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CIGI Papers No. 254 – June 2021

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James Bacchus

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About the Author

James Bacchus is a CIGI senior fellow. He is also Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. He was a founding member and twice served as chairman of the Appellate Body of the World Trade Organization. He is also a former member of the US Congress and a former international trade negotiator for the United States. His books include *Trade and Freedom* and *The Willing World: Shaping and Sharing a Sustainable Global Prosperity*, named by the *Financial Times* as one of the "Best Books of the Year" for 2018; and *Trade Links: New Rules for a New World*, forthcoming from Cambridge University Press.

Acronyms and Abbreviations

ACT		Access to COVID-19 Tools
COVID	-19	coronavirus disease 2019
CUSMA	A	Canada-United States- Mexico Agreement
IP		intellectual property
NAFTA		North American Free Trade Agreement
RCEP		Regional Comprehensive Economic Partnership
SDGs		Sustainable Development Goals
TFA		Trade Facilitation Agreement
TRIPS .	Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
WIPO		World Intellectual Property Organization
WTO		World Trade Organization

Executive Summary

A deadly global pandemic and other unique circumstances have combined to present the World Trade Organization (WTO) with an opportunity to modernize its rules for the trade-related aspects of intellectual property (IP) rights. There is the need to turn the "TRIPS-past" of WTO IP rules agreed in 1995 into the "TRIPS-plus" of improved rules more fit to purpose for the twenty-first century. New rules are needed to help spark new innovations of all kinds and the rapid spread of those innovations worldwide, including rules relating to intangible assets and especially to digital expressions of IP. New rules that have been made in regional and other trade agreements outside the WTO must be imported into the WTO and applied multilaterally among all WTO members. Differing cultures and differing histories give the 164 WTO members differing attitudes toward the protection of IP rights, which presents challenges in making new rules. Yet the WTO members have by consensus struck a balance in the existing WTO rules between exclusivity and access to new knowledge that has served all WTO members well. To continue to serve them well, this negotiated balance must be properly located and properly understood by both developed countries and developing countries, and it must be fulfilled and sustained in modernizing IP trade rules. Much more emphasis must be given by the developed countries to providing technology transfer and technical assistance and other capacity building for the developing countries. At the same time, the developing countries must do much more to comply with the legal requirement in the WTO rules that IP rights be enforced. In updating the WTO IP rules, both the developed countries and the developing countries must be ever mindful of the vital provisions in the current rules that permit case-by-case decisions for WTO members in drawing the line between upholding IP rights and allowing policy space for domestic actions conducive to social and economic welfare. In all respects, special allowances must be made and additional assistance must be provided to the least-developed countries of the world so that they can share in the global bounty from innovation.

Introduction

The coronavirus disease 2019 (COVID-19) pandemic has brought to the fore once more the debate within the WTO over the balance between exclusive ownership of new knowledge and broad public access to it in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights — commonly called the TRIPS Agreement.¹ Continuing questions over the extent to which the TRIPS Agreement protects the exclusivity of IP rights in COVID-19 vaccines (Farge and Nebehay 2020) — even during the lethal course of a global health emergency in which global access to those vaccines is urgently needed — underscore how much uncertainty remains about where the line of this balance is in this multilateral trade agreement, and also how much doubt still exists about whether that line is in the right place.

The inauguration of Joe Biden as president of the United States promises a re-engagement by the United States in the WTO, and thus WTO members are offered a new opportunity to confront mutual trade challenges old and new on a multilateral basis. With the WTO in crisis in the wake of long years of failed trade negotiations and of recent years of willful destruction by the nihilistic presidency of Donald Trump in the United States, WTO members must now "think anew, and act anew" (Lincoln [1862] 1953) on numerous policy fronts relating to international trade. One of these necessary policy fronts is the trade-related aspects of IP rights, where the best place to begin is with a full realization of the negotiated balance between exclusivity and access in the TRIPS Agreement.

Beginning with what has long been an elusive comprehension of this balance is a prerequisite to a much-needed modernization of this multilateral trade agreement. Without a clear comprehension by all the members of the WTO of the meaning of the balance they have established in the text of the TRIPS Agreement, and of the justification for it, there will be little hope of transforming the TRIPS-past of an outdated accord on the nexus of trade and IP rights that was written nearly three decades ago into the TRIPS-plus of an updated agreement that can best serve the new world

¹ See www.wto.org/english/tratop_e/trips_e/trips_e.htm.

of the twenty-first century — a world where that nexus has been greatly altered by time, technology and the transformation of trade.

Behind the Balance

Generally, the debate over the balance between exclusivity and access in the TRIPS Agreement is characterized as a commercial confrontation between the developed countries, which have a huge economic stake in having their IP rights protected in world trade, and the developing countries, which, despite their recent climb up the economic ladder, still, for the most part, do not. For the developed countries, there are millions of jobs and billions of dollars at risk if IP rights are not upheld worldwide. For many developing countries, in the near term, jobs and dollars are at risk if they enforce IP rights by ridding their economies of the vast illegal proceeds of counterfeiting and piracy. Yet counterfeiting and piracy hurt developing countries as well as developed countries, in part by undermining the growth of their own creative sectors. And compliance with the TRIPS Agreement has helped developing countries enjoy greater inflows of foreign direct investment, technology transfer and IP-sensitive imports. The common view of this ongoing confrontation often overlooks the stake that developing countries have in protecting IP rights both now and in the longer term. A balanced updating of the TRIPS Agreement can potentially benefit all WTO members by incentivizing innovation and technology transfer in an inclusive, market-oriented manner, appropriate to anticipated conditions in the global economy for decades to come.

Linked inextricably to this commercial confrontation, of course, and often highlighted in media reports and policy discussions, is a geopolitical contest among the United States, the European Union, China, Japan and other leading economic powers for access to and control over the new technologies that will shape the rest of the twenty-first century. The trade and other disputes between and among these competing countries over the legal rights to the new knowledge that drives automation, delivers digitalization and lifts all kinds of high technologies higher, are not only disputes about jobs and profits. They are equally disputes over acquiring, leveraging and using political power to chart the course of the rest of this century, whether for good or ill.

