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## QUO VADIS WTO? THE THREAT OF TRIPS AND THE BIODIVERSITY CONVENTION TO HUMAN HEALTH AND FOOD SECURITY

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## ABSTRACT

*Just a few years after the creation of the World Trade Organization (WTO) and the Trade Related Aspects of Intellectual Property Rights Agreements (TRIPS), the risks the agency and agreement posed to human health and food security became well known. The WTO, United Nations and commentators have acknowledged the problem. Joined at the hip, the WTO and TRIPS systems, as implemented, seem to have aggravated the severe and debilitating disease burden and food insecurity of many of its developing members. Although the WTO and TRIPS have recognized the problem, their response hardly matches the gravity of the circumstances confronted. The solutions relied on are mostly textual analysis and interpretative devices designed to exploit the so-called internal flexibilities embedded within TRIPS. Little attention has been paid to exploring the source of the problem, which appears to be within the structure, the operating premises supporting the constitutive architecture of TRIPS, and the linkage of the right to trade in all goods and services with the protection of foreign intellectual property rights. The risk to health and food security appears to have its nesting conditions and roots deep within structural flaws of the WTO and TRIPS as a joint system. The marriage of two complex international systems demands the investigation of two critical questions: First, whether under international law there is a fundamental right of states to trade and second, whether an idea, however formed or expressed, has an unmistakable and undeniable national or territorial origin such that the right to trade in all goods and services must be conditioned on its protection. This work seeks to reframe the analysis and discussion of the risks posed by the WTO and TRIPS to human health and food security, by examining these foundational premises and suggesting solutions that go to the heart of the problem. Given the indisputable link between technology and economic development, the history of human advancement across regions and its link to human health and food security, I argue the WTO and TRIPS should be decoupled and TRIPS reconstructed as a separate system. Reconstructing TRIPS would allow the global community to adopt a more balanced system, characterized by a greater sensitivity to issues such as cultural diversity, economic development and health and food security.*

*You cannot kill an elephant by stabbing at its shadow with a spear.*  
– African Proverb

## I. INTRODUCTION

The global community of sovereign states achieved a milestone in the organization of a world trading system in 1994.<sup>1</sup> That year the community of sovereign states, big and small, weak and powerful, adopted the World Trade Organization (WTO) as an umbrella international organ for maintaining, regulating and enforcing a unified global trading system. The WTO, which came into force on January 1, 1995, was an unprecedented achievement for several reasons. It was the realization of long-standing aspirations for an idealized, overarching international trading system inspired by the inhumanity experienced in two successive world wars. Even before the Second World War ended, diplomats, economists, policy makers and others in the United States devoted serious attention to constructing a new post-war international order to confront the causes of war.<sup>2</sup> Widespread protectionism and beggar-thy-neighbor trade policies were deemed significant contributing factors to the Second World War.<sup>3</sup> The solution, policy makers thought, lay in establishing a comprehensive, coherent, international, free and non-discriminatory trade system. The International Trade Organization (ITO), sometimes referred to

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<sup>1</sup> Ministers representing 124 governments and the European Communities participated in the Uruguay Round of Multilateral Trade Negotiations that established the World Trade Organization during the final session of the Trade Negotiations Committee at the Ministerial level held in Marrakesh, Morocco between April 12-15, 1994. *See* Marrakesh Declaration of 15 April 1994, 1867 U.N.T.S. 148 [hereinafter 1994 Marrakesh Declaration].

<sup>2</sup> Laurence H. Shoup & William Minter, *Shaping a New World Order: The Council on Foreign Relations' Blueprint for World Hegemony*, in *TRILATERALISM: THE TRILATERAL COMMISSION AND ELITE PLANNING FOR WORLD MANAGEMENT* 135, 136-139 (Holly Sklar ed., 1980) (discussing how "The War and Peace Studies Project" initiated by a few key members of the Council on Foreign Relations in the U.S. constructed the framework for the post-war new world order, including the U.N. and its institutions). For a history of the ITO and the Havana Charter, *see* KENNETH W. DAM, *THE GATT: LAW AND INTERNATIONAL ECONOMIC ORGANIZATION* 12 (1970) (explaining the role of Secretary of State Hull in framing U.S. post-war trade and economic policies).

<sup>3</sup> JOHN H. JACKSON, *LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS* 396-401 (1977) (discussing the history of the General Agreement on Tariffs and Trade and how the concrete obligations enshrined in it eventually eliminated beggar-thy-neighbor trade policies invoked before the war); EDITH T. PENROSE, *THE ECONOMICS OF INTERNATIONAL PATENT SYSTEM* 151 (1951) [hereinafter PENROSE, *INTERNATIONAL PATENT SYSTEM*] (discussing the nature of beggar-thy-neighbor trade policies in the patent context).

as the Havana Charter, emerged from this policy prescription.<sup>4</sup> Free and non-discriminatory trade found a steady and strong champion in the United States Secretary of State Cordell Hull, who believed that global peace and security hinged on the success of that system.<sup>5</sup> Unfortunately, the ITO suffered a frustrating post-war defeat at the hands of the U.S. Congress.<sup>6</sup> Instead, a less grandiose organization, the General Agreement on Trade and Tariffs (GATT), with a limited focus on negotiated tariff reductions, was established.<sup>7</sup>

The desire for a comprehensive world trade regime materialized fifty years later in the WTO. But the WTO's crowning achievement might have been the broadening of its scope and the consolidation of its power in matters tangentially trade-related.<sup>8</sup> Arguably, the WTO created a

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<sup>4</sup> For a discussion of the history of the ITO, sometimes referred to as the Havana Charter, see JACKSON, *supra* note 3, at 396-99. For a history of the ITO and the Havana Charter, see DAM, *supra* note 2, at 10-16 (discussing the goals of U.S. post-war trade policies).

<sup>5</sup> With the support of Secretary of State Hull as a member of the War Council, the Council on Foreign Relations thoroughly explored the central role of trade as part of a general framework of larger ideas such as freedom, equality, prosperity and peace as the construct for a post war new order. See Shoup & Minter, *supra* note 2, at 144-46. In THE GATT: LAW AND INTERNATIONAL ORGANIZATION, Kenneth W. Dam provides multiple reasons for Congress' failure to adopt the GATT, calling the ITO:

[A] wretched compromise . . . [that] merely registers and codifies the worldwide conflict between freer trade and economic nationalism. The greater part of the Charter consists in exception, enumerating all ways in which governments so inclined can flout the objectives and control their own trade. It is one of the most hypocritical documents of modern times . . . [and] a meaningless document with everybody's name on it.

DAM, *supra* note 2, at 12-16 & n.10.

<sup>6</sup> See *Hearings on Trade Agreements Act and the Proposed ITO Before the H. Comm. on Ways & Means*, 80th Cong. 1 (1947); *Hearings on Proposed ITO Before the S. Comm.*, 80th Cong. 1 (1947); see also JACKSON, *supra* note 3, at 397; WILLIAM DIEBOLD, JR., THE END OF THE ITO, *ESSAYS IN INTERNATIONAL FINANCE* 16 (1952).

<sup>7</sup> According to Jackson, the GATT was not contemplated to be a separate organization but part of the broader concept of trade under the ITO. See JACKSON, *supra* note 3, at 397. The GATT was implemented through a Protocol of Provisional Application to the General Agreement on Tariffs and Trade. See Protocol of Provisional Application to the General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. pts 5 & 6, T.I.A.S. No. 1700, 55 U.N.T.S. 187; see also JACKSON, *supra* note 3, at 398 n.13; DAM, *supra* note 2, at 14 (stating that by 1950, the ITO was dead).

<sup>8</sup> The central focus of the GATT was trade. In an exception provided by Article XX(d), some measures might be taken to address intellectual property issues as distortions within the GATT framework. Broadening the mandate of the GATT into areas tangentially related to trade presented a problem that had to be remedied by the United States in pushing for the link between trade and the protection of intellectual property rights. See Michael Gadbaw & Rosemary E. Gwynn, *Intellectual Property Rights in the New GATT Rounds*, in *INTELLECTUAL PROPERTY RIGHTS, GLOBAL CONSENSUS, GLOBAL CONFLICT* 43-45 (Michael Gadbaw & Timothy J.

power deficit among sovereign member states and existing international organizations with mandates going back to the League of Nations.<sup>9</sup> The WTO's concentration of power is inconsistent with its original charter, which called for good governance, democracy and decentralized political power.<sup>10</sup> Moreover, the structure of the organization is also inconsistent with the prevalent orthodoxy of market-based liberalization of economic policies and promotion of free trade and investment.<sup>11</sup> The mandate of the WTO was expanded beyond traditional trade areas captured in the GATT, especially in intellectual property rights, which were previously the domain of the World Intellectual Property Organization (WIPO).<sup>12</sup>

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Richards eds., 1988) [hereinafter, Gadbow & Gwynn, *Intellectual Property Rights in the New GATT Rounds*] (explaining the U.S. rationalization that the distortion had to be addressed at its source).

<sup>9</sup> 1994 Marrakesh Declaration, *supra* note 1. The agreement expressed concern and demanded cooperation between the WTO, the Bank for Development and Reconstruction (World Bank) and the International Monetary Fund (IMF), although no mention was made of other United Nations organs such as United Nations Conference on Trade and Development (UNCTAD). However, under Article 63(2) of the United Nations Charter, the Economic and Social Council (ECOSOC) has the responsibility of coordinating the activities of the specialized agencies for achieving the economic, social and cultural goals of the Charter. U.N. Charter art. 63(2). For a discussion and commentary on the United Nations Charter, see LELAND M. GOODRICH, EDWARD HAMBRO & ANNE PATRICIA SIMONS, CHARTER OF THE UNITED NATIONS: COMMENTARY AND DOCUMENTS 419-26 (3d ed. 1969) [hereinafter, GOODRICK & SIMONS].

<sup>10</sup> For a discussion of the various U.N. Specialized Agencies such as the International Labor Organization (ILO), World Health Organization, ECOSOC, United Nations Development Program (UNDP) and many others established as part of the United Nations system, see JACKSON, *supra* note 3, at 377-83.

<sup>11</sup> The term "Washington Consensus" is attributed to John Williamson and describes the prescription of the Washington establishment for the economic transformation of Latin America. See John Williamson, Inst. For Int'l Econ., *The Washington Consensus as Policy Prescription for Development* (Jan. 13, 2004), <http://www.iie.com/publications/papers/williamson0204.pdf> (providing ten policy prescriptions based substantially on market principles, privatization, liberalization of trade and investment). *But see* Moisés Naím, *Washington Consensus or Washington Confusion?*, 118 FOREIGN POLICY 86, 87 (2000) (pointing out there is hardly any consensus in the so-called prescriptions of the Washington Consensus).

<sup>12</sup> Although in its preamble TRIPS calls for cooperation between WTO and WIPO, Article 63, and in particular Article 68, leave little doubt about the diminished role of WIPO by putting the responsibility of ensuring compliance and functioning of TRIPS on the WTO. Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 63, 68, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement]. Furthermore, in the Agreement Between the World Intellectual Property Organization and the World Trade Organization, Article 2(2) gives WTO members and the WTO Secretariat free access to WIPO data, and Articles 3(a), (b) and (c) further give the Council for TRIPS and the WTO Secretariat

This expansion of the WTO's scope and jurisdiction had serious implications on the effective functions of the World Health Organization (WHO), the Food and Agriculture Organization (FAO), and other organizations concerned with the human condition and development mandated by Article 55 of the U.N. Charter.<sup>13</sup>

Notwithstanding claims to the contrary, this expansion of the jurisdiction of the WTO is more pro-monopoly than it is pro-free trade.<sup>14</sup> This view maintains that intellectual property rights are so inextricably linked to free trade that their recognition is a *sine qua non* for member states.<sup>15</sup> Under the leadership of the TRIAD (U.S., EU and Japan)<sup>16</sup> and against

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full access to WIPO's collection of laws and regulations. See Agreement Between the World Intellectual Property Organization and the World Trade Organization arts. 2, 3, Dec. 22, 1995, 35 I.L.M. 754. These changes leave WIPO in a subservient position. The question has been raised whether this is good. Prior to the adoption of TRIPS and as part of the WTO, a symposium was organized to discuss the merits of GATT and WIPO as the new way for organizing intellectual property protection. See generally GATT OR WIPO? NEW WAYS IN INTERNATIONAL PROTECTION OF INTELLECTUAL PROPERTY (Friedrich-Karl Beier & Gerhard Schricker eds., 1989) (discussing positions on the question from U.S., European Union and industry perspectives).

<sup>13</sup> *Inter alia*, Article 55 of the U.N. Charter states:

With a view to the creation of conditions of stability and well-being which are necessary for peaceful and friendly relations among nations . . . the United Nations shall promote: (a) higher standards of living, full employment, and conditions of economic and social progress and development; [and] (b) solutions of international economic, social, health and related problems, and international cultural and educational cooperation . . . .

U.N. Charter art. 55.

These provisions, read with Article 63(2), leave one to wonder how the WTO fits into this scheme of mandates to specialized agencies. For a commentary on Article 55, see GOODRICK & SIMONS, *supra* note 9, at 371-80.

<sup>14</sup> The pro-monopoly threat created by TRIPS is best explained in a foreword by Professor Fritz Machlup. See Fritz Machlup, *foreword* to PENROSE, *supra* note 3, at ix. He argues that Penrose's views were not out of line with the Second Interim Report of the Swan Committee, which declared that:

[I]t is wrong in principle that a patent should be used to establish a monopoly wider in scope and longer in duration than conferred by the patent itself, and it is obviously that patent law should keep in step with any measures which may be adopted in the future to limit or control monopoly in the public interest.

*Id.*

<sup>15</sup> Gadbow & Gwynn, *supra* note 8, at 43 (explaining the justification was for solving the problem at its source). Note, however, that under the GATT, intellectual property rights were subservient to and not conditional on the right to trade.

<sup>16</sup> Peter Drahos, *Negotiating Intellectual Property Rights: Between Coercion and Dialogue*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS, KNOWLEDGE, ACCESS AND DEVELOPMENT 167-68 (Peter Drahos & Ruth Mayne eds., 2002) (outlining the coalition formation stages resulting first in the TRIAD (U.S., E.U and Japan), later including Canada (the QUAD) and other developed countries).

the vociferous objections of many developing countries,<sup>17</sup> the Trade Related Aspects of Intellectual Property Rights (TRIPS) was adopted in 1994 and simultaneously came into force with the WTO as part of its system.<sup>18</sup> Under this unprecedented new world trading regime, TRIPS imposed certain minimum levels of mandatory intellectual property protection on WTO member states.<sup>19</sup> Never before had such a marriage between the right to trade and the protection of something as ephemeral as intellectual property been conceived of or implemented.

Prior to TRIPS, no multilateral international trade regime saw it fit to deny sovereign states the political and legislative authority to define for themselves the nature, scope and duration of the protection of ideas. Contracting states retained unfettered sovereignty in their fundamental policy domain, particularly with respect to public health, safety and security.<sup>20</sup> Before TRIPS, over forty countries offered no patent protection for

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<sup>17</sup> See *id.* at 167, 170 (discussion of the opposition of developing countries who reacted angrily at being left out of the process). Prominent among the countries opposing TRIPS were India, Brazil, Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania and Yugoslavia. *Id.* at 170. Many countries did not even participate. *Id.* at 167.

<sup>18</sup> See TRIPS Agreement, *supra* note 12; Drahos, *supra* note 16, at 168-70 (given the opposition of Brazil, India, Nigeria and others, questioning whether the WTO was an agreement negotiated under democratic principles or achieved through the exertion of power and the confluence of ever-increasing circles of influence until TRIPS was achieved through cooption); see also Gadbow & Gwynn, *supra* note 8, at 40 (explaining that with an approach driven by the perception that WIPO and UNCTAD were institutions through which developing countries blocked attempts to broaden the intellectual property regime, neutralization of developing countries seemed essential to the outcome of the negotiations); EDWARD SLAVKO YAMBRUSIC, TRADE BASED APPROACHES TO THE PROTECTION OF INTELLECTUAL PROPERTY 7-25 (1992) (explaining the different perceptions toward intellectual property in developing and newly industrialized countries and its role in international trade).

<sup>19</sup> While Article 28 of TRIPS provides the usual substantive rights for patent protection, Article 33 mandates a minimum duration of 20 years. See TRIPS Agreement, *supra* note 12, arts. 28, 33.

<sup>20</sup> The limitations imposed on member states by the Paris Union are found in Article 2, which, *inter alia*, provided that nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, *as last revised* at Stockholm, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305; see also INTERNATIONAL TREATIES ON INTELLECTUAL PROPERTY 17-20 (Marshall A. Leaffer ed., 2d ed. 1997); Joseph Straus, *Implications of the TRIPS Agreement in the Field of Patent Law*, in FROM GATT TO TRIPS – THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, at 171 (Friedrich-Karl Beier & Gerhard Schrickler eds., 1996) (explaining the adoption of non-discrimination in Article 2 but with the retention of sovereign authority over patentability of all types of patents including scope and use); see also PENROSE, *supra* note 3, at 62-63, 78

pharmaceutical inventions.<sup>21</sup> Such sovereign authority of states has been compromised by TRIPS as part of the WTO system of agreements. The loss of sovereignty over significant policy areas has serious implications and deserves some explanation. Following the collapse of the New International Economic Order (NIEO), a severe global recession and the debilitating Third World debt crisis in the 1980s, developing countries suffered the consequences of serious vulnerability dependence and a resulting diminished bargaining power.<sup>22</sup> The TRIAD seized the moment and exploited the bargaining power asymmetry. Other international economic events of that era further weakened the leverage of developing countries.<sup>23</sup> The 1980s also witnessed the global proliferation of product

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(discussing the retention of sovereignty over patent abuse and compulsory licensing to address domestic technology needs).

<sup>21</sup> WORLD HEALTH ORGANIZATION AND WORLD TRADE ORGANIZATION SECRETARIAT, *WTO AGREEMENTS AND PUBLIC HEALTH: A JOINT STUDY BY THE WHO AND THE WTO SECRETARIAT* 42 (2002) [hereinafter WHO/WTO STUDY], available at [http://www.wto.org/english/res\\_e/booksp\\_e/who\\_wto\\_e.pdf](http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf).

<sup>22</sup> The literature on NIEO is extensive. For an insightful review of that literature from different ideological camps, see Robert W. Cox, *Ideologies and the New International Economic Order: Reflections on Some Recent Literature*, 33 INT'L ORG. 257, 258-66 (1979) (discussing the definition of the new international economic order and offering five intellectual camps engaged in the debate: (1) the establishment view point, (2) the social democratic perspective, (3) the official Third World position, (4) the neo-mercantilist perspective and (5) the historical materialist variant). For other contributions to this literature, see Richard Falk, *Beyond Internationalism, in THE END OF WORLD ORDER* 110 (1983) (discussing the perceived role of geopolitics rather than juridical arrangements the U.S. sought to achieve); see also *THE NEW INTERNATIONAL ECONOMIC ORDER: NORTH-SOUTH DEBATE* (Jagdish N. Bhagwati ed., 1977) (a symposium in which the establishment view point was vigorously expressed); MAHBUB UL HAQ, *THE POVERTY CURTAIN: CHOICES FOR THE THIRD WORLD* ix, 142 (1976) (presenting a Third World viewpoint that the call for a new economic order is precisely what it says: three hundred years of European domination should give way to equity and opportunity); see also Julius Nyerere, *Unity for a New Order, in DIALOGUE FOR A NEW ORDER* (Khadija Haq ed., 1980) (arguing that the Third World needs one voice); INDEP. COMM'N ON INT'L DEV. ISSUES, *NORTH-SOUTH: A PROGRAMME FOR SURVIVAL* 13 (1980) (arguing human beings have a common desire and moral obligation to survive not just by addressing peace and war but also issues of hunger, mass misery and alarming disparities between the rich and poor); ROBERT L. ROTHSTEIN, *GLOBAL BARGAINING: UNCTAD AND THE QUEST FOR A NEW INTERNATIONAL ECONOMIC ORDER* 15, 25-27 (1979) (arguing Third World countries were demanding more than a seat at the table but concluded that debates and a search for a NIEO had reached a stalemate, making progress difficult).

<sup>23</sup> One of the international economic events during the 1980s was the debilitating debt crisis into which many developing countries fell. The literature on this is extensive. For a fascinating account of the phenomenon and its consequences on the dynamics of macroeconomic policies, see, JACKIE RODDICK, *THE DANCE OF THE MILLIONS, LATIN AMERICA AND THE DEBT CRISIS* (1988) (providing an account of the nature, causes and solutions to the Latin American debt crisis); Samson, E. Edo,

counterfeiting.<sup>24</sup> Notwithstanding the globally pervasive character of this phenomenon, it was blamed on weak, ineffectual or non-existent intellectual property laws in developing countries.<sup>25</sup> Pressure from private groups with political clout compelled U.S. trade negotiators to exploit the glaring bargaining power disparities enjoyed by the TRIAD.<sup>26</sup> This exploitation of the inequalities of bargaining power was undertaken at a time when many developing countries were ill equipped or unprepared to appreciate all the implications of TRIPS.<sup>27</sup> Nor did they fully understand the significance of the converging forces at work.<sup>28</sup> In riding the tidal

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*The External Debt Problem in Africa: A Comparative Study of Nigeria and Morocco*, AFRICAN DEV. BANK, 224 (2002) (offering a comparative analysis of the debt crisis and showing the increasing pressure of debt service on Nigeria and Morocco between 1980 and 1989 in the following proportions: Nigeria from 13.1% to 322.5% and Morocco from 85.9 to 478.9%); Vito Antonio Muscatelli and David Vines, *Third World Debt and Macroeconomic Interactions Between the North and South*, 27 J. DEV. STUDIES 146 (describing some of the causes and consequences of the debt crisis in developing countries and their preoccupation with finding solutions); GERARDO ESQUIVEL, FELIPE LARRAIN & JEFFREY D. SACHS, *CENTRAL AMERICA'S FOREIGN DEBT BURDEN AND THE HIPC INITIATIVE 1* (2002) (reviewing the history of the debt burden on two of the poorest countries in Central America and the role of the Heavily Indebted Poor Countries (HIPC) program as a solution).

<sup>24</sup> Janet H. MacLaughlin, Timothy J. Richards & Leigh A. Kenny, *The Economic Significance of Piracy*, in INTELLECTUAL PROPERTY RIGHTS: GLOBAL CONSENSUS, GLOBAL CONFLICT? 89, 96-97 (R. Michael Gadbaw & Timothy J. Richards eds., 1988) (explaining and estimating the cost of piracy and counterfeiting in the U.S.).

<sup>25</sup> Taimoon Stewart, *The Functioning of Patent Monopoly Rights in Developing Countries: In Whose Interest?* 49 SOCIAL & ECON. STUD. 1, 9-13 (2000) [hereinafter Stewart, *Patent Monopoly Rights in Developing Countries*] (offering different explanations for the allegations of counterfeiting some of which was legal under the existing international legal regime: (1) About 50 countries provided no protection for pharmaceuticals; (2) some countries such as India provided protection for the process but not the product; (3) while the laws of developed countries such as the U.S. were revised to accommodate new technological developments developing countries inherited colonial intellectual property laws which remained unrevised or were revised to weaken the protection which would have existed with stronger intellectual property protection).

<sup>26</sup> Gadbaw & Gwynn, *supra* note 8, at 39 (discussing the sources of pressure group politics from the U.S private sector that was heavily represented on the President's Commission on Industrial Competitiveness and concluding that the linkage between TRIPS and GATT was predominantly driven by the private sector).

<sup>27</sup> Drahos, *supra* note 16, at 167-80 (discussing the relative unpreparedness of developing countries and the fact that many did not even participate in the negotiations, amounting to what he termed coercion); *see also* Incoming WTO Head, Conference in Thailand on Access to Pharmaceuticals. *See generally* Gadbaw & Gwynn, *supra* note 8 (explaining the pressure put on those countries seen as obstacles to U.S. objectives).

<sup>28</sup> *See id.* at 169 (asserting that all states were ignorant of the likely effects of TRIPS other than the gains the U.S. would make).

wave of these forces, the developed countries did not merely succeed in linking the right to trade to the protection of intellectual property rights; they also succeeded in setting up a structure whereby, under international law, foreign private interests could subvert the political authority and public interest of the state.<sup>29</sup>

The linkage of intellectual property protection and international trade was then part of a gathering storm of the hegemonic powers that grew stronger during the twentieth century. Frustrated by the structure and functioning of the international intellectual property regime, developed countries saw the WTO as an opportunity for settling old scores and addressing their long-standing concerns.<sup>30</sup> Under the Paris Convention for the Protection of Industrial Property (Paris Union), the unanimity requirements for modification made reform of the patent system to increase protection and address concerns with compulsory licensing virtually impossible.<sup>31</sup> Nor could developed countries compel weaker states to adopt an intellectual property regime similar to their own without interfering with the basic tenets of sovereign equality under international law. TRIPS might then have been the final descent of this powerful storm with pent-up energy seeking, as it were, to unleash an increasingly aggressive, acquisitive and permanent international intellectual property regime that would be oblivious to the needs of large portions of humanity. Just a few years earlier, the Convention on Biological Diversity (Biodiversity Convention) had laid the foundations for TRIPS. Adopted in 1992, the Biodiversity Convention simultaneously created access to biodiversity

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<sup>29</sup> There is naturally some debate over the nature of the impact of the WTO and TRIPS. See Sol Picciotto, *Defending the Public Interest in TRIPS and the WTO*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS, at 224 (Peter Drahos & Ruth Mayne eds., 2002) (questioning claims that the WTO and TRIPS would have a negative impact on the public interest and global welfare and claiming that the alternatives to TRIPS would more harmful).

<sup>30</sup> Stewart, *supra* note 25 at 10-13 (discussion the evolution and long negotiation history indicating the clear North/South divide over intellectual property issues under the leadership of WIPO and the decision of the U.S. to put intellectual property issues under the mantel of the GATT); Gadbow & Gwynn, *supra* note 8 at 40 (explaining how the WIPO exhibits a pro-Third World bias that led the private sector in the U.S. to push for locating intellectual property protection outside WIPO and under the GATT).

<sup>31</sup> PENROSE, *supra* note 3 at 57 (discussing the unanimity requirement for approval of amendments). Subsequent revisions of the Paris Convention as captured in Article 17 required a three-fourths majority for some amendments and a three-fifths majority for others. See, Paris Convention for the Protection of Industrial Property of March 20, 1883, as revised at Brussels on December 14, 1900, available at [http://www.wipo.int/treaties/en/ip/paris/trtdocs\\_wo020.html](http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html) (last visited Mar. 14, 2012).

resources and also mandated the protection of biotechnology inventions derived from those resources.<sup>32</sup>

The combined effect of TRIPS and the Biodiversity Convention is the result of two reinforcing global asymmetries: the digital or technology divide and biodiversity resource concentration. The digital divide refers to the substantial technological, R&D and innovation capacity of developed countries where a comparable capacity is missing or exists only at lower levels in developing countries.<sup>33</sup> Such a favorable technology asymmetry guarantees the location in developed countries of a substantial number of inventive activities where patents that may be of great utility to developing countries will be granted. On the other hand, Biodiversity resources are relatively highly concentrated in developing countries.<sup>34</sup> However, without the appropriate technological capacity

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<sup>32</sup> Convention on Biological Diversity of the United Nations Conference on the Environment and Development art. 15, June 5, 1992, U.N. Doc. DPI/1307, 31 I.L.M. 818. The Biodiversity Convention states that Contracting Parties recognize that intellectual property rights may have an influence on the implementation of the Convention. It then mandates that they cooperate for the protection of intellectual property protection consistent with national legislation and international law, which includes TRIPS.

