Even these types of interpretations with a formally higher status than any agreements under Art.31 (2), (3) VCLT cannot be applied to circumvent the provisions on amending WTO Agreements; ergo are not of equivalent status as the text of the WTO Agreements itself.

¹⁴¹ See *ICTSD / UNCTAD*, as note 92 above, Part One, Chapter 6 section 6.

¹⁴² Those listed include an interpretation based on the TRIPS objectives; the right to grant compulsory licenses and to freely determine the underlying grounds for them; and the right to freely choose a regime of national, regional or international exhaustion.

¹⁴³ “In applying the customary rules of interpretation of public international law, *each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.*” (Emphasis added); see Doha Declaration on TRIPS and Public Health, as note 3 above, at para.5 a).

provisions must be interpreted in accordance with the balancing objective of Art.7 and giving effect of public interest concerns expressed in Art.8.¹⁴⁴ As discussed further in section VI 1. below, such an understanding of Art.8:1 finds additional support from consulting the object and purpose of both TRIPS and the WTO Agreement.

II.2 Right to Foresee Exceptions and Limitations under Art.13, 17, 26:2, 30 TRIPS

This section sketches the flexibilities which the individual TRIPS provisions allowing WTO Members to introduce exceptions and limitations in their national laws provide.¹⁴⁵ Here, a concept deriving from Art.9 (2) of the revised Berne Convention for the Protection of Literary and Artistic Works (RBC)¹⁴⁶ takes centre stage since it served as a general template for constraining domestic policy space relating to exceptions for most IP rights regulated in TRIPS.¹⁴⁷ Three of the four different versions of the so called three step test have been subject to dispute settlement proceedings in the WTO – producing three panel reports where the respective TRIPS provisions played an important role. In *Canada – Patents*¹⁴⁸ two exceptions in the Canadian patent law relating to pharmaceutical patents and the market-entry of generic competitors were scrutinised under Art.30 TRIPS which states that:

“Members may provide *limited exceptions* to the exclusive rights conferred by a patent, provided that such exceptions do *not unreasonably conflict with a normal exploitation of the patent* and *do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*¹⁴⁹

Secondly the dispute *US – Copyright*¹⁵⁰ concerned two exceptions in US copyright law which allow some commercial establishments (like bars, restaurants) to play certain types of musical works on their premises without permission. The EC challenges the consistency of these exceptions with Art.13 TRIPS which obliges WTO Members to:

“confine limitations or exceptions to exclusive rights to *certain special cases* which *do not conflict with a normal exploitation of the work* and *do not unreasonably prejudice the legitimate interests of the right holder.*¹⁵¹

The final dispute, *EC – Geographical Indications*,¹⁵² relates to the EC’s system of protecting geographical indications (GIs) and especially its treatment of trademarks which coincide with a protected GI. Here, the US alleged that the duty of the holder of a prior trademark to tolerate a co-existing similar or identical GI (registered after the trademark) is inconsistent with trademark

¹⁴⁴ Compare C Correa, as note 44 above, at 109; *ICTSD / UNCTAD*, as note 92 above, Part One, Chapter 6 section 6). For a detailed analysis on the TRIPS objective under Art.7 see H Grosse Ruse – Khan, as note 21 above, at 173-178.

¹⁴⁵ Although it allows using patented subject matter without authorisation, the compulsory licensing authorisation in Art.31 TRIPS is also factored in below. In particular in the area of public health and access to medicines, it certainly adds to the policy space available for WTO Members and has been recognised as such in para.5 (b) of the Doha Declaration. Under TRIPS, compulsory licensing however is not available for trademarks (Art.21).

¹⁴⁶ Art.9 (2) addresses the general conditions for national copyright exceptions on the right to reproduction. It provides: It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in *certain special cases*, provided that such reproduction *does not conflict with a normal exploitation of the work* and *does not unreasonably prejudice the legitimate interests of the author.* (Emphasis added)

¹⁴⁷ On the so called ‘three step test’ with its origins in Art.9 (2) of the Berne Convention and which can be found in Art.13 TRIPS as well as – in modified forms’ - in Art.17, 26:2 and 30 TRIPS see M Senftleben, ‘Towards a Horizontal Standard for Limiting Intellectual Property Rights?’ *IIC* (4/2006), at 407-438

¹⁴⁸ *Canada – Patents* as note 120 above.

¹⁴⁹ Art.30 TRIPS (emphasis added).

¹⁵⁰ *United States – Section 110(5) of US Copyright Act (US – copyright)*, Panel Report WT/DS160/R, 15 June 2000.

¹⁵¹ Art.13 TRIPS (emphasis added).

¹⁵² *European Communities – Geographical Indications, (EC – GIs)* Panel Report (WT/DS/174R) 15 March 2005.

protection under Art.16 TRIPS - without being justified under the exceptions allowed by Art.17 TRIPS. The latter regulates that:

“Members may provide *limited exceptions* to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions *take account of the legitimate interests of the owner of the trademark and of third parties*”.¹⁵³

Apart from these three versions of the three step test, Art.26:2, relating to the protection of industrial designs, also contains similar restrictions on the ability of WTO Members to regulate exceptions to IP protection in their domestic laws:

“Members may provide *limited exceptions* to the protection of industrial designs, provided that such exceptions *do not unreasonably conflict with the normal exploitation* of protected industrial designs and *do not unreasonably prejudice the legitimate interests of the owner* of the protected design, *taking account of the legitimate interests of third parties.*”¹⁵⁴

The literature on these different versions of the so called three step test in Art.13, 17, 26:2, 30 TRIPS is immense and this paper is not the place for an extensive discussion of the individual provisions or the way WTO Panels have interpreted them.¹⁵⁵ Instead, this section builds on the existing analysis¹⁵⁶ in order to determine *the scope of domestic policy space left for regulating public interests* under these exception provisions in TRIPS. In a nutshell, both the language of the treaty as well as the Panels’ interpretation point to the main conceptual defect of the three step tests. All versions of the test in TRIPS take the perspective of right holders and their economic interests flowing from the market exclusivity provided by IP protection under TRIPS. It is the scope and degree of impact on these economic interests which serves as a reference point and baseline to judge the TRIPS consistency of domestic exceptions. Exceptions must be “limited” or confined to “certain special cases”; they may not (unreasonably) “conflict with a normal exploitation” of the protected subject matter and may not “unreasonably prejudice the legitimate interests of the right holder”. While Art.17, 26:2 and 30 TRIPS at least add that the “*legitimate interests of third parties*” must also be taken into account, the Panel Reports have so far not made any relevant use of this option to engage in a discussion on the public policy objectives underlying the domestic exceptions.¹⁵⁷ Moreover, given the cumulative nature of the three individual steps,¹⁵⁸ merely taking into account public interests on the third, final level does not suffice. Exceptions which do not meet the requirements of the first or second step, for example by being qualified as not ‘limited’ enough in the case of the Panel Report in *Canada – Patents*,¹⁵⁹ are never examined against their underlying policy objective and its importance for protecting public interests.

¹⁵³ Art.17 TRIPS (emphasis added).

¹⁵⁴ Art.26:2 TRIPS (emphasis added).

¹⁵⁵ See for example Ginsburg, ‘Toward Supranational Copyright Law? The WTO Panel Decision and the “Three Step Test” for Copyright Exceptions’ 187 *RIDA* (2001) 3-65; S Ricketson, as note 82 above; for a review of several of those Panel Reports see M Fisor ‘How Much of What? The Three Step Test and Its Implications in two Recent WTO Dispute Settlement Cases’, 192 *RIDA* (2002) 111-251; M Senftleben, as note 148 above. Several commentaries on TRIPS address all provisions incorporating a three step test – see Correa, as note 44 above; *ICTSD/UNCTAD*, as note 92 above; Gervais, as note 93 above and Beier / Schriker, *From GATT to TRIPS – IIC Studies* Vol.18 (New York, 1996).

¹⁵⁶ See in particular A Kur, as note 81 above.

¹⁵⁷ Instead, the Panels’ main criterion for all of the three steps seems to be how much the exception at hand detracts from the enjoyment of the full exclusive right and so affects the economic interests of right holders; see A Kur, as note 81 above.

¹⁵⁸ The language used in all different versions of the test in TRIPS provides strong evidence that the conditions must be fulfilled cumulatively. A recent joint declaration of various academics however advocates a reading where the test constitutes an indivisible entirety and where the three steps are to be considered as a whole in a comprehensive overall assessment; see the text of the Declaration “On a Balanced Interpretation of the Three Step Test in Copyright Law”, printed in *IIC* Vol.39, No.6 (2008), 707-713; available at http://www.ip.mpg.de/ww/de/pub/aktuelles/declaration_on_the_three_step_cfm (accessed 30 September 2008).