Yet, at its core, the debate over how to treat IP rights within the WTO is part of a larger, longstanding global and geopolitical debate over the merits of property rights, dating back to long before the expression of the contrasting views offered first by Adam Smith and later by Karl Marx during the first century of the Industrial Revolution. Within this larger historical debate over the worth of property rights, is a more specific debate over the worth of IP rights, the justifications for those rights and the appropriate limits of those rights. The debate within the WTO is one aspect of this more specific debate. It is focused on how IP rights relate to trade, not only in vaccines and in other medicines, but in all individual creations that can serve the public good, in commerce and in many other aspects of society, worldwide. The late Harold Demsetz, an American economist steeped in the nuances of property rights, pointed out decades ago that a clear definition of property rights is needed for a market to function, including with respect to intangible intellectual assets (Hubbard 2019).

IP rights are limited property rights. They give individuals exclusive rights for a limited time to the creations of their own minds. These rights can be rights to inventions (patents); literary and artistic works (copyrights); and commercial symbols, names and images (trademarks). They can be rights to industrial designs, trade secrets and geographical indications. IP rights are varied in their nature and thus are varied, too, in their trade and other societal effects. Different protections afforded to different IP rights in different countries can have enormous implications for the dissemination and distribution of wealth and welfare in the global economy. If we unduly weaken protection for IP, then we need to ask ourselves: Where will the next innovation, the next new technology, the next life-saving medicine come from? Likewise, if writers, artists, musicians and others who adorn human civilization are deprived of any legal entitlement to their creations, will society continue to be blessed as much by their creative works?

IP rights are exceptions to free trade. They exist because they are incentives for innovation, which is the main source for long-term economic growth and enhancements in the quality of human life. The exclusivity of IP rights sparks innovation "by enabling innovators to capture enough of the economic gains from their own innovative activity to justify their taking considerable risks" (Ezell and Cory 2019). The new knowledge from the innovations inspired by IP rights spills over to inspire other innovations. The widespread protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know-how.

From the early acknowledgment of IP rights in the Italian city-states of the Renaissance, to their development in Great Britain during the emergence of market-based capitalism, to their enshrinement in the United States Constitution, and to their international recognition beginning in the nineteenth century and continuing today, there have always been disputes over where exclusive IP rights stop and unlimited public access begins. In the twenty-first century, as global economic growth has become increasingly knowledge-based, and as competition for knowledge has matched competition for commodities and natural resources, these disputes have multiplied and intensified.

Today, with the rise of digital trade and other forms of trading in knowledge, an ever-growing portion of the value of traded goods and services is in the IP that is embedded and associated with them. IP is foremost among the intangible assets that are assuming more commercial significance in the new pandemic world.² Trade rules that did not address and protect IP rights would not reflect the true realities of international trade in the twenty-first century. Furthermore, trade rules that do not keep up now with the new developments in IP rights in the digital age will reflect those realities even less. IP protections belong in the WTO, and new rules are needed to help secure those protections.

Even so, because IP rights are exceptions to free trade, the multilateral decision to protect them as a part of the WTO treaty was a legal landmark in both trade law and in broader public international law. Mindful of this exceptional circumstance, when they drafted and established the TRIPS Agreement as part of the new WTO in 1995, WTO members asked themselves: Just how far does the exclusive ownership right of an individual to the financial and other benefits of their own creation extend? Just when and where does that right stop? And precisely when, and under what circumstances, must a property right in an intellectual creation be subordinated to a wider concept of what is in the overall public interest? Their answers to these questions are in the text of the TRIPS Agreement. And today, more than a quarter of a century later, WTO members continue to plumb their answers to these questions as they ponder the ongoing meaning of the balance represented in the TRIPS Agreement while adjusting to the new pandemic world.

Even though they have all signed on the dotted line of the TRIPS Agreement, and therefore have committed to the multilateral obligations in the agreement, the ways in which WTO members read their answers to these questions are not all the same. There are geographical variations in how these treaty obligations are perceived, and thus in the domestic protections provided for IP rights. These geographical variations are, in part, a consequence of the variations in the cultural inheritances of the West and East of the world on the concept of IP rights — a situation that must be faced squarely before TRIPS-past can become TRIPS-plus.

The protection of individual rights in IP is a creation of the West. IP rights can be justified as natural rights arising from John Locke's notion³ that individuals have the right to the fruits of their own labour. In addition, or in the alternative, they can be justified as positive rights created by the state for the benefit of the general well-being. The justification of IP rights as positive rights can be accomplished by means of a utilitarian calculation resulting from Jeremy Bentham's belief⁴ that public policy should be founded on utility — that it should be based on what provides the greatest happiness to the greatest number of people. Theoretical discussion has long continued in the West over whether IP rights are based in natural law, positive law or both. (Bentham thought natural law was "nonsense on stilts";5 others think Bentham's utilitarianism inimical to the very idea of individual rights.⁶) But there is wide agreement in the West that these individual rights exist, that they are limited in time and that they must be protected for as long as they exist.

- 5 See https://iep.utm.edu/bentham/.
- 6 See Himmelfarb (1990).

³ See https://oll.libertyfund.org/page/john-locke-two-treatises-1689#lf0057_head_018.

⁴ See https://en.wikisource.org/wiki/An_Introduction_to_the_Principles_ of_Morals_and_Legislation/Chapter_I.

