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# Between Life and Profit: Global Governance and the Trilogy of Human Rights, Public Health and Pharmaceutical Patents

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# Between Life and Profit: Global Governance and the Trilogy of Human Rights, Public Health and Pharmaceutical Patents

## **Cover Page Footnote**

International Law; Commercial Law; Law

# Between Life and Profit: Global Governance and the Trilogy of Human Rights, Public Health and Pharmaceutical Patents

*Obijiofor Aginam<sup>†</sup>*

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

—*Constitution of the World Health Organization*<sup>1</sup>

*[T]heir relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living . . .*

—*Marrakesh Agreement Establishing the WTO*<sup>2</sup>

*Integrative tendencies in international life, combined with the widely imagined future of a cyber world, ensure that a global civilization in some form will take shape.... The sort of global civilization that is taking shape will be widely perceived, not as fulfillment of a vision of unity and harmony, but as a dystopian result of globalism-from-above that is mainly constituted by economic ideas and pressures.*

—*Richard Falk*<sup>3</sup>

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<sup>†</sup> Ph.D., Associate Professor of Law, Carleton University, Ottawa, Canada. This article is based on a paper I presented at a symposium, "Saving Profits, Saving Lives: A Comprehensive Discussion of the Social, Legal, and Economic Implications of Reverse Engineering and Parallel Importing on the Pharmaceutical Industry," organized by the North Carolina Journal of International Law and Commercial Regulation, February 25, 2006, University of North Carolina School of Law, Chapel Hill, North Carolina. I would like to thank E. Abena Antwi, the NCILJ symposium editor, for inviting me to the symposium.

<sup>1</sup> World Health Org., Constitution, Preamble, July 22, 1946, [http://policy.who.int/cgi-bin/om\\_isapi.dll?hitsperheading=on&infobase=basicdoc&record={21}&softpage=Document42](http://policy.who.int/cgi-bin/om_isapi.dll?hitsperheading=on&infobase=basicdoc&record={21}&softpage=Document42).

<sup>2</sup> Preamble, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 33 I.L.M. 1125 (1994), [http://www.wto.org/English/docs\\_e/legal\\_e/04-wto\\_e.htm](http://www.wto.org/English/docs_e/legal_e/04-wto_e.htm).

<sup>3</sup> Richard Falk, *The Coming Global Civilization: Neo-Liberal or Humanist*, in LEGAL VISIONS OF THE 21ST CENTURY: ESSAYS IN HONOUR OF JUDGE CHRISOPHER

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### **I. Prologue: Global Governance and the Unholy Alliance of Human Rights, Public Health and Pharmaceutical Patents**

At the tripartite levels of academic scholarship, national and international public policy, and civil society activism, global governance orthodoxies highlight the complexities of the irreconcilable tension(s) in the interface of human rights, public health, and pharmaceutical patents in global interdependence of nations and peoples. The Westphalian international system, which is anchored on the primacy of the nation-state has often been driven by the economic and strategic interests of states, but at least in the last two decades, “emerging global issues and institutions” have changed the dynamics and governance architecture of the international system in very complex ways.

The *Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome* (HIV/AIDS)—a virus that decimates the natural immune system of the human body which then leads to a syndrome that leaves the body defenseless against opportunistic infections—is one such emergent global issue as is the World Trade Organization (WTO) such an emergent institution. Tensions, often in the form of mild ideological differences, have been a hallmark of the “anarchical international system.”<sup>4</sup> In the contemporary interdependence of nations and peoples, global governance questions surrounding HIV/AIDS and access to anti-retroviral (“ARV”) drugs, especially in developing countries, and the globalization of intellectual property rights and norms of free-

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WEERAMANTRY 15 (A. Anghie & G. Sturgess eds., 1998).

<sup>4</sup> See generally, HEDLEY BULL, *THE ANARCHICAL SOCIETY: A STUDY OF ORDER IN WORLD POLITICS* (1995).

trade by the WTO add to these classic tensions. Sandwiched between legal and policy issues on access to ARV treatment for HIV/AIDS and intellectual property rights are the age-old human rights norms recognized first in customary law, and then codified by treaty-based international law.

With the establishment of the WTO in 1995 and the list of agreements annexed to its constituent instrument, especially the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS),<sup>5</sup> the discourse of the interface of human rights, public health, and pharmaceutical patents in global economic relations has raised recondite legal and policy issues. In this article, I strive to contribute to the fruitful debate regarding recondite issues from the perspective of international law and emerging perspectives in global governance.

In what has since become a “life versus profit” debate,<sup>6</sup> TRIPS has firmly pitted corporate profit against vulnerable populations who live with HIV/AIDS globally, human right to life against intellectual property rights; and civil society groups against transnational pharmaceutical corporations.<sup>7</sup> The quotations beginning the article illustrate the two most important international institutions whose respective multilateral mandates cut across global health and global trade—the WTO and the World Health Organization (WHO) have clear provisions in the preamble to their respective constituent instruments on “raising standards of living” and the fundamental right to the “enjoyment of the highest

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<sup>5</sup> Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments-Results of the Uruguay Round, 33 I.L.M. 81 (1994).

<sup>6</sup> To illustrate this debate, exonerating patents as a substantial barrier to ARV treatment for AIDS, see Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 J. AM. MED. ASS'N 1886, 1891 (2001) (stating that “the extreme dearth of international aid finance, rather than patents, is most to blame for the lack of antiretroviral treatment in Africa. . . . Patents generally do not appear to be a substantial barrier to antiretroviral access in Africa.”). On the profit maximizing practices of pharmaceutical companies, see Caroline Thomas, *Trade Policy and the Politics of Access to Drugs*, 23 THIRD WORLD Q. 251, 259 (2002) (stating that “R&D priorities are set by companies not according to public health, but rather according to calculations about maximizing the return to shareholders. Developing countries do not represent a lucrative market. The pharmaceutical market is huge—over \$400 billion per annum.”)