¹⁵⁹ *Canada – Patents*, as note 120 above, at 7.30-7.36.

This conceptual deficit automatically leads to a crucial difference in the TRIPS approach when compared to the notion of general exceptions under GATT and GATS. Exceptions whose legality depend on not (significantly) harming the economic interests protected under TRIPS will always be subordinated to these interests and can – in case of conflict – never prevail over these interests. This however is the key feature of Art.XX GATT and Art.XIV GATS where the individual exception clauses are designed to recognise public interests and allow WTO Members to give effect to these interests – even if this action conflicts with trade obligations under WTO rules.¹⁶⁰ Judged against this background, the TRIPS treaty language used in the different versions of the three step test as well as its interpretation by WTO dispute settlement panels so far does not offer anything close to the policy space available in Art.XX GATT and Art.XIV GATS. WTO Members therefore do not seem to have equivalent means to regulate public interests conflicting with the protection of IP as they have under the WTO rules on trade in goods and services.

True, compulsory licensing under Art.31 TRIPS – and in particular the “freedom to determine the *grounds* upon which such licenses are granted”¹⁶¹ – certainly provides some further policy space relating to patent protection. However, the comprehensive procedural requirements set out in Art.31, the debate on lack of manufacturing capacities in poor countries as well as the very poor record of practising the hailed ‘paragraph six solution’ show that the flexibilities under Art.31 TRIPS so far have a rather limited field of practical application.¹⁶² Furthermore, compulsory licensing is a conceptually more limited policy tool as it applies case-specific to individual patents where all the procedural requirements imposed by Art.31 TRIPS must be met. Exceptions and limitations allow regulating public interests on a more general basis.

An initial overall assessment of TRIPS policy space to give effect to other societal concerns and balance them with the interests of right holders therefore must acknowledge the dominance of the latter. While the distinct versions of the three step tests tend to subordinate public policy concerns and provide no real option to override the right holders’ economic interests, the only horizontal exception in Art.8:1 also does not offer any meaningful defence in itself. It might however play an important role in combination with the WTO/TRIPS objectives in determining the scope of TRIPS obligations in general. This initial conclusion will be contrasted with the policy space available under the general exceptions in the two other core areas of WTO regulation.

¹⁶⁰ See section IV for details.

¹⁶¹ Doha Declaration on TRIPS and Public Health, as note 3 above (emphasis added).

¹⁶² The WTO General Council waiver decision of 30 August 2003 (note 3 above) has so far only resulted in one request (by Rwanda) for producing patented medicines under a compulsory license abroad (in Canada) for export into the country without sufficient manufacturing capacities – see http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm (accessed 20 October 2008).

III. POLICY SPACE FOR A BALANCE OF INTERESTS UNDER GATT AND GATS

This section aims to set out the scope for policy space and flexibility for national legislators to give effect to non-trade societal values and interests under the WTO regimes for trade in goods (GATT and other Annex 1A Agreements) and services (GATS). In doing so, it examines the two central provisions (Art.XX GATT and Art.XIV GATS) which allow WTO Members to depart from their WTO obligations as well as the related jurisprudence of the WTO judicial bodies. The aim is to draw a broad picture of the policy space available to national legislators in these areas¹⁶³ which shall be compared with the flexibilities and room for manoeuvre under the TRIPS Agreement in subsequent sections.

The promotion and protection of societal interests and public goods such as the environment, human, animal and plant health, public order, consumer safety and economic development is a core task of government regulation. As outlined above, obligations of international economic law, *inter alia* to liberalise trade and to protect IP, can conflict with measures taken to implement such policy objectives. The more comprehensive and inclusive the global trade regime becomes, the more it reaches ‘behind the border’, the more frequent and intense such conflicts can become. The WTO rules on trade in goods and services primarily address this conflict in the form of a general exception rule in GATT and in GATS. Apart from the two provisions, other provisions exist which in one way or the other allow for domestic policy space or recognise non-trade interests, in particular relating to health and the environment.¹⁶⁴ These provisions however are not equally broad in scope and are generally limited to specific issues - relating for example to technical trade barriers, sanitary measures or subsidies. For these reasons and since the general exception clause continues to play a dominant role in conflicts between trade and a societal interest, this paper focuses on the concept of a general exception. This notion represents a common means in trade law to implement sustainable development concerns and the principle of integrating economic, social and environmental concerns.¹⁶⁵

The most important common feature of these general exceptions in GATT and GATS is that they allow, under specific conditions, WTO Members to adopt and maintain legislation and measures that protect important societal interests, even if inconsistent with other provisions of these agreements. As soon as the exceptions’ requirements are met, the interests pursued in these measures or laws therefore can prevail over conflicting trade interests embodied in WTO rules.¹⁶⁶ In the areas of classic trade regulation, the WTO system thus allows policy space sufficient for non-trade interests to *trump over* trade interests.

¹⁶³ A more detailed analysis of policy space under the WTO regimes on trade in goods and services can be found in H Grosse Ruse – Khan, ‘A Comparative Analysis of Policy Space in WTO Law’ (November 26, 2008), *Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series No. 08-02*, available at <http://ssrn.com/abstract=1309526>. (accessed 8 July 2009)

¹⁶⁴ See Art.2:2 of the WTO Agreement on Technical Barriers to Trade (TBT) allowing introducing (trade-restrictive) technical standards which are necessary to fulfil policy objectives such as the “protection of human health or safety, animal or plant life or health, or the environment”. In a similar fashion, Art.2:1 of the WTO Agreement on Sanitary and Phytosanitary Measures (SPS) allows for e.g. necessary health protection measures. Further, Art.8:2 c) of the WTO Agreement on Subsidies and Countervailing Measures (SCM) and Annex 2 No.12 to the Agreement on Agriculture (AA) contain provisions which address environmental concerns.

¹⁶⁵ See M.C. Cordonier Segger, ‘Introduction’, in M.C. Cordonier Segger & M Gehring (eds), *Sustainable Development in World Trade Law*, (The Hague: Kluwer Law International, 2005), at 16, 20 and M.C. Cordonier Segger, as note 86 above, at 152, 168.

¹⁶⁶ P Van der Bossche, as note 2 above, at 598.

III.1 The Approach of General Exceptions

Stemming from the GATT 1947 origin of the WTO, Art.XX GATT entitled ‘General Exception’ has been drafted as a justification for national laws and measures which are otherwise inconsistent with obligations deriving from *any other* GATT provision.¹⁶⁷ Since all relevant jurisprudence of the GATT dispute resolution mechanism and most of the WTO jurisprudence¹⁶⁸ relates to Art.XX GATT, this section will at first focus on the general exception rule in GATT and then draw parallels to the equivalent general exception in Art.XIV GATS. Art.XX GATT provides:

Article XX - General Exceptions

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

- (a) necessary to protect public morals;
- (b) necessary to protect human, animal or plant life or health;
- (c) relating to the importations or exportations of gold or silver;
- (d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices;
- (e) relating to the products of prison labour;
- (f) imposed for the protection of national treasures of artistic, historic or archaeological value;
- (g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption;
- (...)¹⁶⁹

Drafted as a (general) exception, Art.XX GATT comes into play only if a national measure has been found in violation of an obligation under the GATT. Even though Art.XX GATT constitutes exceptions to obligations in GATT, the Appellate Body has explicitly rejected the notion of an interpretation which constructs exceptions narrowly. Instead, the Appellate Body recognised the importance of the domestic public policies pursued via measures recognised under Art.XX GATT.¹⁷⁰ By relying on, *inter alia*, contextual and objective-based interpretation in accordance with Art.31 (1) VCLT, it advocated a balance of the interests embodied in the applicable exception clause with those incorporated in the conflicting GATT provision.¹⁷¹ On this basis, an interpretation of the exceptions in

¹⁶⁷ This general scope of the exception potentially covering all obligations set out follows from the language “nothing in this Agreement shall ... prevent”; see J Jackson, *World Trade Law and the GATT* (1969), 744.

¹⁶⁸ A comprehensive discussion of the relevant environmental or health related disputes from the GATT 1947 to the current WTO system can be found in Trebilcock / Howse, as note 41 above, at 515-545. On the GATT panels’ history of dealing with Art.XX see J Klabbbers, ‘Jurisprudence in International Trade Law – Art.XX GATT’, *JWT* Vol.26 No.2 (1992), 63 (66-88).

¹⁶⁹ The further sections (h), (i), (j) relate to obligations under international commodities agreements, efforts to ensure essential quantities of materials necessary for the domestic processing industry and products in short supply.

¹⁷⁰ *US – Shrimp*, as note 13 above, at para. 121: Paragraphs (a) to (j) comprise measures that are recognized as *exceptions to substantive obligations* established in the GATT 1994, because the domestic policies embodied in such measures have been recognized as important and legitimate in character.