<sup>33</sup> The terms digital divide and technology gap are generally used to describe similar but not the same technological phenomena that are manifestations of the divide or gap. For a discussion of the digital divide, see Mauro F. Guillén & Sandra L. Suárez, *Explaining the Global Digital Divide: Economic, Political and Sociological Drivers of Cross-National Internet Use*, 84 *SOCIAL FORCES* 681, 681-82 (2005) (defining digital divide within the context of cyberspace as the inequality in access to the internet which on a worldwide basis shows a yawning digital gap between OECD countries and developing countries and a further divide based on class and social structure within countries); Aurore J. Kamssu, Jeffrey S. Siekpe, James A. Ellzy & Aurora J. Kamassu, *Shortcomings of Globalization: Using Internet and Electronic Technology and Electronic Commerce in Developing Countries*, 38 *J. DEV. AREAS* 151, 153 (2004) (describing the digital divide in terms of internet use as follows: today, 96% of internet host computers reside in the highest income nations with 16% of the world's population; there are more internet host computers in Finland than the whole of Latin America and the Caribbean and more in New York City than the entire continent of Africa); Baplab Dasgupta, *Patents Lies and Latent Dangers: A Study of the Political Economy of Patent in India*, 34 *ECON. & POL. WEEKLY* 979, 982 (1999) (explaining how in 1972 about 80-85% of patents held in developing countries were held in foreign interest and how more recently about 95% of patents in Africa, 85% in Latin America and 70% in Asia are held by citizens of developed countries).

<sup>34</sup> While measurement is not easy there is general consensus that biodiversity resources tend to be highly concentrated in the Third World. See Chandra Prsaad Giri, Surendra Shrestha, Timothy W. Foresman & Ashbindu Singh, *Global Biodiversity Data and Information* 1, 9, available at [www.unescap.org/stat/envstat/stwes-26.pdf](http://www.unescap.org/stat/envstat/stwes-26.pdf) (arguing that Africa, Asia the Pacific and Latin America have the highest biodiversity and that moist tropical forests which constitute only approximately 8% of the world's land surface world's land surface hold over 90% of

and infrastructure, such a concentration of biodiversity resources in developing countries does not necessarily translate into local biotechnological inventions and ownership. While access provisions in the Biodiversity Convention provide for access to resources, only those with technological capabilities can meaningfully exploit those resources and convert them into patentable inventions. Not unexpectedly, both TRIPS and the Biodiversity Convention mandate protection of such inventions.

It is now widely acknowledged by most observers that TRIPS is a serious threat to human health security. The fears of those who protested against combining the right to trade with the mantle of intellectual property rights have been found to be legitimate. Barely half a decade after the WTO came into force, the threat posed by TRIPS to human health and food security was widely recognized by the WTO and international organizations.<sup>35</sup> There is also a large and growing body of expository and

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the world's species); James R. Paine, *Status, Trends and Future Scenarios for Forest Conservation Including Protected Areas in the Asia-Pacific Region*, WORKING PAPER SERIES, Working Paper No. APFSOS/WP/04, World Conservation Monitoring Center, (1997) [www.fao.org/DOCREP/003/W5475E00.HTM](http://www.fao.org/DOCREP/003/W5475E00.HTM) at 2 (providing a list of the world's top twenty mega-biodiversity countries, all of which with the exception of Australia are in the Third World).

<sup>35</sup> World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration]. At the Ministerial Conference of the WTO, the gravity of the public health problems faced by countries with no manufacturing capacity was admitted, and it was decided that TRIPS should not stand in the way of member states taking measures to address this problem. However, the Doha Declaration sought to provide solutions within the flexibilities built into TRIPS, as long as their use was consistent with TRIPS. See Food and Agriculture Organization of the United Nations, *The State of Food Insecurity in the World*, at 2 (2008), available at <http://www.fao.org/docrep/011/i0291e/i0291e00.htm> [hereinafter *Food Insecurity in the World*]. The FAO provided the following summary of the key messages from the report: (1) "world hunger is increasing, most recent estimates of hungry people is at 923 million, an increase of 80 million since 1990-1992;" (2) "[h]igh food prices share much of the blame;" (3) "[t]he poorest, landless and female-headed households are the hardest hit;" (4) "[i]nitial government policy measures have had limited effect;" (5) "[h]igh food prices are also an opportunity" for agriculture and the provision of essential public goods, and (6) "a comprehensive twin-track response is required." A combination of various institutional efforts can address the problem. See *id.* The FAO states that it strongly believes in renewed investment in agriculture focusing on smallholder farmers and rural development and food technology, and concludes that it is unacceptable that 862 million people are still hungry. *Id.* at 43-44; see also Organization for Economic Cooperation and Development OECD & Food and Agricultural Organization of the U.N. FAO, *OECD-FAO Agricultural Outlook*, at 62 (2009) (projecting a need for an increase in long-term global food production of more than 40% by 2030 and 70% by 2050); Julian M. Alston, Philip G. Pardey & Johannes Roseboom, *Financing Agricultural Research: International Investment Patterns and Policy Perspectives*, 26 WORLD DEV. 1057, 1063 (1998) (arguing that public R&D expenditures in agriculture

critical literature focusing on various aspects of WTO and TRIPS, including public health.<sup>36</sup> Much intellectual exertion is directed at finding solutions to the public health, medical and pharmaceutical needs of developing countries by focusing on interpreting TRIPS within the framework of the Vienna Convention on the Law of Treaties.<sup>37</sup> These studies

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is a complex picture; agricultural R&D in developed countries doubled between 1985 and 1991 from \$7.3 billion to \$15 billion while developing countries lagged behind); Julian M. Alston, Jason M. Beddow & Philip G. Pardey, *Agricultural Research, Productivity, and Food Prices in the Long Run*, 325 SCI. 1209, 1210 (2009) (arguing that there has been a general decline in state public R&D investment in agriculture from 66% in 1975 to 57% in 2007 and the trend appears universal).

<sup>36</sup> See, e.g., CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT (2007) (providing a thorough analysis of the different intellectual property subject areas covered by TRIPS); Lee Petherbridge, *Intelligent TRIPS Implementation Strategy for Countries on the Cusp of Development*, 22 U. PA. J. INT'L ECON. L. 1029, 1048 (arguing for the use of interpretative devices); Gerald D. Malpass Jr., *Life After the GATT TRIPS Agreement – Has the Competitive Position of the U.S. Changed?* 19 Hous. J. INT'L L. 207, 226 (1996); JOHN WALKER BAXTER, JOHN P. SINNOT & WILLIAM COTREAU, WORLD PATENT LAW AND PRACTICE § 8 (2007) (discussing the local working requirements of section 5A of the Paris Union after TRIPS and laying out approaches used by some countries); Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L. 41, 61 (1998) (explaining the technology gap disfavoring the production of biotechnology inventions in developing countries); Thomas A. Haag, *TRIPS Since Doha: How far Will the WTO Go Toward Modifying the Terms of Compulsory Licensing?*, 84 J. PAT. & TRADEMARK OFF. SOC'Y, 945, 955-66 (2002) (discussing the requirements for triggering the use of Article 31(k)), Sudhir D. Ahuja, *GATT and TRIPS – The Impact on the Indian Pharmaceutical Industry*, 1994 PAT. WORLD 28, 33 (discussing options faced by negotiators dealing with health needs of member states and thereafter settling for strict safeguards). See generally NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS (3d ed. 2010) [hereinafter, CARVALHO, TRIPS PATENT RIGHTS] (devoted entirely to the patent aspects of TRIPS with background explanation of the history and economics of patents); Beier & Schricker, *supra* note 20, at 20 (providing both a general and EU perspective on the provisions of TRIPS); GLOBAL INTELLECTUAL PROPERTY RIGHTS, KNOWLEDGE, ACCESS AND DEVELOPMENT (Peter Drahos & Ruth Mayne eds., 2002) (with contributions from various authors on intellectual property and TRIPS); MARKUS NOLFF, TRIPS, PCT AND GLOBAL PATENT PROCUREMENT (2001) (arguing that TRIPS recognizes various forms of patents and industrial property recognized in contracting states); Daniel Gervais, *Traditional Knowledge: A Challenge to the International Property System*, in INTERNATIONAL INTELLECTUAL PROPERTY LAW AND POLICY 7 (Hugh Hansen ed., 2002); A. Blackett, *Whither Social Change? Human Rights, Trade Theory and Treaty Interpretation*, 31 COLUM. HUM. RTS. L. REV. 1 (1999) (suggesting the reliance on Articles 7 and 8 for interpreting issues of human rights).

<sup>37</sup> HIROKO YAMANE, INTERPRETING TRIPS, GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES, 190 (2011) (discussing the

are mostly concerned with content and textualism rather than structure and contextualism. Little attention is devoted to the structural and systemic problems, which seem to be foundational in the problems posed by TRIPS. Some studies, sponsored by the WTO and TRIPS, have focused on finding solutions to the public health needs of countries within the “so-called” built-in flexibilities of TRIPS.<sup>38</sup> Focused on textual analysis, most of these studies are concerned with options provided in Articles 30 and 31 for addressing the health needs of WTO member states. Unfortunately, these solutions do not confront the structural defects of TRIPS.<sup>39</sup> Other studies are directed at supply and access to medicine at affordable prices.<sup>40</sup> Using simulation models, economists have started to study the

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interpretation of the WTO Agreements including TRIPS under the Vienna Convention on the Law of Treaties); CORREA, *supra* note 36 (explaining in the preface a clause-by-clause interpretation of TRIPS is based on the rules of interpretation codified in the Vienna Convention on the Law of Treaties); CARVALHO, *supra* note 36 (providing an analysis of each clause of TRIPS based on the rules of interpretation in the Vienna Convention on the Law of Treaties).

<sup>38</sup> CARLOS M. CORREA, IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH 13-18 (2002) (discussing various available flexibilities for developing countries to exploit in the text of the TRIPS Agreement); CARLOS M. CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 22 (2000); Carlos M. Correa, *Pro-competitive Measures under TRIPS to Promote Technology Diffusion in Developing Countries*, in Drahos & Mayne, *supra* note 36, at 42-43 (advancing a common theme in some of his work on TRIPS by arguing that WTO members can adopt different measures to advance their interests within the framework of TRIPS obligations: e.g., encouraging price competition, access to products, parallel imports under the so-called Bolar Exception). The Bolar Exception got its name from the decision of the U.S. Federal Court of Appeals in *Roche Products Inc. v Bolar Pharmaceutical Co.* 733 F. 2d 858, *cert. denied* 469 U.S. 856 (1984). In *Bolar*, the court denied Bolar the right to begin Food and Drug Administration approval before the expiration of a patent. *Id.*

<sup>39</sup> CORREA, *supra* note 36, at 22 (discussing the nature and scope of the substantive legal obligations under TRIPS); DE CARVALHO, *supra* note 36, at 1-22 (explaining the structure of legal rights within patents and TRIPS).

<sup>40</sup> Richard D. Smith, Carlos Correa & Cecilia Oh, *Trade, TRIPS, and Pharmaceuticals*, 373 THE LANCET 684, 685-88 (2009) (discussing the issues of patent trade and pharmaceuticals); World Health Organization, *The Public and Private Circuits for the Distribution of Drugs in the Chilean Health System*, 9, 23-41, WHO/D/AP/96.1 (1996) (a study inspired and supported by the collaboration between United Nations Children’s Fund and WHO addressing general health conditions and access to pharmaceutical products in Chile); K.M. Gopakumar, *Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime*, 3 L. & DEV. REV. 325 (2010) (examining the legal tactics and marketing behavior of multinationals with respect to access to pharmaceuticals in India and arguing that internal flexibilities of TRIPS alone cannot improve access to affordable medicine – domestic legislation is necessary). The insecurity is not limited to health, as shown by other studies on the topic. See COMM’N ON GENETIC RES. FOR FOOD &

impact of TRIPS on consumer welfare in developing countries' pharmaceutical industries. These studies confirm that TRIPS has a significant negative impact on domestic prices of pharmaceutical products and health services in developing countries.<sup>41</sup> There are also insightful contributions on trade and health issues within the context of Sanitary and Phytosanitary Measures (SPS).<sup>42</sup>

Exploring the textual content of the WTO and TRIPS for meaningful solutions to the health challenges they pose presupposes a substantive problem that can be solved within the text of TRIPS. However, the returns on such an approach have marginal utility. The structural problems of TRIPS are too significant to be solved by interpretative devices or substantive manipulations within and severely confined by the structural flaws of TRIPS.

The purpose of this study is to redirect the debate over the challenges of TRIPS to human health and food security to its root cause – which is

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AGRIC., FRAMEWORK STUDY ON FOOD SECURITY AND ACCESS AND BENEFITS-SHARING FOR GENETIC RESOURCES FOR FOOD AND AGRICULTURE 7-10 (2009) (accessing national genetic benefit sharing laws and suggesting modification and standardization of the law); *Food Insecurity in the World*, *supra* note 35, at 2 (expressing deep concern over the lack of progress in reducing the number of hungry people in the world, which has remained persistently high).

<sup>41</sup> The welfare impact of patent protection is not a settled matter from theoretical and empirical economic studies. These studies are not only general but focus on developed countries. However, empirical studies based on the welfare effects of pharmaceutical patents under the TRIPS regime in developing countries are only beginning and the results are similarly varied. *See*, Shubham Chaudhuri, Pinelopi K. Golberg & Panle Jia, *Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India*, 96 AM. ECON. REV. 1477, 1480-81 (2006) (empirically finding that consumer welfare loss attributable to reduction in the variety of drugs because of the withdrawal of domestic products would be significant, suggesting a solution of compulsory licensing and/or price regulation, and finding that in the absence of any price regulation, the price of patented products would rise between 100%-400%; with price regulation the profits of foreign producers would be at pre-TRIPS level: \$19.6 million as opposed to \$53 million per year without price regulation). *But see*, Jean O. Lanjouw & Iain M. Cockburn, *New Pills for Poor People? Empirical Evidence after GATT*, 29 WORLD DEV. 265 (2001) (based on surveys data from India in a post TRIPS world, the study reached a tentative conclusion that the historical absence of intellectual protection tended to retard the development of new treatments, with less new research activity directed at tropical diseases perhaps because of divergent market sizes).

<sup>42</sup> Obijiofor Aginam, *Food Safety, South-North Asymmetries, and the Clash of Regulatory Regimes*, 40 VAND. J. TRANSNAT'L L. 1099, 1100-03 (2007) (discussing the issues of food safety within the context of economic globalization and the regulatory regime of WTO SPS). For a discussion of the interaction between WTO trade rules (GATT XX(d) health exemptions and a review of the SPS process) with other GATT rules and domestic health regulatory regimes, *see* CATHERINE BUTTON, *THE POWER TO PROTECT: TRADE, HEALTH AND UNCERTAINTY IN THE WTO* (2004).

substantially structural and aggravated by a web of interwoven substantive provisions. Given the gravity of health and food security risks faced by large numbers of the world's population, a multilateral agreement such as TRIPS should not contribute to the risk or stand in the path to meaningful solutions. If it does, it must be dismantled. To this end, Part II of this study explores the nature of the threat TRIPS presents to human health and food security, with an emphasis on health security evidence. It examines the nature and global distribution of the disease burden and the disequilibrium in the capacity of states to respond. Part III focuses on the response of TRIPS to the health crisis confronting many developing countries. Part IV challenges two of the fundamental premises of TRIPS. First, it poses the question whether under international law there is fundamental right of states to trade, and if so, under what circumstances that right might be qualified. This is a critical question, particularly when the items of trade relate to public health and food security. Second, it challenges the implicit, if not explicit, assumption of TRIPS that an idea has an unmistakable national origin, thereby necessitating mandatory protection as a condition of international trade. Put differently, if under international law a fundamental right to trade exists, can it be qualified by a concept as ephemeral as the origin of an idea? Part V then explores the interplay between the structure and substance of TRIPS, and the risk to human health and food security. Part VI argues that the structural and substantive risks TRIPS poses are substantially due to the framers' failure to draw upon the rich lessons of history. Given these challenges, the Conclusion returns to the central question posed: *Quo Vadis WTO?* What is the road ahead for the WTO and TRIPS? It offers suggestions and solutions that directly confront the root causes, not the symptoms, of TRIPS' risks to human health and food security.

## II. THREAT TO HUMAN HEALTH AND FOOD SECURITY

Barely five years after the creation of the WTO, the threat TRIPS posed to human health was widely acknowledged not only by the WTO, but also by other international organizations and commentators.<sup>43</sup> In Paragraph 6 of the Doha Declaration, the Fourth WTO Ministerial Conference, acknowledged this problem and instructed the WTO Council for TRIPS to address the public health issues of developing countries.<sup>44</sup> More specifically, the Fourth Ministerial Conference instructed the WTO Council on TRIPS to address the pharmaceutical needs of countries lacking sufficient manufacturing capacities.<sup>45</sup> In response to this mandate, the General Council of the WTO issued a decision on August 30, 2003

<sup>43</sup> See generally World Health Organization, *Macroeconomics and Health: Investing in Health for Economic Development* (2001).

<sup>44</sup> See Doha Declaration, *supra* note 35.

<sup>45</sup> *Id.*

outlining the implementation of Paragraph 6 of the Doha Declaration.<sup>46</sup> Against the background of an increasing international debate over the relationship between TRIPS, the protection of intellectual property and public health, WHO decided to establish an independent Commission on Public Health (WHO Commission on Public Health) to study the issue.<sup>47</sup> To facilitate its mandate, the WHO Commission on Public Health commissioned twenty-two separate studies on many broad aspects of the subject. Almost contemporaneously, the WHO and the WTO undertook a joint study of the WTO Agreements and Public Health in 2002.<sup>48</sup> During this time several other studies were conducted either independently or under the auspices of WTO or WHO on the issue of the public health implications of TRIPS.<sup>49</sup>

Some countries have demanded a reopening of the TRIPS Agreement for de novo negotiations, expressing concern about the public health and economic development implications of TRIPS' structural and substantive mandate.<sup>50</sup> The catalogue of legitimate issues raised strongly suggests that TRIPS was not responsive to the needs of countries that account for the vast majority of the world's population. Given that these concerns found wide expression so soon after the WTO came into force, one wonders whether the needs of developing countries were adequately considered in the initial structuring of TRIPS. Certainly the action by the WTO Council on TRIPS was an explicit admission of TRIPS' deficiencies. An explicit or implicit call for revisiting TRIPS by developing countries merely reinforces its inadequacies, both substantive and structural.

#### A. *The Nature and Scope of the Threat*

The nature and scope of the threat posed by TRIPS is better understood by examining, through studies, the nature of the disease burden and food insecurity in developing countries. Such understanding can best be achieved by reviewing studies directed at the threat. Distilled from these studies are certain basic health challenges faced by developing countries

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<sup>46</sup> *Id.*

<sup>47</sup> WHO, PUBLIC HEALTH: INNOVATION AND INTELLECTUAL PROPERTY RIGHTS, REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH (2006) [hereinafter COMMISSION ON PUBLIC HEALTH].

<sup>48</sup> WHO/WTO STUDY, *supra* note 21 (discussing the nature of the disease burden and the attempt in TRIPS to strike a balance between intellectual property protection and access to medicine, medical technology and the need for cooperation between WHO and WTO on matters of health).

<sup>49</sup> See COMMISSION ON PUBLIC HEALTH, *supra* note 47 (providing an extensive list of studies by the WHO, other U.N. organs and entities and institutions addressing the nature of the disease burden and possible global responses).

<sup>50</sup> DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 60-61 (3d ed. 2008) (discussing the position of several developing countries and in particular calling for Article 31 to be amended and viewing it as reopening the agreement).

under TRIPS. A useful starting point is the report of the WHO Commission on Public Health.

The WHO Commission on Public Health Report provides an instructive picture of the nature and distribution of the disease burden worldwide. According to the report, over 80% (5.3 out of 6.3 billion) of the world's population is in developing countries.<sup>51</sup> Viewed from the perspective of the incidence of disease and mortality rates, this population bears a substantial burden of neglected diseases and diseases of poverty. Yearly statistics of adult and infant mortality in poor countries is high. The most vulnerable are children and pregnant women. Each year, there are about 529,000 maternal deaths, 3.3 million stillborn children and 6.6 million deaths of children under five years old.<sup>52</sup> The density of malaria cases in developing countries is relatively substantial. Although malaria accounts for only 3% of the disease burden worldwide, about 90% of malaria cases occur in Africa.<sup>53</sup> Compared to other diseases, malaria poses the greatest public health concern in developing countries.<sup>54</sup> Malaria victims are mostly children and pregnant women.<sup>55</sup> According to reports, about 58% of all malaria cases are found in the poorest 20% of the world.<sup>56</sup>

In the case of tropical and infectious diseases such as malaria, HIV/AIDS and tuberculosis, Sub-Saharan Africa appears to bear the brunt of the impact. Lamenting the lack of incentives for R&D in these diseases, Rachel Glennester and Michael Kremer point out that malaria, tuberculosis and HIV/AIDS have killed more people than all the wars in the last half century.<sup>57</sup> Together they claim 5 million lives each year, mostly in developing countries and particularly in Sub-Saharan Africa.<sup>58</sup> Of the 2.3 million deaths attributable annually to HIV/AIDS, about 70% occur in Sub-Saharan Africa.<sup>59</sup>

The WHO Commission on Public Health Report, like other studies, identifies three different types of diseases in the world. Type I diseases are communicable (measles, hepatitis B) and non-communicable (diabe-

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<sup>51</sup> See COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 2.

<sup>52</sup> *Id.* at 4.

<sup>53</sup> *Id.* at 6.

<sup>54</sup> *Id.* at 4 (explaining that malaria constitutes a greater proportion of major public health concerns in developing countries than any other disease).

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

<sup>56</sup> *Id.*

<sup>57</sup> Rachel Glennester & Michael Kremer, *A Better Way to Spur Medical Research and Development*, 23 REGULATIONS 34, 36 (2000), available at <http://www.cato.org/pubs/regulation/regv23n2/kremer.pdf>.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* (explaining the death rates due to tropical and infectious diseases; that 1.1 million people die of malaria each year, especially children and pregnant women, and 1.9 million die of tuberculosis).

tes, cardiovascular diseases),<sup>60</sup> and afflict the most vulnerable population in both rich and poor countries. They are diseases of equal opportunity that afflict people without regard to their per capita income. However, their impact on countries generally depends on wealth and the technological capacity of a country. High per capita income countries have been better able to support R&D and provide effective treatment and vaccines for Type I diseases.<sup>61</sup> Unfortunately, although vaccines for non-communicable Type I diseases are available, they are inaccessible to poor countries because of cost.<sup>62</sup>

Type II diseases are also incident in both rich and poor countries, although they disproportionately afflict the population of poor countries. For instance, over 90% of the incidence of HIV/AIDS and tuberculosis are in poor countries.<sup>63</sup> Finally, Type III diseases are either substantially or exclusively found in developing countries. Type III diseases, which include African river blindness (onchocerciasis) and sleeping sickness (trypanosomiasis) receive little or no R&D attention.<sup>64</sup> The lack of research interest in these diseases is one of the concerns expressed by public health researchers such as Glennester and Kremer.<sup>65</sup> Type III diseases have not attracted much public or private expenditures on health research in developed countries. Unfortunately, developing countries face the compounding factor of Type I diseases increasingly taking on the characteristics of Type II diseases. This means they suffer a double burden while inadequate treatment persists.<sup>66</sup> One of the negative externalities of globalization is the changing pattern of nutrition and food habits in developing countries. People in poor countries are increasingly shifting their eating habits to imitate those of their counterparts in developed countries.<sup>67</sup> It is a cultural shift with significant implications for the redistribution of the global disease burden, resulting in an increase in the incidence of non-communicable chronic diseases, such as diabetes and stroke, in developing countries.<sup>68</sup> Chronic diseases account for over 60% of deaths worldwide, but 80% of these deaths occur in developing coun-

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<sup>60</sup> COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 13.

<sup>61</sup> See *infra* text and notes discussing global financial flows and health research.

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> Glennester & Kremer, *supra* note 57, at 36.

<sup>66</sup> COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 13.

<sup>67</sup> *Infra*, notes 117 and 118 and text discussing the changing patterns in the eating habits of people in the Pacific Islands region such as Tonga and Fiji. See also Mary Anne Burke, Stephen A Matlin & Jean-Jacques Monot et al., *Monitoring Financial Flows for Health Research 2008: Prioritizing Research for Health Equity*, at iii, xvii (2008), available at <http://www.isn.ethz.ch/isn/Digital-Library/Publications/Detail/?ots591=0c54e3b3-1e9c-be1e-2c24-a6a8c7060233&lng=en&id=93435>.

<sup>68</sup> See, e.g., *infra* notes 117 and 118.

tries.<sup>69</sup> Now, in addition to the traditional infectious tropical diseases, people in remote African villages are confronted with the challenges posed by these new chronic diseases. Globalization has therefore not only complicated trade policies of developing countries, but also their public health policy choices. Globalization has also affected the distribution of innovative technology in agriculture, seed and food production, concentrating it in the hands of global agro-business multinational enterprises (MNE).<sup>70</sup>

The astonishing nature of these statistics should engage the attention of the global community. However, the response of the global community, as demonstrated by health-research expenditures directed at diseases that target those in developing countries, is by all measures disappointing. The disequilibrium in health research expenditures was captured in the first 10/90 Report on Health Research by the Global Forum for Health Research.<sup>71</sup> According to this report, developed countries have been mostly concerned with addressing their own fundamental health needs. In 1986 when global investment in health research stood at about \$30 billion, only \$1.6 billion, or about 5%, was devoted to problems facing developing countries.<sup>72</sup> Just six years later, in 1992, the estimate of global investment in health research jumped to \$56 billion, but the proportion of that amount devoted to developing countries was only \$2 billion (3%), indicating a relative decline in funding.<sup>73</sup> Additional estimates in 1992 and 1995 found a similar imbalance of 5-10% in the percentage of resources devoted to developing countries. This led to the conclusion that there was generally a 10/90 imbalance in global health expenditure.<sup>74</sup>

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<sup>69</sup> Mary Anne Burke, Stephen A Matlin & Jean-Jacques Monot, *Monitoring Financial Flows for Health Research 2008: Prioritizing Research for Health Equity*, at iii, xvii (2008), available at <http://www.isn.ethz.ch/isn/Digital-Library/Publications/Detail/?ots591=0c54e3b3-1e9c-be1e-2c24-a6a8c7060233&lng=en&id=93435>; Burke, Matlin & Monot et al., *supra* note 67, at iii, xvii.

<sup>70</sup> The ECT Group issued a Communiqué in September/October 2005 on the concentration of the global seed industry. It argued that the top world's top eleven seed companies were all from developed countries. At the top was Monsanto (U.S.) followed by Dupont/Pioneer (U.S.). Of the group, the U.S. accounted for four companies, Germany two, Japan two and Denmark, France and Switzerland one each. Furthermore, in the area of genetically modified plants, the U.S. accounted for about 59% and the second largest country, Argentina, had only 20% followed by others nations in the single digits. For a detailed discussion of the nature and impact of the concentration of the global seed companies, see ECT GROUP, COMMUNIQUÉ, *Global Seed Industry Concentration – 2005 September/October, Issue #90*.

<sup>71</sup> Louis J Currat, et al., *The 10/90 Report on Health Research 1999*, at 7, 16 (1999), available at <http://www.isn.ethz.ch/isn/Digital-Library/Publications/Detail/?ots591=eb06339b-2726-928e-0216-1b3f15392dd8&lng=en&id=20437>.