<sup>7</sup> Obijiofor Aginam, *International Law and Communicable Disease*, 80 BULL. WORLD HEALTH ORG. 946, 949 (2002).

attainable standard of health.”<sup>8</sup> Despite the commonalities in these values that touch on human dignity, why has the interface between human rights, public health and pharmaceutical patents shifted from humane partnership to an unholy alliance?

In an indictment of economic globalization, Richard Falk, at the outset, challenges “integrative tendencies in international life” to be more protective of public goods and the capacity of the “sovereign state” to facilitate the delivery of these goods to vulnerable populations.<sup>9</sup> Falk’s indictment is a challenge to international scholars and global institutions to search for viable ways to attain a humane vision of unity and harmony. Focusing on one of the key governance frameworks of economic globalization—the normative architecture of the WTO, especially the TRIPS agreement, this article explores the perceived or real marginalization of public health and human rights by the WTO.

This article is divided into five major parts. Part I gives an overview of the tension between human rights, public health and pharmaceutical patents in the contemporary global interdependence of nations and peoples. Part II explores HIV/AIDS as a global emergency. The global crisis of HIV/AIDS, its prevalence in the less developed regions of the world, and the fact that a sizeable percentage of HIV positive patients in developing countries cannot afford ARV drugs poses a challenge for contemporary global governance orthodoxies to “humanize our global order.”<sup>10</sup> In Part III, because HIV/AIDS is a global emergency, this article explores the interface between the WTO, TRIPS, and access to essential medicines. How can TRIPS flexibilities be employed to save millions of lives, especially in developing countries where the mortality and morbidity burdens of AIDS are high? Part IV traces the public health fingerprints in the global trade regime. Focusing on international trade jurisprudence, this section argues that public health imperatives as well as other public goods are marginalized by the dogma of free trade. Part V presents the conclusion and an agenda for the future based on policy coherence and balancing the imperatives of human rights, public health, and trade liberalization

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<sup>8</sup> WHO, Constitution, Preamble, *supra* note 1; Marrakesh Agreement, *supra* note 2.

<sup>9</sup> Falk, *supra* note 3.

<sup>10</sup> For perspectives on humanizing the global order, see OBIORA C. OKAFOR & OBIJOFOR AGINAM, HUMANIZING OUR GLOBAL ORDER: ESSAYS IN HONOUR OF IVAN HEAD (2003).

within the mandates of the WHO, and the WTO.

## II. AIDS as a Global Emergency

*Our response to AIDS has so far been a failure. There has been scientific progress, but with few dividends for people living with poverty as well as HIV. In most of sub-Saharan Africa, they have access to neither prevention nor treatment. Three million deaths this year, and not yet counted millions of new infections, bespeak massive failure.*

—Paul Farmer<sup>11</sup>

Although HIV/AIDS has become a global emergency with over 45 million cases globally since 1980,<sup>12</sup> the disproportionate infection rate and prevalence of the mortality and morbidity burdens of the disease between the developing and developed regions of the world raises legal, moral, and ethical questions about the global framework for its prevention, control, and most importantly, treatment.<sup>13</sup> Although the HIV/AIDS pandemic is global with the number of infections rising in almost every region of the world, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization estimate that Africa

remains by far the worst-affected region, with 25.4 million [23.4 million—28.4 million] people living with HIV at the end of 2004, compared to 24.4 million [22.5 million—27.3 million] in 2002. Just under two thirds (64%) of all people living with HIV are in sub-Saharan Africa, as are more than three quarters (76%) of all women living with HIV.<sup>14</sup>

Southern Africa, according to the UNAIDS/WHO study, “remains the worst affected sub-region in the world, with data from selected antenatal clinics in urban centers showing HIV prevalence surpassing 25%, having risen sharply from around 5%

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<sup>11</sup> Editorial, *AIDS as a Global Emergency*, 81 BULL. WORLD HEALTH ORG 699 (2003).

<sup>12</sup> See generally UNAIDS, WHO, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC 2002 (2002).

<sup>13</sup> Nicholas Eberstadt, *The Future of AIDS*, Vol.81 No.6 FOREIGN AFF. 22 (2002) (stating that the HIV/AIDS pandemic, although global, is overwhelmingly concentrated in the least developed regions of the world, and that infection will be rapid in Eurasia driven by the spread of the disease in the region's three largest countries: China, India and Russia).

<sup>14</sup> UNAIDS/WHO, AIDS EPIDEMIC UPDATE 2004 at 2 (2004).

in 1990.”<sup>15</sup> Very high HIV prevalence, often exceeding 30% among pregnant women, is still being recorded in four Southern African countries: Botswana, Lesotho, Namibia, and Swaziland; while HIV infections in pregnant women appear to be stabilizing at lower levels in Malawi, Zambia, and Zimbabwe, albeit with little evidence of an impending decline.<sup>16</sup> The UNAIDS and WHO report that

newly published study findings show southern Africa to be firmly in the grip of the AIDS epidemic, as more people succumb to HIV-related illnesses and die. Life expectancy at birth has dropped below [forty] years in nine African countries—Botswana, Central African Republic, Lesotho, Malawi, Mozambique, Rwanda, Swaziland, Zambia, and Zimbabwe.<sup>17</sup>