¹⁷¹ *US – Gasoline*, as note 21 above, at 16 (emphasis added).

Art.XX GATT which allow giving effect to these policies and interests must aim at an *overall balance between trade liberalisation and other societal values*.¹⁷²

These general observations on the nature, function and structure of Art.XX GATT equally apply to the ‘General Exception’ clause applicable to obligations on trade in services in the WTO. Using the Art.XX GATT approach as a template, general exceptions to obligations under the General Agreement on Trade in Services (GATS) have been foreseen in Art. XIV GATS in a very similar manner:

Article XIV - General Exceptions

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where like conditions prevail, or a disguised restriction on trade in services, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member of measures:

- (a) necessary to protect public morals or to maintain public order;¹⁷³
- (b) necessary to protect human, animal or plant life or health;
- (c) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement including those relating to:
 - (i) the prevention of deceptive and fraudulent practices or to deal with the effects of a default on services contracts;
 - (ii) the protection of the privacy of individuals in relation to the processing and dissemination of personal data and the protection of confidentiality of individual records and accounts;
 - (iii) safety;
 - (...) ¹⁷⁴

One may note that the general exception under GATS uses almost identical language in its chapeau. As to the individual exception clauses, they partly match those used in Art.XX GATT (see especially (b) on the protection of human, animal or plant health), while others rely on the same concept as in Art.XX GATT but are tailored to address specific interests more likely affected by trade in services (see for example (c) (a) and (b) on fraud, deception and default in service contracts and on data protection). Summing up, two of the three major regimes of global economic regulation in the WTO – the ones on trade in goods and trade in services – do include a general exception which allows WTO members to give effect to domestic non-trade interests. As a brief survey of the Appellate Body’s jurisprudence in WTO dispute settlement relating to Art.XX GATT (and Art.XIV GATS) will indicate, this system seems to function rather well.

III.2 Necessity Test as Balancing Tool

This section shows how the so called ‘necessity test’ which can be found in various provisions of WTO Agreements¹⁷⁵ functions as a central proportionality element in the most important individual

¹⁷² P Van der Bossche, as note 2 above, at 600; compare also C Godt, as note 31 above, at 251-252, and C Gerstetter, as note 21 above, at 120-124.

¹⁷³ As per original footnote to the GATS Agreement, “the public order exception may be invoked only where a genuine and sufficiently serious threat is posed to one of the fundamental interests of society”.

¹⁷⁴ Subsection (d) and (e) further concern inconsistencies with *specific* GATS obligations due to the collection of direct taxes.

¹⁷⁵ As the WTO Secretariat Note on Necessity Tests in the WTO describes, such tests can be found in, *inter alia*, “Articles XX and XI of the GATT; GATS Articles XIV and VI:4, paragraph 2(d) of Article XII and paragraph 5(e) of the Annex on Telecommunications; Articles 2.2 and 2.5 of the TBT Agreement; Articles 2.2 and 5.6 of the SPS Agreement; Articles 3.2,

exception clauses of Art.XX GATT and Art.XIV GATS. It focuses on a prominent individual exception in Art.XX GATT and Art.XIV GATS allowing WTO Members to adopt measures (even if otherwise inconsistent with GATT or GATS) whenever they are “*necessary to protect human, animal or plant life or health*”.

The individual exception clause at issue here requires two conditions to be met. First, the policy objective followed by the measure at issue must be the protection of human, animal or plant health. WTO jurisprudence has so far not set high thresholds here. It generally relates to both public health as well as environmental policies¹⁷⁶ and effectively allows WTO Members broad discretion as to which measures fall within that scope.¹⁷⁷ Secondly, the measure must be ‘*necessary*’ to achieve this objective.¹⁷⁸ This condition reflects the balance in WTO agreements between two important goals: preserving the freedom of Members to set and achieve regulatory objectives through measures of their own choosing, and discouraging Members from adopting or maintaining measures that unduly restrict trade. Necessity tests typically achieve this balance by requiring that measures, which restrict trade in some way (including by violating obligations of an agreement), are permissible only if they are “*necessary*” to achieve the Member’s policy objective. *In so doing, the necessity tests confirm the right of Members to regulate and to pursue their policy objectives.*¹⁷⁹ The Appellate Body emphasised that judging necessity “*involves in every case a process of weighing and balancing a series of factors*” such as the *contribution of the measure to the achievement of the policy goal, the importance of the common interests or values protected, and the impact of the measure on trade.*¹⁸⁰

Although the Panel and Appellate Body jurisprudence is dynamic and has over time taken distinct approaches on interpreting the necessity test, the following individual elements seem of continuous relevance: Measures are only necessary when they consist of:

- the *least trade restrictive* measure
- which is *reasonably available* to the Member State
- and is *equally effective* in achieving the desired policy objective.¹⁸¹

The Appellate Body further confirmed that WTO Members have the sovereign right to determine the level of protection of health or the environment autonomously – as they consider appropriate in a given situation.¹⁸² Finally, in determining whether an alternative measure is ‘*reasonably available*’ to a WTO Member, difficulties in implementing the measure must be considered.¹⁸³

8.1 and 27.2 of the TRIPS Agreement; and Article 23.2 of the Agreement on Government Procurement”. See WTO Secretariat, ‘Necessity Tests in the WTO’, (S/WPDR/W/27) 2 December 2003.

¹⁷⁶ See P Van der Bossche, as note 2 above, at 604.

¹⁷⁷ H Schloemann, ‘Brazil Tyres: Policy Space Confirmed under GATT Article XX’, *Bridges Monthly Trade Review*, Vol.12 No.1, at 11 (available at http://www.ictsd.org/monthly/bridges/BRIDGES_12-1.pdf - visited 21 April 2008); compare also M Andenas, S Zleptnig, as note 21 above, at 8.

¹⁷⁸ See *US – Gasoline*, Panel Report WT/DS2/R (29 January 1996), para.6.20.

¹⁷⁹ See WTO Secretariat, as note 176 above, para.4.

¹⁸⁰ *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef (Korea – Beef)*, Appellate Body Report WT/DS161/AB/R (11 December 2000), para.164 (emphasis added) and *European Communities – Measures Affecting Asbestos and Products Containing Asbestos (EC – Asbestos)*, Appellate Body Report WT/DS135/AB/R (12 March 2001), at para.172: The more vital or important the societal value at issue, the easier it is to accept as ‘*necessary*’ measures designed to achieve this end.

¹⁸¹ See *Thailand – Cigarettes*, Panel Report DS10/R - 37S/200 (7 November 1990), para.73-78 and *EC – Asbestos*, as note 181 above, at para.174.

¹⁸² Other Members cannot challenge the level of protection chosen as inappropriate or overreaching (*EC – Asbestos*, as note 181 above, at para.168). Compare also *US – Gasoline*, as note 21 above, at para.6.22: At stake is the necessity of the measure to achieve the policy objective – not the necessity of the policy objective.

¹⁸³ See P van der Bossche, as note 2 above, at 606.

More recent jurisprudence of the Appellate Body confirms that the individual weight given to these elements in an overall balancing process may vary from case to case. Against this dynamic background, a comment on the Appellate Bodies' 2007 ruling in *Brazil – Tyres*¹⁸⁴ sums up nicely the overall role of necessity tests in balancing trade obligations and domestic policy space for non-trade interests:

“The ‘necessity’ analysis remains a rather flexible catch-all (or catch-nothing) piece of wax in the hands of the Appellate Body. The ‘weighing and balancing’ test in particular is a thinly veiled proportionality test, miraculously operating rather well without an agreed value system (constitution) to rely on – probably because it comes along with utmost judicial restraint, if not deference to national policy choices. Perhaps ‘disproportionality’ test would therefore be a better word for it.”¹⁸⁵

III.3 Preventing Abuse under the Chapeau

The justification of otherwise GATT (or GATS) inconsistent measures depends further on meeting the requirements of the introductory clause of Art.XX GATT (Art.XIV GATS) – the so called ‘chapeau’. In Art.XX GATT it provides:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of *arbitrary or unjustifiable discrimination between countries where the same conditions prevail*, or a *disguised restriction on international trade*, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures (...)¹⁸⁶

Keeping in mind the comparison with policy space and balancing under TRIPS, it should be emphasised that Art.8:1 TRIPS does not contain anything like the chapeau (but an overall TRIPS consistency test instead).¹⁸⁷

The chapeau and its requirements imposed on WTO Members have been highly relevant in WTO dispute settlement. Several prominent decisions of the Appellate Body have addressed it and found national measures – while provisionally justified under the individual exceptions – in conflict with the chapeau.¹⁸⁸ Since this results in the measure being not justified under Art.XX GATT (which often equals the finding of their overall WTO inconsistency), it has led to the impression that trade interests have been given precedence over those of, for example, the environment or public health. Whether or not this perception is justified, evidence of an implicit structural bias of the world trading system shall not be addressed here. It is however worth noting that a measure which fails to meet the

¹⁸⁴ *Brazil – Tyres*, as note 16 above. The dispute addressed Brazilian measures taken against the importation of retreaded (i.e. recycled) tyres whose waste later pose environmental and health risks. A discussion of the Appellate Body Report (by I Van Damme) can be found in *ICLQ* Vol.57 June 2008, 710-723.

