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Abstract:

Articles 7 and 8 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are entitled 'Objectives' and 'Principles' respectively. These provisions occupy a prominent position within the text of the Agreement, yet have figured sparingly in the legal reasoning of the WTO Dispute Settlement Body (DSB). The illogical nature of this discrepancy is accentuated when considered in light of four key factors. First, the pioneering step taken by the negotiators of the TRIPS Agreement to include broad declarations of intent within the legally operative text. Second, the 2001 reinforcement given to the authority of these provisions through the Doha Ministerial Declaration and the Declaration on TRIPS and Public Health. Third, the verbatim replication of these provisions within other intellectual property instruments, notably, the Intellectual Property chapter of the Trans-Pacific Partnership, the Anti-Counterfeiting Trade Agreement and the WIPO Development Agenda. Finally, the continued use of Articles 7 and 8 to influence political discourse on matters relating to intellectual property regulation. While it may be premature to suggest that Articles 7 and 8 are a customary part of the international IP system, the above information provides compelling evidence for greater investigation into their meaning in order to facilitate future recognition by the DSB.

Keywords:

Intellectual property, TRIPS Agreement, World Trade Organisation, Objectives and Principles, International Law, Treaty Interpretation, Vienna Convention on the Law of Treaties

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THE 'OBJECTIVES' AND 'PRINCIPLES' OF THE WTO TRIPS AGREEMENT: A DETAILED ANATOMY

ALISON SLADE¹

1. Introduction

A striking feature of the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)² is the bold expression of purpose contained within the operative sections of the text. While, it is commonplace to see broad declarations of intent within the preambular sections of key international IP treaties,³ the TRIPS Agreement is the first to articulate such objectives and give them apparent operative force. Articles 7 and 8 refer to the 'Objectives' and 'Principles' of the treaty regime respectively:

Article 7 - Objectives

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.

Article 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

¹ Brunel Law School, Brunel University London. Alison.slade@brunel.ac.uk. I would like to thank Professor Graeme Dinwoodie and Professor Professor Benedict Chigara for their extensive and valuable comments on earlier drafts. As always, any errors or omissions are my own.

² 1869 UNTS 299 (adopted 15 April 1994, entered into force 1 January 1995).

³ See, for example, the Berne Convention for the Protection of Literary and Artistic Works 828 UNTS 221 (entered into force 9 September 1886, last amended 28 September 1979); and the WIPO Copyright Treaty, 1996 36 ILM 65 (adopted 20 December 1996, entered into force 20 May 2002).

sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

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

Their inclusion in Part I of the Agreement entitled ‘General Provisions and Basic Principles’, recognises Articles 7 and 8 as ‘structural’ provisions that affect all other areas of the Agreement.⁴ These provisions ‘overarch the object and purpose of individual standards of protection in the other parts of the TRIPS Agreement.’⁵ Consequently, Articles 7 and 8 ‘are to be systematically applied in the implementation and interpretation of the Agreement.’⁶ The structural, overarching and systematic application of these provisions draws legal authority from the *General Rule of Interpretation* codified in Article 31.1 of the Vienna Convention on the Law of Treaties (VCLT). This states that ‘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 light of its object and purpose.’⁷ Established as binding on the WTO when interpreting all covered agreements⁸, it prescribes a single and holistic rule of interpretation that emphasises the importance of the treaty language. Nonetheless, any meaning attributed to the text must be determined in the context of the treaty and in light of its object and purpose.⁹

Articles 7 and 8 feature in the application of VCLT rule of interpretation, most significantly

⁴ Graeme B Dinwoodie & Rochelle C Dreyfuss, *A Neofederalist Vision of TRIPS: The Resilience of the International Intellectual Property Regime* (OUP 2012) 109-111.

⁵ Susy Frankel, ‘Challenging TRIPS-Plus Agreements: The Potential Utility of Non-Violation Disputes’ (2009) 12 J. Int’l Econ. L. 1023, 1037.

⁶ Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (OUP 2007) 93.

⁷ Vienna Convention on the Law of Treaties, (adopted 23 May 1969, entered into force 27 January 1980) 1153 UNTS 331.

⁸ WTO, *United States: Standards for Reformulated and Conventional Gasoline – Report of the Appellate Body* (29 April 1996) WT/DS2/AB/R, 15-16.

⁹ Ian Sinclair, *The Vienna Convention on the Law of Treaties* (Manchester University Press 1984) 119-135.

by providing *context* and *object and purpose* for the interpretation of the TRIPS Agreement.¹⁰ Support for this understanding is derived from Article 31.2 of the VCLT which defines context to include the *entire text*, preamble and annexes, as well as any connected agreements or instruments that have been made between or accepted by all parties. Additionally, designating Articles 7 and 8 as *objectives* and *principles* is a strong indication that these provisions are relevant for assessing the treaty's object and purpose.¹¹ In fact, this specific role for Articles 7 and 8 has subsequently been reinforced by the WTO Membership through the Doha Declaration on TRIPS and Public Health.¹²

Given that Member States took positive steps to include expressions of general intent within the operative section of the text, it is also remarkable that Articles 7 and 8 have received only minimal attention from the WTO Dispute Settlement Body (DSB).¹³ Much has been written about the DSB's insubstantial analysis and application of these provisions in *Canada – Patent Protection of Pharmaceutical Products*¹⁴ and *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*¹⁵. In both cases the panels acknowledge these provisions, but seem to accept them

¹⁰ Susy Frankel, 'WTO Application of "the customary Rules of Interpretation of Public International Law" to Intellectual Property' (2006) 46 Va. J. Int'l L. 366, 392. Andrew D Mitchell & Tania Voon, 'Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law, (2009) 43 J. World Trade 571, 573. A brief discussion of the good faith obligations, including good faith interpretation derived from Article 31.1 VCLT, can be found at the text accompanying footnotes 111-114. For a detailed discussion of the good faith obligations created by Article 7 please refer to Alison Slade, 'Good Faith and the TRIPS Agreement: Putting Flesh on the Bones of the TRIPS "Objectives"' (2014) 63 ICLQ 353.

¹¹ Susy Frankel, 'WTO Application of "the customary Rules of Interpretation of Public International Law" to Intellectual Property' (2006) 46 Va. J. Int'l L. 366, 392.

¹² WTO, 'Declaration on the TRIPS Agreement and Public Health – Adopted on 14 November 2001' (20 November 2001) WT/MIN(01)/DEC/2 [4] & [5].

¹³ In contrast, these articles have received significant attention from WTO political representatives and from the academic community. For example, see WTO, 'Communication from India – Clarifying TRIPS a Confidence-Building Measure' (6 October 2000) IP/C/W/214; WTO, 'Minutes of Meeting held on 28-29 February 2012' (15 May 2012) IP/C/M/69 [254]; Peter K Yu, 'The Objectives and Principles of the TRIPS Agreement' (2009) 46 Houston L. Rev. 979; Edson Beas Rodrigues Jr., *The General Exception Clauses of the TRIPS Agreement: Promoting Sustainable Development* (2012 CUP).

¹⁴ WTO, *Canada: Patent Protection of Pharmaceutical Products – Report of the Panel* (17 March 2000) WT/DS114/R (*Canada – Pharmaceuticals*).

¹⁵ WTO, *European Communities: Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs* (15 March 2005) WT/DS174 & 290/R (*EC – TMs & GIs*). For a critique of the DSBs application of Articles 7 and/or 8 in these cases see, Slade (n 9) 353-357.

as merely illustrative of the inherent characteristics of the international intellectual property system, having little, if any, legal value in their own right. While, the decisions in *Canada – Term of Protection*¹⁶ and *US – s211 Omnibus Appropriations Act of 1998*¹⁷ suggest a more active role, most notably with Article 7 acting as ‘a form of the good faith principle,’ neither panel takes the opportunity to provide a detailed understanding. Consequently, the following analysis undertakes a dissection of the legislative language within Articles 7 and 8 in order to better realise their meaning, relevance and application.

As stressed by the WTO Appellate Body, ‘The fundamental rule of treaty interpretation requires a treaty interpreter to read and interpret the *words actually used* by the agreement under examination.’¹⁸ As discussed above, the ordinary meaning attributed to the words used must be made in light of a treaty’s context, and object and purpose. Yet, if we follow the VCLT principle of treaty interpretation the analysis becomes somewhat circular – Articles 7 and 8 provide context, and object and purpose for the interpretation of the TRIPS Agreement, but it is necessary first to interpret these provisions before they can be utilised in that role. As observed by Buffard and Zemanek:

[When interpreting ‘programmatic’ provisions of a treaty it is] evident that the process of interpretation prescribed by Article 31 para.1 of the VCLT can only be used with modification for that end. It is not possible to be guided in the interpretation of a treaty by its object and purpose when those have to be elucidated

¹⁶ WTO, *Canada: Term of Patent Protection – Report of the Appellate Body* (18 September 2000) WT/DS170/AB/R.

¹⁷ WTO, *United States: Section 211 Omnibus Appropriations Act of 1998 – Report of the Panel* (6 August 2001) WT/DS176/R (US – s211).

¹⁸ WTO, *European Communities: Measures Concerning Meat and Meat Products (Hormones) – Report of the Appellate Body* (16 January 1998) WT/DS26/AB/R and WT/DS48/AB/R [181] (emphasis added).

first by interpreting the treaty.¹⁹

Yet, how are such provisions to be interpreted? The VCLT is silent on how to establish the object and purpose of a treaty, or how to interpret provisions that seek to express such general intent.²⁰ According to Sir Ian Sinclair, when seeking the object and purpose of a treaty ‘the text is the expression of the intention of the parties; and it is to that expression of intent that one must first look.’²¹ The following analysis will, therefore, be structured according to the individual textual elements expressed within Articles 7 and 8. Yet, Jan Klabbbers cautions against using text alone to define a treaty’s object and purpose:

[U]ndue reliance on the text alone may result in losing sight of the object and purpose of the treaty itself, and instead give rise to propositions relating to object and purpose of singular provisions or parts of provisions, thus resulting in a blunting of the analytical potential of the notion of object and purpose.²²

To avoid this interpretative trap, the analysis of the *specific* words and phrases will call upon other relevant materials to add authoritative meaning to the text. These sources include, *inter alia*, other provisions of the TRIPS Agreement; subsequent agreements between the parties; the wider WTO legal system; and the policy foundations of intellectual property protection and the multilateral trading system. While having recourse to a wide range of supporting materials, the author recognises that ‘introducing obligations through the back door of object and purpose, after those have been refused entry through the front door’ should be avoided.²³

¹⁹ Isabelle Buffard & Karl Zemanek, ‘The ‘Object and Purpose’ of a Treaty: An Enigma?’ (1998) 3 Aust. Rev. Int’l and Euro. L. 311, 333. See also, David S Jonas & Thomas N Saunders, ‘The Object and Purpose of a Treaty: Three Interpretative Methods’ (2010) 43 Vand. J. Transnat’l L. 565, 581-582.

²⁰ Marco Slotboom, *A Comparison of WTO and EC Law: Do Different Treaty Purposes Matter for Treaty Interpretation?* (Cameron May 2006) 53.

²¹ Sinclair (n 8) 131. This approach reinforces the Article 31.1 emphasis on the text as the primary source of interpretative guidance.

²² Jan Klabbbers, ‘Some Problems Regarding the Object and Purpose of Treaties’ (1997) 8 Finnish Yearbook of International Law 138, 157.

²³ Ibid 159.

This is especially so in light of Article 3.2 of the WTO Dispute Settlement Understanding (DSU) which makes it clear that the ‘Recommendations and Rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements.’²⁴ Therefore, in order to balance this interpretative caution against the need to operationalise Articles 7 and 8, the analysis remains firmly grounded in the language actually used, and the supporting materials are those that can be sensibly rationalised in the international IP context.²⁵ This is not to say that the following expresses the object and purpose of the TRIPS Agreement in its entirety; or that it is the definitive word on the interpretation and application of Articles 7 and 8. It is accepted that defining the object and purpose of a treaty ‘*in abstracto*’ will rarely produce a conclusive result.²⁶ Nevertheless, where directly expressed object and purpose exist, as with Articles 7 and 8, the hope is that by conducting a detailed analyses of the individual textual elements greater analogies can be made with existing legal rules and principles. This will augment existing academic writings to provide a meaningful insight into how these steering provisions can be given full effect by State Parties and those interpreting the TRIPS Agreement.²⁷

The replication of Articles 7 and 8 within the operative sections of other international and national intellectual property instruments underscores this growing need for a deeper understanding. The language of these provisions can now be found in the final text of the Trans-Pacific Partnership (TPP),²⁸ the Anti-Counterfeiting Trade Agreement (ACTA),²⁹ the

²⁴ Understanding on the Rules Governing Disputes 1994 (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 40, art 3.2.

²⁵ Nevertheless, Jan Klabbbers does note that indicators of object and purpose are wide ranging and in some cases even ‘intuition and common sense’ may provide useful guidance. Klabbbers (n 21) 155.

²⁶ Klabbbers (n 21) 160; Jonas & Saunders (n 18) 582. The authors note that the meaning of object and purpose depends not only on the treaty alone, but its application to a particular factual problem.

²⁷ Pedro Roffe (UNCTAD-ICTSD), *Resource Book on TRIPS and Development* (CUP 2005) 119-127; Yu (n 6) 982-992; Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th edn, Thomson, Sweet and Maxwell 2012) 227-241; Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (4th edn, Wolters Kluwer 2014).

²⁸ Trans-Pacific Partnership, Intellectual Property Chapter 18, articles 18.2 and 18.3. <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text> accessed 9 April 2016.

WIPO Development Agenda,³⁰ and the amended Indian Patents Act 1970.³¹ It is clear that despite an apparent wane in the influence of the TRIPS Agreement, due to the proliferation of bi-lateral and regional agreements,³² these structural provisions (and the aims and concerns articulated therein) are independently acquiring an ever wider relevance.³³ Reproducing these provisions advocates an enhanced legal and political status in both national and international IP norm setting for the objectives and principles contained therein.³⁴ While it may be somewhat premature to suggest that these provisions are a customary part of the international IP system, their growing use evidently necessitates a more detailed understanding.