Angola, according to UNAIDS and WHO, is an exception in the Southern African region because “during nearly two generations of war, civilians’ movements were restricted, transport links severed, and parts of the country were intermittently cut off from the outside world.”<sup>18</sup>

In East Africa, data from some countries show signs of decline in HIV infection levels. In Uganda, for example, national prevalence fell from 13% in the early 1990s to 4.1% at the end of 2004.<sup>19</sup> HIV prevalence in Kenya and Burundi has also been reported to be declining.<sup>20</sup> However, in other East African countries: Ethiopia, Madagascar, and Tanzania, in particular, there is no evidence of decline in HIV prevalence.<sup>21</sup> In West Africa, the HIV epidemic appears to have stabilized in most countries. According to UNAIDS and WHO “overall, HIV prevalence is lowest in Sahel countries and highest in Burkina Faso, Cote d’Ivoire, and Nigeria. . . . Serious epidemics are underway in Central Africa, with Cameroon and the Central African Republic worst-affected.”<sup>22</sup> Senegal, the often-celebrated HIV success story in West Africa, is slowly witnessing a rising level of HIV

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<sup>15</sup> *Id.* at 23.

<sup>16</sup> *Id.* at 23-24.

<sup>17</sup> *Id.* at 25.

<sup>18</sup> *Id.* at 24.

<sup>19</sup> *Id.*

<sup>20</sup> *Supra* note 14, at 24 (2004).

<sup>21</sup> *Id.* at 26.

<sup>22</sup> *Id.* at 27-28.



infection, especially among commercial sex workers.<sup>23</sup> Compared with other regions of the world, Africa's HIV/AIDS prevalence rate is an unfair and disproportionate share of an estimated 40 million people living with HIV/AIDS globally.

The HIV/AIDS prevalence levels, albeit largely based on the national surveys by most of the African countries themselves, remain problematic largely because, as acknowledged by UNAIDS and WHO, many African countries do not have reliable disease mortality and morbidity data on ailments, clinical cases, hospital admissions, or even causes of death. Most developing countries do not have accurate mortality statistics, morbidity and quality-of-life information, infant mortality rates, disease prevalence rates, and core surveillance structures for a comprehensive understanding of the burdens of disease that they face.<sup>24</sup> Thus, the data used by multilateral institutions to calculate prevalence rates of HIV/AIDS in most of Africa are, at the very best, estimates. Given the high morbidity and mortality burdens of AIDS in most developing and under-developed countries, it is important to note that AIDS, albeit not curable, can be treated with anti-retroviral drugs.<sup>25</sup> In what ways, therefore, have the normative developments on intellectual property protection for pharmaceutical patents at the WTO advanced or impeded access to AIDS treatment in regions of the world with the highest number of HIV/AIDS cases? To explore this question, the next section focuses on WTO and TRIPS.

### **III. The WTO, TRIPS, and Access to Essential Medicines for HIV/AIDS**

The tension between the logic of free trade and promotion of public health is nowhere more apparent than in TRIPS. The establishment of the WTO witnessed a supersonic expansion of global trade and its regulation from goods to areas such as

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<sup>23</sup> *Id.* at 27.

<sup>24</sup> William Foege, *Foreword to GLOBAL BURDEN OF DISEASE*, at xxv, (C.J.L Murray & A. Lopez eds., 1996)

<sup>25</sup> James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 FLA. L. REV. 727, 733-37 (2001) (stating that while AIDS is incurable, it is highly a treatable disease).

services, and intellectual property.<sup>26</sup> As Kamal Malhotra observed,

The transformation of the General Agreement on Tariffs and Trade (GATT) into the WTO in 1995 marked a paradigm shift, resulting in significant differences between the two regimes. The GATT system was primarily about negotiating market access for traded goods. But the WTO's extension into new substantive areas, intrusiveness into domestic policy-making, 'single undertaking' mandate, explicit linkage of trade with the protection of investment and intellectual property rights, and strict enforcement of disputes and cross-retaliation have extended its authority into areas of domestic regulation, legislation, governance and policy-making central to the development process.<sup>27</sup>

Membership in the WTO automatically commits member-states not just to liberalize trade in goods but also to make specific policy choices on services, investment and intellectual property. These commitments affect human development and public goods, especially in developing countries with very weak governance institutions for employment, education, public health, movements of capital and labour, and ownership of and access to technology.<sup>28</sup> Because of the monumental influence of the WTO in global economic relations between countries, and the rules-based global trade regime, it is now perceived that economic globalization either constrains the capacity of the state to finance social safety nets (public goods)<sup>29</sup> or contributes in very complex ways to "democratic deficit."<sup>30</sup>

TRIPS, which was one of the agreements annexed in the

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<sup>26</sup> For a history of international trade and the evolution of the WTO, see JOHN JACKSON, *THE WORLD TRADING SYSTEM: LAW AND POLICY OF INTERNATIONAL ECONOMIC RELATIONS* (1997); M. TREBILCOCK & ROBERT HOWSE, *THE LEGAL REGULATION OF INTERNATIONAL TRADE* (2001).

<sup>27</sup> Kamal Malhotra, *MAKING GLOBAL TRADE WORK FOR THE PEOPLE* 3 (2003).

<sup>28</sup> *Id.*

<sup>29</sup> See generally Dani Rodrik, *How Far Will International Economic Integration Go?* 14 *J.ECON. PERSP.* 177 (2000); Dani Rodrik, *Governance of Economic Globalization*, in *GOVERNANCE IN A GLOBALIZING WORLD* 347 (Joseph S. Nye & John D. Donahue eds., 2000); JOHN HILARY, *THE WRONG MODEL: GATS, TRADE LIBERALISATION AND CHILDREN'S RIGHT TO HEALTH* (2001), [http://www.savethechildren.org.uk/temp/scuk/cache/cmsattach/986\\_wrongmodel.pdf](http://www.savethechildren.org.uk/temp/scuk/cache/cmsattach/986_wrongmodel.pdf).