¹⁸⁵ H Schloemann, as note 178 above, at 11. Compare also the conclusion reached by M Andenas, S Zleptnig as note 21 above, at 10 which emphasises not only the flexible balancing approach adopted by the Appellate Body but equally stresses ‘a certain degree of subjectivity on the part of the judiciary’.

¹⁸⁶ Art.XX GATT (emphasis added). The slightly different wording of Art.XIV GATS goes: “Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where *like* conditions prevail, or a disguised restriction *on trade in services*, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member of measures” (differences highlighted).

¹⁸⁷ Art. 8:1 TRIPS states: “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, *provided that such measures are consistent with the provisions of this Agreement.*” (consistency test highlighted).

¹⁸⁸ See especially *US – Gasoline*, (as note 21 above); *US – Shrimps*, (as note 13 above); *US – Gambling* (as note 14 above – on Art.XIV GATS) and *Brazil – Tyres* (as note 16 above).

conditions set out in the chapeau rather indicates its discriminatory or disguised protective nature – than necessarily serving as evidence of a trade bias in the WTO. Following is a brief overview of the main characteristics of the chapeau, as applied by the Appellate Body.

The object and purpose of the chapeau is to prevent the abuse or misuse of the right to override GATT obligations for various public policy goals.¹⁸⁹ It re-imposes the overall balance between rights (to exercise domestic policy space on public interests) and obligations (to adhere to international trade rules).¹⁹⁰ Hence, the Appellate Body has emphasised the need for a balanced interpretation and application of the chapeau – with due regard to the individual circumstances of the case at hand.¹⁹¹ The WTO jurisprudence shows that again proportionality and flexibility take centre stage. They dominate not only the first, but equally the second step of application of Art.XX GATT. With these important general insights in mind, the following elements in interpreting the terms ‘*arbitrary or unjustifiable discrimination between countries where the same conditions prevail*’ as well as ‘*disguised restriction on international trade*’ are relevant for a comparison with TRIPS policy space. (1) Since at issue is a justification of (otherwise) WTO inconsistent measures (for example infringing the national treatment (NT) or most-favoured-nation (MFN) obligations), discrimination prohibited under the chapeau must necessarily differ from that in NT, MFN provisions.¹⁹² (2) Discrimination which can be avoided and, in that sense, is deliberate, falls under the chapeau – so does insufficient regard to the individual circumstances (in specific importing countries) where different conditions are treated the same in a rigid and inflexible manner.¹⁹³ (3) Unilateral conduct – where multilateral solutions have been found with some and can be sought with others without great pains – equally amounts to arbitrary or unjustifiable discrimination between countries where the same conditions prevail.¹⁹⁴ (4) Overall, as formulated in *Brazil – Tyres*, one must assess whether the discrimination is based on the same objective the protection measure relies on – all other justifications being irrelevant.¹⁹⁵

III.4 Summing Up the Scope of Policy Space under GATT and GATS

For a comparative analysis of the respective room for balancing of interests and domestic policy space under the TRIPS Agreement, the following aspects set the main guiding principles of Art.XX GATT and Art.XIV GATS:

- Non-trade interests can override trade interests under the WTO regulation in trade in goods and trade in services. However, if Member States wish to give effect to domestic non-trade interests over trade obligations, they must fulfil certain conditions under WTO law which aim to balance these two poles overall.
- Exceptions to trade obligations which aim (and allow) to give effect to important societal values and interests on the domestic plane do not need to be interpreted narrowly.

¹⁸⁹ In *US – Gasoline*, the Appellate Body related this to the need to give effect to the trade obligations contained under GATT (principle of effectiveness); see *US – Gasoline*, as note 21 above, at 20.

¹⁹⁰ *US – Shrimp*, as note 13 above, para.156. In the same ruling the Appellate Body further linked the chapeau to the principle of good faith as regarding the exercise of rights by states in public international law.

¹⁹¹ The task of interpreting and applying the chapeau is, hence, essentially the delicate one of locating and marking out a *line of equilibrium between the right of a Member to invoke an exception under Article XX and the rights of the other Members under varying substantive provisions* (e.g., Article XI) of the GATT 1994, so that neither of the competing rights will cancel out the other and thereby distort and nullify or impair the balance of rights and obligations constructed by the Members themselves in that Agreement. *The location of the line of equilibrium, as expressed in the chapeau, is not fixed and unchanging; the line moves as the kind and the shape of the measures at stake vary and as the facts making up specific cases differ.* (*US – Shrimp*, as note 13 above at para.159 - emphasis added)

¹⁹² See *US – Gasoline*, as note 21 above at page 21.

¹⁹³ *US – Shrimp*, as note 13 above at para.164, 165, and 177.

¹⁹⁴ *Ibid*, para.166-174.

¹⁹⁵ See H Schloemann, as note 178 above, at 15.

- The list of non-trade interests recognised is limited and exhaustive – but seems to address the key areas of conflict and the language used allows a wide interpretation so that actual policy space is vast.
- WTO Members can freely choose the extent to which they wish to pursue the (recognised) policy objective.
- The national measures taken to implement the chosen level of protection for the (recognised) non-trade interests must contribute to the protection. In the case of the ‘necessity’ test, the national implementation measure must further be the least trade restrictive, reasonably available measure – alternatives must be equally effective.
- In an overall balancing exercise, the Appellate Body takes into account all the factors above. This includes weighing the importance of the non-trade interests against the amount of trade restriction of the measure. The absence of an agreed set of (constitutional) values calls into question the legitimacy of such normative decisions on the importance of the interests pursued. Hence, general judicial restraint is necessary to place discretion in the hand of WTO Members to regulate non-trade interests for which the WTO (so far) lacks competence.
- Overall, the balancing exercise in Art.XX GATT is and should be a loose check as to whether Members have sufficiently taken their trade obligations into account when pursuing public policies. However, it is and should be stringent when assessing whether these policies are actually a disguise for serving domestic protectionists agendas. This leads to a negative test which prohibits disproportionality instead of a positive one which requires proportionality – i.e. which imposes a specific form of balance on WTO Members.

IV. COMPARING POLICY SPACE UNDER TRIPS, GATT AND GATS

Section II has focussed on Art.8:1 as the only horizontal TRIPS provision which addresses the ability of WTO Members to adopt public interest based measures. Contrasting this provision against the general exceptions in Art.XX GATT and Art.XIV GATS,¹⁹⁶ one important similarity as well as one essential difference is apparent. On the one hand, all three regimes contain individual exceptions, *inter alia* relating to public health and require ‘necessity’. On the other hand, only the TRIPS version includes a clause which requires all measures adopted under Art.8:1 to be *consistent with all other TRIPS provisions*. At face value, Art.8:1 therefore does not allow measures which would conflict with other obligation in TRIPS and so appears rather useless as an exception which would allow public interests to prevail over those of IP right holders.

This impression is confirmed by the detailed analysis of scope and function of Art.8:1. The conclusion is that its TRIPS consistency test establishes a crucial difference as to the function of this public interest principle compared to the public interest exceptions in GATT and GATS. While Art.XX GATT and Art.XIV GATS recognise a self-standing *right of WTO Members to override any individual obligation* contained in the respective agreements, this is not the case with Art.8:1 TRIPS. Even though it does not positively integrate public interests and their relation to IP protection, TRIPS does not contain a comparable general safeguard for domestic regulatory autonomy regarding public interests. Here WTO Members can only give effect to public interests conflicting with TRIPS obligations if their respective measures are *covered by the specific TRIPS exception provisions on individual IP rights*.

