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World Trade Organization as a Barrier to Global Public Health

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Imagination is more important than knowledge.
Albert Einstein

Alas, the WTO's imaginations were limited to creating private wealth at the cost of public health.
Srividhya Ragavan

Introduction

"The World Health Organization Draws Flak for Coronavirus Response," reads the headline of the Wall Street Journal on February 12, 2020.[1] The global struggle with the coronavirus pandemic has highlighted two things: first, the importance of medication; second, the need to access health care and medication. With tens of thousands of individuals infected with COVID-19, and a death toll spreading into almost all countries, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared this virus a "public health emergency of international concern." Disruptive global epidemics – such as the coronavirus, Ebola, and SARS – have time and again raised the issue of global response and preparedness to such pandemics.[2] While the WHO continues to be in the center of the debate, the role of the World Trade Organization (WTO) remains crucial in proactively preventing or addressing pandemics.[3] The harmonized trading system of the WTO was built on an underlying ideology that egalitarian access to health is a barrier to trade and that disparate access to health was the solution to innovation. A public health crisis in one part of the world can affect global trade in unimaginable ways. Thus, protecting public health has become the threshold to protect global trade.

In the face of a global pandemic, access to health care and medication is the one paradigm that can alleviate many global concerns, including those involving and related to trade such as employment, travel, and more. Lack of medications – either from lack of availability of medication or lack of access – can catapult a possible national public health issue into an international global health crisis. In turn, a global health crisis can affect several industries in ways otherwise unimaginable. Hence, there is a need for a balance between innovation and access. The role of the WTO as the gatekeeper for minimizing and eliminating trade barriers remains important in taking a strategic leadership position for health-related matters. If global productivity is affected due to lack of access to available medication, global trade suffers. Despite this reality, the WTO has remained normative and divorced from the real impact of local realities on larger health issues. Its stature as

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[1] Jeremy Page & Betsy McKay, *The World Health Organization Draws Flak for Coronavirus Response*, WALL STREET JOURNAL (Feb. 12, 2020), https://www.wsj.com/articles/the-world-health-organization-draws-flak-for-coronavirus-response-11581525207
[2] Brendan Murray, *Slump in Global Goods Trade to Deepen with Coronavirus, WTO Says*, BLOOMBERG (Feb. 17, 2020), https://www.bloomberg.com/news/articles/2020-02-17/slump-in-global-goods-trade-to-deepen-with-coronavirus-wto-says
[3] https://www.nytimes.com/reuters/2020/02/17/business/17reuters-trade-wto.html

a global organization notwithstanding, the WTO has shown a remarkable tendency to succumb to rhetoric and pressures from corporate interest and powerful countries, which are susceptible to pandering by powerful trade lobbies. Consequently, the WTO has been irrelevant in ensuring access to medication as a means to strengthen productivity and global trade.[4]

Indeed, the WTO's failure to balance innovation with access has caused, contributed to, and affected access to medications. The actions of the WTO has actively contributed to morphing access to lifesaving medications into a luxury by creating an elite global class of people with access to health care and medication or #mediclass – the class with access to medicines. While the WTO's emphasis on patents on lifesaving medications played a role in innovation, it largely facilitated corporations from disengaging with issues that raise public policy, public health, and right to life concerns – both by commissions and omissions that denied access to lifesaving medications.

This chapter outlines seven specific ways in which the WTO has, through its actions, inactions, and/or prescriptions, detrimentally affected access to medicines. Hence, it outlines how the WTO's myopic actions resulted in trade becoming a barrier to public health, and in turn, to trade itself. The chapter emphasizes that minimizing barriers to access medications and health is the lifeline to minimizing barriers to trade. It is imperative to control the pandemic as the first step to rejuvenate trade. Through this pandemic, questions on access to vaccines and global cooperation in costs implicated the role of trade and medication. Despite the impact of the public health crisis on trade, the WTO has largely remained silent without addressing how TRIPS provisions on innovation is a barrier to health and thus, indirectly to trade. In highlighting the ways in which the WTO has been a barrier to the protection of public health, the hope is that the trade regime of the future will promote rather than prevent countries from instituting measures critical to improving global public health, which in turn is the lifeline to improving productivity and trade.

It began with the original draft

When the WTO was established, the TRIPS Agreement mandated that countries provide product patent protection as part of the required minimum standards.[5] At that time, developing countries vociferously pointed to local realities to highlight that the TRIPS Agreement would be detrimental to accessing lifesaving medication in poorer members. Moreover, poorer countries criticized the TRIPS Agreement for not considering their resource restraints before enforcing the establishment of the patent regime. The main criticism against the TRIPS Agreement was that the harmonization effort did not provide for – nor did it factor in – issues of national import. Weaving adequate flexibility to allow countries at different stages of economic growth to balance between "incentives to create and the benefits of free competition" was an important aspect that the TRIPS agenda

[4] *The Dispute Settlement Process of the WTO: A Normative Structure to Achieve Utilitarian Objectives*, (co-authored with Brian Manning, Foreign Service Officer, U.S. Department of State) 79 UMKC L. Rev. 1, at 22 (2010).

[5] Annex IC to the General Agreement on Tariff s and Trade, Uruguay Round, World Trade Organization, *done at* Marrakesh, Apr. 15, 1994, 33 I.L.M 1981 (1994), *reprinted in* World Trade Organization, The Results of the Uruguay Round of Multilateral Trade Negotiations 365 (1995) [hereinafter "TRIPS"] at art. 27.

overlooked.[6] The overwhelming reality was that the "minimum standards" set forth in the TRIPS Agreement represented a maximalist approach.[7]

Particularly, the TRIPS Agreement's approach to access to medication was criticized for not taking the objectives and principles of the Agreement into account. Article 7 of the TRIPS Agreement outlines objectives stating that the enforcement of intellectual property (IP) mechanisms should promote technological innovation and transfer of technology in a manner mutually advantageous to the social and economic welfare of the users.[8] On a plain reading, article 7 emphasizes the welfare paradigm by asserting that the international obligations of protection and enforcement of IP rights should contribute to the national, social, and economic welfare of members. The outlined objectives have been criticized for the primacy they lend to IP protection, and for not providing members with adequate flexibility to address national issues.[9] The principles under which the objectives of article 7 work is outlined in article 8.[10] Entitled "Principles," article 8 recognizes members' rights to adopt public interest or public health measures, provided they are consistent with the TRIPS provisions.[11] Thus, article 8 recognizes limitations on private rights under some circumstances. This article can also be viewed as limiting the policy-making rights of member states in a public health or public interest exigency.[12] Operationally – the assertion of article 7 to balance members' rights with obligations notwithstanding – the TRIPS Agreement was more effective in encouraging fulfillment of obligations than in enabling members to achieve public policy and national developmental goals. Consequently, the WTO faced considerable pushback – most significantly from health activists, patient groups, and nongovernmental organizations (NGOs) – on the grounds that the innovation agenda did not address the question of providing global access to lifesaving drugs.[13] Thus, the WTO draft did not give preference to access to medication.