<sup>30</sup> Robert Howse, *How to Begin to Think About the "Democratic Deficit" at the WTO*, (unpublished draft on file with author) [http://faculty.law.umich.edu/rhowse/Drafts\\_and\\_Publications/howse7.pdf](http://faculty.law.umich.edu/rhowse/Drafts_and_Publications/howse7.pdf) (2003).

Marrakesh Agreement that established the WTO in 1995, covers both aspects of intellectual property rights: literary and artistic property (copyrights and neighboring rights), and industrial property.<sup>31</sup> TRIPS seeks to harmonize certain aspects of intellectual property rights at the global level. It sets a minimum standard of intellectual property protection for all WTO member states' national legislation. Although TRIPS directly and indirectly codified flexibilities found on age-old practices of parallel imports,<sup>32</sup> and compulsory licensing<sup>33</sup> in intellectual property law, legitimate efforts by a few developing countries to pursue these measures in the face of high prevalence of HIV/AIDS among their populations were either blocked or legally challenged by some industrialized member-states of the WTO, especially by the United States.<sup>34</sup>

The well-publicized dispute between leading pharmaceutical companies supported by the United States and South Africa, and the lingering disagreements between United States and Brazil are cases in point.<sup>35</sup> In 1998, forty pharmaceutical companies filed a

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<sup>31</sup> Industrial property rights include trademarks, patents, geographical indications, industrial designs, and trade secrets. Patent protection for pharmaceuticals is set for a minimum of twenty years.

<sup>32</sup> Parallel imports allow for the importation of patented products without the authorization of the patent holder. Parallel importation allows a country to "shop around" for lower prices of the same patented product anywhere it may be found in the global market. Article 6 of TRIPS codifies a well known principle of patent law known as "exhaustion of rights." An intellectual property right is exhausted once the patented product is marketed the first time with the consent of the patent owner. States can take any action they deem fit at the point of exhaustion. TRIPS, *supra* note 5, art. 6.

<sup>33</sup> Compulsory licensing allows a government to authorize local firms to produce generic versions of patented drugs. It is often used during emergencies. TRIPS did not expressly mention the term "compulsory license," but refers in Art. 31 to "other use of the subject matter of the patent without the authorization of the right holder" in a number of conditions including "national emergenc[ies]", and "other circumstances of extreme urgency." *Id.* art. 31.

<sup>34</sup> For an insightful and profound analysis of both the direct and indirect challenges of these practices by industrialized countries, see Caroline Thomas, *Trade Policy and the Politics of Access to Drugs*, 23 *THIRD WORLD Q.* 251 (2002); Naomi A. Bass, Note, *Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21<sup>st</sup> Century*, 34 *GEO. WASH. INT'L. L. REV.* 191 (2002); Ellen t' Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 *CHI. J. INT'L. L.* 27 (2002); Susan K. Sell, *The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive, and Institutional Dimensions*, 77 *TEMP. L. REV.* 363 (2004).

<sup>35</sup> For a discussion of the South Africa and Brazil cases, see Bass, *supra* note 34;

law suit against the government of South Africa, claiming among others, that the South African Medicines and Related Substances Control Amendment Act of 1997 violated the TRIPS agreement.<sup>36</sup> Commenting on this dispute, Ellen t'Hoen stated that the amended Act "introduces a legal framework to increase the availability of affordable medicines in South Africa"<sup>37</sup> through "generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines."<sup>38</sup> Brazil has long been cited not only as a success story but also as a model developing country. The United States launched a dispute settlement process against Brazil at the WTO in 2001 alleging that Article 68 of the Brazilian intellectual property law that requires all patent holders in Brazil to manufacture their product in Brazil violates Articles 27 and 28 of TRIPS. Under Brazilian intellectual property law, failure by a patent holder, unless he proves that it is economically unfeasible or unreasonable, to produce the patented product in Brazil could trigger compulsory license by the government to manufacture the product locally.<sup>39</sup> In both the South African and Brazilian cases, global civil society activism and advocacy targeted at the WTO, the pharmaceutical companies, and their home governments led to the withdrawal of the law suit in South Africa, and the U.S. complaint against Brazil at the WTO.<sup>40</sup>

At least two important lessons should be learned from the South African and Brazilian cases on the challenges to exploiting public health flexibilities in TRIPS. First, the law suit against South Africa by forty pharmaceutical companies set a despicable precedent by which corporations, mostly incorporated in South Africa as subsidiaries of their parent companies, could sue a

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t'Hoen, *supra* note 34.

<sup>36</sup> Stephen Marks, *Health and Human Rights: The Expanding International Agenda*, AM. SOC. INT'L. L. PRO. 64 (2001) (stating that the pharmaceutical companies that filed the suit were among the world's largest even though "governments and activists around the world are supporting the right of South Africa and other countries faced with poverty and the devastating ravages of the AIDS epidemic to import or manufacture generic versions of the AIDS treatment drugs at a fraction of the price the pharmaceuticals charge").

<sup>37</sup> t'Hoen, *supra* note 34, at 30.

<sup>38</sup> *Id.*

<sup>39</sup> For analysis of the patent law in Brazil in this context, *see id.*; Bass, *supra* note 34.