As will be demonstrated below, fundamentally Articles 7 and 8 require those interpreting the TRIPS Agreement to look at interests beyond those directly related to the acquisition and enforcement of intellectual property rights.³⁵ In this regard, these provisions reflect, at the international level, the balancing of interests that has consistently been undertaken at the national level.³⁶ Given that Articles 7 and 8 acknowledge that intellectual property protection is inescapably aligned with other important national development objectives, it seems that, above all, they ought to reinforce national autonomy and, thus, deference to national policy choices.³⁷ As articulated by Graeme Dinwoodie and Rochelle Dreyfuss, ‘international [intellectual property] norms confine national policy choices, but they do not define

²⁹ Anti-Counterfeiting Trade Agreement, Final Draft (May 2011), article 2.3. <https://ustr.gov/acta> accessed 9 April 2016.

³⁰ WIPO, ‘The 45 Adopted Recommendations under the WIPO Development Agenda’ (October 2007) Recommendation 45. <http://www.wipo.int/ip-development/en/agenda/recommendations.html> accessed 9 April 2016.

³¹ India – s83 Patents Act 1970.

³² Henning Grosse Ruse-Khan, ‘Intellectual Property and Trade in a Post-TRIPS Environment’ in H. Ullrich, R.M. Hilty, M. Lamping and J Drexler, *TRIPS plus 20: From Trade Rules to Market Principles* (Springer 2015).

³³ Pires de Carvalho (n 26) 164.

³⁴ Alison Slade, ‘Articles 7 and 8 of the TRIPS Agreement: A Force for Convergence within the International IP System’ (2011) 14 JWIP 413.

³⁵ Jerzy Koopman, ‘Human Rights Implications of Patenting Biotechnological Knowledge’ in Paul L.C. Torresmans, *Intellectual Property and Human Rights* (Kluwer Law International, 2008) 546.

³⁶ Roffe (n 26) 119.

³⁷ TRIPS Agreement, art 1.1 states that ‘Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.’ See also WTO, *India: Patent Protection of Pharmaceutical and Agricultural Products – Report of the Appellate Body* (19 December 1997) WTO/DS50/AB/R [59] (*India – Pharmaceuticals*).

them.³⁸ It is only at the national level that the competing economic and social interests reproduced in these provisions can be reconciled. In that regard, Article 7 and 8 would appear to allow each State significant room to self-determine appropriate levels of intellectual property protection. Accordingly, the following analysis articulates a prevailing principle of national regulatory authority (subject to the WTO requirements of consistency, necessity and reasonableness).³⁹ This being the cardinal approach to effectively elucidating the objectives and principles of the TRIPS Agreement and to give them practical effect.

The observations made below will touch upon numerous topics, each provoking a myriad of issues and complexities, such as the precise interpretative impact on other provisions of the TRIPS Agreement or the support these provisions provide for a human rights framework within the context of the WTO. However, the intention here is not to address each of these issues in turn, but to specifically analyse the meaning and scope of the text of these provisions. It is only with a more comprehensive understanding of how Articles 7 and 8 may be interpreted that many of these intricate and complex questions will be better addressed by the WTO, its Member States, and all those that adhere to other national and international agreements in which these provisions are incorporated.

2. Article 7 - Objectives

Objective: - *Of or pertaining to the object or end as the cause of action.*⁴⁰

³⁸ Dinwoodie & Dreyfuss (n 3) 112.

³⁹ In April 2014, the Max-Planck Institute released a 'Declaration on Patent Protection'. It forcefully asserted that 'Sovereign states should retain the discretion to adopt a patent system that best suits their technological capabilities as well as their social, cultural and economic needs and priorities.' Max Planck Institute for Innovation and Competition, 'Declaration on Patent Protection: Regulatory Sovereignty Under TRIPS' (Munich, 15 April 2014) <https://www.mpg.de/8132986/Patent-Declaration.pdf> accessed 9 April 2016.

⁴⁰ *The Oxford English Dictionary* (OED) (2nd edn, OUP 1989).

As the dictionary definition suggests, the fundamental rationale of the TRIPS Agreement is to realise the aims as expressed within Article 7. For this reason Article 7 provides significant insight into that often posed question – what were the drafters’ intentions?⁴¹ It reminds us of the role that intellectual property rights play in incentivising creativity and innovation, yet alerts us to its detrimental side-effects. During negotiations many countries stressed the central role intellectual property protection plays in the process of innovation. Yet, many others, particularly developing countries, wished to recognise and also actively correct the negative impact that such protection may have on economic and social development.⁴² Therefore, Article 7 requires a middle ground to be reached that optimises innovation, promotes social and economic development, while at the same time lessening the detrimental consequences of intellectual property protection.

Article 7 is certainly not a comprehensive expression of all the goals of the TRIPS Agreement.⁴³ Nevertheless, it is the first attempt at defining the underlying rationale of a multilateral intellectual property instrument.⁴⁴ In short, Article 7 invokes, at the international level, many of the implicit balancing principles that have historically been fundamental to national levels of intellectual property protection.⁴⁵ Additionally, Article 7 unites these

⁴¹ Yu (n 12) 1022.

⁴² For an analysis of the negotiating history of the TRIPS Agreement see Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement* (Routledge 2002) 29-45; Gervais (n 26) 3-31.

⁴³ The Preamble is considered to contain the ‘general goals’ of the TRIPS Agreement, predominant amongst which is recital 1. However, these ‘general goals’ should be read in conjunction with the objectives expressed in Article 7. Henning Grosse Ruse-Khan, ‘Proportionality and Balancing within the Objectives for Intellectual Property Protection’ in Paul L C Torremans (ed), *Intellectual Property and Human Rights* (Kluwer Law International 2008) 173-175; Abdulqawi A Yusuf, ‘TRIPS: Background, Principles and General Provisions’ in Carlos M Correa and Abdulqawi A Yusuf, *Intellectual Property and International Trade: The TRIPS Agreement* (Kluwer Law International 2008) 11; Antony Taubman, Hannu Wager and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (CUP 2012) 12-13.

⁴⁴ Dinwoodie & Dreyfuss (n 3) 110.

⁴⁵ *Ibid.*

national principles with the broader objectives of the WTO as outlined in the recitals to the Agreement Establishing the World Trade Organisation.⁴⁶ Michael Spence observes that:

[L]ike the first recital to the Agreement Establishing the WTO, [Article 7] expresses a concern for increased global welfare. Similarly, like the second recital to the Agreement Establishing the WTO, it demonstrates a particular concern for developing countries which might be assumed to benefit most from the transfer and dissemination of technology.⁴⁷

Notwithstanding these comments, Spence draws attention to the difficulties inherent in a provision that promotes two highly contested functions of the intellectual property system – the promotion of innovation and the transfer and dissemination of technology. He argues that this makes Article 7 an inadequate tool with which to *identify* and *justify* the intellectual property rights that ought to be included in the TRIPS Agreement.⁴⁸ Could this be an underestimation of the drafters intended function(s) for Article 7? The provision is certainly concerned with validating the scope of the TRIPS Agreement, by assessing whether current intellectual property regimes can actually realise the stated objectives. However, in being the first provision within an international intellectual property instrument to articulate a set of guiding principles, Article 7 appears to be more widely concerned with the function and aims of the TRIPS Agreement within the legal systems of both the WTO and the individual Member States. It goes beyond providing an introduction to the scope of the Agreement, to prescribing a set of outcomes that are to guide the political and legal interpreters of the TRIPS Agreement. Hence, it seeks to achieve an optimal level of intellectual property protection aligned to distinct levels of economic and social development. Crucially, the

⁴⁶ Michael Spence. ‘Which Intellectual Property Rights are Trade-Related?’ in F. Francioni and M. Scovazzi (eds), *Environment, Human Rights and International Trade* (Hart 2001) 263, 265.

⁴⁷ *Ibid.*

⁴⁸ *Ibid.*, 265-274.

appropriate standard of protection will be achieved when the objectives listed in Article 7 are attained at the *national level*.⁴⁹

Accordingly, it would be misguided to argue that the objectives expressed in Article 7 require a rigid *international* optimisation of intellectual property standards. First, such an approach would misunderstand the nature of the TRIPS Agreement. It is an instrument which lays down a minimum set of intellectual property rules.⁵⁰ For instance, there is nothing within the Agreement which prevents Members from adopting higher thresholds of protection if Members determine that such would be more conducive to achieving the objectives set out in Article 7.⁵¹ More importantly the TRIPS Agreement includes numerous ‘flexibilities’ that, if interpreted in accordance with Articles 7 and 8, provide sufficient elbow room for Member States to tailor their intellectual property regimes to reflect their own unique economic and social circumstances.⁵² Secondly, optimal levels of intellectual property protection have been notoriously difficult to determine, measure and achieve even at the national level.⁵³ Consequently, any attempt to attain international optimisation would be naively optimistic and necessarily involve complex calculations of economic and social welfare that would prove impossible to resolve. As will be shown below, an analysis of the terminology utilised within Article 7 supports the state-centric nature of the balancing of interests required.

(a) The Terms of Article 7

⁴⁹ Wesley A Cann Jr, ‘On the Relationship Between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply Under A Theory of Progressive Global Constitutionalism’ (2004) 25 U. Pa. J. Int’l Econ. L. 755, 808; Dinwoodie & Dreyfuss (n 3) 111.

⁵⁰ Roffe (n 26) 35.

⁵¹ Article 1.1 states that, ‘Members may, but shall not be obliged to, implement in their law more extensive protection than is required by the Agreement, *provided that such protection does not contravene the provisions of this Agreement.*’

⁵² WIPO, ‘Advice on Flexibilities under the TRIPS Agreement’, http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html accessed 9 April 2016.

⁵³ Keith E Maskus, *Intellectual Property Rights in the Global Economy* (Institute for International Economics, 2000) 28.

(i) ‘The protection and enforcement of intellectual property rights...’

The opening phrase of this provision makes clear that the application of Article 7 extends not only to the scope and nature of the rights granted, but also to the enforcement measures covered by the TRIPS Agreement. More expansively, the focus of the provision is the broader impact of ‘intellectual property rights’, and not merely as a tool to reconcile one provision of TRIPS with another. This has led Peter Yu to conclude that: -

[Article 7] therefore anticipates further balancing within the larger international trading system. As the WTO Panel declared in *United States – Section 110(5) of the U.S. Copyright Act*, “the agreements covered by the WTO form a single, integrated legal system.” Because “[t]he proper balance of rights and obligations is an overriding objective of the WTO system,” the objectives and principles of the TRIPS Agreement need to be considered in relation to this particular objective.⁵⁴

Therefore, the objectives contained within Article 7 need to be explored not merely within the discrete application of the TRIPS Agreement but within the wider context of the WTO trading system. Viewed as a whole, the WTO structure regards an optimised trading system as one that acknowledges a wider purpose. As stated in the opening recital to Agreement Establishing the World Trading Organisation: -

Parties to this Agreement recogniz[e] that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while 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.⁵⁵

⁵⁴ Yu (n 12) 1007 -1008 (citations omitted).

⁵⁵ (adopted 14 April 1994, entered into force 1 January 1995) 1867 UNTS 154.

Recital 2 goes further in recognising that positive action needs to be taken to ensure that developing and least developed nations ‘secure a share in the growth of international trade commensurate with the needs of their economic development’. The Appellate Body has confirmed the unified framework and ‘single undertaking’ nature of the WTO Agreement,⁵⁶ thereby making the WTO’s development objectives applicable to all its Annexes, including the TRIPS Agreement.

Bearing in mind that intellectual property protection creates legal rights with monopolistic tendencies, it would be right to assume that the characterisation and scope of the rights involved should be determined in light of the public interest criteria mentioned above. Particular consideration should be given to the level of social and economic development of each State Party and any circumstances that requires the moderation of recognised rights. Any failure in this regard could undermine the legitimacy of international intellectual property regimes including TRIPS, the WTO and the multilateral trading system that it aims to facilitate.⁵⁷

(ii) ‘should contribute to...’

This phrase marks Article 7 as a provision which contains the primary aims or goals of the Agreement. The assumption is that upon implementation Member States should seek to

⁵⁶ WTO, *Brazil: Measures Affecting Desiccated Coconut-Report of the Appellate Body* (21 February 1997) WT/DS22/AB/R, 13-14.

⁵⁷ Graeme B Dinwoodie and Rochelle Cooper Dreyfuss, ‘WTO Dispute Resolution and the Preservation of the Public Domain of Science under International Law’ in Keith E Maskus and Jerome H Reichman (eds), *International Public Goods and the Transfer of Technology under a Globalized Intellectual Property Regime* (CUP, 2005) 883.

realize all the objectives contained within Article 7. Hence, this provision expresses standards expected of a successfully functioning intellectual property regime.

Much has been made about Article 7 being a ‘should’ provision rather than a ‘shall’ provision.⁵⁸ The argument maintains that the word ‘shall’ places a mandatory obligation on the parties to an agreement, yet the use of ‘should’ indicates a lesser obligation that only encourages parties to achieve the stated aims. This latter approach regards Article 7 as merely hortatory or aspirational in nature.⁵⁹ If we accept this distinction, then as a substantive provision the Article 7 objectives will always be superseded by ‘shall’ provisions or their equivalent.

However, it is generally accepted that the value of Article 7 rests in its ability to steer the interpretation of these ‘shall’ provisions and not to form the content of a substantive obligation.⁶⁰ If this is the case then the distinction appears to be irrelevant. It is not then a case of *weighing* discrete substantive provisions, but of *interpreting* the substantive provisions. The ‘should’ provision then adopts the role of determining what ‘shall’ be achieved. As observed by Pedro Roffe, in the UNCTAD-ICTSD Resource Book on TRIPS and Development, ‘[C]ountries *should* frame the applicable rules so as to promote technological innovation and the transfer and dissemination of technology “in a manner conducive to social and economic welfare.”’⁶¹ The ‘should’ in this instance recognises that the protection and enforcement of intellectual property rights does not always result in the various outcomes listed in Article 7, but that it ‘should’ do so.⁶² In fact, in some instances the

⁵⁸ Correa (n 5) 93; Yu (n 12) 1003; Gervais (n 26) 230.

⁵⁹ Rochelle Cooper Dreyfuss, ‘TRIPS-Round II: Should Users Strike Back?’ (2004) 71 Univ. Chicago L. Rev. 21, 22; Margaret Chon, ‘Intellectual Property and the Development Divide’ (2006) 27 Cardozo L. Rev. 2821, 2843.

⁶⁰ Correa (n 5) 93; Gervais (n 26) 239; Dinwoodie & Dreyfuss (n 3) 110.