There is no comparable intellectual source for the concept of IP rights in the East; it is not a part of Asian history and tradition.⁷ For example, in the Confucian tradition, the Chinese have long conflated the interest of the individual with the interest of the state. The role of the individual in this tradition is to further "the collective well being of society."8 Accordingly, the traditional Chinese view of IP rights is that rights in creative works are not based in nature but, instead, derive from the state and are intended for the benefit of the state, not for the benefit of any particular individual.9 In this view, all works, creative and non-creative alike, belong to the people as manifested in the state. This ancient view was reinforced for the first 40 years that followed the Chinese Communist Revolution in 1949, until after the death of Mao Zedong and the subsequent "reform and opening up" under Deng Xiaoping.10

These conflicting intellectual antecedents clash every day in the WTO in deliberations over the interpretation and implementation of the TRIPS Agreement. To be sure, China and the numerous other developing countries that are members of the WTO have agreed to the TRIPS Agreement. They did so either when the WTO was established in 1995 or (as in the case of China in 2001) upon their later date of accession. All of them are also members of WIPO, a UN agency. Thus, legally, they are all adherents to the protection of IP rights, wherever the concept may have originated. The concept of IP rights may have begun in the West but, for some time now, it has, as a legal concept, been accepted globally.

Despite all this, many of the developing countries continue to have cultural as well as economic reservations about the protection of individual IP. Because of their legal obligations, they generally express their reservations about the protection of IP rights in procedural terms, citing the undeniable difficulties that those countries in the early stages of development have in summoning the resources to enforce IP rights. Yet, even so, much of their lingering hesitation about the protection of IP rights can be traced to the fact of the Western intellectual sources of those rights, which express a kind and a degree of individualism that many in the East still find it hard to embrace, even after decades of economic globalization.

This tacit reservation about the justification for IP rights among many WTO members — not only in the East but across much of the developing Global South — adds to the tensions within the WTO over the scope and the pace of recognizing and upholding such rights. It adds also to the divisions within the WTO over whether, nearly three decades later, the negotiated balance reflected in the text of the TRIPS Agreement between the individual right to a limited ownership interest in intellectual creations and the collective societal right to have early and widespread access to those creations, is still the right balance. These regional tensions have been heightened amid the life-or-death stakes of a global pandemic.

The Balance in the Text

The balance between exclusivity and access that has been agreed by all the members of the WTO on the trade-related aspects of IP property rights is given legal expression in articles 7 and 8 of the TRIPS Agreement,¹¹ as negotiated in the Uruguay Round of multilateral trade negotiations that established the WTO. As to the "objectives" of the TRIPS Agreement, article 7 provides: "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."¹²

In addition, as to the "principles" underlying the TRIPS Agreement, article 8, paragraph 1 states: "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of

⁷ See Fowler, Charoenpot and Chernkwanma (2017).

⁸ See http://factsanddetails.com/china/cat3/sub9/entry-5561.html.

⁹ See JIPEL Blog (2014).

¹⁰ See Lu et al. (2019).

¹¹ WTO, Agreement on Trade-Related Aspects of Intellectual Property Rights (unamended), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, 1867 UNTS 154, 33 ILM 1144 (1994) (entered into force 1 January 1995) [TRIPS Agreement], online: WTO <www.wto.org/english/docs_e/legal_e/ 27/trips_01_e.htm>.

¹² Ibid, art 7.

this Agreement."¹³ Further, article 8, paragraph 2 elaborates: "Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."¹⁴

Of relevance in clarifying the meaning of the balance described in these two TRIPS obligations are certain passages in the preamble of the agreement.¹⁵ In the first words of the preamble, the members of the WTO have voiced their common desire, in their effort "to reduce distortions and impediments to international trade," to take "into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."16 They have gone on in the preamble to recognize that "intellectual property rights are private rights," and to acknowledge "the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives."17

Articles 7 and 8 are not general exceptions to the obligations to protect IP rights in the TRIPS Agreement. They are not textual equivalents to article XX of the General Agreement on Tariffs and Trade¹⁸ and article XIV of the General Agreement on Trade in Services.¹⁹ These TRIPS provisions are not there to excuse a failure to comply with what would otherwise be TRIPS obligations in certain circumstances, although that can often be their effective result. Instead, as the WTO panel in the *Australia* — *Tobacco Plain Packaging* dispute put it in 2018, "Articles 7 and 8, together with the preamble

- 15 Ibid, preamble.
- 16 Ibid.
- 17 Ibid.

of the TRIPS Agreement, set out general goals and principles underlying the TRIPS Agreement, which are to be borne in mind when specific provisions of the Agreement are being interpreted in their context and in light of the object and purpose of the Agreement."²⁰ The panel there added that article 7, specifically, "reflects the intention of establishing and maintaining a balance between the societal objectives mentioned therein."²¹

In the same dispute, the panel stated that article 8.1 "makes clear that the provisions of the TRIPS Agreement are not intended to prevent the adoption, by Members, of laws and regulations pursuing certain legitimate objectives, specifically, measures 'necessary to protect public health and nutrition' and 'promote the public interest in sectors of vital importance to their socioeconomic and technological development', provided that such measures are consistent with the provisions of the Agreement."²² The panel then went on to say, "Specifically, the principles reflected in Article 8.1 express the intention of drafters of the TRIPS Agreement to preserve the ability for WTO Members to pursue certain legitimate societal interests, at the same time as it confirms their recognition that certain measures adopted by WTO Members for such purposes may have an impact on IP rights, and requires that such measures be 'consistent with the provisions of the [TRIPS] Agreement."23

The language in the preamble to the TRIPS Agreement can be used by a treaty interpreter to help confirm the object and purpose of the agreement when clarifying its specific obligations. With this in mind, the panel in the Australia — Tobacco Plain Packaging dispute noted that "the first recital of the preamble to the TRIPS Agreement expresses a key objective of the TRIPS Agreement, namely to 'reduce distortions and impediments to international trade' and takes into account the need, on one hand, 'to promote effective and adequate protection of intellectual property rights' and, on the other, 'to

- 22 WTO Analytical Index, Article 8, supra note 20.
- 23 Ibid.

¹³ Ibid, art 8 at para 1.

¹⁴ Ibid, art 8 at para 2.

¹⁸ General Agreement on Tariffs and Trade, 30 October 1947, 58 UNTS 187, art XX (entered into force 1 January 1948), online: <www.wto.org/ english/docs_e/legal_e/gatt47_02_e.htm#articleXX>.