<sup>40</sup> Bass, *supra* note 34.

sovereign government claiming rights and benefits under TRIPS, an international treaty accepted or ratified exclusively by states as members of the WTO.<sup>41</sup> Second, the attitude of the U.S. government is hypocritical. The United States was willing, and in fact threatened, to issue compulsory license to produce and stockpile Cipro during the bioterrorist threats posed by anthrax deaths shortly after the September 11<sup>th</sup> terrorist attacks. This forced the German company Bayer that had a patent on Cipro to sell the drug to United States and Canada at heavily discounted prices.<sup>42</sup> This is exactly what South Africa sought to do with respect to ARV drugs for the epidemic of HIV/AIDS in South Africa. Sarah Joseph's well founded observation on the emergency posed to the United States and Canada by anthrax and that posed to South Africa by AIDS can hardly be faulted:

It is interesting to note how quickly the United States and Canada were to threaten the Bayer patent, and how quick were media commentators to question Bayer's profit margin on Cipro, at a time when the United States had thirteen anthrax cases with three deaths, and Canada had no cases at all. The North American anthrax scare was not an emergency on a par with the devastating effects of HIV/AIDS in the developing world. The North American response to the anthrax scare was probably legitimate in the circumstances. However it displayed blatant hypocrisy on the part of the West regarding the acceptability of patent relaxation in the context of health emergencies which confront "us," and in the context of health emergencies which constantly confront "them" in the developing world.<sup>43</sup>

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<sup>41</sup> One wonders if, conversely, the South African government or any other developing country could sue a corporation claiming benefits for a breach of an international treaty obligation.

<sup>42</sup> For perspectives on the threat by the U.S. government to issue compulsory licenses to override Bayer's patent on Cipro, see David B. Resnik & Kenneth A. De Ville, *Bioterrorism and Patent Rights: "Compulsory Licensure" and the Case of Cipro*, 2 AM. J. OF BIOETHICS 29 (2002); Divya Murphy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health*, 17 AM. U. INT'L. L. REV. 1299, 1314-1315 (2002).

<sup>43</sup> Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The "Fourth Wave" of Corporate Human Rights Scrutiny*, 25 HUM. RTS. Q. 426, 446-47 (2003). For other perspectives on the threat by the U.S. government to issue compulsory licenses to override Bayer's patent on Cipro, see David B. Resnik & Kenneth A. De Ville, *Bioterrorism and Patent Rights: "Compulsory Licensure" and the Case of Cipro*, 2 AM. J. OF BIOETHICS 29 (2002); Divya Murphy, *The Future of Compulsory Licensing:*

As the debate on the public health flexibilities in the TRIPS agreement raged, on November 14, 2001, after prolonged agitation by developing countries and sustained advocacy by a coalition of civil society groups, the WTO ministerial conference in Doha, adopted the Declaration on the TRIPS Agreement and Public Health.<sup>44</sup> The Declaration affirmed that TRIPS can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health, and in particular, to promote access to medicines for all.<sup>45</sup> The Declaration recognized that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.<sup>46</sup> On August 30, 2003, the General Council of the WTO adopted a decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.<sup>47</sup> The decision provides for the criteria aimed at facilitating access to essential medicines, including anti-retrovirals for HIV/AIDS, by vulnerable populations in the least developed and developing countries. Despite the WTO General Council Decision in 2003, difficult questions still remain on the best ways to maximize access to essential medicines, especially anti-retroviral drugs for HIV/AIDS. While the Decision imposes certain key obligations on exporting and importing countries for these medicines, only two industrialized countries, Canada and Norway, have initiated legislative changes to their national patent laws to allow domestic production of generic drugs for export to poor countries hit by HIV/AIDS and other diseases.<sup>48</sup> The

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*Deciphering the Doha Declaration on the TRIPS Agreement and Public Health*, 17 AM. U. INT'L L. REV. 1299, 1314-15 (2002).

<sup>44</sup> World Trade Organization Doha Declaration on TRIPS Agreement and Public Health, Nov. 20, 2001, WT/MIN(01)/DEC/ 2,41 I.L.M. 755 (2002) [hereinafter Doha Declaration]. On the legal status of the Doha Declaration, see 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. L. & TECH. 291 (2002).

<sup>45</sup> Doha Declaration, *supra* note 44.

<sup>46</sup> *Id.*, ¶ 4.

<sup>47</sup> General Council Decision, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 1 2003), [http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm).

<sup>48</sup> In June 2004, the Canadian legislature passed Bill C-9, which was an Act to amend both the Patent Act and Food and Drugs Act, now enacted as the Pledge to Africa Act. The new legislation is meant to facilitate access to essential medicines by

Decision imposes an obligation on developing countries to notify the WTO of an intention to become an eligible importing member, and to notify the WTO specifically about the products and quantities.<sup>49</sup>

About 80% of developing countries lack a functional pharmaceutical sector with a capacity for domestic production of anti-retroviral drugs.<sup>50</sup> As a result, these countries cannot issue compulsory license for domestic production of generic HIV/AIDS drugs simply because they lack the capacity and technology to do so. The only option for many of these countries remains a dual process that involves importing generics from an industrialized country that is willing to amend its patent legislation to produce generic drugs solely for export to countries in most need of them. But can industrialized countries withstand the pressure and corporate lobby by the pharmaceutical industry? If there is one lesson to learn from the TRIPS negotiations in the 1990s, it is that the industry lobby remains very influential and powerful in international economic relations. As Scott Sinclair observed, “corporate pressure is nothing new in WTO negotiations. Such pressure, largely exerted by U.S.-based firms, is widely acknowledged to have been a driving force in the negotiations.”<sup>51</sup> The entire gamut of international trade and global economic relations is now shaped by the “neo-liberal dogma of minimizing intrusions on the market, and ‘downsizing’ the role of government in relation to the provision of public goods that compose the social agenda.”<sup>52</sup> Promotion of human rights and human dignity; public health and access to essential medicines; respect for the environment, and protection of environmental rights, all come with

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authorizing Canadian generic pharmaceutical companies to produce generic drugs in Canada for export to developing countries that lack their own domestic production capacity. See Pledge to Africa Act, S.C. 2004, c.23.