WTO's elitist attitude towards epidemics

The establishment of minimum standards – which in fact was a maximalist approach towards IP protection – characterized an inadequacy of the TRIPS Agreement in catering to issues such as mobilizing access to lifesaving medicines. For instance, during the early 1990s, the HIV/AIDS

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[6] *Id.*

[7] J.H. Reichman, *Enforcing the Enforcement Procedures of the TRIPS Agreement*, 37 Va. J. Int'l L. 335, 337,339 (1997).

[8] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Art. 7, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

[9] *See, e.g.*, The Doha Round, http://www.wto.org/english/tratop_e/dda_e/dda_e.htm (last visited June 11, 2011).

[10] *Id*. at Art. 8

[11] *Id*.

[12] TRIPS, *supra* note 10, Art. 8(1).

[13] ELLEN F. M. 'T HOEN, *The Global Politics of Pharmaceutical Monopoly Power*, 22, 78 (2009). *See also*, Germán Velasquez & Pascale Boulet, *Globalization and Access to Drugs: The Implications of the WTO/TRIPS Agreement*, HEALTH ECONOMIC AND DRUGS DAP SERIES NO. 7, 25 (1998), http://apps.who.int/medicinedocs/en/d/Jwhozip35e/3.7.1.html. Robert Weissman, *Strange Trips: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 UNIVERSITY OF PENNSYLVANIA JOURNAL OF INTERNATIONAL LAW 1069 (1996), https://scholarship.law.upenn.edu/jil/vol17/iss4/2.

crisis was ravaging the world at an unprecedented rate, particularly in developing countries. The patented medication, which cost $15,000 to $20,000 per patient per year,[14] remained inaccessible to many HIV/AIDS patients who needed the antiretroviral drugs (ARVs) to survive.

Africa was affected the most; thus, the impact of the high price of ARVs was felt more starkly there. Only one in a thousand people living with HIV had access to AIDS treatment at that time.[15] Highlighting the extent of the epidemic, in 1996, South Africa requested the United States (US) to allow access to the medication at an affordable price commensurate with its per capita income.[16] The US treated the issue as a routine noncompliance of the TRIPS Agreement; the then US Trade Representative, Mr. Papovich, asked South Africa to either comply with the TRIPS Agreement or, alternately, face trade sanctions.[17] South Africa could not afford trade sanctions, which could lead to further economic misery. Therefore, South Africa passed the Medicines and Related Substances Act Amendment of 1997[18] to statutorily implement negotiated TRIPS flexibilities. Under the statute, a deteriorating public health condition vested the health minister with the right to import or compulsorily license patents.[19] Condemning the health minister's "sweeping authority," the US denied South Africa permission to export under the generalized system of preference scheme (GSP).[20] Meanwhile, the Pharmaceutical Manufacturers' Association of South Africa (PMA) filed a suit against the South African government to suspend the Medicines Act.[21] The situation exacerbated when an update of public health conditions in 1999 revealed that one in five South

[14] Carmen Perez-Casas et al., *Accessing ARVs: Untangling the Web of Antiretroviral Price Reductions*, 10 (2001), https://msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_report_UTW1_ENG_2001.pdf; *See also*, Ellen 't Hoen et al., *Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All*, 14:15 J. INT. AIDS SOC. 1 (2011).

[15] Barton Gellman, *An Unequal Calculus of Life and Death; As Millions Perished in Pandemic, Firms Debated Access to Drugs; Players in the Debate Over Drug Availability and Pricing*, THE WASHINGTON POST, Dec. 27, 2000, at A1.

[16] Helene Cooper, Rachel Zimmerman & Laurie McGinley, *AIDS Epidemic Puts Drug Firms in a Vise: Treatment vs. Profits*, WALL STREET JOURNAL (March 2, 2001), https://www.wsj.com/articles/SB983487988418159849.

[17] *Id.*

[18] *See* South Africa Statutory Instrument 1997 Act. No. 59 (2002) (as amended) [hereinafter "Medicines Act"]. The 1997 legislation amended the South African Medicines and Related Substances Control Act No. 101 of 1965.

[19] Medicines Act at § 15(c), which reads: "The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public. and in particular may, notwithstanding anything to the contrary contained in the Patents Act. 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine or with his or her consent." While Medicines Act § 22C(1)(a) states "The Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, a license to compound and dispense medicines, on the prescribed conditions."

[20] Naomi A. Bass, *Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement*, 34 GEO. WASH. INT'L L. REV. 191, 211–12 (2002). Pretoria had requested additional benefits under the generalized system of preference scheme. The scheme allows poor countries to export products to the U.S. at reduced duties.

[21] *See* Patrick Marc, *Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?*, 21 N.Y.L. Sch. J. Int'l & Comp. L. 109, 121 (2001) (highlighting America's opposition to attempts by South Africa to legislate compulsory licensing provisions).The PMA is the organization in South Africa representing the Pharmaceutical Manufacturers of the developed nations.

Africans was AIDS-infected.[22] It caused President Clinton to issue an Executive Order to promote access to HIV/AIDS medicines, and extended the South African policy to all poor countries.[23]

Unlike South Africa, Thailand, through amendments to its 1979 patent legislation, facilitated generic drugs, a point highlighted by the chapter in this book authored by Van Anh Le.[24] In 1992, Thailand had extended patent protection to pharmaceuticals and increased the patent term to 20 years.[25] Just like in South Africa, the US threatened to impose sanctions unless amendments were introduced to the Thai patent legislation.[26] However, under trade pressure from the US[27] in 1999, Thailand abolished compulsory licensing and the local-working requirement.[28] These patent-friendly amendments resulted in an increase in AIDS infection with decreasing availability of medication.[29] By 2000, about three percent of the Thai population was reportedly infected with AIDS. The situation was so bad that the Office of the US Trade Representative (USTR) reversed its position, stating that it would not raise further objections "provided the compulsory license is issued in a manner fully consistent with the WTO/TRIPS Agreement."[30]