⁶¹ Roffe (n 26) 126 (emphasis added).

⁶² Correa (n 5) 95.

protection of intellectual property rights will not encourage creative output⁶³ and can even stifle the innovation that it aims to promote. Consequently, Article 7 carries an interpretative function that directs the application of the Agreement to achieve the stated objectives. This makes the word ‘should’ central to the whole provision. Therefore, the ‘should’ in Article 7 indicates an obligation, the nature of which is interpretative rather than substantive.

The phrase ‘contribute to’ is also of note in the provision. Throughout the negotiation of the TRIPS Agreement the protection of intellectual property rights was often promoted as a panacea for many of the social and economic problems facing developing countries. In short, by implementing higher standards of national intellectual property protection, States would encourage corporations to transfer their products or services to the protecting state and even work them locally. This would lead to the transfer of technology to these nations, thereby advancing economic expansion and thus resulting in high standards of living and social development. Yet the expression ‘contribute to’ confirms that intellectual property protection can never be such a panacea. It can only be one of many factors that operate together to promote innovation and the dissemination of information and technology.⁶⁴ In this regard, Article 7 acknowledges the linkages that exist between intellectual property and other factors of development and requires that such protection is sympathetic to a State’s level of social and economic development.⁶⁵

(iii) ‘the promotion of technological innovation...’

⁶³ Carlos A Primo Braga, Carsten Fink and Claudia Paz Sepulveda, ‘Intellectual Property Rights and Economic Development’ (World Bank Discussion Paper No. 412, March 2000) 27-31 http://www-wds.worldbank.org/servlet/WDSContentServer/WDSP/IB/2000/05/13/000094946_00050206013672/Rendered/PDF/multi_page.pdf accessed 9 April 2016; Correa (n 5) 96-97.

⁶⁴ Pires de Carvalho (n 26) 181-182.

⁶⁵ *Ibid*, 100.

A primary justification for the intellectual property system is the incentive it provides for advancement in many fields. The introduction of the TRIPS Agreement extends that stimulus beyond national boundaries. The claim that intellectual property protection can promote innovation is premised upon the notion that protectable subject matter is a ‘public good’. Innovation, unlike real property, is non-exhaustible. Once produced it can be utilised extensively without depleting the social value of the original.⁶⁶ While this in itself is not especially problematic, the difficulties arise when the creator wishes to exclude others from its utilisation once the subject matter has been disclosed to the public. The new development or creation can often be reproduced with little cost or effort on the part of others, thus removing or severely limiting the market for the original product or process. By granting a set of exclusive rights, for a set period of time, rights holders are able to exclude others from commercially exploiting the protected subject matter. This enhances the opportunity to recoup the expenditure incurred in developing the product or service and increases the prospect of additional financial rewards by securing the market for the rights holder. Accordingly, in light of intellectual property protection, an individual or corporation can create and exploit the manifestation of their efforts secure in the knowledge that a competitor cannot ‘free-ride’ at their expense. This rationale behind intellectual property protection is often difficult to reconcile with those of free trade and its underlying philosophies – the former being ‘protectionist’ and the latter being ‘pro-competitive.’⁶⁷ Yet, it does reflect the view that intellectual property protection aims to serve the broader interests of society through the encouragement of innovation and creation, and the transfer of that knowledge to others.⁶⁸ This latter point will be considered in more detail below.

⁶⁶ William M Landes & Richard A Posner, *The Economic Structure of Intellectual Property Law* (Harvard University Press 2003) 11-25; Matthew Fisher, ‘Classical Economics and Philosophy of the Patent System’ (2005) IPQ 1, 4-5.

⁶⁷ Michael Trebilcock, Robert Howse & Antonia Eliason, *The Regulation of International Trade*, 4th edn (Routledge 2013) 518.

⁶⁸ Rodrigues (n 12) 44.

An important distinction has been made between the use of the term ‘technical innovation’ over that of ‘technical invention’.⁶⁹ The former is taken to refer to a fully functioning and marketable product that may take the form of an inventive and completely self-supporting product or process, or it may be an existing product or process that includes a newly inventive component. By contrast, the term invention is understood to characterize the early implementation of the new idea or concept itself, i.e. a model or prototype.⁷⁰ Thus, the TRIPS Agreement suggests that the intellectual property regime it defines is not merely concerned with incentivising creativity or inventiveness at its earliest stages, but with incentivising the production of new products or processes that can demonstrate some practical application and/or trading capability. *Prima facie*, this appears to run counter to the substantive rules of many national intellectual property systems, in particular patent law.

While patent law requires that a protectable invention demonstrate some utility,⁷¹ it is recognised that in many jurisdictions this is not an onerous prerequisite to patent grant.⁷² As long as the invention is *capable*⁷³ of some use in industry or agriculture, it is not necessary to provide evidence of actual operation in such a setting.⁷⁴ However, as mentioned above, Article 7 does not directly prescribe any substantive rules. Rather, it imposes a set of optimised outcomes. Innovation, as a useful end-product, yields the greatest benefits for

⁶⁹ Robert P Merges, ‘Commercial Success and Patent Standards: Economic Perspectives on Innovation’ (1988) 76 Calif. L. Rev. 805, 807; Jan Fagerber, ‘Innovation: A Guide to the Literature’ in Jan Fagerber, David C Mowery and Richard R Nelson (eds), *The Oxford Handbook of Innovation* (OUP 2005) 4-8.

⁷⁰ Merges (n 68) 807.

⁷¹ For a detailed analysis of the application of the utility requirement between states see Christopher Wadlow, ‘Utility and Industrial Applicability’ in Toshiko Takenaka (ed), *Patent Law and Theory: A Handbook of Contemporary Research* (Edward Elgar 2008) 355; Jay Erstling, Amy M Salmela & Justin N Woo, ‘Usefulness Varies by Country: The Utility Requirement of Patent Law in the United States, Europe and Canada’ (2012) 3 CYBARIS 1.

⁷² European Patent Convention, art 57 requires that ‘An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.’ For example, the UK Supreme Court has accepted that in the context of the biotech industry it was in some cases sufficient to demonstrate that industrial application was simply ‘plausible’. *Human Genome Sciences Inc v Eli Lilly and Co.* [2011] UKSC 51 [122]. See also a discussion of the ‘weak’ utility requirement in US law in E Richard Gold & Michael Shortt, ‘The Promise of the Patent in Canada and Around the World’ (2014) 30 CIPR 1, 31-37.

⁷³ TRIPS Agreement, art 27.1.

⁷⁴ The utility requirement within Canadian patent law has been defined as ‘a representation contained in a patent specification, whether implicit or explicit, that the patented invention *will achieve* one or more desirable, or will avoid one or more undesirable outcomes.’ Gold & Shortt (n 71) 3 (emphasis added).

society and it is this that underscores the Article 7 objective. Invention without application, while intellectually meritorious, is economically ineffective, as it does not provide the necessary financial incentives for further advancement. Yet, to impose too high a threshold of utility or industrial application could undermine the production of innovation. Although patent law sets a low threshold for industrial application it does so on the basis that too onerous a standard could undermine the next stated objective of the TRIPS Agreement, namely, dissemination. The granting of patents at the earlier stage of the innovation process encourages disclosure of the invention and thereby their subsequent utilisation in the ultimate quest for functional results.⁷⁵

Nevertheless, the claim that intellectual property protection can promote innovation is highly contested.⁷⁶ It has been noted that levels of intellectual property protection, as applied in the developed nations, is not likely to promote innovation in countries which do not have the necessary infrastructure and capabilities to support such activities.⁷⁷ In fact, by virtue of their monopolistic tendencies intellectual property rights can actually operate to suppress innovation in both developing and developed countries.⁷⁸ In this context Article 7 operates to facilitate an equilibrium between the incentivisation capacity of the intellectual property system and the negative impacts of monopolistic rights.⁷⁹

⁷⁵ Thus, many jurisdictions use the requirement of ‘sufficient disclosure’ or ‘enablement’ to indirectly supplement a weaker utility requirement, thereby simultaneously providing a safeguard against the patenting of inventions that lack utility and ensuring effective dissemination of the underlying knowledge. Gold & Shortt (n 71) 31-37.

⁷⁶ For an analysis of research in this area see Edwin Mansfield, ‘Patents and Innovation: An Empirical Study’ (1986) 32 *Management Science* 173; Adam B Jaffe and Josh Lerner, *Innovation and its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to do About it*, (Princeton University Press 2004); Josh Lerner, ‘150 Years of Patent Protection’ in Robert P Merges (ed), *Economics of Intellectual Property Law* (Edward Elgar 2007).

⁷⁷ Roffe (n 26) 126.

⁷⁸ The way in which IP protection operates to promote or suppress innovation is complex and is dependant upon many factors such as the strength and extent of protection; the nature of the product being protected; and the maturity of the relevant industry. Spence (n 45) 266-271; Jaffe and Lerner (n 75) Chapter 2.

⁷⁹ William D Nordhaus, *Invention, Growth, and Welfare: A Theoretical Treatment of Technological Change* (M.I.T. Press 1969) 76.

One further point that must be made is the curious limitation to certain types of subject matter – *technological innovation*. Interestingly, a broad definition of ‘innovation’, denoting ‘the introduction of novelties or the alteration of what is established by the introduction of new elements or forms,’⁸⁰ is wide enough to encompass all forms of creative activity, i.e. cultural, commercial or technological. Does this mean that Article 7 only has application when certain types of intellectual property are involved, i.e. patents, the layout designs of integrated circuits, certain trade secrets, and copyright when protecting technical creations such as software?⁸¹ This question is especially pertinent given that the reference to ‘technology’ is also repeated in other phrases within Article 7.

Correa writes that the terminology adopted may not signal a deliberate limitation by those negotiating the Agreement. In fact, it may have been a mere oversight on the part of the developing countries who, during negotiations, were preoccupied with the impact the protection of technology related innovation would have upon access to certain products and services.⁸² This reasoning is supported by paragraph 19 of the 2001 Ministerial Declaration.⁸³ This paragraph requires that the objectives and principles, as set out in Articles 7 and 8, guide the Council for TRIPS when examining the relationship between intellectual property and *non-technical* subject matter including traditional knowledge and folklore; and subject matter covered by the Convention on Biological Diversity. While there is no doubt that patent law is an important consideration in these relationships, other non-technical elements of intellectual property law, such as copyright, are also of relevance and are to be guided by the terms of Article 7. Furthermore, the latter objectives of Article 7 seemingly refer to *all* intellectual property rights within the TRIPS Agreement, requiring them to be applied in a ‘manner

⁸⁰ OED (n 39).

⁸¹ Correa (n 5) 92.

⁸² Ibid.

⁸³ WTO, ‘Ministerial Declaration – Adopted on 14 November 2001’ (20 November 2001) WT/MIN(01)/DEC/1 [19].

conducive to social and economic welfare’ and in a way that achieves ‘a balance of rights and obligations.’⁸⁴

Complications would also arise if Article 7 was deemed to have application for only technological innovation, as it would require a definition to be attributed to ‘technology’ for the purposes of the TRIPS Agreement. As documented by commentators and the courts, this approach is fraught with difficulties. Justine Pila observes that: -

[T]he term “technology”, which, and as social theorists have again recognized, is too opaque and elastic to be informative. Indeed, philosophers of technology have noted the “bewildering variety of ways of understanding the word ‘technology’”, and the difficulty of formulating a conception that is “neither so general that it risks vacuity by fitting every conceivable case, nor so specialized that it captures only a tiny range of the phenomena to be explained.”⁸⁵

However, one cannot ignore the possibility that the intention was to limit the application of Article 7 only to protectable technology. Yet this in no way diminishes importance of Article 7 as a structural provision for guiding those tasked with interpreting the substantive content of the treaty’s provisions. It only refines its scope.

(iv) ‘and to the transfer and dissemination of technology,...’

Another primary justification for intellectual property protection is the value it holds for the dissemination of knowledge and the transfer of technology both nationally and internationally. The utility of the intellectual property system rests not merely in protecting the interests of the rights holder, but in doing so for the wider public interest. The protection

⁸⁴ Denis Borges Barbosa, ‘TRIPS art. 7 and 8, FTAs and Trademarks’ (2006) 6.

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=889107 accessed 9 April 2016; Yu (n 12) 1000.

⁸⁵ Justine Pila, ‘On the European Requirement for an Invention’ (2010) 41 IIC 906, 918 (citations omitted). Justice Phelan of the Federal Court of Canada observes that to introduce a *technology test* ‘would be highly subjective and provide little predictability. Technology is in such a state of flux that to attempt to define it would serve to defeat the flexibility which is so crucial to the Act.’ *Amazon.com Inc v The Attorney General of Canada and the Commissioner of Patents* [2010] 86 C.P.R. (4th) 321 [71].

of intellectual property is often premised upon social contract theories: society grants the inventor or creator a selection of exclusive rights and in return the inventor or creator grants full disclosure – the ‘intellectual property bargain.’⁸⁶ Thus, the system is of wider interest to society who are now free to use that knowledge and information (albeit, subject to the requisite licensing arrangements). This in turn fosters further innovation, creation and improvement.

A distinction must be drawn between transfer and dissemination. While these two concepts are similar in their objectives – widening access to information – the transfer of technology has a greater connection with access to information through industry. Effective intellectual property protection reassures rights holders that their intellectual assets will be protected and thereby encourages a willingness to transfer valuable knowledge to others through, for example, licensing agreements and training programmes that see the rights holder and the recipient working in partnership.⁸⁷ Whereas, ‘dissemination’ appears to refer to both the informal mechanisms of information dispersal, such as internet transmission,⁸⁸ and the formal disclosure requirements of the intellectual property system itself, such as the ‘sufficiency’ requirement of patent law.⁸⁹

It is well documented that the promise of international technology transfer in return for stronger intellectual property standards was a key incentive for developing countries in accepting the incorporation of intellectual property regulation within the framework of the WTO.⁹⁰ Here Article 7 expressly integrates this objective within the text of the Agreement itself. This provision together with Articles 8.2 and 66.2 create a reciprocal obligation for

⁸⁶ Fisher (n 65) 20-24.

⁸⁷ Pires de Carvalho (n 26) 184-191.

⁸⁸ Correa (n 5) 99; Pires de Carvalho (n 26) 189-191.

⁸⁹ TRIPS Agreement, art 29.1.