<sup>72</sup> *Id.* at 69

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

<sup>74</sup> *Id.*

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Of the billions of dollars spent annually on health research, only 10% is devoted to the needs of developing countries.<sup>75</sup>

### B. Global Financial Flows in Health Research.

The discussion of the inequity or imbalance in health research expenditures by high-income countries (HIC) is better framed within the context of the financial flows in health research expenditures worldwide. The Global Forum for Health Research investigated this issue and found the higher the income of a country, the more likely it is to invest in health research.<sup>76</sup> In 2005, HICs accounted for a substantial percentage (97%) of such investments, in comparison with only 3% by low- and middle-income countries (LMIC). This concentration is more clearly captured in Table 1 below, which describes the expenditures in health research by the public and private sectors in HICs and LMICs.<sup>77</sup>

TABLE 1\*  
Estimated global of total investment in health R&D, 2005  
(current US\$ billion) compared with 2003, 2001 and 1998.

	2005		2003		2001		1998	
	US\$	%	US\$	%	US\$	%	US\$	%
<b>Total</b>	<b>160.3</b>	<b>100</b>	<b>125.8</b>	<b>100</b>	<b>105.9</b>	<b>100</b>	<b>84.9</b>	<b>100</b>
Total public sector	66.3	41	56.1	45	46.6	44	38.5	45
Total private sector	94.0	59	69.6	55	59.3	56	46.4	55
Total private for-profit	81.2	51	60.6	48	51.2	48	40.6	48
Total private not-for-profit	12.8	8	9.0	7	8.1	8	5.9	7
<i>HIC (a)</i>								
Public sector	63.3	39	53.8	43	44.1	42	36.2	43
Private for-profit sector	79.7	50	59.3	47	49.9	47	40.0	47
Domestic pharmaceuticals(b)	71.0	44	53.2	42	44.1	42	35.0	41
Foreign pharmaceuticals (b)	8.7	5	6.1	5	5.8	5	5.0	6
Private not-for-profit (c)	12.2	8	8.6	7	7.7	7	5.6	7
<b>Total HIC</b>	<b>155.2</b>	<b>97</b>	<b>121.7</b>	<b>97</b>	<b>101.6</b>	<b>96</b>	<b>81.8</b>	<b>96</b>
<i>LMIC (d)</i>								
Public sector	3.0	1.9	2.4	1.9	2.5	2.4	2.3	2.7
Public sector domestic	2.3	1.4	1.9	1.5	2.0	1.9	1.8	2.1
Public funding from foreign	0.6	0.4	0.4	0.3	0.4	0.4	0.4	0.5
<i>ODA (e)</i>								
Public funding for international Research	0.10	0.06		0.06	0.07	0.07	0.07	0.08
Private for-profit sector: foreign and domestic pharmaceuticals	1.6	1.0	1.4	1.1	1.3	1.3	1.0	1.2
Domestic private not-for-profit	0.12	0.07	0.08	0.07	0.08	0.08	0.08	0.10
Foreign private not-for-profit(f )	0.4	0.3	0.3	0.2	0.3	0.3	0.2	0.3
<b>Total LMIC</b>	<b>5.1</b>	<b>3.2</b>	<b>4.1</b>	<b>3.3</b>	<b>4.3</b>	<b>4.0</b>	<b>3.6</b>	<b>4.2</b>

<sup>75</sup> Currat et al., *supra* note 71, at 69.

<sup>76</sup> Burke, Matlin & Monot et al., *supra* note 67, at 25-30.

<sup>77</sup> *Id.* at 28.

\* Global Forum for Health Research, Monitoring Financial Flows for Health Research 2008. Available at *id.* The effect of the change in methods and sources of data for the pharmaceutical industry results in an increase of US\$ 10.1 billion in 1998.

(a) High-income countries: Israel 2001, Singapore 2001.

(b) Foreign pharmaceutical R&D stands for R&D investment outside the United States by United States-owned PhRMA member companies and R&D conducted abroad by the United States divisions of foreign-owned PhRMA member companies. Domestic pharmaceutical R&D corresponds to the global estimates for the pharmaceutical R&D in high-income countries reduced from foreign pharmaceutical R&D.

(c) Private not-for-profit includes US\$ 3.1 billion estimated for private general university funding in 2001, and US\$ 2.5 billion in 1998.

(d) Low and middle income countries: China (including Taiwan) 2001, Brazil 2001/2003, Chile 2001, Cuba 2001, Philippines 2001, Romania 2001, Russian Federation 2001, Slovenia 2001, South Africa 2001/2003, Venezuela 2001.

(e) International research, foreign private not-for-profit and foreign official development assistance (ODA) are very rough estimates.

According to Table 1, total health research expenditures worldwide in 2005 stood at about \$160.3 billion, of which the public and private sectors contributed 41% and 59% respectively. The substantial public sector investment in health is significant. Although TRIPS is designed to protect private intellectual property rights, public expenditure in developed countries on innovation is substantial. HICs dominated the investment scene with \$155.2 billion as compared with \$5.1 billion in LMICs. The concentration is even more startling given a global comparison of these expenditures. According to the Global Forum for Health Research, the U.S. dominated the picture, accounting for about 50% of all investment, leaving other members of the TRIAD far behind.<sup>78</sup> The only developing countries worth mentioning are China and Taiwan, with only 1% combined.<sup>79</sup> The disequilibrium also exists in profit motivated health research, as captured in Table 2 below.<sup>80</sup>

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<sup>78</sup> Burke, Matlin & Monot et al., *supra* note 67, at 30.

<sup>79</sup> *Id.* at 29.

<sup>80</sup> Burke, Matlin & Monot et al., *supra* note 67, at 40.

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TABLE 2\*\*  
Private for-profit health R&D investments by funders, 2005  
(US\$ million)

Global total	77 207	100.05
United States	38 205	49.5
Japan	10 120	13.1
Germany	5 338	6.9
United Kingdom	4 347	5.6
France	3 350	4.3
Switzerland	3 153	4.1
Sweden	1 688	2.2
Canada	1 609	2.1
Other high-income countries	7 826	10.1
<b>Total high-income countries</b>	<b>75 637</b>	<b>98.0</b>
China	595	0.8
India	162	0.2
Other low- and middle-income countries	814	1.1
<b>Total low- and middle-income countries</b>	<b>1 570</b>	<b>2.0</b>

The U.S. dominates private sector investments in health research with about 50%, followed by Japan with 13.1% and Germany with 6.9%. Two developing countries, China and India, register investment of this type with less than 1% each. Furthermore, the geographic distribution of investments by pharmaceutical member companies in 2006 puts U.S. companies in a clearly dominant position with 79.3%, while the remaining pharmaceutical member companies' investments are scattered across the globe with less than 2% in any one country.<sup>81</sup> The picture painted by these statistics is hardly appealing to developing countries.

Certain patterns seem to emerge from this brief survey. The distribution of the disease burden during the TRIPS negotiations and after implementation of TRIPS has remained stubbornly skewed against developing countries. Health research expenditures aimed at the world's disease burden have remained directed significantly at the needs of developed countries. In view of the pattern of concentration in these expenditures, innovation and product development will continue to display a substantial imbalance against the interests of developing countries. Studies by FAO confirm a similar disequilibrium in food security R&D.<sup>82</sup> The struc-

\*\* Global Forum for Health Research, *Monitoring Financial Flows for Health Research* 2008.

<sup>81</sup> *Id.* at 47.

<sup>82</sup> See *Food Insecurity in the World*, *supra* note 35, at 2 (capturing the nature of the food insecurity of developing countries). According to this report, of the 832 million people living in chronic hunger between 2003 and 2005, only seven countries (India, China, The Democratic Republic of Congo, Bangladesh, Indonesia, Pakistan and Ethiopia) accounted for 65% of the total. *Id.* at 12. Part of the problem is food production. *Id.* at 44; see also Carlos M. Correa, *Access to Plant Genetic Resources and Intellectual Property Rights*, COMMISSION ON GENETIC RESOURCES FOR FOOD &

ture and substance of TRIPS accentuate rather than correct the disequilibrium.

Although these imbalances may be shocking, they are hardly surprising. They capture perceptions of states' responsibility and the nature of their health policy matrix. These expenditures clearly demonstrate an uncompromising exercise of sovereignty by developed countries to address the health needs of their citizens. However, health is not simply a fundamental right of citizens, but also characteristically a human right enshrined in international conventions, constitutions and some domestic legislative provisions.<sup>83</sup> In the face of these international obligations and pressing needs, the appropriate policy response by developing countries should not be handcuffed by a regime that is suppressive of sovereignty and the public interest. National health policies must take into account their international obligations in the health arena.

The constitution of the WHO sees health as essential to the happiness and the security of all peoples.<sup>84</sup> It defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."<sup>85</sup> It further states that "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."<sup>86</sup> Article 12.1 of the International Covenant

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AGRICULTURE [hereinafter CGRFA] 6-7 (Apr. 1999), available at <ftp://ftp.fao.org/docrep/fao/meeting/014/aj584e.pdf> (explaining that although 25,000 biotechnology patents were issued between 1990 and 1995, they constituted only 1% of all patents and were highly concentrated in the U.S. (35.4%), Japan (34.9%) and Europe (19.4%) compared with China (1.1%) and the Republic of Korea (0.7%), and that the most active applicants for plant patents were MNCs from developed countries); Walter Smolders, *Commercial Practice in the Use of Plant Genetic Resources for Food and Agriculture*, 9-10 (Comm'n of Genetic Res. for Food and Agric., Background Study Paper No. 27, 2005). From limited data, the report argued that there is a growing consolidation of global seed companies, that the top ten agro-business global enterprises are located in developed countries and that seed companies are increasingly doing less or no basic research. Exotic germplasm or landraces are perceived as having little practical value for a seed company, and their introgression into breeding lines is time-consuming and risky.

<sup>83</sup> Kojo Yelapaala, *Fundamentalism in Public Health and Safety in Bilateral Treaties (Part II)*, 3 ASIAN J. OF WTO & INT'L HEALTH L. & POL'Y 235, 474-79 (2008) (discussing the constitutional protections to health provided by some countries); Constitution of the World Health Organization, 15 U.N.T.S. 185, July 22, 1946 (entered into force Apr. 7, 1948) [hereinafter WHO Constitution], available at [http://www.who.int/governance/eb/who\\_constitution\\_en.pdf](http://www.who.int/governance/eb/who_constitution_en.pdf); COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 9-10.

<sup>84</sup> WHO Constitution, *supra* note 83 (the Preamble states that "THE STATES party to the Constitution . . . declare that the following principles [on health] are basic to the happiness, harmonious relations and security of all peoples").

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

on Economic Social and Cultural Rights also recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>87</sup> As appropriately pointed out by the WHO Commission on Public Health, these obligations of the state are not simply utopian.<sup>88</sup> They constitute both moral and legal imperatives.<sup>89</sup> The point of interest to this study is whether TRIPS directly or indirectly operates to weaken these obligations. Can TRIPS lawfully restrict states from exercising their sovereignty to ensure the enjoyment of the fundamental human right of health for private gain? It is doubtful that the protection of private property rights in ideas trumps the obligation of states to protect the fundamental right to health. The state, in carrying out its human rights obligations, should have the right to deny the protection of private intellectual property rights in furtherance of human rights in health. Indeed, the question has been raised elsewhere as to whether a state can legally abrogate its responsibility to protect the human rights of its citizens by treaty for private gain.<sup>90</sup>

### C. *The Impact of TRIPS on Health and Economic Development*

The dynamics of health policy choice challenges posed by TRIPS transcend the domain of human rights and paradoxically implicate the free trade and economic development objectives of the WTO. From GATT's inception to its transformation into a system of Agreements under the WTO, free trade has always been *purposive*: the achievement of social and economic advancement in the world – something larger than free trade itself.<sup>91</sup> The free trade ideal first captured in GATT in 1947 has continued to find expression in the preamble of the WTO. Some of its major objectives include raising the standards of living, ensuring full employment, steady real income growth and expanding production in

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<sup>87</sup> International Covenant on Civil and Political Rights, Dec. 16, 1966, 999 U.N.T.S. 171, 6 I.L.M. 368 [hereinafter ICCPR]; International Covenant on Economic, Social, and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3, 6 I.L.M. 360; *see also* Yelapaala, *supra* note 83, at 484-92 (arguing that the right to health is governed by international law under conventions and under *jus cogens*).

<sup>88</sup> COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 9.

<sup>89</sup> *Id.* at 8-10; Thomas W. Pogge, *Human Rights and Global Health: A Research Program*, 36 METAPHILOSOPHY 182, 194-97 (2005) (framing the moral arguments and urgency of tackling the global disease burden within the context of the Universal Declaration of Human Rights).

<sup>90</sup> Yelapaala, *supra* note 83, at 236, 240 (raising the question whether a state owes certain indelible duties to its citizens which it may not surrender or abandon in a treaty for private profit).

<sup>91</sup> Article 55 of the U.N. Charter lays out the general purposes to be served by the U.N. subsidiary organs authorized under Article 57. Article 55 calls for the creation of conditions for stability and well being which are necessary for peaceful and friendly relations among nations. For a discussion of the meaning and scope of Article 55 *see* GOODRICK & SIMONS, *supra* note 9, at 371-80.

tradable goods and services.<sup>92</sup> Thus the WTO and its system of agreements are not concerned with achieving free trade per se, but rather with facilitating the social and economic development of its member states. A major component of such development is human health security, which is affected by some of the WTO agreements, including TRIPS. Trade liberalization has also proved to be costly to developing countries in terms of shifting the disease burden and limiting their health policy choices.<sup>93</sup> The costs and benefits of trade liberalization are hardly equitably distributed when compared to the wide gulf between the health impact and expectations of high-income and low-income countries.<sup>94</sup> Again, the complexity of these topics deserve more time and space than is available here. I will focus briefly on the challenges posed by trade liberalization under the WTO on human health and development.

The role of health in economic development is gaining the attention of development theorists and policy makers. Conventional development theories of the 1950s and 60s focused on factor accumulation, physical capital, labor supply and infrastructural investments.<sup>95</sup> Under these theories, health was a mere consequence of, and not an engine of, development. Modern development theories now recognize the central role of human capital in development, in which health is an engine and not a

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<sup>92</sup> The WTO's preamble states in part: "Recognizing that their relations in the field of trade and economic endeavor should be conducted with a view to raising standards of living, ensuring full employment and large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services." Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, preamble, Apr. 15, 1994, 33 I.L.M. 1125, 1144 (1994).

<sup>93</sup> Chantal Blouin, Mickey Chopra & Ralph van der Hoeven, *Trade and Social Determinants of Health*, 373 THE LANCET 502, 502-04 (2009).

<sup>94</sup> *Id.*

<sup>95</sup> The literature on early theories of economic development is vast and cannot be listed here. For a review of these theories which were mostly based on the Cobb-Douglas production function and the basic factors of production excluding health and nutrition, see generally PAN A. YOTOPOULOS & JEFFREY B. NUGENT, *ECONOMICS OF DEVELOPMENT: EMPIRICAL INVESTIGATIONS* (1976); LANCE TAYLOR, *MACRO MODELS FOR DEVELOPING COUNTRIES* (1979); ALLEN C. KELLY, JEFFREY G. WILLIAMSON & RUSSELL J. CHEETHAM, *DUALISTIC ECONOMIC DEVELOPMENT: THEORY AND HISTORY* (1972). For a much more sophisticated statement of the role of health and nutrition to development generally not included in economic development models, see Theodore Morgan, *Economic Development: Concept and Strategy* 167 (1975) (specifically chapter 10, which is devoted to nutrition, disease and climate). Morgan quotes Jacob Viner, who argues "In many countries [if the masses of the population were] . . . literate, healthy, and sufficiently well fed . . . all else necessary for rapid economic development would come easily and of itself." *Id.* Morgan argues the presence or absence of good health affects every aspect of human behavior. *Id.* See also W. HOWARD WRIGGINS & GUNNAR ALDER-KARLSON, *REDUCING GLOBAL INEQUALITIES* 143 (1978) (discussing the role of health and healthcare in global inequalities between nations).

consequence of development.<sup>96</sup> Indeed, health is both a cause and a consequence of development.<sup>97</sup> It is argued that the return on health research investment is often substantially higher than those in conventional infrastructural investments.<sup>98</sup> Health affects education, skills acquisition, labor productivity and economic development.<sup>99</sup> The evidence from the East Asia Miracle (Hong Kong, the Republic of Korea, Singapore and Taiwan) suggests that economic growth, rising per capita income and meaningful international trade require high labor productivity of high-quality and low-cost manufactured exports.<sup>100</sup> The sources of growth and development include a healthy and productive labor force. As appropriately pointed out by Bloom and Canning, there is a health-to-health cause and consequence relationship which has important policy implications.<sup>101</sup> If the goals of the WTO include social and economic development through trade, the logical pro-trade and pro-development policies of the WTO should have included fostering sound member state health policies, easy access to health related technologies and the availability of affordable pharmaceutical products. The limitations TRIPS imposes on member states, even within its so-called flexibilities, seem to contradict the very ideals the WTO preaches.

The relationship between TRIPS, health and economic development, however, is complex and controversial. One way to investigate the impact of TRIPS on health and economic development is to explore the famous Preston Curve on the relation between per capita income and life expectancy. In 1975, Samuel Preston argued there was a complex, but

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<sup>96</sup> Currat, *supra* note 71, at 30.

<sup>97</sup> David E. Bloom & David Canning, *Commentary: The Preston Curve 30 Years On: Still Sparking Fires*, 36 INT'L J. OF EPIDEMIOLOGY 498, 499 (2007).

<sup>98</sup> Currat, *supra* note 71, at 30.

<sup>99</sup> Bloom, *supra* note 97, at 499.

<sup>100</sup> The literature on the East Asia Miracle is voluminous. See, e.g., York W. Bradshaw, Young-Jeong Kim & Bruce London, *Transnational Economic Linkages, the State and Dependent Development in South Korea, 1966-1988: A Time-Series Analysis*, 72 SOCIAL FORCES 315 (1993) (explaining the direct involvement of the state in development that relies heavily on international trade); John Page, *The East Asian Miracle: Four Lessons for Development Policy*, 9 NBER MACROECONOMICS ANN. 219 (1994); Dani Rodrik, *Getting Interventions Right: How South Korea and Taiwan Grew Rich*, 10 ECON. POL'Y 55 (1995) (explaining the complexities of the policy mix used by South Korea and Taiwan for achieving development and riches); Kojo Yelapaala, *Rethinking the Foreign Direct Investment Process and Incentives in Post Conflict Transition Countries*, 30 NW J. INT'L L. & BUS. 23, 53-54 (2010) (discussing the reasons for the East Asian Miracles and the role of the developmental state); Alwyn Young, *The Tyranny of Numbers: Confronting the Statistical Realities of the East Asian Growth Experience*, 110 Q. J. ECON. 641 (1995) (examining the role of factor accumulation in the extraordinary post-war growth of Hong Kong, Singapore, South Korea, and Taiwan).

<sup>101</sup> Bloom & Canning, *supra* note 97, at 499.

concave or non-linear, positive relationship between per capita income and life expectancy between and within countries.<sup>102</sup> Put differently, among the poorest countries, longevity and increases in average income tend to correlate strongly, but the relationship weakens and even flattens out among the richest countries.<sup>103</sup> Beyond a certain point, an increase in wealth does not improve longevity. Thus, income has larger effects on life expectancy among the poor than it does among the rich.<sup>104</sup> A recent investigation of the suggested sensitivity of longevity to variations in average income depicted in the Preston Curve was conducted by Angus Deaton<sup>105</sup> and is captured in Figure 1 below.

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<sup>102</sup> Samuel H. Preston, *The Changing Relation Between Mortality and Level of Economic Development*, 29 *POPULATION STUD.* 231 (1975). The Preston Curve has been the subject of much recent discussion among organizations concerned with the global health crisis and health research. See Burke, Matlin & Monot et al., *supra* note 67, at 8 (discussing the complexity of the Preston Curve in life expectancy across countries); Stephen A. Matlin, et al., *Monitoring Financial Flows for Health Research 2009: Behind the Global Numbers*, at 3-4 (2009), available at <http://www.isn.ethz.ch/isn/Digital-Library/Publications/Detail/?ots591=0c54e3b3-1e9c-be1e-2c24-a6a8c7060233&lng=en&id=111451> (discussing the Preston Curve and life expectancy in the twentieth century); Currat, *supra* note 71, at 76, 85 (discussing differences in life expectancy and poverty between countries).

<sup>103</sup> Burke, Matlin & Monot et al., *supra* note 67, at 8; Matlin, *supra* note 102, at 3-4.

<sup>104</sup> Blouin, *supra* note 93, at 502-07.

<sup>105</sup> Angus Deaton, *Health Inequality and Economic Development*, 41 *J. ECON. LITERATURE* 113, 115-16 (concluding there is no direct link to ill health from income inequality per se, but suggesting that income inequality and health are important to welfare economics; health can be affected by welfare transfer policies through taxes and transfers affecting individual health). But note that redistribution from rich countries through trade could have a positive impact on the health of citizens of poor countries – trade can result in wealth transfer from high-income countries to low income countries, but a healthy work force in both, particularly in low-income countries, would be essential to trade.

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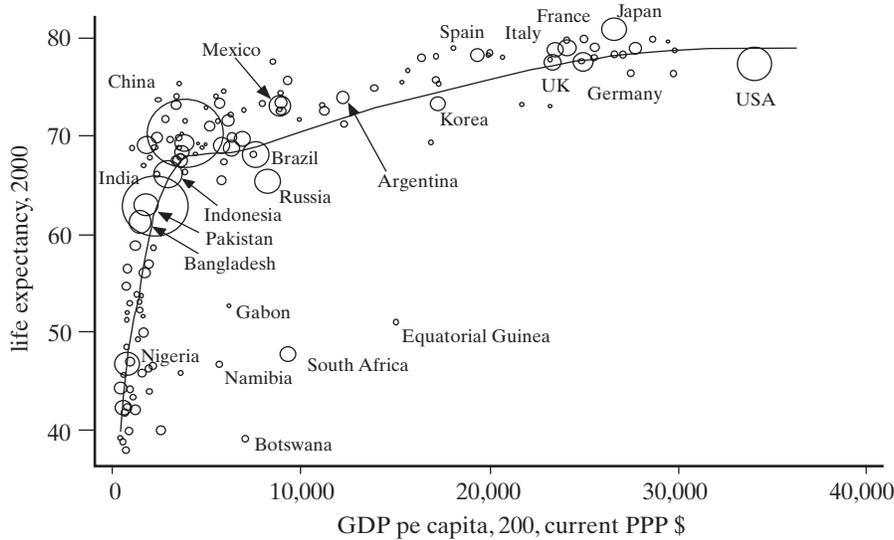


Figure 1. The Preston Curve: Life Expectancy versus GDP Per Capita

Source: World Development Indicators CD-ROM, World Bank (2002)

Note: Circles are proportional to population and some of the largest (or most interesting) countries are labeled. The solid line is a plot of a population-weighted nonparametric regression. Luxembourg, with per capital GDP of \$50,061 and life expectancy of 77.04 years, is excluded.

It is apparent from the above figure that countries at lower levels of the wealth ladder can dramatically improve life expectancy by increasing average wealth. For instance, increasing average income by less than \$10,000 can have a major impact on longevity in China, India and Brazil. On the other hand, life expectancy in high per capita income countries such as the U.S., Japan, Germany and the United Kingdom tends to flatten out at higher average income levels. The association between wealth and health, however, is more complex than is immediately apparent in the Preston Curve because variables other than income or wealth affect health and longevity. For example while countries such as China and those in the Mediterranean region have low average income, they nevertheless enjoy long life expectancy. This suggests factors such as diet, nutrition, clean water, sanitation and preventive public health policies contribute to higher levels of longevity.<sup>106</sup> Besides, further studies have suggested that the direction of causality indicated by the upward slope of the Preston curve might be only part of a much more complex phenome-

<sup>106</sup> COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 2 (indicating that income and health are not necessarily related); Bloom & Canning, *supra* note 97 at 498 (showing there is much debate over the issue).

non. There appears to be not only a reverse direction of causation (health to wealth with multiple mechanisms in play<sup>107</sup>) but also inter-country differences across different income groups.<sup>108</sup>

The connection between the Preston Curve indicia of longevity and TRIPS is therefore neither direct nor obvious. Indeed, the association I seek to make here is not between income and health, but rather between income and the capacity of a state to address fundamental health needs.<sup>109</sup> Such a connection can be made through points already developed above. First, there is a close association between poverty and the disease burden of a country. The poorer a country, the greater the size and impact of the disease burden it is likely to bear. Second, it has also been established that poor countries are financially ill equipped to adequately address health services and research. Third, as indicated by health financial flows, there appears to be a direct relationship between the wealth of a country and its health research expenditures aimed at addressing fundamental health needs. Public and private health research expenditures are predominantly carried out in rich developed countries and are directed to their health needs.<sup>110</sup> On average, about only 10% of these expenditures are directed at the needs of developing countries,

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<sup>107</sup> David Bloom & David Canning, *The Health of Nations*, 287 SCIENCE 1207 (2000) (arguing that a reverse health to wealth causal link exists and is supported by four mechanisms: productivity, education, investment in education and a demographic divide which helps explain reverse causal relations).

<sup>108</sup> There is still much disagreement over many of the issues relating to the Preston Curve. However, there appears to be some agreement on the positive effect of a provision of public health infrastructure on health. For a careful and thorough review of the literature, see, David M. Cutler, Angus S. Deaton & Adrian Lleras-Muney, *The Determinants of Mortality*, NATIONAL BUREAU OF ECONOMIC RESEARCH, Working Paper 11963, <http://www.nber.org/papers/w11963> (2006) (providing a review of the hotly debated issues in history of mortality in developed and developing countries pointing out the arguments for the role of nutrition, disease theory and in particular inter-country health inequalities or gradient effects measuring a wider range of mortality based on socio-economic status).

<sup>109</sup> *Id.* at 22 (discussing issues in history of mortality in developed and developing countries and pointing out arguments for the role of nutrition, disease theory and a public health infrastructure); Joseph E. Stiglitz & Arjun Jaydev, *Medicine for Tomorrow: Some Alternative Proposals to Promote Socially Beneficial Research and Development in Pharmaceuticals*, 7 J. GENERIC MEDICINES 217, 220-24 (2010) (discussing various ways in which governments can fund or intervene in the health related R&D for the development of new medicines to combat neglected diseases).

<sup>110</sup> Currat et al., *supra* note 71, at 45 (arguing that about 95% of R&D resources are devoted to issues relevant only to the needs of 5% of the world's population); Burke, Matlin & Monot et al., *supra* note 67, at 25-27 (confirming the devotion of expenditures on health research mostly toward developed countries).

although their disease burden and mortality rates are substantially greater.<sup>111</sup>

The Preston Curve seems to provide another angle from which to view these phenomena. The concavity of the relationship depicts the burdens and opportunities of poor countries at the base of the rising curve. Up to the point of diminishing returns on rising wealth, poor countries can substantially improve the health and longevity of their populations through health research expenditures, public health policies and economic development.<sup>112</sup> Limitations on the policy choices of the state in a multilateral agreement such as TRIPS are therefore undesirable. The capacity of a state to address its health needs is enhanced by rising GDP and average income. With relatively abundant resources, wealthier countries are better able than their poorer counterparts to allocate the appropriate resources towards health technologies, products and services. The generation of that wealth requires, *inter alia*, a healthy labor force. This is more so because health is now viewed as an engine, not a consequence, of development. It stands to reason that moving up the Preston Curve would require a healthy workforce. If all of this holds true, an international agreement with the goal of social and economic development through trade in goods and services cannot logically adopt measures which interfere with the ability of a country to improve health. Unfortunately, TRIPS does not pass this test – a fact not disputed by the General Council of WTO, WHO and many commentators.<sup>113</sup>

Beyond issues of macroeconomics and health, the health burdens that TRIPS, within the WTO system, places on developing countries seem imbedded in the concept of free trade that the WTO advocates. The liberalization of trade and investments within the shrinking economic geography of the current globalization system appears to have unforeseen negative consequences on public health in developing countries.<sup>114</sup> Trade and investment liberalization have produced certain negative externalities in health in developing countries. Trade liberalization has enabled greater availability of highly processed, calorie-rich and nutrient-deprived food in developing countries.<sup>115</sup> Trade liberalization has also opened up the markets of developing countries to other high health-risk products

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<sup>111</sup> Currat et al., *supra* note 71, at 16 (explaining that in 1996, the WHO Ad Hoc Committee on Health Research concluded that the central problem in health was the 10/90 disequilibrium – of the \$50-\$60 billion dollars spent worldwide each year on health research, only 10% was devoted to the health problems of 90% of the world's population).