The precedents established by South Africa and Thailand resulted in Brazil amending its patent legislation of 1969 to fully comply with the TRIPS Agreement, including flexibilities such as compulsory licensing to preserve public health.[31] Meanwhile, spending $303 million per annum on a single ARV pushed Brazil to its economic limit.[32] When Roche Inc., after six months of

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[22] South Africa accounted for a total of 26 million of the world's 36 million HIV-affected patients. Seven countries in southern Africa reported that 20% of the adults were infected with HIV. Botswana accounted for the highest percentage of the disease with 35.8% infected adults. *See* Sara M. Ford, *Compulsory Licensing Provisions under the TRIPS Agreement: Balancing Pills and Patents,* 15 AM. U. INT'L L. REV. 941, 951 (2000); *see also, Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa,* INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE, 55–90 (2000); *see generally,* Liz McGregor, *Botswana Battles against Extinction,* THE GUARDIAN, July 8, 2002, http://www.guardian.co.uk/aids/story/0,7369,751263,00.html.

[23] Exec. Order No. 13155, 3 C.F.R. 268–70 (2000). The Order prohibits the U.S. government from taking any "[a]ctions pursuant to section 301(b) of the Trade Act of 1974 with respect to any law or policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS pharmaceuticals or medical technologies and that provides adequate and effective IP protection consistent with the TRIPS Agreement." *See also*, Rosalyn S. Park, *The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients,* 11 MINN. J. GLOBAL TRADE 125, 138 (2002).

[24] *CITE TO VAN ANH'S CHAPTER* *See also*, Rosemary Sweeney, *The U.S. Push for Worldwide Patents Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision*, 9 PAC. RIM L. & POL'Y J. 445, 446 (2000).

[25] *See* Thailand Statutory Instruments, Thai (amended) Patent Act (No. 2) B.E. 2535 (1992), as amended.

[26] *See* Sweeney, *supra* note 26, at 446–48. The amended Thai patent legislation retained the authority to issue compulsory licenses of patented goods not locally manufactured. A Pharmaceutical Patent Board was created with the power to compulsorily license patents in a public health crisis, to control prices, and to seek pricing and cost information on drugs. The patent amendment did not protect existing products patented in other countries but not marketed in Thailand.

[27] *Id.* at 461. In 1997, Thailand suffered a severe economic crisis, increasing its reliance on American exports.

[28] *See* Thailand Statutory Instruments, Thai (amended) Patent Act (No. 3) B.E. 2542 (1999). The amended law abolished the Pharmaceutical Review Board. Importation of patented products by the patentee was deemed as working the patent locally. *See generally,* Susannah Markandya, *Timeline of Trade Disputes Involving Thailand and Access to Medicines* (July 23, 2001), http://www.cptech.org/ip/health/c/thailand/thailand.html.

[29] Sweeney, *supra* note 26, at 446.

[30] Consumer Project on Technology, *Timeline of Trade Dispute Involving Thailand and Access to Medicines* (July 23, 2001), http://www.cptech.org/ip/health/c/thailand/thailand.html.

[31] Brazil Industrial Property Law No. 9,279 of May 14, 1996 (effective May 1997).

[32] Melody Petersen & Larry Rohter, *Maker Agrees to Cut Price of Two AIDS Drugs in Brazil,* N.Y. TIMES (Mar. 31, 2001),

negotiations, refused to discount the price of ARVs, Brazil threatened to compulsorily license them.[33] The background of the tremendous success of the AIDS drug distribution program forced the US to drop its claims against Brazil in the WTO.[34] Consequently, Roche and Merck negotiated with Brazil to reduce the cost of the AIDS drugs by 70 percent.[35]The WTO did not have the jurisdiction to interfere directly. But, just like with the COVID-19 pandemic, the WTO chose to stick with the normative questions on trade, if and when presented to it. The WTO's silence and inability to acknowledge the barriers that its agreement creates to public health – and in turn, to global trade – weakens its stature. Further, the extent of unilateral interference and pressure by the US reiterated the susceptibility and disadvantages of the unequal bargaining parities of members. It weakened the rhetoric for a multilateral forum. Furthermore, the WTO's inability to work with the WHO to clarify whether and how countries can utilize flexibilities to safeguard public health, considering the fact that patents increasingly impede medicine access, has impacted the WTO's reputation negatively.

Flexibility gone awry

The AIDS crisis showcased economic and social challenges of poorer nations. Soon, developing nations sought a "broad and balanced" program within the TRIPS Agreement.[36]

In June 2001, a special session of the TRIPS Council heard the views of over 40 countries on issues relating to IP and access to medicine, and identified key elements relating to safeguarding public

http://www.nytimes.com/2001/03/31/health/31AIDS.html?ex=1051934400&en=f9e3ca8f7ee0983c&ei=5070; *See also*, Mario Osava, *Government to Violate Patents on AIDS Drugs*, INTER –PRESS SERVICE, Aug. 23, 2001.

[33] *See* Miriam Jordan, *Brazil to Break Patents on AIDS Medication Nelfinavir*, WALL ST. J., Aug. 23, 2001, at A1 (detailing that Brazil requested Roche Inc. to reduce the cost of the AIDS cocktail drugs, *nelfavir* and *viracept*. Roche Inc. refused to consider anything more than a 13% reduction in price. Brazilian officials announced that the patent in nelfinavir would be compulsorily licensed for local manufacture of generic versions unless the price was reduced; *See also Ministry of Health Announces Compulsory Licensing of Nelfinavir Patent* (Aug. 22, 2001), *available at* http://www.cptech.org/ip/health/c/brazil/nelf08222001.html. See also Amaka Vanni, Patent Games in the Global South: Pharmaceutical Patent Law-Making in Brazil, India and Nigeria 90-94 (2020) on HIV/AIDS medicines and the politics of compulsory license in Brazil.

[34] Helene Cooper, *U.S. Drops WTO Claims against Brazilian Patent Law*, WALL ST. J., June 27, 2001, at B7.