⁹⁰ See, for example, Carlos M Correa, ‘Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?’ In Keith E Maskus & Jerome H Reichman (eds), *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* (CUP 2005) 227.

developed nations to actively facilitate technology transfer, particularly to those nations in need of assistance in generating a ‘sound and viable technological base.’⁹¹

However, once again the narrower understanding of Article 7, in promoting the transfer and dissemination of *technology*, may impact upon the scope of the provision. Nevertheless, the transfer and dissemination of protected subject matter which is not technological in nature may in fact lead to the transfer and dissemination of associated technological information and know-how via foreign direct investment in local production.⁹² As observed by Michael Spence, if a developing country provides strong copyright protection for the creative arts, such as film production or literary publishing, a foreign organisation may be willing to set up an operation in that country bringing with them the technological information and know-how of the industry.⁹³ In addition, the transfer and dissemination of protected technological subject matter may be dependant on adequate intellectual property protection for associated non-technological material, such as trade marks.⁹⁴ An organisation may be unwilling to licence patented technology without being secure in the knowledge that their marketing assets will also be adequately protected.

In summary, the inclusion of ‘*the transfer and dissemination of technology*’ in Article 7 seeks to remind those implementing and interpreting the Agreement that the principal objective of incentivisation cannot be understood in isolation from the equally important objective of dissemination. The diffusion of knowledge and information sought must also be understood to emanate from both formal and informal channels of communication. To ignore or subvert this objective would disturb the overriding public interest objectives of the whole intellectual property system.

⁹¹ WTO, ‘Implementation of Article 66.2, of the TRIPS Agreement: Decision of the Council for TRIPS of 19 February 2003’ (20 February 2003) IP/C/28 [1]; WTO, ‘Implementation-Related Issues and Concerns: Decision of 14 November 2001’ (20 November 2001) WT/MIN(01)/17 [11.2].

⁹² Spence (n 45) 272.

⁹³ Ibid.

⁹⁴ Ibid.

(v) 'to the mutual advantage of producers and users of technological knowledge...'

This objective seeks to refocus the nature of the Agreement. Whilst the Preamble states that an objective of the TRIPS Agreement is the 'effective and adequate protection of intellectual property rights',⁹⁵ this objective in Article 7 aims to reaffirm that higher standards of intellectual property protection are not an end in themselves.⁹⁶ Historical justifications for intellectual property protection regard the protection of rights holders' interests as a means to an end. That end being the wider interest of the public in having access to innovative technological and cultural products.⁹⁷ As discussed, intellectual property policy grants rights of exclusion in return for the adequate disclosure of the protected work.

In addition, this language in Article 7 draws a parallel with the substantive sections of the TRIPS Agreement. Here Article 7 is concerned with user access which is chiefly reflected in the 'exception' provisions, such as Article 13 (copyright), Article 17 (trade marks), and Article 30 (patents). Correa observes that 'users' in this context can be taken to mean both the consumers of end products and producers wishing to use the protected subject matter in their own production processes.⁹⁸ Therefore, not only does the TRIPS Agreement provide protection for producers of technological and cultural products, it also provides for the rights of the users of such products. Furthermore, 'users' of technological innovation could refer to many developing countries themselves. As net importers of protected technologies they are 'largely *users* of technologies produced abroad.'⁹⁹ This means that the requirement of

⁹⁵ TRIPS Agreement, preamble, recital 1.

⁹⁶ Roffe (n 26) 125.

⁹⁷ Edwin C Hettinger, 'Justifying Intellectual Property' (1989) 18 *Philosophy and Public Affairs* 31, 36.

⁹⁸ Correa (n 5) 99.

⁹⁹ Roffe (n 26) 126.

‘mutual advantage’ applies not only between producers and direct consumers, but also between producers and the broader interests of a developing state.

Having acknowledged that the TRIPS Agreement covers a range of competing interests, Article 7 rather obscurely identifies how those interests are to relate to one another. The Agreement is to be interpreted and applied ‘to the *mutual advantage* of producers and users’. Clearly the intention is to find a balance between the various interests that is *equally* advantageous to both producers and users.¹⁰⁰ Producers will wish to be guaranteed a sufficient period of exclusive protection to allow them to recoup their investment. Users will wish to gain access to the product as soon as possible to further their business or research. In the case of governments, they will wish to enhance the public interest as appropriate to their level of development. The balance to be drawn is a fine one and can be difficult to articulate. To overprotect creative and innovative products risks stifling further innovation and delays the entry of competition into the marketplace. Yet, a policy that too readily favours users’ access can weaken the incentive effect of intellectual property protection, and reduce innovative and creative output. Further, it could result in creative or technological advancements being protected by alternative legal means that do not directly facilitate the dissemination of information, i.e. trade secret law.¹⁰¹

The challenges to identifying the appropriate balance are polarised when intellectual property protection stands in the way of achieving important social welfare objectives. Nevertheless, it is important not to try to over-clarify the balance required. Over-clarification can result in rigidity in application and absurdity in outcomes. National development objectives as well as specific factual situations vary greatly. For example, patent protection is often promoted as vital for R&D in the pharmaceutical industry, which requires a period of

¹⁰⁰ Yu (n 12) 1007.

¹⁰¹ Gervais (n 26) 232.

exclusivity to recoup their substantial investment.¹⁰² However, the effect on those that require access to a particular drug is a question of degree and varies between states. In some instances the result is expensive, yet still accessible, healthcare medication, in others, individuals and governments are unable to purchase the necessary medication leading to debilitating and often catastrophic results.¹⁰³ Hence, national regulatory determinations in accordance with the level of social and economic development are to be respected when within the boundaries of international legal requirements.

(vi) ‘and in a manner conducive to social and economic welfare,...’

This phrase has been held to signify that ‘the recognition and enforcement of intellectual property rights are subject to higher social values.’¹⁰⁴ The protection of intellectual property, predominantly influenced by utilitarianism,¹⁰⁵ can never mean that *all* aspects of intellectual property protection will *always* be conducive to social and economic welfare. The rights that are granted by governments and legislature can and sometimes do have negative consequences, including the entrenchment of monopolistic practices that run counter to elementary economic policy. However, this is regarded as a ‘necessary evil’¹⁰⁶ that must be tolerated to bring about greater economic and social benefits. The granting of exclusive rights

¹⁰² See, for example, Harvey E Bale Jr, ‘Patent Protection and Pharmaceutical Innovation’ (1996) 29 NYUJ Int’l & Pol. 95; Henry Grabowski, ‘Patents, Innovation and Access to New Pharmaceuticals’ (2002) 5 JIEL 849. For a contrary perspective see Yi Qian, ‘Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978-2002’ (2007) 89 Review of Economics and Statistics 436.

¹⁰³ See generally, Ellen F M ‘T Hoen, ‘TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond’ (2003) <http://www.who.int/intellectualproperty/topics/ip/tHoen.pdf> accessed 9 April 2016. Whilst patents influence access to pharmaceuticals, it is important not to overemphasise its impact. Bryan C Mercurio, ‘Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines’ (2006) 5 NW. Univ. J. Int’l Hum. Rts. 1.

¹⁰⁴ Correa (n 5) 99.

¹⁰⁵ Maskus (n 52) 28; Landes & Posner (n 65) 11-36; Ruse-Khan (n 42) 174.

¹⁰⁶ The ‘evil’ of monopoly markets is however extensively regulated in most states by extensive competition law and from within IP regimes themselves.

incentivises further creation, innovation and improvement which are seen as desirable. The predominant objective is to achieve a balance between the problems that the scarcity of production creates with the benefits that intellectual property protection brings for encouraging creation.

(vii) ‘and to a balance of rights and obligations.’

The inclusion of this phrase confirms that intellectual property protection does not exist in a vacuum. Once again the emphasis is on recognising that protecting intellectual property rights is not the end objective,¹⁰⁷ but is to be balanced against other obligations arising both within the TRIPS Agreement and beyond.

Accordingly, Member States when implementing their obligations under the TRIPS Agreement must ensure that they do so in a manner that obtains the correct balance. When it comes to procedural obligations, the TRIPS Agreement provides some limited guidance as to what the correct balance between rights and obligations is to be. For example, Article 29 places a condition of disclosure on the grant of patents. However, beyond this procedural guidance, there is no definitive indication of what the correct substantive balance might be. We can look to other expressions within Article 7 which promote innovation, technology transfer and dissemination, and social and economic welfare, but again these merely establish a desired outcome without clear guidance for the obtaining the correct balance of rights and obligations.

That being said, it is possible to draw some guidance from the rest of the TRIPS Agreement. The individual subject matter sections of the TRIPS Agreement establish the

¹⁰⁷ Correa (n 5) 101.

nature of the rights that are to be granted. In turn, in each of the subject matter sections Members may provide for exceptions to the rights conferred. These exceptions are clearly meant to integrate obligations that arise to others, and that the Member State deems to be relevant for both economic and social welfare.¹⁰⁸ The exceptions to the substantive rights are generally cast in rather ambiguous terms, not making the relationship between the rights and exceptions particularly clear. Yet it is here that Article 7 may take on its most informative role. In interpreting the exceptions in the Agreement and their relationship with the rights granted, all the terms within Article 7 can work to guide the interpreter on how to achieve the correct balance of rights and obligations. The exceptions to the Agreement are the instruments through which the objectives contained within Article 7 are realised.¹⁰⁹ The interpretative function of Article 7 is supplemented by the same function in relation to Article 8 and by other provisions of the Agreement that seek to control the rights of the intellectual property owner, such as those relating to anti-competitive practices.¹¹⁰

Article 7 has broader application beyond balancing the rights and obligations that arise under the TRIPS Agreement itself. Concerns that arise in relation to rights and obligations occurring outside of the intellectual property and trade arena need to be observed as part of the application of Article 7. As noted by Cottier and Véron, an example of this broader balancing is expressed in Article 16.5 of the Convention on Biological Diversity. This requires cooperation between contracting parties to ensure that patents and other intellectual property rights ‘are supportive of and do not run counter to its objectives,’ while achieving compliance with national and international laws in the area.¹¹¹

¹⁰⁸ TRIPS Agreement, arts 13, 17, 24.4-24.9, 26.2, 27.2, 30 & 31.

¹⁰⁹ Sisule F Musungu, ‘The TRIPS Agreement and Public Health’ in Carlos M Correa and Abdulqawi A Yusuf, *Intellectual Property and International Trade: The TRIPS Agreement* (Kluwer Law International 2008) 434.

¹¹⁰ TRIPS Agreement, arts 31(k) & 40.

¹¹¹ Thomas Cottier and Pierre Véron, *Concise International and European IP Law: TRIPS, Paris Convention, European Enforcement and Transfer of Technology* (3rd edn, Kluwer Law International 2014) 31.

Notably, the decision of the Panel in *US – s211*¹¹² provides significant insight into what it means for states to achieve a ‘balance of rights and obligations.’ The Panel observed that:

[A]rticle 7 of the TRIPS Agreement states that one of the objectives is that “the protection and enforcement of intellectual property rights should contribute...to a balance of rights and obligations.” *We consider this expression to be a form of the good faith principle...* One application of this principle, the doctrine widely known as the doctrine of *abus de droit*, prohibits the abusive exercise of a state’s right.

In a previous paper, I have argued that this statement may lead Article 7 to be recognised as an effective source of legal obligations within the TRIPS Agreement, invoking both interpretative and substantive commitments under the principle of good faith.¹¹³ This is a significant development. It assimilates into the TRIPS Agreement legal concepts that are not explicit within the text, and expressly recognises Article 7 as their source. For example, by analysing the jurisprudence of the WTO it is possible to identify several good faith corollaries, such as *pacta sunt servanda* and the principles of effectiveness and legitimate expectations.¹¹⁴ These place obligations on all Member States when implementing the Agreement, and the judicial bodies when interpreting it.¹¹⁵ In addition, the doctrine of *abus de droit*, as a derivative of the good faith principle, may give rise to substantive obligations, even though such obligations are again not expressly acknowledged within the text of the Agreement. Consequently, by connecting Article 7 with the principle of good faith, the panel, in *US- s211*, legally obliges Member States and those interpreting the Agreement to conduct

¹¹² (n 16)

¹¹³ For a detailed analysis of the implications of the Panel’s decision in *US – s211* see Slade (n 9).

¹¹⁴ The principle of legitimate expectations within the context of the TRIPS Agreement, has been limited to non-violation complaints which are currently expressly excluded. *India – Pharmaceuticals* (n 36) 36-42. A moratorium against non-violation complaints is currently maintained in accordance with articles 64.2 and 64.3 TRIPS Agreement.

¹¹⁵ Slade (n 9).

‘a balancing of rights and obligations.’ This increases significantly the relevance of this provision and its future application.

However, it must be emphasised that Article 7 is not a tool for eroding the rights granted under the TRIPS Agreement, but for controlling those rights in a way that facilitates achieving the other objectives expressed in Article 7. As noted by Dinwoodie and Dreyfuss: -

[Article 7’s] endorsement of the goal of promoting technological innovation and achieving the “mutual advantage of producers and users” equally safeguards right holder’s interests in effective protection. Thus, a member state might challenge a provision that undermines the innovative environment on the ground that it shifts the balance too far in favor of users. Article 7 is, in short, not a commitment to any particular vision of intellectual property.¹¹⁶

Nevertheless, as noted above, it is a commitment to national autonomy: -

[Article 7] is a structural commitment that helps define the parameters in which members states can make different intellectual property choices appropriate to their needs.¹¹⁷

(b) Summary

Article 7 articulates the objectives of the intellectual property system that have up to this point been implicit within both national and international systems. Their express inclusion within the TRIPS Agreement therefore provides significant insight into the intentions of the drafters of the Agreement. As recognised by Pedro Roffe: -

In litigation concerning intellectual property rights, courts commonly seek the underlying objectives of the national legislator, asking the purpose behind establishing a particular right. Article 7 makes clear that TRIPS negotiators did

¹¹⁶ Dinwoodie & Dreyfuss (n 3) 111.

¹¹⁷ Ibid. See also Antony Taubman, *A Practical Guide to Working with TRIPS* (OUP 2011) 17.

not intend to abandon a balanced perspective on the role of intellectual property rights in society.¹¹⁸

The clear intention is to position intellectual property within the context of not only the WTO trading system but also the wider context of national development. Article 7 ensures that the objectives as stated are not forgotten or ignored in the push for internationally liberalised trade.