The policy goals addressed in Art.8:1 therefore can only play a role in interpreting and implementing the specific conditions in Art.13, 17, 26:2 30, 31 and 40 TRIPS. Whether this way of recognising public interests – especially those potentially clashing with the interests of right holders – is actually sufficient, remains to be seen.¹⁹⁷ It largely depends on the interpretative policy space inherent in the individual TRIPS provisions; and probably even more on the ability of WTO Members to use this flexibility in their domestic implementation of TRIPS – as well as the willingness of WTO Panels and the Appellate Body to take this flexibility seriously when called to judge individual disputes. The latter can be doubted, especially when looking at the Panel Report in the *Canada – Patents* dispute¹⁹⁸ where the Panel acknowledged some relevance of Art.8 and 7 TRIPS, but *a priori* significantly curtailed their role by the conditions set out in Art.30 as well as the non-discrimination test in Art.27 which it considered “*a deliberate limitation rather than a frustration*” of the TRIPS objective.¹⁹⁹ This reasoning turns around the interaction of interpretative cause and effect between the treaty context and objectives expressed in Art.7 and 8 TRIPS and individual terms of the agreement.²⁰⁰ One might hope that the judicial organs of the WTO charged with determining the role of public interest principles under TRIPS in a post-Doha environment would be willing to come to different conclusions on the scope of (interpretative) policy space in TRIPS.

¹⁹⁶ For a detailed analysis on the notion of general exceptions under GATT and GATS see section IV.

¹⁹⁷ See section VI. 1. below.

¹⁹⁸ See *Canada – Patents*, as note 120 above.

¹⁹⁹ *Canada – Patents*, as note 120 above, at 7.26 and 7.92 (emphasis added). For a critique on the panel’s argumentation see A Kur as note 81 above; *ICTSD / UNCTAD*, as note 92 above, Part One, Chapter 6 Section 4; D Shanker, ‘The Vienna Convention on the Law of Treaties, the Dispute Settlement of the WTO and the Doha Declaration on the TRIPS Agreement’, 36 *JWT* (4/2002), at 742 and E Tekeste Biadleng, ‘The Development-Balance of the TRIPS Agreement and Enforcement of Intellectual Property Rights’, in J Malbon & C Lawson, *Interpreting and Implementing the TRIPS Agreement*, (Cheltenham: Edward Elgar Publishing, 2008), (97-130) at 102-104.

²⁰⁰ While it is correct that the limiting conditions in Art.30 (as well as those in Art.13, 17, 26 (2) TRIPS) certainly have to be borne in mind when exercising the policy space Art.8 calls for, *they in turn have to interpreted in light of the object and purpose of TRIPS*. Both Art.7 and 8 as treaty objective and context determine (as far as possible under the VCLT) the meaning of individual terms – not the other way around.

The table below indicates the main similarities and differences between Art.8:1 TRIPS, its original version and Art.XX GATT:

Art.XX GATT	Art.8B (W/76 Draft)	Art.8 TRIPS
<p>General Exceptions <i>Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade,</i> <u>nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:</u> (a) <u>necessary to protect public morals;</u> (b) <u>necessary to protect human, animal or plant life or health; (...)</u> (g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption;</p>	<p>Principles</p> <p>(2) In formulating or amending their national laws and regulations on IPRs, <u>PARTIES have the right to adopt appropriate measures to protect public morality, national security, public health and nutrition,</u> or to promote public interest in sectors of vital importance to their socio-economic and technological development</p>	<p>Principles</p> <p>(1) <u>Members may, in formulating or amending their laws and regulations, adopt measures</u> <u>necessary to protect public health and nutrition, and</u> to promote the public interest in sectors of vital importance to their socio-economic and technological development, <i>provided that such measures are consistent with the provisions of this Agreement.</i></p>

Summing up the comparison thus far, the first section of this paper has revealed a common denominator in all areas of international economic regulation and in particular those addressing trade in goods, services as well as the protection of IP. The structural bias of these specific regimes, pared with the increasing tendency to ‘reach behind the border’ in terms of density and scope of global rules has led to an ever stronger impact on ‘non-trade’ societal interests or individual rights.²⁰¹ While this observation was equally valid for trade in goods and services as well as the protection of IP, sections III and IV have so far identified a clear difference in the WTO rules which suppose to account for these non trade interests and values. GATT and GATS contain a broad, general exception with relatively large policy space for domestic measures giving preference to these policy goals over trade obligations. The corresponding TRIPS provision however does not accomplish this.

If one takes the sustainable development objective applicable to all WTO Agreements seriously, TRIPS must offer a comparable amount of discretion to integrate economic, social and environmental concerns. Hence the question arises whether TRIPS needs a general exception conceptually similar to Art.XX GATT or Art.XIV GATS to achieve this. This however presupposes that the protection of IP and related international obligations under TRIPS have an equivalent impact on domestic public interests measures compared with obligations on trade in good and services. This section examines arguments why this may not be the case.

²⁰¹ See section II above.

IV.1 The Nature of IP Protection: Addressing the ‘Negative Rights’ Justification

One argument stresses that the nature of IP protection is limited to a *negative right to exclude others* from exploitation.²⁰² It does not grant a positive monopoly or guarantee to exploit the protected subject matter. Does this essential feature of IP rights *a priori* diminish or even exclude conflicts between IP protection and public interests measures? In the *European Communities – Geographical Indications (EC – GIs)* dispute,²⁰³ the Panel tried to provide a specific explanation for why there is no need for a general exception (like Art.XX GATT) for public interests within the TRIPS Agreement and why the principles in Art.8:1 TRIPS with its consistency test are sufficient. It stated:

“These principles reflect the fact that the TRIPS Agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather provides for the grant of negative rights to prevent certain acts. This fundamental feature of intellectual property protection inherently grants Members freedom to pursue legitimate public policy objectives since many measures to attain those public policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement.”²⁰⁴

The Panels argument is that there is no need for an Art.XX GATT style exception under TRIPS because of the nature of IP rights as negative rights (instead of positive monopolies). For the panel, this feature allows public policy objectives to be pursued without interference from these (negative) rights.

While this argument sounds convincing at first and does provide an adequate safeguard for various public interest measures, it does not resolve the full range of conflicts between the latter and IP protection. IP rights as negative rights allow a right holder to prevent anyone else from using the protected subject matter (and products or services containing or relying on such matter) in any commercially relevant way – without guaranteeing a positive (exclusive) right to exploit. This limitation of negative rights allows governments to impose further regulatory controls on utilisation and exploitation. For example, a copyrighted computer program containing sexually explicit or violent images may not be sold freely, but only to persons who have reached a certain age. Here, regulations protecting the interests of minors limit the free exploitation of the copyrighted work – arguably without interfering with the exclusive rights in the computer program since they do not grant a positive monopoly for exploitation. In a similar fashion, a patent for a new innovative technology incorporated in a firearm does not provide the right holder with a guarantee to commercialise the firearm without restriction. Instead, rules on gun control and export or import prohibitions may significantly limit the trading of the patented product while leaving the negative right to exclude others from using the patented invention untouched.

However, the realisation of public policy objectives sometimes does require interference with the negative right to prevent others from exploiting the protected subject matter. Whenever a public interest exists to make protected subject matter available to certain interest groups and/or for a specific purpose, this use of the IP protected content will conflict with the concept that the right holder can prevent any (commercially relevant) use of the protected subject matter. For example, making copyrighted (academic) literature available in libraries to students and/or within the research community interferes with the exclusive right to allow or prohibit such use. Furthermore, distributing to farmers patent- or plant variety protected seeds which could better adapt to the changing climate in order to ensure local production and food security, generally conflicts with the exclusivity conferred

²⁰² See Recital 14 of the Directive 98/44/EC of the European Parliament and of the Council of July 1998 on the legal protection of biotechnological inventions.

²⁰³ *EC – GIs* (as note 153 above).

²⁰⁴ *Ibid*, para.7.210.

by the patent- or plant breeder rights. In sum, as soon as the public policy in question is not confined to a limitation of exploitation by the right holder but *necessitates an authorisation of exploitation for state authorities, specific institutions or private third parties*, the concept of negative rights in itself does not ensure the realisation of the public policies in question. In such situations, exceptions and limitations to the exclusive (negative) rights are needed to guarantee a proper balance of interests. These exceptions curtail the right holder's exclusive power to prevent exploitation by others via authorising a certain (limited) use of the protected subject matter by a (limited) group of beneficiaries.

Therefore, Art.8 TRIPS as it stands is not sufficient to give effect to the public policy interests addressed in that provision. This is so because its requirement of TRIPS consistency does not allow measures adopted under Art.8 to give effect to public policies over the interests of right holders as set out e.g. in Art.10, 11, 14, 16, 26 (1), 28, 36 or 39 TRIPS. The explanation for the consistency qualification as given by the Panel in *EC – GIs* thus neglects a very important aspect necessary for a true balance of interests as intended by the sustainable development objective in the WTO Preamble and Art.7 of TRIPS. In sum, the nature of IP protection as a negative right does not justify the absence of provisions which provide WTO Members policy space to override IP obligations conflicting with public interests. Of course, TRIPS does contain specific provisions which allow WTO Members to curtail the exclusive (negative) rights through domestic exceptions and limitations.²⁰⁵ As shown above, the dominant current application of these provisions does not sufficiently integrate public interests demanding for (a specific form of) access to, use or exploitation of IP protected material.