¹⁹ General Agreement on Trade in Services, Annex 1B of the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, 1867 UNTS 154, 33 ILM 1144 (1994) (entered into force 1 January 1995), online: <www.wto.org/english/docs_e/legal_e/ 26-gats_01_e.htm>.

²⁰ WTO, WTO Analytical Index, TRIPS Agreement – Article 8 (Jurisprudence) [WTO Analytical Index, Article 8], online: <www.wto.org/english/res_e/publications_e/ai17_e/trips_art8_jur.pdf>.

²¹ WTO, WTO Analytical Index, TRIPS Agreement – Article 7 (Jurisprudence) [WTO Analytical Index, Article 7], online: <www.wto.org/english/res_e/publications_e/ai17_e/trips_art7_jur.pdf>.

ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."²⁴

Taken together, these provisions in the TRIPS Agreement evidence a consensus among the WTO members that insufficient protection of IP rights will lead to trade distortions, such as counterfeiting and piracy, that will impede development by inhibiting the creation and the spread of new knowledge. Therefore, the WTO members have concluded, minimum standards of IP protection are needed in WTO rules. At the same time, these provisions evidence a consensus that the overzealous protection of IP rights could unduly limit the discretion of WTO members in doing what they may conclude must be done in their own domestic economies to promote social and economic welfare. Thus, WTO members have sought to secure in the TRIPS Agreement both appropriate IP protections and appropriate policy space for individual WTO members to limit those protections domestically whenever they can demonstrate that such limitations are justified.

Locating the Line of the Balance

This is the line of the balance that has been struck between exclusivity and access in the TRIPS Agreement. But where precisely is this line in any given instance? In WTO dispute settlement, the line of the balance has been located, as with other negotiated lines in the WTO treaty, on a case-by-case basis. Going forward, this gradual accumulation of case-by-case clarification through dispute settlement will continue. Locating this line and other negotiated lines in the covered agreements of the WTO treaty to help reach a positive solution to international trade disputes is the purpose of the clarification of WTO dispute settlement. But in negotiations and in other deliberations, WTO members frequently disagree on where the line of the balance is in the TRIPS Agreement, and this explains much about why they have been unable to make progress on addressing TRIPS-plus concerns on both sides of the line.

In the still brief history of the WTO, the question of where this line is to be found has famously centred on the topic of compulsory licensing of medicines by the developing countries during times of health crisis. A compulsory licence²⁵ is a legal authorization asserted by a government or granted by a government to a third party to produce a patented process or product without the express consent of the patentholder. Such a licence overrides what is otherwise the patentholder's exclusive right to keep others from using its patented inventions. A compulsory licence is a right to use patented information for processing or production; it is not a waiver of IP rights. The holder of the patent still retains rights over the patent, including the right to be paid compensation for copies of the product made under the compulsory licence.

Compulsory licensing was a highly controversial issue for the WTO during the height of the HIV/ AIDS crisis at the turn of the century. After years of sometimes contentious debate, in the Doha Ministerial Declaration of November 2001. WTO members issued a Declaration on the TRIPS Agreement and Public Health,²⁶ which affirmed that WTO IP protections do not and should not prevent national measures taken to protect public health by the promotion of access to new medicines and the creation of new medicines. WTO members confirmed in this 2001 declaration that each WTO member "has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."27 In August 2003, WTO members followed up on their 2001 declaration by adopting a waiver that allows poorer countries that do not have the capacity to make pharmaceutical products — and thus cannot benefit from compulsory licensing - to import cheaper generic drugs from countries where those drugs are patent protected.²⁸ This waiver was transformed into an amendment to the TRIPS Agreement in 2017 styled as article 31bis.²⁹

Arguably, as a legal matter, the identical results could have been achieved simply by reference to the texts of articles 7 and 8, which provide

²⁴ WTO, WTO Analytical Index, TRIPS Agreement – Preamble (Jurisprudence), online: <www.wto.org/english/res_e/publications_e/ ai17_e/trips_preamble_jur.pdf>.

²⁵ See www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.

²⁶ WTO, Declaration on the TRIPS Agreement and Public Health (adopted on 14 November 2001), WTO Doc WT/MIN(01)DEC/2 [Public Health], online: <www.wto.org/english/thewto_e/minist_e/min01_e/ mindecl_trips_e.htm>.

²⁷ Ibid.

²⁸ WTO, General Council, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (Decision of the General Council of 30 August 2003), WT/L/540, online: <www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm>.

²⁹ TRIPS Agreement, supra note 11, art 31bis.

broad legal authority for domestic actions for such domestic purposes. Notably, in the 2001 declaration, WTO members emphasized that "in applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."30 These objectives are expressed in article 7, and these principles are stated in article 8. These two articles must be read in the context of the object and purpose of the agreement as set out in its preamble. Therein lies the line of the balance. To adhere to this line, and to extend it into the future, developed and developing countries alike must begin to see it in its proper light and give a living and evolving reality to it.

Fulfilling and Sustaining the Balance

Toward this end, the developed countries must understand more clearly the legal nature of the negotiated balance reflected in the TRIPS Agreement. The balance between exclusivity and access put in the language of the TRIPS Agreement is not something that applies only in exceptional circumstances. It applies all the time. It is a central part of the bargain that is reflected in the agreement. Every obligation in the TRIPS Agreement must always be read with the objectives in article 7, the principles in article 8 and the related language in the preamble much in mind if the balance in the agreement is to be upheld. These two articles are immediate and relevant context that pervades the entirety of the agreement. The relevant language in the preamble reinforces this context by elucidating the object and purpose of the agreement.

Establishing such a negotiated balance is not new in IP law. Although the TRIPS Agreement itself is novel in bringing IP rights within the ambit of international trade law, the balance between exclusivity and access with respect to IP rights is not novel to the TRIPS Agreement. Indeed, this balance is intrinsic to the very nature of IP rights, in which a balance is evidenced by the facts that the scope of IP rights is defined, and the duration of IP rights is limited. Thus, the developed countries must understand that, when the developing countries assert their sovereign rights with reference to the general language in articles 7 and 8, they are not necessarily undermining the bargain in the TRIPS Agreement; it may well be that they are acting fully in accordance with it. Whether or not they are, in any given instance, acting consistently with the import of this balance, will depend on the facts of each specific case.