As a set of interpretative principles they permit and arguably require legislative and legal interpreters to target national intellectual property laws towards achieving the stated outcomes. They logically facilitate domestic flexibility over intellectual property strategy.¹¹⁹ Although Article 7 does not give authority to renegotiate the terms of the TRIPS Agreement,¹²⁰ it does authorise a degree of variation between Member States to accommodate other national and international policies. In its role towards promoting innovation, dissemination, social and economic welfare and a balance of rights and obligations, Article 7 displays an equal responsibility towards the protection of intellectual property rights and the wider economic and social impact. That responsibility would appear to be one that may carry with it legal consequences in the form of the principle of good faith.

3. Article 8 - Principles

***Principle:** -A fundamental truth or proposition, on which many others depend; a primary truth comprehending or forming the basis of, various subordinate truths; a general statement or tenet forming the (or a) ground of, or held to be essential to, a system of thought or belief; a fundamental assumption forming the basis of a chain of reasoning.¹²¹*

¹¹⁸ Roffe (n 26) 126.

¹¹⁹ Yusuf (n 42) 13.

¹²⁰ *Canada – Pharmaceuticals* (n 13) [7.25].

¹²¹ OED (n 39).

The dictionary definition of ‘principle’ seeks to emphasise the foundational nature of the proposition being advanced. It makes clear that a principle is to be regarded as the motivational force behind the line of thought or the course of action being championed. In this regard, Article 8 is complementary to Article 7 in that it underlines the motive and purpose of the TRIPS Agreement. Furthermore, if we take this understanding of principle and place it into the context of a legal agreement we can see that the more general understanding can now be refined into that of a legal norm.

Legal principles are recognized as ‘general, basic or underlying assumptions or precepts [that] embody fundamental regulatory purposes or values and provide a broad guide for the development of legal rules.’¹²² Hence, they are distinct from legal rules, which lay down a series of explicit rights and obligations that are ‘applicable in an all or nothing fashion.’¹²³ As highlighted in the dictionary definition above, principles articulate the fundamental basis or truth of any legal system.¹²⁴ In that regard, we can isolate two functions for legal principles. First, they encompass legal concepts that guide the application of the relevant rules. Secondly, they validate, justify and thus legitimise the scope of any legal regime. To ignore legal principles ‘implies offence not only to a specific command, but to the whole system of commands.’¹²⁵

As a guide to the application of legal rules, principles step in to fill the textual gaps that are an inevitable reality of any legal system. It is impossible to provide explicit guidance for every eventuality that might be encompassed by its rules.¹²⁶ This is especially so in the

¹²² Andrew D Mitchell, *Legal Principles in WTO Disputes* (CUP 2008) 7.

¹²³ Ronald Dworkin, *Taking Rights Seriously*, (Gerald Duckworth 1977) 24.

¹²⁴ For a detailed discussion on the distinction between rules and principles please refer to the renowned works of Ronald Dworkin (n 122) in particular 22-45; In a response to Dworkin see, Joseph Raz, ‘Legal Principles and the Limits of Law’ (1972) 81 *Yale L.J.* 823; John Braithwaite, ‘Rules and Principles: A Theory of Legal Certainty’ (2002) 27 *Aust. J. Leg. Phil.* 47; Mitchell (n 121) 7-23.

¹²⁵ Rodrigues (n 6) 44, quoting Celso Antonio Bandeira de Mello, *Curso de direito administrativo*, 17th ed (Malheiros 2004) 841-842.

¹²⁶ Mitchell (n 121) 2.

international arena where the inherent difficulties in reaching agreement on often complex subject matter leads to ambiguity or even silence in relation to many of the rights and obligations included.¹²⁷ Hence, the most significant role for legal principles rests in providing more or less broadly defined guidance for identifying the correct interpretation to be attributed to an ambiguous rule.

The TRIPS Agreement consists of both principles as well as rules. In the preamble to the TRIPS Agreement Members recognise ‘the need for new rules and disciplines concerning the provision of adequate standards and *principles* concerning the availability, scope and use of trade-related intellectual property rights’ and ‘the need for a multilateral framework of *principles*, rules and disciplines dealing with international trade in counterfeit goods.’¹²⁸ These principles exist in addition to the structural principles that traverse all WTO treaties, such as trade liberalisation, non-discrimination and special and differential treatment.¹²⁹

Therefore, it would appear fortunate for the process of treaty interpretation that, in addition to the substantive rules of the Agreement, Members took steps to define a set of ‘principles’ within the operative section of the text. These principles are to apply when a Member State chooses to adopt measures pursuant to the objectives expressed within Article 8. This approach would mirror that adopted in relation to other provisions within other WTO Agreements such as the General Agreement on Tariffs and Trade (GATT). For example, Article XXXVI of the GATT, entitled ‘Principles and Objectives’ has been held out as containing horizontally applicable principles. Notably, paragraph 8 expresses the principle of

¹²⁷ Joost Pauwelyn & Manfred Elsig, ‘The Politics of Treaty Interpretation: Variations and Explanations across International Tribunals’ in Jeffrey L Dunoff & Mark A Pollack (eds), *Interdisciplinary Perspectives on International Law and International Relations: The State of the Art* (CUP 2012) 447.

¹²⁸ TRIPS Agreement, Preamble, recitals 2(b) and 3 (emphasis added).

¹²⁹ Meinhard Hilf, ‘Power, Rules and Principles – Which Orientation for WTO/GATT Law?’ (2001) 4 J. Int’l Econ. L. 111, 117-121.

non-reciprocity¹³⁰ and, as stated in the explanatory notes, ‘This paragraph would apply in the event of action under Section A of Article XVIII, Article XXVIII, Article XXVIII *bis*,... Article XXXIII, or any other procedure under this Agreement.’¹³¹

Article 8, like Article 7, acknowledges the need for the socio-economic optimisation of intellectual property regulation. It implicitly recognizes that intellectual property protection often demands interventionist action to ensure that it does protect and/or promote social and economic objectives. Nevertheless, unlike Article 7, Article 8 expressly authorises State Parties to take specific action in pursuit of explicit, yet broadly defined, policy objectives.¹³² Consequently, Article 8 would appear to be of greater substantive value than its neighbouring provision, Article 7. As observed by Carlos Correa, ‘Article 8 thus confirms the broad and unfettered discretion that Members have to pursue public policy objectives.’¹³³

However, Article 8 was clearly not intended to be an exception to the exclusive rights granted by the Agreement. Both paragraphs of Article 8 require that any measures adopted by Member must be consistent with the rest of the Agreement. Yet, it is important to assert that the consistency requirement should not overwhelm the application of this provision. To argue otherwise portrays intellectual property protection as ascendant over other national policies, and risks making Article 8 a superfluous provision contrary to established principles of international law. This cannot be the case.¹³⁴ As will be shown from the analysis of the terminology adopted, Article 8 articulates to Member States the significant discretion, even in light of the consistency requirement, that they hold to accommodate other important socio-economic objectives. In doing so, it articulates principles that clearly assist in interpreting and

¹³⁰ Non-reciprocity means that ‘less-developed contracting parties should not be expected, in the course of trade negotiations, to make contributions which are inconsistent with their individual development, financial and trade needs.’ *Ad Article XXXVI Paragraph 8, General Agreement on Tariff and Trade (GATT) 1947, 55 UNTS 194.*

¹³¹ *Ibid.*

¹³² Correa (n 5) 108; Gervais (n 26) 237.

¹³³ Correa (n 5) 108.

¹³⁴ Slade (n 9) 363-371.

applying the substantive rules of the Agreement, most significant of which are *national regulatory autonomy, consistency, necessity and reasonableness*.

(a) The Terms of Article 8.1

(i) ‘Members may, in formulating or amending their laws and regulations, adopt measures necessary...’

The opening phrase of Article 8 plainly recognises the independence State Parties have to institute suitable measures to control some of the negative consequences of intellectual property protection. These can arise either as a result of an intentional manipulation of the system or as an intrinsic side-effect of granting exclusive rights protection. It also recognises that intellectual property rights should not form a barrier to the regulation of other social and economic policy objectives. Such measures include the adaptation of intellectual property laws themselves,¹³⁵ but may also include controls in other areas that impact upon the exercise of intellectual property rights, such as price controls and safety standards.¹³⁶ However, as the measures relate to the formulation or amendment of ‘laws and regulations’ it can be assumed that administrative actions could not be justified under Article 8.1.¹³⁷

The measures that may be taken could ostensibly support an increase in the levels of intellectual property protection. The key requirement being that the law is directed towards achieving the stated purposes, that is ‘to promote public health and nutrition, and to promote

¹³⁵ Aspects of TRIPS that provide flexibility for such measures include the exceptions to the rights granted (articles 13, 17 and 30); the lack of definitions for many of the substantive requirements (i.e. article 27 requires patentable subject matter to be *new*, involve an *inventive step* and be *capable of industrial application*); and in relation to patent law, article 31 provides for the grant of compulsory licences.

¹³⁶ Correa (n 5) 104; Andrés Moncayo von Hase, ‘The Application and Interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights’ in Carlos M Correa and Abdulqawi A Yusuf, *Intellectual Property and International Trade: The TRIPS Agreement* (Kluwer Law International 2008) 117.

¹³⁷ Pires de Carvalho (n 26) 195.

the public interest in sectors of vital importance to their socio-economic and technological development.’ This is supported by Article 1.1 which states that, ‘Members may, but shall not be obliged to, implement in their law more extensive protection than is required by the Agreement, *provided that such protection does not contravene the provisions of this Agreement.*’ For example, enhanced protection of traditional knowledge is directly aimed at attaining the stated objectives because it seeks to preserve traditional lifestyles and improve livelihoods, to conserve the environment, benefit national economies, and prevent bio-piracy.¹³⁸ Nevertheless, it is as an instrument to overcome the obstacles to development created by intellectual property protection that Article 8.1 could be most influential. Therefore, an effective operationalisation of this provision would likely see a reduction in the level of protection afforded.

The use of the term ‘necessary’ within Article 8.1 mirrors the wording within other WTO texts, where, as the ‘necessity test,’ it functions to control the autonomy State Parties have to ensure non-trade objectives.¹³⁹ It attempts to distinguish between, or at least lessen the impact of, those national measures that legitimately pursue a non-trade objective (and as a consequence create barriers to free trade) and those protectionist policies that merely masquerade as sanctioned trade exceptions. It does this by ensuring that domestic measures that restrict trade are only tolerated if they are ‘necessary’ to mitigate against the obstruction of a fundamental national policy objective. For this reason, it is evident that the necessity test

¹³⁸ Carlos M Correa, ‘Traditional Knowledge and Intellectual Property: Issues and Options Surrounding the Protection of Traditional Knowledge’ (2001) The Quaker United Office, 5-10. <http://www.geneva.quno.info/pdf/tkcol3.pdf> accessed 9 April 2016; Graham Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (Earthscan 2004) 97-100.

¹³⁹ Key WTO provisions that contain a ‘necessity’ requirement include Articles XX and XI of the GATT; General Agreement on Trade in Services (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 Agreement on Technical Barriers to Trade (TBT); Articles 2.2 and 5.6 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS); Articles 3.2, 8.1 and 27.2 of the TRIPS Agreement; and Article 23.2 of the Agreement on Government Procurement.

in Article 8.1 is a limitation placed on Member States when acting under the authority of this provision. The other being the ‘consistency’ proviso, which will be discussed below.

‘Necessity’ as interpreted by the WTO Dispute Settlement Body (DSB) objectively requires that the domestic measure pursue a policy expressed within the relevant provision. In the case of Article 8.1 that means public health and nutrition, and/or the promotion of the public interest in sectors of vital importance to socio-economic and technological development. However, the jurisprudence of the WTO dictates that domestic measures which restrict trade will only be considered necessary (and thus WTO compliant) where, as summarised by Ruse-Khan, ‘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.’¹⁴⁰ The Appellate Body has confirmed that it is not essential to show that the measure is ‘indispensable’ to achieving the objective, a more lenient and deferential approach has been adopted. In *Korea – Measures Affecting Imports of Fresh Chilled and Frozen Beef*, the Appellate Body confirmed that it involved a ‘weighing and balancing’ of several factors including, ‘the contribution made by the compliance measure to the enforcement of the law or regulation at issue, the importance of the common interests or values protected by that law or regulation, and the accompanying impact of the law or regulation on imports or exports.’¹⁴¹

The Appellate Body in *United States - Standards for Reformulated and Conventional Gasoline* has acknowledged that the policy objective pursued by State Parties is not the focus of the necessity requirement, but the measure adopted to pursue that objective is. This approach leaves Members free to determine their own policies in relation to objectives

¹⁴⁰ Henning Grosse Ruse-Khan, ‘Assessing the need for a General Public Interest Exception in TRIPS’ in Annette Kur (ed) *Intellectual Property Rights in a Fair World Trade System* (Edward Elgar Publishing 2011) 173 (emphasis added). For a detailed analysis of the DSB’s approach to the necessity test see Rodrigues (n 12) 44-63.

¹⁴¹ WTO, *Korea: Measures Affecting the Imports of Fresh, Chilled and Frozen Beef – Report of the Appellate Body* (11 December 2000) WT/DS161/AB/R and WT/DS169/AB/R [164].

expressed.¹⁴² The level of self-determination was further enhanced in *European Communities - Measures Affecting Asbestos and Asbestos-Containing Products* when the Appellate Body confirmed that State Parties also retain the ‘right to determine the *level of protection* [in relation to the relevant policy] that it considers appropriate in a given situation.’¹⁴³

Having observed that the policy objective is not justiciable, only the measure itself, it is important to note that the underlying policy is considered relevant when adjudicating on the necessity of the measure in question.¹⁴⁴ The ‘weighing and balancing’ exercise offsets the relative importance of the national interest being advanced against the effectiveness of the measure and the extent of its impact upon trade.¹⁴⁵ Sarah Joseph has observed that in the above cases ‘the Appellate Body has signalled a great willingness to concede the necessity of impugned measures when public health issues are at stake.’¹⁴⁶ As considered below, this is significant for the application of the necessity test in Article 8.1, where ‘public health’ is prominent amongst the listed objectives. And while the WTO has stressed that Members must ‘respect the requirements of the *General Agreement* and the other covered agreements,’¹⁴⁷ one would assume this includes the necessity requirement, which clearly mitigates the level of ‘respect’ commanded when acting in the interests of public health and the other interests outlined in Article 8.1.