[35] Jennifer L. Rich, *Roche Reaches Accord on Drug with Brazil*, N.Y. TIMES (Sept. 1, 2001), http://www.nytimes.com/2001/09/01/business/worldbusiness/01DRUG.html?searchpv=day03; *See also* Paulo Rebelo, *Brazil Targets Another AIDS Drug*, WIRED NEWS (Aug. 29, 2001), http://www.wired.com/news/politics/0,1283,46353,00.html; *See generally Roche Surprised by Authorities Declaration* (Aug. 23, 2001), *at* http://www.cptech.org/ip/health/c/brazil/. Brazil provided the AIDS "cocktail" medications free for its citizens and thus reduced the national AIDS mortality rate from 10,592 in 1995 to 1,700 in 2001. To ensure supplies of the drugs to 100,000 HIV/AIDS patients, Brazil manufactures 7 of the 12 medications at a local company—*Farmanguinhos*. *See* Gustavo Capdevila & Mario Osava, *US Drops Brazil Patents Case*, INTER PRESS SERVICE NEWS AGENCY (June 26, 2002), http://www.ipsnews.net/2001/06/trade-us-drops-brazil-patents-case-paves-way-for-low-cost-drugs/.

[36] *See* Helene Cooper & Geoff Winestock, *Poor Nations Win Gains in Global Trade Deal as U.S. Compromises*, WALL ST. J., Nov. 15, 2001, at A1 (discussing issues raised by the Indian Commerce and Industry Minister in the WTO session at Qatar); *See also* World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration].

health.[37] Meanwhile, the US had to address a domestic anthrax scare in 2001.[38] Responding to a relatively small but increased number of patients contracting anthrax from unknown sources, the US Department of Health and Human Services (HHS) immediately sought a workable solution to access medication and determined that compulsorily licensing the anthrax medication *Cipro* was the most viable solution unless the patent owner, Bayer AG Corporation, lowered its selling price![39] This reaction of the HHS destroyed the credibility of the US argument that compulsory licensing of pharmaceuticals was an undesirable option to address public health crises.[40] Consequently, the anthrax issue facilitated concessions to developing nations at the Doha Round of the WTO, which allowed members to derogate from patent rights to prioritize public health issues;[41] it encouraged members capable of manufacturing generic drugs – such as India and Brazil – to tackle prevailing or potential public health needs by locally manufacturing generic medications.[42] Unfortunately, this solution could not help least developed states with no capacity to manufacture generic drugs. Basically, article 31(f) of the TRIPS Agreement required compulsorily licensed medication to predominantly supply the domestic market of the member authorizing such use.[43,44] Thus, the WTO's flexibilities continued to remain ineffective in some countries even after the Doha Declaration on the TRIPS Agreement and Public Health 2001 (Doha Declaration) until the issues arising from the operation of article 31(f) were partly addressed by article 31*bis* of the TRIPS Agreement – allowing export of generics for a limited purpose – was adopted in 2006.[45]

This was the first glimpse post the WTO's establishment of how trade would be affected if public health is left unprotected. The trade regime on the health and medication issues miscalculated this reality for over 25 years! The ideological affinity over the patents and innovation rhetoric erased any semblance to realism; instead, it induced a normative reading of the WTO texts which would ultimately blindside the globe into COVID-19. Realistic issues of local realities were brushed aside as mere poor-country sob stories to help ignore the importance of health for robust trade, representing yet another lost opportunity for the WTO.

WTO reducing the line between domestic and market access issues

[37] TRIPS, *supra* note 10; *TRIPS and Public Health*, THIRD WORLD NETWORK, http://www.twnside.org.sg/title/twr131e.htm (last visited Mar. 29, 2005); *See also* James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties*, 15 Harv. J. Law & Tech. 291, 295–98 (2002)., at 291.
[38] Cecilia Oh, *Developing Countries Call for Action on TRIPS at Doha WTO Ministerial Conference*, Third World Network, *at* http://www.twnside.org.sg/title/twr131d.htm (last visited June 12, 2011)
[39] Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health*, 17 AM. U. INT'L L. REV. 1299, 1302 n.12 (2002).
[40] *Id.*
[41] Doha Declaration, *supra* note 38.
[42] *Id.*
[43] TRIPS, *supra* note 10, at Art. 31(f).
[44] *Id.*
[45] *See* General Council, *Implementation of the Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* WT/L/540 (Aug. 30, 2003).

The WTO's agreements distinguish between domestic regulations and market access restrictions.[46] Domestic regulations are internal national regulations. Market access restrictions are customs and other regulations that affect access to the market by third countries, thus acting as trade barriers. The agreements prohibit members from creating market access restrictions that discriminate unfairly against imports, but provide extensive regulatory autonomy for domestic regulations.[47] In any given dispute, the role of the WTO's Dispute Settlement Body (DSB) is to determine whether a market access restriction exists in the member state in question.[48] While general wisdom favors removal of all market access restrictions, justifiable exceptions can be found in almost any country for several reasons: political, social, and/or market-oriented. Further, a blanket recommendation from a global body or the DSB to remove the market access restriction – without fully appreciating the broader national, regional, or even global effects of such removal – would be myopic and could create economic and social imbalance within a country.

Member governments of the WTO have a larger task to accomplish for national markets. Member governments' resources are limited, in the sense that they demand allocation toward conflicting or directly competing social, economic, and welfare-oriented goals. For instance, should a country prioritize providing patent protection to allow foreign investment in the future, or should it take care of an existing public health crisis by providing generic drugs? States have been traditionally allowed to act as they see fit on issues relating to the political and social heart of their sovereignty, like health-care issues.[49] For member nations, trade regulations represent one part, albeit important, of the paradigm of socioeconomic issues that need resolution. Acknowledging this approach, the WTO treaty envisages sovereign latitude for countries to address issues of national import to resolve complex local issues that each country faces – issues that can interfere with trade obligations.[50]

The DSB's role would be more realistic if it considers the likely effects of a market access restriction – by weighing it against the cost to international trade *as well as to the member*. Instead, the DSB has tended to be more normative. For example, in 1994, when India attained WTO membership, the TRIPS Agreement provided a transitional period until January 1, 2005 to move toward the product patent regime.[51] During this transitional period, article 70.8 of the TRIPS Agreement required members to establish a transitional "mailbox" mechanism, i.e. to establish a