At the same time, the developing countries must realize that their WTO obligation to protect IP rights is not some post-colonial neo-imperialistic imposition that undermines their sovereignty and postpones their further development. Quite the opposite. The protection of IP rights is, in fact, a necessary means to their further development in a world in which the creation of more wealth depends more than ever on the creation of knowledge. There is a tendency in the developing countries (and in some noncommercial enclaves in the developed countries) to view the profits to right holders from the protection of IP rights as contrived, excessive and unearned "rents" rather than as legitimate earnings from investments made in creating knowledge. To be sure, such earnings can be excessive if they are not limited appropriately in scope and duration. But this tendency often betrays a lingering underlying cultural skepticism about the legitimacy of IP rights themselves - a skepticism that, if allowed to prevail, will impede the further economic advancement of the developing countries in the new pandemic world.

The developing countries must understand that upholding IP rights is not of interest only to the United States and the other advanced economies, which have, to date, led the way in knowledgebased enterprise. It is equally of interest to the developing countries. One of them, China, is closing in on the developed countries in the global flows of goods, services, finance and data, which depend for their success on the protection of IP rights. Other developing countries are likewise catching up in these IP-fuelled flows. The evidence clearly shows that, when developing countries protect IP rights, they gain in economic growth (Cavazos Cepeda, Lippoldt and Senft 2010). As shown by the Global Innovation Index of the World Economic Forum, countries that uphold IP rights "have more creative outputs...even at varying levels of development" (Ezell and Cory 2019). This is especially so when firms and individuals in developing countries are connected to global value chains. The capacity for creative innovation is not

³⁰ Public Health, supra note 26 at para 5a.

limited only to people in the developed world, and yet much of that capacity will remain untapped if developing countries do not protect IP rights.

All the members of the WTO - developed and developing countries alike — must comprehend completely that the new pandemic world presents new circumstances that demand that the text of the TRIPS Agreement be revisited to make certain that the agreement is up to date and that it truly fulfills the bargain it represents. It is widely assumed that this will involve additional difficult concessions at the negotiating table by both developed and developing countries. In fact, as difficult as it may be to achieve politically, the needed modernization of the TRIPS Agreement can be comprised entirely of reforms that will benefit all the countries that are members of the WTO; the wealth and the welfare of all of them can be enhanced if the original bargain in the agreement is entirely fulfilled to fit the global economy of the twenty-first century.

To realize fully the balance set out in the TRIPS Agreement, developed countries must keep their original promises made in 1995. Foremost among these is their promise in article 66 of the agreement to engage in "technical cooperation" with the 46 least-developed country members of the WTO, which are on the UN list of the poorest countries in the world.³¹ Article 66, paragraph 2 states that "developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to leastdeveloped country Members in order to enable them to create a sound and viable technological base."³² This is a mandatory obligation that is enforceable in WTO dispute settlement.

The preamble to the agreement recognizes the "special needs" of the least-developed countries.³³ The presence of article 66, paragraph 2 was an important reason why the least-developed countries agreed to join other WTO members in the TRIPS Agreement. Yet the developed countries have not been meeting their end of this key part of the bargain in the TRIPS Agreement (Fox 2019). Although technology transfer has been flowing more swiftly where developing countries have complied with the TRIPS Agreement, developed countries have fallen far short in providing incentives for technology transfer to their enterprises and institutions. Many developed countries have not even bothered to submit required annual reports of their attempts at compliance with this mandatory obligation. If developed countries continue to ignore or artfully evade this mandatory obligation, then they should be challenged in WTO dispute settlement.

If this happens, then WTO jurists should take a broad view of what constitutes technology transfer. As David M. Fox has observed in a thoughtful examination of the meaning of technology transfer, in the modern world, technology includes more than machinery and equipment; it also includes knowledge and skills, human resource development and domestic capacity building (ibid.). Much of all of this happens every day in the normal course of the buy-and-sell of international commerce, but it does not happen automatically, and the developed countries must put incentives in place to help make it happen more often. At the same time, it is vital to build the capacity in developing countries - especially in the least-developed countries — to absorb and benefit from new imported technologies. This requires investments in human capital, human connectivity, better business conditions and, not least, the rule of law.

Substantial technology transfers are already occurring through the mediation of markets, most noticeably in those places where IP rights are upheld in accordance with the TRIPS Agreement (Park and Lippoldt 2008). When IP right holders can be assured that their rights will be protected locally, they are more likely to share their technology by means of licensing, investing or engaging in research and development locally. Foreign direct investment includes not only hardware and software, but also, importantly, the tacit knowledge and the learning by doing that are critical to true development. These kinds of transfers have tended to vary in relation to the stringency of local compliance by developing countries with their legal obligations under the TRIPS Agreement (ibid.). In updating the TRIPS Agreement, the aim should be to create an enabling atmosphere in which these market-based transfers of technology will be maximized (Branstetter, Fisman and Foley 2005).

To achieve the full measure of the balance in the TRIPS Agreement, developing countries must also fulfill their treaty obligations. One obligation

See www.un.org/development/desa/dpad/least-developed-countrycategory.html.

³² TRIPS Agreement, supra note 11, art 6 at para 2.