Much of the case law in this area deals with the necessity standard as required by the ‘General Exception’ provisions in Article XX(b) and (d) of the GATT, and Article XIV of the GATS. However, it would not be accurate to presume that the interpretation applied to the

¹⁴² *US – Gasoline* (n 7) 29. WTO, “‘Necessity Tests’ in the WTO: Note by the Secretariat’ (2 December 2003) S/WPDR/W/27 [12].

¹⁴³ WTO, *European Communities: Measures Affecting Asbestos and Asbestos-Containing Products – Report of the Appellate Body* (12 March 2001) WT/DS135/AB/R [168].

¹⁴⁴ Panagiotis Delimatsis, ‘Who’s Afraid of Necessity? And Why it Matters?’ in Aik Hoe Lim and Bart De Meester. *WTO Domestic Regulation and Services Trade: Putting Principles into Practice* (CUP 2014) 97-98.

¹⁴⁵ *Ibid* 98.

¹⁴⁶ Sarah Joseph, *Blame it on the WTO? A Human Rights Critique* (OUP 2011) 113. See also Adam McBeth, *International Economic Actors and Human Rights* (Routledge 2010) 125.

¹⁴⁷ *US-Gasoline* (n 7) 29; WTO “‘Necessity Tests’” (n 141) [12].

necessity requirement in these instruments can be directly transposed onto the TRIPS Agreement. In fact it has been supposed that the necessity requirement in Article 8.1 is not as restrictive as that in Article XX of the GATT.¹⁴⁸ This is because Members, in ‘promot[ing] the public interest in sectors of vital importance to their socio-economic and technological development’, would appear to have ‘significant room to define domestically the content and scope of the measures they can adopt.’¹⁴⁹ The broad mandate expressed in Article 8.1 is also supported by the Doha Declaration on TRIPS and Public Health, which declares that ‘the TRIPS Agreement does not prevent Members from taking measures to protect public health.’ It is also noteworthy that State Parties did not deem it necessary to restrict state action in this regard by including a requirement of necessity within the Doha Declaration.¹⁵⁰

This understanding aside, it would be wrong to jump to the conclusion that Article 8.1 is an ‘exceptions’ provision like Article XX of the GATT and Article XIV, GATS. Whilst all three articles include a list of potentially trade-restrictive measures that Members may adopt together with a necessity requirement, it is only the General Exceptions in the GATT and GATS that allow Members to directly override their obligations under the Agreements.¹⁵¹ Article 8.1 is constrained by the requirement that all measures must be ‘consistent with the provisions of this Agreement.’¹⁵² As a result, it would appear that Members may only adopt such public interest measures if they can find sufficient space within the TRIPS provisions to do so.¹⁵³

¹⁴⁸ WTO “Necessity Tests” (n 141) [4]. In contrast, Panagiotis Delimatsis states that ‘the GATT/WTO interpretation of the concept of necessity has converged across the WTO Agreements.’ Yet, his analysis only considers the GATT, GATS, TBT and SPS Agreements, with no reference being made to the TRIPS Agreement. Delimatsis (n 143) 96.

¹⁴⁹ Correa (n 5) 107.

¹⁵⁰ WTO, Declaration on the TRIPS Agreement and Public Health (n 11); Yu (n 12) 1016.

¹⁵¹ The measures that can be taken under Article XX of the GATT must conform to the ‘chapeau’ to avoid arbitrary or unjustified discrimination. A similar proviso is included in Article XIV of the GATS.

¹⁵² Roffe (n 26) 126; Gervais (n 26) 238.

¹⁵³ Ruse-Khan (n 139) 195.

Therefore, while the underlying function of the necessity test is to constrain the amount of discretion Member States have in relation to public policy objectives, its limiting affect may be inconsequential by comparison to the obligation of TRIPS consistency. Hence, if a measure is consistent with the TRIPS Agreement it is unlikely to be challenged irrespective of its ‘necessity’ to achieve the stated objective.¹⁵⁴ Nevertheless, the ‘necessity’ requirement may have greater application should non-violation complaints become recognised within the context of the TRIPS regime.¹⁵⁵

Unlike violation complaints which involve a breach of the terms of a WTO treaty, non-violation complaints arise where a state alleges that the expectation of a ‘benefit accruing to it directly or indirectly ...is being nullified or impaired’ or ‘the attainment of any objective of the Agreement is being impeded’ by ‘the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement.’¹⁵⁶ Therefore, Member States may bring a complaint before the DSB where the action being taken by another Member is not illegal *per se* (does not violate an express treaty term), yet it does deny a legitimately expected gain arising from the Agreement.

Notwithstanding the present inapplicability of non-violation complaints in the context of the TRIPS Agreement, it is clear that Article 8 may prove to be most valuable in this context. Member States who wish to adopt TRIPS consistent measures pursuant to the objectives expressed within this provision, such as price controls, licensing restrictions or packaging requirements, can use this provision as a defence against a claim that they were impairing the

¹⁵⁴ Pires de Carvalho (n 26) 117.

¹⁵⁵ A moratorium against non-violation complaints is currently maintained in accordance with articles 64.2 and 64.3 TRIPS Agreement.

¹⁵⁶ GATT, art. XXIII. This article also provides for ‘situation complaints’. However, there is currently no jurisprudence on the application of this provision to the GATT and it has been suggested that these complaints are of little if any relevance. Petros C Mavroidis, ‘Remedies in the WTO Legal System: Between a Rock and a Hard Place’ (2000) 11 EJIL 763, 790-791. Therefore, situation complaints will not be covered in this analysis.

legitimate benefits expected under the TRIPS Agreement.¹⁵⁷ As explained below, Article 8 is an expression of the expectations of Members in relation to the Agreement and thus ‘indicates that [Members] were reasonably expected to adopt such TRIPS-consistent measures.’¹⁵⁸ The only restraint that could have a significant bearing would be the ‘necessity test’. This would operate to ensure that the adopted measure did not exceed what was objectively justified in the circumstances.

(ii) ‘to protect public health and nutrition,...’

Article 8.1 makes clear that the measures taken by Member States are to be directed to achieving certain ends, the first being to protect public health and nutrition. As stated by the 2001 Doha Declaration on TRIPS and Public Health: -

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 reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.¹⁵⁹

This Declaration supports the ability of State Parties to take measures in support of public health¹⁶⁰ that may, in fact, limit the grant and protection of intellectual property rights.

¹⁵⁷ Frederick M Abbott, ‘Non-Violation Nullification or Impairment Causes of Action under the TRIPS Agreement and the Fifth Ministerial Conference: A Warning and Reminder’ (2003) Quaker United Nations Office, Occasional Paper No. 11, 2. <http://www.geneva.quino.info/pdf/QP11-nv.pdf> accessed 9 April 2016.

¹⁵⁸ Frederick M Abbott, ‘The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference’ (2001) Florida State University College of Law, Public Law and Legal Theory Working Paper no. 36, 26. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=285934 accessed 9 April 2016.

¹⁵⁹ WTO, Declaration on the TRIPS Agreement and Public Health (n 11) [4].

Nevertheless the scope of Members' discretion is seemingly constrained by the second sentence in the Declaration which acknowledges the use of flexibilities within the Agreement itself for achieving their public health objectives.¹⁶¹ This interpretation would appear to be in harmony with the requirement in Article 8.1 that any national measures are consistent with the provision of the TRIPS Agreement. However, as will be discussed below, this may not be so restrictive as it first appears.

(iii) 'and to promote the public interest in sectors of vital importance to their socio-economic and technological development, ...'

This is the second purpose to which Member State Parties may direct their necessary measures. It is immediately evident that national measures, in this context, need only 'promote' the public interest rather than actually achieve the stated objective.¹⁶² As a result, any challenge to the legitimacy of such action will be much harder to establish. It is also clear from the language used that this second objective is extremely broad in its scope. Given that the measures adopted may include those within the scope of the intellectual property regime and those without, Carlos Correa has highlighted the significant room this provides for States when implementing and adapting their intellectual property policies.¹⁶³

The 'public interest' is a phrase often used to rationalise political, governmental and legal decision making at both the national and international level.¹⁶⁴ Yet, it is a concept that

¹⁶⁰ Public health in this context must be given a broad meaning. It should extend beyond pharmaceutical products to incorporate all IP that has some application within the public health sector. Pires de Carvalho (n 26) 209.

¹⁶¹ Roffe (n 26) 132.

¹⁶² Correa (n 5) 105.

¹⁶³ Correa (n 5) 105-106. See also Ruse-Khan (n 139) 173; Roffe (n 26) 127.

¹⁶⁴ John D Montgomery, 'Public Interest in Ideologies of National Development' in Carl J Friedrich (ed), *The Public Interest* (Atherton Press 1962) 220.

appears devoid of a precise definition.¹⁶⁵ The Oxford English Dictionary identifies it as ‘the common well-being’¹⁶⁶ and is broadly understood to convey the message that the action or inaction in question has been undertaken because society, as a whole, will derive a benefit. As we have seen, intellectual property and trade are certainly sectors within which the public interest can be advanced. However, the TRIPS Agreement does not attempt to define any optimum levels of well-being to be targeted. In fact, it would be wrong to suppose that the ‘public interest’ could be subject to an internationally recognised measure or definition. While political debates and judicial interpretations often provide context specific understandings of the term,¹⁶⁷ perceptions of ‘common well-being’ and the philosophical origins of the ‘public interest’ inevitably vary amongst states. National perceptions of public interest are tied to economic, cultural, political and historical influences that are as numerous as they are variable.¹⁶⁸ Accordingly, it is a reference point that policy makers can only legitimately begin to determine at the national level.¹⁶⁹

Turning to the phrase ‘of vital importance,’ once again it is only the individual Member States that can determine which sectors are of vital importance to their own socio-economic and technological development and thus where to take relevant action. While the term ‘vital importance’ would seem to stress the imperative nature of the sector in question, it is only the Member State who can determine which sectors are important to ‘*their* socio-economic and technological development.’¹⁷⁰ As observed by Peter Yu, the only significant restriction on scope seems to come from within Article 27.1 of the patent provisions of the TRIPS Agreement, which requires non-discrimination as to ‘the place of invention, the field of

¹⁶⁵ Gerhard Colm, ‘The Public Interest: Essential Key to Public Policy’ in Carl J Friedrich (ed), *The Public Interest* (Atherton Press 1962) 115.

¹⁶⁶ OED (n 39).

¹⁶⁷ Colm (n 164) 127.

¹⁶⁸ Montgomery (n 163) 218.

¹⁶⁹ Roffe (n 26) 127; Correa (n 5) 105.

¹⁷⁰ Correa (n 5) 106; Pires de Carvalho (n 26) 196 (emphasis added).

technology and whether products are imported or locally produced.’¹⁷¹ Although, he does emphasize that this may not be relevant where sectors are identified not on the basis of their technological specialism, but on their size or stage of development, i.e. infant or small to medium-sized businesses.¹⁷²

Finally, the phrase ‘socio-economic and technological development’ must be seen to cover all aspects of a nation’s growth, and reflects the objectives outlined in the fifth recital of the Preamble to the Agreement.¹⁷³ It is difficult if not impossible to conceive of an area of development that would not fall within the categories of social, economic or technological; or an area of intellectual property that would not be impacted by action taken under Article 8.1.¹⁷⁴ When deciding whether a sector is of ‘vital importance’ it is therefore possible for a Member State to look beyond the traditional indicators of development, such as Gross Domestic Product, income levels and total employment, and towards social indicators such as levels of health and education.¹⁷⁵ As discussed above in relation to Article 7, technological development is a fundamental objective of intellectual property protection and the TRIPS Agreement. Yet, Article 8.1, together with Article 7, underscores that intellectual property protection can never prevail where to do so undermines other development objectives.

(iv) ‘provided that such measures are consistent with the provisions of this Agreement.’

This has proved to be the most controversial expression within this provision. Article 8 makes national autonomy to adopt appropriate measures conditional upon their compliance with the rest of the Agreement. At first sight it would be reasonable to conclude that Article

¹⁷¹ Yu (n 12) 1011.

¹⁷² Ibid, 1011-1012.

¹⁷³ Cottier and Véron (n 110) 32.

¹⁷⁴ Cottier and Véron (n 110) 33.

¹⁷⁵ Correa (n 5) 106.

8.1 is therefore almost redundant in application. However, this conclusion is drawn from too strict a reading of the proviso. While Article 8.1 may not be a ‘general exception’ provision analogous to Article XX of the GATT, this does not mean that the provision is of insignificance. Together with Article 1.1 and Article 7, this provision has been described as a ‘functional substitute’ to the General Exception provision of the GATT.¹⁷⁶ Like Article 7, Article 8 has an interpretative function.¹⁷⁷ It guides the national legislator when faced with implementing the often ambiguously worded substantive rules of the TRIPS Agreement. If we analyse the consistency requirement of Article 8 in light of the conditions placed upon the grant of exceptions to the exclusive rights, we can see that ‘consistency’ may not, in fact, be so hard to achieve given the uncertain nature of the exception provisions. For example, copyright limitations and exceptions should ‘not conflict with the normal exploitation of the work’;¹⁷⁸ copyright and trade mark exceptions must ‘take account of the legitimate interests of the owner’;¹⁷⁹ and patent exceptions must ‘not unreasonably conflict with the normal exploitation’ of the right and must ‘not prejudice the legitimate interest of the owner, taking account of the legitimate interests of third parties.’¹⁸⁰ In this interpretative role, Article 8 skews in favour of the wider public interest when it comes into conflict with intellectual property policy.¹⁸¹ How the exceptions within the TRIPS Agreement are interpreted is important for giving practical application to the principles expressed in Article 8.¹⁸²

In addition, Article 8 governs the interaction between intellectual property regulation and measures taken outside of intellectual property law and policy, for example competition regulation and public health. Correa notes that it would be illogical to suppose that the consistency requirement should prevent any TRIPS-inconsistent measures to protect the

¹⁷⁶ Dinwoodie & Dreyfuss (n 3) 89.

¹⁷⁷ Roffe (n 26) 126; Abbott (n 157) 27.

¹⁷⁸ TRIPS Agreement, art 13

¹⁷⁹ Ibid, arts 13 and 17

¹⁸⁰ Ibid, art 30.