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[46] Joost Pauwelyn, *Rien Ne Va Plus? Distinguishing Domestic Regulation from Market Access in GATT and GATS* 132 DUKE LAW SCHOOL, LEGAL STUDIES PAPER NO. 85, *available at* http://ssrn.com/abstract=638303.
[47] *Id.* at 32.
[48] Understanding on Rules and Procedures Governing the Settlement of Disputes art. 1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU]. Article 3.4 specifies that "[r]ecommendations or rulings made by the DSB shall be aimed at achieving a satisfactory settlement... in accordance with the rights and obligations under this Understanding and under the covered agreements." *Id*. at Art. 3.4. Further, Article 3.7 highlights that "the first objective of the dispute settlement mechanism is usually to secure the withdrawal of the measures concerned if these are found to be inconsistent with the provisions of any of the covered agreements." *Id*. at Art. 3.7. Thus, the DSU does not concern itself with the larger question of the effect of a market access restriction on domestic issues. *See also* Marie-Christine Lebret & Arlène Alpha, Factsheet 4—The Application of Rules: Cotton, http://www.gret.org/publications/ouvrages/infoomc/en/F04en.html (last visited July 14, 2010) (highlighting that the DSB's role is limited to enforcing existing rules).
[49] Pauwelyn, *supra* note 49, at 135.
[50] *Id.* at 133.
[51] TRIPS, *supra* note 10**Error! Bookmark not defined.**, at Art. 65.

means to file patent applications which would be considered for patent protection after the transition in 2005.[52] By virtue of article 70.9, members were required to provide exclusive marketing rights (EMR) to patent applications in the mailbox.[53] Thus, patent applications filed by transitioning members would enjoy EMR provided two conditions were met: first, an application had been filed in another member state; and second, the application matured into an actual patent.[54]

When India became a TRIPS Agreement signatory, the President of India promulgated the Patents (Amendment) Ordinance 199[55] for accepting mailbox applications for agricultural and chemical product inventions. The Ordinance detailed application procedures, scope, and enforcement of rights of EMR.[56] When the Ordinance expired, Parliament was not in session; hence the Indian government attempted to meet India's TRIPS obligations by issuing administrative orders[57] instructing the Patent Office to receive patent applications for pharmaceutical, agricultural, and chemical products.[58] Thus, from January 1, 1995 to February 15, 1997, India received and stored 1,339 applications under the administrative scheme.[59] As of late September 1997, no applicant requested an EMR.[60] In July 1996, the US requested consultations with India pursuant to article 4 of the Dispute Settlement Understanding (DSU), read with article 64 of the TRIPS Agreement, claiming that India was in breach of its TRIPS obligations for not statutorily offering the mailbox mechanism.[61] When consultations failed, the US requested that a dispute panel be established to review the claim.[62] The panel determined that India violated article 70.8 of the TRIPS Agreement in not establishing a statutory means to establish such a mailbox mechanism,[63] and article 70.9 of the TRIPS Agreement by not creating a statutory mechanism to grant EMR.[64]

When India appealed the panel's decision,[65] the Appellate Body (AB) determined that the TRIPS Agreement would be interpreted based on the legitimate expectations of the parties at the time of signing the treaty (in contrast to an objective-based interpretation of the treaty, as required in the Vienna Convention).[66] Thus, the AB held that legitimate expectations of parties to a treaty were reflected in the treaty language, leaving the interpreter to examine the words of the treaty *alone* to

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[52] *Id*. at Art 70.8.
[53] *Id*.
[54] Id. at Art 70.9.
[55] *See* Patents (Amendment) Ordinance, 2004, No. 7, (*available at* https://spicyip.com/wp-content/uploads/2020/02/2004-patent-ordinance-later-rejected.pdf
See also INDIA CONST. art. 123 § 1(which authorizes the President to legislate when parliament is not in session when the President deems necessary to take immediate action).
[56] *See* Patent Ordinance, *supra n.* 59.
[57] Robert Pechman, *Seeking Multilateral Protection for Intellectual Property: Th e United States "TRIPS" over Special 301*, 7 Minn. J. Global Trade 179, 196 (1998) (discussing that the U.S. subjected countries with inadequate protection of IP rights to special 301 trade sanctions)
[58] *See* Panel Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, 2.3, 2.5 WT/DS50/R (Sept. 5, 1997)
[59] Id. at 7.4.
[60] Id. at 7.5.
[61] Id. at 1.1.
[62] Id.
[63] Id. at 8.1.
[64] Id.
[65] *See* Notification of an Appeal, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Oct. 16, 1997, WT/DS50/6 (1997).
[66] *Id.* at Sec. 55.

determine the intentions of the parties.[67] Traditionally, international agreements are not interpreted like statutes, which are construed more strictly to defer to the views of the legislature. International agreements are not enforcement mechanisms, but instruments that memorialize collective sovereign intentions. The intentions of parties with respect to international agreements and obligations are generally amenable to local needs and political and economic situations; therefore, a more flexible and broader construction is warranted. Unfortunately, a strict constructionist, textualist, and non-traditionalist approach would be an imperfect treatment of substantive issues. But the AB used a strict normative constructionist approach of article 70.8[68] of the TRIPS Agreement to determine that India failed to establish a legally sound transitional mailbox mechanism.[69]

The AB failed to accept India's position that the scheme was legitimate under the jurisprudence developed by Indian courts.[70] Instead, like the panel,[71] the AB required precedents explicitly showing that a court would uphold the validity of administrative actions,[72] and refused to defer to a nation's interpretation of its own legislation to hold that India violated the TRIPS Agreement.

The normative approach did not consider local issues and disregarded important national ramifications. Even assuming trade improved as a consequence of the patent regime, the ensuing development would not be sustainable, which has proved to be true over time in several developing countries.

WTO's inability to address unilateral action

The WTO has been criticized for its inability to curtail countries with higher bargaining parity, such as the US, from taking actions that result in TRIPS-plus trade privileges being detrimental to countries with lower bargaining parity. For example, in February 2020, the US-India Memorandum of Understanding (MoU) on Intellectual Property Rights – for the exchange of knowledge and training of officials working in offices undertaking IP management in India – presented serious concerns.[73] The US Patent and Trademark Office training Indian patent office personnel on the Indian statute – which incorporates more TRIPS flexibilities than the US – is an appalling proposition.[74]

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[67] *Id.* at Sec. 45.
[68] *Id.* at Sec. 56.
[69] *Id.* at Sec. 58.
[70] India offered case laws in support of its assertion. India cited the two Supreme Court cases to confirm the Indian position that its reliance on an administrative practice regarding the handling of pharmaceutical and agricultural chemical product patent applications is not unconstitutional, *See State of Haryana v. Mahendra Singh & Others*, AIR 1988 SC 1681; *See also Union of India v. H.R. Patankar & Ors.*, AIR 1984 SC 1587 (holding that statutory rules cannot be amended by Executive instructions but "if the rules are silent" on any particular point Government can fill up the gaps by issuing executive instructions, in conformity with the existing rules). *See generally* INDIA CONST. art 73 §1(a).
[71] *See* Panel Report, *supra* note62 at 7.37.
[72] Id.
[73] Joe Mathew, Civil society groups oppose India-US MoU on intellectual property rights (Feb 22, 2020) *available at* Business Today, Feb 22, 2020 https://www.businesstoday.in/
[74] Indian CSO Letter: Concerns regarding proposed US-India MoU on Intellectual Property Rights, From: Malini Aisola; IP-HEALTH, 2/22/2020