<sup>112</sup> JOSEPH E. STIGLITZ, MAKING GLOBALIZATION WORK 118 (2006) (discussing the knowledge gap between developed and developing countries and need for investment in development of new medicines); Stiglitz & Jaydev, *supra* note 109; Currat et al, *supra* note 71 at 118-19.

<sup>113</sup> Doha Declaration, *supra* note 35; Smith, Correa, & Oh, *supra* note 40, at 686.

<sup>114</sup> *Id.* at 684.

<sup>115</sup> Blouin, *supra* note 93, at 503.

such as tobacco.<sup>116</sup> These food exports from global agro-business MNEs are not necessarily what developing countries need.<sup>117</sup> As consumption of these products has increased so has the associated disease burden of non-communicable diseases such as diabetes, obesity, stroke and other chronic diseases previously unknown in developing countries.<sup>118</sup> Thus, trade liberalization has not only changed the nature of the disease burden in developing countries, it has also imposed greater restrictions, through TRIPS, on tackling these new diseases. The only means to address these diseases under TRIPS appear to be the so-called system of flexibilities.<sup>119</sup> As noted above, the inadequacy of TRIPS' internal solutions prompted the WTO General Council to issue the Doha Declaration only a few years after TRIPS' implementation. Although aggravated by its substantive provisions, the problems that TRIPS creates are essentially structural. Structural problems cannot easily or adequately be resolved by analysis of the substantive provisions.

Even as the market for food and tobacco products is liberalized, the market for pharmaceutical products and health technology is hardly regulated under TRIPS in such a way as to address the negative externalities of liberalization. Patent holders can engage in various marketing prac-

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<sup>116</sup> *Id.*

<sup>117</sup> Studies of Pacific Islands point to the general problem of undesirable food exports to developing countries by global agro-business MNEs. See, e.g., Robert G. Hughes & Mark A. Lawrence, *Globalisation, Food and Health in Pacific Island Countries*, 14 ASIA PAC. J. CLIN. NUTR. 298, 299 (2005) (discussing allegations of low nutrition food exports into the Pacific Islands region as "food dumping" or in stronger terms "dietary colonialism," "Coca-colonialism" or "dietary genocide"); Jimaima Tunidau Schultz, *Globalisation, Urbanisation and Nutrition Transition in a Developing Island Country a Case Study: Fiji*, Paper Prepared for the FAO Technical Workshop on "Globalisation of Food Systems: Impact on Food Security and Nutrition," 8-10 October 2003, Rome, Italy, at 11-16 (arguing that the impact of globalization on food in developing countries, particularly Fiji, is not limited to dietary change and malnutrition but also includes social transformation from extended family structure to the nucleus, collectivism to individualism and self-reliance to employment).

<sup>118</sup> Mike Evans, Robert C. Sinclair, Caroline Fusimalohi & Viliami Liav'a, *Globlization, Diet, and Health: An Example from Tonga*, 79 BULLETIN OF THE WORLD HEALTH ORGANIZATION 856, 858 (2001) (listing some of the diet related diseases in Tonga including diabetes, high blood pressure and heart disease).

<sup>119</sup> Correa, *Pro-competitive Measures Under TRIPS*, *supra* note 38, at 42-43 (arguing that WTO member states can adopt different measures to advance their interest consistent with TRIPS, e.g., encouraging price competition and access to products, parallel imports and the so-called "Bolar" exception); Correa, *Implications of Doha Declaration*, *supra* note 38, at 13-17 (suggesting different ways the flexibilities within TRIPS could be exploited); COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 22, 126 (commenting on the flexibilities available within TRIPS); Smith, Correa, & Oh, *supra* note 40, at 690 (suggesting measures within the flexibilities of TRIPS that could be adopted and implemented by developing countries).

tics that are tantamount to market partitioning and patent abuses and face little if any challenges from weak and poor governments.<sup>120</sup> Burdensome patent abuse procedures under TRIPS are likely to create incentives for global pharmaceutical and agro-business MNEs to register patents in foreign countries for the sole purpose of blocking third-party imports.<sup>121</sup> The burdens of patent abuse procedures ensure that only rich countries with the requisite financial, administrative and technical capacity can effectively employ these procedures.<sup>122</sup> Moreover, global food and supermarket MNEs enjoy a liberalized investment regime under which they can freely establish marketing subsidiaries in developing countries.<sup>123</sup> MNEs and their affiliates also enjoy and exploit significant

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<sup>120</sup> Market partitioning patent abuse can take different forms. Prominent among them is the practice of registering patents without the intention of working them or insufficient working but with the purpose of controlling the markets for imports of patented products. See Pedro Roffee, *Abuse of Patent Monopoly: A Legal Appraisal*, 2 WORLD DEV. 15, 17 (1974) (discussing solutions – now arguably outlawed by TRIPS – adopted by several developed and developing countries to the problem of this form of patent abuse which was significant in developing countries where 90-95% of the patents were almost totally unexploited). Commentators on TRIPS have pointed out the risk of patent abuse under TRIPS. Correa, *Pro-competitive Measures Under TRIPS*, *supra* note 38, at 2 (explaining that the right to control imports of products covered by a product or process patent may be exercised to partition markets); *Id.* at 344 (discussing the burden of proof for allegation of process patent infringement under Article 34(1) where judicial authorities are given power to reverse the normal burdens of proof and order the defendant to prove the process to obtain an identical product is non-infringing); GERVAIS, *supra* note 50, at 407-09.

<sup>121</sup> GERVAIS, *supra* note 50, at 407-09; DE CARVALHO, *supra* note 36, at 531-55 (explaining the history and justifications for Article 34 reversal of burden of proof which is found in the domestic legislation of some WTO member states).

<sup>122</sup> The patent abuse solutions in the TRIPS Agreement are arguably found in: Article 30, which allows exceptions to patents by member states; Article 31, which provides for compulsory licensing under numerous conditions; Article 32, which allows patent revocation subject to judicial review; and Article 40, which addresses monopolistic practices. See TRIPS Agreement, *supra* note 12, arts. 31-32, 40. For commentary on these provisions, see GERVAIS, *supra* note 50, at 384-402 (discussion and commentary on the patent abuse provisions in TRIPS); Beier & Schriker, *supra* note 20, at 208-10 (discussing the procedures and burden of proof by states for patent abuse responses).

<sup>123</sup> There is a growing body of literature on what is described as the supermarket revolution in developing and transition countries. See Thomas Reardon, C. Peter Timmer, Christopher B. Barret & Julio Berdegué, *The Rise of Supermarkets in Africa, Asia, and Latin America*, 85 AMERICAN J. AGRIC. ECON. 1140, 1141 (2003) (explaining the supply side determinants of the growth of supermarkets in Africa, Asia and Latin America as driven by the spread of established super markets in the U.S. and Europe which through foreign direct investment (generally through foreign owned subsidiaries) are taking advantage of partial liberalization of retail trade in those regions, higher rates of return than at home and in response to competitive pressures in their domestic markets); Caryn Abrahams, *Transforming the Regional*

information asymmetry of their products' health risks, marketing their products to unsuspecting consumers in developing countries without providing adequate warning.<sup>124</sup> In doing so, they magnify public health and food risks and impose on developing countries a regulatory burden which cannot easily be borne.

#### D. Summary

In summary, TRIPS seems to impede the achievement of the WTO's free trade goals. The ideals of trade and investment liberalization are much more easily attainable if governments retain the greatest possible public health policy options for economic development. Easy access to and control over the production and marketing of pharmaceutical products and medical treatments would ensure that states could address their population's health and food needs. This is not just a matter of economics, but also a matter of ensuring enjoyment of human rights. Unfortunately what the WTO seems to give with one hand it takes away with the other under TRIPS.

### III. THE TRIPS RESPONSE

The WHO Commission on Public Health confronted TRIPS' response to developing countries' public health needs with what it described as a paradox or "fundamental dilemma."<sup>125</sup> The world now has at its disposal incredible human technological capabilities that could be used to con-

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*Supermarkets and the Local Food Economy*, 109 AFRICAN AFFAIRS 115, 119-121 (2009) (arguing that although the narrative of the determinants of the supermarket revolution are complex, the liberalization of investment regimes, particularly in retail trade, played a major role in that revolution); Bart Minten, *The Retail Revolution in Poor Countries: Is it Coming or is it Over?*, 56 ECON. DEV. & CULT. CHANGE 767, 768, 770 (2008) (presenting a case study of Madagascar that showed quality and price differences between supermarket and traditional food products and the competitive disadvantage faced by domestic firms); Mart Minten & Thomas Reardon, *Food Prices, Quality, and Quality's Pricing in Supermarkets Versus Traditional Markets in Developing Countries*, 30 REV. AGRIC. ECON. 480, 481-482, 488 (2008) (presenting price differences in processed food versus fresh food that made processed food cheaper to obtain for poor consumers); Michael T. Weber, John M. Staatz, John S. Holtzman, Eric W. Crawford & Richard H. Bernsten, *Informing Food Security Decisions in Arica: Empirical Analysis and Policy Dialogue*, 70 AMER. J. AGRIC. ECON. 1044 (questioning studies on food and arguing that tackling food security issues in Africa cannot be achieved through planning without facts but must rather be achieved by putting good intentions into long term programs addressing supply and demand through R&D rewards systems and graduate programs).

<sup>124</sup> The studies' evidence of the effects of globalization on consumer health in developing countries does not indicate that the consumers clearly understand or appreciate the health risks associated with the change in their consumption patterns. *Pharm Exec Industry Audit*, PHARMACEUTICAL EXECUTIVE, September 2008.

<sup>125</sup> COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 1.

front human misery and the disease burden of developing countries. Yet that capacity is not being fully utilized.<sup>126</sup> The world's technological advances are locked up in the hands of a few private interests and monopoly, rent-seeking global oligopolies who have little or no desire to tackle the health needs of the poor and vulnerable. The intellectual property regime mandated by TRIPS substantially reinforces the profit motive within an oligopolistic market structure and denies any effective state response in the public interest.<sup>127</sup> Profit is not a dirty word nor is its pursuit undesirable. Rather, the problem is the global community's failure to separate clearly the State's public and political responsibilities from the goals of private interests to seek profits in the private market system.

The central theme in the explanation of this mismatch of capabilities and their use is the incentive theory of innovation.<sup>128</sup> It appears that the framers of TRIPS traced the reasons for the mismatch not to monopoly rents (the concentration of rights in a few private enterprises or the absence of lucrative markets) but rather to the non-existent or weak intellectual property protection in developing countries.<sup>129</sup> To them, guaranteeing minimum intellectual property rights protection in WTO member states would serve as a catalyst for innovation, the transfer of technology and the development of pharmaceutical products.<sup>130</sup> As will be explained below, the link between intellectual property protection and innovation, however appealing on its face, is spurious as a general theory. Precisely because of the *ex facie* appealing nature of the link between intellectual property protection and innovation, it has been suggested that TRIPS tried to strike a balance between the incentive to innovate and access to technology and products.<sup>131</sup> However, such a balance has hardly been achieved.

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<sup>126</sup> *Id.*

<sup>127</sup> See *infra* notes 222-233 and text discussing the limitations on the use of the public policy exception under TRIPS.

<sup>128</sup> See, e.g., Richard Gilbert & Carl Shapiro, *Optimal Patent Length and Breadth*, 21 RAND J. OF ECON. 106 (1990) (discussing the function of incentives in innovation and patent protection).

<sup>129</sup> Gadbow & Gwynn, *supra* note 8. The inadequacy of existing intellectual property regimes prior to TRIPS was blamed for product counterfeiting and the pirating of technology. See Gervais, *supra* note 50, at 8-12.

<sup>130</sup> WHO/WTO STUDY, *supra* note 21, at 12 (claiming that TRIPS sought a balance between incentives and access to future inventions, new drugs and affordable access to existing drugs). Article 7 of the TRIPS Agreement captured this balance by setting as one of its objectives the achievement of a balance between rights and obligations to ensure the transfer and diffusion of technological innovation. See TRIPS Agreement, *supra* note 12, art. 7. See also COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 83.

<sup>131</sup> *Id.*

If the assumption behind the balance was that intellectual property protection would encourage inventive activities in the health needs of developing countries, that has proved to be based on false hope.<sup>132</sup> Years after the implementation of TRIPS, the hoped-for benefits in developing countries are yet to be realized even as the system is placing tremendous burdens on them.<sup>133</sup> Theoretical and incipient empirical studies have suggested that TRIPS will have a significant negative impact on the price of pharmaceutical products and substantial welfare loss in developing countries.<sup>134</sup> A recent empirical study of the impact of TRIPS, after its implementation, on drug prices and economic welfare in India concluded that the adverse consequences of TRIPS on developing countries would be significant. In the case of India, the study found that not only would price increases range between 100% and 400%, but also that the welfare loss would be more significant than estimated by earlier studies.<sup>135</sup> Indeed, the experience of India prior to TRIPS has attracted significant attention for critiques concerned with the negative impact of TRIPS on the availability of affordable drugs in developing countries under the current WTO system.<sup>136</sup> The history of India's patent regime and its impact on the

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<sup>132</sup> *Id.* at 66 (explaining that several years after TRIPS there has been no acceleration in the products reaching patients as anticipated in 1995).

<sup>133</sup> *Id.* at 22, 83 (explaining that diseases that affect the poor are irrelevant to patents and that developing countries with little technological and innovative capacity are bearing the cost of implementing TRIPS).

<sup>134</sup> See, e.g., Alan V. Deardorff, *Welfare Effects of Global Patent Protection*, 59 *ECONOMICA* 35 (1992); Judith C. Chin & Gene M. Grossman, *Intellectual Property Rights and North-South Trade*, in *THE POLITICAL ECONOMY OF INTERNATIONAL TRADE: ESSAYS IN HONOR OF ROBERT E. BALDWIN* 90 (Ronald W. Jones & Anne O. Krueger eds., 1990); Ishac Diwan & Dani Rodrik, *Patents, Appropriate Technology, and North-South Trade*, 30 *J. OF INT'L ECON.* 27 (1991); Gene M. Grossman & Edwin L. C. Lai, *International Protection of Intellectual Property*, 94 *AM. ECON. REV.* 1635 (2004); Elhanan Helpman, *Innovation, Imitation, and Intellectual Property Rights*, 61 *ECONOMICA* 1247 (1993); Jean O. Lanjouw & Iain M. Cockburn, *New Pills for Poor People? An Empirical Evidence after GATT*, 29 *WORLD DEV.* 265 (2001).

<sup>135</sup> Shubham Chaudhuri, Pinelopi K. Goldberg & Panie Jia, *Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India*, 96 *THE AM. ECON. REV.* 1477, 1481, 1507 (2006); Veena Mishra, *TRIPS, Product Patents and Pharmaceutical*, 36 *ECON. & POL. WEEKLY*, (December 1-7) 2001, 4464 (arguing that for global diseases, product patents will imply higher prices for new drugs in developing countries).

<sup>136</sup> The literature on the implications of TRIPS on India is significant. The following is a small sample. SUPID CHAUDHURI, *THE WTO AND INDIA'S PHARMACEUTICAL INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES* (2005) [hereinafter CHAUDHURI, *THE WTO AND INDIA'S PHARMACEUTICAL INDUSTRY*] (discussing the history of the Indian pharmaceutical industry before the Second World War, including policies fostering innovation, local investment, production, price controls, monitoring of quality and training of scientists); Pradeep Agrawal & P. Saiba, *TRIPS and India's Pharmaceutical Industry*,

pharmaceutical industry is illustrative of the concern. In 1970, India amended its colonial Patents and Trademarks Act of 1911 by eliminating product patents and providing only process patents for drugs.<sup>137</sup> This change in the pharmaceutical patent regime, supported by other policies, spurred a startling growth of an active generic drugs industry.<sup>138</sup> The result was the production of significant quantities of off-patent drugs for domestic consumption and exports.<sup>139</sup> With full implementation of TRIPS by India in 2005, process and product patents are now protected;

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39 ECON. & POL. WEEKLY (September 29-October 5) 2001 (suggesting that the Indian pharmaceutical industry will undergo significant changes after 2005); N. Lalitha, *Indian Pharmaceutical Industry in WTO Regime: A SWOT Analysis*, 37 ECON. & POL. WEEKLY (August 24-30) 2002, 3542 (discussing the historical evolution of the pharmaceutical industry from the colonial era to the adoption of TRIPS and its aftermath); Shyama V. Ramani & Augustin Maria, *TRIPS: Its Possible Impact on Biotech Segment of Indian Pharmaceutical Industry*, 40 ECON. & POL. WEEKLY (February 12-18) 2005, 681 (concluding that it is too early to judge the likely impact of TRIPS on the pharmaceutical industry in India after reviewing the history of the Indian patent regime and the narrowing and broadening effects on TRIPS on intellectual property regimes); Sugata Marjit, *Trade Related Intellectual Property Rights and GATT, A Theoretical Foundation* 29 Economic and Political Weekly, 3327 (December 31-January 6) 1994-95, 3327 (arguing uniform long duration patents for all products in all countries cannot be justified and that they eliminate consumers from poor countries); Rakesh Basant, *Intellectual Property Rights Regime: Comparison of Pharma Prices in India and Pakistan*, 39 ECON. & POL. WEEKLY (September 29-October 5) 2007, 3975 (explaining the differences in pharmaceutical prices between Pakistan and India not to be found in differences in the patent regimes (product/process patents) but in the policies of India designed to curb monopolies, reduce market concentration, encourage the development of a generic drug industry, market size and other factors).

<sup>137</sup> See, CHAUDHURI, *supra* note 136; Brian Wright, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries*, by Sudip Chauduri; Book Review, 57 ECON. DEV. & CULT. CHANGE 604, 605 (2009) (explaining that under the Patents and Designs Act of 1911 process and products patents were protected for sixteen years with an additional ten years for new products from the described production process and how the 1970 Act abolished product patents).

<sup>138</sup> Lalitha, *supra* note 136, at 3542-43 (describing the evolution of the pharmaceutical industry in India, the changes in the patent regime, the start of the pharmaceutical industry and the institution of other policies including the Monopolies and Restrictive Trade Practices Act, which facilitated growth the passage of the 1970 Act); Basant, *supra* note 136.

<sup>139</sup> Lalitha, *supra* note 136, at 3543 (providing data on the value of bulk drugs and formulations in India from 1950 to 2001 indicating an increase from two bulk drugs in 1950 to 113 in 1975-76 and estimated to be 4,344 in 2000-01); *id.* at 3545-46 (explaining the positive impact of the drug production on the balance of trade and the share of pharmaceuticals in India's export trade); Agrawal & Saibaba, *supra* note 136, at 3787 (explaining the drop in market concentration by U.S., U.K. and German pharmaceutical multinationals from 85% prior to 1970 to 40% by 1999).

the production of generic drugs under the old regime is now illegal, and so are exports of such drugs. Although price controls remain an option for making drugs affordable, studies have demonstrated such regulatory regimes would have a significant negative impact on new drug launches not only in India but also in other developing countries.<sup>140</sup> As demonstrated in the financial flows above, there is little, if any, health R&D or product development in developing countries. Neither has access to health related technology and pharmaceutical products been realized. Instead the markets in developing countries have been effectively closed by monopoly rent seeking patent holders for certain products and services. Compelled to provide patent protections, developing countries suffer from a WTO-induced market capture with little corresponding benefit. It is hardly surprising that the WHO Commission on Public Health questioned the validity of the incentive theory as universally applicable in developing countries.<sup>141</sup>

Any doubts about the incentive theory's weakness as applied to developing countries can best be addressed by examining research and development activities in the pharmaceutical industry worldwide. The global pharmaceutical industry exhibits characteristic oligopolistic market structures. It is highly concentrated and polarized by region and product.<sup>142</sup> Industry estimates for 2006 found that pharmaceuticals alone account for about 55% of health related trade.<sup>143</sup> The industry is highly concentrated in the TRIAD, which accounted for about 75% of the market share. According to Margaret Kyle, the U.S. is the largest market, with \$97 bil-

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<sup>140</sup> Among the options for addressing the affordability of drugs under the WTO/TRIPS regime are price controls and compulsory licensing. Neither of these seems to be a viable option for many countries. In a fascinating study of sixty-eight countries between 1982 and 2002, Jean O. Lanjouw explored the impact of different levels of patent protection and duration as well as price controls on market entry by pharmaceutical enterprises. See, Jean O. Lanjouw, *Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry*, CENTER FOR GLOBAL DEVELOPMENT, Working Paper Number 61, June 2005 at 17-18 (explaining econometric findings that in the case of LMICs, going from a regime of short to long process patents significantly encourages the introduction of new drugs but price controls, whether moderate or extensive, significantly lower the probability of new pharmaceutical products reaching those countries).

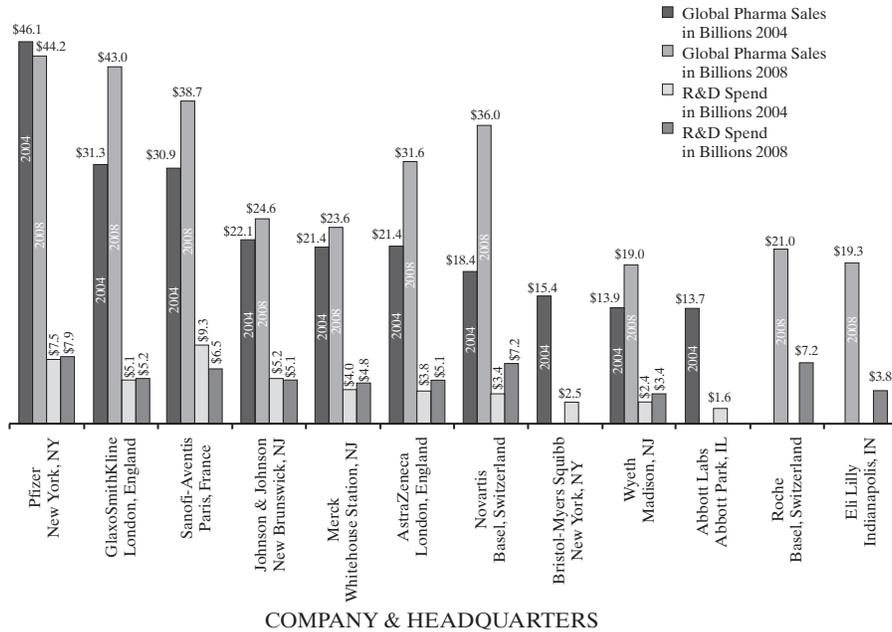
<sup>141</sup> COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 20 (explaining that the necessary conditions for the incentive theory to work, such as mature industries, capital and inventive capacity, are generally absent in many developing countries); Ramani & Maria, *supra* note 136, at 681 (suggesting that given its patentability criteria TRIPS is likely to have a negligible incentive effect on Indian biopharmaceutical firms).

<sup>142</sup> Margaret K. Kyle, *The Role of Firm Characteristics in Pharmaceutical Product Launches*, 37 RAND J. OF ECON. 602, 604 (2006).

<sup>143</sup> *Id.*

lion, followed by five of the largest European markets, with \$51 billion.<sup>144</sup> The geographic distribution is best captured by Table 4 below which describes the country of origin, global sales and R&D expenditures of the top ten pharmaceutical MNEs.

TABLE 4  
TOP 10 PHARMACEUTICAL COMPANIES, 2004 & 2008



It is apparent from Table 4 that the U.S. has the highest concentration of the top ten pharmaceutical companies, accounting for seven of them. According to estimates by Smith, Correa and Oh, the top ten pharmaceutical MNEs account for about 50% of the global market, with North America, Europe, Japan and Latin America counting for about 85% of sales.<sup>145</sup> As is apparent from Table 4, although global sales are measured in the tens of billions of U.S. dollars, only small fractions of MNE resources are devoted to R&D.<sup>146</sup> However, not apparent in this picture

<sup>144</sup> *Id.*

<sup>145</sup> Smith, Correa & Oh, *supra* note 40, at 685.

<sup>146</sup> See Patrice Trouiler, Piero Olliaro, Els Torreele, James Orbinski, Richard Laing & Nathan Ford, *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 THE LANCET 2190, 2190-91 (2002) (reporting that in a survey of the world's top twenty pharmaceutical companies on their research activities for malaria, tuberculosis, African trypanosomiasis, Chags' disease and leishmaniasis, eleven companies responded and seven reported spending less than 1% of their R&D budget in the previous year on any of the five disease; moreover in

is the results of R&D efforts and research in diseases of poverty.<sup>147</sup> Although global health R&D increased in the 1990s, there was nevertheless a fall in innovative productivity and the number of new drugs introduced.<sup>148</sup> Moreover, very little R&D activities were carried out in developing countries or devoted to their health needs. Considering the persistent devastation caused by malaria in developing countries, one would have expected it to be an important issue in the research agenda of MNEs and the global community. Unfortunately, that is not the case. While funds devoted to global health research stood at about \$70 billion in 1998, only \$100 million was directed toward malaria research.<sup>149</sup> Indeed, the WHO Commission for Public Health reported that only three of the top ten pharmaceutical MNEs (GlaxoSmithKline, AstraZaneca and Novatis) were involved in any R&D for diseases of poverty.<sup>150</sup>

This discussion makes apparent the central role of markets and profits in the research agenda of pharmaceutical MNEs. The lack of interest in diseases of poverty is hardly surprising. According to Ken Silverstein, between 1975 and 1999 there were 1,223 new drugs marketed.<sup>151</sup> Of this number, only thirteen were for diseases of poverty.<sup>152</sup> Even more startling is the finding that most of these drugs were not the result of deliberate R&D directed toward diseases in developing countries, but rather a by-product of some other activity.<sup>153</sup> The pure capitalist mindset of global managers of pharmaceutical MNEs could not justify allocating R&D expenditures to activities with a substantial philanthropic element. Thus, no pious and weighty declaration of objectives by TRIPS can spur private R&D activities with no or low potential profitability margins. Without mandates on the direction of R&D and the sharing of innovation, TRIPS cannot deliver to developing countries the objectives articu-

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1998, more than 90% of the worldwide pharmaceutical value and 97% of R&D activities occurred in developed country).

<sup>147</sup> COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 83.

<sup>148</sup> *Id.* at 66.

<sup>149</sup> Remigius N. Nwabueze, *What Can Genomics and Health Biotechnology Do for Developing Countries?*, 15 ALB. L.J. SCI. & TECH. 369, 387 (2005).

<sup>150</sup> COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 70.

<sup>151</sup> Ken Silverstein, *Millions for Viagra*, THE NATION, July 19, 1999, at 13; Bernard Pécoul et al., *Access to Essential Drugs in Poor Countries: A Lost Battle?*, 281 J. AM. MED. ASS'N 361, 364 (1999).

<sup>152</sup> Silverstein, *supra* note 151, at 13. This pattern was confirmed in another study few years later. See Trouiler, *supra* note 146, at 2188-89 (reporting that between 1975 and 1999, 1,393 new chemical entities were granted a market authorization with a quantitative distribution in different therapeutic areas favoring high income countries and with about 68.7% (959 out of 1393) of those agents having little or no therapeutic value).

<sup>153</sup> Nwabueze, *supra* note 149, at 388 (explaining that only four drugs came out of new R&D, nine were improvements on old drugs and seven came from military and veterinary research).

lated in Article 7. The benevolence of profit-seeking MNEs cannot be the basis upon which the global community can address the human right to health.