¹⁸¹ Moncayo von Hase (n 135) 119.

¹⁸² Musungu (n 108) 434.

national interests outlined in Article 8.1, as this would see intellectual property rights gain ascendancy over other national policy objectives.¹⁸³ In support of this opinion, the Doha Declaration on TRIPS and Public Health affirms that the TRIPS Agreement does not prevent Members from taking measures to protect public health. Yet, as discussed, this is seemingly limited by the second sentence of paragraph 4, which reaffirms the right of Members to use the flexibilities within the TRIPS Agreement for this purpose. In addition, the Doha understanding only relates to matters of public health and is not directly relevant for the other policy objectives expressed within Article 8.1.¹⁸⁴ In these situations there is no express support for dispensing with the consistency requirement. Nevertheless, Correa is right to argue that intellectual property protection should and does not assume primacy over other policies. In which case, it may be better to acknowledge that the consistency requirement is there not because negotiators intended intellectual property rights to trump other national policies, but as an indicator that there is sufficient room within the other provisions of the TRIPS Agreement to accommodate those policies whilst also respecting the protection of intellectual property rights.¹⁸⁵ Therefore, returning to the first point above, Article 8.1 is an interpretative tool that asserts the rights of Members to favour other policies should the national situation so dictate, and that any challenge to Members discretion should carry the burden of establishing that the measure is inconsistent with the TRIPS Agreement.¹⁸⁶ As observed by Andres Moncayo von Hase, ‘Articles 7 and 8 impose on Members the correlative obligation to refrain from questioning acts of other Members that make use of the

¹⁸³ Correa (n 5)108.

¹⁸⁴ Dinwoodie & Dreyfuss argue that ‘While the declaration was made in the context of a health crisis and precipitated an amendment to the Agreement, [it] was...not confined to that context and was viewed as explaining-not modifying-the Agreement’ (n 3) 110. In which case, the ability of Members to derogate from their obligations under TRIPS extends not only to public health, but also to the other policy objectives listed. Pires de Carvalho (n 26) 206-213.

¹⁸⁵ As noted by Dinwoodie & Dreyfuss, ‘[The consistency] language is puzzling but it is highly significant because, in fact, it confirms that the Agreement as a whole is flexible and furnishes states with considerable room to manoeuvre.’ (n 3)111.

¹⁸⁶ Roffe (n 26) 126; Correa (n 5) 108.

freedom conferred to them by the said provisions.’¹⁸⁷ Consequently the consistency proviso appears to merely determine the outer limits of that discretion rather than removing it completely.¹⁸⁸

Importantly, when assessing the consistency of such measures it must be remembered that Article 7, and its requirements of social and economic welfare and a balance of rights and obligations, must be taken into account as the objectives of the TRIPS Agreement.¹⁸⁹ ‘Consistent with the provisions of this Agreement’ means all the provisions, including Article 7. Therefore, the consistency enquiry cannot ignore that the optimum levels of intellectual property protection relate to national levels of development, as required by Article 7, which must necessarily include ‘public health and nutrition’ and ‘socio-economic and technological development.’ A national measure which may appear inconsistent with some of the standards expressed within the TRIPS Agreement may not be considered inconsistent with the Agreement if read as a whole.¹⁹⁰

In conclusion, the consistency requirement means that Article 8.1 is not a General Exceptions provision akin to Article XX of the GATT, as it does not generally authorise Members to override the obligations under the TRIPS Agreement (notwithstanding that the Doha Declaration on TRIPS and Public Health may make an exception for public health policies) and it appears to have no substantive application on its own.¹⁹¹ However, it does not prevent Members from adapting their intellectual property laws to accommodate the stated policy concerns where ambiguity or flexibility exists within the substantive provisions of the Agreement. As long as one or more of the stated objectives is the genuine intention behind

¹⁸⁷ Moncayo von Hase (n 135) 118.

¹⁸⁸ Yusuf observes that, ‘The consistency test was apparently considered necessary in view of the broad nature of the public interest principle.’ (n 42) 14.

¹⁸⁹ Correa (n 5) 104 & 110; Yu (n 12) 1014; Dinwoodie & Dreyfuss (n 3) 110-111.

¹⁹⁰ Yusuf (n 42) 14.

¹⁹¹ Cottier and Véron (n 110) 32.

the measure and is not a disguised attempt to weaken the protection provided by the TRIPS Agreement, states are free to act.¹⁹²

(b) Article 8.2

(i) ‘Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed...’

While Article 8.1 authorises measures ‘of a positive nature’, Article 8.2, authorises Member States to take ‘defensive’ action to prevent or resolve any adverse consequences created by the behaviour of intellectual property rights owners.¹⁹³ As with Article 8.1, this provision requires that national measures taken upon the authority of this provision must be consistent with the rest of the Agreement. Therefore, competition law should not be used as a hidden restraint on the rights provided by the TRIPS Agreement.¹⁹⁴ In this regard, the discussion in relation to the consistency proviso in Article 8.1 is equally relevant here.

One noticeable difference between the authorisation provided by Articles 8.1 and 8.2 is that the former requires such measures to be ‘necessary’, whereas the latter requires the measures to be ‘appropriate’ and ‘needed’. Given that the term ‘necessary’ denotes a specific legal norm within the WTO and ‘appropriate’ does not, it is possible to presume that Members may be afforded greater autonomy when it comes to adopting measures under Article 8.2, subject to the consistency requirement. Gervais advances the argument that “‘appropriate” refers to the need for correlation between the measure (nature and

¹⁹² Dinwoodie & Dreyfuss (n 3) 111.

¹⁹³ Correa (n 5) 110.

¹⁹⁴ Frederick M Abbott, ‘Are the Competition Rules in the WTO TRIPS Agreement Adequate?’ (2004) 7 J. Int’l Econ. L. 687, 692.

proportionality) and the abuse or unreasonable restraint that is its target.’¹⁹⁵ If this ‘correlation’ requires a proportionality type assessment similar to that discussed in relation to the ‘necessity’ test then there would seem little reason for departing from the terminology adopted in Article 8.1.¹⁹⁶ Hence, it would seem logical, and in accordance with principles of treaty interpretation, to conclude that ‘appropriate’ signifies a lesser level of scrutiny for national measures. An alternative explanation for this distinction may be that, unlike the policy objectives listed in Article 8.1, the control of anti-competitive practices in contractual arrangements is covered in some detail by Article 40 of the Agreement. This makes it unnecessary for Article 8.2 to include a further limitation when the discretion afforded to Member States is controlled by another provision. Although, it must be noted that the level of direction afforded by Article 40 is far from comprehensive.

The term ‘needed’ has also been equated with that of ‘necessary’ in Article 8.1,¹⁹⁷ and there is certainly a relationship between the ordinary understanding given to both terms. Yet, once again we must question why State Parties chose to depart from the use of the word *necessary*, and thus the established WTO ‘necessity’ principle, if there was no intention to adopt a different benchmark. It is reasonable to argue that ‘needed’ may merely refer to a requirement for Member States to show that some action was required and thus the measure was adopted in good faith.¹⁹⁸ Nevertheless, what is clear from the discussion below is that

¹⁹⁵ Gervais (n 26) 239-240. See also Pires de Carvalho (n 26) 213.

¹⁹⁶ Interestingly, in his book on WTO principles, Mitchell equates the term ‘necessary’ in Article 8.1 with a proportionality type analysis, but does not do the same with the term ‘appropriate’ or ‘needed’ in Article 8.2. Mitchell (n 121) 180 (Table B).

¹⁹⁷ Gervais (n 26) 239.

¹⁹⁸ Gervais, in a more recent article, has noted the overlap that exists with the ‘necessity’ requirement in Article 8 and the ‘justification’ test in Article 20 of TRIPS. Yet, he acknowledges that justification may not be as stringent a requirement as the necessity test – ‘justification may be interpreted as meaning that the measure should implement the stated objective without necessarily being the least trade restrictive.’ This same reasoning may be equally applicable in distinguishing between ‘necessity’ and ‘needed’. Daniel Gervais, ‘Analysis of the Compatibility of Certain Tobacco Product Packaging Rules and the TRIPS Agreement and the Paris Convention’ (2010) Report prepared for Japan Tobacco International <http://www.smoke-free.ca/trade-and-tobacco/Resources/Gervais.pdf> accessed 9 April 2016.

Member States can only intervene under this provision when the activities of private owners produce negative effects for competition, trade or technology transfer.¹⁹⁹

(ii) ‘to prevent the abuse of intellectual property rights by right holders...’

The TRIPS Agreement was introduced to remedy perceived distortions to competition that a lack of adequate intellectual property protection was having in the market place.²⁰⁰ In this regard intellectual property protection is an important aspect of a competitive trading environment.²⁰¹ Yet, the exclusive rights granted to intellectual property owners can also be abused to produce negative consequences for trade and competition both nationally and internationally.²⁰² Indeed, during the Uruguay Round, it was this aspect alone that India felt needed regulating by the WTO (or the GATT as it was at the time). As stated by the Indian delegation, ‘it was only the restrictive and anti-competitive practices of the owners of intellectual property rights that can be considered to be trade-related because they alone distort or impede international trade.’²⁰³ Consequently, the initial proposals to incorporate

¹⁹⁹ Hanns Ullrich, ‘Expansionist Intellectual Property Rules and Reductionist Competition Rules: A TRIPS Perspective’ in Keith E Maskus and Jerome H Reichman (eds) *International Public Goods and Transfer of Technology Under a Globalised Intellectual Property Regime* (CUP 2005) 732.

²⁰⁰ Thomas Cottier and Ingo Meitinger, ‘The TRIPs Agreement without a Competition Agreement?’ (2003) Fondazione Eni Enrico Mattei Working Paper no. 65-99.

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=200622 accessed 9 April 2016.

²⁰¹ Andreas Heinemann, ‘Antitrust Law of Intellectual Property in the TRIPs Agreement of the World Trade Organisation’ in Friedrich-Karl Beier and Gerhard Schricker (eds) *From GATT to TRIPS: The Agreement on Trade-Related Aspects of Intellectual Property Rights* (VCH Publishers 1996) 241.

²⁰² For example, the Court of Justice of the European Union (CJEU) and the General Court has on several occasions addressed the issue of ‘abuse of a dominant position’ in relation to the exercise of IPRs. Cases include C-241-242/91 *Radio Telefis Eireann and Independent Television Publications v E.C. Commission (Magill TV guide Limited intervening)* [1995] ECR I-743; C-418/01 *IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG* [2004] ECR I-5039; T-201/04 *Microsoft Corp v Commission of the European Communities* [2007] ECR II-3601.

²⁰³ GATT, ‘Standards and Principles Concerning the Availability, Scope and Use of Trade-Related Intellectual Property Rights: Communication from India’ (10 July 1989) MTN.GNG/NG11/W/37 [2]; See also Roffe (n 26) 121.

provisions relating to anti-competitive practices came from developing countries.²⁰⁴ It is the balance between appropriate levels of intellectual property protection and competition regulation that the opening recital to the TRIPS Agreement seeks to attain.²⁰⁵ In this regard, the regulation of intellectual property rights in accordance with competition policy is seen by the WTO Membership as essential to ensure the effectiveness of the system.

Article 8.2 allows the overall balance between intellectual property protection and competition rules to be resolved at the national level. It neither attempts to define what practices are to be considered abusive, nor stipulates what measures Members should adopt. It once again exhibits deference to national policy makers to tailor rules and principles to suit national circumstances.²⁰⁶ This is an approach favoured by some commentators who view WTO regulation of competition rules as potentially restrictive for many nations, and the WTO unsuitable for the task.²⁰⁷ In discussing the impact of implementing multilateral rules and principles on competition policy, Correa maintains that ‘The best option for [developing] countries may be to keep the possibility of establishing their competition regimes, according to their own situation and policy objectives, without being bound to rules that may be enforced through the WTO settlement mechanism.’²⁰⁸

The ability to control abusive practices can be addressed from within the TRIPS regime itself. As noted above, there is significant ambiguity in many of the substantive rules to allow Members to adopt pro-competitive intellectual property policies. In addition, Article 40

²⁰⁴ GATT, ‘Communication from Argentina, Brazil, Chile, China, Columbia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay’ (14 May 1990) MTN.GNG/NG11/W/71.

²⁰⁵ TRIPS Agreement, preamble recital 1.

²⁰⁶ Ullrich observes that the reservation maintained in favour of preserving national autonomy in relation to competition policy and rules may be a concession made by developed nations following the collapse of negotiations in relation to a Code of Conduct for the Transfer of Technology. Ullrich (n 198) 731-732.

²⁰⁷ Daniel K Tarullo, ‘Norms and Institutions in Global Competition Policy’ (2000) 94 Am. J. Int’l L. 478; Cecilia Oh, ‘Trade and Competition Policy in the WTO’ (2003) Third World Network Briefings for Cancun. <http://www.ourworldisnotforsale.org/en/article/trade-and-competition-policy-wto> accessed 9 April 2016. Cf. Keith Maskus and Mohamed Lahouel, who argue that a multilateral agreement incorporating minimum standards on competition policy would benefit developing countries. ‘Competition Policy and Intellectual Property Rights in Developing Countries’ (2000) 23 World Economy 595.

²⁰⁸ Correa (n 5) 112.

authorises Members to regulate anti-competitive licensing practices of rights holders;²⁰⁹ Article 6 on exhaustion of rights allows Member States to adopt their own policy and regulation on the matter;²¹⁰ and the rules, for example, on fair use and compulsory licensing also expressly assist to counter abusive practices.²¹¹

Beyond intellectual property policy, abusive practices can be subject to varying degrees of national regulation. The abuse of rights is a concept that has been notoriously difficult to universally define. In the absence of a multilateral agreement on competition rules and policy,²¹² members are free to determine what practices are to be defined as abusive and how to regulate them.²¹³ Thus, taken together with Article 7, this provision would allow Member States to utilise competition rules to ensure that intellectual property rights holders are not over-compensated in relation to their social and economic contribution.

(iii) ‘or the resort to practices which unreasonably restrain trade...’

Here again Article 8.2 is formulated to allow Member States the autonomy to regulate the practices of private business. The intention is to prevent activities that impact upon the

²⁰⁹ Article 40 is again a permissive provision as it does not define specific competition rules, it merely identifies example practices that may amount to abuse of rights, such as ‘exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing.’