<sup>49</sup> For a good discussion of the challenges of implementing the WTO General Council Decision, see Carlos Correa, *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, [http://www.who.int/medicines/areas/policy/WTO\\_DOHA\\_DecisionParolefinal.pdf](http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionParolefinal.pdf).

<sup>50</sup> *Id.*

<sup>51</sup> SCOTT SINCLAIR, *GATS: HOW THE WORLD TRADE ORGANIZATION’S NEW SERVICES NEGOTIATIONS THREATENS DEMOCRACY 2* (2000).

<sup>52</sup> Richard Falk, *The Coming Global Civilization: Neo-Liberal or Humanist*, *supra* note 3, at 15.

this social agenda. The establishment of the WTO has challenged the actors in global governance (both states and non-states) to take the task of balancing neo-liberal ideology with the promotion of global public goods<sup>53</sup> seriously.

#### **IV. Assessing Public Health Fingerprints in Global Trade Regime**

The rules-based international trade architecture, firmly anchored on the institutional pillars of the WTO, has developed a list of powerful norms against which public good like public health policies are measured. These norms, based mainly on National Treatment and Most Favored Nation (MFN) principles, add up to the grand rule of non-discrimination in international trade.<sup>54</sup> There is a certain level of agreement between proponents and critics of trade liberalization that international trade is necessary, but how then should free trade respond to the imperatives of human dignity—human rights, environmental protection, and public health (public goods)? Since the General Agreement on Tariffs and Trade (GATT) 1947, international trade governance frameworks have grappled with the task of reconciling trade liberalization and national protection of public health and other public goods.<sup>55</sup> Article XX (b) of GATT<sup>56</sup> provides:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or

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<sup>53</sup> On the concept of public goods in the global economy, see GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY (Inge Kaul et al. eds., 1999); see also PROVIDING GLOBAL PUBLIC GOODS: MANAGING GLOBALIZATION (Inge Kaul et al. eds., 2003). On aspects of public health as global public goods, see GLOBAL PUBLIC GOODS FOR HEALTH: ECONOMIC AND PUBLIC HEALTH PERSPECTIVES (Richard D. Smith et al. eds., 2003).

<sup>54</sup> Under MFN obligation, countries cannot discriminate between their trading partners. General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT]. A special treatment granted to one country has to be granted to all WTO Members. National Treatment requires that imported and locally-produced goods be treated equally, in terms of competitive opportunities in the importing country's market. *Id.* art. 3.

<sup>55</sup> *Id.*

<sup>56</sup> Part of GATT 1947 became GATT 1994 at the end of Uruguay Round of trade negotiations that led to the establishment of the WTO. General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 17 (1999), 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994) [hereinafter GATT 1994].



unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: necessary to protect human, animal or plant life or health.<sup>57</sup>

This delicate balance, albeit provided in similar but different language in other trade Agreements,<sup>58</sup> raises some serious conundrums in interpretation. To make use of the health exceptions, WTO Agreements generally require that the health measures adopted by a country be no more restrictive than necessary. Relying on the WTO Appellate Panel decision in the *Asbestos Case*,<sup>59</sup> the WTO and WHO secretariats, in a joint study, observed that human health has been recognized by the WTO as being important in the highest degree.<sup>60</sup> However, going by the precedents of GATT and WTO jurisprudence, national measures adopted by countries to protect public health are subjected to very strict scrutiny against immutable trade norms of non-discrimination as driven by principles of MFN, National Treatment, and Elimination of Quantitative Restrictions.<sup>61</sup> A typical WTO trade panel would determine first if the public health policy in question is “necessary,” and if other non-trade restrictive alternative measures could be used to achieve the public health purpose. In this interpretive paradigm, trade therefore takes precedence over national public health measures. Two precedents in international trade law, the first under the GATT, and the second under the WTO, illustrate this point.

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<sup>57</sup> *Id.*

<sup>58</sup> See General Agreement on Trade in Services, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1B, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 284 (1999), 1869 U.N.T.S. 183, 33 I.L.M. 1167 (1994) [hereinafter GATS].

<sup>59</sup> Appellate Body Report, *Canada v European Communities/France—Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R (March 12, 2001) (01-1157).

<sup>60</sup> WHO & WTO, *WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat* 31 (2002). However, based on the predominant cases on Trade-Public Health disputes, this finding is doubtful.

<sup>61</sup> See GATT, *supra* note 54 for rule against quantitative restrictions international trade.

In the *Thai Cigarettes*<sup>62</sup> dispute between United States and Thailand under the GATT, Thailand, pursuant to its 1966 Tobacco Act, prohibited the importation of cigarettes and other tobacco products into Thailand, but authorized the sale of domestic Thai cigarettes. The United States challenged the ban on imports of cigarettes into Thailand as a violation of General Elimination of Quantitative Restrictions in Article XI of the GATT.<sup>63</sup> Thailand defended the ban as a measure under Article XX(b) "necessary" for the protection of public health. While no comparable ban existed on domestic Thai cigarettes, Thailand argued that American cigarettes were more likely to induce women and young persons to smoke because of sophisticated advertising directed at these groups. Thailand also argued that American cigarettes were more addictive or more likely to be consumed in larger quantities than comparable Thai cigarettes due to their higher nicotine and chemical contents. The GATT panel ruled that an import ban would only be necessary for public health reasons within Article XX(b) exceptions if alternative non-trade restricting measures could not be used to achieve the public health objectives in question. The panel found that import restrictions were not "necessary" because other less trade-restrictive tobacco control measures could be used to protect public health on a non-discriminatory basis to both domestic and imported cigarettes.