The pattern of R&D resource allocation discussed above is merely indicative of the characteristic mindset and distinctive behavior of global pharmaceutical MNEs. That mindset involves the selective exploitation of the world's economic geography for the highest return on investments.<sup>154</sup> Such conduct is consistent with prevalent corporate strategic directives that call for focusing on high per capita income markets. This is best illustrated in Table 5 below which describes the top ten selling pharmaceutical drugs in the world in 2005 and 2008.<sup>155</sup>

A few observations ought to be made from Table 5. The top ten drugs are manufactured by leading pharmaceutical MNEs.<sup>156</sup> Not captured in this table is a similar concentration in therapeutic classes of drugs aimed at the needs of developed countries.<sup>157</sup> The top therapeutic drugs marketed in the U.S. included anti-psychotics, lipid regulators, proton pump

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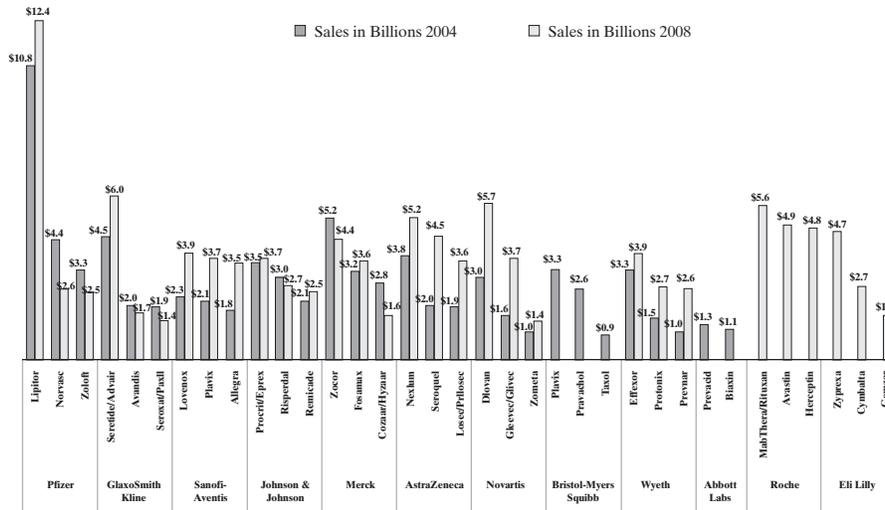
<sup>154</sup> Michael Kremer provides the following highly instructive picture of the global geographic distribution of the pharmaceutical industry in 1998: U.S 39.6%, Europe, 26.1% and Japan, 15.4% (total TRIAD distribution: 81.1%); Latin America, 7.5%, South East Asia and China, 7%; Africa, 1%; Middle East, 0.9%. Michael Kremer, *Pharmaceuticals and Developing Countries*, 16 J. ECON. PERSPECTIVES 67, 70 (2002) (stressing that the market for pharmaceuticals in developing countries is tiny; the state of Connecticut spends more on health than the 38 low-income countries in sub-Saharan Africa (\$4,000 per person out of a per capita income of \$32,000 as opposed to \$18 per person out of an average of \$300 per capita income in the low income countries)). To the extent that patent registration for tropical diseases or diseases of poverty are any indications of profit potential the picture is not encouraging. See, Jean O. Lanjouw & Margaret MacLeod, *Pharmaceutical R&D for Low-Income Countries and Participation by Indian Firms*, 39 ECON. & POL. WEEKLY 4232, 4239-40, 4242 (September 24-30, 2005) (presenting statistics of worldwide patenting of therapeutics of tropical diseases in the U.S and trends in patenting in India and concluding that the number of patents for tropical diseases dealing with all cases is very small, as is the innovative activity relating to diseases of poor countries).

<sup>155</sup> Nicole Gray, *Untying the Gordian Knot*, PHARMACEUTICAL EXECUTIVE at 83, May 2005; *The Pharm Exec 50*, PHARMACEUTICAL EXECUTIVE at 68, May 2009.

<sup>156</sup> *Id.*

<sup>157</sup> In May 2009, Pharmaceutical Executive listed an estimate of the top therapeutic classes of drugs by U.S. sales as follows: Anti-psychotics – \$14.6 billion, Lipid Regulators (Statins Plus) – 14.5 billion, Proton pump inhibitors – \$13.9 billion, Seizure disorder medications – \$11.3 billion, Anti-depressants – \$9.6 billion, Angiotensin II antagonists – \$7.5 billion, Antineo monoclonal antibodies – \$7.5 billion, Erythropoietins – \$7.2 billion, Anti-arthritis – \$6.0 billion and Anti-platelets (oral) – \$5.3 billion. *The Pharm. Exec. 50: We Leap Tall Buildings to Bring You the Definitive Guide to the World's Top Pharma Companies*, PHARMACEUTICAL EXECUTIVE, May 2009, at 74, available at <http://pharmexec.findpharma.com/pharmexec/data/articlestandard/pharmexec/352009/621548/article.pdf>.

TABLE 5  
TOP SELLING DRUGS, 2004 & 2008



inhibitors, seizure disorder medication and anti-depressants.<sup>158</sup> The best selling drugs in Table 5 are high-value drugs aimed at diseases in developed countries. They provide treatment for Type I diseases, including disorders involving the nervous system and lifestyle diseases. None of these drugs are aimed at diseases prevalent in developing countries. This pattern should be expected given the disequilibrium in health research expenditures discussed above and the profit motive of MNEs. Low-value generic drugs are of little interest, and TRIPS does not offer an easy path for off-patent generic manufacturers.

Prior to its implementation of TRIPS in 2005, India was one of the leading generic drug producers in the world.<sup>159</sup> After TRIPS, the Indian producers no longer have the freedom to use their capacity to reverse

<sup>158</sup> See WIPO, *Patent Families by Country of Origin (1990-2007): Aggregate Data* (Jan. 2011), available at [http://www.wipo.int/export/sites/www/ipstats/en/statistics/patents/xls/182\\_patent\\_family\\_by\\_top\\_origin\\_by\\_year.xls](http://www.wipo.int/export/sites/www/ipstats/en/statistics/patents/xls/182_patent_family_by_top_origin_by_year.xls). This list clearly illustrates the divide between patents held by developed countries in comparison with those held by developing countries. *Id.* In 1990, OECD countries held 455,204 patents compared with 9,664 for developing countries. In 2006 the gap widened: OECD – 609,863 patents, developing countries – 119,686 patents. *Id.* A WIPO Reports of patent applications by field, including medical technology, food and agriculture and biotechnology, confirmed the concentration in developed countries. See WIPO, *Patent Applications by Field of Technology (2003-2007 average): By Leading Countries* (Jan. 2011), available at [http://www.wipo.int/export/sites/www/ipstats/en/statistics/patents/xls/184\\_total\\_application\\_technology\\_top\\_origin.xls](http://www.wipo.int/export/sites/www/ipstats/en/statistics/patents/xls/184_total_application_technology_top_origin.xls).

<sup>159</sup> CHAUDHURI, *supra* note 136; Lalitha, *supra* note 136, at 3543.

engineer and manufacture off-patent generics.<sup>160</sup> In fact, TRIPS has imposed two related restrictions on the supply of generics by countries with the capacity to produce them. First, the substantive rights mandated under Article 28 of TRIPS pose a legal impediment. TRIPS PLUS agreements present similar legal impediments, as they extend the life of patents, expand the duration and scope of patent rights to include exclusivity of test data, limit patent revocation in the public interest or directly limit the introduction of off-patent products.<sup>161</sup> Take, for example, the common provisions found in the U.S. TRIPS PLUS agreements, which include test data exclusivity and patent term expansion to compensate for patent issuance and marketing delays.<sup>162</sup> These and other terms in U.S. TRIPS PLUS agreements are the product of “bilateral unilateralism” inherent in the geopolitical, economic and legal disparities in negotiations between the powerful and the weak.<sup>163</sup> Bilateral unilateralism permits

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<sup>160</sup> India had until 2005 to implement the TRIPS Agreement. For a discussion of the implementation, see Lanjouw and MacLeod, *supra* note 154, at 4242 (reporting that company executives in India in the mid-1990s stated their research discoveries would be for global diseases and on products for the global markets; in 2002-2004, although there was an overall surge in pharmaceutical R&D, India’s research had become less targeted at the needs of developing countries).

<sup>161</sup> TRIPS-PLUS extends the obligations of states and limits rights in ten crucial areas:

- (i) [P]rotection for test data exclusivity; (ii) linkages between drug registration and patents; (iii) patent term compensation for granting delay; (iv) patent term compensation for delay of marketing approval; (v) strengthening intellectual property law enforcement; (vi) compulsory licensing restrictions to national emergency for public non-commercial use; (vii) parallel import limitations through contracts with the patent holders; (viii) prohibition of the revocation of patent on public interest grounds; (ix) patentability of new uses of products; and (x) patentability of animals and plants (natural sources of medicines).

Chutima Alkalephan, et al., *Extension of Market Exclusivity and Its Impact on the Accessibility to Essential Medicines, and Drug Expense in Thailand: Analysis of the Effect of TRIPS-Plus Proposal*, 91 HEALTH POL’Y 174, 175 (2009).

<sup>162</sup> *Id.*

<sup>163</sup> Yelapaala, *supra* note 83, at 249. The negotiating power imbalance between developed and developing countries is a recognized phenomenon that leads to unequal exchange of ideas and has attracted commentary. The term bilateral-unilateralism best captures that power asymmetry in bilateral trade relations. See generally Jagdish Bhagwati, *Departures from Multilateralism: Regionalism and Aggressive Unilateralism*, 100 ECON. J. 1304 1313-14 (1990) (explaining how section 301 of the U.S. Trade Act can be used as a powerful tool to extract better trade terms from a country by reducing that country’s trade restrictions); Colin Soneman & Carol Thompson, *Trading Partners or Trading Deals? The EU & US in Southern Africa*, 112 REV. AFRICAN POL. ECON. 227, 239-40 (2007) (explaining how in bilateral negotiations between the E.U. and developing countries the E.U. is entirely in control and how the E.U. imposes its intellectual property regime on developing countries through free trade agreements); Kenneth C. Shadlen, *Exchanging Development for Market Access? Deep Integration and Industrial Policy Under Multilateral and*

powerful states such as the U.S. to limit the opportunities for off-patent generics production.<sup>164</sup> The opportunities for controlling production and flow of generics extend to global pharmaceutical MNEs. Through the strategic use of mergers and acquisitions, pharmaceutical MNEs have been actively engaged in taking over successful generic drugs manufacturers in developed and developing countries to control or redirect the production and marketing of generics to more profitable affluent markets.<sup>165</sup> The acquisition of the largest Indian generic manufacturer, Ranbaxy, by Daiichi-Sankyo, the second largest Japanese pharmaceutical MNE, cer-

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*Regional-Bilateral Trade Agreements*, 12 REV. INT'L POL. ECON 750, 767 (2005) (explaining how developing countries that enter into bilateral trade agreements with the U.S. typically accept obligations in the area of intellectual property rights that go far beyond WTO requirements); Maria Fabiana Jorge, *TRIPS-PLUS Provisions in Trade Agreements and their Potential Adverse Effects on Public Health*, 1 J. GENERIC MEDICINES 199, 202-05 (2004) (examining the cost of implementing TRIPS in U.S. TRIPS PLUS agreements expanding patent rights and restricting governments in policy and legal regime choices).

<sup>164</sup> Alkalephan et al, *supra* note 161; Jorge, *supra* note 163.

<sup>165</sup> Following the example of leading generic drugs manufacturers such as Teva and Sandoz, who grew large through mergers and acquisitions, several generic drugs manufacturers employed mergers and acquisitions as a strategic move to respond to market forces, changing health policies favoring generic drugs and the coming patent expirations of popular blockbuster brand name drugs. See Tommy Erdei, *M&A Strategy within the Generic Pharmaceuticals Sector: Vertical Integration into Active Pharmaceutical Ingredients*, 2 J. GENERIC MED. 18 (2004) (arguing that following the example of leading generic drugs manufacturers, many generic drugs manufacturers, including those from India, entered European markets through mergers and acquisitions); Vijay Karwal, *The Changing Competitive Landscape in the Global Generics Market: Threat or Opportunity?*, 3 J. GENERIC MED. 269, 270-71 (2006) (arguing that one of the driving forces behind mergers and acquisitions in the generic drugs industry is the expiration of patents of several drugs and cost cutting policies of the U.S. government which encourage entry into the U.S. markets by Indian generic drug manufacturers); *Mergers & Acquisitions Update: Changing the Strategic Paradigm in the Global Generics Market*, 6 J. GENERIC MED. 315, 316 (2009) (arguing that between 2000 and 2008 the number of mergers in the generic drugs transactions closed for enhancing competitive position in the market increased from 4 to 16 with a total value of about \$80 billion); James Mittra, *The Socio-Political Economy of Pharmaceutical Mergers: a Case Study of Sanofi and Aventis*, 18 TECH. ANALYSIS & STRATEGIC MANAGEMENT 473 (2006) (arguing that mergers and acquisitions in the pharmaceutical industry are not always controlled by business, economic and financial calculations but sometimes the calculations of other stakeholders such as governments); S. K. Jayaraman, *Indian Generics Companies Go on Spending Spree*, 4 NATURE 616 (2005), available at [www.nature.com/reviews/drugsdisc](http://www.nature.com/reviews/drugsdisc) (discussing how Indian generic pharmaceuticals, large, medium and small, are engaged in mergers and acquisitions of foreign pharmaceutical enterprises for market expansion).

tainly provides the latter with several global strategic rent-seeking options in generic drugs and additional markets.<sup>166</sup>

A. *Implications of the Objectives and Principles of TRIPS*

Enamored with the free trade ideals enshrined in the WTO Agreements, the global community appears to be blind to certain inherent contradictions in the objectives, principles and structure of TRIPS. Objectives and principles are generally guiding posts beckoning to a better future with open arms. In the case of international agreements with complex structural and substantive objectives, such as the WTO and TRIPS, openness to the evolving needs of humanity is a *sine qua non*. For instance, objectives and principles formed part of the bedrock of the U.N. Charter. Captured in it are the aspirations for an ideal global community capable of restraining warfare, achieving political, social and economic progress, establishing free trade and ensuring human rights and self-determination. As noted by Lord Halifax of the United Kingdom, the U.N. Charter preferred to lay down purposes and principles that gave “freedom to accommodate their actions to circumstances which today no man can foresee.”<sup>167</sup> In his words, the hope was to create

[A]n organic body which will have within itself the seeds of a vigorous life, and so may grow into the great society of nations of which, throughout the centuries, men and women have dreamed and which, in our own time, please God, may bring healing and hope to a wounded world.<sup>168</sup>

Put simply, structural flexibility was an indispensable element of the Charter as a constitution or even as a treaty – it was not meant to be a static instrument. The success of objectives and principles in any agree-

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<sup>166</sup> Statement of Daiichi-Sankyo, Ranbaxy to Bring in Daiichi Sankyo as Major Partner Strategic Combination Creates Innovation and Generic Pharma Powerhouse (June 11, 2008) (company statement explaining why Daiichi-Sankyo acquired India’s largest pharmaceutical company and one of the top ten generic producers: complementary business, potential global reach to matured and emerging markets and cost competitiveness). *But see* The Ranbaxy-Daiichi Deal: Good Medicine, or a Harbinger of Future Ills?, INDIA KNOWLEDGE @ WHARTON, <http://knowledge.wharton.upenn.edu/india/article.cfm?articleid=4296>) (expressing surprise in India about the deal – prior to the acquisition, Ranbaxy had been active in acquiring other generic pharmaceuticals outside India such as Italian Allen SpA (a division of GlaxoSmithKline), Romanian Terapia, Belgian Ethimed, Spanish Mundogen (GlaxoSmithKline’s generic business) and South African Be-Tabs Pharma. The deal will give Ranbaxy easier access to the Japanese pharmaceutical market with much cheaper generics. COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 84-85 (reporting that Ranbaxy planned to increase its share of revenue in the developed world from 20% in 2000 to 70% in 2007).

<sup>167</sup> GOODRICH, HAMBRO, & SIMONS, *supra* note 9, at 24.

<sup>168</sup> *Id.*

ment such as the WTO and TRIPS based on the U.N. Charter is dictated by the degree of its structural and substantive flexibility. Notwithstanding claims of its built-in internal flexibilities, structural flexibility does not appear to be one of the hallmarks of TRIPS. Based on certain operating premises, Article 7 merely expresses the hope that protecting intellectual property rights would promote the creation and sharing of technological innovations.<sup>169</sup> On the other hand, as a principle, Article 8 preserves but limits sovereign public health and nutrition policy options to the provisions of TRIPS.<sup>170</sup> These declared objectives and principles of TRIPS have been undermined by its structural organizing scheme, which does not permit structural changes, but instead channels the dynamics and pathways of analysis into a maze of unfriendly substantive provisions.

First, one of the operating premises is the assignment of a transcendent value to markets and a regime of private ordering in a field substantially burdened by the public interest. The 2008 financial crisis in the U.S. has raised legitimate questions about putting unbridled faith in the self-regulating power of markets.<sup>171</sup> The responsibility of the state to achieve the ideals of the U.N. Charter and ensure the enjoyment of health as a human right is not easily discharged by relying on foreign profit making private entities in an unregulated market system. The private sector is not obliged to pursue the public good as its primary goal, but TRIPS seems to assume that private profit making entities will allocate R&D resources to the study of all diseases with significant public health implications, particularly in developing countries. Notwithstanding evidence of substantial public expenditures in health research by developed countries, market principles seem to dictate the structure and substance of TRIPS on this issue. Moreover, the explicit assumption in Article 7 that technological innovations would be shared as a result of TRIPS has

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<sup>169</sup> Article 7 of TRIPS states that the protection of “intellectual property rights *should contribute to the promotion of technological innovation and to the transfer and dissemination of technology . . .*” See TRIPS Agreement, *supra* note 12, at art. 7 (*emphasis added*).

<sup>170</sup> Article 8(1) of TRIPS authorizes member states in their implementation of TRIPS through laws and regulations to “adopt measures necessary to protect public health and nutrition, and to promote the public interest . . . *provided that such measures are consistent with the provisions of this Agreement.*” *Id.* at art 8(1) (*emphasis added*).

<sup>171</sup> Michael P. Malloy provides a lucid biographical analysis of the U.S. mortgage crises. See MICHAEL P. MALLOY, ANATOMY OF A MELTDOWN: A DUAL FINANCIAL BIOGRAPHY OF THE SUBPRIME MORTGAGE CRISIS 5-7 (2010) (arguing that the economic explanations for the financial crisis are not easily captured in the exuberances of the conventional rational choice theory but in behavioral economics of bounded rationality and hyper-optimism).

proved to be a distant, fading hope. The benefit sharing provisions of the Biodiversity Convention reinforces this conclusion.<sup>172</sup>

Second, TRIPS exhibits unfortunate blind spots and contradictions in its philosophical belief in the organizing and self-correcting powers of markets in matters such as sovereignty over health policy. Paradoxically, TRIPS relies substantially on private enterprises to address the health needs of developing countries through innovation, but fails to take into account the role of profitable markets in innovation.<sup>173</sup> The TRIPS incentive theory assumes a link between private intellectual property rights, protection and innovation. Yet, even within the framework of markets and private ordering, intellectual property protection is hardly a stimulant for creativity when there are no profitable markets for the products generated by innovation. The validity of incentive theory variants, such as the transaction function, disclosure and the signaling function, all seem to hinge on the profitability of innovations.<sup>174</sup> Poor developing countries with low purchasing power do not provide the type of markets that would spur R&D and innovation for diseases specific to them. Given the recognition of health as a human right and the significant role of health in economic development, the logical position of TRIPS should have been an unqualified, strong and unequivocal reservation of sovereign authority over health, nutrition and food security.

Finally, one of the leading justifications for the *forced* marriage between a globally enforceable intellectual property protection system

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<sup>172</sup> Article 15(7) of the Convention on Biological Diversity requires Contracting Parties to take legislative, administrative or policy measures “in accordance with Articles 16 and 19 and, where necessary, . . . Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources.” United Nations Convention on Biological Diversity, *supra* note 32, at art. 15(7). “Such sharing shall be on mutually agreed upon terms.” *Id.* Article 16 as whole continues to cover the benefits of sharing but appears more targeted at achieving conservation and sustainable use of biological resources. *Id.* at art. 16. These sharing provisions leave it to the parties to reach an agreement without a guarantee or mandate for one. It is a contractual arrangement which leaves the outcome to influences of bargaining power and information asymmetries.

<sup>173</sup> Baplab Dasgupta, *Patents Lies and Latent Dangers: A Study of the Political Economy of Patent in India*, 34 *ECON. & POL. WEEKLY* 979, 982 (1999) [hereinafter Dasgupta, *Patents Lies and Latent Dangers*] (discussing and questioning various justifications for TRIPS, including the incentive to invent).

<sup>174</sup> COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 19-21 (explaining the transaction function as a necessary condition for markets of certain specialized technologies, the disclosure function as allowing the disclosure of technology which would otherwise be kept as trade secrets and the signaling function as relating to the ability of patentees to raise capital because of their innovative capabilities).

and trade is the incentive theory of innovation.<sup>175</sup> TRIPS, similar to the intellectual property regimes of developed countries, starts from the premise that the protection of intellectual property rights would be a catalyst for innovation, particularly in the fields of health products and technology.<sup>176</sup> However, such a premise is of doubtful universal validity. The wide-ranging implications and impact of the incentive theory should have invited an explicit inquiry into the long and complex history of human ingenuity and creativity from the beginning of time. Certainly, the notion that protecting intellectual property rights would act as an incentive for creativity has a common sense appeal. Unfortunately, TRIPS sought to offer a universal system based on a monolithic orthodoxy hardly reflective of the wealth of plausible alternative choices humanity offered. As such, TRIPS does not exhibit the level of sensitivity to the rich human history of innovation, nor does it seem to acknowledge our growing and deeper understanding of the complexity of the human creative process.<sup>177</sup> TRIPS did not arrive in fifteenth century Venice or nineteenth century Europe when the global diffusion and accessibility of information was much more limited. In a world of shrinking gaps in information and ideas, structural and substantive flexibility in TRIPS should have been pursued. The significant limitations on sovereign authority over the nature, content and duration of intellectual property rights without regard to the impact of such rights on life and living deserves an inquiry into the incentive theory justifications advanced in TRIPS.

Creativity and inventiveness have been an important part of human evolution from the very beginning of the human species. In his insightful Pulitzer Prize winning book *GUNS, GERMS, AND STEEL*, Jared Diamond traced the nesting conditions for certain human inventiveness to the domestication of plants, seeds, animals and food production.<sup>178</sup> In his view, as human beings evolved beyond hunting and gathering to food production, conditions were created for specialization and innovation.<sup>179</sup> But even within this thesis, hunting and gathering and the domestication of seeds, plants and animals required innovation and creativity, all of which occurred without the catalyst of an intellectual property regime. More recent research in the neuroscience of creativity hardly suggests a

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<sup>175</sup> Dasgupta, *Patents Lies and Latent Dangers*, *supra* note 173, at 979-80.

<sup>176</sup> COMMISSION ON PUBLIC HEALTH, *supra* note 47, at 22-24.

<sup>177</sup> For a discussion of the history of human creativity, including the nature, scope and context of the creativity of the brain, see NANCY C. ANDREASEN, *THE CREATIVE BRAIN: THE SCIENCE OF GENIUS* 127-35 (2006) (discussing the raw gift of genius or creativity, the type of environment that fosters creativity and the plasticity of the human brain).

<sup>178</sup> JARED DIAMOND, *GUNS, GERMS, AND STEEL: THE FATES OF HUMAN SOCIETIES* 85-87 (1997).

<sup>179</sup> *Id.*

link between creativity and exclusive rights in ideas.<sup>180</sup> Moreover, any familiarity with the history of metallurgy, alchemy and other inventive activities in archaic societies should lead one to question the necessary link between protection of intellectual property rights and the incentive to innovate.<sup>181</sup> Time and space considerations do not permit the type of analysis this topic deserves. Suffice it to mention that the inventiveness and creativity of our ancient ancestors in Egypt, China, Persia, India, Central America, Greece, Rome and Benin, just to mention a few, achieved unparalleled levels of success without an intellectual property regime.<sup>182</sup> After the initial limited appearance of a patent system in Venice between 1474 and 1550,<sup>183</sup> the modern patent system did not begin to emerge again until the late 1880s – and even then not without a vigorous debate and social agitation.<sup>184</sup> When the general patent system appeared in Elizabethan England, it was not meant to create monopoly rights per se, but to break up the trading monopolies of the guilds in various essential fields of trade vital to the good of the commonwealth.<sup>185</sup> How then could the framers of TRIPS have missed this rich history that demonstrates the need to subjugate private interest for the common good? Or, being conscious of that history, perhaps they chose the wrong instrument as a remedy.

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<sup>180</sup> ANDREASEN, *supra* note 177, at 146.

<sup>181</sup> The history of alchemy across cultures and over time is shrouded with the spiritual relationship between artisan, the supernatural and nature, in which humans play a collaborative role in the work of nature to help nature produce at an ever increasing tempo to change its modalities. See MIRCEA ELIADE, *THE FORGE AND THE CRUCIBLE* 50-65 (Stephen Corpin trans., Harper Torchbooks 1962) (1956) (explaining that gold is the only legitimate child nature desires and the alchemist only accelerates that process as supported by the ancient Chinese text *Huai-nan tsu* from 122 B.C.; including the spiritual dimensions of metallurgy and alchemy from ancient China, Africa, Europe and other regions of the world).

<sup>182</sup> See Ade Abayemi, *The Yoruba and Edo-Speaking Peoples and their Neighbours Before 1600*, in *HISTORY OF WEST AFRICA* 197, 241-63 (J.F.A. Ajayi & Michael Crowder eds., 2nd ed. 1976) [hereinafter Ajayi & Crowder] (discussing the history of Benin City and the complexity of the situation in that era); DIAMOND, *supra* note 178, at 215 (alluding to this phenomenon in the discussion of the origins of writing).

<sup>183</sup> PENROSE, *supra* note 3, at 2.

<sup>184</sup> *Id.* at 7-16 (discussing the intense patent controversy in Europe principally between two opposing forces, those in favor of free trade and the industrialists, manufacturers and engineers pushing for better patent protection).

<sup>185</sup> *Id.* at 4-6 (arguing that under the Elizabethan patent system there were patents for daily necessities such as salt, oils, vinegar, starch and saltpeter, the new patent system had among other things larger social objectives, breaking the power of the guilds to regulate “mysteries” and the terms upon which they could be practiced, to allow innovators to practice their craft in contravention of guild regulations, unifying the nation under central authority and making the country economically independent).

#### IV. THE GENERAL OPERATING PREMISES OF TRIPS

Any analysis of the structural defects of TRIPS which conditioned its substantive response to the needs of human health security, must confront two equally troublesome fundamental questions. The first relates to whether under international law there is a fundamental right of sovereign states to trade. The second relates to the issue of whether an idea, however expressed, has a definite national and territorial origin. Both of these questions seem to have escaped the explicit examination of the framers of TRIPS. They are both examined below.