²¹⁰ This autonomy was reaffirmed in the WTO, ‘Declaration on TRIPS and Public Health’ (n 11) [5(d)].

²¹¹ TRIPS Agreement, art 31(c) & (k). The Doha Declaration on TRIPS and Public Health reinforces the right of Member States to grant compulsory licences and the freedom of each state to determine the grounds upon which the licences are granted (n 11) [5(b)].

²¹² For a detailed discussion on a possible WTO Agreement on competition rules see, for example, Ernst-Ulrich Petersmann, ‘International Competition Rules for Governments and for Private Business: A “Trade Law Approach” for Linking Trade and Competition Rules in the WTO’ (1996-1997) 72 Chi. Kent L. Rev. 545. David J Gerber, ‘Competition Law and the WTO: Rethinking the Relationship’ (2007) 10 J. Int’l Econ. L. 707.

²¹³ Heinemann cautions against placing too much reliance on the interpretation of ‘abusive’ in different contexts. To do so may lead ‘to a premature narrowing of the scope of application. To cite an example, to equate “abuse” with the meaning of the same term in Art [102] of the [Treaty on the Functioning of the European Union] would fail to recognise that in the latter Treaty a *dominant market position* is required, whereas Art. 8(2) merely requires the *existence of a right* in the field of intellectual property, which does not necessarily entail a dominant position in the relevant market.’ (n 200) 243.

fundamental objective of WTO policy – unrestricted trade.²¹⁴ There is clearly an overlap between this objective and the previous concern over abuse of rights. Yet, the ability to control abusive practices would appear to be wider given that some abusive practices may not in fact be considered anti-competitive and thus not an unreasonable restraint on trade, whereas any anti-competitive practice will always be abusive.²¹⁵

The term *reasonable* (or variations of, including *unreasonably*) appears more than 200 times in the legal texts of the WTO, and over 30 in the TRIPS Agreement.²¹⁶ It is often used as a means to limit the nature and extent of measures States are authorised to make.²¹⁷ As in Article 8.2, States are only authorised to act if the practice in question *unreasonably* restrains trade. Within the context of the TRIPS Agreement, Sam Ricketson and Jane Ginsburg observe that the ‘unreasonableness’ of an action or inaction requires an assessment of whether or not it is ‘proportionate or within the limits of reason.’²¹⁸

Whether a practice ‘unreasonably’ restrains trade appears to require the Member State to undertake an investigation into the actual impact the conduct has upon trade before adopting any pro-competitive measures that may negatively affect intellectual property rights. As emphasised by the much quoted Justice Brandeis in the 1918 US Supreme Court decision in *Chicago Board of Trade v. United States*, every contractual agreement restrains trade to some extent it is only those that do so *unreasonably* that warrant legal scrutiny.²¹⁹ What

²¹⁴ TRIPS Agreement, preamble recital 1.

²¹⁵ Correa (n 5) 111; Yusuf (n 42) 15. See also, Pires de Carvalho (n 26) 232, where the author observes that while selling at different prices to different consumers based on unreasonable grounds of discrimination (i.e. the football team supported) is not anti-competitive, it may certainly be considered abusive practice.

²¹⁶ Graham Cook, ‘Reasonableness in WTO Law’ (2013) 1 Lat. Amer. J. Int’l Tr. L. 713, 714.

²¹⁷ For example, the TRIPS Agreement (articles 13, 26 & 30) only allows exceptions to be introduced when, *inter alia*, they ‘do not *unreasonably* prejudice the legitimate interests’ of the rights holder; and the GATS Annex on Telecommunications section 5(g) states that ‘a developing country may, consistent with its level of development, place *reasonable* conditions on access to and use of public telecommunications...’

²¹⁸ Sam Ricketson & Jane C Ginsburg, *International Copyright and Neighbouring Rights: The Berne Convention and Beyond* (2nd edn, OUP 2005) 776. While the authors make this statement in relation to Article 9.2 of the Berne Convention, it is applicable in the context of the TRIPS Agreement. Article 9.1 of the TRIPS Agreement expressly incorporates articles 1-21 of the Berne Convention into the Agreement.

²¹⁹ *Board of Trade of Chicago v United States* (1918) 246 US 231, 238

amounts to unreasonable restraint was articulated in what has become commonly known as the ‘rule of reason’ doctrine: -

The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences.²²⁰

While this private law doctrine has necessarily evolved over time, and finds application in many jurisdictions, the essence of the analysis remains true today.²²¹ Therefore, this established balancing test would appear equally applicable for WTO Members when making a determination as to whether certain restrictive intellectual property practices warrant regulatory measures to be taken.²²²

(iv) ‘or adversely affect the international transfer of technology.’

Conduct of intellectual property owners that could affect the international transfer of technology include many of the licensing practices covered by Article 40, and the grant of compulsory licences in accordance with Article 31. As expressed in Article 7, one of the objectives of the TRIPS Agreement is the ‘transfer and dissemination of technology.’ This

²²⁰ Ibid.

²²¹ For an analysis of how the ‘rule of reason’ has developed in the US see Andrew I Gavil, ‘Moving Beyond Caricature and Characterization: The Modern Rule of Reason in Practice’ (2012) 85 S. Cal. L. Rev. 733. For an analysis of the rule of reason doctrine within European Union see Annette Schrauwen (ed), *Rule of Reason: Rethinking another Classic of European Legal Doctrine* (2005 Europa Law Publishing).

²²² Gervais (n 26) 240; Cottier and Véron (n 110) 36.

was a key factor in persuading many developing countries to agree to the TRIPS Agreement being incorporated into the legal framework of the WTO. Given that the main source of technology transfer for many developing countries is that acquired from overseas,²²³ it was crucial that developing Members were given the tools to ensure, as far as possible, that the promised benefits of intellectual property protection accrued. In this regard Article 8.2, together with Article 66.2, are important provisions that seek to promote the international transfer of technology.²²⁴ Yet it is only the former provision that places credible control in the hands of all recipient nations.

(c) Summary

In sanctioning Member States to adopt measures in relation to certain policy objectives Article 8 appears to have greater substantive authority than its neighbouring provision, Article 7. Yet this authority is curtailed by the inclusion of a consistency requirement. While the controls of *necessity* and *reasonableness* merely seek to ensure that the measures adopted are not disguised restrictions on trade, the *consistency* requirement seemingly prevents Article 8 having free-standing authority to directly override other obligations expressed within the TRIPS Agreement. In requiring consistency Article 8 acts as a ‘rule of restraint for national policies.’ But just how restraining is that rule? The policy objectives expressed within the provision are wide in scope and not clearly defined, leaving Members significant discretion on how to develop that policy. In addition, the provisions within the Agreement that Members could use to support a consistency argument, i.e. Articles 13, 17, 30 and 40, are themselves open to broad interpretation in light of the objectives and principles expressed in

²²³ Musungu (n 108) 445.

²²⁴ The importance of Article 66.2 was given emphasis in the WTO Declaration on TRIPS and Public Health (n 11) [7].

Articles 7 and 8. As noted by Reichman, ‘In principle, both the public interest exception and measures to prevent abuse, respectively stipulated in Article 8(1) and 8(2) of the TRIPS Agreement, could justify resort to compulsory licensing.’²²⁵ Therefore, the consistency requirement may not be as restrictive as it first appears.

Accordingly, the true value of Article 8 rests in its ability to guide the interpretation of other provisions of the Agreement. Many provisions of the TRIPS Agreement are vague and uncertain in legal application and thus would benefit from the guidance provided by Article 8, even if it is only to authorise deference to national standards where such measures are adopted in good faith. Therefore, Article 8 is a complementary provision to Article 7 that is important for framing not only intellectual property laws but also rules relating to other public interests such as health and competition.²²⁶

(d) Identified Principles of Law

The WTO Panel in *EC – TMs & GIs* has acknowledged that ‘Article 8 of the TRIPS Agreement sets out the principles of that agreement.’²²⁷ This is important in understanding the legal authority of this provision. As observed by Andrew Mitchell, ‘a text supporting two readings should be interpreted in a manner consonant with a treaty’s underlying principles.’²²⁸ Thus, when specific legal principles can be identified within the text of an agreement they inevitably carry greater interpretative weight than the more general

²²⁵ Jerome H Reichman, ‘Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement’ in Carlos M Correa and Abdulqawi A Yusuf, *Intellectual Property and International Trade: The TRIPS Agreement* (Kluwer Law International 2008) 34.

²²⁶ Correa (n 5) 104.

²²⁷ *EC – TMs & GIs* (n 14) [VII.73]. For a contrary perspective see Pires de Carvalho (n 26) 193-4.

²²⁸ Mitchell (n 121) 805-806.

expressions of object and purpose.²²⁹ Notwithstanding that the interpretation and application of these legal principles is still influenced by the overall object and purpose of the treaty.

While the panel does not identify any specific legal principles emanating from Article 8, it is clear from the above analysis that each of the requirements of *consistency*, *necessity* and *reasonableness* operate as legal principles. In this role they guide the application of the relevant legal rules and, in doing so, validate and justify the scope of the Agreement. Yet, it would be wrong to let the nomenclature of Article 8 be so restrictive as to deny that same role to its neighbour, Article 7. As mentioned above, the Panel in *US – Section 211 Omnibus Appropriations Act of 1998* characterised the phrase ‘[t]he protection and enforcement of intellectual property rights should contribute...to a balance of rights and obligations’ contained within Article 7 as a ‘form of the *good faith* principle.’²³⁰

In addition, it is also possible to identify a legal principle that finds its origins in the language of both Articles 7 and 8. The principle of *national regulatory autonomy* or *sovereignty* is clearly a guiding principle in several key policy areas, such as health and competition, and when implementing the often ambiguous obligations of the TRIPS Agreement. As discussed throughout this paper, the policy objectives of the TRIPS Agreement can only be truly defined and balanced at the national level. While the principles of consistency, necessity and reasonableness may limit the scope of that autonomy, any challenge to the principle of national regulatory autonomy must necessarily carry the burden of establishing the action or inaction as inconsistent, unnecessary, etc.

²²⁹ As noted by Isabelle van Damme, ‘Principles of treaty interpretation are neither rules nor principles in the classic sense of “something . . . which underlies a rule, and explains or provides the reason for it”. They underlie the interpretation of the rule, not the rule itself.’ Isabelle van Damme, ‘Treaty Interpretation by the WTO Appellate Body’ (2010) 21 EJIL 605, 616.

²³⁰ *US – s211* (n 16) (emphasis added).

The legal principles so far identified as being expressed within both Articles 7 and 8 are reasonably unambiguous in their objectives, and relatively familiar to judicial adjudicators. However, this is not to say that their boundaries and application will be or are easy to define. Caution must be stressed in an intergovernmental organisation such as the WTO, where the Dispute Settlement Understanding makes it clear that the ‘Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements.’²³¹ Nevertheless, this caution must be balanced against the need to recognise the legal and interpretative principles as articulated by its members. Given that these principles are expressed within Articles 7 and 8 it is significant that the terms of reference of the DSU require that any matter of dispute be examined ‘in the light of the relevant provisions of the covered agreements.’²³²

In summary, legal principles are plainly expressed within both Articles 7 and 8, although it is only the principle of ‘good faith’ that has been definitively recognised by the DSB. Whilst above the analysis is not conclusive, it is reasonable to presume that the legal principles that have been identified can effectively function to guide the interpretation of the substantive rules of the Agreement. This guidance derives from a direct use of the legal principle to shape the applicable rule. If applied in this way, the legal principles articulated in Articles 7 and 8 give expression to the broader intentions of all the parties to the Agreement. Article 7 and 8, therefore, demarcate the scope of the Agreement and legitimise its application amongst all Member States. They also provide the foundation for some of the expectations that Members should derive from the implementation of the Agreement and are therefore important provisions should non-violation complaints become an aspect of the TRIPS Agreement.

²³¹ DSU (n 23) art 3.2.

²³² Ibid, art 7.1.

4. Conclusion

In conceptualising the meaning and function of Articles 7 and 8 from the language of the text, it seems evident that these provisions should be of fundamental importance in defining the scope of the TRIPS Agreement. As expressed by Meinhard Hilf, ‘Any established rule in a legal system should be an expression of a finely tuned balance between the underlying principles and objectives.’²³³ This approach is in accordance with the General Rule of Treaty Interpretation expressed in Article 31 of the Vienna Convention on the Law of Treaties, requiring *inter alia* that a treaty be interpreted in light of its object and purpose. Therefore, Articles 7 and 8, entitled Objectives and Principles, provide a system that calibrates the rest of the TRIPS Agreement. Analysis of the text also confirms that this process of calibration can only sensibly be achieved at the national level given the breadth and complexity of social and economic issues in question. Therefore, where ambiguity exists within the provisions of the Agreement deference must be made to the individual choices of member states, as long as they are aimed at achieving the goals articulated in Article 7 or are authorised by Article 8.²³⁴

In addition, the outcomes that these provisions seek to achieve reflect a balance of interests arising from an extensive period of negotiations and to ignore them makes it ‘very hard to make a good faith argument that the TRIPS Agreement was a *legitimate* bargain between developed and less-developed countries.’²³⁵ As tools for validating and justifying the scope of the TRIPS Agreement it is important to recognise that they also implicitly incorporate the development goals of the WTO.²³⁶ Yet this is not to misconstrue these provisions as instruments that only have value for the less developed membership of the

²³³ Hilf (n 128) 112.

²³⁴ Rochelle Cooper Dreyfuss & Andreas F Lowenfeld, ‘Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together’ (1997) 37 Va. J. Int’l L. 275, 304; Frankel (n 9) 393-394.

²³⁵ Yu (n 12) 1023.

²³⁶ Roffe (n 26) 130.

WTO. Clearly Articles 7 and 8 also reflect intellectual property policy that has long been a staple of national regimes. Whether as expressing legal principles, legitimate expectations or defining the outcomes of an optimised intellectual property regime, these two provisions provide important interpretative guidance to all members and institutions of the WTO. Greater trust in the value of the TRIPS Agreement can only be achieved through the application of its objectives and principles, which can only effectively be applied once a better understanding has been articulated. It is hoped that this article goes some way to providing much clarity to the text, such that legal and political representatives can have greater confidence in their future application. Given that the text of Articles 7 and 8 is being steadily replicated in other intellectual property agreements, it is only through an understanding of these *objectives* and *principles* that we fully appreciate how international intellectual property regulation is to function.