³³ TRIPS Agreement, supra note 11, preamble.

many developing countries have not met nearly to the extent they should is to enforce IP rights in accordance with the terms of the TRIPS Agreement. Most WTO obligations are negative obligations: they are legal obligations to not do something (for example, to not discriminate). The TRIPS Agreement is one of the few WTO agreements that contains positive obligations: it includes affirmative legal obligations to do something, namely, to protect IP rights. These affirmative obligations are located in part III of the TRIPS Agreement, "Enforcement of Intellectual Property Rights," which is comprised of articles 41 through 48.³⁴

Under part III of the TRIPS Agreement, it is not sufficient that a legal means for right holders to enforce their IP rights is written into the laws of a WTO member. Under article 42 of the agreement, that means must genuinely be "available to right holders" through "fair and equitable procedures."35 As the Appellate Body of the WTO stressed with respect to the enforcement procedures under article 42 in United States — Section 211 Omnibus Appropriations Act in 2001, "making something available means making it 'obtainable,' putting it 'within one's reach' and 'at one's disposal' in a way that has sufficient force or efficacy"; therefore, "the ordinary meaning of the term 'make available' suggests that 'right holders' are entitled under Article 42 to have access to civil judicial procedures that are effective in bringing about the enforcement of their rights covered by the Agreement."³⁶ Thus, the enforcement of IP rights is not optional for WTO members under the TRIPS Agreement; it is mandatory as part of the bargain struck between exclusivity and access in the balance in the agreement. It is an affirmative legal obligation that requires that the words in laws be matched by actions that give those laws real meaning.

In addition to the enforcement of their own obligations under the TRIPS Agreement, the developing countries must also be able to assert their own rights under the agreement in their IPrelated trade with other countries. As a practical matter, this means they must have the legal and technical means to participate successfully in WTO dispute settlement. Since the establishment of the WTO in 1995, numerous developing countries have acquired significant expertise in the conduct of dispute settlement — a level of expertise that matches or exceeds that of the developed countries. But many of the developing countries remain without such expertise and without the dispute settlement experience that helps hone it. More financial and other support by the developed countries must be provided for the current efforts to provide access to this expertise for these often least-developed countries.

What is more, to make the balance in the TRIPS Agreement work in the new pandemic world, all of the members of the WTO must be willing to make and keep more promises by updating and adding to their obligations in the TRIPS Agreement. The balance between exclusivity and access in the agreement can only be fulfilled and sustained if it is practically fit for purpose for this new world. This means that the TRIPS Agreement must be revised to account for all of the technological and other changes in IP since it entered into force in 1995 — a goal primarily of the developed countries. Moreover, this means also that the TRIPS Agreement must be further revised to address issues that are of special concern mostly to the developing countries.

Most immediately, as the newly elected WTO Director-General, Ngozi Okonjo-Iweala, has said, the balance in the TRIPS Agreement must be reflected in how the members of the WTO respond to the simultaneous urgency of developing new COVID-19 vaccines and providing them quickly to all the billions of people who are waiting for life-saving doses throughout the world. The compounding complexities of the global challenges of confronting COVID-19 and its multiplying mutations are beyond even those of confronting the HIV/AIDS crisis, and, as she has said, there is need for "a third way, in which we can license manufacturing to countries so that you can have adequate supplies while still making sure that intellectual property issues are taken care of" (Okonjo-Iweala, quoted in Josephs 2021). This "third way" may not require an amendment to the text of the TRIPS Agreement; however, as events unfold, it could involve a formal legal interpretation of the agreement or some other form of multilateral action by the members of the WTO.

As it is, the multilateral actions that have been undertaken outside the WTO to fight the COVID-19 pandemic pose no legal difficulties under the trade rules in the TRIPS Agreement. The

³⁴ TRIPS Agreement, supra note 11, arts 41-48.

³⁵ TRIPS Agreement, supra note 11, art 42.

³⁶ WTO, United States – Section 211 Omnibus Appropriations Act of 1998, WT/DS176/AB/R, at para 215 [emphasis in original], online: <www.wto.org/english/tratop_e/dispu_e/cases_e/ds176_e.htm>.

unprecedented global collaboration to accelerate the development, production and equitable access to COVID-19 tests, treatments and vaccines under the auspices of the Access to COVID-19 Tools (ACT) Accelerator³⁷ is perfectly consistent with the TRIPS Agreement. Likewise, COVAX, the vaccines pillar under the ACT-Accelerator, is equally consistent with the WTO trade rules.³⁸ These global endeavours in no way infringe on IP rights. Nor would the voluntary pooling of patent rights and data to COVID-19 vaccines infringe IP rights if done with the participation and/or permission of the patent right holders.

In addition, the new international IP agreements concluded since the writing of the TRIPS Agreement in the early 1990s must be incorporated by reference into the TRIPS Agreement so that they can be enforceable in WTO dispute settlement. The TRIPS Agreement was written before the rise of the internet, and much has happened relating to IP in the nearly three decades since. The agreement incorporates by reference several longstanding international IP conventions, including on patents and copyrights.³⁹ Incorporating these IP conventions into the TRIPS Agreement has had the legal effect of making them fully enforceable for the first time through the WTO dispute settlement system. The same must be instituted now for the new international IP conventions.

In addition to the IP conventions that are already included, two treaties adopted in 1996 by WIPO should be incorporated by reference into the TRIPS Agreement. Commonly described together as the "Internet Treaties," one of these two WIPO agreements provides added protections for copyrights in response to advances in information technology, including the protection of IP rights in computer programs and in databases.⁴⁰ The other WIPO agreement updates protections of the rights of performers and producers of phonograms for the digital age.⁴¹ Incorporating these two Internet Treaties into the WTO rules would make them, too, fully enforceable. Still another WIPO convention that should likewise be incorporated by reference into the TRIPS Agreement is the Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled, which was adopted in 2013.⁴²

Giving more reality to the balance in the TRIPS Agreement by modernizing the agreement must also include making multilateral many of the advances made in recent years in protecting IP rights in bilateral and regional trade arrangements. Because of the ongoing standoff between the developed countries and the developing countries on extending and modernizing IP protections inside the legal framework of the WTO, those who have sought modernization have gone outside the WTO. As Henning Grosse Ruse-Khan (2018) of the University of Cambridge has observed, international IP law has, since the entry into force of the TRIPS Agreement, "primarily developed via a network of bilateral and regional agreements. These range from international investment and free trade agreements (IIAs, FTAs), via treaties on development cooperation, to comprehensive regional integration accords."