In the *Beef Hormones*<sup>64</sup> dispute between United States/Canada and the European Community, following concerns by European consumer groups over the use of growth promotion hormones in livestock, the WHO-Food and Agriculture Organization Joint Expert Committee examined the use of these hormones and their health implications. On the basis of recommendations of the expert committee, the Codex Alimentarius Commission adopted standards for five of the growth-promoting hormones.<sup>65</sup> The

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<sup>62</sup> Report of the Panel, *Thailand—Restrictions on Importation of and Internal Taxes on Cigarettes*, DS10/R, BISD 37S/200 (Nov. 7, 1990) [hereinafter *Thai Cigarette*].

<sup>63</sup> GATT, *supra* note 54, art. 11.

<sup>64</sup> WTO Panel Decision, *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Complaint of the United States, WT/DS26/R/USA, (Aug. 18, 1997).

<sup>65</sup> The Codex Alimentarius Commission was established in 1962 and is jointly governed by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). It has a mandate to protect the health of consumers and ensure fair practices in food trade by standards for food safety. FAO.org, The Codex

standards specified the maximum level of hormone residues in foods that are safe for human consumption. The European Union, following concerns raised by consumer groups on continued use of illegal hormonal substances, imposed a complete ban on the use of growth-promoting hormones in 1988. In January 1996, the United States (followed by Canada in June 1996) challenged the European Union ban as a violation of the WTO's Sanitary and Phytosanitary Measures (SPS) Agreement.<sup>66</sup> In 1988, the Appellate Body of the WTO ruled that the EU's ban violated the SPS Agreement. Since the International Codex standards existed for five out of the six hormones at issue, the Appellate Body ruled that the EU ban violated the SPS Agreement because it was not based on risk assessment.<sup>67</sup> Although the Appellate Body confirmed the rights of WTO Members to have the level of health protection they want, even above international standards, this decision subjects such national measures to scientific evidence and risk assessment, which would likely impose onerous burdens, particularly on developing countries.

The task of protecting and promoting human health through domestic measures in an era of global economic integration is well illustrated in the *Thai Cigarette* and the *Beef Hormones* cases. Even in the *Asbestos Case* (Canada v. European Community and France), and the *Reformulated Gasoline Case*<sup>68</sup> (Brazil and Venezuela v. United States) where the WTO Appellate Bodies upheld Article XX(b) health measures, the dispute settlement bodies did so after subjecting those measures to rigorous scrutiny against immutable trade principles.<sup>69</sup> Had the Panels found those measures discriminatory or trade-restrictive, they would have ruled that they either violated National Treatment or were inconsistent with the requirements of the chapeau of Article XX.

## V. Epilogue: Human Rights, Public Health, and Free Trade—

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system: FAO, WHO and the Codex Alimentarius Commission, [http://www.fao.org/documents/show\\_cdr.asp?url\\_file=////docrep/w9114e/W9114e04.htm](http://www.fao.org/documents/show_cdr.asp?url_file=////docrep/w9114e/W9114e04.htm)

<sup>66</sup> Appellate Body Report, *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998).

<sup>67</sup> *Id.*

<sup>68</sup> Appellate Body Report, *United States—Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R (Apr. 29, 1996).

<sup>69</sup> *Id.*

## Towards Policy Coherence in Global Governance

The intense “life versus profit” debate that has dominated the WTO TRIPS regime has achieved one useful thing: it has placed public health and the human right to health firmly on the global governance agenda. Human rights and public health searchlights will now beam on neo-liberal institutions like the WTO as well as non-state actors like the transnational pharmaceutical industry. International law, since the birth of the United Nations in 1945, is replete with human rights instruments, customary, and treaty law. A significant percentage of these instruments codify aspects of the right to health in very clear and concise language.<sup>70</sup> But as rightly observed by Robert Howse and Makau Mutua,

[r]egional and multilateral investment agreements have proceeded without credible efforts to conceptually and practically address their impacts on legally protected human rights... Trade and investment agreements...must be held accountable to existing human rights law.<sup>71</sup>

In the event of a conflict between human rights guaranteed in an international covenant, and a provision of international trade agreement like TRIPS, which one should take precedent over the other? Should human rights “trump” trade or vice versa? Will international law develop a body of rules that advances free trade while at the same time promoting and protecting human rights?<sup>72</sup> The challenge before the global governance today is, as Robert Howse and Makau Mutua observed, “how to influence the process

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<sup>70</sup> For insightful discussion of the norms of human rights as they relate to health, see Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The “Fourth Wave” of Corporate Human Rights Scrutiny* 25 HUM. R. Q. 425 (2003); Virginia Leary, *The Right to Health in International Human Rights Law* 1 HEALTH & HUM. R. 25 (1994); Phillip Cullet, *Patents and Medicines: The Relationship Between TRIPS and the Human Right to Health*, 79 INT’L AFF. 139 (2003); Katarina Tomaseveski, *Health*, UNITED NATIONS LEGAL ORDER, 859 (Oscar Schachter & Christopher C. Joyner eds., 1995); B. Toebe, *Towards an Improved Understanding of the International Human Right to Health*, 21 HUM. R. Q. 661 (1999); OBIJOFOR AGINAM, *GLOBAL HEALTH GOVERNANCE: INTERNATIONAL LAW AND PUBLIC HEALTH IN A DIVIDED WORLD* 35-40 (2005). For some progressive insights from the United Nations Special Rapporteur on Right to Health, see *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, (Feb. 13 2003), <http://www.unhchr.ch/Huridocda/Huridoca.nsf/0/5f07e25ce34edd01c1256ba60056deff?Opendocument>.