IV.2 Threatening a Century of *Acquis* in International IP Harmonisation?

Another argument draws on the more than 100 years of history in achieving a more and more harmonised system of IP protection.²⁰⁶ Is there a need to protect the 'IP *acquis*' – especially in the form of the revised Berne Convention (RBC)²⁰⁷ or the Paris Convention (PC)²⁰⁸ – from being watered down via extended policy space? The initial question however is whether policy space to give effect to public interest concerns actually does in any significant way threaten the IP *acquis*? Here, one needs to distinguish between two types of policy space when it comes to the protection of IP on the international level. First, there is policy space or flexibility to regulate and *determine autonomously the level of IP protection* – usually in a way which suits the domestic industries and allows them, where necessary, to imitate new technology utilising lax domestic IP protection and enforce stronger protection once they have advanced and become technological innovators themselves. Secondly, a distinct form is policy space to freely regulate and *give effect to public interests outside the IP incentive mechanism* – even if the interests of IP right holders may sometimes clash with these public interests. The policy space concerned here is not about autonomy in setting IP protection standards suited to the economic development needs of an individual country, for example, in the form of protection tailored to the needs of the domestic industry – although historical evidence indicates this as a successful route for development and trade and economic theory argue for such an approach to optimise global welfare.²⁰⁹

²⁰⁵ Such as Art.13, 17, 26:2, 30 and 31 TRIPS.

²⁰⁶ The conclusion of the Paris Convention on the Protection of Industrial Property of 1883 and the Berne Convention on the Protection of Literary and Artistic Works of 1886 were major achievements for creators, inventors and trademark holders of contracting parties which from then on were able to rely on the principle of national treatment preventing any (until then very common) discriminatory treatment of foreigners in domestic IP laws as well as some minimum rights on which the contracting parties agreed. Over time, in various revisions of these two core conventions, more harmonisation was achieved by – especially in the Berne context – adding further minimum 'convention' rights. Compare *S v Lewinski, International Copyright Law and Policy* (Oxford: OUP 2007), at 4.01-4.22.

²⁰⁷ Revised Berne Convention (RBC), as note 88 above.

²⁰⁸ Paris Convention on the Protection of Industrial Property adopted in Paris, 20 March 1883, last revised at Stockholm on 14 July 1967 and amended on 28 September 1979, WIPO Publication No.210, 1.

²⁰⁹ See *UNCTAD, The Least Developed Country Report 2007 - Knowledge, Technological Learning and Innovation for Development* (Geneva, 2007), at 105-107; *World Bank, Global Economic Prospects and the Developing Countries 2002* (Washington DC, 2001), at 129; on the historical evidence for tailoring national IP policy and regulation to the domestic

Instead, the policy space at stake here concerns the right to address and regulate public interests whenever IP protection comes into conflict with these societal values.²¹⁰ Before TRIPS, this form of policy space had always existed within the international IP *acquis*. TRIPS serves primarily as an export-oriented, global security against market failure, imitation and competition abroad. It was only the resulting unprecedented high degree of harmonisation that caused international IP protection to affect and interfere with domestic policies not related to the core realm of IP policy making.²¹¹ Hence this form of policy space (taking measures to protect public health, nutrition and food security, education, research and access to information, free competition and individual freedoms and human rights) has only recently been subjected to IPRs.²¹² Before this qualitative change in the approach to international IP harmonisation, sufficient flexibilities for an autonomous regulation of public interests had existed.²¹³ Even continuous increases in the minimum standards, especially under the Berne Convention, have – until the emergence of the three step test and its globalisation via TRIPS – not really affected the effective pursuit of public interest policies. On the national level, exceptions and limitations to IP were the common tools used to implement domestic public policy concerns whenever these conflicted with IP protection.²¹⁴ This was possible since exceptions were often either not harmonised, widely available, or, if regulated (as after the Stockholm revision of the RBC), at least not subject to any effective enforcement mechanism on the global level so that the option of lax implementation effectively ensured the necessary policy space.²¹⁵

One can thereby conclude that the historical *acquis* of harmonising IP protection on the international level has – until the emergence of TRIPS – always contained sufficient room to regulate public interests on the domestic level. Hence, the ‘pre-TRIPS’ international IP *acquis* will not be constrained by introducing a general public policy exception as found in Art.XX GATT. Only the recent tendency to go beyond this traditional form of harmonisation by attempting to create a uniform high standard of protection with almost no relevant exceptions would be affected by a general public interest exception. This is only because it was this trend (and its global, uniform first-world concept of strong IP rights) in the first place that expanded into areas such as public health, access to information and food security. Against this background, a public interest exception within TRIPS actually is one way of taking back lost ground for domestic public interest regulation. It therefore is one option for a necessary response to re-establish the status quo which existed before TRIPS.

economic, technological and development needs of a country see further *Commission on Intellectual Property Rights (CIPR)* and especially the two related background papers Z Khan, ‘Study Paper 1a: Intellectual Property and Economic Development: Lessons from American and European History’; and N Kumar, ‘Study Paper 1b: Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries’ (all as note 4 above). For an economic and trade theory justification see M Trebilcock & R Howse, as note 44 above, at 397-401.

²¹⁰ Compare Section I above.

²¹¹ By the same token, TRIPS also significantly limits the form of policy space which allows countries to tailor IP protection to the needs of the domestic economic and technological environment; compare section I above.

²¹² Compare section I above.

²¹³ Compare S Ricketson, as note 82 above, at 20, 40-42: with regard to rights of states to regulate abuses of monopolies, Ricketson identifies a general principle whereas a convention concerned with the protection of private rights does not interfere with the power of sovereign states to regulate matters in the public interest. He points out that this is further underlined by an accepted statement in the Report of Main Committee to Stockholm Conference: Questions of public policy should always be a matter for domestic legislation and countries are able to take all necessary measures to restrict possible abuses of monopoly.

²¹⁴ On the general role of exceptions see A Kur as note 81 above.

²¹⁵ While the key international regimes provided, in theory, for a system of resolving disputes in front of the International Court of Justice (ICJ), this option had never been exercised (compare T Cottier, *The Prospects for Intellectual Property in GATT*, CMLR 1991, at 393). Countries with a lax implementation record thus did not have to fear enforcement actions from other contracting states. Secondly, the (more or less unlimited) option to foresee exceptions and limitations to the exclusive rights mandated by the international regime allowed to give due regard to various interests on the national implementation level (for the limited harmonisation in the area of patent law and the resulting freedom to provide for exceptions in national laws, see Straus, ‘Implications of the TRIPS Agreement in the Field of Patent Law’ in Beier / Schrickler, *From GATT to TRIPS – IIC Studies* Vol.18 (New York, 1996) at 170-175).

V. PROPOSED SOLUTIONS FOR ACHIEVING EQUIVALENT POLICY SPACE UNDER TRIPS

The analysis shows that neither the horizontal exception in Art.8:1 TRIPS nor the individual provisions regulating domestic exceptions and limitations can compare with the general exceptions under GATT and GATS. This section therefore proposes an alternative route which still achieves equivalent policy space. This not only ensures coherence in the three main areas of WTO Law. It also takes the balancing objective in Art.7 TRIPS as well as the sustainable development objective in the WTO Preamble seriously.

V.1 Taking the WTO/TRIPS Objectives Seriously: Justifications for a Right to Balance

In para.5 (a) of the Doha Declaration on TRIPS and Public Health, WTO Members emphasized as one of the key flexibilities in TRIPS that all its provisions “*shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.*”²¹⁶ For once, the Doha Declaration therefore highlights the interpretative role of the objectives articulated in Art.7 TRIPS:

“The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”

In essence, this provision encourages WTO Members to implement the IP protection TRIPS provides for in a balanced, proportional manner contributing to both social and economic welfare.²¹⁷ Besides the TRIPS objectives, para.5 (a) of the Doha Declaration refers to the public interests principles of Art.8:1. In Section III 1. c) above, I have already emphasised the impact of the Doha Declaration on the understanding of Art.8:1 TRIPS and its main role within the TRIPS Agreement. Together with the balancing objectives set out in Art.7 TRIPS, the public interest principles of Art.8:1 guide the interpretation of every individual TRIPS provision - as much as the general rules of treaty interpretation, in particular the ordinary meaning of the individual treaty terms, allow. This means that especially in cases of ambiguity, of broad and open treaty language where more than interpretation is possible, TRIPS provisions can and should be interpreted in accordance with the balancing objective of Art.7, giving effect to public interest concerns expressed in Art.8.²¹⁸

Such an understanding finds additional support from the customary rules of interpretation of public international law.²¹⁹ Relying on the object and purpose of a treaty is one central element in the process of interpretation. This not only reinforces the role of the Art.7 balancing objectives in TRIPS interpretation and implementation but also adds weight to the objectives expressed in the WTO Agreement itself. Here, the preamble to the Agreement Establishing the World Trade Organisation

²¹⁶ Doha Declaration, as note 3 above (emphasis added).