In fact, the entire Special 301 reporting system is a caricature of overreach. Traditionally, the USTR, which forms a part of the executive office of the President of the US, oversees the enforcement of US trade policy, including IP policy. As part of that role, the USTR annually lists countries – the Special 301 list – for taking sovereign actions that the USTR believes detrimentally affects US trade. Thus, when India reduced drug prices to protect cancer patients, it featured in the USTR list because it would affect the revenue of American pharmaceutical companies. The Special 301 process is best defined as an overreach mechanism statutorily supported under the Trade Act of the US.[75] Ultimately, the USTR is an American administrative body specifically charged to examine issues from a myopic and limited perspective of US trade from which vantage they summon sovereign nations to defend their trade positions, with little regard to local realities that necessitate sovereign decisions. Consequently, the USTR takes upon itself the righteous role of citing countries for lack of patent protection, even when the nation uses generic drugs to prevent slipping into a public health crisis. The USTR's zealous enforcement mechanism requires it to submit an annual report to both the House and Senate, describing enforcement actions that "have to be taken" against other sovereigns to protect US trade, particularly IP rights.

Considering the above, undue unilateral interference is normal for the US. For example, patentee Bayer AG marketed *soranafib tosylate* as *Nexavar* at approximately $5,000 per month.[76] The price was nearly five times higher than the median annual income in India, although the highlight remains the US' visceral reaction when a compulsory license was issued for the drug in India..[77] On August 2, 2013, the pharmaceutical industry's lobbying effort translated into a request from the chairman of the US Senate Committee on Finance and the House Committee on Ways and Means to the US International Trade Commission to institute an investigation on India's trade practices,[78] using powers under section 1332(g) of the Tariff Act of 1930.[79] The Special 301 Report of the USTR, on which India is usually featured, specifically identified the Bayer decision as "concerning," both in the 2012 and 2013 reports.[80] But the decision continues to be cited in the Special 301 reports as late as in 2020.[81]

In fact, the US established a similar pattern of response in Colombia following the release of Resolution 2475 of 2016 on June 17, 2016 for the issuance of a compulsory license to lower the

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[75] Omnibus Trade and Competitiveness Act of 1988, the Uruguay Round Agreements Act, and the Trade Facilitation and Trade Enforcement Act of 2015, 19 U.S.C. § 2242.

[76] Mike Palmedo, *Graphics on U.S. Pharmaceutical Exports to India, Patents, the Compulsory License, and Prices*, infojustice.org (Feb. 19, 2014), http://infojustice.org/archives/32249; *See also India Grants First Compulsory License to Generic Drug Producer*, ICTSD.ORG (Mar. 14, 2012), *http://www.ictsd.org/bridges-news/bridges/news/india-grants-first-compulsory-license-to-generic-drug-producer*; *See also Bayer v Natco*, M.P. Nos 74–76 of 2012 and M.P. No.108 of 2012.

[77] Srividhya Ragavan, *Patients Win Over Patents*, THEHINDU.COM (Mar. 7, 2013), https://www.thehindu.com/opinion/op-ed/patients-win-over-patents/article4482469.ece.

[78] International Trade Commission Investigation, Notice for Investigation No. 332-543 (Aug. 29, 2013), (on issues relating to trade, investment, and industrial policies in India, with particular reference to its effects on the US economy and US jobs).

[79] 19 USC §1332(g).

[80] 79 Fed. Reg. 421 (Jan. 3, 2014); *see also* Office of the United States Trade Representative, *Special 301 Report* (Washington, 2012, 2013) *available at* www.ustr.gov

[81] Andrew Goldman, *Colombia Issues Public Interest Declaration to Lower Price of Glivec*, KEIONLINE.ORG (June 15, 2016), https://www.keionline.org/23119; Ministry of Health and Social Protection Resolution Number 2475 of June 14, 2016, available at https://www.minsalud.gov.co /Normatividad_Nuevo/Resoluci%C3%B3n%202475%20de%202016.pdf [Accessed October 31, 2016].

price of *imatinib*, a leukemia drug marketed as *Glivec*, whose patentee was Novartis AG.[82] At that time, the cost of 400mg of *Glivec* in Colombia amounted to $15,000 per patient per year, and represented nearly twice the average annual income of Colombians.[83]

The US response to Colombia followed a predictable pattern. In May 2016, the USTR, citing Resolution 2475, indicated that funds intended for a peace accord with Paz Colombia could be at risk.[84] The USTR's response caused the House Democrats to express serious concern over USTR's actions.[85] The letter, addressed to then US Trade Representative Ambassador Michael Forman, asserted that the US would detract from its obligations as a signatory to the TRIPS Agreement and the Doha Declaration, which expressly authorize the use of such licenses for the same situations for which it was used by Colombia. This narrative underscores the lack of legitimacy of US involvement in another country's sovereign actions taken expressly in the public interest or to protect public health, such as the compulsory licensing of pharmaceuticals.

Preserving bargaining (im)parities?

WTO membership entails that all disputes be resolved through the multilateral dispute system of the WTO, using the DSB's process.[86] After the US gained membership to the WTO, the Uruguay Round Agreements Act of 1994 was passed as the implementing legislation.[87] When the US

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[82] *See generally*, Ministro de Salud y Protección Social, "Solicitud de una declaración de interés público en el acceso al medicamento imatinib bajo condiciones de competencia", available at *https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/Solicitud-de-una-declaracion-en-el-acceso-al-medicamento-IMATINIB.pdf* [Accessed October 31, 2016]

[83] Andrew Goldman, *Background FAQ on Glivec (imatinib) Compulsory License in Colombia*, KEIONLINE.ORG, https://www.keionline.org/book/background-faq-on-glivec-imatinib-compulsory-license-in-colombia (last visited Oct. 31, 2016).