<sup>71</sup> ROBERT HOWSE & MAKUA MUTUA, *PROTECTING HUMAN RIGHTS IN A GLOBAL ECONOMY: CHALLENGES FOR THE WORLD TRADE ORGANIZATION* 6 (2000).

<sup>72</sup> *Id.* at 7

of globalization in such a way that human suffering, poverty, exploitation, exclusion, and discrimination are eliminated. Since trade is the driving engine of globalization, it is imperative that, at the very least, rules governing it do not violate human rights but rather promote and protect them.”<sup>73</sup>

Given the jurisprudence of the WTO as exemplified in cases like *Thai Cigarettes* and *Beef Hormones*, an apparent inconsistency between public goods (including health, environmental, and human rights) and principles of free trade is often resolved in favor of free trade if the domestic policy in question is found to be discriminatory or protectionist. The norm of non-discrimination solidly founded on National Treatment and MFN runs through the entire gamut of WTO agreements.<sup>74</sup> At the global level, the WTO’s policies that support free trade and intellectual property rights seem to impede WHO’s policy on the promotion of universal access to “essential medicines”<sup>75</sup> and the right of everyone to the highest attainable standard of physical and mental health.

I propose three possible scenarios to resolve this tension in the future, especially for developing countries. First, I suggest that countries that have the technology should pursue the Brazilian model of domestic production of generic drugs to address the humanitarian catastrophe of HIV/AIDS, and other prevailing health problems like malaria. Following the Brazilian model will allow these countries to meet the human rights and public health needs of their populations without violating TRIPS. Second, because not all countries have provisions on right to health in their constitutions as a justiciable human right (just like the South African constitution), I suggest that a robust/activist interpretation of the right to life is needed as a pathway to ultimately getting the right to health and other social, economic and cultural rights:

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<sup>73</sup> *Id.*

<sup>74</sup> See GATT, *supra* note 54. See generally Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 17 (1999), 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994).

<sup>75</sup> WHO defines essential medicines as “those medicines that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage form.” See World Health Organization, *Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement* 10 (1999), [http://who.int/medicines/areas/policy.who\\_dap\\_98\\_9rev.pdf](http://who.int/medicines/areas/policy.who_dap_98_9rev.pdf).

housing, food, and education. In other words, access to essential drugs must be construed within the right to life. The dichotomy between civil and political rights, and economic, social and cultural rights will begin to dissipate based on the indivisibility of all rights. Third and most importantly, I suggest the need for a robust and feasible project on “policy coherence” domestically and internationally. Since trade agreements affect public health and human rights in complex ways, trade ministers and bureaucrats must talk with their health colleagues to do a “human rights and public health impact assessment” of free trade agreements. This will minimize the negative impact of trade agreements on health and human rights. Internationally, the relevant multilateral institutions, in this case, WTO and WHO, should also assess the commonalities and tensions across their respective mandates. Although the WTO is not part of the United Nations family of organizations, the rationale for international policy coherence for the organizations within the United Nations system is well captured by Judge Weeramantry’s dissenting opinion:

The United Nations family of organizations today is widely expanded, closely knit, and works together, in developing areas of international activity, within the framework of the international rule of law. While each of these organizations has its specific functions, they all interlock in the common service of the ideals of the United Nations and they all operate under the common aegis of international law. Though each of them is given a particular sphere of activity, they do not necessarily function in closed compartments, for the complex nature of United Nations activities may often result in overlapping areas of interest. The work of one organization may interweave with that of other organizations, and hence would have repercussions on the work of other members of the United Nations family.<sup>76</sup>

In the *Nuclear Weapons* opinion, the ICJ ruled that constituent instruments of international organizations, in this case the Constitution of the World Health Organization, are treaties in international law.<sup>77</sup> The interpretation of these constituent instruments requires the application of the relevant provisions of the Vienna Convention on the Law of Treaties.<sup>78</sup> Since the

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<sup>76</sup> Legality of the Use By a State of Nuclear Weapons in Armed Conflict, 1996 I.C.J. 94 (July 8, 1996) (Weeramantry, dissenting) [hereinafter *Nuclear Weapons*].

<sup>77</sup> *Id.* at 75.

<sup>78</sup> *Id.*

majority of the WTO member states are also member states of the WHO, and the WHO was founded decades before the WTO, the key obligations undertaken by states as signatories to WHO Constitution cannot be derogated by mere membership of the WTO that carries with it acceptance of trade agreements that appear inconsistent with the codification of the right to the highest attainable standard of health in the WHO Constitution.

The trade-health tension in global governance is therefore not as simplistic as saying that globalization is inherently bad or innately good, especially given the asymmetry and social inequalities and disparities between countries. What is needed first is a supportive environment for the weaker nation-states (especially the developing countries) to strengthen their institutional capacity to generate and promote public goods, taking into account each country's present specific social and economic conditions. This is the only time when agreements like TRIPS will be humane. The extent to which this would likely occur largely depends on whether the neo-liberal dogma of the free trade will, instead of continuing to champion a corporate agenda, focus on the humanization of the norms of economic globalization through the protection of public goods and the promotion of human dignity.