These non-multilateral, non-WTO and non-WIPO agreements often have IP chapters that provide IP protections over and above those provided in the TRIPS Agreement. This non-multilateral approach can be beneficial, as with, for example, the added protections for trade secrets in the "new NAFTA (North American Free Trade Agreement)," the Canada-United States-Mexico Agreement (CUSMA).43 But this non-multilateral approach can also place smaller and poorer countries in an unequal bargaining position when they are negotiating with larger and wealthier countries. In a typical bilateral trade negotiation between a developing and a developed country, the developing country has no choice but to agree to TRIPS-plus protections if it wants to secure

40 WIPO Copyright Treaty, 20 December 1996, 36 ILM 65 (entered into force 6 March 2002), online: <www.wipo.int/edocs/lexdocs/treaties/en/ wct/trt_wct_001en.pdf>.

³⁷ See www.who.int/initiatives/act-accelerator/about.

³⁸ See www.who.int/initiatives/act-accelerator/covax.

³⁹ WTO, WTO Analytical Index, TRIPS Agreement – Article 1 (Jurisprudence), online: <www.wto.org/english/res_e/publications_e/ ai17_e/trips_art1_jur.pdf>.

⁴¹ WIPO Performances and Phonograms Treaty, 20 December 1996, 36 ILM 76 (entered into force 20 May 2002), online: <www.wipo.int/edocs/ pubdocs/en/wipo_pub_227.pdf>.

⁴² Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled, 27 June 2013 (entered into force 29 September 2016), online: <www.wipo.int/treaties/en/ip/marrakesh>.

⁴³ See de Beer (2020).

more access for its most significant exports to the domestic market of the developed country.

Moreover, this non-multilateral approach can also have the gradual effect of undermining on a piecemeal basis the policy flexibilities that have been afforded to developing countries under articles 7 and 8 of the multilateral TRIPS Agreement. By refusing to negotiate TRIPS-plus IP protections within the WTO, the developing countries have left the developed countries with the option only of going outside the WTO to modernize international IP protections. The TRIPS-plus obligations that have been negotiated in these non-WTO agreements are not constrained by the overarching presence of articles 7 and 8. Thus, ironically, the reluctance of the developing countries to negotiate further on IP rights in the WTO threatens to undermine the local discretions they have been assured in the TRIPS Agreement.

It is, therefore, much in the interest of the developing countries, in the short term and the long term, to centralize the making of international rules on the trade-related aspects of IP once more within the WTO. This would not be a concession to the developed countries; it would be a profession of their long-term self-interest by the developing countries. Moving many of the additional IP protections in these bilateral and regional agreements into the multilateral legal framework of the WTO would have the dual benefit of enhancing IP protections generally while also making certain that these additional protections were subject to the balance between exclusivity and access that has been agreed in the TRIPS Agreement.

Also worthy of consideration for multilateral expression in the TRIPS Agreement are the nuances on the balance between exclusivity and access described in one of the agreements concluded outside the WTO, the Regional Comprehensive Economic Partnership (RCEP),⁴⁴ a new trade arrangement among China, Japan, South Korea and a dozen other Asian and Pacific countries signed on November 15, 2020. In addition to echoing the wording about the needed balance in article 7 of the TRIPS Agreement, the RCEP underscores "the need to maintain an appropriate balance between the rights of intellectual property right holders and the legitimate interests of users and the public interest."45

RCEP parties must adopt appropriate measures "to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."⁴⁶ At the same time, these RCEP procedures must be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse. Most significantly for the new pandemic world, a party to the RCEP "may, in formulating or amending its laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public sectors of vital importance to its socioeconomic and technological development."⁴⁷

Because of the urgent need to promote innovation worldwide, other international IP concerns addressed to varying extents in the ongoing proliferation of non-WTO agreements are also deserving of attention in a modernized TRIPS Agreement. Foremost among them is the pressing need to protect IP rights related to new technologies and to new methods of transmission in ways that facilitate trade. In particular, this should include the explosion of the digital trade that barely existed when the TRIPS Agreement was negotiated and agreed.48 In their current WTO discussions of the pressing need for specific WTO rules that address digital trade, WTO members must keep much in mind the creative role of IP rights to digital trade.

In the wake of the COVID-19 pandemic, the importance of intangible assets is increasing. As Greg Ip (2020) of *The Wall Street Journal* has observed, "value is increasingly derived from digital platforms, software and other intangible investments rather than physical assets and traditional relationships." Jason Thomas, head of global research at The Carlyle Group, a leading global private-equity firm, informs us that the pace of digitalization will accelerate in the new

⁴⁵ Regional Comprehensive Economic Partnership Agreement, 15 November 2020, sec A, art 11.1 at para 1c (not yet entered into force) [RCEP], online: http://rcepsec.org/wp-content/uploads/ 2020/11/Chapter-11.pdf>.

⁴⁶ Ibid, art 11.4 at para 2.

⁴⁷ Ibid, art 11.4 at para 1.

⁴⁸ See www.oecd.org/trade/topics/digital-trade/.

⁴⁴ See https://rcepsec.org/.

pandemic world: "technology-enabled adaptation has opened the door to more sweeping changes in business models and strategies (Thomas 2020a) [and] tech-enabled digital platforms tend to outperform the broader market" (Thomas 2020b).

Rana Foroohar (2020) of the *Financial Times* predicts that, of the new start-up enterprises that will emerge in the aftermath of the pandemic, "it's a fair bet that many will be highly digital. They are likely to hold a large chunk of value in intangible assets such as research and development, brands, content, data, patents or human capital, rather than in physical assets such as industrial machinery, factories or office space." When these new enterprises engage in international trade, whether of goods or of services, they will be more likely to do so digitally. IP will become even more of a trade issue than it is now.

Some of the basics of what should be included in a modernized TRIPS Agreement relating to the link between IP and digital trade through electronic commerce — on transparency, customs duties, online consumer protection, online personal information and more — are in chapter 12 of the RCEP.⁴⁹ Similar provisions are found in chapter 19 of CUSMA⁵⁰ and chapter 14 of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership.⁵¹ The continued economic advance of developed and developing countries alike requires a seamlessness in the treatment of digital trade to maximize the flow of digital trade. This seamlessness can only be achieved if the rules for digital trade are multilateral rules within the WTO.