##### A. *The Fundamental Right of States to Trade Under International Law*

The question of whether under international law there is a fundamental right of states to trade is of great importance to international trade jurisprudence. In preparing for the inclusion of TRIPS in the GATT regime, the U.S. tactically avoided this question.<sup>186</sup> Nevertheless, the answer to this question should have been a prerequisite to, and should have informed the structure and substantive operating provisions of, TRIPS, particularly in matters relating to human health and food security. Assuming such a fundamental right, would the trade in products essential to life and living such as food, seeds, agricultural technology and pharmaceuticals fall into such a category? Would such a fundamental right share the characteristics of other fundamental rights enshrined in municipal constitutions and international conventions? Fundamental rights might be imbued with some elements of indelibility, or at least require heightened scrutiny for modifications. If so, under what circumstance might trade involving those fundamental rights be interfered? Claims that Article 30 of TRIPS offers an escape valve for WTO member states appear to be a feeble response to the requirements of such a fundamental right.<sup>187</sup> Under the Treaty of Rome, the right to trade is so firmly established that intellectual property rights are conditioned on the provision of free movement of goods and services.<sup>188</sup> The same cannot be said of TRIPS. Under TRIPS, the protection of intellectual property rights is

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<sup>186</sup> Gadbow & Gwynn, *supra* note 8, at 41-44 (explaining the conceptual basis for the inclusion of intellectual property protection in the GATT system as based on nullification and impairment and the distortion of trade effects of counterfeit products; these do not address the right to trade and the accepted use of tariffs to control trade).

<sup>187</sup> GERVAIS, *supra* note 50, at 379-83 (commenting on Article 30).

<sup>188</sup> Treaty Establishing the European Economic Community, March 25, 1957, 298 U.N.T.S. 11 [hereinafter Treaty of Rome], as amended by Single European Act, 1987 O.J. (L 169/1), in *Treaties Establishing the European Communities* (EC Off'l Pub. Off., 1987). Article 36 of the Treaty of Rome established an exception to Articles 30-34, which prohibited quantitative restrictions on the free movement of goods or measures having equivalent effects on the grounds of protecting industrial or commercial property. *Id.* at art. 36. A long line of European Court of Justice

firmly established. Article 30 is only a limited qualification of the protection to which the right to trade is subservient. Again, the issue of whether there is a fundamental right to trade is a major undertaking which time and space limitations cannot permit a full exploration of. For the purposes of this inquiry it is sufficient to mention that the right to health and food security engaged the attention of the Covenants of the League of Nations and the United Nations as evidenced in the establishment of the FAO and WHO. Moreover, human exchange in goods and services seems to be as old as organized society. Examples of this phenomenon include the famous trans-Saharan trade routes in West Africa, the East/West spice and silk trade, and the Polynesian *kula* popularized by the work of Malinowski.<sup>189</sup>

The rights and expectations of nations to engage in international trade triggered political conflict and serious diplomatic exchange and protests following the Papal Bulls of the fifteenth century, which granted exclusive trading rights to specific Christian nations of Europe such as Spain and Portugal.<sup>190</sup> To facilitate orderly trade through colonization, the partition

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jurisprudence has emerged from an interpretation of these provisions within the context of free movement principles.

<sup>189</sup> For a discussion of the problems faced by European countries in using the old trade routes to the Far East, see Bailey W. Diffie & GEORGE D. WINIUS, FOUNDATIONS OF THE PORTUGUESE EMPIRE, 1415-1580 195-209 (1977) (discussing the problems posed by Muslims to East-West trade and national determination to address the problem which affected not just Spain and Portugal but also Venice and other Italian city-states). See also F. AGBODEKA, THE RISE OF THE NATION STATE: A HISTORY OF WEST AFRICAN PEOPLES 1800-1964 5-6 (1965) (describing the trans-Saharan trade in gold); Nehemia Levtzion, *The Early States of the Western Sudan to 1500*, in Ajayi & Crowder, *supra* note 182, at 114-18 (explaining the fame of ancient Ghana reaching as far as Baghdad and the rise of the trans-Saharan trade with the introduction of the camel; the Arab conquest of the region and the arrival of Islam accelerating the trans-Saharan trade). For a description of the *kula*, see BRANISLAW MALINOWSKI, ARGONAUTS OF THE WESTERN PACIFIC: AN ACCOUNT OF NATIVE ENTERPRISE AND ADVENTURE IN THE ARCHIPELAGOES OF MELANESIAN NEW GUINEA 83 (1922). See also Kojo Yelapaala, *Legal Consciousness and Contractual Obligations*, 39 MCGEORGE L. REV. 193, 236-41 (2008) (discussing the nature of contractual obligations from the perspective of anthropology).

<sup>190</sup> The narrative of the role of Papal Bulls, which partitioned the world between Portugal and Spain and gave them exclusive trading rights to certain territories discovered or to be discovered, is a complex narrative and the subject of extensive literature. The major thrust was the desire of the monarchs of Portugal and Spain to monopolize trade in certain territories to the exclusion of other European powers. Dating back to the Papal Bull of June 18, 1452, *Dum Diversas*, Pope Nicolas V, credited with ushering in the West African Slave Trade, gave the King of Portugal the full and free permission to invade, search out and subjugate the Saracens and pagans and any other unbelievers and enemies of Christ wherever they may be. This was followed in 1455 by the Bull *Romanus Pontifex* of Nicholas V which expanded the earlier Bull and contained express language giving King Alfonso of Portugal exclusive

of Africa in the Berlin Conference of 1883-1884 followed centuries later.<sup>191</sup> The struggle among nations over the right to trade in goods and

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rights of possession, trade and fishing in Guinea and its shores and seas and prohibited other countries from doing so without the express permission of King Alfonso. Subsequent Papal Bulls, by Pope Calixtus III in 1456, *Inter Caetera*, confirmed the Bull *Romanus Pontifex*. In 1481 Pope Sixtus issued the Bull *Aeterni Regis* which not only sanctioned Portuguese claims to exclusive rights in Guinea (West Africa) but also brought pressure on Spain to respect the Treaty of Alcacovas and to promise to avoid trade and mission work in Guinea and Portuguese Atlantic possessions. By 1492 and the discovery of America by Columbus, issues of trade had become an important part of Papal Bulls. Pope Alexander VI, in 1493 in Bull *Inter Caetera* granted Spain exclusive trading rights in all of Spanish America on the pain of excommunication and strictly forbade any person to go to any Spanish possession, island or mainland for the purpose of trade. In the same Bull, Pope Alexander VI partitioned the world outside of Europe into two parts, one part for Spain and the other for Portugal. With this, the right to trade in foreign lands was divided between the two nations. For further discussion of the line of demarcation and the desire of Isabella of Spain to secure monopoly exploitation rights over Spanish discoveries, see Linden H. Vander, *Alexander VI and the Demarcation of the Maritime and Colonial Domains of Spain and Portugal 1493-1494*, 22 *AMER. HIST. REV.* 1, 13 (1916). For a discussion of Papal Bulls, see HENRY HARRISSE, *THE DISCOVERY OF NORTH AMERICA: A CRITICAL, DOCUMENTARY, AND HISTORIC INVESTIGATION* 55-56 (1961) (explaining the diplomatic maneuvering between Portugal and Spain that followed because of vagueness in Bulls). See also DIFFIE & WINIUS, *supra* note 189, 173-74 (explaining the Second Bull made a fundamental change to the division of territories between Portugal and Spain). The second bull “set a line one hundred leagues west of either the Azores or Cape Verde Islands, thus imposing limitation on Spain not [found] in either of the other [B]ulls . . .” leading to negotiations and the signing of the Treaty of Tordesillas on June 7, 1494. *Id.* However, part of the driving force behind the Papal Bulls was rivalry and warfare over trade between Portugal, Italian city-states, Pope Nicolas V and advances made by the Turks. *Id.* at 108. For further discussion of the role of Papal Bulls and Portuguese and Spanish exploration along the West Coast of Africa, see JOHN DOS PASSOS, *THE PORTUGAL STORY: THREE CENTURIES OF EXPLORATION AND DISCOVERY* 162 (1969) (arguing that Pope Alexander VI issued three successive Papal Bulls, each setting narrower limits to Portuguese claims in order to return a favor owed to the Spanish King and Queen for supporting his elevation to the Papacy). After the Treaty of Tordesillas, King John of Portugal immediately began preparing a fleet to uphold his right to navigation and trade with the Guinea Coast while Ferdinand and Isabella started outfitting fresh ships to secure Columbus’ discoveries. *Id.* See also C.H. Alexandrowicz, *Freitas Versus Grotius*, 35 *BRIT. Y. B. INT’L L.* 162, 168-69 (1959) (arguing that centuries later, Dutch jurist Hugo Grotius mounted an attack on the validity of the Papal Bull *Inter Caetera* of 1493 and the authority of Pope Alexander VI to grant exclusive trading rights to Spain and Portugal in support of the right of the Dutch East Indian Company to trade in the East Indies).

<sup>191</sup> For a discussion of the partition of Africa, see ABODEKA, *supra* note 189, at 71-74 (explaining the rivalry among European powers that precipitated the Berlin Conference for the partition of Africa).

services seems to have been one of the root causes of the Second World War.<sup>192</sup> The negotiations leading to the ITO and the formation of the GATT were a direct response to the need to reaffirm this right in concrete terms.<sup>193</sup> Years of negotiations, generally referred to as “The Rounds,” tried to refine and put trading rights under the GATT on a firmer footing. This effort seems to have suffered a major setback in 1994 when the WTO sought to link the right to trade to the protection of foreign intellectual property rights. Certain types of technology, goods and services essential to life and living involve trade. These weighty issues did not seem to trigger caution or temperance as TRIPS sought to subjugate the public interest of states to the protection of foreign private intellectual property rights.

The complexity of this topic is only matched by the negotiating history of TRIPS, which took several years and involved numerous working groups.<sup>194</sup> Even after such extensive negotiations, approval of the WTO by the U.S. Congress came only after assurances by the Executive Branch that U.S. membership would be reviewed if consecutive WTO decisions were unfavorable to the U.S.<sup>195</sup> The same fear of loss of sovereignty led to rejection of the Havana Charter by the U.S. Congress.<sup>196</sup> If the preservation of sovereignty was so important to the U.S., why was it not extended to all WTO member states, particularly in the most sensitive areas of trade? But the implicit link between the protection of intellectual property rights and trade was not lost on several countries. Submissions by India argued that problems such as product counterfeiting, technology and product pirating should only be dealt with as trade issues if trade distortion was found.<sup>197</sup> Such a distortion seems to have been the purpose of Article XX(d) of GATT. Similarly, Chile argued for a bifurcation of the process by which any corrections of the Paris Union and the

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<sup>192</sup> See JACKSON, *supra* note 3, at 396 (explaining that one aspect of American policy recognized the role of international economic relations as a cause of the Second World War and wanted to prevent the reoccurrence of these events); See also DAM, *supra* note 2, at 12 n.5 (quoting a statement on the philosophy of Secretary of State Hull on the essential relationship between war and peace and non-discriminatory free trade). Dam quotes Secretary of State Hull as saying: “I have never faltered, and I will never falter, in my belief that enduring peace and the welfare of nations are indissolubly connected with friendliness, fairness, equality and the maximum practicable degree of freedom in international trade.” *Id.*, citing CORDELL HULL & HAMILTON FISH ARMSTRONG, *ECONOMIC BARRIERS TO PEACE* 14 (1937).

<sup>193</sup> JACKSON, *supra* note 3; DAM, *supra* note 2.

<sup>194</sup> GERVAIS, *supra* note 50, at 12-13 (stating that there were fourteen separate negotiating groups established, including one on TRIPS).

<sup>195</sup> *Id.* at 4.

<sup>196</sup> DAM, *supra* note 2, at 14.

<sup>197</sup> GERVAIS, *supra* note 50, at 14-19.

Berne Convention should remain in the domain of WIPO.<sup>198</sup> Other developing countries, concerned about overprotection and denial of access to technology, argued for an approach generally referred to as Paris-Plus and Berne-Plus.<sup>199</sup> It is obvious from these interventions that many countries saw the linkage between intellectual property protection and trade as troublesome. Yet, an explicit assertion of the fundamental right to trade was not made; neither was the fundamental right to trade invoked as a challenge to the restrictions imposed on trade in essential products and technologies pertaining to health and food.

#### B. *Does an Idea have a National Origin?*

The second fundamental question that also seems to have escaped the explicit examination of the TRIPS framers is perhaps even more troublesome. It concerns the origins of ideas. Implicit in the structure and operating premise of TRIPS is the assumption that an idea, however expressed, distilled or framed has an unmistakable national identity or is unambiguously traceable to a specific territorial sovereign state. Based on this assumed territorial link between ideas and sovereign states, the framers of TRIPS sought to link the right to trade in goods and services to the protection of certain categories of ideas expressed in the form of patents, copyright, trademark and others. However, as already pointed out, from the perspective of the U.S., the linkage was not so much about the origin of ideas as it was about maintaining its competitive advantage in technology based exports.<sup>200</sup> The debates and submissions by countries leading up to the adoption of TRIPS suggest there was significant unease about the implications of TRIPS' operating premise, upon which international trade would be hinged.<sup>201</sup>

TRIPS provided a rigid framework for mandatory minimum protection of intellectual property rights by WTO member states. Violations of the protective substantive provisions of TRIPS entitle an aggrieved state to interfere with trade flows from the non-compliant state under the WTO dispute resolution process, which provides for sanctions and remedies.<sup>202</sup> Violations are not excused even if trade distortion cannot be established. One of the basic principles of international trade theory advocates the use of first-best solutions, targeted at the source of the problem, which by their nature would be at most free of or produce only minimal trade dis-

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<sup>198</sup> *Id.* at 17.

<sup>199</sup> *Id.* at 16.

<sup>200</sup> Gadbow & Gwynn, *supra* note 8, at 45.

<sup>201</sup> See GERVAIS, *supra* note 50, at 16-19 (submissions by groups of developing countries suggest at least a subconscious awareness of this problem).

<sup>202</sup> Article 64 of TRIPS incorporates the GATT dispute settlement provisions of Articles XXII and XXIII of GATT as elaborated and applied to TRIPS. See TRIPS Agreement, *supra* note 12, at art. 64. For a commentary, see GERVAIS, *supra* note 50, at 506-15.

tortion.<sup>203</sup> Certainly, this principle seems to have been discarded in TRIPS. Intellectual property rights are seldom directly the subject of the bulk of global trade. Infringement of these rights by counterfeiters and technology pirates are generally criminal violations under municipal law. Statistical evidence of counterfeiting before and after TRIPS is mostly based upon speculations and exaggerated estimates by interested parties.<sup>204</sup> Even if these claims of counterfeiting were true, the evidence clearly indicates that counterfeit goods originate from very few countries and constitute but a very small fraction of global trade.<sup>205</sup> In a more

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<sup>203</sup> In his celebrated book on trade policy, W.M. Corden provides a hierarchy of policy choices: there is the first best optimal policy or set of policies which involves making the appropriate policy correction as close as possible to the point of divergence, and he suggests a hierarchy of policy choices, proceeding from the first-best to the second-best and so on. W. M. CORDEN, *TRADE POLICY AND ECONOMIC WELFARE* 28 (1974). In a discussion of whether tariffs constitute the first-best policy for income redistribution, he argues that tariffs might fit this model and the use of income taxes for subsidies might best suit income redistribution for social welfare purposes. *Id.* at 109. The argument is that tariffs for income redistribution do not get to the source of the problem and would distort trade. *Id.*

<sup>204</sup> The estimated cost of counterfeits to the United States by the U.S. Trade Commission in 1982 was \$5.5 billion. ACG, *Statistics on Counterfeiting and Piracy* (Sep. 25, 2011), <http://www.unc.edu/courses/2010spring/law/357c/001/ACG/stats.html>. Just two years later in 1984, the International Anti-Counterfeiting Coalition estimated the value of counterfeits sold at \$60 billion. *Id.* In 1986 the estimate stood at \$61 billion, and by 1994 it reached \$200 billion. *Id.* In 1998, the OECD published a report on the economic impact of counterfeiting, in which it estimated the impact to be 5-7% of world trade, but admitted that although this estimate was not based on accurate statistics to support this perception, the figures are now accepted. HEMA VITHLANI, *ORG. FOR ECON. CO-OP'N AND DEV., THE ECONOMIC IMPACT OF COUNTERFEITING* 10, 18-23 (1998) (estimating the sales of pirated products in the music industry in 1996 from a few priority countries in the millions of dollars and examining the sales levels for other industries, examining the origins of counterfeit goods and identifying ten countries, none of which falls into the world's poorest); Gadbow & Richards, *Introduction to INTELLECTUAL PROPERTY RIGHTS*, *supra* note 24 (estimating the value of pirated products generally and by country of origin for 1986 to be in the millions of dollars); Maclaughlin, Richards & Kenny, *supra* note 24, at 89, 94-98 (indicating the level of piracy from a few select countries in 1982 in various industries to be in the low millions of dollars); *Product Counterfeiting: How Fakes Are Undermining U.S. Jobs, Innovation, and Consumer Safety: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce*, 109th Cong. 2 (2005) [hereinafter *U.S. Product Counterfeit Hearing*] (estimating the increase in the value of pirated products rose from \$5.5 billion to \$600 billion between 1982 and 2005).

<sup>205</sup> See Maclaughlin, Richards & Kenny, *supra* note 24, at 89, 94-98; *U.S. Product Counterfeiting Hearing 2005*, *supra* note 205, at 2 (reporting that over 60% of the goods seized by U.S. Customs originated from China); MINXIN PEI, *ASIA BUSINESS COUNCIL, INTELLECTUAL PROPERTY RIGHTS: A SURVEY OF THE MAJOR ISSUES 2* (2005) (identifying eight countries (China, Russia, Brazil, Mexico, Italy, South Korea,

sophisticated analysis, the OECD reported that counterfeit products could have been worth about \$200 billion in 2005, but estimated the growth rates of intangible products between 2000 and 2007 to be 1.85% and 1.95% of world trade.<sup>206</sup> Estimates based on type of product have a similar characteristic. All these estimates constitute a small percentage of the estimated \$12.178 trillion of global merchandise traded in 2009.<sup>207</sup> To impose such a rigid system on all countries for the relatively minor sins of a few seems to violate principles of equity and fairness. Poor countries without the capacity for counterfeiting are called upon to answer for the deeds of a few and to the benefit of yet another few.<sup>208</sup> The fact that the U.S. and Japan, supported by the E.U., launched a round of negotiations for an additional counterfeiting agreement between the TRIAD and a few other countries to combat counterfeiting (which resulted in an agreement in 2010) is sufficient proof that TRIPS was the wrong instrument for solving this problem.<sup>209</sup> Moreover, the E.U. stated what appears to have been the real reason for TRIPS, a position also held by the U.S.: to help technologically advanced states maintain their competitive technological edge.<sup>210</sup> Certainly, technological competitiveness has but an indirect

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Canada and India) as countries placed on the U.S. Trade Representative's Special 301 priority list for pirated copyright materials, and noting WHO estimated that 10% of all pharmaceuticals sold worldwide are counterfeited while in some developing countries counterfeit pharmaceuticals account for over 60% of all drugs sold).

<sup>206</sup> OECD, *Magnitude of Counterfeiting and Piracy of Intangible Products: An Update*, at 1 (Nov. 2009), <http://www.oecd.org/dataoecd/57/27/44088872.pdf>.

<sup>207</sup> WTO, *International Trade Statistics 2010*, at 10 (2010), [http://www.wto.org/english/res\\_e/statis\\_e/its2010\\_e/its2010\\_e.pdf](http://www.wto.org/english/res_e/statis_e/its2010_e/its2010_e.pdf). The insignificance of counterfeiting in global trade goes back to the decades of the 1980s when the debate over linkage of intellectual protection to international trade to curb counterfeiting had just started. In 1983, world merchandise trade stood at almost two trillion U.S. dollars (\$1,882 billion). In 1993 it was \$3,786 billion, in 2003 it stood at \$7,689 billion and in 2009 it was \$12,421 billion. *Id.* at 12.

<sup>208</sup> See Maclaughlin, Richards & Kenny, *supra* note 24, at 89, 94-98 (noting that a small number of countries are actually involved in counterfeiting).

<sup>209</sup> Office of the U.S. Trade Representative, *Anti-Counterfeiting Trade Agreement - Summary of Key Elements Under Discussion* (2009), <http://www.ustr.gov/about-us/press-office/fact-sheets/2009/november/acta-summary-key-elements-under-discussion> (outlining the purpose of the Anti-Counterfeiting Trade Agreement, its initiating members and basic structure). ACTA is open for signature by participating members and other WTO members until March 31, 2013 and will come into force "thirty days after the date of deposit of the sixth instrument of ratification, acceptance, or approval as between those Signatories that have deposited their respective instruments of ratification, acceptance, or approval." Anti-Counterfeiting Trade Agreement arts. 39-40, Dec. 3, 2010, available at [http://trade.ec.europa.eu/doclib/docs/2010/december/tradoc\\_147079.pdf](http://trade.ec.europa.eu/doclib/docs/2010/december/tradoc_147079.pdf) [hereinafter ACTA Agreement].

<sup>210</sup> European Commission, *Trade Topics: Intellectual Property* (Sept. 25, 2011), <http://ec.europa.eu/trade/creating-opportunities/trade-topics/intellectual-property> [hereinafter European Commission]. For a similar discussion, see *U.S. Product*

impact on trade and hardly offers the first-best solution to the free flow of goods and services TRIPS seeks to address. It is remarkable that a system with such serious potential impact on the free flow of trade, particularly products of necessity, was put in place given the mission of free trade espoused by the WTO system of agreements.<sup>211</sup>

In any case, the very notion of attaching a national identity or territorial origins to something as ephemeral as an idea is of dubious validity. From the beginning of time, and from our knowledge of origin myths and the evolution of human creativity, ideas have always been diffusible without regard to geography or culture.<sup>212</sup> The moral from the Ghanaian Akan Ananse origin myth teaches us that knowledge and ideas are in the air we breathe from the moment of birth.<sup>213</sup> Ideas are therefore highly diffusible with no respect for territorial boundaries and national political

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*Counterfeiting Hearing 2005*, *supra* note 204 (statement of Hon. Cliff Stearns, Chairman, H. Comm. on Energy and Commerce). Rep. Stearns opened the hearing by outlining the disturbing nature of counterfeiting and what is at stake for the U.S. economy and consumers. *Id.* at 2. In his opening remarks, he said: “My concern today is about how fakes are robbing our U.S. companies of the hard earned intellectual property and ingenuity that they own and need to compete globally.” *Id.* His language appeared even stronger as to the purpose behind the anti-counterfeiting measures of the U.S. *Id.* He emphasized:

As I said at last week’s hearing . . . intellectual property rights [IPR] are critical to [the U.S.] economy and to the engine of innovation. The fortress around our ingenuity, technological leadership, and creativity is the rule of law. And as we will hear today, it is time to ensure that our laws are just as robust as they can be, that they are aggressively enforced, and that all relevant parties be required to live up to our international agreements regarding IPR especially obligations under the WTO and the [TRIPS] agreement.

*Id.* See also Gadbow & Gwynn, *supra* note 8, at 41 (arguing that the purpose of introducing intellectual property rights in the GATT negotiations was to maintain U.S. competitive advantage).

<sup>211</sup> ACTA Agreement, *supra* note 209, at 1 (the preamble recognizing the health issues in TRIPS).

<sup>212</sup> DIAMOND, *supra* note 178, at 254, 259-261. See generally ELIADE, *supra* note 181 (demonstrating the simultaneous, sequential, multicultural and geographically dispersed phenomenon of metallurgy in history).

<sup>213</sup> According to the Ghana Akan Ananse origin myth, Ananse, already the most clever of all God’s creatures, devised a scheme to monopolize and totally control all knowledge. He collected all knowledge and put it in a gourd that he tried to hang on the tallest tree in the forest out of reach to all except him. As he stretched to hang the gourd he slipped and fell. Down went Ananse and the gourd, which shattered, allowing the knowledge stored in it to evaporate into the air we breathe from the moment we are born. PEGGY APPIAH, *THE PINEAPPLE CHILD AND OTHER TALES FROM ASHANTI* 19 (1969). Thomas Jefferson, in a letter to Isaac McPherson, captured the fleeting character of idea expressed in the Ananse myth. He said:

It would be curious . . . if an idea, the fugitive fermentation of an individual brain, could, of natural right, be claimed in exclusive and stable property. If nature has made any one thing less susceptible than all others of exclusive property, it is the

demarcations. They can be exploited simultaneously by everyone without depletion, the prototypical public good that does not suffer from overuse or contagion.<sup>214</sup> Moreover, studies of the evolution of human creativity demonstrate that some of the most famous inventions that have changed the technological landscape of the world were the result of borrowing and sharing of ideas across cultures and nations.<sup>215</sup> Throughout history, without regard to geography, culture or nationality, famous inventors such as James Watt and Thomas Edison stood on the shoulders of others.<sup>216</sup> Modern technologically advanced societies are the beneficiaries of past and present diffusion of ideas from other cultures. History also teaches that some ideas emerged simultaneously in different parts of the world. Take for example the domestication of seeds, plants or animals. Diamond suggests that they emerged independently in different parts of the world.<sup>217</sup> How then can one assign, with any degree of certainty, an unambiguous national origin to any idea? This question is even much more pertinent today with the emergence of modern information technology such as the internet, which has created a single and simultaneous information system, facilitating the flow of ideas seamlessly across territorial boundaries with little or no restrictions.

A powerful insight captured in the famous Arrow's paradox captures the fleeting and nature of an idea.<sup>218</sup> There is little debate over this characterization of ideas. One may argue that linking the right to engage in

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action of thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself . . . .

*Letter from Thomas Jefferson to Isaac McPherson* (Aug. 13, 1813), in 13 THE WRITINGS OF THOMAS JEFFERSON 326, 333 (Andrew A. Lipscomb & Albert Ellery Bergh eds., 1903).

<sup>214</sup> See ANTHONY B. ATKINSON & JOSEPH E. STIGLITZ, LECTURES ON PUBLIC ECONOMICS 482-86 (1980) (providing an extensive discussion of public goods). Atkinson and Stiglitz describe what many consider the prototypical public good: "usage by one person does not reduce the amount that others can consume. In other words, the cost of supplying a fixed quantity to another *individual* is zero. Examples typically given include . . . information (my knowing something does not detract from others knowing the same thing); and national defence." *Id.* at 484.

<sup>215</sup> DIAMOND, *supra* note 178, at 242-45.

<sup>216</sup> *Id.* at 242-45.

<sup>217</sup> *Id.* at 125-28.

<sup>218</sup> The tendency of information markets to fail and the resultant difficulty of transacting business in those markets has been the subject of investigation by economists. See, e.g., KENNETH J. ARROW, ESSAYS IN THE THEORY OF RISK-BEARING 150-56 (1971) (discussing the peculiar attributes of information markets that make them susceptible to imperfections and the difficulties of adopting appropriate pricing policies for contracts involving information); see also MARK CASSON, ALTERNATIVES TO THE MULTINATIONAL ENTERPRISE 36-38 (1979) (discussing the diffusibility of information and the difficulties encountered in the transfer of technology because of market failure resulting in internalization of such information within the firm).

international trade to the protection of the foreign origin of ideas is not only unprecedented in human history, but perhaps of doubtful legality and certainly bad global trade policy – particularly when such trade policy comes without sufficient safeguards for trade in the essentials to life and health. In the modern non-territorial world of information, is the national origin of an idea traceable to the place where the technical patentability requirements are satisfied or to the country of origin of the constituent elements of the ideas synthesized or crystallized? Take, for example, a French scientist who has been studying the DNA structures and biochemical composition of prostitutes in three African countries resistant to HIV/AIDS while on vacation in Yosemite in the U.S. Watching the sunset over Half Dome, he was suddenly inspired to pull together all the scientific and chemical pieces for an effective AIDS vaccine and jots it down in his notebook. What would be the national origin of that breakthrough: the U.S., the African countries where the research took place or France, the researcher's nation of citizenship? The answer to this question is not obvious nor does it suggest itself. It is therefore hardly surprising that the U.S. suggestion of a first-to-invent system was rejected during TRIPS negotiations.<sup>219</sup> Moreover, under TRIPS, countries with indigenous cultures and useful traditional knowledge or ideas, but without technical capacity, are at a disadvantage.