[84] WOLA, *Excerpts from the August 24 Announcement of a Final Peace Accord between the Colombian Government and the FARC: The Joint Communiqué*, COLOMBIAPEACE.ORG, https://colombiapeace.org/excerpts-from-the-august-24-announcement-of-a-final-peace-accord-between-the-colombian-government-and-the-farc/ (last visited Oct. 31, 2016). The conflict with FARC ended after more than 50 years. Unfortunately, Paz-Columbia was never implemented because the deal was rejected in a referendum. *See* Sibylla Brodzinsky, *Colombia referendum: voters reject peace deal with Farc guerrillas*, THEGUARDIAN.COM (Oct. 3, 2016), https://www.theguardian.com/world/2016/oct/02/colombia-referendum-rejects-peace-deal-with-farc; *See* Stephanie Burgos, *Does Colombia Really Have to Choose between Poverty and Public Health*, OXFAMAERICA.ORG (May 23, 2016), *http://politicsofpoverty.oxfamamerica*.org/2016/05/does-colombia-really-have-to-choose-between-peace-and-public-health/.

[85] Andrew Goldman, *15 House Dems Press USTR to Clarify Position on Compulsory Licensing of Cancer Drug Patent in Colombia*, KEIONLINE.ORG (May 26, 2016), https://www.keionline.org/23097; *See* Zach Carter, *Colombia Fears U.S. May Reject Peace Plan to Protect Pharma Profits*, HUFFPOST.COM (May 11, 2016), http://www.huffingtonpost.com/entry/colombiagleevec_us_5733d4ece4b077d4d6f224ee; Carolyn Y. Johnson and Karen DeYoung, *Dispute with Swiss Drug Maker Has Colombian Officials Worried about U.S. Peace Funding*, WASHINGTONPOST.COM (May 18, 2016), https://www.washingtonpost.com/business/economy/dispute-with-swiss-drugmaker-has-colombian-officials-worried-about-us-peace-funding/2016/05/18/6f1903ee-1c5e-11e6-8c7b-6931e66333e7_story.html.

[86] *See* Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Annex 2, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY, 33 I.L.M, 1125, 1226, 1244 [hereinafter DSU]. (Article 6 of the Understanding provides for the establishment of the Dispute Settlement Body);

[87] Omnibus Trade and Competitiveness Act of 1988, the Uruguay Round Agreements Act, and the Trade Facilitation and Trade Enforcement Act of 2015, 19 U.S.C. § 2242.

Congress failed to repeal section 301 of the Trade Act of 1974[88] – which unilaterally authorizes the USTR to identify and pursue countries perceived as denying adequate and effective protection of IP rights or fair and equitable market access to US industries or entities that rely on IP protection – the European Union (EU) claimed that "by imposing specific, strict time limits within which unilateral determinations must be made and trade sanctions must be taken, Sections 306 and 305 of the Trade Act of 1974" violated the US commitment to the WTO to resolve multilateral disputes through the DSB process.[89] Hence, the EU requested consultation as required under the DSU with the US.[90]

This failure resulted in a panel being established to determine whether the Special 301 program violated the US obligations under article 23(1) and (2) of the DSU in *United States – Sections 301–310*.[91] The panel opined that the statutory language of section 304 constituted a serious threat to multilateral dispute resolution. Nevertheless, a "Statement of Administrative Action (SAA)" from the US administrative authorities, the panel held, alleviated the concerns.[92] The SAA was treated as an "authoritative expression" by the US on the subject of reconciling its domestic laws with the country's international trade obligations.[93]

The SAA was effectively a pledge by the US that the USTR will: (a) invoke the DSU dispute settlement procedures, as required under current law; and (b) base any section 301 determination of violation or denial of US rights under a relevant WTO agreement on a panel or AB findings adopted by the DSB.[94] Considering the SAA, the panel held that Special 301–310 provisions did not violate US international trade obligations, provided the US did not repudiate or remove its SAA undertakings. However, the panel noted that even a *mere threat of trade sanction* could be perceived as a threat to the WTO. The panel report notes that threat alone can enable a member to exert undue leverage and can "disrupt the very stability and equilibrium which multilateral dispute resolution was meant to foster and consequently establish, namely equal protection of both large and small, powerful and less powerful Members through the consistent application of a set of rules and procedures."[95]

The WTO's DSB has consistently failed to appreciate local realities that impede IP implementation requiring sovereign intrusions. For example, in stark contrast to WTO's deference to the SAA, the

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[88] 19 USC § 2242; §182 of the Trade Act of 1974

[89] Panel Report, *US — Section 301 – 310 of the Trade Act of 1974*, WT/DS152/R, para. 1.3, 1.4 (Dec. 22, 1999) [hereinafter *Section 301 Dispute*].

[90] Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Annex 2, Legal Instruments—Results of the Uruguay Round, 33 I.L.M, 1125, 1226, 1244 [hereinafter "DSU"]. Article 6 of the Understanding provides for the establishment of a panel at the instance of the complaining party, which is the Dispute Settlement Body. *See also*, European Communities request for the establishment of a panel pursuant to Article 6 of the DSU, (WT/DS152/11).

[91] *Section 301 Dispute*, *supra* note 91, *at* Para 4.8. The EU asserted that that its own WTO implementation mechanism, being, Trade Barriers Regulation (Council Regulation (EC) No. 3286/94, 22 December 1994, conformed in letter and spirit with Article 23 of DSU).

[92] Statement of Administrative Action, *reprinted in* H.R. Doc. No. 103-316, at 1029 (US Exhibit 11), Chapter B, subchapter 2, littera b (enforcement of US rights), p. 364 (hereinafter, SAA).

[93] Id.

[94] Id. at 365-366.

[95] *Section 301 Dispute*, *supra* note **Error! Bookmark not defined.** at para 7.89.

DSB (panel and AB), in the *India-Mailbox* dispute,[96] refused to accept India's rationale wherein administrative orders are treated as legally tenable tools to implement certain aspects of the statute in question.[97] The DSB's tendency is to ignore domestic realities and rationale in determining perceived derogations of international obligations.[98] Deference to domestic lawmakers' wisdom has been difficult to generate at the WTO, particularly the DSB, when the wisdom is from a developing country.