Also, there is need for a negotiated compromise on an appropriate balance between exclusivity and access for protections of new pharmaceutical products, including the biological drugs — the biologics — that are made from living organisms or that contain components of living organisms. WTO members must make certain, of course, that the legal lines they draw between exclusivity and access in such new protections will indeed foster innovation and will not simply create undue global rents for the IP right holders.⁵² Getting the balance between exclusivity and access right on the biologics that may increasingly typify medicines is especially significant.

At the same time, there is equal need for providing more international protections in the TRIPS Agreement for the traditional knowledge that has been passed down for generations as the heritage of Indigenous communities, often in developing countries where there are inadequate domestic rights to such knowledge.53 And, more broadly, at a time when biodiversity is imperiled worldwide, WTO members must forge a stronger consensus on the line dividing where animal, plant and other natural resources can be patented and where they cannot. Those who create knowledge should be able to enjoy a limited right to the exclusive ownership of that knowledge; however, knowledge is not created by those who merely misappropriate traditional knowledge for commercial profits.54

A pioneering feature of the RCEP is that it includes — for the first time in any trade agreement provisions to protect genetic resources, traditional knowledge and folklore. Section G of chapter 11 of the RCEP, on IP, specifies that, subject to their international obligations, parties to the RCEP "may establish appropriate measures to protect genetic resources, traditional knowledge, and folklore."⁵⁵ In particular, in patent examinations, "relevant publicly available documented information related to traditional knowledge associated with genetic resources may be taken into account."⁵⁶ Similar provision should be made by the members of the WTO in a TRIPS-plus agreement.

In addition, a modernized TRIPS Agreement should emulate the novel WTO Trade Facilitation Agreement⁵⁷ (TFA) in doing much more to help provide many of the developing countries with the capacity to meet their obligations to protect IP rights. Conceivably, like the TFA, a

⁴⁹ RCEP, supra note 45, chap 12, online: http://rcepsec.org/wp-content/uploads/2020/11/Chapter-12.pdf.>

⁵⁰ Canada-United States-Mexico Agreement, 10 December 2019 (entered into force 1 July 2020). online: <www.international.gc.ca/tradecommerce/trade-agreements-accords-commerciaux/agr-acc/cusmaaceum/text+texte/toc-tdm.aspx?lang=eng>.

⁵¹ Comprehensive and Progressive Agreement for Trans-Pacific Partnership,8 March 2018, c 14 (entered into force 30 December 2018), online: <www.mfat.govt.nz/assets/Trade-agreements/CPTPP/CPTPP-Text-English.pdf>.

⁵² See Ciuriak (2017).

⁵³ See www.wipo.int/pressroom/en/briefs/tk_ip.html.

⁵⁴ See Nayak (2019).

⁵⁵ RCEP, supra note 45, c 11, online: http://rcepsec.org/wp-content/uploads/2020/11/Chapter-11.pdf>.

⁵⁶ Ibid.

⁵⁷ See www.wto.org/english/tratop_e/tradfa_e/tradfa_e.htm.

modernized TRIPS Agreement could allow the developing countries — particularly the leastdeveloped countries — to determine when they will implement specific new obligations in the agreement, and to identify obligations they will only be able to implement upon the receipt of technical assistance and support for capacity building. The developing countries — especially the least-developed countries cannot be expected to assume a whole slew of new IP obligations if developed countries do not provide them with sufficient technical support and adequate capacity-building and financial assistance to be able to fulfill those obligations.

The details of what the members of the WTO decide to include in fully realizing the balance in the TRIPS Agreement should be informed by the common commitment they expressed when creating the WTO to sustainable development. The first paragraph in the preamble on the first page of the WTO treaty proclaims that "trade and economic endeavour" should be conducted 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."58 The WTO Appellate Body has explained that this language in the preamble "gives colour, texture and shading to the rights and obligations of Members under the WTO Agreement."59

The objective of sustainable development is reflected in the Sustainable Development Goals (SDGs) of the United Nations for 2030.⁶⁰ These global goals were agreed in 2015 by all the members of the United Nations — including all the members of the WTO. Goal 9 of the 17 SDGs is, in part, to "foster innovation." This global goal cannot be achieved without the incentives provided by the protection of IP. At the same time, the SDGs also aim to end poverty and hunger, ensure health and education, promote sustainable and inclusive economic growth, and achieve much more on many fronts by the end of this decade. Implicit in the "integrated and indivisible" nature of these global goals is the assumption that achieving them all will depend on balancing them all through concerted international cooperation. With this global balancing in mind, WTO members can contribute most to achieving the goal of fostering innovation by upholding the balance between exclusivity and access in the WTO rules on the protection of IP rights.

Conclusion

The new pandemic world requires new innovations of all kinds, not least in new medicines to help prevent and cure new diseases. The protection of IP rights provides incentives for these new innovations. Multilateral incentives for innovations can be much more productive than bilateral and regional incentives because of the global reach of multilateral incentives and the global protections of the WTO rules against discrimination. In trade, more multilateral incentives for needed innovations will not be agreed unless and until all members of the WTO first agree on the meaning of the balance they have struck between exclusivity and access to new knowledge in the TRIPS Agreement and work together to realize that balance fully in their ongoing implementation of that agreement. Only once they have done this, will they be able to transform TRIPS-past into TRIPS-plus by fostering innovation and fulfilling their overall commitment to the objective of sustainable development, which is reflected in the UN SDGs.

⁵⁸ Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, 1867 UNTS 154, 33 ILM 1144 (1994) (entered into force 1 January 1995) [emphasis added], online: <www.wto.org/english/ docs_e/legal_e/04-wto_e.htm>.

⁵⁹ WTO, Appellate Body, United States – Import Prohibition of Certain Shrimp and Shrimp Products, WTO Doc WT/DS58/AB/R, 12 October 1998 at para 155, online: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/DS/58ABR.pdf&Open=True>.

⁶⁰ See https://sdgs.un.org/2030agenda.

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