It is apparent from this brief survey that the system of intellectual property rights is so complex that it deserves a separate regime of its own. It was a serious policy error to marry a subject of such complexity to another complex system of international trade. The magnitude of that error is glaring given the explicit goal of the E.U. and U.S. of maintaining the technology gap<sup>220</sup> between the haves and the have-nots, which helps to uphold a regime of sustained uneven trade. More attention should have been paid to the suggestions by countries such as Chile to locate the TRIPS regime in WIPO.<sup>221</sup> The concentration of power in the WTO is widely inconsistent with current global good governance modalities that call for checks and balances on the exercise of power. The concentration of such power in the WTO is particularly troublesome when intellectual property rights are not directly trade related but affect the health, safety and food needs of humanity.

### C. *The Interplay of Structure and Substance of TRIPS*

As demonstrated in the preceding section, the quality of the structure and substance of a complex international agreement depends in large measure on its operating premises and assumptions. The goal of this section is to explore briefly how the structural defects of TRIPS interplay

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<sup>219</sup> See GERVAIS, *supra* note 50, at 338.

<sup>220</sup> See European Commission, *supra* note 210; U.S. Product Counterfeiting Hearing, *supra* note 205.

<sup>221</sup> See GERVAIS, *supra* note 50, at 17.

with its substantive provisions to magnify the risks to human health and food security.

Standardized structures in agreements are often both a blessing and a curse. Structure often affects substantive provisions in two ways. Structure may provide a rigid framework as a shield against future modifications of both structural and substantive provisions, an important factor for those seeking certainty. Structure also affects procedure that determines access to and enjoyment of substantive rights. Rigid and unfriendly procedural hurdles may erect a high cost barrier and render otherwise meaningful substantive rights inaccessible to those with such meaningful claims. The so-called TRIPS flexibilities may fall into this category. Inflexible structural and substantive provisions make it unlikely that agreements will be responsive to future needs of member states. The structure of TRIPS is no exception.

The framers of TRIPS delivered a globally standardized and mandatory intellectual property protection regime based on the prevailing standards of developed countries. This new universal normative order for intellectual property rights was virtually blind to other forms of knowledge, ideas or other social, economic and political choices. In an era of neo-liberalism, a one-size-fits-all approach was adopted for a complex subject and diverse world. Prior to TRIPS, no international intellectual property system had enough clairvoyance to pronounce what was good for all nations and cultures far into the future. Previous international intellectual property conventions did not seek to impose such an ideologically driven concept as that of rights in ideas upon every nation irrespective of its history, culture, needs and level of development. Nor did any previous regime try to impose the subject matter of patentability on all nations. All of these complex issues were left as sovereign political choices reflective of each nation's values, needs and the protection of its public interest. Almost with a single stroke, TRIPS has changed the landscape in all these areas.

### 1. Patentable Subject Matter

One of the places where the interplay between structure and substance manifests itself is the unprecedented prescription of patentable subject matter in Article 27 of TRIPS. Under Article 27(1), any invention in any field of technology is patentable, provided that it is new, involves an inventive step and is capable of industrial application.<sup>222</sup> These technical

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<sup>222</sup> TRIPS Agreement, *supra* note 12, at art. 27(1); see GERVAIS, *supra* note 50, at 343-45 (discussing the complexity of the concept '*ordre public*' as used in Article 27 of TRIPS and the fact that it does not equate with the English term 'public policy' and seems to conform more to the French term '*bonnes moeurs*'). See also Rainer Moufang, *The Concept of "Ordre Public" and Morality*, in PATENT LAW, ETHICS AND BIOTECHNOLOGY 69 (Geertrui Van Overwalle ed., 1998); Kojo Yelapaala, *Owning the Secrets of Life: Biotechnology and Property Rights Revisited*, 32 MCGEORGE L. REV.

requirements, prevalent in developed countries, were transported into TRIPS, even though they could not easily be satisfied in many developing countries because of missing capacity or the traditional nature of their ideas and knowledge. However, once the technical requirements are met, TRIPS prohibits any discrimination based on the place of invention or type of technology.<sup>223</sup> The mandatory protective veil of TRIPS was expanded under Article 39, which mandates the protection of undisclosed data and information submitted to governments or their agencies.<sup>224</sup> Protection under Article 39 extends to pharmaceutical data, thereby denying access of such data to generic drug manufacturers and delaying the introduction of generics.<sup>225</sup>

The prescription of a mandatory regime for subject matter patentability is a new and significant surrender of sovereignty in an area of critical importance to development and matters relating to health and food security. First, under Article 27(2) a state may deny patentability on grounds of *ordre public*, morality or for the protection of human, animal or plant life and the environment.<sup>226</sup> Framed as a protective shield, Article 27(2) can only be invoked against inventions the exploitation of which would be harmful under its terms. A state cannot therefore deny patentability to a “harmless” exploitable invention with the purpose of making it widely available on public health and food security grounds. However, as has been argued elsewhere, certain subject matter or inventions,

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111, 200-10 (2000) (discussing the concept of public policy under the U.S. patent system and suggesting ways to address patentability of biotechnological inventions under a revised patent regime).

<sup>223</sup> The primary provisions in TRIPS dealing directly with the issue of discrimination are Article 3 (National Treatment) and Article 4 (Most Favored Nation Treatment). TRIPS Agreement, *supra* note 12, at arts. 3-4. Article 27(1) appears to limit the choices of sovereign states as to the subject matter of patents and Article 28 dictates what rights must be conferred. *Id.* at art. 27(1). However, there is some disagreement over the nature of Article 27. It is argued that a distinction should be drawn between differentiation and discrimination. The former allows some flexibility while the latter does not. *See, e.g.,* GERVAIS, *supra* note 50, at 357-59.

<sup>224</sup> *See* TRIPS Agreement, *supra* note 12, at art. 39 (dealing with the protection of undisclosed information).

<sup>225</sup> *Id.*

<sup>226</sup> *Id.* at art. 27(2) (providing for exemptions to patentable subject matter in Article 27(2), including ‘*ordre public*’). ‘*Ordre public*’ is a French term not susceptible to an easy definition. According the European Patent Office Guidelines the literal meaning of ‘*ordre public*’ is ‘public disorder’ but in the case of patents it refers to inventions that are “likely to induce riot or public disorder, or to lead to criminal or other generally offensive behavior.” *See* Guidelines for Examination in the European Patent Office, (European Patent Office, 2000) C-IV. For an extensive discussion of ‘*ordre public*’ as compared with the public policy exception under U.S. patent law, *see* Yelapaala, *supra* note 222, at 200-210 (proposing Norm 3 for framing extensive public policy discussion as a larger concept than is provided for under Article 27(2) of TRIPS).

because of their importance to the life and health needs of humanity, may justify exclusion from patentability.<sup>227</sup> Patentability is denied not because these inventions pose a threat to humanity, but rather precisely because they are essential to maintaining health or sustaining life. As a matter of public interest a state may reasonably conclude that such inventions should not be patentable so that widespread exploitation would serve the public good.<sup>228</sup> Such an explicit exception is essential in an agreement such as TRIPS, especially with respect to public health and food security. With such an explicit exemption, the problems of access to pharmaceutical products that the WTO General Council Declaration sought to address might be eliminated. Any risks associated with retention of sovereignty by WTO members in this area could be addressed with certain checks and balances. Unfortunately, absent a complete overhaul, the door to such a solution appears to be permanently shut under the present TRIPS regime.

Second, the loss of sovereignty over the subject matter of patents is significant through the prescription of rights in general and the protection of certain forms of expressed ideas in particular. Prior to TRIPS, several countries excluded pharmaceutical inventions from their patent regime.<sup>229</sup> For example, pharmaceutical inventions were not patentable in Italy until 1978.<sup>230</sup> Evidence does not show that innovation came to a halt. The pharmaceutical industry has always been a highly concentrated

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<sup>227</sup> See Yelapaala, *supra* note 222, at 196. I suggest three norms for governing patentability. Norm 2 states: "That which can be owned may nevertheless not be patentable." *Id.* This suggests that a deliberate policy choice may put certain useful patentable inventions in the public domain to achieve some public policy objectives.

<sup>228</sup> *Id.*

<sup>229</sup> WHO/WTO STUDY, *supra* note 21, at 42. It is instructive to note that several of the countries that only recently provided patent protection for pharmaceutical products and inventions were not developing countries. See, e.g., Jean O. Lanjouw, *Intellectual Property and the Availability of Pharmaceuticals in Poor Countries*, 3 INNOVATION POL'Y & ECONOMY 91, 96 (2003) (providing the following list of countries that adopted patent protection for pharmaceutical products between 1976 and 1992: Japan (1976), Switzerland (1977), Holland (1978), Sweden (1978), Canada (1983), Denmark (1983), Austria (1987), Spain (1992), Portugal (1992), Greece (1992), Norway (1992)).

<sup>230</sup> See Case 187/80, *Merck v. Stephar*, 1981 E.C.R. 2063, 2079 (involving a referral to the European Court of Justice from the District Court of Rotterdam under Article 177 of the Treaty of Rome for a preliminary ruling on whether a patentee in the Netherlands could rely on national patent legislation and Article 36 to prevent some importation of pharmaceuticals it manufactured under its patent and distributed in Italy where pharmaceutical patents were prohibited by Italian statute). In reciting the facts of this case, the Court described the context of the Italian law by saying:

The company markets the drug in Italy where it has not been able to patent it owing to the fact that at the time when the drug was sold in Italy the Italian Patent Law (Regio Decreto [Royal Decree] No 1127 of 29 June 1939) — which was subsequently declared unconstitutional by a judgment of the Italian Corte

and resilient oligopoly with significant technical and financial entry barriers providing it a protective shield.<sup>231</sup> Pharmaceutical MNEs hardly needed the doubly fortified shield of Zeus provided by TRIPS. Moreover, the concept of what constitutes property is imbued with such deep cultural sensibilities that there must be some room for cross-culture variation. Relative to the whole world, or even to specific African countries, the E.U. is a geographically small and culturally diverse environment. Yet the framers of the Treaty of Rome, which established the European Economic Community, displayed remarkable sensitivity to the question of what constitutes property by leaving that determination to member states in Article 222.<sup>232</sup> Additionally, as discussed above, Article 36 of the same treaty, that recognized the protection of industrial and commer-

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Costituzionale [Constitutional Court] delivered on 20 March 1978 — prohibited the grant of patents for drugs and their manufacturing processes.

*Id.*

<sup>231</sup> See Peter Drahos & John Braithwaite, *Intellectual Property, Corporate Strategy, Globalisation: TRIPS in Context*, 20 WIS. INT'L L.J. 451, 463-67 (2001-2002) (offering the history and profitability of the leading pharmaceutical multinationals within the context of their power and what is described as information feudalism). In determining the nature of market power within the context of Article 86 of the Treaty of Rome, the European Court of Justice takes into account not only the market share of undertakings but also their financial and other resources. The nature of entry barriers created by global pharmaceuticals can be appreciated in cases dealing with abuse of dominant positions and cases of monopolization in the U.S. and E.U. For example, in *Europemballage v. Commission*, the European Commission described the hallmarks of a dominant position:

Undertakings are in a dominant position when they have the power to behave independently, which puts them in a position to act without taking into account their competitors, purchasers or suppliers. That is the position when, because of their share of the market combined with the availability of technical knowledge, control over production or distribution for significant part of the products in question. This power does not necessarily have to derive from an absolute domination . . . but it is enough that they be strong enough as a whole to ensure to those undertakings an overall independence of behavior.

Case 6/72, *Europemballage v. Commission*, 1973 E.C.R. 215, 257

Although this case did not involve pharmaceuticals, it was followed by Case 85/76, *Hoffman-La Roche v. Commission*, 1979 E.C.R. 467 (applying similar reasoning to the distribution of pharmaceutical products). See also Case 27/76, *United Brands Co. v. Comm'n*, 1978 E.C.R. 209 (following the same line of reasoning with regard to the distribution of bananas). For an example of a monopolization case in the U.S., see *United States v. United Shoe Machinery Corp.*, 110 F. Supp. 295 (D. Mass. 1953), *aff'd per curiam*, 347 U.S. 521 (1954) (discussing monopoly power by looking not only at market share but also at financial and other resources defendant commanded as a corporation).

<sup>232</sup> Article 222 of the Treaty of Rome states: "This Treaty shall in no way prejudice the rules in Member States governing the system of property ownership." Treaty of Rome, *supra* note 188, at art. 222. See also *Beier & Schrickter*, *supra* note 20, at 170-75.

cial property rights, has been interpreted as being subservient to the free movement provisions of the treaty.<sup>233</sup> The Paris Union did not see it fit to impose a mandatory system of patent rights upon its members. It is hard to find any compelling justification for a mandatory system of rights in TRIPS given the complexity of the subject and its importance to economic development. Assuming the existence of a compelling justification for such a standardized and universal system of intellectual property rights, the WTO should demonstrate prudence by creating an exception for matters of such importance to humanity as public health and food security. Apparently the light of wisdom shone on a different subject; in its shadow, the subjugation of the public interest to that of foreign private interests received greater attention.

## 2. Risks Posed by Substantive Patent Provisions

The significance of the interplay between structure and substance on the risk to human health and food security continues to unfold in the nature, scope and duration of rights conferred upon patent holders. Under Article 28(1) all patentees enjoy the usual exclusive and monopoly rights prevalent in developed countries.<sup>234</sup> Standing alone, the nature and scope of these rights do not pose as serious a threat as does the interaction between Article 28 and other provisions of TRIPS. For instance, while Article 33 mandates a minimum of 20 years for patent protection, Article 3, building on the anti-discrimination provisions of the Paris Union, prohibits nationality-based discrimination.<sup>235</sup> However, Article 4 for the first time introduces most favored nation (MFN) treatment, generally used in international trade agreements, into an international intellectual property protection agreement.<sup>236</sup> This is unprecedented and

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<sup>233</sup> In Case 15/74, *Centrafarm BV v. Sterling Drugs Inc.* 1974 E.C.R. 1147, ¶¶ 8-9, the European Court of Justice interpreted the scope of Article 36 regarding patents to be limited to the specific subject matter of patented property, which guarantees the exclusive right to put the relevant industrial product into circulation for the first time either directly or through a licensee. The Court reasoned that to hold otherwise would permit the patentee to partition markets and undermine one of the fundamental principles of the Treaty – creating a single market for the free movement of goods. *Id.* at ¶¶ 10-12. For a discussion of this interpretation of Article 36, see DERRICK WYATT & ALAN DASHWOOD, *EUROPEAN COMMUNITY LAW* 576 (3d ed. 1993).

<sup>234</sup> Article 28(1) confers exclusive rights “where the subject matter of a patent is a product, to prevent third parties . . . from . . . making, using, offering for sale, selling, or importing . . . that product.” TRIPS Agreement, *supra* note 12, at art. 28(1). In the case of process patents, article 28(2) provides similar rights. *Id.* at art. 28(2).

<sup>235</sup> Article 3 mandates the national treatment formerly part of the Paris Union. *Id.* at art. 3.

<sup>236</sup> In an unprecedented move, Article 4 introduced MFN treatment into TRIPS by providing that “with regard to the protection of intellectual property, *any advantage, favour, privilege or immunity granted by a Member to the nationals of any*

carries serious implications. Paradoxically, even under a system of standardized rights, TRIPS managed to retain the old territorial independence of patents issued by member states.<sup>237</sup> Moreover, the mandatory rights conferred by TRIPS are considered minimum rights. Skeptics may ask why these rights and obligations? Certainly, beyond mandated minimum protection, member states may independently grant more rights and protections. The combination of these provisions provides a gaping loophole for expanding rights through bilateral arrangements now expressed in what is generally called TRIPS PLUS agreements, often detrimental to public health and food security of developing countries that enter in such agreements.<sup>238</sup> The introduction of MFN and retention of territorial independence of patents represent a major achievement for countries such as the U.S. After failing several times since 1880 to introduce a reciprocity requirement in patent protection in the Paris Union, the U.S. seems to have achieved its in TRIPS.<sup>239</sup> With MFN and territorial independence of patents, powerful countries can now use bilateral trade

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*other country* shall be accorded immediately and unconditionally to the nationals of all other Members.” *Id.* at art. 4 (emphasis added). Reaction to MFN treatment has been varied. Compare GERVAIS, *supra* note 50, at 189 (arguing it was a novelty with limited initial impact because of exemptions provided within Article 4) with CORREA, *supra* note 36, at 66 (arguing the principle was absent from pre-TRIPS conventions) and DE CARVALHO, *supra* note 36, at 161 (arguing that although the MFN principle appears to be the natural expansion of GATT into other areas, the reason behind Article 4 was to address the practice advantages and privileges granted by states in bilateral agreements not prohibited under the Paris Union).

<sup>237</sup> Although TRIPS determines the subject matter of the patent, the nature of the rights granted and the duration of those rights are still governed by local law, which must conform to the terms of TRIPS. TRIPS Agreement, *supra* note 12. Thus, patents remain territorially independent under TRIPS yet are combined with MFN treatment, which may pose serious risks. See, e.g., DE CARVALHO, *supra* note 36, at 163 (arguing that the use of language in Article 4 referring to “any advantage, favour, privilege or immunity” granted to nationals of any other country expands the scope of intellectual property rights in bilateral agreements between WTO members and non-member states). *But see*, CORREA, *supra* note 36, at 66.

<sup>238</sup> See GRAIN, “TRIPS-plus” Through The Back Door (July 2001), [http://www.grain.org/briefings\\_files/trips-plus-en.pdf](http://www.grain.org/briefings_files/trips-plus-en.pdf); GRAIN, *FTAs: Trading Away Traditional Knowledge* (March 2006), [http://www.grain.org/briefings\\_files/fta-tk-03-2006-en.pdf](http://www.grain.org/briefings_files/fta-tk-03-2006-en.pdf); David Vivas-Eugui, *Regional and Bilateral Agreements and a TRIPS-plus World: the Free Trade Area of the America (FTAA)*, TRIPS ISSUES PAPER 1, 4 (2003) available at <http://www.quno.org/geneva/pdf/economic/Issues/FTAs-TRIPS-plus-English.pdf>; CORREA, *supra* note 36, at 69 (admitting the troublesome impact of free trade agreements by the U.S., E.U. and Japan under MFN treatment but nevertheless arguing the impact of MFN treatment would be limited by the scope of coverage of the TRIPS Agreement).

<sup>239</sup> Article 4 of TRIPS, which mandates MFN treatment, together with the fact that the TRIPS protection is minimal, opens the door for reciprocity under TRIPS-PLUS agreements. See TRIPS Agreement, *supra* note 12, at art. 4.

agreements to impose greater intellectual property protection on weaker states for the benefit of other WTO members.

Thus, while the WTO may be criticized for allowing a loophole in TRIPS that could facilitate discriminatory treatment, it seems the loophole was a strategic ploy for the general expansion of intellectual property rights. By exploiting this loophole, economically and politically powerful states such as the U.S. and the E.U. have negotiated TRIPS PLUS bilateral agreements with various developing countries, which has expanded intellectual property rights beyond TRIPS minimums.<sup>240</sup> The process and its results, driven by bargaining power asymmetries, have been termed bilateral/unilateralism.<sup>241</sup> Put differently, although these agreements were labeled as bilateral, they were essentially unilateral in the sense that TRIPS PLUS agreements are uneven in the rights and obligations of the parties. Reciprocity has been resisted for about a century because of its invidious implications for weak states in a global system.<sup>242</sup> This is because in return for unrealizable hoped-for access to trade and investments, developing countries tend to yield to an expansion of patentable subject matter and protection that has a negative impact on those countries' health security. The same pattern of bilateral/unilateralism has been unfolding in thousands of bilateral investment treaties.<sup>243</sup>

The risk to health security created in these agreements has far-reaching implications for countries in disadvantaged bargaining positions and ultimately for patent rights under TRIPS. Although Article 4 provides some exceptions, they are less beneficial to developing countries.<sup>244</sup> However,

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<sup>240</sup> Some differences exist between TRIPS-PLUS agreements in the U.S. and the E.U. See Carlos M. Correa, *Internationalization of the Patent System and New Technologies*, 20 WIS. INT'L L.J. 523, 528-31 (2001-2002). See also Samantha A. Jameson, *A Comparison of the Patentability and Patent Scope of Biotechnological Inventions in the United States and the European Union*, 35 AIPLA Q.J. 193, 242-57 (2007).

<sup>241</sup> Yelapaala, *supra* note 83, at 249 (discussing the concept of bilateral unilateralism as the use of bilateral negotiations to achieve the same level of investment protection which could be unilaterally imposed without a treaty – with results generally “lopsided and hardly equal, symmetrical or reciprocal in actual fact”).

<sup>242</sup> PENROSE, *supra* note 3, at 64-66 (explaining that although reciprocity was rejected in 1880, the U.S. engaged in the only serious but unsuccessful push for reciprocity, particularly between 1897 and 1900, with opponents of reciprocity fearing it would undermine the very foundation of the Paris Union and render it a mere series of bilateral agreements).

<sup>243</sup> Yelapaala, *supra* note 83, at 237-40 (discussing the proliferation of bilateral investment treaties: in 1999 there were about 1,857 BITS, by 2008 there were over 2,500).

<sup>244</sup> Article 4 of TRIPS offers the following four exceptions: advantages “(a) deriving from international agreements on judicial assistance . . . (b) granted in accordance with the . . . Berne Convention or the Rome Convention . . . (c) in respect of the rights of performers . . . , and (d) deriving from international agreements

under the MFN provision of TRIPS, it is doubtful whether developing countries that have agreed to expand TRIPS PLUS rights can deny third states the same rights. Thus, third states, without providing any bargained for trade and investment benefits, can simply walk through open gates as free riders, even when the privileges and advantages are extended to non-WTO member states. One can thus plausibly argue the guarantee of minimum rights under TRIPS followed by the MFN clause was a deliberate strategy to expand intellectual property rights without creating safeguards for human health and food security. States with relative bargaining power can systemically expand the international intellectual property regime by selectively negotiating TRIPS PLUS agreements with important developing countries governed by the MFN. One can gain a greater appreciation for the severity of these TRIP PLUS by examining the application of MFN provisions in bilateral investment treaties.<sup>245</sup>

It would therefore appear that countries seized upon the opportunity presented by the WTO and TRIPS to achieve what was not possible under the Paris Union. If the goal of these countries was to maintain the existing digital divide thereby ensuring their technological advantage and competitive advantage, the strategy worked. However, the goal was achieved at the expense of the world's weak and vulnerable populations, who face the greatest exposure to neglected diseases and persistent hunger. If, as we have seen, the right to health is not only a constitutional right in some countries but, more importantly, a human right, can member states easily carry out their obligations under TRIPS and TRIPS PLUS? Should an international instrument designed to advance the

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related to the protection of intellectual property . . . [in existence] prior to the entry into force of the WTO Agreement" if notified to the TRIPS Council. TRIPS Agreement, *supra* note 12, at art. 4.

<sup>245</sup> For a discussion of MFN clauses in bilateral investment treaties, see Jarrod Wong, *The Application of Most-Favored-Nation Clauses to Dispute Resolution Provisions in Bilateral Investment Treaties*, 3 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 171, 173 (2008) (arguing that although the use of MFN clauses in bilateral investment treaties has come into question, their use might be consistent with Article 31 of the Vienna Convention on the Law of Treaties under the plain meaning interpretation in the particular case of a specific provision). However, the Argentine financial crisis in late 2001 exemplified the cause célèbre of the risks posed to sovereign policy choices under bilateral investment treaties. See William W. Burke-White, *The Argentine Financial Crisis: State Liability Under BITS and the Legitimacy of the ICSID System*, 3 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 199, 205 (2008). In response to the financial, economic and political crisis that followed, the government took corrective measures that adversely affected local and foreign investors' interests. Over 40 investment arbitration disputes were filed against Argentina by foreign investors and questions were raised about interpretation of bilateral investment treaty provisions when a state faces a widespread crippling economic crisis. See *id.*

goals of the UN Charter provide opportunities for undermining those goals and fundamental rights?

### 3. Risk of Patent Abuse Under TRIPS

One of the themes that dominated the Paris Union deliberations was the threat of patent abuse in the new international patent regime. The threat of patent abuse also dominated deliberations during the Vienna Conference of 1878 and continued during discussions in Paris culminating in adoption of the Paris Union in 1883 and treaty ratification in 1884.<sup>246</sup> It is noteworthy that the Vienna Conference adopted a resolution permitting compulsory licensing in the public interest to control monopolistic and restrictive practices of patentees.<sup>247</sup> Given that members of the Paris Union were at different levels of economic and technological development, and had different international trade policies, patent abuse loomed large. They feared patents would be registered with no intent to use, but purely as instruments for monopolistic practices and market reservation.<sup>248</sup> Patents would prevent exploitation and imports that would be detrimental to the development of local industry and leave the fate of weaker countries in the hands of foreign patentees.<sup>249</sup> Such an outcome was unacceptable to many countries, including those that had no patent system and those that subscribed to international free trade.<sup>250</sup>

Three potential solutions were debated during negotiations surrounding the Paris Union. One solution was to give states the right to revoke patents for non-working. The second solution, preserved in the Paris Union, was for sovereign states to retain the power to determine patentable subject matter in the public interest as an expression of sovereignty. The third, which was also eventually adopted as part of Article 5A, was to allow states to use compulsory licensing as a sanction for non-working of patents subject to some conditions. In addition, Article 5A offered a series of solutions to patent abuse.<sup>251</sup> A state could legislatively revoke a patent for non-working if compulsory licensing proved itself an inadequate response. The power to revoke was substantially left to the state.

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<sup>246</sup> PENROSE, *supra* note 3, at 178-80 (concluding that the abuse of patent monopoly provisions had a turbulent history because they directly impinged on the interest of less industrialized states, their national economies and the interests of individual patent holders).

<sup>247</sup> *Id.* at 47 (detailing how after a vigorous debate, the resolution was accepted against the objection of the U.S. by a vote of 42 to 7).

<sup>248</sup> *Id.*

<sup>249</sup> *Id.* at 80-82 (explaining that interests of states would be hurt by the abolition of compulsory working – Japan, Yugoslavia, and Poland blocked the United States for that reason).

<sup>250</sup> *Id.* at 65 (specifying Switzerland and the Netherlands had no patent system at the time).

<sup>251</sup> For a discussion of conditions imposed by Article 5A of the Paris Union on compulsory licensing, see Beier & Schricker, *supra* note 20, at 173.

Between 1897 and 1934, the U.S. tried unsuccessfully to eliminate this provision, since modifications required unanimity.<sup>252</sup> In 1925, Japan, Yugoslavia and Poland blocked another U.S. attempt on the grounds it would be detrimental to the growth of industry.<sup>253</sup> Professor Penrose, after an exhaustive examination of the subject, concluded that,

[I]n subsequent conferences the fight to obtain suppression of revocation of the patent as a sanction for non-working will undoubtedly be resumed. If the principle of the international recognition of the inventor's right to patent protection is accepted, then the question of what restrictions each country may impose on the exercise of this right is of fundamental importance.<sup>254</sup>

Professor Penrose's remarks proved prophetic since the search for a solution to the patent abuse problem remained a thorny issue until its resolution in 1994 in TRIPS.<sup>255</sup>

If the disparities in economic development and technological advancement compelled the reservation of sovereign authority over patent abuses in the Paris Union, what changed in 1994? Certainly, the number of countries experiencing economic and technological gaps increased significantly following decolonization. Additionally, the pressing needs of many WTO member states for a health and food security blanket are similar to the political pressures that shaped the construction of the Paris Union. The logic which led to the preservation of the right of patent revocation or compulsory licensing as a sanction for non-use in the Paris Union was more compelling when TRIPS was negotiated. Unfortunately, developing countries faced an almost insurmountable bargaining and hegemonic power deficit that affected the outcome.