²¹⁷ Art.7 calls for balancing (1) incentives for the “promotion of technological innovation” with measures for “the transfer and dissemination of technology”; (2) the interests of “producers and users of technological knowledge” and, more generally, (3) WTO Members’ “rights and obligations”. For a more detailed analysis on the TRIPS objective under Art.7 see H Grosse Ruse – Khan, as note 21 above, at 173-178.

²¹⁸ Compare C Correa, as note 44 above, at 109; *ICTSD / UNCTAD*, as note 92 above, Part One, Chapter 6 section 6.

²¹⁹ See Art.31 (1) VCLT which lists the treaty objectives as one of the main sources of treaty interpretation besides ordinary meaning and context (further defined in Art.31 (2)), (3) VCLT) as well as the principle of good faith. Art.3:2 DSU declares these principles of interpretation decisive for all WTO Agreements.

further widens the scope of interpretative policy space to balance economic and public interests. That Agreement provides the overall framework for all other Agreements concluded during the Uruguay Round. Its objective is therefore also relevant and decisive for the interpretation of TRIPS.²²⁰ According to its first paragraph, the *Parties* concluded the WTO Agreements

“(…) allowing for the optimal use of the world’s resources in accordance with the *objective of sustainable development*, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development (…)”²²¹

In the words of the Appellate Body, the WTO treaties’ objective of sustainable development calls for “integrating economic and social development and environmental protection”.²²² As a tool for reconciling and balancing economic and public interests,²²³ “it must *add colour, texture and shading* to our interpretation of the Agreements annexed to the WTO Agreement”.²²⁴ TRIPS is one of those Agreements. Therefore, beyond the balancing and recognition of public interests advocated by Art.7 and 8:1 TRIPS, the objective of sustainable development influences the interpretation of TRIPS. With its concept of integrating and reconciling economic, social and environmental interests it further emphasises the need to interpret and implement TRIPS provisions in a way which not only reflects right holders’ interests but equally takes competing public interests into account. In this way, the overall objective embodied in the preamble to the WTO Agreement further increases the policy space WTO Members enjoy in giving effect to public interests in the implementation of TRIPS.

This increase in domestic policy space aligns with the general analysis of the role of sustainable development in international law in section II above. As long as TRIPS does not contain provisions which perform the integration of economic, social and environmental concerns on the international plane, it must primarily take place on the domestic level. This in turn requires sufficient policy space in the implementation of TRIPS. Hence, the principle of integration as the core element of the sustainable development objective²²⁵ provides additional support for balancing all relevant economic, social and environmental concerns in the process of TRIPS implementation.

However, giving effect to the objectives and principles of TRIPS as well as the general sustainable development aim of the WTO Preamble depends on the role of other sources for treaty interpretation. One cannot disregard or override unambiguous language in individual TRIPS provisions,²²⁶ for example on the scope of exclusive rights of copyright-, trademark or patent holders

²²⁰ Compare the Appellate Body’s decision in *US – Shrimp*, as note 13 above, at para.152.

²²¹ Preamble to the WTO Agreement, first paragraph (emphasis added). This language differs significantly from the original GATT preamble that encouraged GATT contracting parties to engage in a “full use of the resources of the world”.

²²² *US – Shrimp*, as note 13 above, at para.129 (fn.107). For a detailed discussion of the Appellate Body’s reliance on the concept of sustainable development in *US – Shrimp* and other cases on trade and environment, see G Marceau, as note 74 above.

²²³ Also several other international courts and institutions recognised such a conflict-resolution and balance of interest role of the concept of sustainable development: See the International Court of Justice (ICJ) Judgement in the *Gabcikovo – Nagymaros Case*, (25 September 1997) at 78; Arbitral Award of the Permanent Court of Arbitration for the *Arbitration Regarding the Iron Rhine (“Ijzeren Rijn”) Railway (Belgium v. Netherlands)* (24 May 2005); and *International Law Association*, New Delhi Declaration on Principles of International Law Related to Sustainable Development (2002), principle of integration and interrelationship, in particular in relation to human rights and social, economic and environmental objectives, as note 26 above. For further literature on the notion of sustainable development in international law see M.C. Cordonier Segger & A. Khalfan, *Sustainable Development Law: Principles, Practices & Prospects* (Oxford, Oxford University Press, 2004) and M.C. Cordonier Segger & C. G. Weeramantry, (eds) *Sustainable Justice: Reconciling Economic, Social and Environmental Law* (Leiden, Martinus Nijhoff, 2004) and the website of the Centre for International Sustainable Development Law (CISDL), <http://www.cisd.org> (accessed 20 October 2008).

²²⁴ *US – Shrimp*, as note 13 above, at para.152.

²²⁵ *US – Shrimp*, as note 13 above, at para.129 (fn.107). See further section II. above

²²⁶ Compare J Pauwelyn, ‘WTO Dispute Settlement: Of Sovereign Interests, Private Rights and Public Goods’, in K Maskus, J Reichmann, *International Public Goods and Transfer of Technology* (Cambridge University Press, Cambridge, 2005) at 828.

in Art.11, 16 and 28 TRIPS.²²⁷ The ordinary meaning of a treaty provision and its context²²⁸ are equally important; with the ordinary meaning serving as a logical starting point for interpretative exercise.²²⁹ Adding ‘colour, texture and shading’²³⁰ via the treaties’ objectives then is a secondary, corrective step²³¹ whose importance depends on the strength and concreteness of ordinary meaning and context.

Therefore, an explicit and plain wording on how to protect the economic interests of right holders (e.g. the obligation to grant 20 years of patent protection, Art.33 TRIPS) cannot be overcome by the balancing principles in Art.7, 8 TRIPS or the WTO preamble – even if public health concerns might call for a significant shortening of protection (e.g. to 10 or 15 years in order to encourage generic competition).²³² The decisive question then is how much weight can and should be attached to the objectives in the process of interpretation? Following from the analysis above and of course subject to the individual circumstances at hand, the following general guiding principle applies: the more specific the ordinary meaning in the treaties’ context is, the less room there is for a significant impact of any modification by the treaties’ object and purpose. The more ambiguous, indefinite and multi-layered a provision’s common understanding in relation to the treaty is, the more it needs further determination and concretisation by the treaties’ objective. Therefore, provisions incorporating *broad and open legal concepts* which cannot rely on significant concretisation from their context will not only lend themselves to, but demand an interpretation which draws heavily on the object and purpose of the international agreement at stake.²³³

V.2 Recommendations for a Balanced TRIPS Interpretation and Implementation

Translating this general assessment on treaty interpretation into the scope for policy space under TRIPS, the above analysis confirms the conclusions reached on the role of Art.8:1 TRIPS: giving effect to public interest considerations has to take place via broad and open terms in individual TRIPS provisions which allow for Art.7 and 8:1 TRIPS as well as the WTO preamble to unfold its balancing objective. The following recommendations identify some potential ways for an integrative approach to IP protection.

Developing a Tailored, Integrative Approach to IP Protection

Countries should acknowledge the need for a comprehensive integration of economic, social and environmental concerns in all areas of decision-making.²³⁴ This requires action on the international and the national level.

- On the international plane, further provisions which directly integrate other economic, social or environmental concerns into IP regulation must be considered. Both Art.27:3

²²⁷ Even though one may find individual terms within these provisions which are open enough for an interpretation which – in appropriate scenarios – gives effect to public interest considerations – see e.g. “product *obtained directly*” by a patented process in Art.28:2 or “*likelihood of confusion*” in Art.16:1 TRIPS.

²²⁸ Context not only includes the complete treaty text including its preamble and annexes but also additional and subsequent agreements and agreed practice on the interpretation and application of treaty provisions; compare Art.31 (2) and (3) VCLT.

²²⁹ It is however “to be not determined in the abstract, but in the context of the treaty and in light of its objective and purpose” see *Yearbook of the International Law Commission*, as note 143 above, at 221; see also M Lennard, as note 130 above, at 29.

²³⁰ *US – Shrimp*, as note 13 above, at para.152.

²³¹ *I Sinclair*, as note 132 above, at 130.

²³² Compare *G Marceau* (as note 74 above, at 138) who cites the Panel in *EC – Hormones* (para.8.157) stating that a general principle – even as part of the customary international law – cannot override explicit WTO treaty provisions.