Instead, the DSB panel's exceptional deference to the SAA undertakings of a powerful member implies that the system has merely worked to reinforce the balance of power inequities. The DSU has been consistently criticized for lacking important paradigms required to appreciate the complexities involved in establishing an IP regime.[99] The DSU's inability to appreciate local realities and overreliance on WTO negotiating history – when the balance of powers was even more skewed than in current times – are all internal barriers that have impeded the WTO from achieving the spirit of the overall objectives.[100]

Spinning alone and in an unrealistic zone

The WTO's trade and health agenda should be couched within the "broader societal interests and especially development-oriented concerns" outlined in article 7 of the TRIPS Agreement.[101] Other international organizations such as the World Intellectual Property Organization (WIPO) – and now, the WHO in the post-COVID scenario – have all embarked more seriously on cooperating on the health sphere.[102] For instance, the WIPO's recent IP and Development Agenda outlines in Agenda 45 that IP enforcement should be contextualized within developmental concerns stated in article 7 of the TRIPS Agreement.[103] The WIPO agendas define larger public interest concerns and implicate the work of the UN, WTO, and WHO.[104] The WTO should work with international organizations such as the WIPO, UN, and WHO on issues that converge for global organizations.

The lack of a formal platform for institutional involvement and intervention creates functional issues. Issues emanating from the WTO's trade regime – such as IP and access to lifesaving medications – are converging platforms. Like the WIPO, the WHO's objectives for trade and

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[96] *See* Panel Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/6 (Oct. 16, 1997); *See also* Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997).
[97] *See* Panel Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/6 (Oct. 16, 1997); *See also* Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997).
[98] *See* Srividhya Ragavan, Patents and Trade Disparities in Developing Countries, Oxford Univ. Press, (2012) at p. 366.
[99] Thomas Cottier, *The Agreement on Trade-Related Aspects of Intellectual Property Rights*, P.F.J. Macrory, A.E. Appleton and M.G. Plummer (eds); *The World Trade Organization: Legal and Political Analysis*, 1 New York Springer 1063 (2005).
[100] *Id.*
[101] *Id* at Agenda 45.
[102] Convention Establishing the World Intellectual Property Organization, July 14, 1967, 21 U.S.T. 1770, 1772–73, 828 U.N.T.S. 3, 11, 13 [hereinafter "WIPO Convention"] *available at* http://www.wipo.int; *See also The World Health Organization* [WHO] 2016 *available at* www.who.int
[103] *Id*.
[104] *Id.*

health diplomacy include a commitment to support national health initiatives by increasing global negotiation capabilities to enable collective action to address health challenges. Similarly, the UN Report on Access to Medicines also calls for WTO members to "commit at the highest political levels, to the letter and spirit of the Doha Declaration" and promote the use of TRIPS flexibilities.[105]

Formal cooperation between global organizations seems to be the way forward. The WTO typically cites the DSB's periodic consultation with the WIPO. For instance, in *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*,[106] the WIPO, responding to the DSB panel's request, submitted factual information from the official records of various diplomatic conferences regarding the interpretation of articles 5(1), 5(2), and 17 of the Berne Convention.[107] But these are exceptions and limited to seeking factual information, rather than working towards a cooperative solution. Further, DSBs have traditionally provided limited deference to the WIPO even where it has sought input.[108] In *United States—Section 211 Omnibus Appropriations Act of 1998*, for instance, the AB's report mentions the Director-General of the WIPO's response to a request for information by the DSU panel, noting that "the Panel did not discuss this. However, the Panel seems to have taken [a different] the view." [109] Also, the WIPO has limited powers to intervene in the DSB process unless input is requested, except by filing an *amicus* brief. Unfortunately, most *amicus* briefs, while accepted, have limited value.[110] There is need for a platform for institutional involvement of international organizations.

The WIPO's Development Milestone in 2007 provided an opportunity to be involved in development and public health-related matters.[111] It was hoped that the WIPO would evolve as a negotiator for developing nations to work with the WTO and restore the WIPO's relatively weak image in the post-WTO era. The Committee on Development and Intellectual Property, established by the WIPO General Assembly in 2008, has the objective of implementing the Development

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[105] *See* U.N. Secretary-General, *Report Of The United Nations Secretary-General's High-Level Panel On Access To Medicines*, (Sep. 2016), (available at https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf).

[106] Panel Report: *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/R (Jan. 26, 2009).

[107] *Id*., at 4; *See also* Berne Convention for the Protection of Literary and Artistic Works, 25 U.S.T. 1341, 828 U.N.T.S. 221, 223 (Sept. 9, 1886, rev. July 24, 1971).

[108] *See e.g*. *United States—Section 211 Omnibus Appropriations Act of 1998*, *United States*, (WT/DS176/AB/R); (WT/DS176): *See also United States—Section 211 Omnibus Appropriations Act of 1998*, *United States*, Report of the Appellate Body. *See also —*, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/R (Jan. 26, 2009); *European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs* (WT/DS174, WT/DS290).; *See* Thomas Cottier & Marina Foltea, *Global Governance in Intellectual Property Protection: Does the Decision-making Forum Matter?*, 3(2) THE WIPO JOURNAL 139, 158 (2012).

[109] Appellate Body Report: *United States—Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R at para 189 (Jan. 2, 2002).

[110] *See e.g.*, Appellate Body Report, *Mexico — Tax Measures on Soft Drinks and Other Beverages*, WT/DS308/AB/R (adopted Mar. 24, 2006).

[111] *See Development Agenda for WIPO*, WIPO.INT, http://www.wipo.int/ip-development/en/agenda/ (last visited, Sep. 26, 2019).

Agenda recommendations,[112] which set the right tenor for the WIPO to work on issues relating to development in the IP context, but not much progress was made.[113]

The coronavirus pandemic is proof that unrelated global systems and larger global trade can collapse from pandemics and epidemics. Therefore, the need for innovation balanced with access is the next global agenda. The goal should be to intensify cooperation of global organizations on IP-related issues, an ideal already memorialized under Agenda 40.[114]

In conclusion, even a pandemic has kept the WTO elitist and out of touch

While innovation is an important mandate, the IP regime's imbalances have not accounted for local realities, largely contributing to a crisis in global access to medication. While the TRIPS Agreement's deficiencies and its disengagement with realities are important aspects, the WTO's inaction – and its singular focus on trade dissociated with local realities – have mired the organization since inception. Meanwhile, the rhetoric of innovation has not helped innovation nor helped establish the patent regime as a vehicle for innovation. In fact, the patent regime has transformed into a barrier to innovation and access to medicine, profoundly impacting the WTO negatively to a point of rendering it irrelevant.

[112] *See Committee on* Development and Intellectual Property, WIPO.INT, http://www.wipo.int/policy/en/cdip/ (last visited Sep. 26, 2019).
[113] *The 45 Adopted Recommendations under the WIPO Development Agenda*, WIPO (adopted 2007), (available at http://www.wipo.int/ip-development/en/agenda/recommendations.html).
[114] *Id.* at Agenda 40.