The resolution of the controversy over patent abuse, which came in two forms, was naturally affected by complex and intertwined asymmetries. The first was under Article 32, which permits a state to revoke a patent for any reason, including non-use or health and safety reasons, provided the decision is subject to judicial review.<sup>256</sup> The burden of judicial review, while a check on the abuse of power, is a complex one. Some reasons for revocation may be non-justiciable under municipal law or the resolution of an issue may be complex and protracted. Besides, as one commentator has remarked, the judicial review process could lead to a stalemate.<sup>257</sup> A stalemate could have severe consequences during a public health emergency if the patentee protracts the review process due to a challenge or if

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<sup>252</sup> See PENROSE, *supra* note 3, at 81-86.

<sup>253</sup> *Id.* at 84.

<sup>254</sup> *Id.* at 86.

<sup>255</sup> See TRIPS Agreement, *supra* note 12, at art. 31 (providing for compulsory licensing under numerous conditions).

<sup>256</sup> See TRIPS Agreement, *supra* note 12, at art. 32.

<sup>257</sup> GERVAIS, *supra* note 50, at 402.

it becomes indeterminate. TRIPS does not assign the appropriate qualitative value to the public interest in times of emergency.

The second form, compulsory licensing as a sanction for non-working, is addressed in Article 31 of TRIPS. Dubbed a compulsory licensing provision, Article 31 comes with numerous conditions, restrictions and qualifications which, read together, seem to contradict the very notion of compulsory licensing.<sup>258</sup> These conditions severely limit the utility of Article 31 to many countries, particularly in the health and food security arena. The requirement that consent of the patent holder must first be sought presents a major hurdle and potential detrimental delays if the need is immediate and serious.<sup>259</sup> The further condition that compulsory licensing can only be used to supply domestic market needs until such needs are resolved is virtually meaningless for many developing countries with small domestic markets and weak purchasing power.<sup>260</sup> Basic economic theories instruct that economies of scale have a significant impact on efficient low-cost production, low prices and consequently affordable pharmaceuticals. This is not achievable in countries with small markets and no technical capacity. Unfortunately, TRIPS does not provide for nor contemplate an exception for the formation of regional organizations in the area of compulsory licensing, similar to Article XXIV of GATT, to address the problems of small countries and markets.<sup>261</sup> The exemption

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<sup>258</sup> Article 31 of TRIPS offers twelve conditions for compulsory licensing. TRIPS Agreement, *supra* note 12, at art. 31. Read together these conditions do not make compulsory licensing easy. See Carlos M. Correa, *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, UNIV. OF BUENOS AIRES, 1, 15-26 (Apr. 2004) available at [http://www.who.int/medicines/areas/policy/WTO\\_DOHA\\_DecisionPara6final.pdf](http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf) (discussing the conditions for use of compulsory licensing under paragraph 6 of the Doha Declaration).

<sup>259</sup> Article 31(b) states that compulsory licensing “may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms.” TRIPS Agreement, *supra* note 12, at art. 31. This places the burden on the state seeking reliance on Article 31 and makes it difficult to determine what constitutes reasonable commercial terms while the market for information is notoriously imperfect and often unique. See *id.*

<sup>260</sup> Article 31(f) states that “such use shall be authorized to predominantly for the supply of the domestic market of the Member authorizing such use.” *Id.*

<sup>261</sup> The goal of the exemption canvassed is similar to those that inspired the exemptions to GATT obligations. Article II of GATT, the Most Favored Nation Clause, is one of the most fundamental obligations of GATT. It obligates member states to offer other States the terms of trade offered to their most favored trading partner. However, Article II provides certain exceptions, including the formation of customs unions or free trade areas under Article XXIV. The justification for the Article XXIV exemption was that the formation of a customs union would eliminate trade barriers between the members of the union, thereby moving them closer to full trade liberalization. For an explanation of the Most Favored Nation Clause and customs unions under GATT, see JACKSON, *supra* note 3, at 515, 560. See also JACOB

to Article 31(f) provides for the importation of pharmaceutical products by countries within a Free Trade Area under GATT. Article XXIV does not confront the core issues addressed here.<sup>262</sup> Unfortunately, this approach falls short of what is needed, as indicated above. Moreover, TRIPS does not authorize joint ventures between several small developing countries in using compulsory licensing to take advantage of economies of scale.

As it stands, only more advanced developing countries with the requisite domestic markets, technical capacity and resources to tackle the conditions imposed by Article 31 can employ compulsory licensing. One wonders how Article 31 addresses the needs of developing countries, facing the greatest disease and food security burdens, and possessing limited territorial markets and technical capacity to justify domestic production for local consumption. Although the WTO General Council Declaration recognizes this problem, it hardly provides a meaningful solution. The problem is structural and the various measures suggested do not confront structural impediments. Article 31 resolved decades of frustrated attempts by the U.S. to eliminate the sanction-based use of compulsory licensing. When the Paris Union was initially ratified there were only ten contracting states, several of them with colonies or colonial aspirations.<sup>263</sup> Even when the number of countries increased, our knowledge of the disease and food security problems of the world was limited compared to what is known today. With the knowledge that over 80% of the world's population faces critical health and food insecurity, how could the drafters of TRIPS justify Article 31? Its justification might be evidence of poor governance and mistrust of the exercise of state power. But, the abuse of state power is hardly a new phenomenon, nor is it limited to weak and small states. It existed under the Paris Union, yet the wisdom of that system was to give sovereign states the power to address patent abuse domestically. A property rights expansion justification would also fail as a justification for rejecting a much more liberal regime of compulsory licensing. Private property rights are always subservient to society's public interest based on some criteria of reasonableness. Article 31 is essentially a meaningless provision for most countries and appears blind to the wealth of information regarding the health and food needs of the

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VINER, *THE CUSTOMS UNION ISSUE* (1950) (providing an account of the trade creation and diversion impact of customs unions). For a discussion of the benefits of customs union relevant to the discussion of the exception under TRIPS, see WILLEM MOLLE, *THE ECONOMICS OF EUROPEAN INTEGRATION* 9 (3d ed. 1990) (arguing that economic integration is not an objective in and of itself but serves a higher purpose of raising the economic prosperity for all cooperating units).

<sup>262</sup> Correa, *supra* note 258, at 36.

<sup>263</sup> PENROSE, *supra* note 3, at 57 (listing the original signatories of the Paris Union as: Belgium, Portugal, France, Guatemala, Italy, Netherlands, San Salvador, Serbia, Spain, and Switzerland; another twenty-nine countries subsequently joined).

world's most needy populations. Some commentators have suggested that developing countries should more effectively exploit the internal flexibilities of TRIPS to address their pharmaceutical and health needs.<sup>264</sup> Unfortunately, most countries in need lack the technical, legal and economic resources to examine and exploit the flexibilities, which are nested in a structural maze. Instead of confronting the issue from the point of view of flexibilities, we should admit that a structural transformation of TRIPS is what is most needed.

#### V. TRIPS AND LESSONS OF HISTORY

The preceding discussion of TRIPS focused on its numerous structural and substantive pitfalls. I have argued that one major source of TRIPS' threat to human health and food security is the link between trade and intellectual property protection. Such a link is based on the dubious notion that ideas have an unmistakable national identity or origin, the protection of which must be a condition for trade in all goods and services, without exception. Negotiated during peacetime about a decade after the collapse of the attempt by developing countries to establish a New International Economic Order, some higher human ideals needed to serve as a guiding light. Unfortunately, circumstances invited the exploitation of the significant asymmetrical distribution of economic, technological and political power between the north and south and a higher human ideal was elusive.<sup>265</sup> The WTO derived its moral and human aspirations from GATT, a product of a post war mentality sharply focused on an international free trade regime as the solution to war. Over the years, rounds of GATT negotiations sought to move the global trading regime closer to that ideal, not for trade *per se*, but for economic and human development and the peaceful coexistence of states. It appears that the structure and substance of TRIPS, particularly its marriage to the WTO, was a major setback because of the failure to draw on the lessons of the twentieth century's wars.

Wars tend to have a sobering and introspective effect, awakening transcendent though often latent idealisms that dwell in humanity. From the carnage and violence of warfare there often arises the hope for, and faith in, a transcendent path forward for the benefit not just of the victors but of humanity in general. This is neither the time nor place to examine this statement against the history of all regions and cultures. However, a brief examination of Western Europe shall suffice to make the point.

Although we could go back further, let us start with the improbable defeat of the Roman army by Constantine in 312 AD.<sup>266</sup> After that bat-

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<sup>264</sup> Correa, *supra* note 258, at 36.

<sup>265</sup> See Drahos, *supra* note 16, at 172-73, 179-80 (suggesting TRIPS was negotiated under coercion).

<sup>266</sup> See W.H. CROCKER III, TRIUMPH, THE POWER AND GLORY OF THE CATHOLIC CHURCH – A 2,000 YEAR HISTORY 1-5 (2001) (providing an account of Constantine's

tle, the unification of the Western and Eastern Roman Empires was achieved, and Constantine stood as the sole temporal and military leader. What followed was the creation of a controversial new order: the unification of temporal and spiritual powers under the dominion of the Holy See as God's sole representative on Earth.<sup>267</sup> The outcome of this union was the eventual creation of the Holy Roman Empire. Supposedly, Constantine was not concerned with himself but rather with advancing the goals of God's universal moral order for humanity. Henceforth, the sword would be lifted only in defense of this universal moral order.<sup>268</sup> Indeed, Constantine's first decree was to prohibit religious persecution.<sup>269</sup> But, the new order under the Holy Roman Empire was unstable as restless European princes backed by powerful armies and rigorous intellectual disputations over the legitimacy of centralizing the spiritual and temporal authority in the Pope led to a collapse of the unified powers of the Papacy and eventually to the Reformation. The new order that emerged was the duality of powers, the temporal exercised by the state and the spiritual by the Church. What was achieved was not simply the defeat of the Church or the success of the state but the establishment of two institutions serving the different needs of European society.

The Peace of Augsburg in 1555 essentially formalized the declining influence of the Holy Roman Empire with the doctrine of *cuius regio eius religio*.<sup>270</sup> This ideal was the principle of religious sovereignty of states.<sup>271</sup>

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victory). After successive victories against very powerful foes (including his own father and former emperor Maximian as well as Diocletian, arguably the greatest emperor at the time), Emperor Maxentius of Rome appeared invincible, particularly with a heavily armored cavalry called the *katafractoi*. *Id.* at 1. After an initial setback from a surprise attack by Maxentius's forces, Constantine and his army charged across the Milvian Bridge. In the resultant slaughter at the hands of enemy forces, Emperor Maxentius drowned. *Id.* at 3-4.

<sup>267</sup> *Id.* at 55 (discussing the Council at Nicea called by Constantine in 325 A.D. at which a definitive summary of Christian beliefs was formulated).

<sup>268</sup> *Id.* at 59 (explaining that "the best form rule was when cross, sword, crozier and scepter, worked in unison" and that there was a "divine right of kings as guardians" of the Christian faith).

<sup>269</sup> *Id.* at 4 (noting the grant of religious freedom by the Edict of Milan).

<sup>270</sup> The Peace of Augsburg, propagated on September 25, 1555, was the first permanent legal basis for the existence of Lutheranism and Catholicism in Germany. *Peace of Augsburg*, ENCYCLOPÆDIA BRITANNICA, <http://www.britannica.com/EBchecked/topic/42767/Peace-of-Augsburg> (last visited Feb. 27, 2012). Against the wishes of the Holy Roman Emperor Charles V of Spain, but by the authority of his brother Ferdinand I, who would himself eventually become Emperor, Charles V issued the Imperial Diet, where he:

[D]etermined that in the future no ruler in the empire should make war against another on religious grounds and that this peace should remain operative until churches were peacefully reunited . . . . Moreover, in each territory of the empire, only one church was to be recognized, the religion of the ruler's choice being thus made obligatory for his subjects.

Unfortunately religion and other political objectives continued to be the source of conflict leading to thirty years of warfare ending with the Peace of Westphalia in 1648, which reaffirmed the principles expressed in the Peace of Augsburg.<sup>272</sup> Each Prince could choose what faith to profess without the risk of an attack by others of a different faith. One may argue that stripped down to its barest elements the attempt was to establish a higher and more pervasive system of human ideals against the desires of empire builders and their supporters, often powerful economic interest groups. The struggle to establish and sustain higher human ideals found further expression centuries later in the Peace of Versailles, which concluded the First World War. The Treaty, among other things, sought to provide protection for human health and food security in the establishment of WHO and FAO.<sup>273</sup>

The focus on human health and food security reemerged as two important elements in a network of international institutions established by the Allies following the end of the Second World War.<sup>274</sup> Even before the

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*Id.* It appeared that the Peace of Augsburg helped to maintain peace for at least 50 more years. *Id.*

<sup>271</sup> See Ali A. Mazrui, *Panel Discussion*, in Bhagwati, *supra* note 22, at 371-73 (arguing that the Peace of Augsburg was a doctrine of religious sovereignty, one that prohibited interference by one prince in the religious affairs of another).

<sup>272</sup> *Peace of Westphalia*, ENCYCLOPÆDIA BRITANNICA, <http://www.britannica.com/EBchecked/topic/641170/Peace-of-Westphalia> (last visited Feb. 27, 2012) (detailing the events and effects of the Peace of Westphalia). The settlement was negotiated beginning in 1644 in the Westphalian towns of Munster and Osnabruck and was concluded on October 24, 1648 after the Spanish-Dutch Treaty was signed on January 30, 1648. One of the important points of the Treaty was the ecclesiastical settlement. The Peace of Westphalia confirmed the Peace of Augsburg and extended the doctrine of religious toleration for the three great religions of the Empire: Roman Catholicism, Lutheranism and Calvinism. Significantly, it also granted recognition to and tolerance of religious minorities. The political implications of the Peace of Westphalia were significant for Germany and the Holy Roman Empire. For the Holy Roman Empire and the Diet, what was left was but a shadow of its former power. The central authority of the empire was replaced by that of 300 princes along with the loss of vast amounts of territory. *Id.* See generally CROCKER, *supra* note 266, at 297-302 (providing an account of the Thirty Years War which led to the Treaty of Westphalia in 1648).

<sup>273</sup> Abdullah El-Erian, *The Legal Organization of International Society*, in *MANUAL OF PUBLIC INTERNATIONAL LAW* 55, 60-65 (Max Sorensen ed., 1968) (discussing the establishment of the League of Nations and various international organizations following the end of the First World War).

<sup>274</sup> Several United Nations subsidiary and specialized agencies were established. For a discussion of context and reasons for those agencies, including WHO and FAO, see Max Sorensen, *Institutionalized International Co-operation in Economic, Social and Cultural Fields*, in *id.* at 615 (explaining the structure and purpose of the economic and social relations established by the U.N. Charter under the direction of ECOSOC and the establishing of WHO and FAO). See also GOODRICH, HAMBRO &

war ended, the Allies, under the leadership of the U.S., were already reflecting on the root causes of the two successive world wars that had taken such a heavy toll on humanity.<sup>275</sup> They were determined to construct a new comprehensive international system that would constrain aggression, but more importantly, appeal to a deeper sense of humanity. A better and more powerful guarantee for a transcendent human existence based on international peace and security, economic development, free trade, the co-equality of sovereign states and health and food security was called for.<sup>276</sup> These were the guiding principles upon which the Charter of the U.N. and its numerous autonomous but interdependent organs, including WHO and FAO, were established.<sup>277</sup> To further the economic development and trade objectives, the Bretton Woods system and GATT were also established.<sup>278</sup> It was evident that trade required both economic development and the capacity to trade. The establishment of the Bank for Reconstruction and Development and the IMF was meant to create development and monetary systems essential for trade.<sup>279</sup> The Marshall Plan for Europe is a prime example of how the goals of the new system were to be achieved – through deliberate and effective support. This is the context within which one should understand the evolu-

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SIMONS, *supra* note 9, at 385 (discussing the establishment of FAO and its approval by the General Assembly on December 14, 1946), 386 (discussing the approval of WHO by the General Assembly on April 7, 1948).

<sup>275</sup> Shoup & Minter, *supra* note 2; DAM, *supra* note 2.

<sup>276</sup> Article 55 of the U.N. Charter states:

With a view to the creation of conditions of stability and well-being which are necessary for peaceful and friendly relations among nations based on the principle of equal rights . . . the United Nations shall promote: (a) a higher standard of living, full employment, and conditions of economic and social progress and development; (b) solutions of international economic, social, health, and related problems; and international cultural and educational cooperation; and (c) universal respect for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion.

U.N. Charter art. 55. The question is whether WTO and TRIPS advance these principles. For a discussion of Article 55, see GOODRICH, HAMBRO & SIMONS, *supra* note 9, at 371-80.

<sup>277</sup> See *supra* text accompanying *id.*

<sup>278</sup> See Gerald M. Meier, *The Bretton Woods Agreement—Twenty-five Years After*, 23 STAN. L. REV. 235 (1971) (explaining that the Bretton Woods Agreement sought to create an ancillary institution that would reduce obstacles to international trade and give effect to the principle of multilateral and non-discriminatory trade between nations). Note that GATT originated under the authority of ECOSOC.

<sup>279</sup> See Articles of Agreement of the International Monetary Fund and Articles of Agreement of the International Bank for Reconstruction and Development No. 20, Dec. 27, 1945, 2 U.N.T.S. 39, 40. For a discussion of the IMF, see Joseph Gold, *The International Monetary Fund in International Law: An Introduction*, IMF PAMPHLET SERIES No. 4, at 8 (1965) (describing the structure and governance of the IMF).

tion of the WTO and the threat it poses to human health and food security in TRIPS.

The natural question is, what are the ideals of the WTO and TRIPS when examined as a single system? Ideals are aspirational, always unfolding and demanding adjustments, sometimes major but often incremental and marginal. Health, food, security and technology are some of the most important engines of modern development and trade. What are the aspirations and ideals of a system designed to move the world towards a better free-trade system when it puts into jeopardy the goals of economic development and trade in goods and services in essential areas of access to technology, health and food security of so many countries? The centralization of power in the WTO in areas tangential to international trade, but important for access to technology, threatens and interferes with the effective and smooth functioning of other semi-autonomous United Nations organs, such as WHO and FAO. Perhaps unintended, the centralization of power in the WTO has created a hierarchy among U.N. organs, with the WTO at the top of the pyramid and the WIPO expressly sidelined.<sup>280</sup>

One wonders whether the ideal of free trade (the initial mission of GATT) is not seriously compromised by the marriage of WTO to TRIPS. Free-floating ideas are not an ideal; they are the basis upon which humanity has evolved from the beginning of time. The survival of the species depends on creativity and the free flow of ideas. It is a necessity, not an ideal. Access to air, light, food and health are an integral part of existence and deserving of their own independent consideration. They should not be awkwardly fitted into a complex system of trade.<sup>281</sup> Historically, the technology gap has explained differences in economic and military power between states.<sup>282</sup> Constructing an artificial regime of

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<sup>280</sup> See World Trade Organization: Agreement Between WIPO and WTO of 22 December 1995, 35 I.L.M 754 (1996). Article 2 of the agreement leaves little doubt as to the dominant role of the WTO in carrying out obligations under TRIPS and mandates cooperation from WIPO when requested as well as WTO accessibility to WIPO databases. *Id.*

<sup>281</sup> Drahos argued that differences in intellectual property protection lead to trade distortion and seeks to justify the existence of TRIPS on that account. Drahos, *supra* note 16, at 177. It should however be noted that most trade theorists would argue any such trade distortion should be addressed when it occurs and be targeted at the source of the distortion. See, e.g., CORDEN, *supra* note 203. But see Robert M. Sherwood, *Why a Uniform Intellectual Property System Makes Sense for the World*, in GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY 68 (Mitchel B. Wallerstein et al. eds., 1993) (seeking to stimulate discussion on what the global intellectual property system is and what its costs and benefits are, including the ethics of the system).

<sup>282</sup> Celso Cintra Mori, *Informatics in Brazil*, in LICENSING AGREEMENTS: PATENTS, KNOW-HOW, TRADE SECRETS AND SOFTWARE 350, 350-55 (Kojo Yelapaala et al. eds., 1988) (providing the background to Brazilian policies and law on

monopolies and exclusive rights in some technological ideas, even if necessary, reinforces the gap and should not be part of the GATT's free trade ideal as refined under the WTO. Monopolies and exclusive rights in ideas essential to life and health are distinguishable, for example, from inventions of robotic machines and industrial systems for the manufacture of ordinary goods.<sup>283</sup> Conditioning the right to trade in all goods irrespective of their nature and importance to life and health is unprecedented in the history of humanity. A brief reflection on the history of the human struggle for achieving a transcendent existence might have saved the drafters of TRIPS from what appears to be a serious global trade policy error in an age when we know more about humanity and its needs than ever before.

## VI. QUO VADIS WTO?

We have seen the root cause of the risk posed by TRIPS to human health and food security is substantially structural. If, for instance, there is a fundamental right of states to trade, the linkage of trade to the protection of foreign intellectual property rights poses a threat to that right. Moreover, contrary to the history of human creativity and innovation, TRIPS appears to have been constructed on the dubious assumption that every idea has an undeniable territorial or national origin. Although this assumption is flawed, the right to trade in all goods and services was made conditional on the protection of some foreign origin intellectual property. If these structural problems exist, what should be the road ahead for the WTO and TRIPS? Put more directly, *quo vadis WTO?* I have argued that reliance on substantive revisions to TRIPS would have a marginal transformative effect on structural root causes. Perhaps the starting point in confronting the solution is to pay attention to the wisdom of the African proverb at the beginning of this work: "You cannot kill an elephant by stabbing at its shadow with a spear." In the context of this discussion, the elephant is the disease burden and food insecurity faced by many developing countries, and the response by the WTO is no more than attacking the shadow. It is in the spirit of this proverb that several suggestions are offered that go to the root structural problems of TRIPS as part of the WTO system.

The first and most logical response to the question of the future of the WTO should address the link between TRIPS and the WTO. Not only should the WTO and TRIPS be separated, but TRIPS should also be dis-

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informatics and arguing that technological developments, such as new navigation techniques, know-how and the technological innovation behind the industrial revolution played and continues to play a role in differences in levels of development and global competitiveness).

<sup>283</sup> Yelapaala, *supra* note 222, at 186-88 (arguing that the current U.S. patent system was originally designed for mechanical devices and is now out of sync with the biotechnological and scientific world).

mantled and reconstructed to address its larger shortcomings. The right to health is both a constitutional right in several countries and a human right recognized under several multilateral instruments.<sup>284</sup> The obligation of states to advance human rights is both a moral and positive legal imperative under international law and several municipal legal systems.

No country should be deprived of the right to protect the health and food security of its citizens. No international instrument should unreasonably limit the sovereign right of a state to determine for itself what is patentable or the nature and duration of intellectual property rights. As a historical matter, sovereignty has always carried with it some risk of abuse. The solution to this risk is not to suppress sovereignty but to reasonably regulate. The reinstatement of sovereign authority in this area would empower states to confront their public health needs, disease burden and food security, subject to accepted limitations under international and municipal law. This is particularly important when one considers the imposition of an international order of intellectual property rights that is simply a replication of a system with its foundation in the policy choices of a few countries. The restoration of sovereignty in this area would change the debate over access to affordable pharmaceutical products for developing countries and render the measures adopted by the WTO General Council moot.

Disparities in economic and technological development and industrial capacities of states have followed a consistent pattern throughout human history. A rational international trading system and its implementation should not systematically consign a large number of states to the backwaters of under-development by elevating private rights of foreign patentees to the detriment of the development objectives and fundamental public interests of states. The so-called built-in flexibilities of TRIPS are inadequate and misleading because they are inaccessible to the most needy states. At best, they merely pay lip service to ideals of free trade and advancement of humanity. To advance the core ideals found in the U.N. Charter, the WTO must dismantle TRIPS since it is in the best interest of humanity and, in particular, it would satisfy fundamental needs of developing states.

In reconstructing TRIPS, particular attention should be paid to a deeper understanding of the history of human creativity and its role in the evolution and advancement of humanity. From the beginning of time, ideas have always been fluid and ephemeral, having the qualities of air and light. Unimpeded access to ideas played a critical role in the advancement of human society. Some ideas emerged simultaneously in different parts of the world while others were borrowed and transformed to suit local needs. The building blocks of modern technological society came from many civilizations and cultures, which borrowed from others over time. To ascribe national or territorial origins to all ideas, however

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<sup>284</sup> Yelapaala, *supra* note 83, at 474-79.

expressed or manifested, suggests a serious misunderstanding of the history of human creativity and innovation. A return to what has been described as Paris Union-Plus or Berne-Plus would be a useful starting point in reconstructing TRIPS as a process separated from the WTO.

Presently, the world faces a moral imperative that mandates democratization of human political governance institutions and liberalization of trade and investment policies. It seems contradictory that in this age of democratization there appears to be a centralization of power in the WTO. There was wisdom in the initial construction of semi-autonomous and interdependent organs by the U.N. to carry out its mission. The concentration of power in the WTO undermines the wisdom of decentralizing the governance of those institutions for greater efficacy and effectiveness. The current structure and functioning of the WTO and TRIPS interferes with the effective functioning of WHO and FAO and explicitly relegates the functions of WIPO to a diminished and subsidiary role. One may ask to what end? The combination of two complex global systems not directly related complicate the effectiveness of U.N. organs, among other things, should be immediately decoupled.

Finally, the measures suggested for addressing the structural flaws of TRIPS do not offer immediate relief, nor do they confront the reasons why developing countries face the problems they do. In the short term, in addition to exploring whatever flexibilities TRIPS offers, developing countries should be permitted to coordinate their compulsory licenses policies and practices to form regional or sub-regional productive joint ventures and strategic alliances to address fundamental health and food security needs. Public-private productive joint ventures between countries with insufficient markets and purchasing power would address cost and profitability constraints. This policy would permit immediate coordination between middle-income countries with good capacity, such as Brazil, China and India, and those countries those without the capacity to address the issues of generic drugs and affordable pharmaceutical products.

In the long term, developing countries must confront issues such as the digital divide and the disequilibrium in health and food R&D. The primary responsibility of developed countries is toward their own citizens. It is foreseeable that the current disequilibrium in health research expenditures favoring developed countries will persist into the future. Little attention will be paid to addressing the fundamental needs of developing countries. In view of this, developing countries must start the process of taking their destiny into their own hands with respect to eliminating or at least reducing the digital divide. This cannot be done through eloquent oratory, but through concrete proactive visionary R&D policies and funding for health and food research aimed at addressing fundamental needs. The issue will then be what modalities and business models will be most effective within and outside TRIPS.

In thinking about the fundamental health and food technology needs of developing countries, two points should be kept in mind. First, developing countries contain about 90% of biodiversity resources global pharmaceutical and agro-business MNEs presently seek to exploit, largely for purposes other than addressing the needs of developing countries. Second, under U.N. General Assembly Resolution 1803 (XVII) of 1963, developing countries continue to have permanent sovereignty over their biodiversity resources, even in light of the Biodiversity Convention. Given these advantages and the characteristic behavior of global R&D entities, access to and R&D activities based on biodiversity resources must be redirected toward the fundamental needs of developing countries. There are various market-based modalities that would permit formation of public-private corporate regional and sub regional R&D entities in which foreign research institutions can play a secondary supporting role. The governments of developing countries should provide the appropriate funding for these research entities as pure and simple investors similar to European governments' funding of Airbus. However, the mission and vision of the R&D entities must be directed squarely at confronting the fundamental health and food security needs of developing countries.

In the long run, developing countries must take their destiny into their own hands. This is particularly true when it comes to bridging the technology gap, which contributes to their vulnerability in health, food and trade. It is misguided for these countries to rely on the benevolence of MNEs or their home governments to share technical innovations. Colorful dreams, visionary conferences and eloquent speeches will not suffice. Critical and concrete policy measures and actions must be taken today. Short of this, the struggle for recalibrating the global economic relations of the 1970s and 80s to achieve the lofty goals of a more equitable distribution of the benefits of global economic progress will be recurrent and frustrated.