²³³ With regard to TRIPS, see *Canada – Patents*, as note 120 above, at 7.26; Compare also the commentary of the ILC (*Yearbook of the International Law Commission*, as note 127 above, at 221) citing the Advisory Opinion of the International Court of Justice on the *Competence of the General Assembly for the Admission of a State to the United Nations*: “If the relevant words in their natural and ordinary meaning make sense in their context, that is the end of the matter.”

²³⁴ See *Agenda 21*, as note 72 above, at chapter 8 and the analysis in section II above.

TRIPS negotiations as well as the WIPO Development Agenda should provide a good forum for these issues.²³⁵

- Issues not so far addressed within the IP system but with significant impact on or in relation to IP protection must be integrated and reconciled with IP rules. The IP system cannot be silent about the global problems of today, such as climate change, food security and eradication of poverty. Intersections such as the transfer of ‘green’ technology to reduce carbon emissions and patent protection or securing sustainable, local agricultural production and plant variety- or patent protection must be investigated. The work and perspective of other international institutions such as WHO, UNEP, FAO, UNCTAD or UNHCHR can provide useful insights.
- On the domestic level, countries should develop national IP strategies and align these with their national strategies for sustainable development (NSSD).²³⁶ IP protection should be tailored to domestic needs, in particular with respect to social and environmental concerns. This requires connecting the relevant actors and stakeholders in order to identify domestic intersections between IP and ‘other’ concerns.
- International obligations – especially under TRIPS – should not *a priori* prevent envisaging flexible solutions to integrate all relevant interests affected by IP protection. The policy space identified above should generally offer sufficient discretion for a tailored domestic attempt to give effect to public interests. There are many options to justify such good faith measures under the broad and open terms of the various ‘three step tests’ in TRIPS.²³⁷

IP Limitations are no Exception to the Rule

The WTO/TRIPS balancing objectives support an understanding of the general relationship between IP protection and exceptions to it, as one of balance instead of (universal) rule and (minor) exception.²³⁸ As explained above, the Appellate Body has developed an overall equilibrium between trade liberalisation and public interests as a guiding principle for interpreting the exceptions relating to obligations on trade in goods.²³⁹ The same applies to the protection of IP and recognition of public interests under TRIPS. Such a general balance does not only follow from the overarching objective of sustainable development in the WTO preamble, but equally from Art.7 and 8 TRIPS. It emanates from the need for internal consistency of the WTO as a legal system: allowing a proper balance in one area but denying it in another threatens legitimacy and acceptance of that area as well as the whole system and could easily be perceived as biased.

Exercising Discretion in Implementing the ‘Three Step Test’

The primary provisions with broad and open terms are the various versions of the three step test regulating the right to foresee exceptions and limitations to IP rights. In Art.13 TRIPS for example,²⁴⁰ confining exceptions to ‘*special*’ cases, avoiding conflict with a ‘*normal*’ exploitation as well as ‘*unreasonable*’ prejudice of the ‘*legitimate*’ interests of right holders offers ample room for a normative understanding which recognises public interests:

²³⁵ See Section II. 4. above.

²³⁶ See *Agenda 21*, as note 72 above, at chapter 8 (8.7).

²³⁷ See the examples in this section below and the justification in section VI. 1. above.

²³⁸ *Singularia non sunt extendenda*. See also C Godt, as note 31 above, at 244 -245 who focusses on the relation between Art.27:1 (establishing the criteria for patent protection and the need to cover all fields of technology) and Art.27:2 (allowing exceptions from patentability based on public policies) as an example where a balancing paradigm, instead of a rule-exception principle should apply.

²³⁹ See section II. for details.

²⁴⁰ One may recall the wording of Art.13 stating “Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder”.

- ‘*Special*’ cases may include those which address public interests recognised in Art.8:1 or the concept of sustainable development.
- Exploitation could be considered ‘*normal*’ only if it does not significantly interfere with such interests.²⁴¹
- Any ‘prejudice’ which is caused by good faith measures (necessary for) protecting those interests may be understood as not being ‘*unreasonable*’; furthermore, ‘*legitimate*’ interests of right holders may only be those which sufficiently reconcile the public interests recognised in the WTO/TRIPS objectives.²⁴²
- Other versions of the three step test which explicitly call for “*taking account of the legitimate interests of third parties*”²⁴³ provide even more options for reconciling economic with public interests and other (fundamental) rights of third parties.

²⁴¹ See *Declaration on a Balanced Interpretation of the Three Step Test*, as note 159 above, at point 4; compare further S Ricketson, as note 82 above.

²⁴² See A Kur, as note 81 above, at IV. 5. b) dd) (ii), who favours an accumulation of public interest balancing on the third step while at the same time ensuring that the individual steps are not separate units but merge into an overall assessment. See also the *Declaration on a Balanced Interpretation of the Three Step Test*, as note 159 above, at point 6.

²⁴³ See Art.17, 26:2, 30 TRIPS. Interests could be considered ‘*legitimate*’ *inter alia* if they pursue recognised public policy concerns or other interests addressed in TRIPS or the WTO Agreements’ preamble.

VI. CONCLUSION

TRIPS *can* be interpreted and – more importantly – implemented in a manner which offers an amount of policy space for domestic regulation of public interests equivalent to GATT and GATS. Achieving this primarily calls on national implementation legislation (as well as technical assistance provided in this regard) to make use of the discretion available and also places an obligation on WTO Panels and the Appellate Body to take the relevant treaty objectives seriously. Given the rather disappointing TRIPS jurisprudence of Panels so far, one might nevertheless be better off with a comprehensive public interest exception integrated into TRIPS – for example by simply removing the consistency test in Art.8:1 TRIPS. Operating with a general exception in TRIPS however would call for a re-conceptualisation of a chapeau-like safeguard against the abuse of public interest exceptions in order to favour domestic industries.²⁴⁴ Several recent developments, initiatives or scholarly ideas further support the notion of a comprehensive general exception or other means to enlarge domestic policy space for public interests.²⁴⁵

Under the existing TRIPS regime however, achieving a comparable degree of policy space in all three core areas of WTO regulation requires different implementation techniques. Under GATT and GATS, domestic measures to protect public interests are shielded under a broad exception clause with sufficient discretion for balancing interests on the domestic level. Under TRIPS, a similar degree of delegating regulatory autonomy does not follow from an explicit right to override economic interests but must be developed from the overall WTO/TRIPS objectives and their role in interpreting and implementing TRIPS. This may imply a greater responsibility for national implementers and international adjudicators. More crucially however, it limits the scope of international obligations under the TRIPS regime: as those who are implementing and interpreting TRIPS, we are not applying rigid rules – but rather flexible provisions with a relative amount of discretion to determine an appropriate balance of economic and public interests on the domestic level.

²⁴⁴ An example for such an abuse would be using public health and access to medicines arguments in order to boost the domestic generics industry. The problem however is to distinguish good faith public health measures (which might entail ‘positive’ side effects for the generic industry) from using poor patients as a disguise for discriminatory industrial policies. Ideas could be to demand equal treatment for all (domestic and foreign) ‘like’ subject matter protected by IP (insofar borrowing from the notion of like products in Art.III GATT and the underlying rationale of preventing a modification in the conditions of competition) or require the WTO Member relying on the public interest exception to prove a good faith application of the domestic measure.

²⁴⁵ First of all, the IP in Transition Project whose results in re-drafting a more balanced version of TRIPS takes such an approach in its version of Art.8, 8a, 13, 17, 26:2 and 30. Also, the Economic Partnership Agreement (EPA) between the EC and its Members and the group of CARIFORUM contains in its Art.224 a general exception clause which from its systemic positioning and its language does not only apply to obligations relating to the trade in goods and services, but also all other EPA provisions, including those relating to IP protection. Finally, several leading academics in the area of WTO law have recently called for extended policy space, *inter alia* to regulate public interests on the domestic level – see J Pauwelyn, ‘New Trade Politics for the 21st Century’, *JIEL* Vol.11 No.3 (2008), 559-573 (at 569-570); J Trachtmann, ‘Ensuring a Development Friendly WTO’, *Bridges* Vol.12 No.1 (2008), at 18; compare also R Wade, ‘The World Trade System’, *The Economist*, 24th July 2008 and B Hoekman, ‘Operationalizing the Concept of Policy Space in the WTO: Beyond Special and Differential Treatment’, *JIEL* Vol.8 No.2 (2005), 405-424 (410-411). Along similar lines, M Chon ‘Substantive Equality in International Intellectual Property Norm Setting and Interpretation’, in D Gervais, *Intellectual Property, Trade and Development* (Oxford University Press, Oxford, 2007), 475-526, at 479, 502-503, 525-526) proposes a substantive *equality* principle which allows national law makers more policy space in the regulation of IP tailored to domestic development needs, *inter alia* to integrate public interest (embodied for example in the UN Millennium Development Goals) considerations in the protection of IP.

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